

Assessing America's Local Public Health Laboratory Capacity

A 2002 Institute of Medicine report found that the nation's "antiquated laboratory capacity" leaves Americans vulnerable to exotic infectious organisms as well as more mundane microbes, suggesting a pressing need to document and eliminate deficiencies in the nation's laboratory system.¹ Yet, despite the important niche local public health laboratories (LPHLs) occupy in this system, they tend to be overshadowed by their more prominent state counterparts in the public health arena and by the vastly more numerous commercial laboratories in the medical arena. Little information has been collected on their overall capabilities and technical and workforce needs.

To provide a better understanding of America's local public health laboratory assets, the Association of Public Health Laboratories (APHL) conducted the first-ever survey of local public health agencies focusing on laboratory services, staffing and support systems. Findings indicate that America's local public health laboratories face some of the same major challenges as public health laboratories at the state level: insecure and insufficient funding, difficulty recruiting qualified staff and outdated information management systems.

If America's *antiquated laboratory capacity* is to be improved, policymakers, planners and all those engaged in outreach to local public health laboratories must work to resolve these problems. For example, enhanced collaboration among federal, state and local agencies is essential to secure the immediate funding needed to maintain and improve basic laboratory operations at the local level.

APHL will continue to research and highlight the needs of local public health laboratories nationwide and to propose strategies to better integrate these critical partners into the nation's public health system.

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Local Public Health Laboratories: Vital Public Health Assets

It is standard public health practice to provide laboratory services *where the people are*. Thus, as of 2002, an estimated 1,900 local public health laboratories—affiliated with city, county or other local governments—were serving communities throughout the United States.²

Local public health laboratories are a vital asset to the public health system. Although their size and capabilities vary from one jurisdiction to another, local public health laboratories may provide any number of valuable services, ranging from sexually transmitted disease testing to lead abatement evaluation. Generally, they offer:³

- Familiarity with local health problems, enabling them to prioritize laboratory work to better serve the community.
- Strong ties and proximity to community clinicians, public health professionals, private labs, and the local media, enabling a great degree of vigilance to detect emerging health problems and an efficient response in times of crisis.

And especially in larger city or county public health laboratories:

- On-site assistance to health department inspectors for real-time enforcement of local codes and state statutes.
- Capacity to assume the workload associated with most local emergencies. This workload may not necessarily be readily transferable to the state public health laboratory.

An accurate profile of local public health laboratory capabilities is particularly relevant today in light of state and national efforts to better link and support laboratories—public and private—to improve the nation's disease surveillance and emergency response capabilities.

For example, the **National Laboratory System** is an initiative to improve the general level of cooperation and coordination among the more than 170,000 laboratories operating in the United States. With novel infectious agents infiltrating the US at a quickened pace and the evolution of drug-resistant strains of familiar pathogens, a closer working relationship is necessary to speed the verification and reporting of infectious and toxic agents with the potential to impact community health.

The **Laboratory Response Network (LRN)** was formed in 1999 to help laboratories prepare for and respond to acts of terrorism. All of the 125 LRN members—including at least 36 local public health laboratories—use the same validated methods to assure rapid and certain identification of the microbes that cause anthrax, plague and other deadly illnesses.⁴ The network also provides a known chain-of-command for reporting results, managing consequences and sharing data.

Tailoring Services To Meet Community Needs

America's local public health laboratories represent the full spectrum of the nation's cities, townships and counties. Here are snapshots of two local public health laboratories in vastly different communities.

The *City of Milwaukee Health Department's Public Health Laboratory* directly serves the 597,000 residents of Milwaukee and also performs advanced reference testing, fee-for-service testing, and public health surveillance for area clinical laboratories serving the greater metropolitan area. Altogether the city laboratory—with a staff that fluctuates between 30 and 35 employees and an annual budget of about \$2 million—performs work for area laboratories serving roughly 1.5 million people.

The vast majority of all laboratory tests support health department activities, such as outbreak investigations, river and beach pollution monitoring, refugee screening programs, sexually transmitted disease control activities, and consumer safety surveillance. In recent years the laboratory has performed tests to address a number of Milwaukee-area public health problems, including:

- ♦ An *E. Coli* O157:H7 outbreak linked to city restaurants.
- ♦ An outbreak of the waterborne parasite *Cryptosporidium*.
- ♦ Illegal asbestos dumping.
- ♦ Sewer leaks (evaluated using bacteriological studies).
- ♦ Outbreak of multi-drug resistant *Shigella* in day care centers.
- ♦ Influenza (monitored via ongoing surveillance).
- ♦ Lead in candy and seasonings.

The laboratory provides technical support to local community clinic labs serving low-income populations, participates in the national Laboratory Response Network and regularly collaborates with scientists at the Centers for Disease Control and Prevention, local universities, and the county medical examiner on special studies (e.g., the role of viruses in sudden infant death syndrome).

The *Warren County Public Health Laboratory* serves the 20,000 or so residents of Warren County, North Carolina, a rural jurisdiction on the North Carolina-Virginia border about 50 miles north of Raleigh. The laboratory has one full-time technician, supported by four registered nurses.

All services—including tests for pregnancy, fecal occult blood (to screen for colon cancer), Strep and bacterial infections, anemia, gonorrhea, diabetes, and a few others—are provided in support of health department activities and are charged to the programs requesting services (such as the maternal and child health program). The laboratory is covered under a regional CLIA certificate held by the North Carolina state public health laboratory and has no independent budget.

In 2003 laboratory staff performed more than 5,500 tests in-house and sent roughly 1,700 specimens to the North Carolina State Public Health Laboratory for advanced testing for HIV and other diseases. The laboratory also supports some local health investigations. For example, in summer 2004 staff collected blood from elementary school students for lead testing in the wake of an environmental health investigation. The county laboratory recently acquired Internet connectivity to the state laboratory as part of a statewide effort to ramp up surveillance for communicable diseases and bioterrorism.

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Methodology

Invitations to participate in a Web-enabled, 37-question survey were e-mailed in August 2003 to a list of 2,318 local public health agency contacts with e-mail addresses provided by the National Association of County and City Health Officials. Discounting inoperative e-mail addresses and multiple addresses for people in the same local public health agency, invitations reached an estimated 1,800 non-duplicative local public health agencies. There were 525 respondents representing non-duplicative local public health agencies, giving a response rate of about 29%.^{*}

Additional information was collected through four focus groups: one with about 60 directors and other staff of local California public health laboratories held in conjunction with a meeting of the California Association of Public Health Laboratory Directors in October 2003, and three conducted via telephone in January 2004 with a total of 14 local public health agency laboratory directors representing 12 states.

Because not all survey respondents answered all questions, the number of those responding (n) is listed for each datum below.

Testing Services

Most local public health agencies provide services that require laboratory testing.

The majority of local public health agencies (82%) provide services that require some type of laboratory testing and fully 70% provide services that require testing of both human specimens (such as blood or urine) and environmental samples (such as drinking water). Of the fraction of local public health agencies (18%) that provide no services requiring laboratory work, most (88%) serve populations under 100,000 people.[†] (n=451)

Local public health agencies use a variety of sources for laboratory testing.

Overall, about two-thirds (68%) of America's local public health agencies (n=383) rely on in-house public health laboratory services for at least a portion of their testing needs, with the likelihood of using in-house laboratory services directly related to the size of the population served. That is, local public health agencies serving larger cities or counties are more likely to depend on their own laboratories for some clinical and/or environmental testing.

Volume-wise, local public health laboratories in less populous jurisdictions (populations under 100,000) handle on average about 46% of all human testing (n=53) and 30% of all environmental testing (n=133) performed for local public health agencies. In larger jurisdictions (populations of 100,000 or more) these

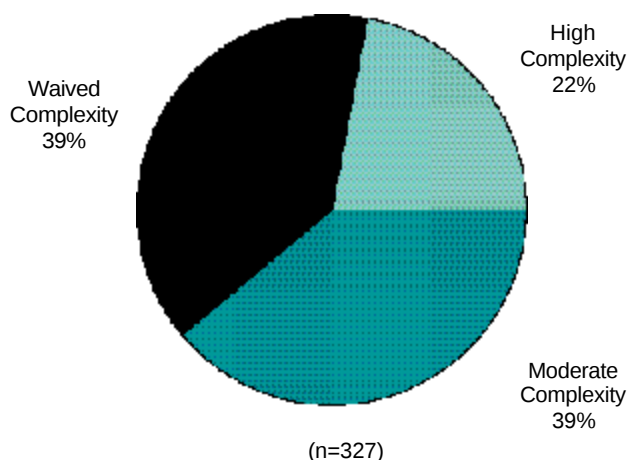
^{*} In cases where more than one response was received from the same local public health agency, the most complete response was used and others discarded. Responses were received from local public health agencies in all states except Alaska, Delaware, Louisiana, Mississippi, New Hampshire, Rhode Island, and South Carolina, most of which have few, if any, locally-governed local public health agencies. Disproportionately more responses were received from larger local public health agencies, which are more likely to have an in-house laboratory.

[†] The fraction of local public health agencies that provide no services requiring laboratory work may be somewhat higher than suggested by the survey data since local public agencies serving populations under 25,000 people were under-sampled and those serving populations of 50,000 or more were over-sampled.

figures rise to an average of almost three-quarters (73%) of all human testing (n=80) and 55% of all environmental testing (n=123) performed on behalf of local public health agencies.

In addition to their own laboratories, local public health agencies use a variety of outside laboratory resources. State public health laboratories are the single greatest source of outside testing and provide most of the laboratory work done for local public health agencies serving populations under 50,000. Other resources, although used less frequently, include commercial laboratories, local hospital laboratories, and laboratories in other local public health agencies, out-of-state state health departments, and universities.

Local Public Health Laboratories' Highest Level of CLIA Certification



Focus group comments indicate that some local public health laboratories are having difficulty maintaining current testing programs due to understaffing, budget cuts and difficulty finding qualified laboratory directors. One county public health laboratory would like to provide more services but is prohibited by county charter from offering tests that compete with private laboratories, even though not all local residents can afford commercial laboratory tests.

Despite obstacles, some local public health laboratories are assuming new responsibilities. For example, a county laboratory in Florida may soon take on clinical testing for local government employees. Several local public health laboratories are participating in a federal program to provide clinical testing services (such as blood cholesterol tests) to low-income, uninsured women over age 45. And local public health laboratory directors in Michigan and Missouri report that their state laboratories are working to beef up bioterrorism test capabilities at the local level.

The bulk of testing performed by local public health laboratories is of low complexity.

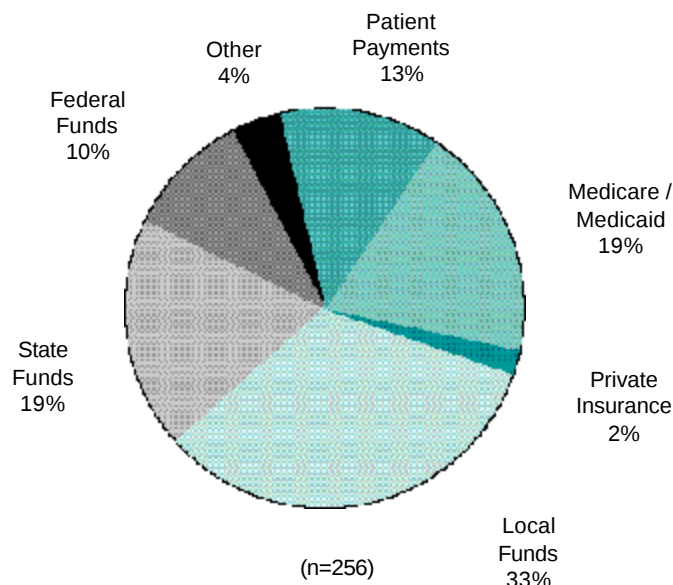
Sixty-nine percent of all local public health laboratory tests are so-called *waived* tests; that is, low-complexity services that can be performed in settings that are waived from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[†] Twenty percent of the tests performed by local public health laboratories are moderate complexity and 11% are high complexity as defined by CLIA. (n=323)

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Seventy-one of 327 respondents (22%) reported that the local public health laboratory has CLIA certification for high complexity testing. Another 39% reported CLIA certification for moderate, but not high, complexity testing, and the remainder (39%) reported that they perform only waived tests.

Laboratories serving more populous communities tend to offer higher-complexity testing services. For example, of the 71 laboratories with high-complexity CLIA certification, 60 serve populations greater than 100,000 and 23 serve populations greater than 500,000. Conversely, 108 of the 128 laboratories performing only waived tests serve populations under 100,000.

Local Public Health Laboratory Revenue Sources



Challenges for Policymakers, Planners

The two greatest challenges facing local public health laboratories are unstable financial support and workforce shortages.

Fiscal Challenges

Almost 40% of respondents rated “poor/unstable financial support” as either 1 or 2 on a five-point scale where 1 represents the “most significant challenge in performing laboratory work for public health programs.” (n=357)

[†] The Clinical Laboratory Improvement Amendments of 1988 (CLIA) establish quality standards for all laboratory testing on specimens derived from humans to provide information to assess health status or diagnose/treat disease or impairment. CLIA regulations are based on the complexity of the test method; thus, the more complicated the test, the more stringent the requirements. Three categories of tests have been established: waived complexity, moderate complexity and high complexity. CLIA specifies quality standards for proficiency testing, patient test management, quality control, personnel qualifications and quality assurance for laboratories performing moderate and/or high complexity tests. Laboratories performing tests that are exempt from CLIA requirements (i.e., waived tests) must enroll in the CLIA program and follow manufacturers' test instructions.

Annual Local Public Health Laboratory Budget By Size of Population	
Size of Population Served	Average Annual Budget
<100,000	\$54,021 (n=96)
100,000 to 500,000	\$229,914 (n=73)
>500,000	\$1,253,723 (n=34)

On the whole, local public health laboratories receive about half of their funding from local (33%) and state (19%) treasuries combined, followed by payments from public and private health insurers (21%), direct payments from patients (13%), and federal grants (10%). (n=256)

Of note, several local public health laboratories rely heavily—or exclusively—on just one revenue source. For example, 50 laboratories (20%) receive at least three quarters of their funding from the local government, and, of these 26 receive *all* of their funding from the local jurisdiction. Six laboratories receive all of their funding from the state, 2 from the federal government, 2 from direct patient payments, and 1 from Medicare/Medicaid.

Workforce Challenges

The US Bureau of Labor Statistics reports that fewer than 5,000 new laboratory scientists enter the workforce annually, less than half those that are needed each year.⁵⁶ While all of America's medical laboratories are suffering the effects of this shortage, several local public health agency staff reported in focus groups that their laboratories are particularly disadvantaged because of government hiring constraints and generally lower salaries than in the private sector.

Almost a third (29%) of local public health laboratories employ no microbiologists and no chemists. (n=257) Conversely, 90% use medical staff or paraprofessionals to perform at least some laboratory tests; presumably waived complexity tests since CLIA does not authorize these professionals to perform higher-level tests. (n=293) Just under half (44%) of local public health laboratories have no designated laboratory director. (n=364)

Once staff are on board, training is also problematic. More than half of local public health laboratories (56%) have no budget for continuing education for laboratory staff (n=308), and a significant minority of respondents (44%) reported difficulty finding continuing education opportunities for laboratory staff. (n=252)

Inadequate Information Technology Support

Two-thirds (67%) of local public health laboratories have no dedicated laboratory information management system (LIMS) to track specimens, record and report test results, and otherwise handle laboratory operations. (n=330) In focus groups, some local laboratory directors reported the use of paper systems to manage laboratory work. Of those with an electronic LIMS, about half (53%) lack the ability to communicate directly with the state public health laboratory, a significant omission given the large number of local specimens referred to the state laboratory for analysis overall. (n=142)

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Inconsistent Communication Between Local and State Public Health Laboratories

Legal ties between state and local public health laboratories vary across jurisdictions and impact the level of communication between the state and local levels. Thirty-eight percent of local public health laboratories are subject to governance by the state laboratory as a result of state statutes or regulations. Sixty-two percent of local public health laboratories report local governance. (n=455) (However, some locally-governed public health laboratories may be subject to regulatory oversight by the state if the local laboratory is covered under a multiple-site CLIA certificate held by the state public health laboratory.)

Survey results show that staff in a third of local public health laboratories (33%) communicate with the state laboratory at least weekly. About another third (36%) communicate monthly or quarterly, and the remainder communicate “very infrequently.” (n=360)

Such communications are important as the state public health laboratory is a critical source of information on laboratory technologies, quality assurance practices, and disease trends (such as the emergence of a multi-drug resistant strain of a familiar bacterium). At least one subject raised in focus group conversations suggests a need to improve communications between state and local public health laboratories. Several focus group participants—including all of those in one group—indicated that they were unaware of the national Laboratory Response Network, a well-defined laboratory scheme for testing samples associated with suspected biological and chemical terrorism. All state public health laboratories are members.

Acknowledgements

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End Notes

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