# Guest Editorial

## PUBLIC HEALTH LABORATORY SYSTEMS: AT THE CROSSROADS

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Twenty years ago, Walter Dowdle[1] 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."[2] 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.[3,4] 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.[5] 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).[6] 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.[7,8]

### 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.[9] 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.[10] 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,[11] 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.[12] 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[13] 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[8] have raised significant interest in the topic of fee-for-service testing.[14] The article by Loring et al.[15] 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.[9,14] 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.[15] 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.[11] 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.[8] 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.[15] 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.[15] Although previously the topic of billing was rarely addressed publicly or systematically, the National Vaccine Advisory Committee[16] and Trust for America's Health[14] 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.[13] 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.[3,6,8,15]

## 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)[17] and the Public Health Accreditation Board (PHAB).[18]

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.[19]

## 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.[20] APHL and others have helped to identify and publish core functions of state PHLs;[21] 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.[22]

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 have helped to renew and support APHL's efforts for program integration. The Laboratory Efficiencies Initiative described by Ridderhof et al.[23] 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.[24] 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.[25] 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.[23] 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[26] 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.[22,23] Other articles showcase efforts and tools needed to strengthen the role of PHL systems in the community along with clinical and public health stakeholders.[19,27] 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,[28] while also providing evidence for strengthening the PHL infrastructure through workforce initiatives.[29]

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.[30] 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.[29] 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.[31] 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[23] 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.[32] 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,[4] 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.

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