

The Laboratory Efficiencies Initiative: Partnership for Building a Sustainable National Public Health Laboratory System

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ABSTRACT

Beginning in early 2011, the Centers for Disease Control and Prevention and the Association of Public Health Laboratories launched the Laboratory Efficiencies Initiative (LEI) to help public health laboratories (PHLs) and the nation's entire PHL system achieve and maintain sustainability to continue to conduct vital services in the face of unprecedented financial and other pressures. The LEI focuses on stimulating substantial gains in laboratories' operating efficiency and cost efficiency through the adoption of proven and promising management practices. In its first year, the LEI generated a strategic plan and a number of resources that PHL directors can use toward achieving LEI goals. Additionally, the first year saw the formation of a dynamic community of practitioners committed to implementing the LEI strategic plan in coordination with state and local public health executives, program officials, foundations, and other key partners.

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Centers for Disease Control and Prevention (CDC) Director Thomas R. Frieden, MD, MPH, spurred the formation of the Laboratory Efficiencies Initiative (LEI) following visits to state and local public health departments and laboratories during the economic decline of the late 2000s. Years of repeated budget cuts had led to deep reductions in staffing and infrastructure of many public health laboratories (PHLs) and, in some cases, a reduction or elimination of critical testing services. These trends posed threats to the ability of laboratories and the entire public health system to respond to emergencies, conduct essential surveillance, and support public health interventions.¹

Developed in collaboration with PHL leaders and other partners, the LEI is a joint Association of Public Health Laboratories (APHL)-CDC initiative aimed at helping PHLs adopt key strategies to build the robust, effective infrastructure required to support and sustain their critically important role in protecting America's health.

PHLs: A VITAL BUT VULNERABLE NATIONAL ASSET

Every state and many local jurisdictions operate PHLs, which are a vital component of the public health infrastructure that protects the health of all Americans.^{2,3} They are an important resource for reference testing, helping to detect terrorist acts, responding to naturally occurring outbreaks, and other important events affecting public health. Many PHLs also advise, support, and provide training to clinical laboratory scientists for tests of public health importance.⁴

Once operating largely in isolation from each other, PHLs today are part of a national laboratory system.^{5,6} Many of these laboratories work together to assure the availability of important public health testing. They also interact closely with CDC programs and laboratories. CDC laboratories conduct reference testing, provide technical assistance and financial support through grants, deliver training, and provide many other resources to PHLs in support of public health priorities on a national basis. Examples include CDC's influenza, tuberculosis, human immunodeficiency virus, and vaccine-preventable disease programs.

Public health and CDC laboratories are at the core of an emerging, multisector system of laboratories that conduct testing and other services that are vital to the nation's health. In this context, PHLs interact increasingly with other government laboratories (e.g., environmental, food safety, agricultural, and forensic), university-based laboratories, and private clinical laboratories to foster state PHL systems⁷ that provide unique

and highly specialized testing and other services.⁸ In addition to growing participation in such networks, PHL leaders, working through APHL and with CDC support, have defined consensus core functions and capabilities.⁹ Many PHL leaders have conducted systematic assessments of their statewide PHL systems, using the Laboratory System Improvement Program (L-SIP) Performance Measurement Tool.¹⁰

Despite these positive developments, PHLs face unprecedented challenges. The most immediate challenge stems from deep cuts in state and federal funds.¹¹ Additional challenges are posed by the advent of highly sophisticated and costly testing technologies, with associated bioinformatics requirements, rapid evolution of the health-care system, and escalating demands on a shrinking and aging workforce.

These trends have had significant impacts on many PHLs. For example, several PHLs reported losses of more than 15% of their professional employees in 2010, and more than 45% of PHLs anticipate losing at least 15% of their workforce in the next five years.¹² Some laboratories have eliminated testing for one or more diseases, and several large states have recently closed one or more local PHLs. The cumulative impact of these developments has significantly reduced the capacity of individual PHLs, and the ability of public health departments, to conduct essential population-based services. A major, widely held concern driving the LEI is that it could be extraordinarily costly and difficult to rebuild that fundamental capacity if it became seriously compromised.

LEI MANAGEMENT PRACTICES AND TOOLS

The LEI has engaged a large number of PHL leaders, CDC colleagues, and other key partners to set priorities for the initiative, define cross-cutting activities, and take practical steps toward achieving the LEI's goals (Figure 1). PHL directors are closely involved in identifying promising management practices and new resources that laboratory leaders can use to implement those practices. APHL convened four teleconferences in the spring and summer of 2011 in which the directors of 42 state and 16 local PHLs described steps they had taken, or were considering taking, to operate within reduced budgets while still delivering essential, high-quality testing services. That rich exchange informed subsequent discussions of specific approaches to greater efficiency and led to the identification of key strategies to support the adoption of seven management practices (Figure 2):

- Organization of laboratory testing services
- Procurement cost savings

- Standardization of testing platforms
- Laboratory informatics assessment and guidance
- Revenue generation
- Workforce development
- Laboratory workflow improvement

Four cross-cutting activities that support the seven management practices were identified and are listed in Figure 1.

- Development of an overall LEI strategy that represents stakeholder consensus and addresses specific objectives and tasks to be completed during the course of three years.
- Creation of a directory of all the test services that are performed by PHLs. This directory will help laboratory directors and decision makers identify opportunities for sharing testing services with each other.

Figure 1. Forums and consultations convened by CDC and APHL to establish cross-cutting activities, infrastructure, and metrics that support the LEI

LEI activity	Consultations	Completed or proposed products
Development of overall LEI strategy	<ul style="list-style-type: none"> • APHL convened four conference calls with members in 2011 (February 11, February 28, March 4, and June 1) • Internal CDC meetings with laboratory leadership to develop the LEI concept (March 18 and 22, 2011) • CDC Laboratory Policy and Practice Workgroup; Laboratory Program Forum • APHL partners meeting (January 11, 2012) • APHL Board of Directors meeting (January 12, 2012) • Regional forums with 23 state and local/county PHL directors (April 17 and April 24, 2012) • Strategic planning meeting with 15 APHL and CDC directors and program leaders (June 6–7, 2012) 	<ul style="list-style-type: none"> • Inclusion of LEI in CDC's fiscal year 2013 budget • Regional Forum summary report^a • Strategic Plan^b
Consolidated test services data and directory	<ul style="list-style-type: none"> • APHL-CDC PHL service data consultation (December 6–7, 2011) • APHL-CDC Subcommittee on Public Health Laboratory Service Data (April 6, 2012) 	<ul style="list-style-type: none"> • APHL/CDC PHL service data consultation^{c,d} • Database that consolidates existing CDC and APHL test service data (housed in APHL's Survey Resource Center) • Existing CDC/Office of Infectious Diseases laboratory management database converted to state-based database
Metrics for ROI	<ul style="list-style-type: none"> • Focus groups/consultations (August 15 and August 22, 2011) 	<ul style="list-style-type: none"> • Framework of proposed metrics for evaluating ROI (in development)
Public health law and policy tools	<ul style="list-style-type: none"> • Consultation with five state PHL directors, five APHL staff/leaders, and 20 CDC policy and science staff (August 17, 2012) 	<ul style="list-style-type: none"> • Policy guide identifying best practices for sharing test services to be published later in 2013

^aAssociation of Public Health Laboratories. Laboratory Efficiencies Initiative (LEI) public health laboratory director forums meeting summary. Silver Spring (MD): APHL; April 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012April_PHL-Directors-Forum.pdf [2013 Apr 25].

^bAssociation of Public Health Laboratories. Laboratory Efficiencies Initiative strategic plan 2012–2015. Silver Spring (MD): APHL; July 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012-2015_Strategic-Plan.pdf [cited 2013 Apr 25].

^cAssociation of Public Health Laboratories and Centers for Disease Control and Prevention (US). Summary: APHL/CDC public health laboratory service data consultation. Silver Spring (MD): APHL; December 2011. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012Jan_PHL-Service-Data-Meeting-Summary.pdf [cited 2013 Apr 25].

^dAssociation of Public Health Laboratories and Centers for Disease Control and Prevention (US). Summary: APHL/CDC joint committee on public health laboratory service data. Silver Spring (MD): APHL; April 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012April6_APHL-CDC-PHL-Service-Data.pdf [cited 2013 Apr 25].

CDC = Centers for Disease Control and Prevention

APHL = Association of Public Health Laboratories

LEI = Laboratory Efficiencies Initiative

PHL = public health laboratory

ROI = return on investment

Figure 2. Overview of LEI activities, consultations, and products related to the LEI's seven key strategies

<i>LEI strategy</i>	<i>Consultations</i>	<i>Completed or proposed products</i>
Organization of laboratory testing services	<ul style="list-style-type: none"> • Consultations with 12 state PHL directors and their staff (December 7, 2011, and March 26, 2012) 	<ul style="list-style-type: none"> • A Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes^a • An Overview of Legal Considerations in Assessing Multijurisdictional Sharing of Public Health Laboratory Testing Services^b
Procurement cost savings	<ul style="list-style-type: none"> • National Center for Public Health Laboratory Leadership Forum, January 19–20, 2012 	<ul style="list-style-type: none"> • Report from the forum workshop with specific recommendations^c
Standardization of testing platforms	<ul style="list-style-type: none"> • Consultation with APHL Infectious Disease committee and CDC program representatives (April 11, 2012) 	<ul style="list-style-type: none"> • Report from the consultation with recommendations^d
Laboratory informatics assessment and guidance	<ul style="list-style-type: none"> • December 15, 2011, and May 8–9, 2012 	<ul style="list-style-type: none"> • Self-assessment tool to be completed and disseminated in mid-2013
Revenue generation	<ul style="list-style-type: none"> • Discussion at regional forums 	<ul style="list-style-type: none"> • Regional Forums report^e
Workforce development	<ul style="list-style-type: none"> • Competencies workgroup meeting with APHL members and CDC program representatives (October 17–18, 2012) 	<ul style="list-style-type: none"> • New and sustainable EID Fellowship funding models • Full set of PHL workforce competencies by December 2013 • Development of a PHL workforce strategy by December 2013
Laboratory workflow improvement	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Regional workshops in Lean training on February 28–29 and June 26–27, 2012

^aAssociation of Public Health Laboratories, Centers for Disease Control and Prevention (US). A practical guide to assessing and planning implementation of public health laboratory service changes. Silver Spring (MD): APHL; 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_April2013_Service_Change_Practical_Guide.pdf [cited 2013 Apr 25].

^bBerkery MR, Penn MS. Legal considerations in cross-jurisdictional sharing of public health laboratory services. *Public Health Rep* 2013;128(Suppl 2):70-4.

^cAssociation of Public Health Laboratories. NCPHLL leadership forum series: procurement improvement strategies. Silver Spring (MD): APHL; March 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012March_NCPHLL-Procurement-Meeting-Summary.pdf [cited 2013 Apr 25].

^dAssociation of Public Health Laboratories and Centers for Disease Control and Prevention (US). Summary report: harmonizing test platforms to increase efficiencies in public health laboratories. Silver Spring (MD): APHL; April 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012April11_Standardization-Platforms-Summary-Report.PDF [cited 2013 Apr 25].

^eAssociation of Public Health Laboratories. Laboratory Efficiencies Initiative (LEI) public health laboratory director forums meeting summary. Silver Spring (MD): APHL; April 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012April_PHL-Directors-Forum.pdf [cited 2013 Apr 25].

LEI = Laboratory Efficiencies Initiative

PHL = public health laboratory

APHL = Association of Public Health Laboratories

CDC = Centers for Disease Control and Prevention

EID = Emerging Infectious Disease

- Development of metrics for the return on investment (ROI) in PHLs. These metrics will include measurements used in gauging the impact of implementing the seven management practices and in explaining the value of PHLs to stakeholders.
- Understanding the laws and policies that support or hinder implementation of the seven management practices.

Beginning in mid-2011, workgroups were organized to develop and implement action plans in each of these areas. APHL and CDC continued to sponsor forums for PHL leaders' ongoing engagement in the LEI. These forums covered topics including a review of the proposed LEI management practices.

PHLs are critically important, not only to state public health programs but also to CDC's mission. CDC established the new, internal CDC Laboratory Program

Forum, whose members direct the CDC programs that provide financial support via grants and technical assistance to PHLs and rely on PHLs for different types of information. Forum members worked with PHL leaders and APHL senior staff to develop a three-year strategic plan for the LEI, which was published in July 2012 (Figure 3). An LEI governance structure was established in mid-2012 to engage PHL directors, state and local public health officials and epidemiologists, as well as APHL and CDC in shaping and guiding the initiative to have maximum benefit for the entire public health system.

Ensuring success

The PHL community recognizes that the LEI's success will require a focus on priorities and, in many cases, substantial change in conventional laboratory management practices. Many PHL leaders took steps to address financial and other challenges well before the onset of the recession. The LEI builds on their innovations, adding new perspectives and developing new tools that laboratory leaders can use toward sustainability of the joint strategic goal.

A set of key questions was proposed that PHL directors, together with health department leaders,

Figure 3. The Laboratory Efficiencies Initiative strategic plan: 2012–2015^a

Goals	Activities
Goal I: Implement and sustain innovative laboratory management practices	<ul style="list-style-type: none"> • Collect data and develop models to expand interstate and intrastate sharing of testing services. • Collect data on what tests are performed by the continuum of PHLs (federal, state, and local) and make this information available so that PHLs can explore sharing services. • Evaluate current approaches to the sharing of testing services (both within and between states) and implement the most effective solution(s). • Identify what tests are core to each state (based on formal discussions with epidemiology at the state level; discussions will be a continuing process as needs will change) and engage in dialogue within a national forum across the continuum of PHLs and epidemiology to identify core testing needs and referral mechanisms. • Pursue cost-efficiency measures across laboratories. • Assist PHLs in revenue generation by exploring billing practices. • Provide tools, resources, and information for the PHL community that can assist in decision making and implementation of efficiency initiatives.
Goal II: Assure that PHLs have full informatics capability to participate in electronic information exchanges	<ul style="list-style-type: none"> • Develop a common strategic informatics plan for CDC and the PHLs. • Provide the information, tools, and training to support members in their ability to implement and sustain a comprehensive, state-of-the art LIMS that meets national standards. • Coordinate the participation of, and share and assist with, the implementation of best practices among PHLs in the development of national and regional health information exchanges. • Prioritize and align programmatic and state resources for informatics enhancements. • Assure the implementation of bidirectional electronic exchanges (eTORS, PHLIP, LIMS_i, ERLN, and NBS) across the continuum of PHLs. • Develop and assure the full adoption of standardized codes (LOINC, SNOMED). • Ensure the capacity to meet Meaningful Use.
Goal III: Identify and address institutional, legal, and policy barriers to greater efficiency	<ul style="list-style-type: none"> • Identify and prioritize the barriers to greater efficiency (e.g., the current disease-specific restricted funding model). • Identify and assess implemented solutions from the field. • Develop tools for overcoming legal and institutional barriers.
Goal IV: Assure that resources, infrastructure, and partnerships are adequate to meet the LEI mission	<ul style="list-style-type: none"> • Develop the governance structure for the LEI. • Explore/assess funding models. • Ensure needed staffing to implement the LEI from CDC, APHL, and PHLs. • Ensure member and partner engagement (including other global laboratory networks). • Develop metrics for objectives and tasks, assess progress, and continuously evaluate and update the strategic plan.
Goal V: Communicate, inform, and educate on the critical purpose of PHLs and the value of LEI in sustaining them	<ul style="list-style-type: none"> • Define the mission and purpose of PHLs and the vision for the PHL system in a manner that communicates the benefits and value (with evidence) of the PHL. • Develop a strategic communications plan that includes all PHL partners and stakeholders to explain LEI, encourage input into the process, and create stakeholder support of its initiatives.

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Figure 3 (continued). The Laboratory Efficiencies Initiative strategic plan: 2012–2015^a

Goals	Activities
Goal VI: Transform all laboratories in the public health system to a culture of efficiency	<ul style="list-style-type: none"> • Define the new culture, the business case for pursuing it, and the behaviors that exemplify a culture of efficiency. • Identify the metrics for demonstrating culture change; translate culture change into specific efficiency metrics and outcomes. • Ensure that system incentives and funding principles support efficiency. • Continuously develop a vision for the future.
Goal VII: Develop a comprehensive PHL workforce strategy	<ul style="list-style-type: none"> • Develop a PHL workforce that exhibits the competencies of the “new culture.” • Address workforce issues. • Improve human resource systems.

^aDeveloped by CDC program representatives, PHL leaders, and APHL senior staff in June 2012

PHL = public health laboratory

CDC = Centers for Disease Control and Prevention

LIMS = Laboratory Information Management System

eTORS = electronic test ordering system

PHLIP = Public Health Laboratory Interoperability Project

LIMSi = LIMS integration

ERLN = Environmental Response Laboratory Network

NBS = newborn screening

LOINC = logical observation identifiers names and codes

SNOMED = systemized nomenclature of medicine clinical terms

LEI = Laboratory Efficiencies Initiative

APHL = Association of Public Health Laboratories

laboratory staff, and other key stakeholders, can ask to define the scope of services their laboratories should provide in the future:

- What will be the priorities of the health department my laboratory serves in the foreseeable future?
- What laboratory-based information and testing services will be required to support those priorities?
- Which of those information and testing services should my PHL provide?

While they share certain core functions, the services that PHLs perform are as diverse as the health priorities of the states and communities they serve. Thus, their answers to these three questions will differ but can lead to greater clarity about the essential services each laboratory should be prepared to perform. Identifying essential testing services, in turn, can help laboratory directors specify the underlying capacities their PHLs require and the high-efficiency management practices they can adopt to ensure their laboratories' long-term sustainability.

The following sections outline the approaches and activities for the management practices identified by LEI partners and describe achievements and action

plans as of mid-2012. All of the management practices represent significant stakeholder consensus on the direction, specific activities, and expected short- and long-term outcomes in improving both the efficiency and effectiveness of PHL testing. Figure 2 provides an overview of LEI activities, consultations, and products.

Key strategy #1: organization of laboratory testing services.

One promising approach to fulfilling LEI goals is for PHLs to adopt new and alternative models for providing testing services. The classic model is for each laboratory that serves a given state, county, or other jurisdiction to perform all the different types of tests needed to support the health priorities of that jurisdiction and its public health department. In recent years, financial and other pressures have led many laboratory directors to reconsider this approach, as many laboratories can no longer maintain costly testing platforms for low-volume or noncritical tests. Among the alternatives to the classical approach are (1) sharing testing services with PHLs in other jurisdictions, (2) combining testing services formerly performed by multiple laboratories within a state, (3) merging PHLs with environmental or other types of public-sector laboratories, and (4) contracting for testing services.

In teleconferences and workshops that APHL and CDC sponsored beginning in early 2011, it became

clear that a number of states had adopted such new approaches. Examples include:

- The merger of New Hampshire's state environmental laboratory with its PHL;
- Michigan's closure of a regional branch laboratory, followed by transfer of its infectious disease testing to the central state laboratory and transfer of water testing to private laboratories;
- The formation of the four-state Northern Plains Consortium to facilitate the sharing of testing services, training, and other services among the Montana, North Dakota, South Dakota, and Wyoming state PHLs; and
- The performance of newborn screening testing by the state PHL in Oregon for five other states, birthing centers of the Navajo Nation, several U.S. territories, and military bases.

Benefits of implementing these new approaches included optimized use of testing platforms, reduced duplication of testing services in the same jurisdiction or state, enhanced surge capacity due to staff cross-training, cost savings, access to subject-matter experts (SMEs) in other jurisdictions, and greater leverage with vendors through consolidated purchasing.

Many PHL directors expressed interest in learning more about such approaches. In response, CDC and APHL, with significant PHL leadership input, developed a guide that directors could use to explore the potential benefits that alternative testing service modalities could have for their laboratories. "A Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes" was released for public access at the May 2012 APHL annual meeting.¹³ CDC's Public Health Law Program researched and published the companion report, "An Overview of Legal Considerations in Assessing Multijurisdictional Sharing of Public Health Laboratory Testing Services."¹⁴

As forecast by such organizations as the Congressional Budget Office and the Government Accountability Office, federal and state fiscal trends almost certainly will intensify pressures on PHLs.^{15,16} PHL leaders have exhibited extraordinary innovation and resilience in the face of unprecedented change and are likely to continue exploring and adopting alternatives to the classical organization of testing services. CDC and APHL will support them with technical assistance and the development of additional practical tools they can use for that purpose.

Key strategy #2: procurement cost savings. One area that has potential for cost savings is the method by which goods and services are procured. In 2010, the aver-

age cost per state PHL for laboratory supplies was \$3,574,436, second only to personnel costs.¹⁷ To identify models to improve the purchasing of laboratory equipment and supplies, APHL's National Center for Public Health Laboratory Leadership convened a forum focused on procurement improvement strategies.¹⁸ The forum brought together representatives of the major stakeholders, including laboratory management, procurement professionals, vendors, and purchasing cooperatives.

Discussions showcased the unique aspects of PHLs that translate into specific procurement needs. For example, PHLs are intimately involved in emergency preparedness and must stock certain supplies in sufficient quantity to meet local needs, even though they may never be used. This procurement strategy can be contrary to traditional purchasing practices where buying is based on past need. In addition, many states' PHLs provide a specific array of services, such as screenings for newborns, which are not traditionally provided by any other source.¹⁴ Many of these screenings are required by state law and must be provided regardless of funding constraints.

The equipment needs of PHLs are also unique. In some cases, only one vendor can provide a necessary piece of equipment, which means that multiple bids cannot be obtained. PHLs want to have arrangements in place to maintain and repair equipment and face challenges obtaining preventive maintenance and repair contracts. For example, a service contract may only cover one piece of equipment, which means that a laboratory must have numerous service contracts, all with different terms and procedures, to obtain services.

State agencies are required to work within their own systems to purchase equipment, supplies, and services, and these systems can vary widely from state to state. For example, one state may require multiple quotes for any non-contract purchase of \$250 or more. Another state may have a threshold of \$5,000 for similar purchases.

It is important to note that, given the differences across PHLs and state systems, there is no single quick fix. Instead, PHLs will want to explore various strategies, consider the options that align with their state's policies, and select the option(s) that best fits their needs.

Many LEI procurement activities overlap and would ideally take place concurrently. To bring about change will require a long-term initiative that will need to identify goals, develop strategies, and build on successes. The draft details of such a plan are in the procurement improvement recommendations.¹⁸

In the interim, to assist PHLs in exploring opportunities for cost savings in procurement, participants identified possible activities and roles for various

stakeholders. The first, which has already occurred, is the creation of a listserv by APHL for use by member laboratory and procurement staff to request and share information about products and services in use or being considered by PHLs. A Procurement Improvement workgroup has been formed, with the first task of developing an inventory of a subset of supplies commonly used by PHLs in virology, which can be used to identify potential vendors and sources for a group contract. In addition, APHL leadership has reached out to the National Association of State Procurement Officials and the Western States Contracting Alliance for potential collaboration with APHL.

Key strategy #3: standardization of testing platforms. Multiple CDC programs work closely with APHL and state and local PHLs to build capacity for public health testing to support surveillance, disease control, and prevention. This support consists of technical advice, training, and provision of assays or assay components developed at CDC that are used for surveillance and reference testing. To date, there has not been a coordinated or conscious effort to develop these assays or assay components in a manner that considers existing state/local PHL testing platforms, which includes instrumentation (e.g., detection and extraction) and related resources. Maintaining multiple testing platforms at CDC and PHLs requires significant costs related to purchasing, maintenance, staff training, and proficiency testing to achieve optimal results. As funds from the CDC Public Health Emergency Preparedness (PHEP) Cooperative Agreement (a major source of state laboratory funding) and other federal grants continue to decline,¹¹ CDC is exploring how to strategically select testing platforms for CDC-provided technologies (e.g., assays, protocols, and reagents) deployed to state and local PHLs.

To address this issue, CDC, APHL, and representatives from state and local PHLs met in April 2012 to clarify the issues at hand and make recommendations for improvements in the development of assays and the selection of testing platforms. Initially, the focus is on molecular testing assays and platforms used to test for surveillance of infectious disease and biological threat agents. Methods for extraction as well as pathogen identification, detection, and characterization are being reviewed. As a model, the group is looking at the Laboratory Response Network (LRN), which was established to provide a standard way in which laboratories perform critical biodefense testing. This structured network provides reagents and standard protocols to detect agents of bioterrorism and chemical terrorism using a limited number of testing and specimen extraction platforms. The LRN model of introducing, implementing, and supporting standardized testing

platforms could be leveraged more broadly across all laboratory program areas. Similar support mechanisms have been successfully developed for testing influenza and chemical terrorism.

Several recommendations for CDC and APHL were made at the April 2012 meeting,¹⁹ and many of these recommendations are currently being addressed.

Key strategy #4: laboratory informatics assessment and guidance. CDC and APHL hosted two meetings on laboratory informatics with representatives from APHL's Informatics Committee and other interested SMEs within CDC. The group became the LEI Informatics workgroup and it established a goal to identify tools and management practices that improve laboratory informatics capabilities.

The initial discussions centered on CDC's proposal to document the long-term cost savings and value of PHL informatics enhancements. The workgroup recognized that PHLs need to have appropriate informatics resources, including hardware, software, equipment, and informatics, and that these resources must be managed appropriately. In the future, PHLs may also need to explore different models for data collection and management (e.g., centralized, cloud-based, or networked approaches based on the solution that appropriately supports their business processes). Data management processes must be interoperable with other types of public health data systems. Interoperability is particularly critical because common standards for data exchange between hospitals/private laboratories and PHLs are essential.²⁰ Interoperability requires standards for data type, data quality, forms, messaging formats, and message payload schemas. In addition, there needs to be agreement on common vocabulary and standards for exchanging laboratory data on clinical, animal, and environmental specimens. All data-exchange activities must support PHLs' business processes. Engaging in messaging and data-exchange efforts will help maximize efficiencies and enable them to benefit from automating their systems. It can also establish efficient practices to maintain data streams to and from submitters.

There was consensus that PHLs would benefit from the development of a self-assessment tool that PHLs could use to evaluate their current informatics capabilities and that also would help management and laboratory decision makers set fiscal-year operational priorities. This tool would assist the PHL in identifying needs for improvement based on current national standards that could then be communicated to key stakeholders. The workgroup began developing the primary framework for this tool in May 2012. The initial capabilities matrix design was a broad overview

of informatics capabilities. The working group further enhanced the matrix by linking the informatics capabilities with APHL's requirements document for Laboratory Information Management Systems (LIMS),²¹ which highlights 16 business process specifications for laboratory operations. This format resulted in 19 capability areas for review. These capability areas, and their associated capability statements, capture all informatics activities desirable for an enterprise-level operation. The matrix also emphasizes the drive toward interoperability and data exchange in all capability areas and is used as the basis for the tool.

These activities led to the development of the new Public Health Laboratory Informatics Self-Assessment Tool, which was distributed by APHL to its members in June 2013. PHL directors and senior staff can use this resource to assess their laboratories' current informatics capabilities against a systematic and common framework. The assessment results will help to prioritize each PHL's investments in needed improvements. In addition, the results will enable, for the first time, an understanding of PHLs' existing informatics capacity nationally, helping APHL and CDC align their support for PHLs' informatics most effectively.

Key strategy #5: revenue generation. Billing for testing services has become a necessity for many PHLs, and there is high interest in understanding how focused investments in billing mechanisms, policy, and software might increase revenue. Many PHLs already engage in some form of billing for services, including billing Medicare, Medicaid, other state agencies, and private insurance, and charging hospitals for screenings and/or test kits. Yet, charges often do not cover the full cost of service. In some states, payments are credited to the state's general fund and do not benefit the PHL. Further, some states' laws prohibit billing and/or perceived competition with private clinical and environmental laboratories.

PHL directors identified multiple challenges to billing for services. They stressed that there are costs related to billing and that the funds collected may not cover the combined cost of testing and billing. Some PHLs use third-party billing services to handle all or portions of the billing process. Whether done by health department staff or third-party services, billing requires expertise in Current Procedural Terminology (CPT) coding and provider enrollment processes, along with the ability to extract key data for the PHL. Laboratories need robust automated systems to extract billable tests from their LIMS.

A regional forum addressed this topic in April 2012.²² Billing-related challenges identified by participants included:

- The reality that many PHLs' LIMS do not have billing capabilities or are not compatible with billing software,
- Privacy considerations (e.g., related to sexually transmitted disease testing in minors),
- Diversion of payments away from the laboratory,
- Legal prohibitions or limitations,
- Determining charge amounts and whom to charge for testing during outbreaks,
- The potential need for legislative approval of fees or for promulgation of related regulations,
- How to set prices for low-volume tests when the reimbursement rate is less than the cost per test, and
- Lack of staff with experience in billing and CPT coding and alignment of billing activities with new electronic medical records requirements.

Forum participants suggested that APHL could identify competent third-party billing services and explore enhanced reimbursement for PHL services. Based on these recommendations, APHL is developing a document that will combine information on billing and associated requirements that will be distributed to PHLs as guidance as they consider implementing or expanding reimbursement.

Key strategy #6: workforce development. Every LEI-related consultation has outlined the critical need for strategies to address important issues related to the PHL workforce. The laboratory workforce is critical to implementation of advanced testing technologies and efficient management practices. National public health leaders have recognized a major gap in the number of science, mathematics, and engineering majors needed to fill the scientific and technology needs of PHLs. A steering group of CDC staff and the APHL Workforce Committee identified short- and long-term priorities as a focus for workforce development, including restoring the Emerging Infectious Disease (EID) Fellowship Program, developing PHL workforce competencies, and developing a broad, long-term PHL strategy to guide workforce development.

The EID Fellowship Program has been in place since January 1996; has wide support across CDC, APHL, and the states; and has become a vital pipeline of appropriately trained laboratory scientists who will fill the critical leadership and research roles in PHLs. The program provides fellowships for doctoral-level graduates (e.g., doctor of philosophy, medical doctor, or doctor of veterinary medicine) who train as research fellows for two years, and bachelor's- or master's-level graduates who serve as training fellows for one year. The program has

recently experienced sizeable funding cuts and, subsequently, a more than 50% reduction in fellows since its peak in 2007, despite the ever-increasing demand for, and interest in, the fellowships. Plans are in development to create a sustainable funding solution and make structural improvements (e.g., competency-based training approaches) in the program.

The lack of defined PHL workforce competencies is a major gap in workforce development. The APHL Workforce Development Committee has engaged in developing leadership and management competencies for public health, environmental, and agricultural laboratory (PHEAL) workers to address multiple needs, such as determining appropriate job descriptions, evaluating personnel based on standardized criteria, and developing career ladders. An APHL/CDC panel of experts assembled in October 2012 to provide direction, guidance, and oversight to a year-long engagement of various SMEs who will develop PHL workforce competencies based on the PHEAL draft competencies. The final competencies will align with the Council on Linkages Between Academia and Public Health Practice format²³ and will be based on the Core Functions of State PHLs.⁹ SME teams are developing cross-cutting competencies (e.g., informatics, quality management systems, and safety) that apply to all laboratory workers; more general competencies (e.g., management and communication) that are tailored to laboratory scientists; and technical competencies that are specific to disciplines (e.g., microbiology and chemistry). The competencies are projected to be completed by December 2013 and published thereafter. The published competencies will help PHL directors develop career ladders and will serve as a basis for competency-based training, among several other uses. CDC and APHL had worked together previously to develop laboratory competencies in biosafety.²⁴

APHL and CDC will form a working group to draft a workforce strategic plan that will constitute an agenda for the future of the PHL workforce. The working group will bring together a national group of SMEs, including federal, state, and local stakeholders, to build on the work already begun by the 2012 Public Health Workforce Summit and other disciplines related to laboratory practice. This group will identify critical deficiencies, recommend strategies for addressing them, and prioritize key activities for immediate response. The workgroup will create innovative programs for leadership development; develop proposals for funding models to increase the pipeline of new laboratory scientists; and explore national partnerships with academic institutions, professional associations, and state and federal PHLs.

Key strategy #7: laboratory workflow improvement. Laboratory workflow management is critical to providing efficient, accurate, reliable, and timely test results. Improving workflow practices yields multiple benefits, including decreased costs, improved efficiency, and decreased turnaround time of test results. If not managed properly, poor workflow practices can result in increased costs, wasted resources, and undesirable patient outcomes.²⁵

One method of improving laboratory workflow is the adoption of Lean Six Sigma principles, which have long been recognized as enhancing cost saving and process improvement in the manufacturing world, and for which implementation is increasing in the clinical laboratory,²⁶ although little has been documented about their use in PHLs. APHL has conducted two workshops on the basics of Lean principles for its members to promote the use of workflow management improvement processes. Additional information on the Lean activities is available at APHL's Member Resource Center.²⁷

APHL is partnering with Abbott Diagnostics to conduct some Lean process analysis activities in selected PHLs, and the findings and recommended solutions will be shared with all PHLs. Suggestions for additional Lean tools include conducting follow-up training sessions on Lean activities, developing self-assessment checklists that will enable PHLs to identify their current workflow management capabilities and areas for improvement, providing tools to assist laboratories in implementing workflow management, and encouraging PHLs to post process maps and lessons learned from their own experiences in the APHL Member Resource Center.

The LEI is also advancing efforts on some essential resources and requirements that underpin the adoption of efficiencies. These supporting efforts are described hereafter.

Supporting activity #1: consolidated test services data and directory. An LEI priority is improving access to information on PHL testing capabilities, which is critical to guide program investments and serves as a baseline for future efforts to sustain PHLs. Such data are also essential for states and local entities when making decisions regarding changes in test services and surge or shared services scenarios. Currently, data on state and local PHL test services and volumes are collected in a disparate fashion by APHL through its various surveys and by a number of CDC programs that support laboratory testing in states.²⁸ Aggregate data on state and local test services are shared through APHL's biennial surveys; however, a comprehensive annual report of state-by-state test services and volume has

not been published since 2000.²⁹ To recreate an up-to-date consolidated annual report, data were collected both electronically and in hard copy from seven CDC program and funding mechanisms (PHEP, Epidemiology and Laboratory Capacity, Vector-Borne Diseases, Tuberculosis, Laboratory Response Network—Biological, Laboratory Response Network—Chemical, and Foodborne Diseases) and from APHL's Core and Comprehensive Laboratory Service surveys (which included 50 states and the District of Columbia). These data were put into a uniform format for visualization and analysis of testing capabilities by state. Analytic findings served as the basis for a CDC/APHL consultation in December 2011 to develop guiding principles for improved data management within and between the two entities.³⁰ The recommendations from this consultation are summarized in Figure 4. A new APHL/CDC Test Service Data Subcommittee that convened in April 2012 developed recommendations³¹ that led to the following ongoing activities:

- Data-sharing agreements: Leverage existing agreements to create a test service data-sharing

agreement between state and local PHL staff and appropriate CDC staff. States are willing to share data when agreements are made that prevent the unauthorized sharing or releasing of individual laboratory data as a result of Freedom of Information Act requests.

- Survey reports: All survey reports developed by CDC and APHL are being collected to identify which formats may serve as a good framework for PHL test service data. An outline of a potential standard report will be created for review by the subcommittee.
- Consolidating survey data: APHL has redesigned its Survey Resource Center (SRC) to allow users to access state profiles and search a database of APHL surveys. The SRC has the potential to consolidate CDC and APHL test service data, which can then be shared with PHL directors and selected CDC staff in a user-friendly format. A subset of these data can be distributed broadly to improve transparency at the state and local level.

Figure 4. Recommendations from an APHL/CDC consultation in December 2011 for strengthening the management of PHL test services data^a

<i>Test service data management element</i>	<i>Recommendations</i>
Principles for data analysis and reporting for the joint data-collection process	<ul style="list-style-type: none"> • Coordinate data requests and responses. • Standardize terms, definitions, and data format. • Identify and address areas of sensitivity. • Articulate clear data-collection purpose. • Explore the use of data use/sharing agreements.
Guiding principles for data access and transparency	<ul style="list-style-type: none"> • Allow a broad process for the most technologically feasible transparency and access. • If you contribute, you should have access. • Make it user friendly. • Allow access and collaboration between CDC and APHL and among their programs, internally and externally.
Framework for improving the data-collection process	<ul style="list-style-type: none"> • Develop a governance structure and charter for the group that will improve the data-collection process. • Foster a culture of change at CDC and APHL, and among APHL's members, engaging stakeholders from all three groups. • Knowledge exchange: share data beyond the current audience in user-friendly interfaces and make past questions and responses available. • Create a business plan in which PHLs focus their efforts on the future and what efficiencies they can realize in the near term (continuous improvement). • Ensure sustained involvement from CDC and APHL leadership as well as APHL's members to keep momentum and allocate appropriate resources.

^aAssociation of Public Health Laboratories and Centers for Disease Control and Prevention (US). Summary: APHL/CDC public health laboratory service data consultation. Silver Spring (MD): APHL; December 2011. Also available from: URL: http://www.aphl.org/aphlprograms/iss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012Jan_PHL-Service-Data-Meeting-Summary.pdf [cited 2013 April 25].

APHL = Association of Public Health Laboratories

CDC = Centers for Disease Control and Prevention

PHL = public health laboratory

- PHL management database: The CDC Office of Infectious Disease Laboratory database, which contains information on staffing, equipment, regulatory requirements, quality systems, testing capabilities, methodologies, and volumes, will be modified and disseminated for use by state and local PHLs. The modified database will improve internal (state-specific) management of information and streamline survey responses, as it will import and export test service data to APHL and CDC, thereby eliminating the need for some survey activities.

As a result of these deliberations, CDC and APHL have consolidated their existing test service data, which were posted on the APHL SRC and made accessible in June 2013 to all PHL directors to assist with decision making. Relatedly, the PHL management database developed for use by all state and local PHLs for data entry and local analyses is planned for distribution in September 2013. This new management database will also enable APHL to collect consistent and comprehensive data on more than 500 tests and methods, which will be compiled in a national test directory to inform state and local decisions on PHL test services. Most important is the opportunity to reduce duplication, increase consistency, and focus on gaps, such as providing the national directory of specific testing methods rather than general testing services.

Supporting activity #2: metrics for ROI. As budgets for PHLs will continue to be strained in the foreseeable future, it is critical to demonstrate the ROI in PHLs. With the goal of identifying metrics for evaluating ROI, two focus groups were convened in August 2011. The group members represented PHL directors, private laboratories, CDC partner organizations, and CDC, and included evaluators and economists. They concluded that (1) determining ROI in terms of public health impact is complex but can be done with modeling, following extensive data collection and analysis; and (2) measures for accessing efficiency and capability are more easily described and are very appropriate for LEI. Recommendations from the groups were used to develop a framework of proposed metrics for evaluating ROI for LEI. Additional metrics may be needed as the recommended practices are refined.

Several measurements were identified as having the potential to show a positive ROI in the laboratories, including cost per reportable result, operating cost, number of tests per full-time equivalent employee, and cost of purchased supplies and reagents per test. The informatics measures identified were the percentage of (1) orders received or processed electronically,

(2) reports shared by interoperable mechanisms, (3) laboratory tests supported by the LIMS, (4) test results delivered electronically, as well as (5) time required to deliver test results to strategic partners (especially epidemiologists). The workforce capability measures identified were the number of hours of training for current staff and the measurement of changes in good practices following training.

PHLs that implement one or more LEI strategies will be asked to use one or more applicable metrics for each strategy to evaluate the baseline state (pre-LEI strategy adoption) and status following implementation.

Supporting activity #3: legal and policy tools. From the LEI's inception, laboratory directors and workgroups highlighted legal and policy issues important to PHLs' adoption of higher-efficiency management practices. Laboratory directors mentioned laws and other types of policies that could limit or facilitate adoption of these practices. Examples of the former included requirements that certain tests be performed exclusively by a state's PHL (limiting its ability to share testing services between states) and that fee-for-service revenues be deposited to the state's general fund (resulting in financial losses to the laboratory, which would bear the cost of billing but not benefit from the fee payments). Examples of the latter were statutes authorizing counties to share and jointly manage a laboratory, standardized contracts used for one state laboratory to conduct newborn screening for other states, and broad statutory authority that devolved operating discretion to laboratory managers.

The aforementioned "A Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes"¹³ suggested that PHL directors who explore new approaches to conducting testing services assess related legal and policy implications. This guidance was based on lessons learned in the field. As one example, when weighing the possibility of closing a regional laboratory, PHL leaders in Michigan researched existing laws to determine if there was a mandate to maintain laboratories at the sub-state level.

APHL and CDC convened the first meeting of the LEI Legal and Policy Workgroup in August 2012, with participation by the APHL Policy Committee, whose members are five state PHL directors. The workgroup focused on (1) identifying legal and policy issues relevant to the successful implementation of LEI high-efficiency management practices and (2) recommending resources that could be developed for laboratory directors to use in addressing those issues. The committee and the workgroup put highest priority on issues relevant to the sharing of testing services among states' PHLs. The committee's deliberations led

it to call for the development of a guide that laboratory directors could use in determining the impact that existing laws and policies have on the sharing of testing services across multiple states. In response, APHL and CDC initiated the development of a policy guide for publication and dissemination to all APHL members in late 2013, based largely on PHLs' real-world experiences in exploring and implementing multistate test sharing.

LESSONS LEARNED

The professionals who work in the nation's PHLs play unique and indispensable roles in protecting America's health. Their capacity to address established and newly emerging threats, however, was deeply stressed during and following the recession of the late 2000s. More generally, the Institute of Medicine concludes that public health funding is "inadequate, unstable, and unsustainable."¹

The goal of LEI is to help individual PHLs reestablish sustainability and the capacity to conduct critically needed testing and other services. In addition, the LEI provides a collaborative space that brings together stakeholders to have candid exchanges, learn from each other, and sustain a vibrant PHL system for the future. The emphasis on heightened efficiency and cost savings stems from forecasts that state and discretionary federal government budgets are likely to remain tightly constrained in the foreseeable future.^{15,16} Indeed, public health funding is unpredictable, inadequate, and uncoordinated.¹ The LEI generated valuable new information and tools in its first year, and more are in development. The strategic plan outlines many of the activities and initiatives to be developed or launched through 2015. Most activities outlined in the LEI strategic plan are voluntary and may require additional personnel resources, which may limit integration of the initiative strategies and products within PHLs. However, the eventual sharing of experiences between PHLs as the initiative advances may help others see the benefits that justify the initial outlays of staff time and resources.

An important, additional achievement is the heightened recognition of PHLs that the LEI has stimulated among such partners in the larger public health system as state and local public health leaders and including the Association of State and Territorial Health Officials, the Council of State and Territorial Epidemiologists, and the National Association of County and City Health Officials. The entire public health system faces acute, multipronged challenges,¹ and these and other partners are all actively exploring ways to achieve greater

impact through new focus, new efficiency, and assured capacity to deliver the testing, health monitoring, and interventions required in the coming decades. Additional information about the LEI, its achievements, and ways to contribute to it is available at <http://www.aphl.org/lei> and <http://www.cdc.gov/OSELS/lspppo/lei>.

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REFERENCES

1. Institute of Medicine. For the public's health: investing in a healthier future. Washington: National Academies Press; 2012.
2. Wilson ML, Gradus S, Zimmerman SJ. The role of local public health laboratories. *Public Health Rep* 2010;125 Suppl 2:118-22.
3. Dowdle WR, Mayer LW, Steinberg KK, Ghiya ND, Popovic T. Laboratory contributions to public health. *MMWR Morb Mortal Wkly Rep* 2011;60(04):27-34.
4. Skeels MR. Toward a national laboratory system for public health. *Emerg Infect Dis* 2001;7(3 Suppl):531-2.
5. Astles JR, White VA, Williams LO. Origins and development of the National Laboratory System for public health testing. *Public Health Rep* 2010;125(Suppl 2):18-30.
6. Inhorn SL, Astles JR, Gradus S, Malmberg V, Snippes PM, Wilcke BW Jr, et al. The state public health laboratory system. *Public Health Rep* 2010;125(Suppl 2):4-17.
7. Association of Public Health Laboratories. Definition of a state public health laboratory system. Silver Spring (MD): APHL; June 2007. Also available from: URL: http://www.aphl.org/AboutAPHL/publications/Documents/Definition_of_a_State_PHL_System_2007.pdf [cited 2013 Apr 18].
8. Wilcke BW Jr, Inhorn SL, Astles JR, Su B, Wright A, White VA. Laboratory services in support of public health: a status report. *Public Health Rep* 2010;125(Suppl 2):40-6.
9. Witt-Kushner J, Astles JR, Ridderhof JC, Martin RA, Wilcke B Jr, Downes FP, et al. Core functions and capabilities of state public health laboratories: a report of the Association of Public Health Laboratories. *MMWR Recomm Rep* 2002;51(RR-14):1-8.
10. Association of Public Health Laboratories. Laboratory System Improvement Program: performance measurement tool. Silver Spring (MD): APHL; August 2011. Also available from: URL: http://www.aphl.org/AboutAPHL/publications/Documents/LSS_2011_LSIP_PerformanceMeasurementTool.pdf [cited 2013 Apr 25].
11. Trust for America's Health. Investing in America's health: a state-by-state look at public health funding and key health facts. Washington: Trust for America's Health; 2012. Also available from: URL: <http://healthyamericans.org/report/105> [cited 2013 May 8].
12. University of Michigan Center of Excellence in Public Health Workforce Studies and Association of Public Health Laboratories. National laboratory capacity assessment, 2011: findings and recommendations for strengthening the U.S. workforce in public health, environmental, and agricultural laboratories. Ann Arbor (MI): University of Michigan; 2012.
13. Association of Public Health Laboratories and Centers for Disease Control and Prevention (US). A practical guide to assessing and

- planning implementation of public health laboratory service changes. Silver Spring (MD): APHL; May 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_April2013_Service_Change_Practical_Guide.pdf [cited 2013 Apr 25].
14. Berkery MR, Penn MS. Legal considerations in cross-jurisdictional sharing of public health laboratory services. *Public Health Rep* 2013;128(Suppl 2):70-4.
 15. Congressional Budget Office (US). The budget and economic outlook: fiscal years 2013 to 2023. Washington: Congressional Budget Office; 2013. Also available from: URL: <http://cbo.gov/sites/default/files/cbofiles/attachments/43907-BudgetOutlook.pdf> [cited 2013 May 8].
 16. Government Accountability Office (US). State and local governments' fiscal outlook: April 2013 update. Washington: GAO; April 2013. Also available from: URL <http://www.gao.gov/assets/660/654255.pdf> [cited 2013 May 8].
 17. Association of Public Health Laboratories. Data summary of the 2010 core laboratory profiles survey. Silver Spring (MD): APHL; August 2011. Also available from: URL: http://www.aphl.org/AboutAPHL/publications/Documents/LSS_2011August_CLSS_SurveyReport.pdf [cited 2013 Apr 25].
 18. Association of Public Health Laboratories. NCPHLL leadership forum series: procurement improvement strategies. Silver Spring (MD): APHL; March 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012March_NCPHLL-Procurement-Meeting-Summary.pdf [cited 2013 Apr 25].
 19. Association of Public Health Laboratories and Centers for Disease Control and Prevention (US). Summary report: harmonizing test platforms to increase efficiencies in public health laboratories. Silver Spring (MD): APHL; April 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012April11_Standardization-Platforms-Summary-Report.PDF [cited 2013 Apr 25].
 20. 45 C.F.R. Part 170. Final Rule (July 28, 2010).
 21. Association of Public Health Laboratories. Requirements for public health laboratory information management systems: a collaboration of state public health laboratories, the Association of Public Health Laboratories, and the Public Health Informatics Institute. Silver Spring (MD): APHL; September 2003. Also available from: URL: http://www.aphl.org/aphlprograms/informatics/Documents/INF_2003Sept_Reqs-for-PHL-IMS.pdf [cited 2013 Apr 18].
 22. Association of Public Health Laboratories. Laboratory Efficiencies Initiative (LEI) public health laboratory director forums meeting summary. Silver Spring (MD): APHL; April 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012April_PHL-Directors-Forum.pdf [cited 2013 Apr 25].
 23. Council on Linkages Between Academia and Public Health Practice. Core competencies for public health professionals. Washington: Public Health Foundation; May 2010. Also available from: URL: http://www.phf.org/resourcestools/Pages/Core_Public_Health_Competencies.aspx [cited 2013 Apr 18].
 24. Delany JR, Pentella MA, Rodriguez JA, Shah KV, Baxley KP, Holmes DE. Guidelines for biosafety laboratory competency: CDC and the Association of Public Health Laboratories. *MMWR Morb Mortal Wkly Rep* 2011;60(02):1-6.
 25. Clinical and Laboratory Standards Institute. Quality management system: continual improvement; approved guideline. 3rd ed. Wayne (PA): CLSI; 2011.
 26. Joint Commission on Accreditation of Healthcare Organizations. Advanced lean thinking: proven methods to reduce waste and improve quality in health care. Oakbrook Terrace (IL): Joint Commission Resources; 2008.
 27. Association of Public Health Laboratories. Member resource center [cited 2013 Apr 25]. Available from: URL: <http://www.aphl.org/MRC/pages/searchresults.aspx?Keywords=Lean>
 28. Inhorn SL, Wilcke BW Jr, Downes FP, Adjanor OO, Cada R, Ford JR. A comprehensive Laboratory Services Survey of State Public Health Laboratories. *J Public Health Manag Pract* 2006;12:514-21.
 29. Association of State and Territorial Public Health Laboratory Directors. Consolidated annual report on state and territorial public health laboratories, fiscal year 1991. Washington: Association of State and Territorial Public Health Laboratory Directors; 1994. Also available from: URL: <http://www.aphl.org/MRC/Documents/CAR1991.pdf> [cited 2013 Apr 25].
 30. Association of Public Health Laboratories and Centers for Disease Control and Prevention (US). Summary: APHL/CDC public health laboratory service data consultation. Silver Spring (MD): APHL; December 2011. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012Jan_PHL-Service-Data-Meeting-Summary.pdf [cited 2013 Apr 25].
 31. Association of Public Health Laboratories and Centers for Disease Control and Prevention (US). Summary: APHL/CDC joint committee on public health laboratory service data. Silver Spring (MD): APHL; April 2012. Also available from: URL: http://www.aphl.org/aphlprograms/lss/Laboratory-Efficiencies-Initiative/Documents/LEI_2012April6_APHL-CDC-PHL-Service-Data.pdf [cited 2013 Apr 25].