GUEST EDITORIAL
Public Health Laboratory Systems: At the Crossroads
JC Ridderhof, BW Wilcke, Jr.

COMMENTARY
The Affordable Care Act, Meaningful Use, and Their Impact on Public Health Laboratories
SH Hinrichs, P Zarcone

Supporting Public Health Laboratory Systems Research
BW Wilcke, Jr., SY Del Rio Daher, KJ Breckenridge

Newborn Screening: From Guthrie to Whole Genome Sequencing
M Caggana, EA Jones, SI Shahied, S Tanksley, CA Hermerath, IM Lubin

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

State Public Health Laboratory System Quality Improvement Activities
B Su, P Snippes Vagnone

Milwaukee Laboratory System Improvement Program (L-SIP)
MS Gradus, S Bhattacharyya, A Murphy, JN Becker, BK Baker

Laboratory System Improvement Program: First in the Nation—New Hampshire Reassessment
JJ Power, CL Bean, A Cosser, A Vazquez

The Indiana Laboratory System: Focus on Environmental Laboratories
JM Madlem, KR Hammes, SR Matheson, JC Lovchik

Using Interorganizational Partnerships to Strengthen Public Health Laboratory Systems
K Hsieh, P Kimsey, G Buehring

Legal Considerations in Cross-Jurisdictional Sharing of Public Health Laboratory Services
MR Berkery, MS Penn

RESEARCH
Evaluation of Three Influenza Neuraminidase Inhibition Assays for Use in a Public Health Laboratory Setting During the 2011–2012 Influenza Season
W Murtaugh, L Mahaman, B Healey, H Peters, B Anderson, M Tran, M Ziese, M Paz Carlos

Evaluation of the Novel Respiratory Virus Surveillance Program: Pediatric Early Warning Sentinel Surveillance (PEWSS)
PA Armour, LM Nguyen, ML Lutman, JP Middaugh

Using Fee-for-Service Testing to Generate Revenue for the 21st Century Public Health Laboratory
C Loring, RB Neil, L Gillim-Ross, M Bashore, S Shah

Core Courses in Public Health Laboratory Science and Practice
JM DeBoy, AJ Beck, ML Boulton, DH Kim, MD Wichman, PF Luedtke
Public Health Reports is the journal of the U.S. Public Health Service (PHS) and the Office of the U.S. Surgeon General and is published through an official agreement with the Association of Schools and Programs of Public Health (ASPPH), 1900 M St. NW, Ste. 710, Washington, DC 20036. All manuscripts are peer reviewed. Opinions expressed are the authors’ and do not reflect the views of Public Health Reports, PHS, or ASPPH. Trade names are used for identification only and do not represent an endorsement by PHS or ASPPH.

Printed on 30% recycled paper.


A subscription form appears on the back cover.

Please visit the Journal’s website at http://www.publichealthreports.org
This supplement was supported by Cooperative Agreement #U60HM000803 from the Centers for Disease Control and Prevention (CDC) and/or Assistant Secretary for Preparedness and Response. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC and/or Assistant Secretary for Preparedness and Response. The Laboratory Efficiencies Initiative program was 100% funded from federal funds, with a budget of $721,559.
RESEARCH

Evaluation of Three Influenza Neuraminidase Inhibition Assays for Use in a Public Health Laboratory Setting During the 2011–2012 Influenza Season ...............75
William Murtaugh, Lalla Mahaman, Benjamin Healey, Heather Peters, Barbara Anderson, Mandy Tran, Marci Ziese, Maria Paz Carlos

Evaluation of the Novel Respiratory Virus Surveillance Program: Pediatric Early Warning Sentinel Surveillance (PEWSS) .........................88
Patricia A. Armour, Linh M. Nguyen, Michelle L. Lutman, John P. Middaugh

Using Fee-for-Service Testing to Generate Revenue for the 21st Century Public Health Laboratory ........97
Carol Loring, R. Brock Neil, Laura Gillim-Ross, Matthew Bashore, Sandip Shah

Core Courses in Public Health Laboratory Science and Practice: Findings from 2006 and 2011 Surveys ....105
John M. DeBoy, Angela J. Beck, Matthew L. Boulton, Deborah H. Kim, Michael D. Wichman, Patrick F. Luedtke

The contents, findings, and views contained in this supplement are those of the authors and do not necessarily represent the official programs and policies of the Centers for Disease Control and Prevention or the U.S. Department of Health and Human Services.
Subscription, Permission, and Copyright Information

Subscription is on a yearly basis. The annual rates are US $50 for students (print only), US $150 for individuals (print and online), US $90 for individuals (online or print only), and US $167 for institutions (print only). Pricing information for online institution subscriptions is available at http://www .publichealthreports .org. An international shipping charge of US $50 will apply to subscriptions outside of North America. Single issues are available for US $30 (PDF or limited quality of print available). All prices include postage. Individual rates are only applicable when a subscription is for individual use. All subscriptions, single issue orders, changes of address, inquiries, and claims for missing issues should be sent to: Public Health Reports, c/o ASPPH, 1900 M St. NW, Ste. 710, Washington, DC 20036; tel. 877-478-2468, 202-296-1099; e-mail <support@publichealthreports .org>.

Display, Classified, and Recruitment Advertising, Sponsorships, Supplements, and Reprint inquiries should be addressed to: Public Health Reports, c/o ASPPH, 1900 M St. NW, Ste. 710, Washington, DC 20036; tel. 877-478-2468, 202-296-1099; e-mail <support@publichealthreports .org>.

Requests for Permissions, Reprints, and Photocopies: All rights reserved; no part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission of: Public Health Reports, c/o ASPPH, 1900 M St. NW, Ste. 710, Washington, DC 20036; tel. 877-478-2468, 202-296-1099; e-mail <support@publichealthreports .org>.

It is a condition of publication in the Journal that authors assign copyright to the Association of Schools and Programs of Public Health (ASPH). This ensures that requests from third parties to reproduce articles are handled efficiently and consistently and will also allow the article to be as widely disseminated as possible. Although assigning copyright, authors may use their own materials in other publications provided that Public Health Reports is acknowledged as the original place of publication.

Material published in this Journal may be used, modified, reproduced, and distributed by the U.S. government for government purposes.

Public Health Reports is printed on acid-free paper that meets the minimum requirements of ANSI Standard Z39.48-1984 (Permanence of Paper).

For more information about ASPPH, please visit http://www .aspph.org

Copyright ©2013 Association of Schools and Programs of Public Health
Advertising Rates & Deadlines for Vol. 129

Public Health Reports (PHR) is a bimonthly peer-reviewed journal offering articles in three main areas: public health practice, research, and viewpoints/commentaries. PHR has been one of the public health community’s key information resources for more than 130 years. PHR is distributed to members, the research community, academic libraries, government agencies, and many health-related industries.

**DEADLINES**

Vol. 128, no. 6 (Nov/Dec 2013): **September 3, 2013**
Vol. 129, no. 1 (Jan/Feb 2014): **November 4, 2013**
Vol. 129, no. 6 (Nov/Dec 2014): **September 5, 2014**

*All ad submissions must first be approved by the editor and publisher for content and professionalism in keeping with the publication’s standards.*

**ADVERTISING DESIGN**

The ad can be designed from a Word document at no additional charge. Please be prepared to submit completed copy and high-resolution images.

The following file formats are accepted: **DOC, PDF, EPS, or high-resolution JPG.**

**GENERAL ADVERTISING RATES**

PHR is printed in **black and white**; no color ads will be accepted.

<table>
<thead>
<tr>
<th></th>
<th>1x</th>
<th>3x</th>
<th>6x</th>
</tr>
</thead>
<tbody>
<tr>
<td>Half page</td>
<td>$250</td>
<td>$242</td>
<td>$235</td>
</tr>
<tr>
<td>Full page</td>
<td>$500</td>
<td>$480</td>
<td>$461</td>
</tr>
</tbody>
</table>

Discounted Rate:

<table>
<thead>
<tr>
<th></th>
<th>1x</th>
<th>3x</th>
<th>6x</th>
</tr>
</thead>
<tbody>
<tr>
<td>Half page</td>
<td>$200^</td>
<td>$194^</td>
<td>$188^</td>
</tr>
<tr>
<td>Full page</td>
<td>$400^</td>
<td>$384^</td>
<td>$369^</td>
</tr>
</tbody>
</table>

^Discounted rate for members and affiliate organizations.

**MECHANICAL REQUIREMENTS**

- **Full page**: 7.25 x 9.75 inches
- **Half page Horizontal**: 7.25 x 4 inches
- **Half page Vertical**: 3.25 x 9.75 inches

**SUBMISSION**

E-mail ad copy to: scarter@aspph.org

Mail check payments to:
(payable to Public Health Reports)
Association of Schools and Programs of Public Health
1900 M Street NW, Suite 710
Washington, DC 20036

Questions: Stella Carter, 202-296-1099 ext 146

Payment must be submitted at the time the ad is submitted.
PUBLIC HEALTH LABORATORY SYSTEMS: AT THE CROSSROADS

JOHN C. RIDDERHOF, DRPH, HCLD(ABB)
BURTON W. WILCKE, JR., PHD, SM(ASCP)

Twenty years ago, Walter Dowdle observed that the word “laboratory” did not even appear in the index of the now classic 1988 Institute of Medicine (IOM) report, “The Future of Public Health.” It was Dr. Dowdle’s contention that despite the significant role of laboratories dating back more than 100 years to the earliest days of public health, a point had been reached where laboratories and their many contributions to public health were being taken for granted. During the last 20 years, much has changed to elevate the visibility of public health laboratories (PHLs). Their expanded roles, their engagement with partners, and their core functions have all been described and reaffirmed.

This special supplement of Public Health Reports (PHR) is devoted to PHL systems, with an emphasis on activities and approaches that represent managing and improving the system across many different dimensions.

It has become clear that, to meet the broad array of laboratory services required to support both public health and health care in the United States, PHLs have been and will continue operating within systems, especially state public health laboratory (SPHL) systems. How those systems are set up and funded and which entities are included vary by state or locality. Irrespective of how laboratory systems are put together, the evidence confirms that the laboratory services provided by these systems go well beyond the mere performance of laboratory tests and analyses. These systems are critical in their support of the 10 Essential Public Health Services (hereafter, Essential Services).

PHLs at all levels, along with their respective leaders and partners, have in the past maintained and will continue to maintain the important linkages required to strengthen and sustain their respective systems.

In 2010, PHR published a supplement on PHLs that focused on their many evolving roles and how they provide unique and ever-changing functions in support of public health and health care. The evolution of PHL systems, which was primarily influenced by emerging diseases, threats, programs, technologies, and innovation, is now being driven by a convergence of health reform, state and federal funding cuts, and the evolving role of public health.

HEALTH REFORM

The challenges that exist for PHL systems are many; however, one area that has the potential for significant impact is that of health-care reform. Health-care reform is occurring at both the federal and state level; as such, it has implications for all of public health. Impending health-care reform initiatives hold the promise of increasing access to health insurance with corresponding access to medical services. This fast-approaching era of increased coverage has led to a national dialogue about the changing role of public health departments, most of which still provide direct clinical care and serve as a safety net for underserved populations. The ultimate impact of health-care reform on public health and specifically PHL systems has yet to be determined.

One critical aspect of the changing landscape that transcends both health care and public health is the move toward electronic health records. At one time, PHLs were focused primarily on information systems related to laboratory management. Now, however, it is clear that PHLs must also be able to receive and transmit large amounts of data and information in a fast, secure, and retrievable manner to serve the needs of the provider, the patients, and the community at large. This need will challenge PHLs’ capacity for electronic information exchange. Activities such as test ordering and reporting that may provide both clinical results to providers and critical public health surveillance data programs are moving into a new era of information technology. The PHLs are reviewing their roles and upgrading their capacity to report electronically at the same time that many are working to sustain services in the face of a recession and corresponding budget constraints.

Advances in analytical technology are also driving the capabilities for disease detection, as outlined in a comprehensive overview of the PHL success story of newborn screening, with new molecular sequencing methods potentially changing the landscape of confidentiality and challenging quality practices for rare disease testing. Although the article in this supplement by Murtaugh et al. addresses very specific testing of drug-resistant influenza strains, it is also a good
example of method evaluation for rapidly evolving PHL testing for surveillance.

**FINANCIAL PRESSURES**

The way in which we finance health care in the U.S. is changing. In this issue, Heinrichs and Zarcone propose that one potential outcome of this changing paradigm is the prospect of reducing or removing federal funding for certain screening tests that are traditionally performed by PHLs. These funding streams have simultaneously contributed to supporting basic PHL infrastructure and capacity. In the past, there were increases or at least stable funding for key programs such as Public Health Emergency Preparedness (PHEP) and Epidemiology and Laboratory Capacity. National program cuts in these areas combined with reductions in state-level funding have raised significant interest in the topic of fee-for-service testing. The article by Loring et al. in this supplement provides information that, for the first time, educates the broader public health audience about the true extent of fee-for-service practices and the role that these fees play in supporting PHLs.

The recession and resulting focus on sustainability have brought renewed interest in public health financing. There has been a parallel effort to examine financing for PHLs, many of which are indirectly funded through categorical public health programs. As outlined by Loring et al. in this issue, the Association of Public Health Laboratories (APHL) collects funding information from the 50 state PHLs through its biennial core survey. Although the 2010 survey had a relatively low response (37/50), the aggregate state-reported data indicated that the overall federal contribution was about one-third of the total PHL funding sources. Although the PHLs vary by mission, this funding information clarifies that the cost of PHL testing services is supported by a roughly equal distribution of fees and state and federal funding. Many states rely heavily on fee-for-service testing, and some tests (e.g., newborn screening) are funded almost entirely by fee-for-service testing, with the federal contribution supporting national guidance, technical assistance, and quality assurance programs. Other programmatic areas, such as bioterrorism preparedness and the Laboratory Response Network (LRN), are relatively new and this capacity has been developed with ongoing support through the PHEP grant, although this funding line has also been reduced in recent years.

Another resource-related topic, pointed out in this issue by Heinrichs et al., is PHLs’ dependence on federal funds to help support core capacity, in the form of equipment and staff that can be extended to special testing services that have limited funding and are performed exclusively in PHLs. They note that the PHEP grant for LRN capacity has been critical to purchasing capital equipment and technical infrastructure that also support other public health testing services, such as testing for vaccine-preventable diseases (VPDs). Most categorical program contributions fall in between, with federal funds often supporting a fraction of the total staff, equipment, and reagent costs, excluding the overhead costs of facilities and utilities that might not come directly from the PHL budget. Lastly, there are some longstanding public health functions, such as rabies testing, that save millions of dollars from unnecessary prophylaxis due to animal exposures and that are funded almost entirely by states.

Billing for services is a relatively recent priority, although the majority of PHLs have implemented some form of fee-for-service testing for years. The Loring et al. article uses a recent survey in addition to existing APHL core surveys to characterize the extent, mechanisms, and challenges for various forms of fee for service, including third-party billing. Although previously the topic of billing was rarely addressed publicly or systematically, the National Vaccine Advisory Committee and Trust for America’s Health have both developed positions that public health should bill for services among those clients who visit public health clinics and have some form of reimbursable health insurance. There are still remaining concerns that expansion and increased visibility of billing will increase competition for reimbursable tests, leaving only nonreimbursable tests in the public sector. Others argue for increased revenue from reimbursable clinical tests, such as testing for sexually transmitted diseases, to support key public health testing services that are not reimbursable and for which state government support has decreased. Recognizing that these decisions are governed by state and local policies and statutes, current strategies include the provision of information on billing requirements, such as specific billing software, to assist those PHLs that want to increase their revenue sources.

The public health world has always had its own share of issues and responsibilities that complement the world of health care and personal health. That list of public health issues continues to grow with new challenges such as health-care facility-acquired infections, increasing antimicrobial resistance, food safety concerns that are international in scope, emerging zoonotic diseases, and emergency response preparedness. At the same time, there is no indication that many of the traditional public health issues (e.g., newborn
screening, safe water, VPDs, and radiologic health) are diminishing or disappearing. Meanwhile, consumers of PHL services, clinical providers, and public health programs expect that the services of PHL systems will continue to be conducted at a high level of quality despite the funding challenges.\(^6,8,15\)

**QUALITY IMPROVEMENT**

PHLs have always had a focus on quality, whether it has been the quality control of analytical procedures performed in-house, the quality assurance of laboratory processes, or facilitating training in quality assurance for other laboratories within their state or region. In fact, PHLs and clinical laboratories have been steadfastly focused on quality for many decades. The need for attention to quality has now expanded to measure quality within systems, even to the overall public health systems that exist throughout the U.S. Two initiatives that are currently underway address the need for quality assessment at the laboratory system level and quality at the local, state, and tribal public health agency level. These initiatives are the Laboratory System Improvement Program (L-SIP)\(^7\) and the Public Health Accreditation Board (PHAB).\(^8\)

PHAB has just recently initiated its process of accrediting state and local health departments that meet the required standards of performance. PHAB follows a broad approach that spans 12 domains, each of which covers specific standards. The domains represent performance associated with the Essential Services plus one domain focused on administration and another on governance. PHAB does not look at performance in a categorical or discipline-specific way; however, access to quality PHL services is essential for PHAB accreditation.

L-SIP was designed to assess how laboratory systems are fulfilling the needs of their communities and to determine if and where improvements are warranted. L-SIP also tracks laboratory system performance in line with the Essential Services. Slightly more than half of the states plus one local municipality have gone through the L-SIP process. One state has gone through the process twice. Participants have indicated that L-SIP has been particularly useful in strengthening partnerships, enhancing communication, evaluating system goals, forming advisory bodies, and developing workforce strategies. Specific quality improvement activities that were derived from the L-SIP process are covered in the article by Su and Vagnone.\(^9\)

**NEW APPROACHES TO AN EFFECTIVE AND SUSTAINABLE LABORATORY SYSTEM**

The recent state and federal budget constraints\(^8\) have provided urgency to many previous recommendations to identify a core set of testing services that all PHLs could provide vs. tests that might be referred to other PHLs or CDC, which are better positioned to provide and maintain specialized testing services. Various national efforts to identify sustainability strategies for public health have recommended defining and identifying “foundational capabilities” that represent services that should be provided by every public health department.\(^9\) APHL and others have helped to identify and publish core functions of state PHLs;\(^10\) however, identifying a distinct set of testing services has been challenging. PHLs vary based on the characteristics of their respective jurisdictions, which in turn affect programmatic priorities. Although a core test list for PHLs has not been published, APHL and CDC have worked together in some program areas, such as tuberculosis and influenza, to provide national guidance on core testing services. One concern is that developing a national list of core tests for PHLs may put pressure on states to discontinue any test that is not included on such a list. Additionally, sharing tests and the perceived savings from discontinuing selected specialized tests do not always take into account the shared core operating costs for facilities, staff, and equipment. Sharing testing services is one strategy among many, but other promising approaches may emerge through the expanding area of PHL systems and services research described by Wilcke et al.\(^11\)

In the spring of 2011, Dr. Thomas Frieden became the first CDC director to call for an initiative focused on the sustainability of PHLs that cuts across individual program areas.\(^23\) Dr. Frieden’s and CDC’s support has helped to renew and support APHL’s efforts for program integration. The Laboratory Efficiencies Initiative described by Ridderhof et al.\(^24\) has helped enable support for a number of sustainability strategies, including system-wide approaches to improving the PHL workforce, informatics, data accessibility, procurement, billing, interstate sharing, and optimal organization of test services.

An ongoing area of change is determining a balance between access to both routine and specialized testing services within and between state and local jurisdictions. Hsieh et al.\(^25\) explore the funding and agreements that have allowed the merger of selected county PHLs in California while still maintaining continued services and sharing the oversight between jurisdictions. Referral structures for testing between states have been developed and funded with selected
programs such as the LRN, but new models will be required to assure access across all public health testing services. An example of one proposed strategy for efficiency is regionalization of selected PHL services, but this approach does not take into account the fact that many services are primarily funded by state revenues or fees that cannot easily be redirected to other states.

Test sharing is a new term that reflects the desire of many PHLs to manage their own decisions on retaining or referring specific testing services, whether to other PHLs or CDC. CDC and APHL collaborated to publish “A Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes” so that PHLs could learn from the experience of colleagues who have established interstate sharing of testing services in addition to intrastate consolidation of PHLs. One key national strategy is recognizing that these decisions are primarily local and that the role of national organizations and agencies is to assure that PHLs have access to complete information, such as a national directory of PHL testing services, to make informed decisions on whether or not to make service changes. When samples are referred to other PHLs, state and local PHLs still need to maintain basic capacity to receive, accession, package, and ship. In this supplement, Berkery and Penn provide an overview of the various legal considerations and several models involved with sharing testing services between and among states.

Several articles in this supplement touch on various approaches to strengthening the SPHL systems as well as advancing sustainability strategies. Other articles showcase efforts and tools needed to strengthen the role of PHL systems in the community along with clinical and public health stakeholders. These articles represent a critical balance of both progressively moving ahead with models by which PHLs provide valuable services to health-care providers, as exemplified by a state-based sentinel network for pediatric respiratory diseases, while also providing evidence for strengthening the PHL infrastructure through workforce initiatives.

Providing support for the PHL workforce is a key role for APHL that evolved with the development of the CDC/APHL cosponsored National Laboratory Training Network in the 1980s to make training workshops and courses more accessible to state and local audiences. There is increasing interest for additional system-wide approaches to address all the workforce challenges in recruiting and retaining staff with specific expertise for the unique technologies, roles, and responsibilities of PHL testing services. Among the many barriers is a lack of specific degrees and educational programs to help fill leadership roles at every level of PHLs. The article by DeBoy et al. highlights core courses identified as priority subject-matter content by PHL directors, with additional survey data on completion of this coursework by a large sample of PHL staff. These core courses provide valuable material for the potential development of master’s and doctoral degrees that might be provided as distance-based learning formats accessible by the entire PHL workforce. Complementing these efforts are the APHL/CDC workforce activities that include developing a comprehensive set of PHL workforce competencies as the basis for training, education, and professional development. Another step in developing system-wide solutions is an APHL/CDC workforce strategy and policy working group (convened May 13–14, 2013) that identified a comprehensive list of priorities, activities, and innovative approaches to support the activities.

CONCLUSION

It has only been 15 years since McDade and Hughes introduced the concept that laboratories must operate within systems to fully serve the needs of health care and public health. Both CDC and APHL have responded to that concept by helping to define the makeup, roles, and core functions of PHL systems. As was seen in the previous PHR supplement on PHL systems, these systems have already gone through a significant period of evolution. Now, although still in their formative stages, these PHL systems are at a crossroads. All of the aforementioned issues are forcing PHL systems to determine the right mix of services, informatics capability, and shared infrastructure required to both sustain and thrive. This focus on sustainability of PHL services, although under very difficult circumstances, has helped shape new ideas among local, state, and federal partners and refocused thinking on the interdependence of individual PHLs within a national laboratory system. How can services be provided and assured within and among various state public health systems? How can local, state, and federal laboratories work together more effectively? How will the PHL systems fare under health reform? What unique combination of financial mechanisms should be used to support PHL services? What existing partnerships need to be strengthened and which new partnerships need to be developed? How can PHL systems actively engage in systems research to identify and implement best practices? How can all of the potential system changes be carried out in a way that still assures quality laboratory services in support of the Essential Services? There is clearly much remaining work to be...
done to answer these questions and identify the best solutions. Even stronger partnership efforts among the local, state, and federal components of the national PHL system will be required. Dr. Dowdle was correct in pointing out the important contributions that are made by PHLs in support of public health, but now it is incumbent upon the PHL community to find the best ways to continue to make these important contributions in the most collaborative, sustainable, and cost-effective way.

The authors thank the staff of the Laboratory Systems and Standards group at the Association of Public Health Laboratories, especially Karen Breckenridge and Sadira Daher, for all of their work in developing this supplement along with support from the Centers for Disease Control and Prevention’s (CDC’s) Laboratory Science Policy and Practice Program Office.

The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of CDC or the Agency for Toxic Substances and Disease Registry.

John Ridderhof is a Senior Advisor for Planning, Laboratory Science, Policy and Practice Program Office, Office of Surveillance, Epidemiology and Laboratory Services, Centers for Disease Control and Prevention in Atlanta, Georgia. Burton Wilcke is an Associate Professor and Chair of the Department of Medical Laboratory and Radiation Sciences, College of Nursing and Health Sciences, The University of Vermont in Burlington, Vermont.

Address correspondence to: John C. Ridderhof, DrPH, HCLD (AB), Centers for Disease Control and Prevention, Office of Surveillance, Epidemiology and Laboratory Services, Laboratory Science, Policy and Practice Program Office, 1600 Clifton Rd. NE, MS-E94, Atlanta, GA 30333; tel. 404-498-0469; fax 404-498-6410; e-mail <jridderhof@cdc.gov>

REFERENCES

29. DeBoy JM, Beck AJ, Boulton ML, Kim DH, Wichman MD, Luedtke PF. Core courses in public health laboratory science and


The Affordable Care Act, Meaningful Use, and Their Impact on Public Health Laboratories

While much discussion of the Affordable Care Act (ACA) has focused on improved access to medical care through expanded insurance coverage, the effect on the laboratory community has yet to be determined. Laboratory testing plays a critical role in health care, with more than 70% of medical decisions based on laboratory results.\(^1\) One important aspect of the ACA is its mandate for improvements in the way laboratory test results are exchanged and transmitted to electronic health records (EHRs), including a process for “meaningful use” of laboratory data throughout the medical care continuum.\(^2\) (Meaningful use refers to getting laboratory data back to the point of care for use by clinicians to make better, more informed, and meaningful decisions for their patients.)

The benefits of laboratory test results extend beyond primary patients and their physicians. The impact of meaningful use reaches to public health authorities at the local level who are responsible for tracking outbreaks of new conditions such as antibiotic resistance or seasonal disorders such as influenza or West Nile virus infections.\(^3\) This public health impact results from improved reporting of certain laboratory tests to health epidemiologists who can share the discovery of unusual trends with state and national experts. Therefore, while much of the discussion regarding the impact of the ACA on laboratory testing has focused on data usage and lower costs, public health laboratorians are working to prepare for a much different outcome. This effort is needed to prevent well-intentioned plans from producing the unintended degradation of public health laboratory (PHL) preparedness and services.

Testing services provided by PHLs have traditionally been covered by public funds, including city, county, state, and federal sources. This support has paralleled the priorities of political leadership and the recognized need to control outbreaks of disease and maintain the public health. To ensure that all potential cases were found, the cost of obtaining the appropriate screening test for such diseases as acquired immunodeficiency syndrome was covered by the local health authority. These assays are referred to as screening tests because they are performed even when the patient may have no symptoms, as may be the case for detecting lead poisoning in children or Chlamydia infection in...
women. One of the major changes brought about by the ACA is that tests for screening purposes will be covered by third-party insurance companies. Because a large number of previously uninsured individuals will acquire benefits that include screening tests for preventable and treatable diseases, a major impact on public health is expected. As a result, the public sector may be relieved from this expense. The problem is that many PHLs have used the funds received from public sources to perform tests for screening purposes as a way to cover their core operational costs. As with many commercial enterprises, PHLs provide some services that carry a larger proportion of the operating costs than others. Some services have little margin and are provided only to meet local needs. As the ACA takes hold, universal insurance is expected to pay for all types of testing, including tests that have traditionally been within the public health domain, such as testing for sexually transmitted diseases. Therefore, traditional testing services performed by PHLs may cease. The expectation is that there will be no reduction in test services because the work will be done by the private sector. The result is that PHLs will either cease to exist or be required to compete with the private sector, including those laboratories with national reach.

During the next five years, the greatest impact of the ACA on PHLs is expected to be on test services provided solely for epidemiologic purposes; that is, to detect the outbreak of an epidemic or to demonstrate the likelihood of contamination of food or water supplies, such as the confirmation and subtyping of salmonella, an organism that may contaminate vegetables or fruit. One strategy for survival calls for PHLs to provide these specialized services to multiple accountable care organizations within a region. Another strategy is for the PHL community to demonstrate to the public health authority that some patients are unlikely to obtain screening services for certain diseases with a social stigma, such as gonorrhea; therefore, public funds must be set aside for the PHL, or disease control would be eventually lost. In other words, under either scenario, PHLs must redirect their efforts. To accomplish this goal, the PHLs must be on par with the private sector in terms of electronic test ordering and reporting. In addition, PHLs must become expert in other key capabilities such as third-party billing. Fortunately, PHLs have been preparing for this change for the past six years through a variety of collaborations with each other and with federal and state programs.

One of the most successful programs that has laid the groundwork for this transformation has been the Public Health Laboratory Interoperability Project (PHLIP). Since 2006, the PHL community, in collaboration with the Centers for Disease Control and Prevention (CDC), has been working to improve the information technology infrastructure to increase the use of cutting-edge data standards and interoperability protocols by the public health system. These improvements have allowed PHLs to exchange health-care information in a secure, standard fashion that is on par with the private health-care industry. This project, conducted under the auspices of the Association of Public Health Laboratories (APHL), assisted the public health community with incorporating industry standards to exchange laboratory test results and remain relevant in an ever-changing political and technological environment.

The U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology developed concepts and processes involved in implementing meaningful use for health-care electronic information exchange. Provisions of the ACA identified more than $600 million for the private health-care industry to meet the national goals, but very little funding was allocated to public health programs directly. Public health will benefit, however, when the health information mandated by meaningful use is directed toward the public health authorities. The assumption is that public health will be capable of receiving and using encrypted, secure, standardized messages from “eligible providers” (under the Medicare EHR Incentive Program, eligible providers include doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatry, doctors of optometry, and chiropractors; under the Medicaid EHR Incentive Program, eligible providers include physicians [primarily doctors of medicine and osteopathy, nurse practitioners, certified nurse-midwives, dentists, or physician assistants furnishing services in a Federally Qualified Health Center or Rural Health Clinic]) who are being incentivized to provide these data. CDC has been the leading federal agency responsible for preparing the public health community to receive these data, and several initiatives have improved the public health communities’ capabilities. Through a combination of local and federal funds, PHLs have upgraded their infrastructures and implemented the required nationally recognized data standards, such as Health Level 7 (HL-7), Logical Observation Identifiers Names and Codes (LOINC), and Systematized Nomenclature of Medicine (SNOMED) Clinical Terms. Without CDC’s support, local and state PHLs would be hard-pressed to meet the goals and opportunities provided by meaningful use.

Through PHLIP, the APHL has provided assistance to more than 53 state and local PHLs in the U.S. The
The Affordable Care Act and Meaningful Use

The first priority of this work was to provide for electronic reporting of influenza virus test results to CDC and improve national monitoring. As a result of the PHLIP effort, 2012 data were transmitted directly from the Laboratory Information Management System (LIMS) to the CDC Influenza Epidemiology Division for active surveillance of influenza. With the advent of automated reporting and the elimination of manual reports, data are transmitted to CDC within minutes of a case being finalized, rather than weeks or months. The opportunity now exists to expand to other diseases, such as measles, mumps, and pertussis, which could provide real-time information to CDC and state agencies on the success or failure of vaccine programs.

The success of PHLIP and the methodologies it created to help the nation’s PHLs could also be used by public health agencies to assist with the receipt and processing of electronic laboratory reports (ELRs) from private institutions under the meaningful-use mandates. Along with vaccine registries and syndromic surveillance, processing ELR is one of the three public health-mandated activities for eligible providers within the meaningful-use criteria. Because each state may have a specific requirement for reporting certain conditions and diseases to the local public health authority, PHLs could provide valuable assistance to state public health agencies.

With assistance from CDC, APHL is moving forward to help public health agencies improve their capabilities to receive ELRs. The Electronic Laboratory Reporting Technical Assistance (ELRTA) program began in 2012. Through ELRTA, a public health agency can request technical assistance to achieve the opportunity provided by meaningful use. To date, 52 requests have been processed across the country, with assistance directed toward a broad array of needs, including system integration for end-to-end ELR messaging, data routing between disease surveillance systems, ELR message transformation to include LOINC and SNOMED coding, and messaging compliance to upgrade HL-7 2.3 messages into 2.5 formats. This work is already helping some public health authorities receive and use meaningful-use data from eligible providers and is expected to play an even larger role in helping meaningful use reach its full potential.

The ability to adapt to electronic data exchange will be a defining feature of successful PHLs in the future. At the same time that PHLs are facing funding challenges, they must adapt to a changing environment and develop capabilities in data collection, validation, and processing. If successful, the transformation of PHLs will result in improved monitoring of disease and make timely response to unexpected developments and new outbreaks of disease possible.

This article was supported by Cooperative Agreement #U60HM00803 from the Centers for Disease Control and Prevention (CDC) and/or the Assistant Secretary for Preparedness and Response. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC and/or the Assistant Secretary for Preparedness and Response. The Association of Public Health Laboratories informatics program was 100% federally funded, with a budget of $5,160,638.

REFERENCES

Supporting Public Health Laboratory Systems Research

Burton W. Wilcke, Jr., PhD, SM(ASCP)¹
Sadira Y. Del Rio Daher, MA²
Karen J. Breckenridge, MBA, MT(ASCP)²

In the earliest days of public health laboratories (PHLs) in the United States, many PHLs were actively engaged in research activities, most of which were either basic or applied in nature. Some state PHLs were active in the development of vaccines, while others were active in the development of diagnostic assays and procedures. Over time, much of this type of research migrated to academic institutions and the private sector. Now there is a renewed research role for PHLs in the area of systems and services research. While basic research is hypothesis-driven, systems and services research examines the organizations, financing, and delivery of public health services in communities, and assesses the impact of these services on public health.¹

During the past two decades, there have been a number of sentinel events and the release of several important documents and publications that reflect the ongoing evolution in the roles of PHL systems. In 1994, the Core Public Health Functions Steering Committee released the 10 Essential Public Health Services (hereafter, Essential Services), which were established to provide a guiding framework for the responsibilities of public health systems. One of the Essential Services is “research for new insights and innovative solutions to health problems.”² In 1998, McDade and Hughes published a seminal paper that described the need for a national laboratory system.³ The Centers for Disease Control and Prevention (CDC) followed up in 2000 with its initiative to support a national PHL system.⁴ This initiative evolved over time into the concept that the national laboratory system in support of public health in the United States actually comprises many state PHL systems, all working in concert with their respective partners.

In 2002, a publication entitled “The Core Functions of State Public Health Laboratories” was published.⁵ As with the Essential Services, this publication, which was adapted from an Association of Public Health Laboratories (APHL) consensus document, also included public health-related research as a core PHL function. This report represented a new concept when compared with the historical view of the role of laboratories in public health practice.⁶ Previ-
ously, PHLs were seen simply as the providers of analytical services, while now they are being called upon to assume a broader role. Soon thereafter, CDC and APHL collaborated to develop a performance standards program for state and local PHL systems. This program formally became the Laboratory System Improvement Program (L-SIP) in 2008 and included research activity assessment as one of its measurements. Most recently, a Healthy People 2020 goal was added that specifically called for measuring the performance of PHL systems at the state, tribal, and local level to support the Essential Services.

Measuring the performance of PHL systems in their progression toward meeting Healthy People 2020 targets includes a metric on research activities.

In recognizing the changing role of PHL systems with regard to research, APHL formed a Research Advisory Council (RAC) that convened in 2008 to identify the most critical research questions to address in support of improved system performance. The RAC recommended defining public health research using six research questions. They encompass the following areas of inquiry:

- What is the impact of the PHL system on the public’s health?
- What quality systems assure PHL quality?
- What does it mean that there is a PHL workforce shortage, and what solutions are available?
- What do PHLs need (functionally) from the next generation of Laboratory Information Management Systems (LIMs)?
- What does the ideal PHL system look like?
- What are the benefits of new technology?

Having established that PHL systems have a legitimate and valuable role in conducting research—particularly public health systems and services research—and focusing on the six identified thematic areas for research with defined research questions, APHL next addressed research support. Support for research may involve infrastructure, personnel, and funding. Even with state PHL systems that have close partnerships with academic research institutions, there is still a need for targeted funding. Most research activities in the health field are supported by governmental grants, foundations, or professional societies. Often, academic institutions will give researchers “seed” grants. The concept behind a seed grant is to award modest funds on a competitive basis to spur interest and possibly demonstrate outcomes that will ultimately lead to external support for research.

THE INNOVATIONS PROJECT

APHL first established its Innovations in Quality Public Health Laboratory Practice Project (hereafter, Innovations Project) in 2010. Thus far, the program has been offered in three consecutive years (2010, 2011, and 2012), and 20 projects have received funding. The Innovations Project was designed to stimulate research activities in the areas of PHL systems, service, and practice. State and local PHLs were encouraged to create or further develop partnerships with other public health agencies, academic institutions, or laboratories in submitting their research proposals. The call for proposals asked the submitters to identify which of the six research questions was being addressed by their project proposal.

A selection process was established using objective reviewers who were asked to rate the proposals based on:

- Demonstrated understanding of the applicable research question,
- Generalizability of the proposal to other PHL systems,
- Specific proposal goals and objectives,
- Evaluation steps incorporated into the proposal,
- Evidence of collaboration with system partners and stakeholders, and
- Evidence of in-kind effort.

The proposals that were accepted received up to $20,000 to support their projects. The funding support could not be used for PHL staff salaries. The submitters were encouraged to report their findings at the APHL Annual Conference and to publish their results in the peer-reviewed literature. Following are some improvements made through Innovations Project-funded proposals.

Southern Nevada PHL PEWSS system

The Southern Nevada PHL received an Innovations Project grant that enabled it to evaluate and then expand its health district Pediatric Early Warning Sentinel Surveillance (PEWSS) system. The PHL recruited five pediatric medical practices in Southern Nevada to serve as sentinel sites for the PEWSS program. Sentinel staff collected specimens from ill children who met the influenza-like illness case definition, and submitted specimens for molecular testing for influenza and six non-influenza viruses. Laboratory results were analyzed and reported to the medical and general communities in weekly bulletins, which are used to establish viral respiratory seasonal baselines, and also in influenza vaccination campaigns. The surveillance program
was evaluated using the CDC Updated Guidelines for Evaluating Public Health Surveillance Systems.9

The program was well accepted by stakeholders who found it to be a useful public health surveillance system that is simple, flexible, accessible, and stable. Through the Innovations Project grant, the Southern Nevada Health District was able to fund the program in 2011 and 2012, and planned to expand the program to include additional respiratory agents in 2013.

Arizona State PHL
An Innovations Project grant awarded to the Arizona State PHL helped the laboratory create a crosswalk of the regulations, standards, and guidance documents affecting state environmental laboratories to aid in the process of meeting various accreditation and certification programs. The crosswalk provided a quick quality assurance guide for developing programs and integrating programs cohesively and uniformly. The crosswalk was made available for all PHL staff to use through the APHL Member Resource Center. The ability to quickly determine how standards and requirements relate to each other has allowed for a more efficient and effective quality management system.

Texas Department of State Health Services Laboratory
The Texas Department of State Health Services Laboratory received an Innovations Project grant to determine how best to deal with staffing shortages and the potential impact on laboratory services. The laboratory initially set up a three-day Lean Six Sigma training course, which provided participants with a foundation in the Lean philosophy for workplace organization.10 The goal of providing the Lean Six Sigma training was to give participants the ability to identify, diagnose, and improve specific processes within the laboratory. The Texas Department of State Health Services Laboratory plans to continue moving forward with the implementation of Lean Six Sigma to execute more detailed, in-depth quality improvement projects.

Wisconsin State Laboratory of Hygiene
An Innovations Project grant allowed the Wisconsin State Laboratory of Hygiene (WSLH) to produce a guide intended to assist PHLs in conducting a LIMS needs analysis and requirements-gathering process. WSLH evaluated the efficacy of its needs analysis and reengineering efforts, and then organized the best practices identified into a package for other PHLs to use in completing their LIMS replacement/acquisition efforts. Information was obtained through a systematic review of relevant documentation and interviewing stakeholders.

The project yielded an accurate and specific list of system requirements; a concise, yet comprehensive, documentation of all the major pre-analytical, analytical, post-analytical, and business processes used by WSLH; a core group of engaged project participants who helped build the project teams for LIMS implementations; the basis for several high-level and significant process changes that will have long-lasting positive effects on laboratory operations; and the establishment of clear communication channels for all stakeholders in the effort, including users, senior/executive leadership, and external vendor partners. Templates created or adapted for use by other PHLs included posters, presentations, tracking spreadsheets, training materials, workflow diagrams, and business process recommendations. The WSLH guide, which will be available through APHL, may also serve to assist laboratories with LIMS implementation after its selection and purchase.

City of Milwaukee Health Department PHL
The City of Milwaukee Health Department PHL (MHDL) received an Innovations Grant to focus on research activities as a key element of an ideal public health system. To facilitate collaborative research, researchers from multiple organizations convened to share areas of research interest and activity, which resulted in the creation of a research inventory. The inventory will continue to grow and be made available in a searchable online format. Community research leaders were better able to understand what networks were already in place and how they could complement each other’s research strengths through L-SIP. The grant also facilitated the creation of internships in the MHDL project.

As a result of this project, the MHDL has gained insight into activities that could result in improved efficiencies. The MHDL determined that ongoing communication with stakeholders was particularly valuable in keeping it apprised of ongoing developments and receiving additional input. Overall, it was felt that this grant-funded work could serve as a model for other local PHLs that wanted to enhance their research output and aspired to go through the L-SIP process. The MHDL project is detailed in an article by Gradus et al. that appears in this supplement.11

Arkansas Department of Health
An award given to the PHL at the Arkansas Department of Health in 2010 enabled it to explore and
evaluate new biomonitoring technology, specifically liquid chromatography-tandem mass spectrometry, to detect synthetic cannabinoids (K2 Spice) exposure. K2 Spice is a mixture of herbs and spices that is typically sprayed with a synthetic compound that is chemically similar to the psychoactive ingredient in marijuana. The information generated from this project has been used to educate and inform the community about the dangers of this illicit drug. In addition, numerous publications in the peer-reviewed scientific literature have resulted from this Innovations Project-funded work.13-15

PUBLIC HEALTH IMPLICATIONS

Based on the three years of supporting projects conducted by PHLs in conjunction with their system partners, there is a clear indication that systems and services research is extremely valuable for continuously improving PHL systems in support of the Essential Services. Furthermore, all of the awardees stated that they would not have been able to conduct this systems and services research without the funding support offered through the Innovations Project grants. The six areas of focus outlined by APHL in 2008 continue to be important areas for inquiry and innovation. This type of research is essential to determine what works in public health and how to best structure, fund, and support the public health system and its various components.

Laboratories have been an important part of public health since their inception in the late 1800s. In 1993, Dowdle made the strong case for PHLs continuing to play an important role in the future of public health. He also noted that, “One feature that is common to all top public health laboratories is research.” There is no denying that the role of PHLs is evolving and the ways that PHLs are now being encouraged to operate within systems represent a change. PHLs are being encouraged to reach out to their partners and collaborators in the clinical, environmental, and agricultural sectors. They are also being called upon to strengthen their relationships with the end users of laboratory data and information, namely the public health program specialists and epidemiologists. Much of what laboratories continue to contribute supports disease prevention, surveillance, health protection, and health promotion. For PHLs to continue to offer such valuable support, they will have to engage in collaboration with their system partners in ongoing investigations and evaluations followed by the implementation of their findings. As these systems and services research projects expand and are disseminated, they will contribute to an expanding body of literature that identifies the best practices for PHL systems. It is imperative that we identify a sustainable means for supporting and funding such important systems and services research going forward.

This article was supported by Cooperative Agreement #U60HM000803 from the Centers for Disease Control and Prevention (CDC) and/or the Assistant Secretary for Preparedness and Response. The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of CDC and/or the Assistant Secretary for Preparedness and Response. Funding for the project was 100% from the federal government.

REFERENCES

Newborn Screening: From Guthrie to Whole Genome Sequencing

Newborn screening (NBS), a comprehensive system that includes testing, diagnosis, follow-up, treatment, education, and evaluation, was recently named one of the Top 10 Great Public Health Achievements by the Centers for Disease Control and Prevention (CDC).\(^1\) Each year, approximately 10,000 infants are identified with NBS conditions, which frequently go unnoticed at birth.\(^2\) NBS is administered by state public health programs across the country and provides for early identification of newborns with certain congenital, metabolic, endocrine, hematologic, and other genetic conditions. Early identification of these conditions in newborns facilitates timely interventions that result in significant decreases in morbidity, mortality, and disability.\(^3\)

Screening begins by pricking a newborn’s heel to get enough blood to fill a few circles on a filter paper card. The specimen, referred to as a dried blood spot, is collected by a health-care provider—typically at the birthing facility—during the first 24–48 hours of life. Some states are required to collect two specimens, in which case the second specimen is collected between seven and 15 days of life. The specimens are then sent to a state-designated NBS laboratory for analysis. When a test result is out of normal range, laboratory or follow-up personnel contact the birthing facility and the newborn’s physician to ensure the child receives the appropriate diagnostic work-up and treatment. NBS goes beyond blood-spot screening to include point-of-care testing for hearing and, in some states, critical congenital heart disease. These tests are performed at the hospital shortly after birth, and the state NBS program performs follow-up testing. Although there is some variability in protocols among states, most NBS programs have similar components, including specimen collection, laboratory testing, follow-up, education of providers and the public, verification of a diagnosis, treatment, and ongoing program evaluation.\(^3\)
THE HISTORY OF NBS

The year 2013 marks an important milestone for NBS: the 50th anniversary of the first legislatively mandated state NBS programs. NBS began in 1963 when Massachusetts, Delaware, Vermont, and Oregon began testing for phenylketonuria (PKU) with Robert Guthrie’s bacterial inhibition assay for the quantification of phenylalanine levels in dried blood spots.4–6 The ACMG taskforce used data from the American College of Medical Genetics and Genomics’ (ACMG) taskforce recommended that state NBS programs mandate testing for core conditions and report secondary target conditions that could be identified during screening, including clinically significant conditions and the definitive identification of carrier status.10

The development of a core panel, which is now called the Recommended Uniform Screening Panel (RUSP), has been the responsibility of the U.S. Secretary of Health and Human Services’ (HHS Secretary’s) Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC).12 SACHDNC has used a nomination and evidence-review process to identify new conditions that should be included on RUSP. The HHS Secretary has traditionally approved or rejected nominations from SACHDNC, and these recommendations serve as guidance for NBS programs to develop state screening panels.13 In 2010, SACHDNC recommended to the HHS Secretary that severe combined immunodeficiency and critical congenital heart disease be added to the RUSP.12 Both conditions were approved, bringing the RUSP to 31 conditions. States have been working to adopt the RUSP despite barriers to implementation for some conditions, including lack of funding and other resources.

Subsequent to the Guthrie bacterial inhibition assay for PKU, there have been many technological advances in NBS, including radioimmunoassay, colorimetric and fluorometric immunoassays, isoelectric focusing, high-performance liquid chromatography, MS/MS, and molecular testing (e.g., deoxyribonucleic acid [DNA] tests). In the 1990s, MS/MS allowed the simultaneous testing of an array of metabolic conditions using a single 3 millimeter-sized specimen punched from a dried blood spot.14 MS/MS was well-suited for the analysis of amino acids and acylcarnitines in dried filter-paper blood specimens.14,15 It provided a revolutionized means to better use the limited blood specimen and increase screening capabilities through improved sensitivity and specificity.14 As MS/MS increased in use, NBS programs relied on organizations such as CDC for assistance with quality assurance services. The Newborn Screening Quality Assurance Program assisted state health departments and laboratories in maintaining and enhancing the quality of test results by providing proficiency testing, reference materials, consultation, and training.16

Research advances in the late 1980s and early 1990s enabled the extraction of DNA from dried blood spots on filter paper. Subsequently, DNA testing was introduced into NBS, allowing the dual use of the dried blood spot specimen matrices for both biochemical and molecular tests.17 DNA testing in the context of NBS has, until recently, been primarily used as a second-tier
test for conditions such as cystic fibrosis. It has recently expanded to other uses in programs and as part of the diagnostic work-up as follow-up to the newborn screen.

In NBS, second-tier molecular testing is performed after a primary test using the same specimen. It can improve sensitivity and specificity, increase the speed of diagnosis and treatment, and reduce the number of false-positives that can add significant cost to follow-up.\(^{18}\) Molecular testing allows for differentiation between specific disorders, such as sickle cell anemia and sickle/beta-thalassemia.\(^ {19}\) Although testing varies by state, second-tier molecular tests are performed for conditions such as hemoglobinopathies, galactosemia, cystic fibrosis, and medium-chain acyl-CoA dehydrogenase deficiency. In 2008, the Wisconsin NBS program began screening for severe combined immunodeficiency (SCID), marking the first time a program used molecular technology as the primary screen.\(^ {20,21}\) The Association of Public Health Laboratories (APHL) has been collaborating with CDC’s Newborn Screening and Molecular Biology Branch to address recent trends and developments in molecular testing. This collaboration has led to the development of a data-sharing molecular resources website for NBS programs as well as the molecular assessment program, where NBS laboratories can receive an assessment of their molecular capabilities.\(^ {22}\) Quality improvement for laboratory tests, as well as for the NBS system as a whole, will continue to be a priority in the years to come.

The prospects for advancing NBS are significant in light of new technologies. Microfluidic techniques have been developed to simultaneously perform many of the analytical procedures used in NBS laboratories, including current immunoassays, enzyme assays, and molecular methods.\(^ {23}\) Some of these lab-on-a-chip platforms allow for several or all testing methods to be performed on a single, highly compact chip. Test platforms have become efficient, able to perform high-throughput testing on small volumes of patient samples. They are designed to handle everything from specimen preparation to specimen processing, mixing, incubation, and detection.\(^ {21}\) It is possible that these platforms will be used at the bedside, but they will more likely be used in the hospital’s clinical laboratory. In theory, the newborn’s test results would be known before discharge, allowing for faster time to diagnosis and treatment initiation. This type of testing would also reduce the number of missed diagnoses due to untestable specimens or the inability to locate infants with out-of-range results after discharge. Additionally, DNA sequencing technologies are entering clinical laboratory practice and, in some circumstances, may augment current NBS strategies. Further work is needed to determine if DNA sequencing has utility in this setting and whether the benefit of using this technology outweighs the cost.

Advances in our understanding of the human genome and associated technologies are anticipated to provide important tools for evolving NBS services. The map and sequence of the human genome were completed in 2003, thus enhancing the study of genetic disease and predisposition. In the future, entire human genomes may be sequenced at birth, allowing individuals to have the option of receiving information about later-onset diseases for which effective interventions may be available. In 2012, The National Human Genome Research Institute and the Eunice Kennedy Shriver National Institute of Child Health and Human Development initiated a $25 million grant program to fund studies that explore how genome sequencing may be used in NBS. The intent of this program was to encourage research associated with the challenges and opportunities of applying whole genome sequencing or whole genome data into newborn care.\(^ {24}\) As research in this area continues, there will be debate regarding the risks and benefits of disclosing and using genetic information in the NBS realm.\(^ {25}\) Genome sequencing provides the means to report health-related information that goes beyond immediate risks to the newborn. The extent to which NBS programs will evolve in this direction requires significant consideration.

**CHALLENGES FOR NBS PROGRAMS**

Logistical, ethical, and legal challenges have always existed for NBS programs. Most recently, some of the most prominent issues have involved informed consent, justification for the storage and use of residual dried blood spots, addressing additional information that results from genetic testing, and dealing with practical issues that affect NBS programs, such as increased costs.

Most state NBS programs have an opt-out policy, requiring testing for all newborns unless parents or guardians decline testing due to religious or other reasons. Some groups have opposed these opt-out policies, arguing that parents and guardians should submit consent documentation for testing.\(^ {26}\) Screening programs have typically relied on the opt-out policy with the premise that the best interest of the child is priority and should override the family’s decision-making rights, as many NBS conditions have severe and rapid consequences when undetected and left untreated.\(^ {27}\) NBS programs continue to work with organizations such as APHL and Genetic Alliance to encourage NBS by educating parents and providers on the benefits of screening babies.\(^ {28,29}\) Additionally, screening programs...
ensure that measures are in place to protect privacy and confidentiality throughout the process.

Residual sample present on dried blood spots has proven absolutely essential as quality control material, for the improvement of current methods, and to add new conditions to the RUSP. After screening, a small amount of dried blood remains on the filter paper card. This residual blood is often stored for varying durations for use by laboratories in accordance with state statutes and/or policies and may not require parental consent. Justifying the importance of using and storing residual dried blood spots when NBS has been completed is a sensitive issue for NBS programs and parents. Residual dried blood spots are primarily used for internal laboratory quality control and quality assurance purposes, including confirmation of original results, method validation, assay quality control, and lot-to-lot reagent validations, which are required of clinical laboratories. Residual dried blood spots are also used for quality improvement initiatives, such as refinement of current methodologies and new method development. These activities are performed by the testing laboratories and support the public health mission to improve the NBS system.

Some state NBS programs allow controlled access to residual dried blood spots for purposes other than NBS, including requests for additional screening as well as for academic, public health, or medical research. The Michigan Newborn Screening Program stores residual dried blood spots indefinitely in the Michigan BioTrust for Health, where specimens may be used for research purposes such as studying birth defects, genetic and chronic diseases, and exposures to toxic substances. Additionally, the Newborn Screening Translational Research Network has developed a Virtual Repository of Residual Dried Blood Spots, where researchers can have access to de-identified information from more than two million dried blood spots. Although the use of residual dried blood spots is proving beneficial in many arenas, it has not been without challenges.

In recent years, Texas and Minnesota courts handled lawsuits pertaining to issues of storage and use of residual dried blood spots. In Texas, privacy concerns brought up in the case of Beleno et al. v. Texas Department of State Health Services et al. (2009) led to changes in legislation that required a parental option to request the destruction of residual dried blood spots after completion of NBS. As a result of the case of Higgins et al. v. Texas Department of State Health Services (2012), further statutory changes became effective requiring parental consent for the use of residual dried blood spots for public health research outside the state public health agency and storage for more than two years. The Minnesota Supreme Court ruled against the Minnesota Department of Health in the case of Bearder et al. v. State of Minnesota (2011). Written consent is now required for the long-term storage and use of residual dried blood specimens and test data. Legislation was passed in 2012 specifying timelines by which blood specimens and test data must now be destroyed. Specimens with negative results may be retained for 71 days, presumptive positive specimens for two years, and data for two years unless authorized by written consent.

NBS programs are making it a priority to ensure the transparency of state policies and create an atmosphere of open dialogue with the public when it comes to issues related to the storage, use, and destruction of residual dried blood spots. Education about the benefits of using residual dried blood spots to support NBS and the public health mission may help alleviate public misperceptions. Residual dried blood spots are a unique matrix and an invaluable resource for quality control and improvements in NBS. Evidence exists that these residual dried blood spots can be used anonymously, responsibly, and without privacy risk to the infant from whom the blood was collected. Therefore, continued efforts are important to protect this valuable resource.

One of the byproducts or results of NBS is that occasionally, clinical and family information is revealed from the screen, including carrier status. For example, newborns heterozygous for hemoglobinopathies, cystic fibrosis mutations, and other conditions may be detected by screening. State programs differ with reporting and follow-up services for detected carriers. Additionally, DNA sequence analysis performed as part of screening protocols can identify variants of unknown clinical or functional significance, making it difficult to interpret their impact on infant health. Although some variants may be benign, there are inadequate data to assess whether they cause disease. Information about paternity or about a mother’s genetic risk may be identified through molecular testing of family members during clinical follow-up. Biochemical testing can also elucidate a mother’s genetic status. State NBS programs are typically restricted to reporting results solely from tests on their approved panels. However, when programs report only the mandated information when more is available, it may appear that important medical information was withheld. For example, there are several conditions that can be detected through NBS that do not fit the description of classic SCID, and these conditions may or may not be reported. The need for consensus recommendations for reporting and follow-up of this additional clinical information obtained as a result of NBS exists for the public health community.
CONCLUSIONS

As advancing technologies allow for the detection of biomarkers for more conditions and public advocacy increases, there will be continued pressure for state NBS programs to expand their screening panels. However, many programs are experiencing stagnant or reduced funding levels, making this goal difficult to attain. Implementing new conditions for screening requires significant effort, not only in developing and implementing the laboratory test, but also in quality management, follow-up, diagnosis, and the education of parents and the medical community. Test development requires expenditures for instrumentation and equipment, personnel, supplies/reagents for validation studies, the availability of residual blood specimens from infants with the condition, and regulatory inspections. These considerations, along with the limited amount of blood on a specimen collection form, have driven laboratories to employ a strategic process of adding new disorders to their NBS testing panels. Fortunately, improvements in the sensitivity and specificity of screening technologies, as well as advances in multiplexing capability, or the screening of multiple disorders at the same time, will make future program expansions more practical and help keep costs more manageable. NBS programs continue to collaborate with federal agencies, parent advocates, and public health organizations to find solutions to these challenges as part of their mission to provide high-quality services.

Since 1963, NBS programs have worked to establish a comprehensive system that identifies, saves, and improves the lives of infants affected with a variety of genetically based conditions. The lessons learned over time and the advent of molecular testing have led NBS programs to incorporate new ideas, technologies, and processes into their systems. Continued emphasis on applying technologies to screen for and detect genetic disorders is critical for advancement and quality improvement. NBS programs will be critical in determining which technologies will lead to improvements in the overall health of newborns and can appropriately be integrated into the NBS setting.

The authors thank the Association of Public Health Laboratories staff and its members from the Newborn Screening and Genetics Program, with a budget of $1,300,000. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC, the U.S. Agency for Toxic Substances and Disease Registry, and/or the Molecular Biology Branch. Funding for this project was supported 100% by federal funds from the Newborn Screening and Genetics Program, with a budget of $1,300,000.

REFERENCES

2. American College of Medical Genetics and Genomics. September is National Newborn Screening Awareness Month. American College of Medical Genetics and Genomics strongly recommends new uniform panel of screening tests for all newborns in America [cited 2013 Feb 22]. Available from: URL: http://www.acmg.net/AM/Template.cfm?Section=Search&template=/CM/HTMLDisplay.cfm&ContentId=1637


35. Beleno et al. v. Texas Department of State Health Services et al. (2009).

36. Higgins v. Texas Department of State Health Services et al. (2012).


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

John C. Ridderhof, DrPH, HCLD(ABB)
Anthony D. Moulton, PhD
Renée M. Ned, MMSc, PhD
Janet K.A. Nicholson, PhD
May C. Chu, PhD
Scott J. Becker, MS
Eric C. Blank, DrPH
Karen J. Breckenridge, MBA, MT(ASCP)
Victor Waddell, PhD
Charles Brokopp, MT(ASCP), DrPH

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.
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 National and local health-care providers that serve millions of patients in every corner of the nation rely on PHLs to 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.

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

<table>
<thead>
<tr>
<th>LEI activity</th>
<th>Consultations</th>
<th>Completed or proposed products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of overall LEI strategy</td>
<td>• APHL convened four conference calls with members in 2011 (February 11, February 28, March 4, and June 1)</td>
<td>• Inclusion of LEI in CDC’s fiscal year 2013 budget</td>
</tr>
<tr>
<td></td>
<td>• Internal CDC meetings with laboratory leadership to develop the LEI concept (March 18 and 22, 2011)</td>
<td>• Regional Forum summary report&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>• CDC Laboratory Policy and Practice Workgroup; Laboratory Program Forum</td>
<td>• Strategic Plan&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>• APHL partners meeting (January 11, 2012)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• APHL Board of Directors meeting (January 12, 2012)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Regional forums with 23 state and local/county PHL directors (April 17 and April 24, 2012)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Strategic planning meeting with 15 APHL and CDC directors and program leaders (June 6–7, 2012)</td>
<td></td>
</tr>
<tr>
<td>Consolidated test services data and directory</td>
<td>• APHL-CDC PHL service data consultation (December 6–7, 2011)</td>
<td>• APHL/CDC PHL service data consultation&lt;sup&gt;c, d&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>• APHL-CDC Subcommittee on Public Health Laboratory Service Data (April 6, 2012)</td>
<td>• Database that consolidates existing CDC and APHL test service data (housed in APHL’s Survey Resource Center)</td>
</tr>
<tr>
<td>Metrics for ROI</td>
<td>• Focus groups/consultations (August 15 and August 22, 2011)</td>
<td>• Existing CDC/Office of Infectious Diseases laboratory management database converted to state-based database</td>
</tr>
<tr>
<td>Public health law and policy tools</td>
<td>• Consultation with five state PHL directors, five APHL staff/leaders, and 20 CDC policy and science staff (August 17, 2012)</td>
<td>• Policy guide identifying best practices for sharing test services to be published later in 2013</td>
</tr>
</tbody>
</table>

<sup>a</sup>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 [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
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.

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

<table>
<thead>
<tr>
<th>Goals</th>
<th>Activities</th>
</tr>
</thead>
</table>
| Goal I: Implement and sustain innovative laboratory management practices | • 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 | • 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.  
• Prioritize and align programmatic and state resources for informatics enhancements.  
• Assure the implementation of bidirectional electronic exchanges (eTORS, PHLIP, LIMSi, 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 | • 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 | • 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 | • 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. |

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 (continued). The Laboratory Efficiencies Initiative strategic plan: 2012–2015*

<table>
<thead>
<tr>
<th>Goals</th>
<th>Activities</th>
</tr>
</thead>
</table>
| Goal VI: Transform all laboratories in the public health system to a culture of efficiency | • 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
• Develop a PHL workforce that exhibits the competencies of the “new culture.”  
• Address workforce issues.  
• Improve human resource systems.

*Developed 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  
PILIP = 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. 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.”

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. 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 average cost per state PHL for laboratory supplies was $3,574,436, second only to personnel costs. 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.

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. 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 fit 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.

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, 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), 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. 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
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 format and will be based on the Core Functions of State PHLs. 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.

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.

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, 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.

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. 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.\textsuperscript{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.\textsuperscript{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 recommendations\textsuperscript{31} 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**

<table>
<thead>
<tr>
<th>Test service data management element</th>
<th>Recommendations</th>
</tr>
</thead>
</table>
| Principles for data analysis and reporting for the joint data-collection process | • 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 | • 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 | • 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. |


APHL = Association of Public Health Laboratories  
CDC = Centers for Disease Control and Prevention  
PHL = public health laboratory
As budgets for PHLs 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” 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.”

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.7 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/lsspoo/lei.

Many dedicated state and local public health laboratory directors and professionals, staff of the Association of Public Health Laboratories (APHL), and colleagues at the Centers for Disease Control and Prevention (CDC) contributed to this article. The authors particularly thank Cassandra Hadley from APHL for her input on the informatics section.

This article was supported by Cooperative Agreement #U60HM008083 from CDC and/or the Assistant Secretary for Preparedness and Response. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of APHL, CDC, and/or the Assistant Secretary for Preparedness and Response. The Laboratory Efficiencies Initiative project was 100% funded from federal funds, with a budget of $721,559.

REFERENCES

13. Association of Public Health Laboratories and Centers for Disease Control and Prevention (US). A practical guide to assessing and


State Public Health Laboratory System Quality Improvement Activities

ABSTRACT

The Association of Public Health Laboratories (APHL) and the APHL Laboratory Systems and Standards Committee manage the Laboratory System Improvement Program (L-SIP). One component of L-SIP is an assessment that allows the members and stakeholders of a laboratory system to have an open and honest discussion about the laboratory system’s strengths and weaknesses. From these facilitated discussions, gaps and opportunities for improvement are identified. In some cases, ideas for how to best address these gaps emerge, and workgroups are formed. Depending on resources, both monetary and personnel, laboratory staff will then prioritize the next component of L-SIP: which quality improvement activities to undertake. This article describes a sample of quality improvement activities initiated by several public health laboratories after they conducted L-SIP assessments. These projects can result in more robust linkages between system entities, which can translate into improvements in the way the system addresses the needs of stakeholders.
Public health laboratory (PHL) systems are continually challenged by how best to improve and advance their operations and the services they provide for the public’s health. To move forward, the system must determine where its strengths lie, where opportunities for improvement and collaboration exist, and what resources are available.\(^1\) Participation in the Association of Public Health Laboratories’ (APHL’s) Laboratory System Improvement Program (L-SIP) allows for this in-depth study. Past PHL participants have used L-SIP\(^2\) as a springboard for quality improvement (QI) activities, which can result in a more connected laboratory system.

L-SIP began as a collaborative effort between the Centers for Disease Control and Prevention and APHL in 2004 and focuses on the evaluation of system performance within the framework of the 10 Essential Public Health Services (Figure 1)\(^3\) and 11 Core Functions of State Public Health Laboratories (Figure 2).\(^4\) Through a series of discussions about public health system standards, assessment tool development, and pilot testing, the program was formally implemented in 2007. L-SIP is based on a performance management tool that allows assessment participants to systematically evaluate the PHL system against an optimal level of performance with respect to each of the 10 Essential Public Health Services.\(^5\)

As of February 2013, L-SIP assessments had been completed by 29 state PHL (SPHL) systems and one local PHL system. New Hampshire is the first and only state to complete a follow-up L-SIP reassessment (Figure 3).

**Figure 1. The 10 Essential Public Health Services**

1. Monitor health status to identify and solve community health problems.
2. Diagnose and investigate health problems and health hazards in the community.
3. Inform, educate, and empower people about health issues.
4. Mobilize community partnerships and action to identify and solve health problems.
5. Develop policies and plans that support individual and community health efforts.
6. Enforce laws and regulations that protect health and ensure safety.
7. Link people to needed personal health services and assure the provision of health care when otherwise unavailable.
8. Assure a competent public and personal health-care workforce.
9. Evaluate the effectiveness, accessibility, and quality of personal and population-based health services.
10. Research for new insights and innovative solutions to health problems.

Following an assessment, the L-SIP coordinators review the findings and determine how to address the weaknesses and system gaps identified during the process. The PHLs and their systems have embarked on a variety of post-assessment QI activities that have impacted their respective systems in a positive way. This article describes several examples of post-L-SIP assessment QI activities, which are divided into four categories: improving laboratory operations, network building, increasing awareness of the laboratory system, and convening a reassessment. Lack of funding had prevented the SPHL systems from beginning these QI activities soon after their assessments, but APHL was subsequently able to secure grant funding to help defray the costs.

**IMPROVING LABORATORY OPERATIONS**

QI can be measured quantitatively by determining a baseline of performance, implementing a program, and comparing the end results with the baseline. For example, as a result of conducting an L-SIP assessment in 2007, the Utah PHL system identified problems with the quality and timeliness of test results that are crucial in the justice system. The laboratory results were not reliably relayed to appropriate authorities in a timely fashion; as such, evidence was not available for hearings, trials, or death certification. Because customers had expressed their dissatisfaction with the quality and timeliness of test results, the laboratory focused on Essential Service 4 (mobilize community partnerships and action to identify and solve health problems) and Essential Service 9 (evaluate the effectiveness, accessibility, and quality of personal and population-based health services) and sought to decrease its turnaround time of 28–29 days.

**Figure 2. The 11 Core Functions of State Public Health Laboratories**

- Disease prevention, control, and surveillance
- Integrated data management
- Reference and specialized testing
- Environmental health and protection
- Food safety
- Laboratory improvement and regulation
- Policy development
- Public health preparedness and response
- Public health-related research
- Training and education
- Partnerships and communication


To address the issues, Utah’s forensic toxicology laboratory staff members were trained on Lean Six Sigma principles during a 12-week pilot program as one of their post-assessment QI activities. The Lean Six Sigma approach to QI is based on the philosophy that all activities with an organization must be valuable. Each process needs to be defined, measured, and assessed as to how much value it contributes to the organization and its customers. Optimal performance is characterized as sustaining and improving valuable processes while removing activities that have no added value. This intervention in Utah resulted in positive changes, including a decrease in test result turnaround time to 10–14 days and a measurable increase in the number of cases reported daily. Daily reports increased by about 300% for driving under the influence toxicology cases and 200% for postmortem toxicology cases. These improvements consequently reduced backlog by 50%–75%.

Improving the laboratory operations, in turn, strengthened the laboratory’s relationships with its system partners. The positive feedback received from the customers improved employee satisfaction and morale. The success of this pilot project was documented in a blog called Diary of a Lean Six Sigma Lab that received positive attention from the state health department’s Performance Improvement Program. This publicity is anticipated to lead other state and local public health departments (e.g., the medical examiner’s office) to consider implementing Lean Six Sigma Principles to improve their processes.

As of December 2012, approximately a year and a half following implementation, the group has maintained the turnaround time at levels comparable with that of the beginning of the project. The group has also demonstrated that the new workflow is rigorous enough to withstand scheduling changes necessitated by events such as holidays, court testimony responsibilities, maternity leave, and even the intense pressures of preparing for a first-ever laboratory accreditation inspection. The Utah PHL system has also embarked on a new post-assessment project related to improving the testimonies toxicologists give in court by reaching out to the Utah Prosecution Council to provide moot court opportunities so prosecutors and toxicologists can practice court procedures.

Figure 3. Laboratory System Improvement Program participation map: U.S., 2007–2013

NETWORK BUILDING

PHLs can use the L-SIP assessment to generate momentum for bridging system partners together, both to build new partnerships and strengthen existing ones. For example, the State Hygienic Laboratory of Iowa’s post-assessment QI activity was to begin building an environmental laboratory system network by holding a summit and improving communication with environmental partners. This activity specifically addressed Essential Service 4 (mobilize community partnerships and action to identify and solve health problems). The first Iowa Environmental Laboratory Response Network (I-ELRN) Summit on June 28, 2011, brought together representatives from many environmental-related departments across the state, including commercial, county, municipal, and state laboratories; the Iowa Department of Natural Resources; and the Iowa Department of Public Health. The summit allowed partners to have an open discussion about how a system would be beneficial for all parties and what common needs must be met for the system to be successful. The group determined that a functional system ideally would allow departments to come to each other’s aid during emergencies and collaborate to share each other’s strengths and resources when budgets are strained. To give this new network structure, an I-ELRN Laboratory Advisory Board, including members from the State Hygienic Laboratory, commercial laboratories, local laboratories, Iowa Department of Public Health, and Iowa Department of Natural Resources, was created at the summit.

The results from the post-summit evaluation survey completed by meeting participants showed that 83% of the respondents would either consider joining or would join the I-ELRN. There were two follow-up meetings in 2012; unfortunately, the laboratory has experienced difficulty in maintaining interest and momentum in the consortium. One possible reason is that some of the laboratories that have joined the network are in direct competition with each other for business; therefore, there is not enough incentive for them to actively participate in the I-ELRN. The I-ELRN has since decided to concentrate on broader system goals (e.g., assuring the sustainability of environmental health service and enhancing the capacity to identify and respond to environmental health risks) rather than laboratory-specific goals.

While post-assessment follow-up meetings and activities generally require some advanced planning and may occur after an extended period of time, Alabama, the 28th state to convene an L-SIP assessment, experienced an almost immediate positive impact in terms of network building as a result of the interest and publicity the event garnered. With the focus on the SPHL and what it offered, the January 2012 L-SIP assessment determined that some participants were unaware of its services, as recorded in comments captured on the tool and on the evaluation. A couple of days after the assessment, laboratory staff were invited to several speaking engagements, among which was a local university’s Laboratory and Medical Technology Honor Society function to reaffirm students’ decisions to explore clinical laboratory science careers. The laboratory was also invited to the department’s area public health nurses’ orientation session to educate them about the laboratory’s services and their roles as partners of the system. While these presentations are not formal QI activities, new interactions between system entities will help foster budding relationships by better educating system partners about roles and responsibilities, thereby facilitating future collaboration.

INCREASING AWARENESS OF THE LABORATORY SYSTEM

Often, the “system” concept is new to L-SIP assessment participants, and they want to understand it more fully before addressing system gaps. Fortunately, the L-SIP assessment day is designed to educate participants about the system. Results of Minnesota’s June 2010 L-SIP assessment demonstrated that the assessment process is effective at developing an understanding of the laboratory system. Pre- and posttest data showed that 19% of L-SIP participants felt they understood the difference between the SPHL and the SPHL system before participating in the L-SIP assessment, while 76% felt they understood the difference after participating in the assessment process. However, the assessment process revealed that many system partners desired a more formalized definition of “laboratory system” as a next step in the system’s development. Through an APHL L-SIP grant, Minnesota set off to develop the concept of an ideal SPHL system. A design group was created with system partners comprising broad representation and perspectives from all areas of the SPHL system, including clinical, environmental, and newborn screening disciplines. The group was challenged with the following three goals: (1) design and create a map with explanatory narrative detailing an ideal SPHL system, (2) articulate and communicate the roles and responsibilities of stakeholders in an ideal SPHL system, and (3) develop a high-level work plan for implementing an ideal SPHL system. All of these goals would be transferable to other SPHL systems for implementation.

A result of the design was an overarching steering...
committee and two domain-specific councils—the Clinical Domain Council and the Environmental Domain Council—that were created to oversee their respective parts of the laboratory system. The system was also formally defined. Identified next steps included development and dissemination of educational materials to inform stakeholders about the importance and rationale of the system, as well as the benefits of being an active system participant. Additional funding and staff resources would be required to implement the ideal SPHL system fully in Minnesota. The philosophy moving forward was that the more people are aware and knowledgeable about the system and its benefits, the more willing they would be to actively participate. Minnesota’s final report for the design process, “Implementing an Ideal State Public Health Laboratory System,” is available on the APHL Member Resource Center for all APHL members to use.

Sometimes, post-assessment QI activities require some creativity. After its 2009 assessment, the Michigan PHL system had created a Laboratory System Advisory Group (LSAG) to allow system partners to meet to discuss common concerns and collaborate to address system problems. Over time, participation and interest in the LSAG started to wane until current events reenergized the group. The political scene in Michigan at the time of the November 2010 elections created unprecedented citizen interest in state government and resulted in a turnover in approximately 65% of the Michigan Legislature the following January. Logistically, holding a workshop for legislators would not have been feasible given their complicated schedules. However, there was still value in helping the new decision makers understand the importance of laboratory and epidemiology science to the public’s health.

Therefore, Michigan laboratory system partners, including members of the LSAG and the Michigan Association of Local Public Health, sponsored a one-day workshop on the legislative process and related practical communication skills for laboratorians, epidemiologists, and health-care workers throughout the state. Sessions on health policy issues, laboratory medicine, and the bill approval process, as well as tips on interacting with legislators and the communication of science, were enthusiastically received by participants.

Benefits of the workshop included the engagement of a new group of clinical and academic laboratory partners who were attracted by the unique topics and increased interest in and knowledge of the Michigan state government process among laboratory system partners who attended the workshop, as measured by survey results. In addition, the workshop raised awareness of the SPHL system and the current laboratory workforce shortage with two key state senate committee chairs, one of whom toured the Michigan Department of Community Health Bureau of Laboratories a few weeks later.

**CONVENCING AN L-SIP REASSESSMENT**

To have an accurate reading on the laboratory system’s performance, system partners should convene every few years to reevaluate the system’s strengths and weaknesses and discuss how they compare with the prior assessment’s findings. In May 2011, New Hampshire was the first state to hold an L-SIP reassessment. The initial assessment had taken place in March 2007, and a low newsletter circulation was identified as an opportunity for improvement. Many interested staff members worked to strengthen the content of the newsletter and increase its circulation, resulting in positive feedback from the readership. The laboratory leadership decided that it would be valuable to bring the partners back together to reassess the system using the performance measurement tool and then compare the 2011 results with those from 2007.

On the day of the reassessment, 51 participants worked through the assessment tool, scoring the system based on the 10 Essential Services. At day’s end, the 2011 scores were projected alongside those from 2007, revealing that the scores for five of the Essential Services (Essential Services 3, 4, 6, 9, and 10) had increased. Two scores (Essential Services 2 and 8) remained the same, and three scores (Essential Services 1, 5, and 7) had decreased. Since the reassessment, the New Hampshire PHL has helped the University of New Hampshire’s veterinary laboratory set up a quality management system, which was an identified need. In turn, the New Hampshire PHL director was invited to sit on the university’s Veterinary Diagnostics Laboratory Advisory Board, strengthening relationships between the two partners.

A reassessment can recharge the PHL system by acknowledging how the system has improved since the initial assessment and also by identifying gaps that have yet to be filled or new ones that need to be addressed. One caveat learned from the New Hampshire experience is that scores will change depending on a variety of factors, such as participating stakeholders, their involvement in the previous assessment, and public health-related events occurring at the time of the assessment. The increase in scores between assessments may also be attributed to educating the laboratory system members about the 10 Essential Public Health Services. While it is important to document the scores from each assessment, capturing the themes during the discussions is more valuable, as it will help the system participants better understand the reasoning behind the scores and how to address
the concerns identified during the assessment. All of these factors must be taken into consideration before time and resources are invested in post-reassessment QI activities. Because only one PHL system has conducted a re-assessment, APHL continues to encourage PHL systems that have conducted an initial assessment to reconvene for reassessment. This reconvenation will ultimately demonstrate the impact a reassessment and continuous QI has on the PHL system.

LESSONS LEARNED

The aforementioned examples demonstrate that the L-SIP assessment process is very effective at identifying opportunities for improvement in the laboratory system; however, moderate resources are often required to address these gaps. QI activities identified by L-SIP have a positive impact on how partners connect and how the laboratory system operates. Regardless of the size of the project, all activities impact the system and its partners in some way, including helping system partners become more aware of each other’s strengths and resources, which is advantageous as operational budgets continue to be strained. Partners within the laboratory systems must build closer relationships to collaborate on QI efforts, research projects, workforce development, and other important laboratory issues, as political and financial climates continue to change. It is also important that systems seek QI activities that answer the question, “What’s in it for me?” As described in a few of the state examples, one of the biggest challenges to a truly collaborative laboratory system is that partners need to clearly see how being engaged in the system adds value. Without this knowledge, their participation may become a low priority.

Many times, ideas for QI activities are explored during post-assessment stakeholder meetings, but additional financial resources are required to bring them to fruition. To help ensure that the laboratory system advances in the way it operates and serves its stakeholders, public health organizations need to continue to offer grant opportunities so that laboratory systems can maintain the momentum of their post-L-SIP assessment QI activities. The QI projects and the resulting positive changes to the laboratory systems that are mentioned in this article would not have been possible were it not for the modest funding provided by grants.

The authors thank the following people for their contributions to this article: Eric Blank, Martha Boehme, Karen Breckenridge, Gambrell Layco, Sharon Massingale, Jill Power, Amy Terry, and Michael Wichman.

This article was supported in full by Cooperative Agreement #U601CCU30319-22 from the Centers for Disease Control and Prevention (CDC) and/or the Assistant Secretary for Preparedness and Response. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC and/or the Assistant Secretary for Preparedness and Response. The program was funded 100% from federal funds, with a budget of $1,512,776.

REFERENCES

Milwaukee Laboratory System Improvement Program (L-SIP)

M. Stephen Gradus, PhD, D(ABMM) a
Sanjib Bhattacharyya, PhD a
Amy Murphy, MPH b
Julie N. Becker, BA a
Bevan K. Baker, MHA, FACHE a

ABSTRACT

The Laboratory System Improvement Program (L-SIP) of the Association of Public Health Laboratories aims to improve state public health laboratory (PHL) system performance through continuous quality improvement. We successfully applied this state assessment tool to a local PHL (LPHL) system by tailoring it to reflect local system needs and created an LPHL system definition explaining how a local system differs from, yet complements, a state system.

On November 18, 2010, 75 stakeholders from 40 agencies assessed the Milwaukee, Wisconsin, PHL system, capturing themes, strengths and weaknesses of the system, and scores for each of the 10 Essential Public Health Services. A Laboratory Advisory Committee analyzed assessment results to identify a strategic focus of research and workforce development and define an action plan, which is now being carried out. Milwaukee’s L-SIP process is effectively improving LPHL system research and workforce development while raising community awareness of the system.

©2013 Association of Schools and Programs of Public Health

aCity of Milwaukee Health Department, Milwaukee, WI
bAmy Murphy Consulting, Milwaukee, WI

Address correspondence to: M. Stephen Gradus, PhD, D(ABMM), City of Milwaukee Health Department, 841 N. Broadway, Room 205, Milwaukee, WI 53202; tel. 414-286-3526; fax 414-286-5098; e-mail <sgradu@milwaukee.gov>.
The public health laboratory (PHL) system is a relatively new concept that defines the efforts of individual states to develop laboratory networks. In 2007, the Association of Public Health Laboratories (APHL) defined a state PHL (SPHL) system as a network consisting of all the participants in PHL testing, including those who initiate testing and those who ultimately use the test results. The PHL system comprises laboratories and other partners within a state or locality that support the 10 Essential Public Health Services (hereafter, Essential Services), with members and stakeholders operating in an interconnected and interdependent way to facilitate the exchange of information, optimize laboratory services, and help control and prevent disease and public health threats. The goal of the PHL system is to create a comprehensive local or statewide system that can respond to all public health needs and threats (Figure 1).

To improve and assess performance of SPHL systems, APHL, in collaboration with the Centers for Disease Control and Prevention (CDC), developed the Laboratory System Improvement Program (L-SIP). As of April 2013, 29 states have performed the L-SIP assessment, which is modeled after the proven performance standard assessment process used by local and state public health departments for the last decade. Because the model performance standards were developed for both state and local health departments, it stands to reason that L-SIP could also be used to measure a local PHL (LPHL) system. A convergence of events

**Figure 1. L-SIP partnership organizational chart: alliances and connections within the local public health laboratory system**

**Local Public Health Laboratory System**

A public health laboratory system is an alliance of organizations and individuals that operate in an interconnected and interdependent way to facilitate the exchange of information, optimize laboratory services, and help control and prevent disease and public health threats.

**Project and Partnership Development History**

November 2010 Assessment

June 2011 System Priorities Identified

August 2011 Strategic Planning

December 2011 Action Planning

**Purpose:** Maximize LPHL system resources and optimize partnership capacity in support of workforce development, research, and service.

L-SIP = Laboratory System Improvement Program
EMS = emergency medical services
CHC = community health center
USPS = U.S. Postal Service
LPHL = local public health laboratory
presented this opportunity to the City of Milwaukee Health Department Public Health Laboratory (MHDL) in Milwaukee, Wisconsin, in 2009.

THE MHDL L-SIP ASSESSMENT

In 2009, due to severe budget projections, the role and capacity of Milwaukee’s PHL was reviewed and examined through an analysis of strengths, weaknesses, opportunities, and threats; development of strategies to sustain and improve service to its customers; and development of a business model for the department. Through MHDL participation in the APHL L-SIP subcommittee, it became evident that the direction of the laboratory and structured goals of the L-SIP process could be merged to complement one another to address the needs of the department and improve laboratory operations, ultimately addressing the entire local laboratory system. The pandemic H1N1 outbreak in Milwaukee in 2009 provided the final boost to project the L-SIP process forward by necessitating updated and improved communication with stakeholders, including courier service and a revised laboratory requisition, all of which contributed to a major revenue boost for the department and additional administrative support to proceed with L-SIP. Laboratory revenue allowed the hiring of a consultant/facilitator in 2010 to assist in the early planning stages of the first-ever local use of L-SIP in the nation.

To date, Milwaukee’s L-SIP and its partners have (1) conducted an assessment of the LPHL system, (2) analyzed the assessment results and identified system priorities for improvement, (3) developed strategic plans related to workforce development and research, and (4) developed action plans to achieve system improvements. In so doing, the LPHL system has benefited from system-strengthening activities of numerous interactions and partnerships.

THE SYSTEMS APPROACH

The Essential Services, which were first introduced in 1994 and defined as those practices or functions that must be in place to assure a fully operational public health system, whether at the local, state, or national level, form the basis for an L-SIP assessment. The 10 Essential Services are presented in Figure 2. The concept of practicing public health through a systems approach began to grow following elucidation of the Essential Services.

The 11 Core Functions of Public Health Laboratories (hereafter, Core Functions) are also considered in the assessment. They serve as a foundation for measuring various PHL quality systems goals and are the functions that SPHLs provide or assure and describe their expected capabilities in safeguarding the public’s health. These Core Functions consist of disease prevention, control, and surveillance; integrated data management; reference and specialized testing; environmental health and protection; food safety; laboratory improvement and regulation; policy development; public health preparedness and response; public health-related research; training and education; and partnerships and communication.

Figure 2. Results of an L-SIP assessment at the City of Milwaukee Health Department Public Health Laboratory, 2010

<table>
<thead>
<tr>
<th>10 Essential Public Health Services</th>
<th>Activity level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Monitor health status to identify community health problems.</td>
<td>83.4</td>
</tr>
<tr>
<td>2. Diagnose and investigate health problems and health hazards in the community.</td>
<td>89.0</td>
</tr>
<tr>
<td>3. Inform, educate, and empower people about health issues.</td>
<td>67.0</td>
</tr>
<tr>
<td>4. Mobilize partnerships to identify and solve health problems.</td>
<td>33.0</td>
</tr>
<tr>
<td>5. Develop policies and plans that support individual and community health efforts.</td>
<td>30.3</td>
</tr>
<tr>
<td>6. Enforce laws and regulations that protect health and safety.</td>
<td>44.3</td>
</tr>
<tr>
<td>7. Link people to needed personal health services and assure provision of health care when unavailable.</td>
<td>67.0</td>
</tr>
<tr>
<td>8. Assume a competent public and personal health-care workforce.</td>
<td>61.2</td>
</tr>
<tr>
<td>9. Evaluate the effectiveness, accessibility, and quality of personnel and population-based services.</td>
<td>50.0</td>
</tr>
<tr>
<td>10. Research for new insights and innovative solutions to health problems.</td>
<td>16.7</td>
</tr>
</tbody>
</table>


Local public health laboratory system performance in each of the 10 Essential Public Health Services was rated on a scale from 0%–100%, based on the level at which the system meets each described activity, where optimal activity = >75%, significant activity = 51%–75%, moderate activity = 26%–50%, minimal activity = >0% to 25%, and no activity = 0%.

L-SIP = Laboratory System Improvement Program
**Purpose and evaluation criteria**

The purpose of L-SIP is continuous process improvement of the LPHL system. Bringing together the stakeholders to decide how to achieve this goal is unique to each system but ultimately drives the overarching functions of a PHL system to assure that (1) public health threats are detected and intervention is timely; (2) stakeholders are appropriately informed of potential threats; (3) reportable conditions are monitored; (4) specimens and isolates for public health testing are sufficient to provide comprehensive public health surveillance and response; and (5) PHL data are transmitted to appropriate local, state, and federal agencies responsible for disease surveillance and control. Achieving optimal activity within the Essential Services strengthens the system and assures that these functions are met.

The L-SIP assessment provides a measurement tool that evaluates how the system measures up to gold standards, not minimum standards, for each Essential Service. Because an assessment and continuous improvement are the goals of L-SIP, a reassessment is recommended every three to five years.

**METHODS**

**Funding**

Grants and other funding streams were necessary to hire a consultant to facilitate and assist with the L-SIP process. Laboratory revenue allowed the initial hiring of a consultant to initiate L-SIP and other related functions in the summer of 2010. Four grants were provided by APHL with CDC support: one mini-grant for the assessment and three consecutive competitive Innovations in Quality Public Health Laboratory Practice grant awards. Additional departmental funding through laboratory-generated revenue allowed the consultant to continue to facilitate meetings and complete additional grant writing between APHL grant awards.

**The assessment**

Working with APHL, MHDL modified the state L-SIP assessment tools to accommodate an LPHL system, with the understanding that a local system is different from, but complements, an SPHL system.

As the first LPHL in the nation to implement the L-SIP assessment, MHDL, with the assistance of APHL staff and APHL L-SIP committee membership, took the following steps: (1) developed a definition of an LPHL system; (2) modified the L-SIP performance-measurement tool so that it was relevant for local application; and (3) customized the visual depiction of an SPHL system to represent a local system. Using those tools and through facilitator-guided discussion, assessment participants rated the performance of the LPHL system in the Essential Services and key ideas.

MHDL’s L-SIP assessment, which took place on November 18, 2010, was conducted by 75 system stakeholders representing more than 40 agencies and departments. Participants included clinical and environmental laboratory scientists, local and state epidemiologists, first responders, environmental health professionals, academicians, researchers, regulators, primary care providers, and multidisciplinary state and local public health professionals. As of April 2013, MHDL was the only local laboratory system that conducted an L-SIP assessment.

**The Web communicator**

Prior to the assessment, an L-SIP Web page using APHL’s Web communicator template was set up on the MHDL website. This page proved invaluable in informing stakeholders and providing regular progress updates.

**Milwaukee Laboratory Advisory Committee**

The next step following the assessment was forming the Milwaukee Laboratory Advisory Committee (MLAC), a group of 14 leading stakeholders who reviewed the results of the assessment and identified LPHL system issues in need of improvement. The group first met on June 3, 2011.

**Subject-matter experts**

Once system priorities for improvement were identified, MHDL, supported by MLAC leadership with help from the consultant, recruited 15 additional LPHL system subject-matter experts (SMEs) in the area of laboratory workforce development (i.e., internships and promotion) and research. In August, September, and December of 2011, these stakeholders worked together to develop strategic and action plans to improve the LPHL system.

At the December 2011 MLAC-SME meeting, three subcommittees were identified to implement a strategic action plan for 2012 with specific outcome deliverables related to goals and objectives for (1) research, (2) workforce development-internships, and (3) workforce development-promotion.

**Subcommittees and community cochairs**

In 2012, four members of the MLAC and SME group were asked to serve as community cochairs, joining with MHDL leadership to work with stakeholder committees to advance and strengthen system partnerships and define L-SIP goals and objectives. Two cochairs assisted
the Research Subcommittee activities, and one cochair each assisted the Workforce Development—Promotion and Workforce Development—Internships subcommittees. In addition to holding committee meetings, the cochairs also reached out to their contacts in the community through one-on-one discussion and various forums to further amplify and strengthen system efforts.

**OUTCOMES**

Assessment
The final L-SIP assessment score was calculated automatically and provided to attendees on assessment day (Figure 2). This score revealed the main strengths and weaknesses of each of the Essential Services, which were broken down into 25 indicators (1–3 for each Essential Service). The indicators were then further broken down into 44 key ideas (1–3 per indicator), all of which served as the basis for discussion and evaluation. The assessment group rated LPHL system activity for each key idea under the corresponding Essential Service as falling at the levels of optimal, significant, moderate, minimal, or no activity. An optimal rating indicated that >75% of the activity described was met within the system, a significant rating indicated that the system met 51%–75% of the activity described, moderate corresponded with a range of 26%–50%, minimal corresponded with a range of 0% to 25%, and no activity indicated 0% of the activity described.

Notetakers on laptops and facilitators with flip charts captured 109 comments as themes and 72 suggested next steps for analysis and consideration. A 59-page assessment report was compiled and e-mailed to participants and posted to the MHDL L-SIP website, and a webinar report was presented to stakeholders in March 2011. Based on a post-assessment participation evaluation completed by 42 attendees, 90% rated the assessment as a valuable process and said they would participate again, with some also expressing interest in being involved in next steps of L-SIP.

Strategic planning team and goals
The MLAC was tasked with using assessment results to guide L-SIP strategic planning. Through its initial meeting, the MLAC determined that Milwaukee’s L-SIP improvement efforts should focus on Essential Services 8 (workforce development) and 10 (research), and further refined the system improvement goal as follows: maximizing the LPHL system resources and optimizing partnership capacity in support of workforce development and research and, in so doing, support the Milwaukee Health Department mission to become an academic health department.

With the assistance of 10 SMEs, the MLAC met in August to inventory existing research and workforce development efforts within the system and develop a framework with strategic directions aimed at strengthening workforce development and enhancing research efforts. Through a facilitated process, the MLAC produced five strategic objectives for research and workforce development, followed by 16 and 24 potential action steps for research and workforce development, respectively.

The five strategic objectives for research were:
- Establish leadership and objectives to facilitate LPHL system research.
- Develop a network of scientists and infrastructure to support research.
- Assure sustained funding to empower research.
- Create mechanisms to train researchers.
- Communicate LPHL system research to the public.

The five strategic objectives for workforce development were:
- Educate the public and health-care professionals on the importance of the LPHL system.
- Attract a motivated and highly skilled workforce.
- Retain an engaged and competent workforce.
- Invest in innovative technology to improve efficiency and capacity.
- Capitalize on outbreaks and public health emergencies to highlight the work of the PHL system.

These strategies were further distilled in a December MLAC-SME meeting to actionable and measurable activities for implementation in 2012 (Figure 3), using community cochair leadership with consultant-facilitated subcommittee meetings from February through June 2012.

Cochair and committee activities: February through June 2012
Community cochairs were secured in late 2011 to assure LPHL system organization as well as stakeholder ownership and commitment to the project. The cochairs met three times from February through July 2012 to provide coordinated leadership for L-SIP and the three subcommittees. They identified three strategies for implementation: (1) facilitating cross-institutional, multidisciplinary research; (2) promoting the LPHL system to attract a competent workforce; and (3) strengthening internships.
Research Subcommittee
On June 22, 2012, a diverse group of 19 stakeholders met to identify research capabilities, themes, and possible collaborations; determine how best to facilitate laboratory system research; and create an LPHL system research inventory—a searchable database depicting profiles of community researchers, including their current research, research interests, and resources. Common themes that emerged from the discussion on current research, research interests, and resources included:

- Current research: methods (e.g., chemical, biological, microbial, and engineering), biological systems, modeling, and surveillance
- Research interests: linking to other disciplines (outreach), microbiology, contaminants, toxicology and immunology, methods, and surveillance
- Resources: models/centers of excellence, databases, specimen/sample repositories, instrumentation, and students/interns and staff

As a result of this meeting, nine researchers identified 15 new potential collaborations of interest that would complement their ongoing work. Further discussions have been initiated to link community research databases from the various networks.

Workforce Development–Internships Subcommittee
A cochair meeting in May 2012 with the committee cochair and the Director of Workforce Development and the Public Health Workforce Development Project Coordinator for the Wisconsin Department of Health Services led to the identification of a potential workforce shortage in the area of certified medical laboratory technicians (MLTs). Relevant questions were then incorporated into the 2012 Wisconsin Clinical Laboratory Science Workforce Survey, which has been distributed to laboratories throughout the state.

Next steps include working with stakeholders to assess workforce development issues, such as the capacity of academic/training programs for MLTs, the number of students in the pipeline, internship capacity, graduation rates, and employment outcomes, ultimately determining how to get more students into programs with meaningful internships.
Workforce Development—Promotion Subcommittee
The Workforce Development—Promotion Subcommittee met in April 2012 and developed strategies to promote the LPHL system, including media outreach, community events, and academic events (e.g., college open houses or career fairs); laboratory tours during National Public Health Week or Medical Laboratory Week; an application for smartphones; a conference for students on laboratory professions; a traveling display focused on LPHL system stories for stakeholders to put in their lobbies; and APHL resources and best practices aimed at LPHL system promotion/workforce development. In July 2012, a student intern drafted three stories on the work of MHD laboratory employees, which will be used to promote laboratory professions within the LPHL system.

In summary, L-SIP has produced a progressive, stakeholder-guided strategic plan with actionable goals and objectives. Some goals have been achieved while others are in varying degrees of definition and execution by community cochaired committees (Figure 4). The results to date should enhance the public health community response due to increased collaboration and communication. Measurable system improvements in research and workforce development are yet to be determined.

Incidental system-strengthening activities
A number of incidental system-strengthening goals and activities also have been developed as a result of L-SIP discussions. They include:

- Visiting researchers to LPHLs to discuss possible research collaborations

Figure 4. Research and workforce development strategic goals: 2011 City of Milwaukee Health Department Public Health Laboratory L-SIP assessment

| L-SIP = Laboratory System Improvement Program |
| UWM = University of Wisconsin-Milwaukee |
| MCW = Medical College of Wisconsin |
| MHD = City of Milwaukee Health Department |
| MSOE = Milwaukee School of Engineering |
| LPHL = local public health department |
| FBI = Federal Bureau of Investigation |
• Speaking requests regarding public health, L-SIP, and PHLs
• Strengthening ongoing relationships
• Interfacing with other local research consortia or planned discussions
• Applying for grants

LESSONS LEARNED

MHDL, like other PHLs, has not typically had a forum for involving multiple system stakeholders. However, the L-SIP process has shown that, when given the opportunity, LPHL system stakeholders are eager to be involved in shaping the public health priorities of the community and recognizing the benefits for their own agencies. Based on Milwaukee’s observation, as well as that of many state assessments, the buy-in by local stakeholders would likely hold true for other LPHL systems. As a result of L-SIP, many connections have been forged or strengthened, and partners now better understand one another’s roles in the LPHL system. Participants’ positive responses to the post-assessment survey indicated that stakeholders find overwhelming value in the L-SIP process and are committed to remaining involved. The L-SIP process has generated a strategic action plan, and stakeholders continue to enthusiastically participate and offer encouragement and support as improvement strategies are actualized for L-SIP.

As L-SIP continues, efforts will shift to being more action- and results-oriented to reach goals that have been set. Translating strategies into action takes weeks and often months. Consequently, additional time will be required before the true results of L-SIP become apparent: measurable improvements in workforce development and research in the LPHL system. While measuring those outcomes will be challenging, the ongoing activities, interactions, and partnerships accomplished to date offer encouragement and are visible signs of system strengthening.

Delays in meeting the goals of the L-SIP strategic action plan have occurred as a result of scheduling conflicts of busy stakeholders, reflecting the need to plan meetings in advance as much as possible. Another challenge observed is that over time committee members may change, and logistics and strategies require modification to keep the process moving. Means to achieve the goals will change to meet the realities that new stakeholders bring to the table, along with new opportunities, experiences, and ongoing dynamic programs that each new stakeholder can bring to bear in achieving desired results.

The availability of grant funding to support a consultant/facilitator with a strong public health background has contributed significantly to the success of Milwaukee’s L-SIP. Therefore, future funding would enable the continuation of Milwaukee’s L-SIP, particularly the ongoing implementation of the workforce development and research strategies. Without such a grant, efforts and progress will be greatly diminished. However, the creation of a new job position, Laboratory Operations Manager, will entail some responsibilities to sustain L-SIP activities. Also, several stakeholders and consortia have expressed support and interest in maintaining L-SIP momentum. Another benefit is that L-SIP will factor into the departmental accreditation process that is currently underway, illustrating community assessment and involvement for improved public health delivery.

Through L-SIP, MHDL is clearly filling a community need to lead cross-disciplinary research and workforce development initiatives with a host of community stakeholders. Innovative and significant actions have enhanced the laboratory system and public health delivery.

This article was supported by the Association of Public Health Laboratories (APHL) under cooperative agreements #U60/CD303019, #U60HM000803, and #U60HM000803 (CFDA#95.065) from the Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of APHL, CDC, and/or the Assistant Secretary for Preparedness and Response.

The cost of the assessment day function and the subsequent 18 months of funding were made possible solely through a mini-grant from APHL and three consecutive Innovations in Quality Public Health Laboratory Practice grant awards from APHL/CDC. The assessment would not have been feasible without the foresight, encouragement, and support of the City of Milwaukee Health Department’s (MHD’s) administration, a key factor for implementing the Laboratory System Improvement Program (L-SIP) process.

The MHD Public Health Laboratory acknowledges the continued commitment and support of the four L-SIP community cochairs: Gul Afshan, PhD, Professor, Department of Physics and Chemistry, and Program Director, BioMolecular Engineering, Milwaukee School of Engineering; Dara Frank, PhD, Professor, Microbiology and Molecular Genetics, and Director, Center for Infectious Disease Research, Medical College of Wisconsin; Randall Lambrecht, PhD, Senior Vice President, Research and Academic Relations, Aurora Health Care; and David Petering, PhD, Distinguished Professor, Chemistry and Biochemistry, and Director, Children’s Environmental Health Sciences Core Center, University of Wisconsin-Milwaukee. Without their efforts, along with the participation of numerous other local public health laboratory system stakeholders, the progress made thus far in defining and executing Milwaukee’s L-SIP goals would not have been possible.
REFERENCES


11. City of Milwaukee Health Department Laboratory. Laboratory System Improvement Program (L-SIP) [cited 2012 Sep 7]. Available from: URL: http://city.milwaukee.gov/LSIP


Laboratory System Improvement Program: First in the Nation—New Hampshire Reassessment

JILL J. POWER, MS, M(ASCP)*
CHRISTINE L. BEAN, PhD, MBA,
MT(ASCP)*
AMANDA COSSER, BS*
ALMA VAZQUEZ, BS*

ABSTRACT
The New Hampshire Public Health Laboratories (NH PHL) conducted an initial Laboratory System Improvement Program (L-SIP) assessment in March 2007 and a reassessment in May 2011. New Hampshire was a pilot state for the initial L-SIP assessment in 2007 and was the first laboratory system in the United States to conduct an L-SIP reassessment. The New Hampshire reassessment was also used as a pilot for revising the assessment tool. The NH PHL performed a high-level comparison benchmarking the work done between the two assessments. This comparison revealed areas of improvement and other areas that needed continued focus to align with model standards of the 10 Essential Public Health Services. This article outlines achievements, improvements, and outcomes made since 2007, as well as participants, activities, plans, resources, and other factors that contributed to the change in scores between assessments.
In 2002, the Centers for Disease Control and Prevention (CDC) established the National Public Health Performance Standards Program (NPHPSP)\(^1\) to measure components of public health systems and local public health governance against a gold standard and to identify areas for improvement. Based on the 11 Core Functions of State Public Health Laboratories\(^2\) and designed within the framework of the 10 Essential Public Health Services (hereafter, Essential Services)\(^3\) (Figure 1), the Association of Public Health Laboratories (APHL), in conjunction with CDC, developed a similar assessment program for public health laboratory (PHL) systems. Called the Laboratory System Improvement Program (L-SIP),\(^4\) this performance measurement project is used to determine state and local PHL systems’ capabilities and capacity to provide adequate and appropriate laboratory system functions and services.

A state public health laboratory (SPHL) system is defined by the APHL as a partnership between PHLs and other state agencies, private laboratories, and other organizations and health-care providers to assure laboratory services essential to the health of the public.\(^5\) The performance assessment process was created to engage and leverage SPHL system partnerships to build a stronger foundation for public health, promote continuous quality improvement, and strengthen the scientific basis of public health practice improvements. Within the L-SIP, APHL developed an assessment tool to evaluate systems.\(^6\) Created in 2006, the assessment tool was used for the New Hampshire (NH) 2007 assessment, as well as in many other states from 2007 through 2009. In May 2011, NH was the first laboratory system to conduct a reassessment. Additionally, NH also piloted a newly revised assessment tool. Because this reassessment was an improvement project, APHL representatives were present during the NH reassessment and captured the efficacy of the newly revised tool. In August 2011, the tool was adopted and became the final assessment tool to be used for future laboratory system assessments throughout the U.S.

The intent of a reassessment is to determine the strengths and weaknesses of the system, benchmark rates of performance for each Essential Service, and recognize the improvements made since the initial assessment. After an initial assessment, APHL recommends that a reassessment take place periodically, about every three to five years, to benchmark system performance.

**METHODS**

As one of nine pilot state systems, the NH Public Health Laboratories (NH PHL) conducted an initial L-SIP assessment on March 26, 2007, with 89 participants. NH then held the first L-SIP reassessment in the U.S. on May 4, 2011, with 51 participants. The following were the objectives of the NH L-SIP assessment and reassessment:

- Inform participants about the NH PHL and build an appreciation of the interdependence of system partners.
- Improve communications among system partners.
- Expand collaboration with system partners.
- Recognize system strengths.
- Identify opportunities for improvement.
- Articulate the resources needed for optimal system functionality.
- Compare improvement rates between the initial assessment and the reassessment.

To complete the L-SIP assessment in one day, all participants were assigned to join in a plenary session and then organized into three workgroups to review and evaluate three of the Essential Services. Participants

---

**Figure 1. The 10 Essential Public Health Services**\(^a\)

1. Monitor health status to identify community health problems.
2. Diagnose and investigate health problems and health hazards in the community.
3. Inform, educate, and empower people about health issues.
4. Mobilize community partnerships to identify and solve health problems.
5. Develop policies and plans that support individual and community health efforts.
6. Enforce laws and regulations that protect health and assure safety.
7. Link people to needed personal health services and assure the provision of health care when otherwise unavailable.
8. Assure a competent public health and personal health-care workforce.
9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services.
10. Research for new insights and innovative solutions to health problems.

invited to the NH reassessment were those individuals and agencies (i.e., stakeholders) who use the laboratory system in some capacity or contribute to it (Figure 2).

To maintain and standardize each workgroup, a core participant group of key stakeholders was created, including a PHL manager, a public health administrator, a hospital laboratory director, a Laboratory Response Network (LRN) representative, a public health nurse, an NH Bureau of Disease Control representative, a PHL technical supervisor, and a PHL representative with either technical or administrative skills within a PHL. Each group also had a core-facilitated cohort that included a professional facilitator, a system theme-taker, and an APHL theme-taker. Theme-takers assisted the facilitator and captured information conveyed and discussed throughout the assessment.

The L-SIP assessment process simulates the NPHPSP assessment process used to evaluate local and state public health systems but is adapted to laboratory services. Each Essential Service represents a major system component, activity, or practice, and is assessed individually. The L-SIP assessment tool consists of the breakdown of each Essential Service into model standards that describe high-level performance aspects, key ideas, and points of discussion. As components of a model standard, one or more key ideas are used to measure the L-SIP performance. Points of discussion are not measured but are used to trigger and facilitate participant dialogue of each key idea. Upon discussion, participants are asked to rate the performance of the system in achieving the key idea against the model standard. Scoring of the Essential Service takes place when consensus among the group is achieved for each key idea and is voted upon as a group. The key idea scores are then tabulated to provide an overall performance rate for each Essential Service. Prior to consensus, any discussion among the participants serves as a platform to close the gap between scores and improve the overall performance of the system. Issues are noted as either “next steps” or “parking lot” issues. The parking lot issues are used later as a basis for system improvement.

Figure 2. Suggested participant list of key partners and stakeholders for APHL L-SIP assessments, as used for the 2011 NH PHL L-SIP reassessment

<table>
<thead>
<tr>
<th>Academia/researchers</th>
<th>Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agriculture community</td>
<td>Other laboratories—clinical, veterinary, forensic, environmental, and food safety</td>
</tr>
<tr>
<td>Business community</td>
<td>Pharmacists</td>
</tr>
<tr>
<td>Chronic disease providers</td>
<td>Physicians</td>
</tr>
<tr>
<td>Community leaders</td>
<td>Policy makers</td>
</tr>
<tr>
<td>Customers of laboratory services</td>
<td>Professional organizations/associations (e.g., laboratory, hospital, medical, and national)</td>
</tr>
<tr>
<td>Emergency management partners</td>
<td>Public information officers</td>
</tr>
<tr>
<td>Federal partners</td>
<td>Public safety and other first responders</td>
</tr>
<tr>
<td>Finance administrators</td>
<td>Radiological partners</td>
</tr>
<tr>
<td>General public</td>
<td>Safety personnel</td>
</tr>
<tr>
<td>Grant administrators</td>
<td>Schools/career counselors</td>
</tr>
<tr>
<td>Health insurers</td>
<td>State public health officials</td>
</tr>
<tr>
<td>Health-care organizations/clinics</td>
<td>Users of the test results, including epidemiologists and public health programs</td>
</tr>
<tr>
<td>Hospitals (e.g., administration, clinical laboratory, and infection control)</td>
<td>Veterinarians</td>
</tr>
<tr>
<td>Human resources department staff</td>
<td>Water/air quality partners</td>
</tr>
<tr>
<td>Information technology organizations</td>
<td></td>
</tr>
<tr>
<td>Laboratory regulators/accrediting agencies</td>
<td></td>
</tr>
<tr>
<td>Laboratory staff training programs</td>
<td></td>
</tr>
<tr>
<td>Legislators and other elected officials</td>
<td></td>
</tr>
<tr>
<td>Local epidemiologists</td>
<td></td>
</tr>
<tr>
<td>Local health departments and health officials</td>
<td></td>
</tr>
<tr>
<td>Local public health laboratories</td>
<td></td>
</tr>
</tbody>
</table>


APHL = Association of Public Health Laboratories
L-SIP = Laboratory System Improvement Program
NH PHL = New Hampshire Public Health Laboratories
Outcomes

The scoring definition by which the NH system was graded in 2007 is different from the 2011 evaluation. The wording of the scoring system changed to more descriptive terms in determining the system’s achievement in fulfilling Essential Service activities. The new 2011 scoring system defines the percentage of the rate of performance rather than activity of the Essential Service met by the system. A word score is chosen that directly correlates to a weighted score within the scoring tool. The previous word scoreings—no activity, no, no partially, yes partially, yes, and does not apply (Figure 3)—were replaced with new word scoreings—none, minimal, moderate, significant, and optimal (Figure 4)—in the revised assessment. The definitions of the word scores were changed to reflect tangible activities such as meetings, project coordination, and deliverable items, as well as to include system relationships, team-building, and more conceptual work.

The score of each key idea was entered into a Microsoft Excel spreadsheet provided by the APHL L-SIP assessment kit, and a cumulative score for the Essential Service was calculated. Each key idea has an assigned weighted value that, when added to all of the key idea scores in an Essential Service, yields an overall score. All overall scores are then added to create a final summary score result. During the final session of the NH reassessment, the 2007 initial assessment scores were compared with the 2011 reassessment scores and displayed in a modified trend chart (Figure 5), which was shown to the entire group of participants to visualize the progress of each Essential Service and where to channel resources for improvement. Two of the Essential Service scores remained the same (Essential Services 2 and 8), three decreased (Essential Services 1, 5, and 7), and five increased (Essential Services 3, 4, 6, 9, and 10).

Observations of those Essential Services with scores that remained unchanged for both assessments

---

**Figure 3. Scale for rating activity of the 10 Essential Public Health Services:**
NH PHL L-SIP assessment, 2007

<table>
<thead>
<tr>
<th>Word score for activity</th>
<th>Activity rate of Essential Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>No activity</td>
<td>None of the members of the SPHL system perform any activity in this area.</td>
</tr>
<tr>
<td>No</td>
<td>No more than 25% of the activity described within the question is met within the SPHL system.</td>
</tr>
<tr>
<td>No partially</td>
<td>&gt;25% but not more than 50% of the activity described within the question is met within the SPHL system.</td>
</tr>
<tr>
<td>Yes partially</td>
<td>&gt;50% but not more than 75% of the activity described within the question is met within the SPHL system.</td>
</tr>
<tr>
<td>Yes</td>
<td>&gt;75% of the activity described within the question is met within the SPHL system.</td>
</tr>
<tr>
<td>Does not apply</td>
<td>Activities included in the key idea and referenced in the questions are not relevant to the SPHL system.</td>
</tr>
</tbody>
</table>


NH PHL = New Hampshire Public Health Laboratories
L-SIP = Laboratory System Improvement Program
SPHL = state public health laboratory

---

**Figure 4. Scale for rating performance of the 10 Essential Public Health Services:**
NH PHL L-SIP reassessment, 2011

<table>
<thead>
<tr>
<th>Word score for activity</th>
<th>Rate of performance of Essential Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>0% or absolutely none of the performance described is met within the PHL system.</td>
</tr>
<tr>
<td>Minimal</td>
<td>&gt;0% but not more than 25% of the performance described is met within the PHL system.</td>
</tr>
<tr>
<td>Moderate</td>
<td>25% but not more than 50% of the performance described is met within the PHL system.</td>
</tr>
<tr>
<td>Significant</td>
<td>50% but not more than 75% of the performance described is met within the PHL system.</td>
</tr>
<tr>
<td>Optimal</td>
<td>&gt;75% of the performance described is met within the PHL system.</td>
</tr>
</tbody>
</table>


NH PHL = New Hampshire Public Health Laboratories
L-SIP = Laboratory System Improvement Program
PHL = public health laboratory
New Hampshire Laboratory System Reassessment

Figure 5. Comparison of the 2007 vs. 2011 Laboratory System Improvement Program scores of the 10 Essential Public Health Services* in New Hampshire

<table>
<thead>
<tr>
<th>Essential Service</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate</td>
<td>Optimal</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
</tr>
<tr>
<td></td>
<td>Significant</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
</tr>
<tr>
<td></td>
<td>Minimal</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
<td>XX</td>
</tr>
</tbody>
</table>

Change in Score: Decrease | Same | Increase | Increase | Decrease | Increase | Decrease | Same | Increase | Increase


ES = Essential Service

(Essential Services 2 and 8) revealed that work conducted since the initial assessment had not resulted in any dramatic improvements, but no worsening had occurred. Essential Service 2 received a score at the optimal level for both assessments. In 2007, Essential Service 7 was the subject of the plenary session; however, for 2011, Essential Service 2 was selected for the plenary session, which may have contributed to an overall high score due to a broader range of participants involved. The larger group’s rating of Essential Service 2 at the highest level indicates that the system has continued to maintain high-quality services through federal and state regulations. This Essential Service review also indicated that rapid response to emergencies has been effective in assisting in the diagnosis of health problems in the system by offering ongoing training for specimen and sample collection, transport, and communication. Plans for continuity of operations have had a significant impact on the system’s ability to continue with the LRN and other emergency responders during public health events. Weaknesses discussed included the lack of published turnaround times for testing and the assurance of communication between partners when tests were outsourced. Purchasing procedures from partners were questioned as group members observed that resources were quickly made available during critical events, such as the 2009 H1N1 influenza pandemic, yet are not routinely available.

Essential Service 8 remained unchanged at the significant level, indicating that workforce development will continue to be an issue for employers in the system, especially during a downward slope in the economy. One possible reason the score did not change is that all laboratories within the system have continued to satisfy the key ideas in this Essential Service. Since 2007, members of the system have taken part in many activities that assure a competent public health and personal health-care workforce. All clinical laboratory representatives in attendance were from institutions accredited by the Clinical Laboratory Improvement Amendments (CLIA)* to perform human testing. CLIA requires defined job requirements and qualifications, as well as competency assessment for testing personnel. Laboratory staff performing nonhuman testing are not within the scope of CLIA but are overseen by other regulatory agencies such as the International Organization for Standardization, U.S. Environmental Protection Agency, and U.S. Food and Drug Administration. These agencies also require a level of competency within the workforce. Another reason why the Essential Service 8 score did not change was that the system offers continual support for staff development through training, education, and mentoring. To assure best laboratory practices in a safe work environment, NH PHL created and provided physician office laboratory training at three locations in the state, and other stakeholders have hosted similar workshops. Although the system has performed highly to achieve Essential Service 8, there is room for improvement. One reason for the less-than-optimal rating may be the inability to offer competitive salaries and benefits, which is important for workforce recruitment.
Review of the five Essential Service scores that increased from 2007 to 2011 (Essential Services 3, 4, 6, 9, and 10) showed that improved communication tools were a common factor. System members worked with the Health Alert Network (HAN), CDC’s primary communication method, to assure that the system received rapid updates and advisories during public health events. The NH PHL’s biannual newsletter, Extracts from the Lab, was also redesigned to disseminate information about laboratory events, testing updates, and other relevant system news, nationally and internationally. Increasing the use of the HAN and revising the newsletter proved direct correlations to improvement in Essential Service 3 (minimal to optimal).

Improvements in Essential Service 4 (significant to optimal) reflected new emergency communication procedures established among public health nurses, the NH PHL, and the LRN. A “call tree” (i.e., a telecommunication chain for notifying specific individuals of an event) was implemented for after-hours contact. Additionally, in federal grant proposals, system partners incorporated resource sharing (e.g., equipment and training) among stakeholders to assist in covering system needs when resources are scarce. To sustain this optimal level of performance, the strong relationships among system partners, such as the NH LRN and the NH PHL, should be maintained. Collaboration among the partners in response to community health issues proved successful during the NH public health incident of patients potentially exposed to the hepatitis C virus during a hospital stay.

In the discussion of Essential Service 6 improvements (significant to optimal), those who claimed improvements were experienced in laboratory-related laws and regulations that protect health and assure safety. Many of these stakeholders were not present at the 2007 assessment; so by being present in 2011, they helped increase the rating by sharing their experiences. An NH Division of Public Health Services spokesperson described how laws and regulations are created and monitored. System members were aware of laboratory-related regulations but unsure of state statutes regarding individual entities. Improvements since 2007 reflected partner relationships that were responsible for supporting regulatory enforcement functions; however, the lack of funding for enforcement efforts, due to the loss of incoming fees, was identified as a problem, especially assigning designated personnel to oversee compliance issues. Future planning will include efforts to improve compliance and enforcement.

Understanding the voice of the customer drives change and assists in improving the quality of services. System partners revealed that many of their organizations are using feedback from customer satisfaction surveys to improve the effectiveness of laboratory test results and how they are used within their systems. This feedback has led to the improvement in scores for Essential Service 9 (none to minimal). Since 2007, many organizations have developed individual mission and vision statements for their own entities, yet none exist for the NH system. Plans to improve the rate of performance in this Essential Service include bringing partners together to develop a system mission statement that will define the system, set goals, and promote improvement activities by the next reassessment. Improvements in Essential Service 10 (minimal to moderate) revealed an increased use of electronic surveillance programs to gather data for research activities along with ongoing encouragement of staff to further their education by working with stakeholders to develop thesis projects. The development of quality improvement teams among stakeholders and the establishment of publishing groups to assist in writing research findings also helped to raise the score.

For those Essential Services with decreased ratings (Essential Services 1, 5, and 7), no action steps had been taken for some key ideas since 2007. The decrease in score for Essential Service 1 (significant to moderate) was attributed to a lack of information technology among the systems on a regular and user-friendly basis. As a system, communication worked well among partners, but there was no mechanism to offer a single electronic information system to assist with surveillance activities. Since 2007, the NH PHL implemented a Laboratory Information Management System (LIMS), which facilitated and improved the systems’ capacity to exchange limited information. The LIMS provides an efficient method to track samples from receiving time until the report has been submitted to the provider. Real-time reporting of laboratory results allows for timely action among users and will be monitored for improvement.

The decreased rating for Essential Service 5 (optimal to significant) may be attributed to some participants lacking an accurate understanding of how policies are developed using laboratory data. Overall, a common theme was that the system is not robust in identifying ways it can capture public health data to incorporate into policies to support individual and community health. PHL staff typically do not have the expertise to create policies and usually are not allowed to advocate for state policy unless instructed to do so. To be successful in creating policies, the participants felt the need to be more proactive rather than reactive. In 2007, legislative activity was considered a weakness in the
system, and this weakness was also reflected in the 2011 reassessment. While they were invited, no legislative or rule-making partners were present for the initial assessment or the reassessment. Partnership development improved among public health cohorts as the strength of planning for critical incidences proved successful in handling the 2009 H1N1 influenza pandemic.

A decrease in the score for Essential Service 7 (significant to moderate) was likely due to the 2010 cancellation of a state-funded courier to transport specimens. Many of the participants who had been directly affected by the loss of the courier were present, yet more input would have been helpful in discussing the impact this budget cut had on turnaround times, specimen integrity, and scope of services for private laboratories, physicians, and the general public. This Essential Service had an additional key idea added to it since 2007, so the scoring may have been lower due to the additional factor in calculating the overall score.

LESSONS LEARNED

The revised assessment tool consolidated, eliminated, or updated key ideas, which may have changed the scoring rates of each key idea as well as the overall score of each Essential Service. Scoring descriptions in the revised assessment are more detailed, reflecting performance rather than activities.

In NH, the 2007 and 2011 final scores were almost identical. The NH system participants believe this outcome does not truly reflect improvements made within each Essential Service; therefore, individual Essential Service scores are NH’s target value for system improvement.

The L-SIP tool recommends assessments using a core group of participants and a suggested group of subject-matter experts and partners who are main contributors to an Essential Service. The decrease in attendees in 2011 seemed to elicit more sharing of information, contributions, and experiences from participants than it did in 2007. The selection of participants whose expertise and job functions align within the domain of an Essential Service contributed to increased scores, as participants were to share their knowledge and applicable facts and data during the discussion period. Some of the same attendees were present for both the 2007 assessment and the 2011 reassessment. Their experience with the process likely enhanced their participation and the formation of the scoring.

Since the reassessment, the NH PHL has collated the results, the “parking lot” issues, and participant feedback for each Essential Service. A voluntary core group has been tasked to evaluate and identify next steps for improvement. As the NH PHL moves toward optimal performance, the group will continue to monitor improvement projects as well as relate any new activities to an Essential Service. In NH, formal meetings such as forums or advisory boards have not been instituted, but future plans include reviewing and celebrating improvement activities by others within the system to promote the sustainability of high-quality laboratory services.

CONCLUSIONS

L-SIP assessments are not mandatory and require dedicated resources such as staff, time, and money. In 2007, the initial L-SIP assessment provided a baseline analysis of the system, and the reassessment in 2011 served as a benchmark that identified best practices used to substantiate the hard work and commitment of resources in achieving improvements within the system. Many system partners have interacted during the four years between the assessments and realize how important it is to have a system in place. Because several agencies have had to reorganize or downsize some of their programs, resource sharing has become critical. Networking and positive system relationships can foster collaborations and allegiances, encourage the sharing of assets and ideas, and help improve communications, especially during crucial times. Bringing partners together on a regular basis with a common goal strengthens relationships and ultimately helps improve the system.

Voluntary assessments of continual evaluations produce standardizations and help offset the propensity of system relationships to become stagnant. Proactively conducting a self-reflection and review of the system demonstrates caring about the system’s customers, clients, and the public. With each new project, team meeting, or management meeting, awareness of implementing Essential Services as guiding principles will make an impact in changing the culture of continual system improvement in NH. To maintain that culture and be effective, the NH PHL system is committed to continuing evaluation and will perform another reassessment in the coming years.

This manuscript was supported by Cooperative Agreement #U60HM00803 from the Centers for Disease Control and Prevention (CDC) and/or Assistant Secretary for Preparedness and Response. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC and/or Assistant Secretary for Preparedness and Response.
REFERENCES


The Indiana Laboratory System: Focus on Environmental Laboratories

Jyl M. Madlem, MS, MT(AMT)
Kara R. Hammes, MPH
Shelley R. Matheson, BS
Judith C. Lovchik, PhD, D(ABMM)

Indiana State Department of Health Laboratories, Indianapolis, IN

Address correspondence to: Jyl M. Madlem, MS, MT(AMT), Indiana State Department of Health Laboratories, 550 West 16th St., Ste. B, Indianapolis, IN 46202; tel. 317-921-5574; fax 317-927-7801; e-mail <jmadlem@isdh.in.gov>.

©2013 Association of Schools and Programs of Public Health

ABSTRACT

The Indiana State Department of Health (ISDH) Laboratories are working to improve Indiana's state public health laboratory system. Environmental laboratories are key stakeholders in this system, but their needs have been largely unaddressed prior to this project. In an effort to identify and engage these laboratories, the ISDH Laboratories organized and hosted the First Annual Environmental Laboratories Meeting. The focus of this meeting was on water-testing laboratories throughout the state. Meeting objectives included issue identification, disaster recovery response, and communication efforts among system partners. Common concerns included the need for new technology and updated methods, analyst training, certification programs for analysts and sample collectors, electronic reporting, and regulation interpretation and inspection consistency. Now that these issues have been identified, they can be addressed through a combination of laboratory workgroups and collaboration with Indiana's regulatory agencies. Participants were overwhelmingly positive about the meeting's outcomes and were willing to help with future laboratory system improvement projects.
As of August 2012, 28 states and one city have worked with the Association of Public Health Laboratories (APHL) to assess and improve their public health laboratory (PHL) systems. To date, these assessments have largely focused on the role of clinical laboratories without evaluating the role of environmental laboratories. Environmental laboratories are also contributors to public health testing and have been overlooked because of the clinical focus during the improvement phase.

The Indiana Laboratory System (ILS) consists of all contributors to public health testing. These contributors include those who initiate testing and those who use test results. The Indiana State Department of Health (ISDH) Laboratories conducted a statewide laboratory system assessment in 2009. Targeted areas for improvement included partnership development and communication plans. Relationship building, website use, information sharing, and collaboration were identified as potential solutions to address these issues. Since the ILS assessment, communication needs have been addressed with clinical laboratories.

Current collaboration and communication efforts with Indiana’s clinical sentinel laboratories include the ISDH SharePoint website (http://myshare.in.gov/ISDH/islabs/default.aspx) and an e-mail listserv and e-mail address exclusive to the ISDH Laboratories Outreach Team (isdh-lab-info@isdh.in.gov). Clinical sentinel laboratories throughout the state are familiar with the communication and training format of the ISDH Laboratories. However, the network of Indiana’s nonclinical laboratories still needs to be defined and established.

METHODS

Communication
The ISDH Office of Public Affairs designed a logo and slogan to market the concept of partnership development and network creation among nonclinical laboratories in Indiana. The logo depicts environmental, veterinary, and clinical laboratories connected within a molecule-like graphic with the slogan “Get Connected” (Figure 1).

Indiana’s nonclinical laboratories were identified using resources from within ISDH, as well as from external agencies and laboratory associations. These agencies and associations included the Indiana Board of Animal Health, the Indiana Department of Environmental Management (IDEM), the Indiana American Water Works Association (IAWWA), and the Indiana Rural Water Association (IRWA). The resulting database includes contact information for dairy, veterinary, and water laboratories. This database is housed on the ISDH Laboratories’ SharePoint website. It was used to develop geographical mapping tools to serve as a general reference and to facilitate site visit scheduling. An interactive Web page map provides the name and address of the laboratory, the laboratory director’s name, as well as the phone number and e-mail address of a designated contact person. This website is designed for ease of use by member laboratories and can be accessed at http://gis.in.gov/apps/ISDH/ILSLabs.

The ISDH Laboratories Program Advisor scheduled statewide visits with nonclinical laboratories. These visits promoted the concept of the laboratory system and provided a better understanding of their individual needs within the context of the system. ILS information packets were distributed to each laboratory. Specific resources used for these visits included travel time and hotel accommodations. Travel time was minimized by scheduling northern and southern visits in regional bundles. These face-to-face meetings were very successful and provided the data leading to the environmental focus of the meeting. The packets included the ILS flier, the interagency partnerships graphic, the U.S. Environmental Protection Agency (EPA) Water Alliance Response Plan flier, the elements of emergency response plans flier, the APHL state laboratory system graphic, the Web-mapping graphic, and
contact information for ISDH Laboratories personnel by testing section.

Laboratorians from Indiana’s water laboratories were invited to the First Annual Environmental Laboratories Meeting held on June 25, 2012. Invitations were sent via the LabInfo e-mail notification system, which was previously used only for communication with the clinical sentinel laboratories. In addition, professional organizations such as IAWWA and IRWA agreed to forward the invitation to their members to inform smaller municipal water facilities. By using electronic forms of communication, the invitation was easily forwarded to additional participants.

Meeting focus
The meeting was divided into two main discussion sessions entitled Scenario Response and Table Talk. Scenario Response consisted of three separate scenarios focused on disaster recovery. It also served as a networking icebreaker. Scenario 1 described a passing thunderstorm resulting in widespread flooding, power outages, and closure of a local health department. Scenario 2 recalled a recent ice storm covering much of the Midwest that resulted in the loss of utilities and water with recovery time unknown. Scenario 3 depicted increased reporting of patients in area hospitals with watery diarrhea consistent with cryptosporidiosis along with statistics of mortality, surge in testing, and recreational area closures. During the Scenario Response portion, attendees were given the opportunity to converse in small, informal groups and share information and stories from their respective laboratories. A representative from each small group then addressed the larger group about the disaster recovery plans for his or her discussion group. The Table Talk session was an opportunity for attendees to voice their concerns and discuss issues affecting their individual laboratories.

OUTCOMES
None of the laboratories involved in this project had prior knowledge of the system or their part in it; however, all were receptive to learning about the ILS. The water laboratories were especially concerned with understanding their role within the system and how to improve system-related processes. Issues associated with wastewater laboratory certification, analyst certification, new methods, electronic reporting to IDEM, and proficiency testing frequency were identified during initial site visits. To better understand and address these issues, water laboratories were the focus of the First Annual Environmental Laboratories Meeting.

There were 29 attendees representing 21 different laboratories at the Environmental Laboratories Meeting. When asked which water types each laboratory tested, attendees indicated that their laboratories test drinking water (20%); wastewater (12%); both drinking water and wastewater (4%); drinking water, surface water, groundwater, and wastewater (60%); or other (4%) (Figure 2). Half of the attendees had been in the

---

Figure 2. Type of water testing performed by attendees (n=25) at the First Annual Environmental Laboratories Meeting: Indianapolis, Indiana, June 25, 2012

- Drinking water (20%)
- Waste water (12%)
- Drinking- and wastewater (4%)
- Drinking-, waste-, surface-, and groundwater (60%)
- Other (4%)
Common concerns identified during the Table Talk session were similar to concerns addressed during site visits. Once these issues were recognized, attendees were asked to select their three highest priorities in order of importance and relevance to their respective laboratories. Scores were weighted such that the first selection was given more weight than the second and third, respectively. In order of the highest- to lowest-ranked issues, the top three issues were (1) updated methods and new technology acceptance; (2) analyst training, which was regarded as greatly needed by smaller municipalities; and (3) regulation interpretation consistencies from IDEM inspectors, which was noted among senior members of laboratories because interpretations of regulations can differ between inspections and among inspectors.

The most significant issue was the need for updated methods and new technology acceptance. Participants preferred better methods with faster turnaround times. In a follow-up survey of attendees using SurveyMonkey®, respondents reported that funding (55%) and approval of methods by the EPA (36%) were the primary barriers preventing the implementation of updated methods at their laboratories.

Evaluation results for the Environmental Laboratories Meeting indicated that 100% of the attendees gained information, would attend again next year, and would recommend this meeting to colleagues. Furthermore, more than 80% of attendees volunteered to assist in ILS improvement activities. They offered to serve on workgroups to resolve systematic issues and workforce development activities through the production and distribution of a training video series for environmental analysts.

LESSONS LEARNED

The initial site visits played a critical role in understanding the basic issues facing environmental laboratories. Ultimately, the visits gave structure to the Environmental Laboratories Meeting. Face-to-face meetings with a subset of state laboratories provided vital information. Not only were laboratories unaware of the system or their part in it, they were also unaware that the system could provide assistance in resolving process issues with state agencies. The Environmental Laboratories Meeting allowed further discussion, identification of primary issues, networking among participants, and disaster recovery planning for emergency preparedness. Attendees were also given the opportunity to volunteer to assist with future efforts to improve the ILS.

The ISDH Laboratories have a leadership role in developing and promoting the ILS through active collaboration with the system’s stakeholders. The ISDH

---

*A parallel was noted between environmental and clinical laboratory workforces; 50% of the laboratorians attending the Environmental Laboratories Meeting had been in the workforce for 15 years. However, 22% of attendees had held their positions for ≤5 years, indicating some influx into the field by younger scientists.*

---

**Figure 3. Length of time* attendees (n=26) at the First Annual Environmental Laboratories Meeting had been in the workforce: Indianapolis, Indiana, June 25, 2012**

- <2 years (7.7%)
- 2–5 years (15.4%)
- 6–8 years (7.7%)
- 9–14 years (19.2%)
- 15–20 years (15.4%)
- >20 years (34.6%)

---

A parallel was noted between environmental and clinical laboratory workforces; 50% of the laboratorians attending the Environmental Laboratories Meeting had been in the workforce for 15 years. However, 22% of attendees had held their positions for ≤5 years, indicating some influx into the field by younger scientists.
Laboratories will fulfill this role primarily by acting as a liaison with IDEM, while also facilitating meetings and discussions among laboratories throughout the state. Several of the concerns discussed during the Environmental Laboratories Meeting will only be resolved through the collaboration of multiple laboratories and laboratory associations. These issues include analyst training, increased public outreach, and analyst certification programs. The ISDH Laboratories are facilitating and encouraging the formation of workgroups to address these issues.

Although some issues identified during the Environmental Laboratories Meeting can be resolved by the laboratories alone, other concerns need to be addressed in different ways. Indiana environmental laboratories are regulated by IDEM, not the ISDH. Although all laboratories included in this project perform testing that impacts the health of the public, these individual laboratories are not well-equipped to contact and work with IDEM on issue resolution. As a partner state-level agency, the ISDH Laboratories regularly work with IDEM and can bring concerns to quarterly ISDH Laboratories/IDEM meetings for discussion. Several regulatory-related issues, such as electronic reporting, regulation interpretation, and inspection consistencies, were identified during the Environmental Laboratory Meeting. Key environmental laboratory staff from throughout the state will be invited to attend these meetings to provide additional input.

Even though environmental laboratories perform testing of public health importance and play a critical role in disaster preparedness and recovery efforts, the recognition of environmental laboratories as a fundamental component of the PHL system improvement program is a relatively recent development. The existence of the Water Laboratory Alliance, the Environmental Response Laboratory Network, and the Laboratory Response Network for Chemical Threats efforts are vitally important in the improvement of state laboratory systems. However, given the scope of this project and the information gathered from the initial site visits, it was clear that improving communication efforts in Indiana is the necessary first step in improving the environmental component of the ILS. Progress has been made with clinical sentinel laboratories regarding communication, training, and outreach, but similar growth is needed with the environmental laboratories. Fortunately, Indiana’s water laboratories are interested in improving the ILS.

In an effort to apply these lessons to other environmental or nonclinical laboratories within the state, the ISDH Laboratories have implemented quarterly partner meetings with the Food Protection Division and have strengthened outreach and communication efforts with local health departments and environmental health specialists. These efforts allow the ISDH Laboratories to engage the data users in the laboratory system. In addition to the laboratories that generate data, data users are also considered primary stakeholders in the laboratory system.

CONCLUSIONS

This project allowed for the exploration of the nonclinical laboratory portion of the ILS and the strengthening of those relationships. Environmental laboratories in Indiana have been overlooked during the building of the clinical sentinel areas of the system. The state PHL system is a new concept to member laboratories in Indiana and in many other states. The lack of awareness of the state system indicates that marketing and outreach are essential to moving forward in system improvement activities.

However, for marketing and outreach to be effective, basic communication networks must be established. In fact, communication with these member laboratories is the foundation of a successful system. Without appropriate communication, there cannot be emergency preparedness, effective disaster recovery, timely public policy change, or necessary workforce development. In fact, many of the issues identified through this project, during site visits, and at the Environmental Laboratories Meeting will be addressed through avenues provided by the ILS.

Ultimately, the realization that the system is fluid is the key to building the ILS from an environmental perspective. People and test systems change, technology and environmental threats change, and, therefore, the needs of the system will change. Improving these systems requires communication, funding, time, and patience.

This project was supported by the Association of Public Health Laboratories under Cooperative Agreement #U60HM000803 from the Centers for Disease Control and Prevention (CDC). The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

The initial Indiana State Department of Health state public health laboratory system assessment was funded by the CDC Preventive Health and Health Services Block Grant, award #2009-B1-IN-PRVS.

REFERENCES

2. Association of Public Health Laboratories. Definition of a state


Using Interorganizational Partnerships to Strengthen Public Health Laboratory Systems

Krisitna Hsieh, DrPH
Paul Kimsey, PhD
Gertrude Buehring, PhD

ABSTRACT
Due to the current economic environment, many local and state health departments are faced with budget reductions. Health department administrators and public health laboratory (PHL) directors need to assess strategies to ensure that their PHLs can provide the same level of service with decreased funds. Exploratory case studies of interorganizational partnerships among local PHLs in California were conducted to determine the impact on local PHL testing services and capacity. Our findings suggest that interorganizational forms of cooperation among local PHLs can help bolster laboratory capacity by capturing economies of scale, leveraging scarce resources, and ensuring access to affordable, timely, and quality laboratory testing services. Interorganizational partnerships will help local and state public health departments continue to maintain a strong and robust laboratory system that supports their role in communicable disease surveillance.
California has a decentralized public health laboratory (PHL) system consisting of one state PHL and multiple local PHLs (LPHLs) serving 61 health jurisdictions. The establishment of LPHLs began in the early 1950s. By the 1970s, 39 LPHLs were established across California. Four laboratories have since shut down in Mendocino, Napa, Yolo, and Marin counties. The Napa, Yolo, and Marin county PHLs consolidated with the Solano County PHL in 1999, 2011, and 2013, respectively. The Mendocino County health department is contracting for laboratory services with the Sonoma County PHL. As of July 2013, there were 35 LPHLs in operation in California. The cost of establishing and maintaining a PHL is borne by the city or county. Thus, the LPHLs operate fairly independently from each other and the state PHL. Table 1 provides a comparison of the number of PHLs in California with states that have a comparable population or land mass.1–5

Multiple economic and regulatory constraints are impacting the sustainability of LPHLs and the state PHL in California and across the nation. Increased commercial laboratory competition in past years has reduced the volume of tests being sent to PHLs.6 Prior to and during the 2008 economic recession, budgetary pressures decreased funding allocations for health departments and, ultimately, the laboratories.7,8 In addition to economic pressures, regulatory pressures have impacted the sustainability of PHLs. The PHL director (PHLD) workforce has been affected since the introduction of the federal Clinical Laboratory Improvement Amendments in 1988. These federal amendments mandate that PHLDs have a doctoral degree and a board certification to supervise an accredited moderate- to high-complexity PHL.9 In California, a qualified PHLD must meet federal and state requirements. The California requirements include obtaining a post-baccalaureate-level public health microbiologist certification and four years of training in a PHL. A limited number of qualified applicants are able to meet both federal and state requirements. As the current PHLDs retire, there is an anticipated shortage of individuals to fill the pipeline.5 The compounding nature of the workforce shortage and economic environment is affecting the sustainability of PHLs across California.

The California PHL system has been in place for more than 100 years and has been successful in averting public health threats (e.g., the plague, smallpox, 2009 H1N1 pandemic, and, in recent years, Hantavirus and pertussis outbreaks). However, economic pressures are forcing local and state health administrators to assess their laboratory needs. If health department administrators are considering closing a PHL or eliminating and/or outsourcing testing services as a means of cost savings, strategies to ensure seamless provision of quality laboratory testing services are needed. We explored interorganizational partnerships (i.e., a strategic alliance, or formal arrangement, between two or more organizations for the purpose of ongoing cooperation and mutual risk/gain sharing through a long- or short-term contract) as a means of bolstering laboratory capacity and maintaining a robust PHL network in California.10,11

Table 1. Comparison of land mass, population, and number of moderate- to high-complexity PHLs within the PHL systems in California, New York, Texas, and Florida: 2012–2013

<table>
<thead>
<tr>
<th>Variable</th>
<th>California</th>
<th>New York</th>
<th>Texas</th>
<th>Florida</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total area (in square miles): 2013</td>
<td>163,696</td>
<td>54,556</td>
<td>268,581</td>
<td>65,755</td>
</tr>
<tr>
<td>Population (in millions): 2012</td>
<td>38</td>
<td>20</td>
<td>26</td>
<td>19</td>
</tr>
<tr>
<td>Number of moderate- to high-complexity local and state PHLs: 2011</td>
<td>35</td>
<td>4</td>
<td>16</td>
<td>11</td>
</tr>
</tbody>
</table>


PHL = public health laboratory
METHODS

We conducted exploratory case studies to highlight different forms of strategic cooperation/partnerships implemented among LPHLs in California to cope with budgetary and regulatory constraints. Factors deemed significant by PHLDs and health administrators for maintaining long-term partnerships are documented across each case study to elucidate criteria necessary for successful interorganizational relationships. As described by Stake and Yin, it is important to understand how different cases perform in different environments; therefore, the evidence from multiple case studies may be more convincing than from a single case study. 12,13

We conducted seven in-depth interviews for two case studies. Interviews were conducted either in person or by phone. The interviewees were limited to individuals with specific knowledge of the partnership between laboratories. Information gathered from interviews was written up descriptively. Case studies of the consolidation of the Napa County and Solano County laboratories and the contractual agreement between Sonoma County and Mendocino County are described in the next section.

OUTCOMES

Case one: Napa County and Solano County PHL consolidation

In 1997, the Health and Human Services Agency in Napa County received funding from the county to update its campus. The PHL was located in a trailer and was invited to participate in the campus update. However, after reviewing the cost of building a new laboratory facility and maintaining a PHL, the administration realized that it could not afford to undertake this endeavor. The Napa County health department administrators and PHLD decided to explore the option of consolidating with another PHL to continue provision of laboratory services. The Solano County health department administrators were advocating for obtaining economies of scale with public health programs. Napa and Solano counties were facing major budget deficits and problems with hiring laboratory personnel and decided to engage in a strategic alliance by consolidating their PHLs as a cost-saving measure. Table 2 includes the county demographics and PHL profile of Napa and Solano counties pre- and post-consolidation.

Initiation of PHL consolidation. The Napa County health department administrators and PHLD agreed upon two criteria to assess a partnering laboratory: (1) compatibility of testing capabilities and (2) distance of specimen transport. Bids were sent to the neighboring counties of Sonoma, Contra Costa, and Solano. Solano County PHL was chosen as the partnering laboratory due to compatibility of testing capabilities and distance (about 20 miles). In addition, the following two factors were critical in the decision-making process:

1. Prior working relationship. The Solano County PHL acted as a backup laboratory when Napa County needed assistance with testing. The laboratory personnel at the Solano County PHL were familiar with the procedures and protocols for handling specimens from Napa County. This knowledge streamlined the transition process during the initial phases of the merger.

2. Use of Napa County personnel at the joint laboratory. The Solano County health department was willing to create an assistant laboratory

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Napa County PHL</th>
<th>Solano County PHL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-consolidation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of personnel (year)*</td>
<td>3 (1999)</td>
<td>9 (2009)</td>
</tr>
<tr>
<td>Number of specimens tested (year)</td>
<td>1,500 (1999)</td>
<td>12,871 (2009)</td>
</tr>
<tr>
<td></td>
<td>Napa-Solano County PHL</td>
<td></td>
</tr>
<tr>
<td>Post-consolidation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of personnel (year)*</td>
<td>11.25 (2012)</td>
<td></td>
</tr>
<tr>
<td>Number of specimens tested (year)</td>
<td>12,000 (2011)</td>
<td></td>
</tr>
<tr>
<td>Population served (year)</td>
<td>756,613 (2011)</td>
<td></td>
</tr>
</tbody>
</table>

*Personnel includes technical and clerical categories denoted in full-time equivalents.

PHL = public health laboratory
director position in the joint Napa-Solano County PHL for the Napa County PHLD. This staffing solidified and strengthened the partnership as the laboratory directors adjusted to managing a joint PHL.

In 1999, a joint powers agreement (JPA) was created and approved by both the Napa County and Solano County health department administrators and boards of supervisors. A JPA is a contract between a city, a county, and/or a special district in which the city or county agrees to perform services, cooperate with, or lend its powers to the other city, county, or special district. The JPA allows a single laboratory to serve multiple adjacent counties and leverage scarce resources to create economies of scale for specimen testing, proficiency testing, supplies, and reducing personnel needs. This agreement resulted in the closure of the Napa County PHL and creation of the joint Napa-Solano County PHL. The employees are hired and paid by Solano County, but Napa County provides financial support to maintain the PHL and continued provision of laboratory services for Napa County. Health department administrators from both counties have deemed this venture successful, as evidenced by the renewal of the JPA in 2005, 2008, and 2010. Areas of success. The joint laboratory established a courier service to pick up specimens in Napa County to ensure that samples are transported in a timely manner. If specimens had to be packaged and shipped to a new facility, there would likely be delays in shipment or mishandling of samples. By engaging in a consolidation effort, Napa County is able to offer a broader testing menu to its clients and a faster turnaround time for reporting results. For example, human immunodeficiency virus testing was conducted once a week at the Napa County PHL due to low specimen volume. At the Solano County PHL, the same test is conducted several times a week. Health department administrators from both Napa and Solano Counties are equally invested and responsible for the PHL and work collaboratively to ensure that the needs of both their health departments are met. In addition to enhanced testing services, cost savings have been achieved. Napa County reduced its annual fiscal expenditures by sharing a laboratory facility, and Solano County benefited from increased funding support.

According to health department administrators and the PHLD, an area of implementation that is integral for the success of this partnership is the use of a JPA rather than a contract or memorandum of understanding (MOU). The benefits of the JPA include:

1. Joint name for the laboratory. The JPA allows the use of a joint name for the laboratory—something that cannot be granted under a contract or an MOU.
2. Access to government funding. The JPA allows government funding designated for the Napa County PHL to be accessible to the joint PHL. If the agreement was contractual, Solano County would not have access to funding designated for Napa County.
3. Equal footing and responsibility for the PHL. The counties jointly operate the laboratory, and both counties’ health officers function in an advisory capacity for decisions relating to the laboratory. This equality provides assurance to the Napa County health department that the Solano County health department cannot make changes to the PHL without its involvement.

Points of improvement. This partnership has many successful components; however, one improvement to the agreement has been suggested—allowing greater flexibility with funding. With the renewal of the 2010 JPA, health administrators from both counties have agreed to detach funding to a specific position and allow the use of funds for any laboratory-associated needs. In addition, a new provision to the JPA was added to link Napa County’s financial contribution to the consumer price index to reflect inflation. Prior to the 2010 agreement, Solano County did not request an increase in financial support from the Napa County health department even though operating costs have gone up considerably over the years. By leveraging partnerships, both Napa and Solano counties are able to obtain economies of scale for the provision of laboratory services.

The consolidation of these two PHLs has been very successful. As one Napa County health officer put it: “The whole process really worked because of the people involved. Everyone had the same goal in mind, which was to strengthen the laboratory services in both counties and become more efficient and cost-effective, and that was accomplished and is still being accomplished with this agreement.”

Case two: contractual agreement for laboratory services in Mendocino County

The Mendocino County health administration was unable to recruit a qualified candidate for its PHLD position when its director retired. An alternative solution was to contract for the services of a PHLD to meet federal regulations for operation. An agreement was established with a neighboring health department’s PHLD to manage the PHL. The PHLD agreed to visit
the Mendocino County PHL once a month and provide supervision through telecommunication. Table 3 summarizes the county demographics and PHL profiles pre- and post-closure of the Mendocino County PHL.

During this period, the Mendocino County PHL was supported by a laboratory manager and two public health microbiologists (PHMs). During the first year, one PHM retired, leaving one microbiologist and the laboratory manager to handle the workload for the laboratory. When the laboratory manager retired and the health department could not successfully recruit a qualified applicant, sustaining the PHL became problematic. Under federal and state requirements, PHLs may employ a part-time PHLD if there is a full-time supervising PHM working in the laboratory. After having difficulty recruiting for both the PHLD and supervising PHM positions, the Mendocino County health officer decided that the $250,000 needed to maintain the PHL should be directed to other programs. In 2009, Mendocino County health department administrators and boards of supervisors decided to close the PHL and outsource laboratory testing. Laboratory samples were sent to clinical laboratories in hospitals around Mendocino County, and specimens of public health concern (e.g., rabies and Mycobacterium tuberculosis) were sent to the Sonoma County PHL, which was located approximately 63 miles away. A fee-for-service contractual agreement was established.

**Points of improvement.** A fee-for-service contract does not foster the same level of mutual reliance and commitment for the PHL that a JPA requires. According to Sonoma County laboratory personnel, the fee-for-service arrangement does not contribute to the overhead cost of supporting a PHL or the costs of maintaining a federally qualified PHLD. In spring 2010, a different contractual model was proposed by the Sonoma County PHLD and health department administrators. The revised contract establishes a partnership similar to the JPA that requires the Mendocino County health department to increase its share of financial support for the laboratory. Monetary support will be scaled up during a three-year period. The Mendocino County health department will cover one-third of the cost in the first year, two-thirds of the cost in the second year, and the full cost in the third year. This support plan allows the Mendocino County health department to increase its budget for laboratory services during a three-year cycle. This contract was established in the 2011–2012 fiscal year. Both health department administrators agreed that there are minimal governance issues and decided to continue with a contractual agreement rather than use a more formalized JPA. After three years, both counties will reevaluate the contract and adjust to future needs.

**LESSONS LEARNED**

Due to the decentralized manner in which LPHLs in California function, a one-size-fits-all model will not work due to political, legal, financial, and structural differences among health departments. In the case of the Napa-Solano County PHL consolidation, a JPA was selected to allow for equal governance of the joint laboratory. The Mendocino County and Sonoma County health department administrators decided to use a contract rather than a JPA due to minimal governance issues. Health department administrators and the PHLD must work together and analyze factors that are important and pertinent to their specific needs and circumstances. In addition, the alignment of goals, open communication, and continued support of leaders is imperative to ensure a successful long-term relationship, as exemplified in the consolidation of the Napa County and Solano County PHLs. A summary

---

**Table 3. Number of personnel, specimens tested, and population served at the Sonoma and Mendocino County PHLs pre- and post-closure of the Mendocino County PHL: California, 2007–2011**

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Sonoma County PHL</th>
<th>Mendocino County PHL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prior to closure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of personnel (2007)*</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>Number of tests conducted (2007)</td>
<td>31,000</td>
<td>3,808</td>
</tr>
<tr>
<td>Population served (2009)</td>
<td>472,102</td>
<td>86,040</td>
</tr>
<tr>
<td><strong>Following closure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of personnel (2013)*</td>
<td>8.75</td>
<td>NA</td>
</tr>
<tr>
<td>Number of specimens tested (2012)</td>
<td>17,500</td>
<td>NA</td>
</tr>
<tr>
<td>Population served (2011)</td>
<td>575,669</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Personnel includes technical and clerical categories denoted in full-time equivalents.

PHL = public health laboratory

NA = not applicable
of the factors discussed in the case studies that are integral in a successful long-term partnership is shown in the Figure.

The LPHL system in California is the largest network of LPHLs in the U.S., with 35 LPHLs serving 61 health jurisdictions. Multiple factors are impacting LPHLs today, including shifts in federal regulations, competition from clinical and commercial laboratories, and local and national economic pressures. To cope with resource limitations, health department administrators and PHLDs may be forced to assess different strategies to address these constraints. Provision of public health services (e.g., PHLs) may benefit from assessing the feasibility of engaging in interorganizational forms of cooperation.

CONCLUSIONS

The economic climate locally and nationally has had a detrimental impact on the public health system during the past several years. Laboratories in California and across the nation have had to downsize their staff, outsource and/or eliminate services, and close laboratories to cope with economic and regulatory pressures. As economic conditions continue to worsen, health department administrators need to assess different options to maximize the use of resources for public health services such as PHLs. One option to improve efficiency and maintain access to quality PHL testing and services is engagement in partnerships to leverage resources and obtain economies of scale. By partnering with other laboratories, costs are shared, and expertise and testing services are expanded. This partnership can ensure that a robust PHL network continues to support public health efforts to detect, identify, and monitor emerging and reemerging public health threats and emergencies.

This article was made possible by contributions from state, local, and city health department administrators and public health laboratory directors. Sincerest gratitude is extended to those individuals who took the time to share their experiences regarding interorganizational partnerships from among their public health laboratories.

REFERENCES

9. Centers for Disease Control and Prevention (US). Subpart M: per...
Legal Considerations in Cross-Jurisdictional Sharing of Public Health Laboratory Services

MOLLY R. BERKERY, JD, MPH
MATTHEW S. PENN, JD, MLIS

ABSTRACT

The Centers for Disease Control and Prevention and the Association of Public Health Laboratories initiated the Laboratory Efficiencies Initiative in 2011 to help address issues related to public health laboratory (PHL) capacity to perform critically needed tests and services. One approach to improving capacity and efficiency is sharing PHL services with other states or jurisdictions. Cross-jurisdictional sharing implicates numerous federal and state laws, including federal and state privacy laws, laboratory certifications, packaging and shipping requirements for laboratory specimens, and state laws regarding fees and revenue. While federal laws generally do not present insurmountable barriers to sharing PHL services, state laws vary greatly, even within the same region of the country. This article summarizes some of the potentially relevant federal and state legal issues related to cross-jurisdictional sharing. It is important that states interested in cross-jurisdictional sharing consider all relevant laws, potential conflicts of law, as well as inconsistencies with agreements already in place among health departments and laboratories.
Public health laboratories (PHLs) play a critical role in advancing and protecting the public’s health. Both state and local PHLs monitor community health conditions, perform the vast majority of public health reference tests, help shape population-based interventions, advise health-care providers on appropriate patient care, and play a critical role in detecting the onset of disease threats and performing a high volume of testing during public health emergencies. They are an integral part of the nation’s laboratory system and serve as a first line of defense to protect the public’s health.¹

Due to recent economic constraints, many PHLs have suffered serious financial pressures, including budget and staffing cuts. As a result, some PHLs have had to stop performing certain tests, posing potential public health risks, including impairing the ability of public health authorities to respond effectively to conventional health risks and public health emergencies. The Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) initiated the Laboratory Efficiencies Initiative in 2011 to address issues related to PHL capacity to perform critically needed tests and services. The Laboratory Efficiencies Initiative aims to strengthen PHLs through the achievement of long-term sustainability by adopting practices that improve laboratory operating efficiency and strengthen their resilience in the face of financial and capacity challenges.¹

CROSS-JURISDICTIONAL SHARING OF PHL TESTING SERVICES

One approach to improving laboratories’ operating efficiency is to share testing services with PHLs in other states or jurisdictions. Cross-jurisdictional sharing of PHL services represents an innovative and effective practice that can strengthen the PHL system. The spectrum of sharing includes informal, customary arrangements (e.g., ad hoc arrangements), service-specific arrangements (e.g., memoranda of understanding or contractual arrangements), shared functions with joint oversight (e.g., shared capacity or joint projects), and regionalization (e.g., mergers or the creation of new entities).² One example of an existing shared services arrangement is the Northern Plains Consortium, formed by the state PHLs of Montana, North Dakota, South Dakota, and Wyoming. Another example is the performance of newborn screening tests by the Oregon State Public Health Laboratory for six states, birthing centers of the Navajo Nation, Guam, the Marshall Islands, Saipan (in the Northern Mariana Islands), and a military base in California.

PHL directors have expressed interest in understanding the potential legal issues relevant to cross-jurisdictional sharing of testing services. In May 2012, CDC’s Public Health Law Program, in collaboration with CDC’s Laboratory Science, Policy, and Practice Program Office, published a report, “An Overview of Legal Considerations in Assessing Multijurisdictional Sharing of Public Health Laboratory Services,” to help PHL directors and their legal counsel explore these issues.³ The Overview of Legal Considerations is a companion report to “A Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes,” which was published by APHL and CDC.¹ The report provides a brief account of the range of federal and state laws that may be implicated in cross-jurisdictional test service sharing. This article is based on that report and focuses on legal considerations in interstate sharing of PHL services.

FEDERAL AND STATE LEGAL CONSIDERATIONS

Federalism

The U.S. Constitution establishes a government system based on “federalism,” or the sharing of power between the federal and state governments. During the drafting of the Constitution, a number of state-specific authorities were given to the federal government and are now referred to as the enumerated powers. However, states retained many inherent powers, particularly with regard to protecting the public’s health and welfare. The 10th Amendment to the Constitution recognizes the states’ reservation of authorities and provides that “powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”¹ The public health powers reserved by the states are part of what are called the police powers. Further, although the police powers are considered a state authority, some states share the powers with local governments. Local governments are creatures of state constitutions and statutes, and, generally, local government powers are enumerated much like the federal government.

Public health activities occur at all three levels of government. Widespread sharing of PHL testing services cross-jurisdictionally may implicate federal constitutional law. For example, Article 1, Section 10, Clause 3 of the U.S. Constitution, also known as the Compact Clause, states that “no State shall, without the Consent of the Congress . . . enter into any Agreement or Compact with another state . . . .” Despite a literal reading of the Compact Clause, the U.S. Supreme Court has
held that only a limited number of interstate agreements require Congressional consent. The Supreme Court has consistently held that application of the Compact Clause is limited to agreements that lead to an increase or decrease of political power of any one state, or “which may encroach upon or interfere with the just supremacy of the United States.” Depending on the structure of sharing PHL services, states may need to address federal Constitutional issues. States may also need to consider state constitutional issues.

State public health legal authorities
Most states have enabling statutes that establish PHLs. Additionally, most states authorize the department of health or another state agency to promulgate rules or regulations regarding PHL activities. For example, North Carolina requires that the Commissioner of Health “adopt rules necessary for the operation of the State Laboratory of Public Health.” Two important legal considerations regarding the sharing of testing services are (1) whether a state is required to establish and operate a PHL and (2) where the PHL is located. For example, North Carolina establishes “[a] State Laboratory of Public Health . . . within the Department [of Health and Human Services],” whereas Iowa establishes “[t]he state hygienic laboratory . . . as a permanent part of the state university of Iowa.”

Other considerations include whether the state PHL must perform all PHL testing, whether a state can contract out for all or certain testing services, and whether a state PHL can perform services on out-of-state specimens. Public health-enabling statutes and related regulations may either facilitate or restrict shared services arrangements.

Another consideration is the relationship between arrangements for sharing day-to-day laboratory services and existing laws and arrangements triggered by public health emergencies or other surge events. Many states have laws that address cross-jurisdictional mutual aid agreements specifically for PHL services during declared emergencies. For example, Maryland has a specific law that addresses mutual aid agreements and PHLs in other states. In this context, Maryland defines a mutual aid agreement as “a written agreement between a public health laboratory in the State and a public health laboratory operated by another state to establish and carry out a plan to assist each other in providing temporary testing services to alleviate an emergency at one of the laboratories.” Maryland law requires that “[a] public health laboratory operated by another state that enters into a mutual aid agreement shall provide written documentation of the statutory authority required for that state to meet the responsibilities set forth in the agreement.” Maryland law further includes specific requirements for mutual aid agreements, including employee travel, workers’ compensation, and expenses. Additionally, the Emergency Medical Assistance Compact (EMAC) is an interstate mutual aid agreement that enables states to share resources during emergencies and disasters. Congress ratified EMAC, and all 50 states, three territories (the U.S. Virgin Islands, Puerto Rico, and Guam), and the District of Columbia have enacted legislation to become members of EMAC.

PHL fees
State laws related to PHL fees are an important consideration to cross-jurisdictional test service sharing. Whether and how much a state PHL is authorized to charge for services varies from state to state. For example, some state laws limit fees to the actual cost of the test performed. South Dakota requires the fee for each PHL service or test to be “based on the actual cost of performing the service or test and the cost of operating the public health laboratory.” In Illinois, “the Laboratory’s service fees . . . shall not exceed the Department’s actual costs to provide the Laboratory’s services, and shall consider the current fees charged by private laboratories for comparable services.” Other states require specific dollar amounts to perform certain tests. For example, Wyoming mandates a $5 fee for the testing of “[v]iral serology for vaccine status (IgG) [and for] each viral antigen (rubella, rubeola, mumps, or chickenpox).”

Some states also have laws governing where PHL revenue is directed. South Dakota, for example, requires “any money that may be received . . . shall be deposited in a special revenue fund in the state treasury which is established and designated as the state laboratory fund.” It is important to note that states often have separate laws related to PHL fees for specialized laboratory testing (e.g., newborn screening tests).

In addition, contracting mechanisms vary from state to state. For example, procurement issues may depend on the structure of shared services arrangements (i.e., PHLs to PHLs vs. PHLs to private health laboratories), among other factors. It will be important to engage legal counsel when considering different shared services arrangements.

Health privacy
The applicability of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule is an important consideration to any agreement to share services. The HIPAA Privacy Rule outlines the requirements for covered entities’ use and disclosure
of protected health information, including the disclosure of protected health information for public health activities. A covered entity is defined as a health plan, a health-care clearinghouse, or a health-care provider that transmits any health information in electronic form in connection with a covered transaction.\textsuperscript{16} It is important to note that a PHL may be a hybrid entity that engages in covered and non-covered functions. For example, a PHL that provides health care, as defined under the HIPAA Privacy Rule, and bills for the services in electronic form will be subject to the rule. However, a PHL may also perform non-covered functions, such as testing services for a health department’s disease investigations or tuberculosis screening. While HIPAA may not impede cross-jurisdictional agreements for sharing PHL services between state health departments, PHLs vary from state to state, and such federal privacy laws should be considered and addressed.

In addition to federal health privacy laws, all states have laws related to health data privacy and security. State privacy laws are expansive and cover a range of topics from disease reporting to genetic testing, mutual aid, and forensic deoxyribonucleic acid. These laws may also cross-reference other state or federal privacy provisions. For example, Rhode Island’s disease reporting regulation states that “[t]he HIPAA Privacy Rule expressly permits disclosures without individual authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, public health surveillance, investigation, and intervention. . . .”\textsuperscript{17} It is important that states contemplating cross-jurisdictional sharing of PHL services review all applicable privacy laws. All state parties may wish to ensure that their own privacy laws are properly addressed as laboratory services are shared. States may also consider developing security and confidentiality agreements (e.g., business associate agreements or data use agreements) to address data privacy and security.

**Newborn screening**

Most states have newborn screening laws, and PHLs are often primarily responsible for newborn screening tests. Ohio requires the state PHL to perform all newborn screening unless the state PHL is unable to perform screenings for a required disorder. If the director determines that the state PHL is unable to perform screenings, the director is required to select an alternative laboratory to perform screenings through a request for proposals, which may include both in-state and out-of-state laboratories. Rescreening may be performed by the Ohio State Public Health Laboratory or another designated laboratory.\textsuperscript{18} In contrast, Mississippi allows any laboratory in the U.S. to perform newborn screening testing, provided that the testing laboratory complies with all standards in Mississippi’s newborn screening laws.\textsuperscript{19}

Some states have laws that specifically address newborn screening and mutual aid agreements. Texas law allows the Department of State Health Services to “enter into a mutual aid agreement to provide newborn screening laboratory services to another state and to receive newborn screening laboratory services from another state in the event of an unexpected interruption of service, including an interruption caused by a disaster."\textsuperscript{20} Maryland law states that “[e]xcept as set forth in a Departmental mutual aid agreement, the Department’s public health laboratory is the sole laboratory that may hold a State permit to perform and that may perform a first-tier newborn screening test on a newborn infant.” However, “[a] medical laboratory other than the State’s public health laboratory may obtain a permit to perform: [a] supplemental test; [a] second-tier test; or [s]upplemental and second-tier tests.”\textsuperscript{21}

**Laboratory certification**

States should consider federal and state laboratory certification requirements. The Clinical Laboratory Improvement Amendments of 1988 (CLIA)\textsuperscript{11} “[s]et forth the conditions that all laboratories must meet to be certified to perform testing on human specimens” for health assessment or the diagnosis, prevention, or treatment of disease.\textsuperscript{22} CLIA probably does not provide any barriers to shared service agreements; however, as states plan sharing arrangements, they may want to consider and address all necessary laboratory certifications.

**Shipping laboratory specimens**

States sharing PHL services with other states must comply with all applicable local, state, and federal laws governing shipping, packing, marking, and labeling. For example, laboratory specimens containing or suspected of containing infectious substances must be shipped according to applicable U.S. Department of Transportation and International Air Transport Association regulations.

**Risk management**

Lastly, states will want to address risk management issues. Liability, immunity from liability, indemnity, choice of law, and dispute resolution are important issues that states may want to address in formal agreements to share PHL services. States may also want to review constitutional provisions related to governmental...
or sovereign immunity and state statutes, including tort claims acts. It is critical to consult with legal counsel on this issue. State tort claims and sovereign immunity laws can be drastically different from state to state. Failure to adequately address liability in an agreement could expose a state to significant financial losses that could have been avoided and addressed at the outset.

CONCLUSION

PHLs play a critical role in protecting the public’s health. Cross-jurisdictional sharing of PHL services is an innovative public health practice aimed at improving laboratory capacity and efficiency. This article offers states that are interested in cross-jurisdictional sharing of PHL services a starting point for considering potential federal and state legal issues. PHL directors should contact their attorneys and request assistance during any legal assessment. While federal laws may not present any inordinate barriers, state laws vary greatly, even within the same region of the country. States interested in cross-jurisdictional sharing should consider all relevant laws, potential conflicts of law, as well as inconsistencies with agreements already in place between health departments and laboratories.

The findings and conclusions in this article are those of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention. This article is a general overview of potential legal issues related to the interstate sharing of public health laboratory (PHL) services and should not be construed as legal guidance or advice on how state PHLs should navigate legal considerations discussed. The authors recommend seeking the advice of an attorney or other qualified professional with questions regarding the application of law to a specific circumstance.

REFERENCES

5. U.S. Constitution, Art. I, §10, Cl. 3.
14. WY Adm. Hlth Phil Ch. 1 S 5 (2010).
16. 45 C.F.R. §160.
Evaluation of Three Influenza Neuraminidase Inhibition Assays for Use in a Public Health Laboratory Setting During the 2011–2012 Influenza Season

William Murtaugh, MPH\textsuperscript{a,b}
Lalla Mahaman, MPH\textsuperscript{a}
Benjamin Healey, BS\textsuperscript{a}
Heather Peters, BS\textsuperscript{a}
Barbara Anderson, BS, MT(ASCP)\textsuperscript{a}
Mandy Tran, BS\textsuperscript{a}
Marci Ziese, MS\textsuperscript{a}
Maria Paz Carlos, MBA, PhD\textsuperscript{a,b}

\textbf{ABSTRACT}

\textbf{Objectives.} We evaluated the implementation of three commercially available neuraminidase inhibition assays in a public health laboratory (PHL) setting. We also described the drug susceptibility patterns of human influenza A and B circulating in Maryland during the 2011–2012 influenza season.

\textbf{Methods.} From January to May 2012, 169 influenza virus isolates were tested for phenotypic susceptibility to oseltamivir, zanamivir, and peramivir using NA-Fluor\textsuperscript{TM}, NA-Star\textsuperscript{®}, and NA-XTD\textsuperscript{TM} concurrently. A 50\% neuraminidase inhibitory concentration ($IC_{50}$) value was calculated to determine drug susceptibility. We used the standard deviation based on the median absolute deviation of the median analysis to determine the potential for reduced drug susceptibility. We evaluated each assay for the use of resources in high- and low-volume testing scenarios.

\textbf{Results.} One of the 25 2009 influenza A (H1N1) pandemic isolates tested was resistant to oseltamivir and peramivir, and sensitive to zanamivir, on all three platforms. Eighty-two influenza A (H3N2) and 62 B isolates were sensitive to all three drugs in all three assays. For a low-volume scenario, NA-Star and NA-XTD took 120 minutes to complete, while NA-Fluor required 300 minutes to complete. The lowest relative cost favored NA-Star. In a high-volume scenario, NA-Fluor had the highest throughput. Reagent use was most efficient when maximizing throughput. Cost efficiency from low- to high-volume testing improved the most for NA-Star.

\textbf{Conclusions.} Our evaluation showed that both chemiluminescent and fluorescent neuraminidase inhibition assays can be successfully implemented in a PHL setting to screen circulating influenza strains for neuraminidase inhibitor resistance. For improved PHL influenza surveillance, it may be essential to develop guidelines for phenotypic drug-resistance testing that take into consideration a PHL’s workload and available resources.

\textsuperscript{a}State of Maryland Department of Health and Mental Hygiene, Laboratories Administration, Division of Virology and Immunology, Baltimore, MD
\textsuperscript{b}Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Address correspondence to: Maria Paz Carlos, MBA, PhD, State of Maryland Department of Health and Mental Hygiene, Laboratories Administration, Division of Virology and Immunology, 201 W. Preston St., Room 4A6, Baltimore, MD 21201; tel. 410-767-6151; fax 410-410-333-7790; e-mail <maria.carlos@maryland.gov>.

©2013 Association of Schools and Programs of Public Health
This article contributes to the understanding of influenza drug resistance by describing the phenotypic susceptibility of human influenza A and B viruses to two commonly used neuraminidase inhibitors (NAIs), oseltamivir (Tamiflu®, Genentech, San Francisco, California) and zanamivir (Relenza®, GlaxoSmithKline, Research Triangle Park, North Carolina), and one investigational NAI, peramivir (BioCryst Pharmaceuticals, Durham, North Carolina), as observed during the 2011–2012 influenza season. We evaluated the implementation of three neuraminidase inhibition (NI) assays (NA-Fluor™ Influenza Neuraminidase Assay Kit, NA-Star® Influenza Neuraminidase Inhibitor Resistance Detection Kit, and NA-XTD™ Influenza Neuraminidase Assay Kit [Life Technologies Corp., Carlsbad, California]) for the detection of phenotypic influenza antiviral drug resistance in a public health laboratory (PHL) setting.

Currently, two classes of antiviral drugs for chemoprophylaxis and treatment of human influenza viruses are approved by the U.S. Food and Drug Administration (FDA). Adamantanes were the first to be developed and include amantidine and a methyl derivative, rimantidine. Widespread resistance of circulating influenza viral strains to the adamantane drug compounds has paved the way for reliance on a class of drugs called NAIs, which target the envelope glycoprotein neuraminidase (NA) required for viral replication and successful establishment of infection. The FDA-approved NAIs include oseltamivir, which is administered orally, and zanamivir, which is administered through inhalation directly to the site of the viral replication. Additionally, the FDA-investigational NAI, peramivir, which is administered intravenously, is available under the Emergency Use Act for treatment of severe cases of influenza during the 2009 H1N1 influenza pandemic (hereafter, influenza A [H1N1] pdm09).4

Due to differing chemical structures, oseltamivir requires NA to undergo a conformational change that effectively inhibits NA, whereas zanamivir does not. NA mutations that alter the oseltamivir binding domain may affect the virus’s ability to adjust the required conformational changes, which translate as oseltamivir resistance. The differences in the mode of action have been attributed to the higher probability of oseltamivir encountering resistance. This vulnerability became apparent during the 2007–2008 influenza season in the United States, when an H275Y mutation characterized in the NA gene of the seasonal influenza A (H1N1) virus displayed patterns of near-universal oseltamivir resistance. However, during the influenza A (H1N1) pdm09 in the U.S., drug resistance to oseltamivir was detected in <1% of tested influenza A (H1N1) strains. Resistance was correlated with hospitalized and immunocompromised individuals with prior exposure to oseltamivir.

There have only been isolated and sporadic incidences of influenza A (H1N1), influenza A (H3N2), and influenza B viruses’ resistance to zanamivir. Additionally, peramivir is still in clinical trials in the U.S., and resistance patterns have not been fully established. However, in vitro cross-resistance to oseltamivir and peramivir has been reported in influenza A (H1N1) strains with the H275Y mutation. To date, seasonal influenza strains remain largely susceptible to both oseltamivir and zanamivir.

**METHODS**

**Viruses, cells, and reagents**

During the 2011–2012 influenza season, at the State of Maryland Department of Health and Mental Hygiene (MD DHMH) Laboratories Administration Division of Virology and Immunology, available seasonal influenza virus isolates (n=169) were propagated in primary rhesus monkey kidney cell lines (Diagnostic Hybrids, Athens, Ohio) and were stored at ≤−70°C for use in NAI susceptibility testing. The 169 isolates were previously identified as influenza A (H3N2) (n=82), influenza A (H1N1) pdm09 (n=25), and influenza B (n=62) by real-time reverse transcription polymerase chain reaction (RT-PCR) at the MD DHMH Laboratories Administration Division of Molecular Biology. Each influenza virus isolate was tested for NAI susceptibility using one fluorescent-based NI assay (NA-Fluor) and two chemiluminescent-based NI assays (NA-Star and NA-XTD) against three NAIs. The NAIs were oseltamivir as the active metabolite oseltamivir carboxylate (Tamiflu), zanamivir (Relenza), and peramivir. The 96-well assay plates were read using the Victor™ X4 Multilabel Plate Reader (PerkinElmer, Shelton, Connecticut). The measurements were reported as the concentration of NAIs required to inhibit 50% of the NA activity, called an inhibitory concentration (IC_{50}) value. An influenza virus isolate reference panel including the IC_{50} values was kindly provided by the Centers for Disease Control and Prevention (CDC) (Table 1). The MD DHMH Laboratories Administration Division of Virology and Immunology reconfirmed the established range of IC_{50} values for each NAI in the reference panel listed in Table 1 with the three NI assays (Table 2).
<table>
<thead>
<tr>
<th>Strain designation</th>
<th>Type of influenza</th>
<th>Neuraminidase mutation (genotype)</th>
<th>Fluorescent neuraminidase assay</th>
<th>Chemiluminescent neuraminidase assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oseltamivir IC$_{50}$ value (nM)</td>
<td>Zanamivir IC$_{50}$ value (nM)</td>
</tr>
<tr>
<td>A/Washington/10/2008</td>
<td>A (H1N1)</td>
<td>WT</td>
<td>0.62</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>~0.4</td>
<td>0.25</td>
</tr>
<tr>
<td>A/Florida/21/2008</td>
<td>A (H1N1)</td>
<td>H275Y</td>
<td>483.92</td>
<td>1.02</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>~140.00</td>
<td>0.56</td>
</tr>
<tr>
<td>A/Washington/01/2007</td>
<td>A (H3N2)</td>
<td>WT</td>
<td>0.06</td>
<td>0.79</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>~0.16</td>
<td>~0.54</td>
</tr>
<tr>
<td>A/Texas/12/2007</td>
<td>A (H3N2)</td>
<td>E119V</td>
<td>40.42</td>
<td>0.43</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>9.18 ± 0.78</td>
<td>0.51 ± 0.05</td>
</tr>
<tr>
<td>B/Memphis/20/1996</td>
<td>B</td>
<td>WT</td>
<td>4.57</td>
<td>1.23</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.01 ± 0.69</td>
<td>4.10 ± 1.79</td>
</tr>
<tr>
<td>B/Memphis/20/1996</td>
<td>B</td>
<td>R152K</td>
<td>690.89</td>
<td>66.96</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>77.24 ± 23.94</td>
<td>40.99 ± 27.88</td>
</tr>
<tr>
<td>A/California/07/2009</td>
<td>A (H1N1) pdm09</td>
<td>WT</td>
<td>0.2</td>
<td>0.21</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>~0.14–0.34</td>
<td>0.25</td>
</tr>
<tr>
<td>A/North Carolina/39/2009</td>
<td>A (H1N1) pdm09</td>
<td>H275Y</td>
<td>180.80</td>
<td>0.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>A/Texas/48/2009</td>
<td>A (H1N1) pdm09</td>
<td>H275Y</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.32</td>
<td>3.66</td>
</tr>
</tbody>
</table>


$IC_{50}$ = 50% inhibitory concentration
nM = nanomolar
CDC = Centers for Disease Control and Prevention
MD DHMH = State of Maryland Department of Health and Mental Hygiene
pdm09 = 2009 pandemic
NA = not available
Table 2. Observed IC$_{50}$ values (nM)* for reference strains obtained from CDC tested using three commercially available neuraminidase inhibition assays against oseltamivir, zanamivir, and peramivir at the MD DHMH Laboratories Administration in 2011

<table>
<thead>
<tr>
<th>Strain designation</th>
<th>Type</th>
<th>NA mutation (genotype)</th>
<th>NA-Fluor™</th>
<th>NA-XTD™</th>
<th>NA-Star®</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oseltamivir IC$_{50}$ value (nM)</td>
<td>Zanamivir IC$_{50}$ value (nM)</td>
<td>Peramivir IC$_{50}$ value (nM)</td>
</tr>
<tr>
<td>A/Washington/10/2008</td>
<td>A (H1N1)</td>
<td>WT</td>
<td>0.96</td>
<td>0.19</td>
<td>0.06</td>
</tr>
<tr>
<td>A/Florida/21/2008</td>
<td>A (H1N1)</td>
<td>H275Y</td>
<td>500.23</td>
<td>2.38</td>
<td>6.08</td>
</tr>
<tr>
<td>A/Washington/01/2007</td>
<td>A (H3N2)</td>
<td>WT</td>
<td>0.04</td>
<td>0.85</td>
<td>0.07</td>
</tr>
<tr>
<td>A/Texas/12/2007</td>
<td>A (H3N2)</td>
<td>E119V</td>
<td>70.26</td>
<td>0.32</td>
<td>0.11</td>
</tr>
<tr>
<td>B/Memphis/20/1996</td>
<td>B</td>
<td>WT</td>
<td>10.84</td>
<td>0.84</td>
<td>0.28</td>
</tr>
<tr>
<td>B/Memphis/20/1996</td>
<td>B</td>
<td>R152K</td>
<td>748.14</td>
<td>50.97</td>
<td>178.23</td>
</tr>
<tr>
<td>A/California/07/2009</td>
<td>A (H1N1) pdm09</td>
<td>WT</td>
<td>0.45</td>
<td>0.15</td>
<td>0.05</td>
</tr>
<tr>
<td>A/Texas/48/2009</td>
<td>A (H1N1) pdm09</td>
<td>H275Y</td>
<td>231.43</td>
<td>0.16</td>
<td>16.28</td>
</tr>
</tbody>
</table>

*IC$_{50}$ values are the mean of three independent assays.

IC$_{50}$ = 50% inhibitory concentration
nM = nanomolar
CDC = Centers for Disease Control and Prevention
MD DHMH = State of Maryland Department of Health and Mental Hygiene
NA = neuraminidase
pdm09 = 2009 pandemic
NI assays
The fluorescent NI assay, NA-Fluor, and the chemiluminescent NI assays, NA-Star and NA-XTD, are used to monitor phenotypic influenza NA susceptibility. The manufacturers’ protocols were followed for NA-Fluor, NA-Star, and NA-XTD.13–15 These assays provide a quantitative measurement of how well an NAI inhibits the activity of the viral NA as a means of assessing an isolates’ relative susceptibility. Variables that affect the IC₅₀ value ranges for each NAI include influenza subtype, associated NA mutations, and NI assay.16–18

Both NA-Star and NA-XTD use a 1,2 dioxetane derivative of sialic acid as a substrate. The NA-XTD substrate provides about 12 times more signal stability than NA-Star. Moreover, the sensitivity of these two chemiluminescent substrates is five- to 50-fold higher by the signal-to-noise ratio than the fluorescent-based assay.13,14 NA-Fluor uses the fluorogenic reagent 2’-(4-methylumbelliferyl)-α-D-N-acety neuraminic acid substrate with a 240-minute signal stability at room temperature.15 NA-Fluor required the generation of a 4-Methylumbelliferone sodium salt (4-MU [SS]) standard curve to determine the linear range of substrate turnover detection of the Victor X4 Multilabel Plate Reader. The raw data were plotted on a scatter-plot graph as relative fluorescent units (RFUs) vs. 4-MU (SS) concentration using Microsoft® Excel. The NA activity/RFU range corresponding to 10 micromolar 4-MU (~200,000 RFU) was determined as the set point for the optimal viral dilution factor obtained from the following pretitration step.

As a result of the substrate differences, the IC₅₀ values of fluorescent vs. chemiluminescent NI assays were comparable only in their interpretations of drug susceptibility; thus, no absolute and comprehensive measure of resistance has been established.19 However, elevated IC₅₀ values were indicative of reduced susceptibility.

Data analysis
The IC₅₀ values were calculated using JASPR version 1.2 according to the equation V = Vmax * (1 - ([I]/(Ki + I))), and a best-fit dose-response curve was generated.19,20 An observed IC₅₀ value greater than the cutoff of threefold above the expected wild-type IC₅₀ value (Table 1) was established as one criteria for interpreting isolates as having reduced susceptibility to a given drug compound (i.e., resistant).20 If a sample’s IC₅₀ concentrations were greater than threefold higher than the subtype-specific reference range, the sample was retested to confirm the result. If data points did not fall along the best-fit curve in the IC₅₀ graph, the sample was retested.

An additional criterion for determining the rel-

evance of IC₅₀ values that differ quantitatively from the wild-type reference strains is to identify cutoff values for mild outliers and outliers based on seasonal observations, as an indication of the potential for resistance to a given NAI. The cutoff values for each influenza strain type were calculated using a standard deviation (SD) based on the median absolute deviation of the median (SMAD) analysis of the common logarithm (log₁₀) transformed NAI-specific IC₅₀ values for each assay. SMAD analysis was performed using all data from the influenza isolates considered susceptible according to the first criterion of an IC₅₀ value within threefold of the expected wild-type strains. Log transformation was necessary because IC₅₀ values were not considered normally distributed. The SMAD-determined cutoff for mild outliers was set at median +1.65SD and outliers as median +3SD. Results were back-transformed and the SD was presented. Influenza isolates with IC₅₀ values greater than tenfold were excluded from SMAD analysis as well as calculations of the mean and median. The second criterion for resistance was defined as an IC₅₀ value that was both 3SD and ≥tenfold above the seasonal strain-specific median.21

Assay evaluation
Each NI assay was evaluated for its impact on resources (i.e., time, reagents, cost, supplies, and personnel) based on two testing scenarios and workflow. Both scenarios assumed testing against three NAIs, one plate per NAI, and eight samples per plate (including one NAI-sensitive and one NAI-resistant control per day), performed by one technologist. Scenario 1 evaluated the three assays for a period of low volume of influenza virus isolates for testing, where testing was limited to a maximum daily throughput of six specimens including two controls. Scenario 2 was evaluated for a period of high volume of influenza virus isolates, in which the total assay time and the hands-on technologist time were considered to be equal. Lastly, we evaluated the relative cost per isolate. Possible implementation guidelines for a PHL setting were applied to influenza A (H1N1) pdm09, the 2010–2011 influenza season, and the 2011–2012 influenza season as examples.

RESULTS
A total of 169 influenza virus isolates identified during the 2011–2012 influenza season were tested against the NAIs oseltamivir, zanamivir, and peramivir for NAI susceptibility using the NA-Fluor, NA-Star, and NA-XTD NI assays. Of the 25 influenza A (H1N1) pdm09 isolates tested, one isolate was resistant to oseltamivir and peramivir and sensitive to zanamivir in all three NI
assays. All of the 82 influenza A (H3N2), 62 influenza B, and the remaining 24 influenza A (H1N1) pdm09 isolates were sensitive to oseltamivir, zanamivir, and peramivir in all three NI assays (Figure 1).

The observed IC$_{50}$ values of sensitive influenza viruses relative to the three NAIs for each of the NI assays were summarized according to the influenza virus type isolated during the 2011–2012 influenza season in Table 3A. The highest mean and median IC$_{50}$ values for all strain types across each NI assay were observed with zanamivir followed by oseltamivir, while the lowest mean and median IC$_{50}$ values were observed with peramivir (Table 3A). Through SMAD analysis, isolates identified as mild outliers (from IC$_{50}$ median +1.65SD and IC$_{50}$ median +3SD) and outliers (≥IC$_{50}$ median +3SD) were observed in the dataset and summarized in Table 3B. However, none of the isolates consistently met the key criteria of a mild outlier or an outlier in all three assays for a given NAI. Furthermore, each of these isolates identified as outliers were within threefold of the corresponding wild-type reference viruses.

Figure 1. Summary of influenza virus isolates (n=169) tested for NAI susceptibility to oseltamivir, zanamivir, and peramivir on three neuraminidase inhibition assays (NA-XTD™, NA-Star®, and NA-Fluor™): 2011–2012 influenza season, MD DHMH Laboratories

One influenza A (H1N1) pdm09 virus isolated during the 2011–2012 influenza season was determined to be resistant to oseltamivir and peramivir but sensitive to zanamivir based on an IC$_{50}$ value greater than tenfold higher than the wild-type reference strain. As a result, it was excluded from SMAD analysis. However, resistance to oseltamivir and peramivir was further established in comparison with the mean IC$_{50}$ values of the other 24 influenza A (H1N1) pdm09 isolates tested. This isolate had an oseltamivir IC$_{50}$ concentration that was 357-fold greater than the mean in NA-XTD, 561-fold greater than the mean in NA-Star, and 807-fold greater than the mean in NA-Fluor. The IC$_{50}$ values for peramivir were 124-, 70-, and 438-fold higher than the influenza A (H1N1) pdm09 means for NA-XTD, NA-Star, and NA-Fluor, respectively (Table 3C).

The evaluation of the three commercially available NI assays on parameters of workflow and use of resources were summarized in two testing scenarios with NA-Fluor as the reference assay. In Scenario 1 (Table 4A), the time to prepare reagents, perform the assay, analyze, and interpret the results of six specimens and one sensitive and one resistant reference virus against all three drugs using NA-Star® and NA-XTD™ assays was approximately 180 minutes for each assay, with 100 minutes of hands-on technologist time for NA-Star and 120 minutes of hands-on technologist time for NA-Fluor. The NA-Fluor assay was completed in approximately 300 minutes, with 210 minutes of hands-on technologist time.

**DISCUSSION**

Our purpose was to evaluate and provide guidance on the use of NI assays in a PHL setting during the 2011–2012 influenza season. We compared the performance of three commercially available NI assays (NA-XTD™, NA-Star®, and NA-Fluor™) by testing a panel of 169 influenza virus isolates for susceptibility to oseltamivir, zanamivir, and peramivir. We found that the NA-Fluor assay had the highest mean and median IC$_{50}$ values for all strain types across each NI assay, followed by oseltamivir and then peramivir. Through SMAD analysis, isolates identified as mild outliers (from IC$_{50}$ median +1.65SD and IC$_{50}$ median +3SD) and outliers (≥IC$_{50}$ median +3SD) were observed in the dataset and summarized in Table 3B. However, none of the isolates consistently met the key criteria of a mild outlier or an outlier in all three assays for a given NAI. Furthermore, each of these isolates identified as outliers were within threefold of the corresponding wild-type reference viruses.

In Scenario 2 (Table 4B), the highest maximum daily throughput using the NA-Fluor assay was 30 specimens. The NA-XTD and NA-Star assays both had a maximum daily throughput of 22 specimens. The maximum number of specimens tested per assay kit for all three assays was higher in Scenario 2, with 14 specimens for NA-Fluor, 28 specimens for NA-XTD, and 40 specimens for NA-Star. While the overall cost per specimen was lower for NA-XTD but decreased for NA-Star compared with the NA-Fluor assay.
<table>
<thead>
<tr>
<th></th>
<th>Oseltamivir IC_{50} values (nM)</th>
<th>Zanamivir IC_{50} values (nM)</th>
<th>Peramivir IC_{50} values (nM)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Range</td>
<td>Median</td>
</tr>
<tr>
<td><strong>Influenza A (H1N1) pdm09 (n=24^a)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA-XTD^{TM}</td>
<td>0.27</td>
<td>0.14–0.45</td>
<td>0.26</td>
</tr>
<tr>
<td>NA-Star^{®}</td>
<td>0.17</td>
<td>0.08–0.41</td>
<td>0.16</td>
</tr>
<tr>
<td>NA-Fluor^{TM}</td>
<td>0.25</td>
<td>0.05–0.67</td>
<td>0.23</td>
</tr>
<tr>
<td><strong>Influenza A (H3N2) (n=82)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA-XTD</td>
<td>0.18</td>
<td>0.05–0.40</td>
<td>0.17</td>
</tr>
<tr>
<td>NA-Star</td>
<td>0.13</td>
<td>0.04–0.36</td>
<td>0.12</td>
</tr>
<tr>
<td>NA-Fluor</td>
<td>0.09</td>
<td>0.02–0.34</td>
<td>0.08</td>
</tr>
<tr>
<td><strong>Influenza B (n=62)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA-XTD</td>
<td>3.54</td>
<td>0.77–6.34</td>
<td>3.38</td>
</tr>
<tr>
<td>NA-Star</td>
<td>2.53</td>
<td>0.76–5.83</td>
<td>2.21</td>
</tr>
<tr>
<td>NA-Fluor</td>
<td>11.50</td>
<td>2.23–20.34</td>
<td>11.29</td>
</tr>
</tbody>
</table>
Table 3 (continued). Characterization of phenotypic susceptibility and IC$_{50}$ values for influenza virus isolates tested using three commercially available neuraminidase inhibition assays against oseltamivir, zanamivir, and peramivir: 2011–2012 influenza season, MD DHMH Laboratories Administration

<table>
<thead>
<tr>
<th>Isolate susceptibility</th>
<th>Oseltamivir</th>
<th>Zanamivir</th>
<th>Peramivir</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NA-XTD$^\text{TM}$</td>
<td>NA-Star$^\text{®}$</td>
<td>NA-Fluor$^\text{TM}$</td>
</tr>
<tr>
<td>Number of isolates within range</td>
<td>23</td>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td>Number of mild outliers</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Number of outliers</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

### Influenza A (H1N1) pdm09 (n=24)$^a$

### Influenza A (H3N2) (n=82)

### Influenza B (n=62)

---

*continued on p. 83*
### Table 3 (continued). Characterization of phenotypic susceptibility and IC₅₀ values for influenza virus isolates tested using three commercially available neuraminidase inhibition assays against oseltamivir, zanamivir, and peramivir: 2011–2012 influenza season, MD DHMH Laboratories Administration

<table>
<thead>
<tr>
<th>NA assay</th>
<th>Oseltamivir</th>
<th>Fold change&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Zanamivir</th>
<th>Fold change&lt;sup&gt;d&lt;/sup&gt;</th>
<th>Peramivir</th>
<th>Fold change&lt;sup&gt;d&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA-XTD&lt;sup&gt;TM&lt;/sup&gt;</td>
<td>92.83</td>
<td>348</td>
<td>0.53</td>
<td>0.74</td>
<td>11.24</td>
<td>122</td>
</tr>
<tr>
<td>NA-Star&lt;sup&gt;®&lt;/sup&gt;</td>
<td>89.77</td>
<td>515</td>
<td>0.71</td>
<td>1.74</td>
<td>2.81</td>
<td>61</td>
</tr>
<tr>
<td>NA-Fluor&lt;sup&gt;TM&lt;/sup&gt;</td>
<td>185.75</td>
<td>737</td>
<td>0.32</td>
<td>1.12</td>
<td>17.53</td>
<td>408</td>
</tr>
</tbody>
</table>

<sup>a</sup>The IC₅₀ value was excluded for the identified resistant influenza A (H1N1) pdm09 strain.

<sup>b</sup>Robust estimates of the log<sub>10</sub> transformed SD calculations were performed using SMAD analysis on log<sub>10</sub> transformed data, and results presented were back-transformed.

<sup>c</sup>Resistant to oseltamivir and peramivir and sensitive to zanamivir

<sup>d</sup>Fold change refers to the ratio of isolates’ observed IC₅₀ value to the observed mean A (H1N1) pdm09 IC₅₀ value.

IC₅₀ = 50% inhibitory concentration

MD DHMH = State of Maryland Department of Health and Mental Hygiene

pdm09 = 2009 pandemic

nM = nanomolar

NI = neuraminidase inhibition

SD = standard deviation

NA = neuraminidase

SMAD = standard deviation based on the median absolute deviation of the median

NAI = neuraminidase inhibitor
influenza season. The aforementioned results represent screening for NAI susceptibility of influenza A and B viruses circulating in Maryland during the 2011–2012 influenza season as identified by the MD DHMH Laboratories Administration. Through the implementation of the three NI assays—NA-Fluor, NA-Star, and NA-XTD enzyme inhibition assays—we have presented multiple references for baseline IC\textsubscript{50} values (and, thus, phenotypic characterization) of seasonally circulating influenza viruses in Maryland. Generating these data will further enable the characterization of IC\textsubscript{50} values for future influenza seasons to monitor changes in NAI susceptibility over time.

Due to the variability and inherent differences in the chemistry of fluorescent and chemiluminescent assays, the IC\textsubscript{50} values for a given isolate have been different for each assay. The MD DHMH Laboratories Administration tested a panel of reference viruses with recognized NA mutations and documented IC\textsubscript{50} values provided by CDC to verify each assay. If the decision is made to use a combination of different assays, it is necessary to verify the ability to detect accurately and consistently the susceptibility of a variety of virus strain types to all NAIs for each assay. Verification ensures that the interpretation of the results remains reliable.

We suggest that it may be worth the return on investment to consider implementing fluorescent and chemiluminescent NI assays to accommodate influenza seasonal needs. Improved preparedness may be manifested by an efficient response, with a high throughput assay for high-volume scenarios or a faster turnaround time for low-volume scenarios that may contribute to reducing both economic and personnel resources. Additionally, this strategy provides the ability to compare and better characterize inconclusive results through additional testing. We have indicated the advantages of implementing multiple assays and considered the challenges presented in performing statistical analysis. While the results of the two chemiluminescent assays may be more closely comparable, thus presenting less of a challenge for combined analysis, the established differences in IC\textsubscript{50} values between the chemiluminescent and fluorescent assays suggest that they cannot be directly compared. While quantitative differences in the results may not be an issue for gross screening, it may present challenges for deeper analysis.

We recognize that the availability of PHL resources may require using a single NI assay. The use of a single assay involves less time for training and maintaining competencies of the technologists, which may provide logistical and resource benefits. For long-term statistical analysis, the results from a single assay will make it easier to detect a significant elevation in IC\textsubscript{50} values. Due to the innate variability between the NI assays and between day-to-day testing, it is necessary to create several criteria to define reduced susceptibility and to

Table 4. Evaluation of three commercially available NI assays using three NAIs for low-volume (Scenario 1) and high-volume (Scenario 2) testing situations: 2011–2012 influenza season, MD DHMH Laboratories Administration

<table>
<thead>
<tr>
<th>NI assay</th>
<th>Maximum specimens daily throughput</th>
<th>Maximum number of specimens per assay kit</th>
<th>Approximate relative cost to test each isolate for three NAIs (minutes)</th>
<th>Total assay time (minutes)</th>
<th>Hands-on technologist time (minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Scenario 1: low volume of influenza isolates—limited by quantity, maximum six specimens (with two controls) tested per day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA-Fluor\textsuperscript{TM}</td>
<td>6</td>
<td>12</td>
<td>Reference assay</td>
<td>300</td>
<td>210</td>
</tr>
<tr>
<td>NA-Star\textsuperscript{®}</td>
<td>6</td>
<td>30</td>
<td>0.9 times the cost of the reference assay</td>
<td>180</td>
<td>100</td>
</tr>
<tr>
<td>NA-XTD\textsuperscript{TM}</td>
<td>6</td>
<td>24</td>
<td>1.2 times the cost of the reference assay</td>
<td>180</td>
<td>120</td>
</tr>
<tr>
<td>B. Scenario 2: high volume of influenza isolates—limited by time, maximum eight-hour work day</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA-Fluor</td>
<td>30</td>
<td>14</td>
<td>Reference assay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA-Star</td>
<td>22</td>
<td>40</td>
<td>0.8 times the cost of the reference assay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA-XTD</td>
<td>22</td>
<td>28</td>
<td>1.2 times the cost of the reference assay</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NI = neuraminidase inhibition
NAI = neuraminidase inhibitor
MD DHMH = State of Maryland Department of Health and Mental Hygiene
identify isolates that may warrant further investigation. Our results show that, overall, the three assays are comparable in terms of their ability to identify an isolate as “resistant” or “sensitive.” The differences in interpreting NAI susceptibility are most apparent when defining outliers. There was a discrepancy in the interpretation of outliers and minor outliers among assays; however, none of them also met the first criteria for resistance when comparing IC_{50} values with the reference panel. Although there is little evidence for any immediate implications of outliers and minor outliers, these data may be valuable for future trend analysis of identifying the emergence of novel resistance markers.

Additionally, we have observed that in vitro cross-resistance exists for oseltamivir and peramivir in an influenza A (H1N1) pdm09 strain. Such information continues to be vital to public health treatment decisions, including implications for treatment with the investigational NAIs, such as peramivir, in high-risk patients having influenza A (H1N1) pdm09 infections. Hence, an important aspect of NAI susceptibility testing is to include a broad panel of NAIs. The value of performing NAI susceptibility testing on investigational NAIs may be underscored by the effort and expense involved in developing, testing, and approving new drugs. In the future, it may be beneficial to establish panels to include other investigational NAIs.

Whether or not to screen all the samples is a multi-faceted decision that may be based on the PHL’s available resources and surveillance needs. In this study, we did not limit the quantity of virus isolates tested. Virus culture was attempted on all available samples. The quantity of viral isolates available for NAI susceptibility testing was generally limited by which samples propagated in cell culture produced sufficient viral titers.

Primarily, our data suggest a general comparability of the NI assays, allowing the PHL to use the most appropriate NI assay regardless of the seasonal burden. These experiences may provide valuable information toward the development of general guidelines for phenotypic drug-resistance testing that consider a PHL’s workload and available resources.

Considering Scenario 1, when the number of influenza-positive samples is low and early detection is crucial (Figure 2), total time, sensitivity, and costs are the highest priority. For this reason, NA-Star is highly recommended because it takes less technologist time, costs less per sample than NA-XTD and NA-Fluor, and is

---

**Figure 2. Considerations for the use of three NI assays using the 2009 influenza pandemic and the 2010–2011 and 2011–2012 influenza seasons** as examples

---

*As identified by real-time reverse transcription-polymerase chain reaction at the Maryland Department of Health and Mental Hygiene Laboratories Administration Division of Molecular Biology

NI = neuraminidase inhibition
more sensitive than NA-Fluor. The higher sensitivity of NA-XTD compared with NA-Star and NA-Fluor may be advantageous for detecting NA activity in virus isolates that have low titers or possible decreased viral fitness resulting from resistance-inducing mutations.\textsuperscript{17,18} In a situation such as the 2011–2012 influenza season, in which the average number of viruses isolated was fewer than eight per day, NA-Star could be used as the sole NI assay throughout the season (Figure 2). NA-Star is also recommended during the beginning stages of a pandemic, similar to that of the 2009 influenza pandemic, in which it is essential to characterize the phenotypic NAI susceptibility early using a cost-effective, high-sensitivity assay (Figure 2). It is important to note that CDC’s guidance must be followed before a PHL can propagate a novel influenza virus in cell culture, which may delay the ability to conduct early, targeted testing in an efficient manner.

The optimal virus dilution required for the NA-Star assay was comparable with the NA-XTD platform. However, the low stability of the NA-Star substrate signals in each well necessitates reading the plates immediately by a luminometer equipped with an injector. With a substrate incubation period of 30 minutes, there can be a queue of no more than three plates (10 minutes to read each plate). The longer stability of NA-XTD allows more plates to be read, and wait time in the queue can be increased from 30 minutes to two hours without affecting signal strength.

Considering Scenario 2, when the number of influenza-positive virus isolates available for NI assays is in high volume (e.g., at the peak of an influenza season or in the middle of a pandemic) (Figure 2), the limiting factor is considered to be the normal eight-hour workday. NA-Fluor is highly recommended because it has the advantage of maximizing throughput. This higher throughput of NA-Fluor is mainly the result of productivity that occurs during the one-hour incubation period after the addition of the substrate, which provides enough time to set up additional specimens for testing without the overlap of time-sensitive, manually intensive steps. Furthermore, the signal stability improves the workflow to accommodate larger batches of specimens in each set of tests. For each additional set of eight samples tested in a given day, there is a gain of two samples (as only one set of controls is needed per day), which results in a faster turnaround time and larger datasets for timely and robust PHL surveillance. If early resistance to one or more of the NAIs is detected as seen in Scenario 1 by using one of the NI assays, targeted screening of subpopulations with similar subtypes, regional distributions, or from an outbreak cluster may be necessary. Switching to a fluorescent-based assay, such as NA-Fluor, may allow for a relatively cost-effective, high-throughput screening of additional influenza isolates.

Overall, the higher throughput of Scenario 2 offers more cost savings than Scenario 1. The most dramatic increase was seen in the case of NA-Star, where 2 milliliters of NA-Star Accelerator (limiting reagent) were saved per eight samples because there was no need for injector priming, resulting in a total gain of 10 tested samples per assay kit. During periods of high-volume testing and limited available resources, maximizing throughput with NA-Star may offer the most cost-effective method of drug-resistance screening.

CONCLUSION

Our experience suggests a general comparability of the three NI assays, providing the MD DHMH Laboratories Administration guidelines for using the most appropriate NI assay regardless of the seasonal influenza burden. Generating phenotypic NAI susceptibility data for a broad range of type-specific seasonally circulating influenza strains contributes to robust PHL surveillance through monitoring and characterizing baseline IC\textsubscript{50} values and identifying future patterns that may indicate clinically relevant changes in NAI susceptibility. While the results show that a majority of all influenza A (H3N2), influenza A (H1N1) pdm09, and influenza B isolates tested were sensitive, they also suggest that resistant influenza A (H1N1) pdm09 viruses do emerge. For each of the three NI assays, we have shown that the same criteria can be used to identify influenza viruses with reduced NAI susceptibility. Lastly, our results contribute valuable information for PHLs toward the development of general guidelines for phenotypic drug-resistance testing that consider a PHL’s workload and available resources.

The authors William Murtaugh, Lalla Mahaman, and Benjamin Healey had equal contributions as first authors on this article.

The authors thank the Centers for Disease Control and Prevention (CDC), State of Maryland Department of Health and Mental Hygiene (MD DHMH) Laboratories Administration Division of Molecular Biology, CDC/Association of Public Health Laboratories Emerging Infectious Diseases Fellowship Program, Johns Hopkins Bloomberg School of Public Health (JHSPH) Office of Public Health Practice and Training, and the JHSPH Public Health Applications for Student Experience Program. The findings in this article are those of the authors and do not necessarily represent the official position of the MD DHMH, CDC, or Johns Hopkins University.

REFERENCES

1. Food and Drug Administration (US). Influenza (flu) antiviral drugs and related information [cited 2012 Jul 16]. Available from: URL:
Evaluation of the Novel Respiratory Virus Surveillance Program: Pediatric Early Warning Sentinel Surveillance (PEWSS)

ABSTRACT

Objectives. Infections caused by respiratory viruses are associated with recurrent epidemics and widespread morbidity and mortality. Routine surveillance of these pathogens is necessary to determine virus activity, monitor for changes in circulating strains, and plan for public health preparedness. The Southern Nevada Health District in Las Vegas, Nevada, recruited five pediatric medical practices to serve as sentinel sites for the Pediatric Early Warning Sentinel Surveillance (PEWSS) program.

Methods. Sentinel staff collected specimens throughout the year from ill children who met the influenza-like illness case definition and submitted specimens to the Southern Nevada Public Health Laboratory for molecular testing for influenza and six non-influenza viruses.

Results. Laboratory results were analyzed and reported to the medical and general communities in weekly bulletins year-round. PEWSS data were also used to establish viral respiratory seasonal baselines and in influenza vaccination campaigns. The surveillance program was evaluated using the Centers for Disease Control and Prevention’s (CDC’s) Updated Guidelines for Evaluating Public Health Surveillance Systems. PEWSS met three of six program usefulness criteria and seven of nine surveillance system attributes, which exceeded the CDC Guidelines evaluation criteria for a useful and complete public health surveillance program.

Conclusion. We found that PEWSS is a useful and complete public health surveillance system that is simple, flexible, accessible, and stable.
Influenza infections are associated with recurrent epidemics and the associated widespread morbidity and mortality. Monitoring and surveillance of the seasonal circulation of respiratory illness is necessary for community preparedness, public health management, and minimizing community impact. In response to the influenza A (H1N1) 2009 pandemic, the Southern Nevada Public Health Laboratory (SNPHL) collaborated with the Southern Nevada Health District (SNHD) to develop a medical practice and laboratory-based influenza surveillance system to identify the occurrence of influenza virus in the Southern Nevada community.

Our surveillance program focused on collecting samples from ill children, followed by molecular laboratory testing. This approach differed from passive surveillance systems for laboratory-confirmed cases of influenza, which are often dependent on the health-care provider’s decision to test and the type of test ordered. Thus, a surveillance system more robust than passive surveillance is necessary to provide the clear and consistent reporting that forms the basis for evidence-based public health and medical practice.

The Enhanced Pediatric Influenza Surveillance (EPIS) program started in June 2009 and enlisted local pediatric practices as sentinel sites to provide nasal swab samples for influenza testing. The surveillance system was based on the assumption that pediatric patients, due to their susceptibility to respiratory diseases and increased visits to health-care providers, would provide early indications of influenza activity and trends in the broader community. Test results data were analyzed and reported back to the community in the form of weekly bulletins.

The results of the EPIS pilot project from 2009–2010 were highly encouraging. The participating pediatricians fully supported the project and collected appropriate specimens from children who presented with acute upper respiratory illness. The information obtained from analysis of the EPIS data proved valuable in creating public messaging during the influenza A (H1N1) 2009 pandemic, and in SNHD efforts to encourage the public to receive the annual influenza vaccine.

In 2010, an Association of Public Health Laboratories (APHL) Innovations in Quality Public Health Laboratory Practice grant enabled the SNPHL to partially fund the expansion of the EPIS program. With the addition of six non-influenza viruses (human metapneumovirus [HMPV], adenovirus, respiratory syncytial virus [RSV], and parainfluenza 1, 2, and 3), the name was changed to Pediatric Early Warning Sentinel Surveillance (PEWSS), and it was established as a year-round program. Because the program used the EPIS project design, the pediatricians who participated in the EPIS project also consented to participate in PEWSS.

We evaluated PEWSS in 2011 using the Centers for Disease Control and Prevention (CDC) Updated Guidelines for Evaluating Public Health Surveillance Systems (hereafter, Guidelines). In this article, we describe the PEWSS program design and implementation and show the results of the evaluation.

**METHODS**

**Program design**

The design of the PEWSS program was based on the following assumptions:

- The laboratory-based surveillance system will detect respiratory viral pathogens (RVPs) more quickly and accurately than passive surveillance systems.
- Early detection of these viruses could provide important information to clinicians about locally circulating viral pathogens to enhance clinical treatment decisions.
- Detecting RVPs among children is a valid indicator of virus activity in the community.
- Knowledge of respiratory virus activity in the community provides valuable information for public health prevention and education.
- Molecular testing is consistently superior to rapid testing in both sensitivity and specificity.
- Educating program participants on appropriate specimen collection and storage will enhance the laboratory’s ability to detect viral pathogens.
- Sentinel sites will follow program protocols and provide sufficient samples that will allow the surveillance system to succeed in its objectives.
- Simple enumeration of influenza cases has little potential to impact patient outcomes, public health, or medical decisions.

**Sample collection**

Each week, sentinel site staff collected nasal swab samples from the first 10 children who presented at the facility with acute respiratory illness characterized by a fever (≥100°F) and one or both of two symptoms, cough and/or sore throat. We used a flocked nasal swab for sample collection due to its comparability with nasopharyngeal swabs and superior yield of epithelial cells for viral testing. To ensure that SNPHL testing capacity was not exceeded, 10 individual sample col-
lection kits were provided to each PEWSS site every week. The standard kits included flocked nasal swab, viral transport media (VTM), and an SNPHL test requisition. If needed, SNPHL provided the sentinel site with a small refrigerator to store collection kits prior to and after sample collection. During initial site visits, we instructed clinic staff on proper nasal swab collection techniques. Following sample collection, the flocked swab was placed in the VTM and mixed. The entire sample was refrigerated until pickup by the SNPHL courier, which occurred three times per week. A designated person coordinated sample collection and test reports at each sentinel site.

There was no charge to the physician, the patient, or the patient’s insurance for sample collection and testing performed for the PEWSS program.

Sample analysis
At the SNPHL, 100 microliters (µL) of each VTM sample were extracted on the Roche Compact analyzer using the Roche MagNA Pure Compact Nucleic Acid Isolation Kit 1 with external lysis (Roche Applied Science, Indianapolis, Indiana). Each extracted nucleic acid sample was analyzed on the Applied Biosystems® 7500 Fast DX Real-Time PCR Instrument (Life Technologies Corporation, Carlsbad, California) using the CDC11 and APHL real-time reverse transcriptase polymerase chain reaction protocols for influenza, HMPV, adenovirus, RSV, and parainfluenza 1, 2, and 3.

Results reporting
Each PEWSS site received a written report for the samples submitted from its site. The SNHD prepared a weekly aggregate report of the samples analyzed from the previous week and distributed these weekly PEWSS bulletins to local health-care providers and the general public by fax, e-mail, and website.

The results of the weekly molecular testing were also submitted to the CDC National Respiratory and Enteric Virus Surveillance System using a Web-based reporting system.

Influenza viral resistance and surveillance testing
As one of 85 U.S. World Health Organization collaborating laboratories participating in virologic surveillance for influenza, the SNPHL submitted a subset of influenza-positive samples to CDC for further characterization, including genetic analysis (sequencing), antiviral resistance testing, and antigenic characterization. The results of the additional CDC testing performed on the samples submitted by the participating laboratories were used to identify the influenza strains to include in the 2011–2012 influenza vaccine. SNPHL did not report the results of the CDC testing back to the submitting facility.

Program implementation
Five pediatric sentinel sites participated in the PEWSS program. The sites were chosen based on their receptiveness to participating in the pilot project, the volume of clients, and the economic diversity of the clinic patients. Program enrollment was voluntary and physicians could choose to stop participating at any time. Active communication with each sentinel site occurred through weekly visits by SNPHL couriers, phone notifications of positive results, and quarterly site visits.

Program evaluation
The PEWSS program (Unpublished master’s thesis, Lutman ML. Evaluation of the pilot program, Pediatric Early Warning Sentinel Surveillance (PEWSS) program, and its efficacy in monitoring pediatric illness in Clark County, Nevada. Las Vegas: University of Nevada, Las Vegas; 2011) was evaluated in 2011 using the CDC Guidelines.8 We examined the program’s operational period from June 1, 2010, to May 31, 2011. The CDC Guidelines recommend using the following six tasks to evaluate a public health surveillance system, with a focus on how well the system operates to meet its purpose and objectives.

Task A: engage the stakeholders in the evaluation. PEWSS stakeholders were defined as those who receive the weekly information (the general public, which includes medical health professionals; the scientific community; and the lay population) and those who provide the data (sentinel site staff). We created two surveys—one for the general public (Task A.1) using SurveyMonkey®,12 and the other for the sentinel sites (Task A.2). The electronic link to the general public survey was e-mailed or faxed along with two weekly PEWSS bulletins, and the sentinel site survey was in paper format. Participation in the survey was voluntary.

Task B: describe the surveillance system evaluated. A description of the PEWSS system, which included program objectives, resources, activities, outputs, and outcomes, was developed. The funding sources and cost analysis to run the program were also calculated.

Task C: focus the evaluation design. We identified our agency’s priorities for evaluating the system. We determined whether the specific purpose of PEWSS was understood by all the stakeholders in the evaluation and whether stakeholders were committed to using the information generated from the program. We conducted a literature review to find sentinel-based surveillance programs similar to PEWSS.
Task D: gather credible evidence regarding surveillance system performance. According to the CDC Guidelines, a surveillance system might be considered useful if it satisfactorily addresses at least one of the following questions. Briefly, does the system:

1. Detect diseases, injuries, or adverse or protective exposures of public importance in a timely way?
2. Detect trends that signal changes in the occurrence of disease, including the detection of epidemics (or outbreaks)?
3. Lead to improved clinical, behavioral, social, policy, or environmental practices?
4. Provide estimates of the magnitude of morbidity and mortality, and the identification of factors, of the event under surveillance?
5. Permit assessment of the effect of prevention and control programs? or
6. Stimulate research intended to lead to prevention or control?

The Guidelines also define nine attributes that affect the usefulness and completeness of a public health surveillance system. We rated PEWSS against the following attributes on a scale of high, medium, low, or not applicable:

- Simplicity—ease of program operation
- Flexibility—adaptability to changing information needs
- Acceptability—willingness to participate in the program
- Stability—system reliability (i.e., the ability to collect, manage, and provide data properly without failure) and availability (ability to be operational when it is needed)
- Data quality—completeness and validity of the data
- Timeliness—speed between steps in a system
- Representativeness—the occurrence of a health-related event over time and its distribution in the population
- Sensitivity—proportion of cases of a disease detected by the system
- Predictive value positive—proportion of reported cases that actually have the health-related event under surveillance

Tasks E and F: justify and state conclusions and recommendations, and ensure the use of evaluation findings. We employed our ratings of PEWSS, along with the results of the stakeholder surveys, to help us determine if the system is addressing an important public health problem, meeting its objectives, and identifying how evaluation findings will be distributed.

RESULTS

Program implementation

The Table shows the molecular test results of the 872 total specimens provided by the five sentinel sites during the evaluation period of June 1, 2010, through May 31, 2011. Respiratory viruses were detected in 503 (57.7%) of the specimens. Of these specimens, the viruses detected most often were influenza A or B (n=196, 39.0%) and RSV (n=100, 19.9%). There were 29 (5.8%) coinfections, where multiple viruses were detected in a sample. These viruses were counted as positive results in their respective test categories.

Program evaluation

Task A: engage the stakeholder in the evaluation.

Task A.1: survey of the general public stakeholders. Weekly PEWSS bulletins were well received by the general public stakeholders, and their regard for the program was high. Respondents to the public survey included physicians, nurses, laboratory staff, educators, administration staff, and day care providers. The public stakeholders were located in different areas of practice settings, such as hospitals, clinics, private offices, and small and large group practices. Of the 19 public stakeholder survey respondents, 17 (89.5%) replied that they frequently read the weekly PEWSS report. Of these respondents, 12 (70.6%) and five (29.4%) respondents reported reading the reports weekly and frequently, respectively.

Table. Respiratory virus distribution (n=872) in Clark County, Nevada, determined through PEWSS testing from June 1, 2010, through May 31, 2011

<table>
<thead>
<tr>
<th>Testing results</th>
<th>N</th>
<th>(percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>369</td>
<td>(42.3)</td>
</tr>
<tr>
<td>Total positive</td>
<td>503</td>
<td>(57.7)</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>59</td>
<td>(11.7)</td>
</tr>
<tr>
<td>Human metapneumovirus</td>
<td>29</td>
<td>(5.8)</td>
</tr>
<tr>
<td>Human parainfluenza 1</td>
<td>16</td>
<td>(3.2)</td>
</tr>
<tr>
<td>Human parainfluenza 2</td>
<td>26</td>
<td>(5.2)</td>
</tr>
<tr>
<td>Human parainfluenza 3</td>
<td>77</td>
<td>(15.3)</td>
</tr>
<tr>
<td>Influenza A</td>
<td>117</td>
<td>(23.3)</td>
</tr>
<tr>
<td>Influenza B</td>
<td>79</td>
<td>(15.7)</td>
</tr>
<tr>
<td>Respiratory syncytial virus</td>
<td>100</td>
<td>(19.9)</td>
</tr>
<tr>
<td>Coinfections*</td>
<td>29</td>
<td>(5.8)</td>
</tr>
</tbody>
</table>

*Multiple viruses detected in a sample. These viruses were counted as positive results in their respective test categories.

PEWSS = Pediatric Early Warning Sentinel Surveillance
More than 80% (range 82%–88%) of the public survey respondents rated the information within the PEWSS bulletins as very timely, accurate, relevant, and useful. All public respondents reported that they use the PEWSS bulletin for general information on circulating viruses in the community.

Among the 17 public respondents who answered regarding PEWSS bulletin usage, six (35.3%) said they never use the information to guide clinical diagnosis, nine (52.9%) said they never use the information to guide empirical treatment, and 11 (64.7%) said they never use it to guide laboratory testing. These high percentages were likely due to the number of public respondents who were not physicians and did not diagnose or treat patient illness.

The public stakeholders reported that the most useful information provided by the PEWSS bulletins was the weekly update on the current viral pathogens circulating in the community. Their suggested changes to the weekly report included adding more sentinel sites, changing graph displays, and adding national influenza data or more technical information regarding the surveyed pathogens. Changes were made to the weekly PEWSS bulletin to accommodate some of these suggestions (data not shown).

**Task A.2: survey of sentinel site stakeholders.** Nineteen responses were received among the five sentinel sites. Eight of the sentinel respondents (42.1%) were physicians. Almost all sentinel respondents reported that they strongly agreed or agreed that they received prompt responses from surveillance program administrators, test requisition forms were easy to complete, automatic courier transport of specimens was convenient, patient reports and the weekly PEWSS bulletins were easy to understand, sentinel site workers felt competent in collecting the specimens, and they would recommend their colleagues to partner with the SNPHL and the SNHD (data not shown).

Sentinel sites primarily received their weekly PEWSS bulletins by fax and e-mail, with eight (42.1%) and four (21.1%) respondents indicating they read them every week or frequently but not every week, respectively. The majority of sentinel respondents (n=15, 78.9%) said they use the PEWSS bulletins for general information, and eight (42.1%) said they use the information to guide their clinical diagnoses. Nearly all sentinel respondents thought the information in the weekly PEWSS bulletins was timely, accurate, relevant, useful, and easy to read and understand. Sentinel staff members who collected the PEWSS specimens were physicians, nurses, or medical assistants. Sentinel staff also reported they used the weekly bulletins to show their patients the viruses circulating in the community and to reinforce the idea of not using antibiotics when viruses were circulating widely (data not shown).

**Task B: describe the surveillance system evaluated.** We created a logic model (Figure 1) to explain the program objectives, resources, activities, outputs, and outcomes. The PEWSS program was funded through a combination of federal grant and local property tax revenues. Personnel costs per year included $50,220 and $14,961 for laboratory and epidemiology support, respectively, for a total annual personnel cost of $65,181. The laboratory calculated the average cost of sample analysis, including reagents and supplies, as $55 per sample. A total of 872 samples were tested during the evaluation period. The total testing cost was $47,960 ($55 × 872 samples/year). The total annual operating cost (personnel and supplies) for the program was $113,141 (data not shown).

**Task C: focus the evaluation design.** The priority system attributes identified by our agency for evaluating the PEWSS system were simplicity, flexibility, acceptability, and stability. These attributes were based on our main program objectives (Figure 1), which included reporting respiratory virus test results data to the community and participating in the CDC national influenza surveillance program. Additionally, the CDC Guidelines proposed that meeting these four specific attributes may indicate that a surveillance system will likely be more useful and complete for public health action. Our rating of these four priority attributes as “high” was in agreement with the stakeholders’ ratings of the program. Stakeholders were committed to using the information generated from the system. The majority of stakeholders read the PEWSS bulletins every week to update themselves on circulating respiratory pathogen trends, and some also incorporated the PEWSS data to care for patients at their medical practices.

We did not identify any program similar to PEWSS in the literature review, particularly ones that employed similar objectives and test menus. PEWSS appeared to be a unique public health surveillance program.

**Task D: gather credible evidence regarding surveillance system performance.** As presented in the CDC Guidelines, a surveillance system may be considered useful if it satisfactorily addresses at least one of six questions. The following results show that PEWSS exceeded this program usefulness criterion by satisfactorily answering three of six program usefulness questions in the Guidelines. The PEWSS program:

1. Detected current circulating respiratory pathogens, which may help to increase the awareness of prevention measures to limit the spread of these pathogens.
Figure 1. Program logic model showing program objectives, resources, activities, and outputs: PEWSS program, Clark County, Nevada, June 1, 2010–May 31, 2011

Objectives
- Provide laboratory surveillance data to track respiratory diseases within the community.
- Provide early detection of seasonal RVPs.
- Report findings to the health-care community, public health partners, and general public.
- Participate in the CDC national influenza surveillance systems.

Resources
- Funding to support program
- Clinical laboratory scientists
- Epidemiologists
- Administrative support staff
- Courier services
- Short- and long-term sample storage
- Pediatrician sentinel sites
- Laboratory supplies and reagents
- Laboratory equipment
- Validated testing methods
- Trained and competent sentinel site and laboratory staff

Activities
- Secure funding.
- Recruit sentinel sites.
- Train sentinel sites on program procedures, specimen collection, and storage.
- Encourage program compliance through direct contact with sentinel site staff.
- Collect patient samples per protocol.
- Supply sentinel site with specimen collection kits.
- Transport nasal swab samples to SNPHL three times per week.
- Access, extract, and analyze samples at SNPHL.
- Store samples at SNPHL for possible future testing.
- Review individual patient results and investigate cases if indicated.
- Analyze data and generate reports.
- Provide selected samples to CDC for additional characterization and resistance testing.
- Perform periodic evaluation of sentinel sites and surveillance system (by OOE and SNPHL).

Outputs
- OOE analyzes results for public health planning, decision making, and communication of others (i.e., incidence, epi curves, and risk factor analysis).
- Sentinel site receives individual patient laboratory results for clinical decision making and analysis.
- Other agencies (CDC, state) and the medical community receive weekly summary data and other analyses as needed.
- The public receives news and advice via SNHD website, public service announcements, and technical bulletins about RVP activity.

Short-term outcomes
- Early detection of emergence of seasonally expected RVPs
- Early detection of RVPs not often detected, including novel influenza viruses
- Understanding trends of common RVPs, including prevalence, severity, and mutation
- Availability of samples for additional characterization at CDC

Middle-term outcomes
- Understanding trends of less common RVPs (besides influenza and RSV)
- Identification and impact of viral coinfections

Long-term outcomes
- Better understanding of seasonality of RVPs, including influenza and RSV
- Potential to identify emerging or novel respiratory viruses
- Potential to strengthen community partnerships
- Potential to develop a standardized process for laboratory-based surveillance of infectious diseases in the community
- Collection of molecular data for long-term trend analyses

PEWSS = Pediatric Early Warning Sentinel Surveillance  
RVP = respiratory viral pathogen  
CDC = Centers for Disease Control and Prevention  
SNPHL = Southern Nevada Public Health Laboratory  
OOE = Office of Epidemiology  
SNHD = Southern Nevada Health District  
RSV = respiratory syncytial virus
2. Developed trends for each pathogen under surveillance. Abnormal occurrences of surveyed pathogens were detected, and the information was relayed weekly to the community to notify people of increased seasonal cases or a potential outbreak.

3. Led to improved clinical, behavioral, social, policy, or environmental practices. We intended to use the surveillance data to inform health professionals about respiratory pathogens circulating in the community. This information may help clinicians inform their patients of the viral etiology of the diseases, which may reduce the demand for antibiotics to treat these infections. The weekly PEWSS bulletins also emphasize the need for public health prevention during peak pathogen circulation.

However, the PEWSS program did not provide estimates of the magnitude of morbidity and mortality related to circulating respiratory diseases, or identify factors associated with the event; permit assessment of the effect of prevention and control programs; or stimulate research intended to lead to prevention or control.

We rated the nine public health surveillance system attributes listed in the CDC Guidelines on a scale of low, medium, high, or not applicable. Six of the nine attributes were rated as high, one attribute was rated medium, and two attributes were not applicable to the PEWSS program. All four of our agency’s priority attributes of simplicity, flexibility, acceptability, and stability were rated as high.

- Simplicity was rated high: Because of the ease of collection and transport of specimens, the training of sentinel site staff was minimal. The case definition was easily understood by the sentinel site staff. The weekly reports to the community were simple and easy to understand.
- Flexibility was rated high: The PEWSS program can easily expand to include additional sentinel sites and/or pathogens for surveillance.
- Acceptability was rated high: All sentinel sites expressed their eagerness to continue their participation in the program. Their enthusiasm and dedication earned each of the sites the 2011 SNHD Public Health Heroes Award. The partnership between the laboratory and epidemiology to develop and maintain the program was a significant factor in the program’s acceptability.
- Stability was rated high: The systems that provide support to the PEWSS program were very stable. Laboratory delays were rare, courier pickup of specimens was consistent, and reports were always distributed weekly throughout the year.
  - Data quality was rated high: The data quality of the PEWSS program was complete and valid. Minimal patient information was solicited, which helped to minimize clerical error.
  - Timeliness was rated high: Specimens for analysis were collected three times a week. Laboratory testing was performed at least once a week. Results were analyzed and reports summarizing the surveillance results were distributed to the community once a week.
  - Representativeness was rated medium: Samples from five sentinel sites were used to generate data. However, sentinel-based surveillance does not allow the results to be generalized to the entire population of pediatrics in the community.
  - Sensitivity and predictive value positive attributes were not applicable to the PEWSS program.

**Tasks E and F: justify and state conclusions and recommendations, and ensure the use of evaluation findings.** We successfully established the PEWSS program, a sentinel surveillance system to monitor circulating respiratory diseases throughout the year in Clark County, Nevada. The CDC Guidelines were used to assess the usefulness and completeness of the surveillance system.

The CDC Guideline tasks, evaluation activity, and evaluation results are summarized in Figure 2. The results (Task D) showed that PEWSS was an effective system for accurately capturing and relaying information about the surveyed pathogens to the community, and stakeholders were committed to using the information provided by the program. PEWSS exceeded the CDC Guidelines minimum level of system usefulness (addressing one of six program usefulness questions) by satisfactorily addressing three questions. Results also revealed that the PEWSS public health surveillance system was simple, flexible, operationally stable, timely, and well accepted by stakeholders. As defined by the CDC Guidelines, these attributes indicate that the system will likely be more useful and complete for public health action.

Although they also cause substantial illnesses, non-influenza viruses (other than RSV) under surveillance by the PEWSS program were not reportable illnesses. PEWSS was a unique system, as there was no comparable surveillance system that monitored as many circulating viruses and was as timely in delivering the information back to the community. We also implemented a hospital- and coroner-based sentinel system that followed the PEWSS model to monitor for
viruses that cause severe respiratory illnesses. Future plans include expansion of the PEWSS test menu to survey rhinovirus,\textsuperscript{16,17} coronavirus,\textsuperscript{18,19} and pertussis, a reemerging public health threat.\textsuperscript{20}

**DISCUSSION**

Public health surveillance systems are developed to address a specific public health need. The data collected from these systems have a wide variety of uses including implementing public health action, monitoring disease trends, and planning programs. Periodically, these systems should be evaluated to ensure that resources and personnel are efficiently used to meet the program objectives and that the system effectively monitors the specific public health issue.\textsuperscript{6} Use of a standardized evaluation format ensures that the appropriate system attributes are assessed and that the results can be used for follow-up evaluations.

The CDC Guidelines provided a standardized format for our evaluation of the PEWSS program. We successfully evaluated the program for all six tasks listed in the CDC Guidelines.

**Limitations**

This evaluation was subject to several limitations. The first limitation was that samples collected from sentinel surveillance were not representative of the general public.\textsuperscript{5} Samples were obtained only from ill pediatric patients, and results were generalized among residents of the whole community. Although there are advantages to sentinel surveillance systems,\textsuperscript{5} the program sensitivity and predictive value positive could not be calculated. However, these attributes were not the objectives of PEWSS, and we did not seek to measure the burden of diseases that were associated with the surveyed viruses.

Second, the cost of starting and maintaining a surveillance system may serve as a potential hurdle...
for public health agencies that want to institute such programs. Although these expenses may have been comparatively high, grants were used to partially offset the program’s cost. Because the results of this evaluation indicated that PEWSS was a valuable surveillance system that fostered relationships between public health agencies and the medical and general communities, the SNHD also committed funds toward the continuation of the program.

CONCLUSION

Our evaluation indicated that PEWSS met three of six program usefulness criteria and seven of nine surveillance system attributes, which exceeded the CDC Guidelines evaluation criteria for a useful and complete public health surveillance program. PEWSS monitored the respiratory viruses circulating in our community, was well accepted by the health-care and general community, and met its purpose and objectives.

The authors thank the following people for their assistance in this project and for their continuing collaboration: the staff of the Southern Nevada Public Health Laboratory, including Erin Buttery, Suzanne Quianson, and Sharon Johnson; the staff at the Southern Nevada Health District, Office of Epidemiology, including Dr. Tony Fredrick, Brian Labus, and Patricia Rowley; and the physicians of the Pediatric Early Warning Sentinel Surveillance program sites, including Dr. Ralph Conti, Dr. Claudia Garcia, Dr. Blair Duddy, Dr. Emmanuel Taguba, Dr. Rutu Ezhuthachan, and the staff at each location.

This article was supported by the Association of Public Health Laboratories and Cooperative Agreement #U60/CD303019 from the Centers for Disease Control and Prevention (CDC). Funding support was received from the following institutes: CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention; Coordinating Center for Infectious Diseases; Office of Workforce and Career Development; National Center for Environmental Health; National Center for Zoonotic, Vector-Borne, and Enteric Diseases; Coordinating Office of Global Health; Coordinating Office for Terrorism Preparedness and Emergency Response; and the National Center for Health Marketing.

The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

REFERENCES


ABSTRACT

Objectives. The decrease in appropriations for state public health laboratories (SPHLs) has become a major concern as tax revenues and, subsequently, state and federal funding, have decreased. These reductions have forced SPHLs to pursue revenue-generating opportunities to support their work. We describe the current state of funding in a sampling of SPHLs and the challenges these laboratories face as they implement or expand fee-for-service testing.

Methods. We conducted surveys of SPHLs to collect data concerning laboratory funding sources, test menus, fee-for-service testing, and challenges to implementing fee-for-service testing.

Results. Most SPHLs receive funding through three revenue sources: state appropriation, federal funding, and fee-for-service testing (cash funds). Among SPHLs, state appropriations ranged from $0 to more than $6 per capita, federal funding ranged from $0.10 to $5 per capita, and revenue from fee-for-service testing ranged from $0 to $4 per capita. The tests commonly performed on a fee-for-service basis included assays for sexually transmitted diseases, mycobacterial cultures, newborn screening, and water testing. We found that restrictive legislation, staffing shortages, inadequate software for billing fee-for-service testing, and regulations on how SPHLs use their generated revenue are impediments to implementing fee-for-service testing.

Conclusions. Some SPHLs are considering implementing or expanding fee-for-service testing as a way to recapture funds lost as a result of state and federal budget cuts. This analysis revealed many of the obstacles to implementing fee-for-service testing in SPHLs and the potential impact on SPHLs of continued decreases in funding.
The origin of modern state public health laboratories (SPHLs) is rooted in outbreaks of typhoid fever and cholera in the cities of 19th century America. Rapid advances in scientific knowledge were achieved in the ensuing years, including identifying the causative agents of many diseases and developing public health interventions to prevent the spread of disease. The first SPHLs were charged with improving sanitation through the detection and control of bacteria in municipal drinking water. Following successes in this area, SPHLs were at the forefront of vaccine and antitoxin development and diagnosis of infectious diseases. Recognized as a benefit to the health of all, SPHL services were offered free to clinicians and municipalities.1

The role of the SPHL has evolved during the last century, and SPHLs are now charged with responsibilities as varied as the states in which they are located. These services include ensuring a safe food supply, biomonitoring for chemical pollutants in the population, surveilling for newly emerging and reemerging communicable diseases, preparing for influenza pandemics, and responding to chemical or biological terrorism attacks.2 In 2010, the Association of Public Health Laboratories (APHL) defined the 11 Core Functions of SPHLs as (1) disease prevention, control, and surveillance; (2) integrated data management; (3) reference and specialized testing; (4) environmental health and protection; (5) food safety; (6) laboratory improvement and regulation; (7) policy development; (8) public health preparedness and response; (9) public health-related research; (10) training and education; and (11) partnerships and communication.3,4 Unfortunately, despite their increasing role in protecting the health of the public from infectious diseases and environmental threats, SPHLs face a crisis of decreased funding.5

Funding for SPHLs generally comes from three sources: general funding allocated through state legislatures, federal funding in the form of grants, and revenues generated through fee-for-service testing (e.g., third-party billing of insurance providers, contract work as part of cooperative agreements with grant-funded partners, and direct billing of submitters). Federal grants that support the work of SPHLs include the Epidemiology and Laboratory Capacity grant; the Public Health Emergency Preparedness cooperative agreement; the Food Emergency Response Network; and other grants that support testing for human immunodeficiency virus, tuberculosis (TB), sexually transmitted diseases (STDs), and environmental health analysis.

Since the economic downturn of 2008, many state legislatures have reduced appropriations to SPHLs, which saw their funding cut by an average of $405,000 per laboratory ($39 million nationally).6 It has long been known that uncertainty surrounding federal funding is an added threat to the fiscal stability of SPHLs.6 A 2011 analysis by Trust for America’s Health concluded that federal budget cuts are “chipping away at gains made [since 2001] in public health preparedness,” with budget cuts directed toward chemical and biological terrorism preparedness programs. The report further concluded that, “Federal funds for state and local preparedness declined by 38% from fiscal year 2005 to 2012 (adjusted for inflation), and additional cuts are expected under budget sequestration.”7

These economic uncertainties have forced more SPHL directors to consider instituting or expanding fee-for-service testing. Charging for services is a radical notion for many SPHLs, which traditionally have not charged fees for their efforts to reduce disease in their communities. In this study, we examined the wide diversity and variability of funding for SPHLs, the challenges of implementing and expanding fee-for-service (i.e., revenue-generating) testing in SPHLs, and the possible consequences of decreased funding for SPHLs to perform their defined core functions.

METHODS

Two surveys were distributed to SPHLs to gather information about their funding levels, funding sources, and experiences with fee-for-service testing. The first survey was developed by the National Center for Public Health Laboratory Leadership (NCPHLL) and distributed to 40 SPHLs in December 2011 with a goal of receiving responses from 25 states. This survey gathered information on the current state of fee-for-service testing practices in SPHLs, including (1) which tests were performed as fee for service, (2) how fee-for-service testing was implemented, (3) types of entities billed for testing, (4) percentage of laboratory revenue derived from fee-for-service testing, (5) anticipated changes in the fee-for-service testing structure (e.g., addition of third-party billing), and (6) impediments to implementing fee-for-service testing.

The second survey, the APHL 2011 Core Survey,3 was distributed to all SPHL directors in all 50 states in early 2011. This survey gathered information pertaining to fiscal year 2010 and included publicly available financial information. The APHL 2011 Core Survey included questions concerning funding levels from different sources (i.e., federal grants, state appropriations, or fee-for-service cash revenues, including third-party billing), staff positions supported by grant funds, and overall laboratory expenditures.

Data obtained from both surveys were compiled
to illustrate the current state of funding sources and fee-for-service revenue generation for SPHLs. We calculated per capita funding using 2010 national Census data for each state.8

RESULTS

Twenty-four of 40 (60%) SPHLs responded to the NCPHLL survey, representing states in the Northeast, Southeast, Midwest, and Mountain West. The median population of responding states was five million, with a range of 0.6–25.0 million residents.8 Survey respondents represented states with both small and large geographical areas. The APHL 2011 Core Survey was sent to all SPHLs, and 37 of 50 SPHL directors (74%) responded. Fee-for-service testing was defined as any testing from which revenue was generated by charging a fee directly to submitters (i.e., health-care providers or private citizens), third-party payers (i.e., Medicaid and private insurance carriers), or other state agencies. In this analysis, fee-for-service testing did not include testing for which the laboratory directly received state or federal funding.

The percentage of responding SPHLs that have implemented some form of fee-for-service testing for specific assays is shown in the Table. These data indicated a large degree of variation in the tests offered as fee for service in each SPHL. Of the SPHLs answering the survey, the majority have implemented billing for STD-related assays, TB cultures, newborn screening, and water testing. We did not collect information on which specific entities (i.e., health-care providers, private citizens, third-party payers, or other state agencies) were charged a fee for each assay.

The 2011 APHL Core Survey identified SPHLs that charged a fee for at least one testing service offered (Figure 1). Medicaid, private citizens, and other state agencies were the entities that were most frequently charged a fee for testing. Of the states that responded to the APHL 2011 Core Survey, five of 37 (13.5%) reported that no revenue was generated from fee-for-service testing to private citizens and insurance, while a sixth state indicated negligible revenue from fee-for-service testing to these sources (Figure 2). Responses to the two surveys revealed that, among the states that responded, SPHLs fell into three categories regarding the ability to use fee-for-service testing to generate revenue. The first category included five of 37 states that do not perform fee-for-service testing (13.5%); these states acquire all needed funds through federal and state sources. The second category included two of 37 states reporting that they receive no state appropriations and must acquire all operational funds through federal and/or fee-for-service revenue sources (5.4%). The third and largest category included 30 of 37 states in which the SPHLs acquire operational

Table. Percentage of state public health laboratories (n=37) that charge at least one entity for assays: NCPHLL survey,* U.S., 2011

<table>
<thead>
<tr>
<th>Assay</th>
<th>Percent</th>
<th>Assay</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>83</td>
<td>Viral culture</td>
<td>46</td>
</tr>
<tr>
<td>Chlamydia/gonorrhea</td>
<td>83</td>
<td>Herpes serology</td>
<td>42</td>
</tr>
<tr>
<td>Water testing</td>
<td>75</td>
<td>Susceptibility testing</td>
<td>42</td>
</tr>
<tr>
<td>Mycobacteria culture</td>
<td>71</td>
<td>Hepatitis C</td>
<td>38</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>67</td>
<td>Lyme serology</td>
<td>33</td>
</tr>
<tr>
<td>Newborn screening</td>
<td>67</td>
<td>Bacteria serogrouping</td>
<td>33</td>
</tr>
<tr>
<td>Rapid plasma reagin</td>
<td>58</td>
<td>Genotyping</td>
<td>33</td>
</tr>
<tr>
<td>Syphilis confirmation</td>
<td>54</td>
<td>Influenza PCR</td>
<td>29</td>
</tr>
<tr>
<td>Parasitology</td>
<td>54</td>
<td>Mumps PCR</td>
<td>25</td>
</tr>
<tr>
<td>Shigatoxin screen</td>
<td>54</td>
<td>Food testing</td>
<td>25</td>
</tr>
<tr>
<td>Serum immunoglobulin M</td>
<td>50</td>
<td>Blood-lead testing</td>
<td>25</td>
</tr>
<tr>
<td>Arbovirus serology</td>
<td>50</td>
<td>Measles PCR</td>
<td>21</td>
</tr>
<tr>
<td>Norovirus PCR</td>
<td>50</td>
<td>Parovirus B19</td>
<td>21</td>
</tr>
<tr>
<td>Bacterial culture</td>
<td>50</td>
<td>PFGE</td>
<td>21</td>
</tr>
<tr>
<td>Mycology culture</td>
<td>50</td>
<td>Milk testing</td>
<td>21</td>
</tr>
<tr>
<td>Serum immunoglobulin G</td>
<td>46</td>
<td>Seawater testing</td>
<td>17</td>
</tr>
</tbody>
</table>

*NCPHLL Emerging Leaders Cohort IV environmental scan, 2011

NCPHLL = National Center for Public Health Laboratory Leadership
HIV = human immunodeficiency virus
PCR = polymerase chain reaction
PFGE = pulsed-field gel electrophoresis
funds through federal, state, and fee-for-service revenue sources (81.1%) (data not shown). Each SPHL varied significantly in the proportion of its budget comprising each of the funding sources (Figure 2).

Of the 37 SPHLs shown in Figure 2, 32 (86%) indicated that they generate some revenue from fee-for-service testing, and the proportion of total revenue that resulted from fee-for-service testing ranged from ~1% to 80% of the SPHL total revenue. Figure 3 illustrates per capita funding by state, federal, and fee-for-service revenue sources. The data indicate that total per capita funding varies significantly among SPHLs, ranging from $1 per capita to $9 per capita. The per capita range of funding resulting from fee-for-service testing was $0–$4 per capita. Five of 37 responding states had fee-for-service per capita funding that was >50% of the responding states’ total per capita funding.

The remaining questions on the NCPHLL survey identified how fee-for-service testing was implemented in each SPHL and common challenges or obstacles encountered in its implementation. Several barriers to efficient and adequate revenue generation through fee-for-service testing were repeatedly identified by the 17 SPHLs that responded to this portion of the NCPHLL survey. Billing software was listed by 65% of respondents as a major impediment to implementing fee-for-service testing. Several SPHLs specifically mentioned software that can interface with the Laboratory Information Management System (LIMS). The second most common barrier identified by the NCPHLL survey involved legislative restrictions to both implementing fee-for-service testing and depending on the legislature to set fees (53%). Other barriers included lack of staffing (35%) and obtaining billing information from clients (12%) (data not shown).

One barrier to implementing fee-for-service testing that was identified by respondents was the inability of many SPHLs to access and use collected revenues generated through testing activities due to legislative mandates and state-specific regulations. Six of 20 respondents (30%) to the NCPHLL survey reported that their SPHLs would not directly receive collected revenue generated from fee-for-service testing; rather, the revenue would be remitted to the state’s general fund. Five other states (25%) responded that while their SPHLs would not receive all of the collected revenues generated by fee-for-service testing, they would receive at least a portion of the revenue. Nine of the 20 states (45%) said the SPHLs would receive all the fee-for-service funds. One responding SPHL director strongly recommended the development of a “retained revenue account” (i.e., an account that would enable

**Figure 1. Percentage of state public health laboratories (n=37) that charge various payers for services provided: APHL Core Survey, U.S., 2011**

![Bar chart showing percentage of state public health laboratories that charge various payers for services provided.](chart.png)
the laboratory to directly access funds generated by fee-for-service testing) (data not shown).

**DISCUSSION**

According to survey respondents, there is significant variability among SPHLs in the sources and percentage of funding (i.e., state, federal, and fee-for-service) used to support their activities. While many SPHLs currently charge fees to certain entities for selected tests, revenue generated from these tests comprises a smaller proportion of the total SPHL budget in the majority of states surveyed than do state and federal funds. These observations demonstrate SPHLs’ continued reliance on state and federal appropriations and grants, even with the implementation of fee-for-service testing. However, one responding SPHL reported receiving up to 80% of its funding through fee-for-service testing, and nine more SPHLs reported receiving more than half of their total funding through fee-for-service testing, indicating that fee-for-service testing could be a major source of revenue for other SPHLs in the future. The heterogeneity in funding from federal, state, and other revenue sources among SPHLs indicates that a one-size-fits-all approach to SPHL funding is unrealistic despite a shared set of core functions. This finding is further illustrated by per capita funding that ranges from $1 to $9 in states responding to the APHL 2011 Core Survey.

**Challenges of fee-for-service testing**

Responses to the NCPHLL survey indicate that the implementation of fee-for-service testing in SPHLs presents many challenges that hinder broad
implementation in many state and local public health laboratories (PHLs). Multiple respondents commented on several barriers, which are detailed hereafter.

**Legislative authority.** Commonly, state and local governments must legislate authority to a PHL to charge for testing that is not part of an outbreak or surveillance investigation. While the steps to obtaining the necessary legislation might be manageable, political opposition may exist. One view holds that SPHLs should not compete with private or commercial laboratories. However, within the unique circumstances of each state, there may be very good reasons for the SPHLs to offer fee-for-service testing that is also available through private laboratories. One example is the consolidation of the clinical laboratory industry causing many local laboratories to close, thus leaving a gap in the availability of testing in rural areas. Legislation that permits fee-for-service testing may exclude testing that is fully funded through state or federal grants. Once implemented, another challenge facing some SPHLs is their inability to change the price of testing services without legislative approval. This challenge could be overcome by legislation that allows the price for fee-for-service testing to be changed by rulemaking or to be linked to the Medicaid fee schedule. Doing so would eliminate the need for legislative approval whenever the price to perform a test changes.

**Billing processes.** Another hurdle to implementing fee-for-service testing is the billing process itself; there is a lack of billing and tracking software that is compatible with the LIMS currently in use in SPHLs. A second challenge is a mandate requiring a state-approved contract with any entity that the SPHL charges for services. It is this mandate for contracts with potentially hundreds of entities that can make fee-for-service testing impractical in some states. Some SPHLs have overcome this obstacle by contracting with a third-party billing company that, for a small fee, can bill
any entity for which the laboratory performs testing. Contracting with a third-party billing company allows the SPHL to have one contract with the third-party biller and let the billing company use its own software to bill and track the laboratory’s customers. Several of the smaller or less densely populated states responding to the NCPHLL survey indicated that the cost of contracting out billing services may be cost-prohibitive due to lower testing volumes. Creative solutions to this problem could include partnering with similarly situated SPHLs or other state government entities that charge for services.

Generating revenue through fee-for-service testing
The surveys discussed in this article identified a major question that each SPHL must consider if building a fee-for-service testing menu: Will new or expanded fee-for-service testing actually accomplish the desired result of sufficient funds to operate the laboratory? In some of the responding states, revenue received via fee-for-service testing is transferred to the state general fund; in others, the revenue, or a portion of it, is used strictly to support the SPHL’s functions. Both scenarios raise issues that are worthy of careful consideration. In the first scenario, revenue that is remitted to the state general fund may not be accessible to the SPHLs. These SPHLs may continue to lose funding and have difficulty maintaining their core functions despite generating revenue through fee-for-service testing. The second scenario concerns potential decreases in state funding for the SPHLs due to increased revenue generated through fee-for-service testing. The state might argue that the laboratory can support itself. In addition, charging for tests could reduce test volume, resulting in decreased fee-for-service revenues. A third scenario is that once fee-for-service testing is implemented, there may be no way to go back to a government-funded model. This latter scenario could become problematic if the private laboratory industry views the change of an SPHL to a fee-for-service model as government-subsidized competition. This changing view could lead to outside efforts to change the SPHL funding model back to government funding only.

The SPHL system has historically been a government-funded entity with the role of protecting the public’s health, especially the populations most at risk for disease. In the United States, the populations most at risk are the underinsured; thus, many of the customers served by SPHLs are either covered by Medicaid or have no health insurance. Consequently, the majority of responding SPHLs that have implemented fee-for-service testing have developed, or are in the process of developing, a mechanism to bill Medicaid for services provided. The data generated from providing these services are used by state epidemiologists and the Centers for Disease Control and Prevention to deliver disease surveillance in the U.S. and are not intended to compete with private industry.

The surveys discussed in this study also highlighted the disparity of state and federal per capita funding for SPHL testing. This disparity deserves further investigation to determine if lower per capita funding for SPHLs has a negative effect on the overall health of the population of that state or if the services are being provided by another entity within the state. Other issues that will affect funding for SPHLs in the future include population shifts; immigration; climate change; natural disasters; environmental insult and contamination; and the rapid spread of infectious, vector-borne, and antimicrobial-resistant organisms. It is imperative that SPHLs, as well as state and federal funding entities, develop contingency plans to maintain the core functions as PHls face these issues.

Limitations
The surveys discussed in this article were limited by the number of states providing responses; as such, all findings must be taken as general observations that may not apply to those states that did not respond.

CONCLUSION
As a result of the national economic downturn, SPHLs face significant challenges in acquiring the funding necessary to perform their core functions. These challenges have already led to tough decisions to reduce the workforce, eliminate laboratory programs, and shutter smaller laboratories, all of which further erode SPHLs’ ability to fulfill their core functions. SPHL revenue from fee-for-service testing may enable service continuity during these uncertain economic times. The methods and experiences of SPHLs that have already implemented fee-for-service testing mechanisms can serve as a framework by which other PHls can address funding challenges and continue to meet their core functions.

This manuscript was supported by Cooperative Agreement #U50HM006803 from the Centers for Disease Control and Prevention (CDC) and/or Assistant Secretary for Preparedness and Response. Its contents are solely the responsibility of the authors and do not necessarily represent the views of CDC and/or Assistant Secretary for Preparedness and Response. The National Center for Public Health Laboratory Leadership program was funded 100% from federal funds, with a budget of $958,233.
REFERENCES


Core Courses in Public Health Laboratory Science and Practice: Findings from 2006 and 2011 Surveys

JOHN M. DEBOY, DRPHab
ANGELA J. BECK, PHD, MPHc
MATTHEW L. BOULTON, MD, MPHad
DEBORAH H. KIM, MPHb
MICHAEL D. WICHMAN, PHDd
PATRICK F. LUETTKE, MD, MPHf

ABSTRACT

Objectives. We identified academic training courses or topics most important to the careers of U.S. public health, environmental, and agricultural laboratory (PHEAL) scientist-managers and directors, and determined what portions of the national PHEAL workforce completed these courses.

Methods. We conducted electronic national surveys in 2006 and 2011, and analyzed data using numerical ranking, Chi-square tests comparing rates, and Spearman’s formula measuring rank correlation.

Results. In 2006, 40 of 50 PHEAL directors identified 56 course topics as either important, useful, or not needed for someone in their position. These course topics were then ranked to provide a list of 31 core courses. In 2011, 1,659 of approximately 5,555 PHEAL scientific and technical staff, using a subset of 25 core courses, evidenced higher core course completion rates associated with higher-level job classification, advanced academic degree, and age. The 2011 survey showed that 287 PHEAL scientist-managers and directors, on average, completed 37.7% (n=5/13) of leadership/managerial core courses and 51.7% (n=6/12) of scientific core courses. For 1,659 laboratorians in all scientific and technical classifications, core-subject completion rates were higher in local laboratories (42.8%, n=11/25) than in state (36.0%, n=9/25), federal (34.4%, n=9/25), and university (31.2%, n=8/25) laboratories.

Conclusions. There is a definable range of scientific, leadership, and managerial core courses needed by PHEAL scientist-managers and directors to function effectively in their positions. Potential PHEAL scientist-managers and directors need greater and continuing access to these courses, and academic and practice entities supporting development of this workforce should adopt curricula and core competencies aligned with these course topics.

aMaryland Department of Health and Mental Hygiene, Laboratories Administration, Baltimore, MD
bAssociation of Public Health Laboratories, Silver Spring, MD
cUniversity of Michigan, School of Public Health, Center of Excellence for Public Health Workforce Studies, Ann Arbor, MI
dUniversity of Michigan, School of Medicine, Ann Arbor, MI
eState Hygienic Laboratory at the University of Iowa, Iowa City, IA
fLane County Department of Health and Human Services, Eugene, OR

Address correspondence to: John M. DeBoy, DrPH, Association of Public Health Laboratories, 8515 Georgia Ave., Ste. 700, Silver Spring, MD 20910; tel. 240-485-2745; fax 240-485-2700; e-mail <jack.deboy46@gmail.com>.

©2013 Association of Schools and Programs of Public Health
Employees working in public health, environmental, and agricultural laboratories (PHEALs) comprise only 1% (5,555/448,254² full-time equivalent workers) of the U.S. public health workforce. However, the laboratories they staff play a critical role in protecting the public by monitoring and identifying newly emerging infections, sporadic outbreaks, hazardous chemical exposures, treatable hereditary disorders, environmental hazards, and effects of natural disasters.

A well-trained cadre of PHEAL scientist-managers and directors is required to administer these laboratories. A scientist-manager is a laboratory scientist possessing an earned doctoral degree with scientific and supervisory work experience who develops, oversees, and consults on a wide range of laboratory testing and services in a particular field (e.g., environmental chemistry, microbiology, or newborn screening). A director is a scientist-manager with sufficient experience and professional certification as required to meet federal and state qualifications to direct a laboratory in one or more laboratory specialties.³

Until recently, a scientific or professional doctoral degree was considered sufficient to qualify someone for a leadership position in a PHEAL. While such a degree may provide the basic scientific knowledge to direct one or more scientific specialty areas in a research or diagnostic laboratory, PHEAL scientist-managers and directors require an education that prepares them to effectively carry out a much broader range of complex professional duties that include disease prevention, control, and surveillance; integrated data management; environmental health and protection; food safety; outbreak investigation; laboratory law and regulations development; public policy development; public health preparedness and response; training and education; and partnerships and communications.⁴

Despite an increasing demand for qualified PHEAL leaders, an impending shortage of laboratory professionals has been anticipated for more than a decade.¹⁻⁷ The need for more broadly educated PHEAL leaders combined with an anticipated shortage of these professionals makes it especially important to maximize return on the limited educational resources available to address this issue. In 2002, the Institute of Medicine’s Committee on Assuring the Health of the Public in the 21st Century made recommendations that stressed integrated disciplinary learning and curricula based on core competencies.⁷ In 2008, the Robert Wood Johnson Foundation (RWJF) issued a report on a strategic planning process and plan to ensure competent, sustainable public health laboratory (PHL) leadership, which highlighted the importance of both core academic and professional courses in PHL science and practice.⁹

As a follow-up to the RWJF plan, the field of PHL science and practice needs to identify workplace competencies and core courses to help students and mid-career scientists attain the competency-based knowledge and training needed to qualify as PHEAL scientist-managers and directors. PHEAL workplace competencies are currently being developed under a joint project of the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) (Personal communication, Catherine Johnson, APHL, National Center for Public Health Laboratory Leadership, March 2013).

In this article, we identify courses or course topics believed to be most important to individuals who are working toward effective leadership positions in PHEALs in the U.S. and discuss the implications of these findings as they relate to workplace competencies and the future education of these scientists. Throughout this article, the terms “course” or “core course” indicate an academic course or training topic and are not intended to identify an actual current or future course taught in any specific educational or training entity.

**METHODS**

This study presents findings from two separate surveys—a 2006 survey distributed to public health and environmental laboratory directors and a 2011 survey distributed to all PHEAL scientific and technical staff.

**2006 survey**

As part of a year-long National Public Health Leadership Institute project at the University of North Carolina, Chapel Hill, a team of four current PHL directors developed and refined by consensus a comprehensive list of 56 courses⁸ presumed to be important to functioning effectively as a PHEAL scientist-manager or director. The 56 course topics were developed into survey items and submitted to APHL to be formatted into an electronic questionnaire using SPSS® MrInterview™.¹⁰ The key designated respondents were the 50 state public health and environmental laboratory directors in the U.S. in the spring of 2006. The survey participants were asked to rank the 56 course topics as “important,” “useful,” or “not needed” based on their past experience and professional opinion. Survey results were collected from May 6 through June 3, 2006, with an electronic reminder to nonresponders issued in mid-May 2006. Responses to each of the 56 items were tallied electronically.
The respondents to the 2011 survey were approximately 5,555 PHEAL scientific and technical employees of the 105 laboratories comprising the APHL membership in February 2011. These respondents consisted of laboratories in all 50 states, the District of Columbia, and Puerto Rico, including 50 state PHLs, 41 local (municipal and county) PHLs, eight environmental laboratories, and six agricultural laboratories. While the total number of PHLs in the U.S. is unknown, the PHEALs of interest in this study number fewer than 150, and the APHL umbrella accounted for more than 90% of the employees in these laboratories (Personal communication, Scott Becker, APHL, February 2012). This 2011 follow-up survey asked employees whether they had completed academic courses in 25 of 31 core subjects identified from the 2006 survey.

After pilot testing the survey instrument using SPSS MItnterview with four directors and 13 workers in several job classifications, APHL distributed this electronic survey to 105 PHEAL directors, with instructions to disseminate the survey to all scientific and technical employees in their laboratories. MItnterview was the standard interview tool used by APHL at the time this project was undertaken. Data collection took place from April to July 2011. Throughout this period, APHL staff followed up with e-mails and telephone calls to encourage responses. Data were compiled using Microsoft Excel.

Analysis
A core course was defined as one meeting one of two cutoffs: (1) ranked as important by $\geq$50% of total respondents in the 2006 survey or (2) ranked as important by $\geq$45% of total respondents plus ranked as useful by $\geq$45% of total respondents in the 2006 survey.

Data from the 2011 survey were compiled for analysis by standard job classifications (i.e., laboratory aide/assistant, laboratory technician, bench scientist, scientist supervisor, scientist manager, developmental scientist, and director); laboratory type (i.e., public health, environmental, agricultural, and university); highest academic degree earned (i.e., high school, associate, bachelor’s, master’s, academic doctorate [doctor of philosophy (PhD), doctor of public health (DrPH/DPh), and doctor of science (ScD/DSc)], and professional doctorate [doctor of medicine, doctor of osteopathic medicine, doctor of veterinary medicine, and doctor of dental surgery]); and employee age group (i.e., 30–39, 40–49, 50–59, and 60–69 years of age).

Each of the 31 core courses identified using the 2006 survey was assigned a numerical ranking based on its importance given as a percentage. Core courses with the same percentage received the same numerical ranking. Similarly, each of the 25 core courses employed in the 2011 survey was assigned a “completion rate” numerical ranking based on its completion rate ranking given as a percentage. Simple linear correlation between rankings of core subject “importance” and core-course “completion rate” was determined using Spearman’s formula for rank correlation. Chi-square tests to calculate the significance of differences in core-course completion rates between scientific and professional degree and among age cohorts were performed for equality of two independent proportions.

RESULTS
In 2006, 40 of 50 (80%) state PHEAL directors completed the survey. The 2011 survey was completed by 1,659 of approximately 5,555 (29.8%) PHEAL employees. Thirty-one of 56 courses (55%) met the definition of a core course and are listed by course type and importance by numerical rank and percentage in Table 1. Of 31 core courses, 14 (45%) were leadership/managerial and the remaining 17 (55%) were scientific. The four top-ranked core courses by importance were all in the leadership/managerial category, as were five of the next 10 core courses.

Core course completion rates and numerical rankings for 25 core subjects reported by 1,659 technical and professional PHEAL employees in 2011 are also presented in Table 1. The average completion rate of 25 core courses by all 1,659 laboratorians was 33.7% (1,659/4,923 core courses completed) (data not shown).

For 1,659 respondents, the average numbers of core courses completed per laboratorian are presented by age cohort, education, job classification, and laboratory type in Table 2. Higher numbers of completed core courses were associated with higher-level job classification, possession of an advanced degree, and increasing employee age. Laboratorians with master’s degrees completed as many or more core courses as those with scientific doctorates. On average, more core courses were completed by laboratorians in local laboratories than in other laboratory types. The mean number of core courses completed by laboratorians $\geq$51 years of age (range: 9.5–9.8) was significantly higher than the number of core courses completed by laboratorians $\leq$50 years of age (range: 8.8–9.3) ($\chi^2 = 0.002, p<0.05$), although the difference between core courses completed by 41- to 50-year-olds (9.0) and 31- to 40-year-olds (9.3) was not statistically significant ($\chi^2 = 0.04, p>0.05$). The difference in the mean number of core courses...
Table 1. Rankings by importance of 31 course subjects core to the education and training of PHEAL scientists in the U.S.: 2006 APHL survey (n=40 laboratory directors) and 2011 APHL survey (n=1,659 laboratorians)

<table>
<thead>
<tr>
<th>Core course</th>
<th>Course type</th>
<th>Importance numerical ranking(^a)</th>
<th>Importance ranking as a percent</th>
<th>Completion rate numerical ranking</th>
<th>Completion ranking as a percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory quality assurance, mission evaluation, and government regulations</td>
<td>L</td>
<td>1</td>
<td>95</td>
<td>4</td>
<td>53.2</td>
</tr>
<tr>
<td>Public health laboratory management</td>
<td>M</td>
<td>2</td>
<td>93</td>
<td>22</td>
<td>9.9</td>
</tr>
<tr>
<td>Laboratory safety and security</td>
<td>L</td>
<td>3</td>
<td>85</td>
<td>6</td>
<td>50.0</td>
</tr>
<tr>
<td>Writing grant proposals</td>
<td>M</td>
<td>4</td>
<td>80</td>
<td>17</td>
<td>23.2</td>
</tr>
<tr>
<td>Molecular biology and molecular diagnostics</td>
<td>S</td>
<td>4</td>
<td>80</td>
<td>9</td>
<td>42.6</td>
</tr>
<tr>
<td>Leadership</td>
<td>L</td>
<td>6</td>
<td>78</td>
<td>12</td>
<td>37.2</td>
</tr>
<tr>
<td>Principles of management</td>
<td>M</td>
<td>7</td>
<td>75</td>
<td>20</td>
<td>13.5</td>
</tr>
<tr>
<td>Epidemiology</td>
<td>S</td>
<td>7</td>
<td>75</td>
<td>18</td>
<td>20.3</td>
</tr>
<tr>
<td>Clinical/medical/pathogenic bacteriology</td>
<td>S</td>
<td>9</td>
<td>74</td>
<td>5</td>
<td>53.0</td>
</tr>
<tr>
<td>Immunology</td>
<td>S</td>
<td>10</td>
<td>73</td>
<td>3</td>
<td>55.3</td>
</tr>
<tr>
<td>Virology</td>
<td>S</td>
<td>10</td>
<td>73</td>
<td>3</td>
<td>39.5</td>
</tr>
<tr>
<td>Ethics</td>
<td>L</td>
<td>12</td>
<td>70</td>
<td>8</td>
<td>46.0</td>
</tr>
<tr>
<td>Emergency preparedness and response</td>
<td>L</td>
<td>12</td>
<td>70</td>
<td>10</td>
<td>37.8</td>
</tr>
<tr>
<td>Surveillance systems in public health</td>
<td>M</td>
<td>14</td>
<td>68</td>
<td>24</td>
<td>8.7</td>
</tr>
<tr>
<td>Medical virology</td>
<td>S</td>
<td>15</td>
<td>65</td>
<td>NA(^b)</td>
<td>NA(^b)</td>
</tr>
<tr>
<td>Environmental/water microbiology</td>
<td>S</td>
<td>16</td>
<td>64</td>
<td>16</td>
<td>25.9</td>
</tr>
<tr>
<td>Laboratory design/workflow/operations</td>
<td>M</td>
<td>17</td>
<td>63</td>
<td>19</td>
<td>17.6</td>
</tr>
<tr>
<td>Politics/partners/public relations in government</td>
<td>L</td>
<td>18</td>
<td>60</td>
<td>23</td>
<td>9.7</td>
</tr>
<tr>
<td>Information management/communications</td>
<td>M</td>
<td>19</td>
<td>57</td>
<td>21</td>
<td>12.5</td>
</tr>
<tr>
<td>Epidemiology of infectious diseases</td>
<td>S</td>
<td>20</td>
<td>55</td>
<td>NA(^b)</td>
<td>NA(^b)</td>
</tr>
<tr>
<td>Writing for scientific publications</td>
<td>S</td>
<td>20</td>
<td>55</td>
<td>NA(^b)</td>
<td>NA(^b)</td>
</tr>
<tr>
<td>Public health administration</td>
<td>M</td>
<td>20</td>
<td>55</td>
<td>NA(^b)</td>
<td>NA(^b)</td>
</tr>
<tr>
<td>Doctoral-level basic/applied research</td>
<td>S</td>
<td>23</td>
<td>53</td>
<td>NA(^b)</td>
<td>NA(^b)</td>
</tr>
<tr>
<td>Environmental science/health</td>
<td>S</td>
<td>24</td>
<td>51</td>
<td>13</td>
<td>37.0</td>
</tr>
<tr>
<td>Biochemistry</td>
<td>S</td>
<td>24</td>
<td>51</td>
<td>1</td>
<td>68.4</td>
</tr>
<tr>
<td>Epidemiology of food/waterborne diseases</td>
<td>S</td>
<td>26</td>
<td>50</td>
<td>NA(^b)</td>
<td>NA(^b)</td>
</tr>
<tr>
<td>Statistics/biostatistics</td>
<td>S</td>
<td>26</td>
<td>50</td>
<td>14</td>
<td>30.9</td>
</tr>
<tr>
<td>Public health law</td>
<td>M</td>
<td>28</td>
<td>48</td>
<td>25</td>
<td>6.9</td>
</tr>
<tr>
<td>Laboratory instrumentation/instrumental analysis</td>
<td>S</td>
<td>29</td>
<td>45</td>
<td>7</td>
<td>46.9</td>
</tr>
<tr>
<td>Bacteriology laboratory</td>
<td>S</td>
<td>29</td>
<td>45</td>
<td>2</td>
<td>61.7</td>
</tr>
<tr>
<td>Virology laboratory</td>
<td>S</td>
<td>29</td>
<td>45</td>
<td>15</td>
<td>28.9</td>
</tr>
</tbody>
</table>

\(^a\)Core courses were ranked by importance, with courses ranked 1–26 considered "important" by \(\geq 50\%\) of survey respondents, and courses ranked 28–29 considered "important" by \(\geq 45\%\) of survey respondents.

\(^b\)Completion data were not collected for these core courses in the 2011 survey.

PHEAL = public health, environmental, and agricultural laboratory

APHL = Association of Public Health Laboratories

L = leadership

M = managerial

S = scientific

NA = not available

completed by individuals with a scientific doctorate (11.4) and those with a professional doctorate (13.4) was not statistically significant \(\chi^2 = 0.08, p > 0.05\).

Completion rates for 25 core courses completed by 287 laboratory scientist-managers and directors are presented in Table 3. Average core course completion rate by job classification for 13 leadership/managerial courses (total managerial and leadership subjects completed divided by total individuals in job classification) increased in going from scientist-manager (4.4) to deputy director (5.4) and laboratory director (6.2). The average core course completion rate by job classification for 12 scientific courses (total scientific courses completed divided by total individuals in job classification) also increased in going from scientist-manager (3.3) to deputy director (5.7) and laboratory director (7.9).

On average, fewer leadership/managerial core
Table 2. Overall completion rate for 25 course subjects core to the education and training of PHEAL scientists in the U.S.: 2011 APHL survey (n=1,659 laboratorians)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean number of courses completed</th>
<th>Total courses/number of laboratorians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤30</td>
<td>8.8</td>
<td>2,026/231</td>
</tr>
<tr>
<td>31–40</td>
<td>9.3</td>
<td>3,522/380</td>
</tr>
<tr>
<td>41–50</td>
<td>9.0</td>
<td>3,421/381</td>
</tr>
<tr>
<td>51–60</td>
<td>9.5</td>
<td>4,718/495</td>
</tr>
<tr>
<td>≥61</td>
<td>9.8</td>
<td>1,657/170</td>
</tr>
<tr>
<td>All ages</td>
<td>9.3</td>
<td>15,348/1,657</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>3.2</td>
<td>246/76</td>
</tr>
<tr>
<td>Associate degree</td>
<td>7.2</td>
<td>565/78</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
<td>8.8</td>
<td>8,969/1,022</td>
</tr>
<tr>
<td>Master’s degree</td>
<td>11.5</td>
<td>3,826/332</td>
</tr>
<tr>
<td>Scientific doctorate&lt;sup&gt;b&lt;/sup&gt;</td>
<td>11.4</td>
<td>1,563/137</td>
</tr>
<tr>
<td>Professional doctorate&lt;sup&gt;c&lt;/sup&gt;</td>
<td>13.4</td>
<td>188/14</td>
</tr>
<tr>
<td>All education levels</td>
<td>9.3</td>
<td>15,357/1,659</td>
</tr>
<tr>
<td>Job classification&lt;sup&gt;d&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory assistant</td>
<td>3.7</td>
<td>287/77</td>
</tr>
<tr>
<td>Laboratory technician</td>
<td>7.2</td>
<td>1,272/178</td>
</tr>
<tr>
<td>Bench scientist</td>
<td>9.0</td>
<td>6,972/777</td>
</tr>
<tr>
<td>Scientist supervisor</td>
<td>9.9</td>
<td>3,089/313</td>
</tr>
<tr>
<td>Scientist-manager</td>
<td>11.2</td>
<td>2,133/190</td>
</tr>
<tr>
<td>Developmental scientist</td>
<td>11.8</td>
<td>294/25</td>
</tr>
<tr>
<td>Agricultural/environment deputy director</td>
<td>10.2</td>
<td>92/9</td>
</tr>
<tr>
<td>Public health deputy director</td>
<td>14.9</td>
<td>538/36</td>
</tr>
<tr>
<td>Agricultural/environment laboratory director</td>
<td>10.2</td>
<td>92/9</td>
</tr>
<tr>
<td>Public health laboratory director</td>
<td>15.6</td>
<td>766/49</td>
</tr>
<tr>
<td>All classifications</td>
<td>9.3</td>
<td>15,357/1,659</td>
</tr>
<tr>
<td>Laboratory type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>University</td>
<td>7.8</td>
<td>791/101</td>
</tr>
<tr>
<td>Environmental</td>
<td>7.8</td>
<td>2,947/376</td>
</tr>
<tr>
<td>Agricultural</td>
<td>9.0</td>
<td>234/26</td>
</tr>
<tr>
<td>Public health</td>
<td>9.5</td>
<td>13,680/1,432</td>
</tr>
<tr>
<td>Federal</td>
<td>8.6</td>
<td>172/20</td>
</tr>
<tr>
<td>State</td>
<td>9.0</td>
<td>8,479/937</td>
</tr>
<tr>
<td>Local</td>
<td>10.6</td>
<td>1,071/101</td>
</tr>
</tbody>
</table>

<sup>a</sup>Ages not provided by two respondents
<sup>b</sup>Doctor of philosophy, doctor of science, or doctor of public health
<sup>c</sup>Doctor of medicine, doctor of osteopathy, doctor of veterinary medicine, or doctor of dental surgery

PHEAL = public health, environmental, and agricultural laboratory
APHL = Association of Public Health Laboratories

courses (4.9 of 13) were completed than scientific core courses (6.2 of 12); however, this difference was not statistically significant ($\chi^2=0.04, p>0.05$). Combining completion data for all 25 managerial and scientific core courses from all 287 laboratory scientist-managers, deputy directors, and directors together yielded an overall average core course completion rate of 44.4% (11.1 of 25 courses) per individual, with weighted average completion rates for individual core courses ranging from 10.8% to 79.1% (Table 3).

Spearman’s formula for rank correlation produced a moderately negative correlation ($r_{rank} = -0.58$) between core course numerical rankings of importance percentage and numerical rankings of core-course completion rate (Table 1) for the 25 core subjects with completion rates.
DISCUSSION

Directors of PHEALs must provide leadership in public health emergencies, address resource shortages, formulate and evaluate policy, and actively engage in the politics of governmental bureaucracies. These varied demands are fully reflected in the 31 core courses identified in this article.

The dual set of qualifications, being an active scientist and leader/manager, can be a barrier to ensuring an adequate pool of qualified PHEAL scientist-managers and directors. Individuals seeking these dual qualifications must be encouraged through insuring their access to the 31 core courses identified in this article, which will help maximize return on investment given limited educational resources. Consequently, the findings of low completion rates for many of these core courses by scientist-managers and directors is disconcerting and may call for major new emphases in training current and future PHEAL leaders.

Table 3. Course completion rates for 13 leadership/managerial and 12 scientific course subjects core to the education and training of PHEAL scientists in the U.S.: 2011 APHL survey

<table>
<thead>
<tr>
<th>Core courses</th>
<th>Scientist-manager (n=190)</th>
<th>Deputy director (n=39)</th>
<th>Laboratory director (n=58)</th>
<th>Weighted average (n=287)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership/managerial</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory quality assurance, mission evaluation, and government regulations</td>
<td>56.3</td>
<td>51.3</td>
<td>58.6</td>
<td>56.1</td>
</tr>
<tr>
<td>Public health laboratory management</td>
<td>25.8</td>
<td>28.2</td>
<td>36.2</td>
<td>28.2</td>
</tr>
<tr>
<td>Laboratory safety and security</td>
<td>61.1</td>
<td>48.7</td>
<td>69.0</td>
<td>61.0</td>
</tr>
<tr>
<td>Writing grant proposals</td>
<td>34.7</td>
<td>61.5</td>
<td>51.7</td>
<td>41.8</td>
</tr>
<tr>
<td>Leadership</td>
<td>63.7</td>
<td>71.8</td>
<td>75.9</td>
<td>67.3</td>
</tr>
<tr>
<td>Principles of management</td>
<td>24.7</td>
<td>41.0</td>
<td>43.1</td>
<td>30.7</td>
</tr>
<tr>
<td>Ethics</td>
<td>54.7</td>
<td>69.2</td>
<td>51.7</td>
<td>56.1</td>
</tr>
<tr>
<td>Emergency preparedness and response</td>
<td>46.3</td>
<td>59.0</td>
<td>70.7</td>
<td>53.0</td>
</tr>
<tr>
<td>Surveillance systems in public health</td>
<td>13.2</td>
<td>25.6</td>
<td>58.6</td>
<td>24.0</td>
</tr>
<tr>
<td>Laboratory design/workflow operations</td>
<td>22.1</td>
<td>25.6</td>
<td>34.5</td>
<td>25.1</td>
</tr>
<tr>
<td>Politics/partners/public relations in government</td>
<td>13.2</td>
<td>23.1</td>
<td>27.6</td>
<td>17.4</td>
</tr>
<tr>
<td>Information management/communications</td>
<td>13.2</td>
<td>30.8</td>
<td>20.7</td>
<td>17.1</td>
</tr>
<tr>
<td>Public health law</td>
<td>7.9</td>
<td>7.7</td>
<td>22.4</td>
<td>10.8</td>
</tr>
<tr>
<td>Total leadership managerial courses completed, N (percent)</td>
<td>830 (33.6)</td>
<td>212 (41.8)</td>
<td>360 (47.7)</td>
<td>1,402 (38.0)</td>
</tr>
<tr>
<td>Average number of 13 leadership managerial courses completed per person</td>
<td>4.4</td>
<td>5.4</td>
<td>6.2</td>
<td>4.9</td>
</tr>
<tr>
<td>Scientific</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular biology and molecular diagnostics</td>
<td>42.6</td>
<td>41.0</td>
<td>58.6</td>
<td>45.6</td>
</tr>
<tr>
<td>Epidemiology</td>
<td>30.0</td>
<td>38.5</td>
<td>46.6</td>
<td>34.5</td>
</tr>
<tr>
<td>Clinical/medical/pathogenic bacteriology</td>
<td>56.8</td>
<td>64.1</td>
<td>79.3</td>
<td>62.4</td>
</tr>
<tr>
<td>Immunology</td>
<td>58.9</td>
<td>46.2</td>
<td>75.9</td>
<td>60.6</td>
</tr>
<tr>
<td>Virology</td>
<td>40.0</td>
<td>43.6</td>
<td>72.4</td>
<td>47.0</td>
</tr>
<tr>
<td>Environmental/water microbiology</td>
<td>30.5</td>
<td>35.9</td>
<td>37.9</td>
<td>32.8</td>
</tr>
<tr>
<td>Environmental science/environmental health</td>
<td>42.6</td>
<td>41.0</td>
<td>51.7</td>
<td>44.3</td>
</tr>
<tr>
<td>Biochemistry</td>
<td>77.9</td>
<td>64.1</td>
<td>93.1</td>
<td>79.1</td>
</tr>
<tr>
<td>Statistics/biostatistics</td>
<td>43.2</td>
<td>56.4</td>
<td>70.7</td>
<td>50.5</td>
</tr>
<tr>
<td>Laboratory instrumentation/instrumental analysis</td>
<td>56.3</td>
<td>56.4</td>
<td>55.2</td>
<td>56.1</td>
</tr>
<tr>
<td>Bacteriology laboratory</td>
<td>70.0</td>
<td>48.7</td>
<td>86.2</td>
<td>70.4</td>
</tr>
<tr>
<td>Virology laboratory</td>
<td>31.6</td>
<td>35.9</td>
<td>60.3</td>
<td>38.0</td>
</tr>
<tr>
<td>Total scientific core courses completed, N (percent)</td>
<td>1,013 (44.4)</td>
<td>223 (47.6)</td>
<td>457 (65.7)</td>
<td>1,783 (51.8)</td>
</tr>
<tr>
<td>Average number of 12 scientific courses completed per person</td>
<td>5.3</td>
<td>5.7</td>
<td>7.9</td>
<td>6.2</td>
</tr>
<tr>
<td>Average number of 25 courses (13 leadership/managerial + 12 scientific) completed per person</td>
<td>9.7</td>
<td>11.2</td>
<td>14.1</td>
<td>11.1</td>
</tr>
</tbody>
</table>

PHEAL = public health, environmental, and agricultural laboratory
APHL = Association of Public Health Laboratories
Core courses
The 2006 survey showed that sitting PHEAL directors placed more importance on courses, skills, and experience related to management and leadership than on scientific knowledge and experience. This finding is supported by earlier reports that the average directors of governmental laboratories spend most of their time leading and managing a scientific organization rather than acting as a laboratory scientist. This finding is especially true in large PHEALs in which leadership and managerial responsibilities are paramount to a director’s success, and doctoral-level scientist-managers answering to the director serve as chief scientists in various scientific specialties.

However, data from the 2006 survey also show that laboratory directors must continue to possess a strong background in laboratory science as a basic qualification for their positions. PHEAL scientist-managers and directors still view themselves first as scientists and have advanced to their current positions by being productive and successful in that realm. This perception is important because they must be seen and respected as scientifically competent by both their employees and the communities they serve before they can provide the leadership and managerial expertise associated with operating a complex scientific organization.

The continuing need for this scientific background is reflected in high rankings of importance given to molecular biology, epidemiology, bacteriology, immunology, and virology. The list of useful courses identified from the 2006 survey revealed that while state laboratory directors believe that knowledge of other fields (e.g., toxicology, mycology, and medical genetics) may be useful to individuals in their positions, they were seldom important in those positions. At the same time, a list of unnecessary courses, also identified from the 2006 survey, revealed that PHEAL directors were least willing to complete advanced coursework in fields in which they were not personally involved on a routine basis.

Course importance and completion rate
The 2011 survey showed that most current PHEAL scientist-managers and directors have not completed a majority of the 25 core courses, which runs contrary to these same leaders’ belief in the importance of these subjects. This dissonance is supported by the moderately negative rank correlation (−0.58) between the completion rankings of 25 core courses and their importance rankings. While this finding may be due in part to individuals not appreciating some core courses until they are needed, we believe most of this dissonance is related to course availability and access. Most scientific doctoral degrees obtained by PHEAL scientist-managers and directors emphasize science and allow for core courses such as biochemistry, bacteriology, or immunology to be easily accessed and taken. However, these doctoral programs may provide little time or opportunity to pursue such core courses as public health law, surveillance systems in public health, or laboratory management. In addition, mid-career laboratory leaders, when balancing the day-to-day demands of both professional and personal responsibilities, may find it very difficult to pursue additional coursework.

The finding that the average number of core courses completed generally increased with higher-level job classification and education level was expected. However, the two exceptions must be interpreted with caution due to the small numbers of employees in these subgroups who completed the 2011 survey.

The decreasing core course completion rates by laboratory type, when going from local laboratories to state, federal, environmental, and university laboratories, may reflect a need by the smaller laboratories to employ more broadly and highly cross-trained employees. As laboratories become larger with more employees, as positions become more specialized, and as organizational structures become more hierarchical, it also may become less important for a large laboratory to support having nonscientist-managers and non-directors take many courses core to functioning effectively as a laboratory scientist-manager or director.

The significant difference in core course completion rates between laboratorians aged ≤50 years and those aged ≥51 years may be attributed to two factors. One factor may be that core courses become more accessible to individuals as they age and climb the career ladder because both the individuals and their laboratories see greater value in supporting the completion of more core courses. Another factor may be that the older age cohort may have obtained a broader graduate education that included more core courses than did the younger cohort.

A similar core course completion rate for laboratorians with a master’s degree compared with those with a scientific doctorate may be related to the type of master’s degree earned. For example, a professional master’s degree (e.g., master of public health, master of business administration, or master of public administration) may provide graduates with a greater boost to completion rates for core courses than a master of science or PhD in a scientific specialty. Likewise, the higher core course completion rate for laboratorians with a professional doctorate compared with those with
a scientific doctorate may mean the former group had greater access to more core courses during or after their formal education and training.

**Educational and training program needs**

From 2000 through 2010, only 1.8% (1,341/75,203) of students earned degrees from U.S. schools of public health in the program area of biomedicine (e.g., biomedical and laboratory sciences, microbiology, parasitology, immunology, cancer biology, biochemistry, and pathobiology). In 2010, only 1.3% (77/6,109) of students earned master's degrees in biomedicine.\(^{15}\)

Within the past 10–15 years, a number of master's-level programs have been established in which students can choose to emphasize public health microbiology or epidemiology with a practicum or capstone project that involves partnering with a PHL in a state or local health department. However, with rare exception,\(^{16}\) these programs do not provide a primary emphasis on PHL science and practice.

The pool of future PHEAL scientist-managers and directors consists of approximately 5,000 existing scientific and technical PHEAL workers without doctoral degrees and an unknown number of students pursuing doctoral degrees in the biological and chemical sciences. Historically, many PHEAL scientist-managers and directors earned a DrPH or ScD in biomedicine. However, in 2009–2010, only 53 biomedicine students graduated from schools of public health with doctoral degrees,\(^{15}\) and in 2010, only one of these 53 students earned a DrPH, and none earned an ScD.\(^{14}\) More specifically, there is currently no doctoral program in PHL science and practice in the U.S., which makes it very difficult to recruit and maintain, let alone expand, the current PHEAL workforce of 529\(^{1}\) PHEAL scientists with doctoral degrees. To do so, PHEALs must recruit and retain 21 new employees each year with appropriate doctorates in or applicable to PHL science and practice.\(^{17}\)

Today’s limited educational resources and relatively small size of the student population for this specialty area call for only one or two institutions to establish a program in PHL science and practice. Furthermore, currently employed PHEAL scientists are unable or unwilling to leave work for two to four years to pursue a campus-based doctoral degree. These limitations can best be overcome by establishing a doctoral program employing Internet-based distance learning with research performed in the laboratory of the student’s current employer. Such a program could fully support the pipeline needs of the entire PHEAL workforce in the U.S. at minimum cost without requiring students to leave jobs and uproot families. Distance learning also would allow such a program to readily employ PHEAL leaders from across the country to prepare the best training materials and serve as part-time faculty and mentors for students. There is currently an effort under the aegis of the APHL to identify a willing academic entity to establish such a joint academic and PHL doctoral program (Personal communication, Brock Neil, APHL Workforce Development Committee, February 2013).

We recognize that the list of core courses presented in this article represents a comprehensive range of scientific, managerial, and leadership knowledge, and it is unlikely that any one individual would complete all of them. However, scientist-managers and directors must have a broad working knowledge and be capable of applying that knowledge if they are to be successful leaders in today’s public health climate. The U.S. needs academic institutions that offer master's and doctoral degrees in PHEAL science and practice that maximize return on educational investment by successfully merging PHEAL science, management, and leadership components. These core courses also should be emphasized in predoctoral traineeships and postdoctoral fellowships in PHEAL science and practice. However, existing pre- and postdoctoral training opportunities for PHL scientists have emphasized the laboratory sciences while mostly excluding management and leadership.

In addition, these same core courses will prove useful when looking for vehicles to help laboratorians acquire workplace competencies. The ongoing national project to develop workplace competencies for public health laboratorians is developing a dozen domains.\(^{9}\) The 31 core courses identified in this article align closely with 10 of the 12 competency domains. Four of these 10 domains cover scientific discipline-specific laboratory practices (i.e., general laboratory science, chemical sciences, microbiological sciences, and bioinformatics), and six domains cover discipline cross-cutting laboratory practices (i.e., communications, informatics, management and leadership, research, safety and security, and surveillance).

Core courses and competencies also provide important building blocks for creating PHEAL career paths or ladders. As presented elsewhere,\(^{3}\) PHEAL career ladders should be based on levels of education (i.e., high school diploma or general educational diploma through doctoral degree), supervision requirements, experience, and other promotional criteria that depend in large part on core coursework and workplace competencies.

Bringing academic institutions, PHEAL competency-based core courses, workplace competencies, and
field-based PHEAL scientist-managers and directors together should be an important objective if academic and fellowship programs are to prove effective in recruiting, educating, and training an adequate pool of competent future leaders in the field of PHEAL science and practice.

**Study limitations**
The findings in this study were subject to several limitations. First, the data on course importance and course completions were self-assessed and, therefore, subject to personal bias. Second, the response rate for the 2006 survey was 80%, and it’s possible that responding laboratory directors differed in a systematic way from nonresponding laboratory directors. Likewise, the response rate to the 2011 survey was 29%, and responding PHEAL workers may have differed in a systematic way from nonresponding workers. For example, 22 of 105 laboratories that did not provide respondents in the 2011 survey were mostly local public health (n = 11), environmental (n = 4), or agricultural (n = 4) laboratories. Data may have been skewed toward state PHLS, as those laboratories’ employees comprised a majority of respondents in both surveys. Although response rates for survey populations involving thousands of possible respondents often achieve response rates of 25%–40, such low response rates reduce the ability to fully generalize or accurately interpret survey results. Third, because no statistical weights were developed to account for nonresponding laboratorians, the results of the Chi-square tests performed on comparisons of course completion rates among various age cohorts must be reviewed with caution. Data obtained from the small numbers of agricultural and university laboratorians must be interpreted with particular caution.

**CONCLUSIONS**
Thirty-one scientific and leadership/managerial core courses were identified that may provide current and future PHEAL scientist-managers and directors with the knowledge and training needed to function effectively in their positions. PHEAL directors did not identify advanced specialty courses as important if the knowledge they provided was not routinely used by those directors. There was a moderately negative correlation between the rankings of 25 core courses by importance and completion rates. Although completion rates for these core courses generally increased with higher-level job classification, higher academic degree, and employee age, a notable educational weakness among current laboratorians with leadership roles in PHEALs is that they completed, on average, fewer than half of 25 core courses.

There is currently no doctoral program in PHL science and practice in the U.S. In addition, PhD programs in the biological and chemical sciences provide little or no access to management/leadership courses and training needed by PHEAL scientist-managers and directors. These limitations make it difficult to maintain or expand this workforce. Strategies are needed to encourage current and future PHEAL leaders to complete more of these core courses, to encourage academic institutions offering programs and degrees in PHL science and practice to adopt curricula that emphasize these core courses, and to encourage the use of these core courses as vehicles for laboratorians at PHEALs to acquire a wide range of workplace competencies.

The authors gratefully acknowledge the contributions of the many laboratory directors and employees who completed the 2006 and 2011 surveys. The authors also thank Jim Ford and Jamie Hidalgo of the Association of Public Health Laboratories (APHL) for electronically formatting and compiling data for the 2006 survey and Douglas McNamara of APHL for electronically formatting the 2011 survey.

This manuscript was supported by Cooperative Agreement #U60HM00803 from the Centers for Disease Control and Prevention (CDC) and/or Assistant Secretary for Preparedness and Response. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC and/or Assistant Secretary for Preparedness and Response. The National Center for Public Health Laboratory Leadership program was funded 100% from federal funds, with a budget of $958,233.

**REFERENCES**
12. IBM Corp. MrInterview™: Version 5.5. Armonk (NY): IBM Corp.; 2010
Writing for Public Health Reports

Public Health Reports (PHR) welcomes contributions that complement the mission and purpose of the Journal:

• To facilitate the movement of science into public health practice and policy to positively affect the health and wellness of the American public.
• To publish scholarly manuscripts that describe new and innovative ways to deliver essential services, leading to improved quality, enhanced efficiency, and reduced costs.
• To publish evaluations of public health programs that describe models of practice that can be replicated by others and that describe lessons learned.

PHR conforms to Uniform Requirements for Manuscripts Submitted to Biomedical Journals, which is available online at http://www.icmje.org/index.html, including all ethical considerations. International authors are strongly encouraged to seek writing and editing assistance from a native English-speaking editor prior to submitting their manuscript. Submit manuscripts electronically as one inclusive attachment in a Microsoft Word or PDF file to: Editor, Public Health Reports, e-mail <manuscripts@publichealthreports.org>.

We accept manuscripts in each of the following categories: original research (qualitative and quantitative), public health evaluation, public health methodology, case study/practice, brief report, reports and recommendations, systematic review, commentary, and letter to the Editor. Potential authors should indicate for which category papers are to be considered and be familiar with review criteria for that category. Category-specific descriptions, acceptable word counts and number of tables/figures, manuscript formatting, and review criteria are available at: URL: http://www.publichealthreports.org/Authors.cfm#writing. Published manuscripts are indexed or abstracted in MEDLINE/PubMed, Current Contents, EMBASE/Excerpta Medica, País International, LexisNexis, and EBSCOhost.

WHAT TO EXPECT AFTER SUBMISSION

Corresponding authors will receive acknowledgment of receipt within 48 hours. Typically, decisions regarding external peer review are provided within two to three weeks. External peer review does not imply acceptance for publication by PHR. Evaluation criteria for all submissions include, but are not limited to the following: addresses at least one of the core public health functions (http://www.cdc.gov/nphpsp/essentialServices.html), increases the body of knowledge on the topic, employs clear and succinct writing that is free of jargon, offers results/conclusions based on data provided, and is not overly influenced by the opinions and biases of the authors.

YOUR SUBMISSION

Page numbering and line spacing/numbering: To aid in the review process, please include page numbers, use continuous line numbering, and use 1.5-line spacing. Manuscripts should be formatted with 0.75-inch margins on all sides and use 12-point Times New Roman font.

Cover letter: When submitting your manuscript, include a cover letter that contains the following information:

• A description of the article and explanation of why it is unique, relevant, and applicable to PHR.
• A statement that the material has not been published nor is being considered for publication elsewhere.
• A statement indicating Institutional Review Board determination (approval or waiver) for all studies involving people, medical records, and human tissues.
• A statement regarding any potential conflict of interest.
• A disclosure not involving similar or related work submitted or published elsewhere.

Title page: (a) title (short and descriptive); (b) working title; (c) full names of all authors, including their graduate degrees (please limit number of authors to 10); (d) all authors’ institutional affiliations and job titles during the course of the research (and current affiliation and title for corresponding author if different); (e) name, advanced degrees, affiliation, street address, telephone number, fax number, and e-mail address of corresponding author; (f) word count of the text (exclusive of abstract, tables, and references), and the number of charts, tables, and figures.

PHR provides a review timeline within 48 hours. Typically, decisions regarding external peer review; these manuscripts are sent to two or more external reviewers. Recommendations of peer reviewers will not be accepted from authors. For manuscripts being considered for publication after peer review, authors will be required to make a point-by-point response to all peer-review comments and include these responses along with the revised manuscript. PHR makes final decisions on all submissions and will not engage in discussion with authors related to those decisions.

CONTRIBUTIONS TO THE FROM THE SCHOOLS AND PROGRAMS OF PUBLIC HEALTH SECTION

Contributions by ASPPH member faculty and students are also needed for the three ASPPH-sponsored columns of the Journal. Faculty members may submit articles for the following two columns: On Linkages, practice-based activities at the schools and programs; and On Academics, articles about academic public health.

Students, fellows, or working professionals up to two years post-graduation from ASPPH member schools may submit articles for the Student Column. Information on the Student Column may be found at: URL: http://www.publichealthreports.org/resourcecenter/StudentColumnPublicHealthReports_flyer.pdf.

To submit your work for any of the ASPPH columns (On Academics, On Linkages, or the Student Column), first e-mail an abstract to PHRSubmissions@aspph.org using these guidelines found at: URL: http://www.asph.org/document.cfm?page=713. A review committee will decide whether to request a full manuscript.

For complete PHR Writer’s Guidelines, go to http://www.publichealthreports.org/Authors.cfm#writing
Public Health Reports

Subscribe to Public Health Reports

Public Health Reports (PHR) is an informative and accessible resource for practitioners, teachers, and students of public health. The Journal provides important research and key discussions on the major issues confronting the public health community:

- Up-to-date information on disease prevention, health promotion, public policy, and interventions
- Articles on contemporary issues such as tobacco control, immunization, civilian preparedness, drug policy, lead screening, Native American health, tuberculosis control, occupational disease and injury, and environmental justice
- Original, peer-reviewed research and public health practice articles, as well as thoughtful commentary


Mary Beth Bigley, DrPH, MSN, ANP
Acting Editor
marybeth.bigley@hhs.gov

Return this completed card TODAY to renew your subscription to Public Health Reports!

Name
Institution
Address
City State Zip
Country
E-mail (for online access)

How did you hear about PHR?

Individual $90.00 $90.00 $150.00
Institutional $167.00 see website for pricing see website for pricing
Student** $50.00

International Shipping Charge (outside North America): $50.00

Print Only Online Only* Print and Online*

Rates effective August 1, 2013. Price in U.S. dollars and payable in U.S. funds. Price subject to change.

* Includes online access via individual logon account only for individuals, IP address authorization for institutions. Other restrictions apply. Please visit www.publichealthreports.org/OrderNow.cfm for complete details.

** For student subscriptions sent to North America only; students outside of North America must pay individual rate.