

The Role and Value of Public Health Laboratories in STD Response (Updated)

According to the Centers for Disease Control and Prevention (CDC), the reported cases of all three nationally notifiable bacterial Sexually Transmitted Diseases (STDs), chlamydia, gonorrhea and syphilis, have risen at alarming rates since 2006. The 2015 CDC report further calls for better diagnosis, treatment and prevention of these STDs.¹ Improving diagnosis requires a functioning health-care delivery system of which the public health laboratory is a critical piece of that system. However, the role of the public health laboratory (PHL) in this system has changed over time.

When PHLs were established around the turn of the 20th century, the need for gonorrhea and syphilis testing made them the very first offered clinical tests. Over a hundred years later, STDs remain an important public health problem, and PHLs continue to respond to this challenge, albeit in a slightly different manner.

The increased availability of CLIA-waived and Food and Drug Administration (FDA)-cleared moderate complexity molecular and immunologic testing platforms combined with changes in the healthcare delivery system, such as implementation of the Affordable Care Act (ACA), have resulted in a shift in testing services. The majority of public health screening and diagnostic testing is now performed in clinical and reference laboratories, not in PHLs. Public health laboratories are no longer looked to as the primary provider of STD and infectious diseases screening tests, but rather as a reference laboratory where specialized techniques are used to confirm diagnosis and aid in disease surveillance and response.

This shift of STD screening from PHLs to other settings such as hospital, clinic and commercial laboratories, or community-based outreach sites, combined with the financial challenges brought on by the 2008-2010 recession, has led to the elimination of STD screening tests in some PHLs and raises the question about the future role of local and state PHLs in STD diagnosis, surveillance and response.

This document is intended to update the May 2011 Issue Brief "[The Role of Public Health Laboratories in STD Testing](#)," and to foster continued discussion among PHLs and their partners regarding the current and future value that PHLs add to STD response. The May 2011 Issue Brief raised the following questions, and this document will attempt to provide some insight into the discussions that have taken place in the PHL and public health community in the past four years.

How can PHLs remain competitive in an era of shrinking budgets?

Working with the National Coalition of STD Directors (NCSD), public health laboratorians and program directors have suggested areas for improvement that will allow PHLs to be more competitive, and meet the challenges of sustainability in an era of healthcare reform. These areas include third-party billing, electronic data exchange, use of courier services and consolidation of testing to increase volume and reduce cost-per-test through economies of scale.

While the impact of the 2008-2010 recession to PHLs has not been fully measured, there are published indicators of its impact on funding. An APHL survey covering the time period 2007-2010 identified that state PHL funding decreased by an average of 40 percent and local PHL funding by 11 percent overall.² At the same time, there was a loss of federal cooperative grant funding to many STD programs, including testing, which resulted in further budget turmoil for PHLs. One mechanism used by public administrators to cope with budget restrictions was to incentivize early retirement of higher-paid personnel and thus save on salary and benefits.² However, many of the vacated positions have still not been filled due to budget cuts, hiring freezes and shortages of appropriately trained (and/or certified) medical technologists resulting in an additional work burden for the remaining staff. The loss of institutional memory and experience also has a significant

impact on laboratory operations. The Michigan State Public Health Laboratory reported that it lost more than 300 years' worth of staff experience over the course of three months in 2010-2011.²

Billing

With a decrease in funding sources and potential staffing shortages, PHLs have had to develop diverse strategies to adapt to these changes. One strategy PHLs are investigating is implementing billing capacity with Medicaid and third party insurers. This is not a simple undertaking for PHLs which must work through legislative roadblocks and legal implications, as well as developing a new coding and billing skill set within the PHL. PHLs should also work to ensure that the billing revenue goes directly to the laboratory and not general funds. Despite these hurdles, instituting billing of third party insurers for STD testing services is one way to remain competitive.

Shared Services

Another way to remain competitive and sustainable is to evaluate testing menus, and ensure that the offered services are still vital, necessary and of sufficient volume and/or value to warrant maintenance of the testing services. To address sustainability, APHL and CDC partnered to develop the Laboratory Efficiencies Initiative (LEI) to provide tools that PHLs can utilize to meet the challenges of shrinking budgets and workforce shortages. In some instances, the strategy of developing inter-organizational partnerships can strengthen PHL systems. California PHLs were able to successfully establish inter-organizational forms of cooperation such as consolidation of services and contractual agreements, which improved efficiencies and maintained access to high quality PHL services.³ Other consortiums, such as the Northern Plains Consortium (MT, ND, SD, WY and ID), and the Northeast Environmental and Public Health Lab Directors (NEEPHLD) Consortium (NY, NJ, RI, CT, MA, VT, ME, NH) are working on developing multi-state sharing of testing services.⁴ By providing shared testing services, the availability of high quality testing in any one jurisdiction is assured, although the testing may not be provided locally. In addition, sharing testing services increases testing volumes, and can reduce operating costs, similar to the efficiencies that commercial laboratories experience.

Electronic Data Exchange

Finally, PHLs need to be looking at their informatics capabilities. Although PHLs were not direct recipients of federal funding for meaningful use and electronic data exchange, many are looking for alternative funding sources to improve their capacity for exchanging electronic test orders and results between clinical laboratories, other PHLs, and their PHL laboratory information management system (LIMS). Providing bidirectional interfaces between PHL LIMS and other laboratories is another means to remain competitive in today's current healthcare climate.

What unique benefits can PHLs offer to program partners that reference laboratories cannot?

PHLs are in a unique position to provide specialized testing, subject matter expertise on STD test performance and interpretation and recommendations for improved diagnostics. Specialized testing can include confirmatory testing, surveillance testing for outbreak/cluster response or detection of drug resistance and testing with methods that may not have routinely available commercial assays. Much of this specialized testing relies on the ability to culture the organism, a practice not commonly performed in commercial laboratories with the advent of sensitive molecular assays. PHLs continue to serve as a conduit for referral of specimens to CDC for advanced testing.

Many sexually transmitted infections are reportable conditions, and some states require the submission of a specimen or

The ability to maintain culture also allows for additional specialized testing such as monitoring *Neisseria gonorrhoeae* resistance through both phenotypic and genotypic testing methods, whole genome sequencing of isolates for cluster/outbreak response, or providing validated testing for the detection of oropharyngeal and rectal *Chlamydia trachomatis* and *N. gonorrhoeae* infections.

isolate for confirmation at the PHL. Developing a good working relationship with clinical and other private laboratories within the affiliated jurisdiction allows PHLs to facilitate the submission of additional specimens for enhanced surveillance, test development or method verification.

Public health laboratory experts can also provide value-added consultative services to clinicians and STD program managers on the interpretation of STD test results and suggestions for additional testing that can be used to resolve problem cases or discrepant results. Training on STD testing algorithms, screening guidance, and other aspects of STD laboratory diagnostics can also be a role for PHLs. PHLs could partner with community outreach programs to improve linkage to the PHL and provide technical assistance on appropriate quality management systems and test performance/interpretation for waived STD diagnostic testing. Recent efforts to strengthen the public health workforce have highlighted the need to utilize data driven research to advance public health services. **PHLs are uniquely positioned to assist the public health workforce with subject matter expertise and testing capabilities to achieve population health improvement goals.**⁵

In addition, subject matter experts can encourage for the commercial development of new and improved STD tests that will benefit public health, such as a genital ulcer disease molecular panel, a molecular test that will detect *N. gonorrhoeae* and also indicate fluoroquinolone resistance, or FDA clearance of extra genital specimens (rectal and oropharyngeal) for detection of *C. trachomatis* and *N. gonorrhoeae*. PHL professionals can play a vital role as a key opinion leader in the need for STD diagnostics.

Are there unique testing niches that make sense to pursue in my jurisdiction?

As PHLs develop their informatics capabilities, the storage of STD test data and test utilization can provide a unique niche. Data reported through reportable condition administrative rules only capture numerator data. When testing is performed in the PHL, access to both denominator and numerator data will allow, in partnership with epidemiologists, tracking of prevalence and positive rates, geographic trends and other determinants to better respond to STD cases and outbreaks.

PHLs can become centers for applied research as they develop whole genome sequencing capacity, bioinformatics capacity, and look for better ways to detect antimicrobial resistance in both cultured and culture-independent specimens. PHLs can also partner with academic laboratories and manufacturers to conduct clinical trials and pilot or test performance for new assays coming to market.

PHLs can be looked to as a leader in policy development for STD prevention and control, specifically for testing practices. Working with partners in epidemiology, STD program managers and Title X providers, PHL leaders can help shape the future direction of STD policies.

In conclusion, for optimum STD detection and response, PHLs must demonstrate the value of their services to public officials, program staff, clinicians, and to the general healthcare community. PHLs have a unique opportunity to respond by identifying role(s) that best meet their needs, the needs of STD programs, and the needs of the clients being served. Possible roles have not changed since the May 2011 Issue Brief, but the capacity of each PHL to provide these roles may need to be re-evaluated:

- PHL as a diagnostic screening laboratory
- PHL as a referral and surveillance laboratory
- PHL as a subject matter expert (SME) and key opinion leader
- PHL as an applied research center
- PHL as an advocate for policy development

Where do we go from here?

PHL leaders have the opportunity to guide the future role of PHLs in STD response.

- Does the PHL community work to ensure that all STD screening is of high quality, even if the screening is performed outside of the PHL?
- Does the PHL maintain subject matter expertise in STD diagnostics so that they are looked to for technical consultations?
- Does the PHL develop advanced methodologies for outbreak response investigations, or develop relationships with other laboratories to ensure that advanced methodologies are available?
- Does the PHL look at alternative revenue streams to sustain STD testing, such as third party billing?
- Does the PHL partner with industry to evaluate new testing methods or participate in clinical trial?
- Does the PHL community work with partners to develop policy for STD prevention and control?

PHLs can remain a vital part of the public health system of STD prevention, control and response. It is important that PHL professionals continue to advocate for and help shape their role in public health efforts to reduce the burden of STDs and other infectious diseases of public health significance.

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Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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