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Public Health Laboratories in a Changing Health Care Landscape

The nation's disease control infrastructure is vulnerable to changes in the financing and delivery of health care services.

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- ◆ *Consolidations, mergers, and buyouts of health care systems, with complex referral patterns and business relationships.*
- ◆ *"Critical path management" of patients, and corporate oversight of physicians' practices.*
- ◆ *Inpatient care shifting to outpatient settings.*
- ◆ *Capitated managed care emerging as the dominant form of health care delivery.*
- ◆ *Downsizing and strict financial controls in clinical laboratories.*
- ◆ *A change in the clinical laboratory's role from a revenue center to a cost center.*
- ◆ *Emergence of "non-culture" technologies for microbial diagnosis.*
- ◆ *Increased use of empirical antibiotic therapy.*
- ◆ *Fewer cultures typed or referred for identification beyond the needs of an individual patient's care.*

Current health care trends are having a profound impact on private sector clinical microbiology laboratories, as documented in a recent Lewin Group Report commissioned by ASM¹. What do these trends mean for the nation's public health system, including government-operated public health laboratories (PHLs)? Plenty, as it

¹The complete Lewin Group report is available on-line through the ASM website at <http://www.asmtusa.org/pasrc/reports.htm>.

turns out.

The Laboratory's Central Role in Disease Control

Disease surveillance and reporting, the backbone of communicable disease control, depend heavily upon the work of clinical and public health laboratories. In every state, laboratories and physicians report infectious diseases to public health authorities, and many microbial isolates are referred to PHLs for confirmation and typing. These reports are monitored by epidemiologists for trends and disease clusters, which may trigger prevention and control measures. This system assures the early detection and prompt response needed to stop community outbreaks before they can spread out of control, and serves as a sentinel for the identification of newly emerging or resurging pathogens. Typically, this work goes on outside of the public view, protecting families and communities from microbial threats which they never knew existed. It is made possible by a partnership of clinical and public health laboratories operating with the necessary resources to "go beyond" individual patient care and to provide population-level services and information. However, recent health care trends have made this partnership vulnerable.

Clinical Laboratories and Public Health

Private sector clinical laboratories contribute to public health efforts in at least two ways: by diagnosing and reporting communicable diseases and by working with PHLs for the referral, confirmation and typing of microbial isolates. These laboratories provide a wide range of microbiology services, primarily focused on individual patient diagnosis and treatment, but sometimes having community-wide implications. Because clinical laboratories contribute a large share of the infectious disease reports in the U.S., they

are an integral part of population-level community health efforts. In addition to this primary diagnosis and reporting, they frequently refer selected cultures to PHLs for confirmation and typing, and work closely with public health departments to control disease outbreaks.

The quality and scope of microbiology services in clinical laboratories has improved dramatically over the past 15-20 years, to the point that the largest ones have reference capabilities that exceed those of many PHLs. However, many clinical microbiology directors report that they are no longer allowed to perform "extra" testing on patients' samples for public health purposes which go beyond the needs of individual patient care. These decisions have been shifted away from laboratorians, to administrators and insurers, who now require "critical path management" of patients, often with the view that public health testing is an unnecessary added cost.

The Role of Public Health Laboratories

For over 100 years, PHLs have played a pivotal role in disease surveillance, by providing specialized reference microbiology for clinical laboratory isolates, by performing serological or molecular typing needed to identify disease clusters and sources, and by providing primary laboratory services for high risk clients seen in both public and private sector clinics. In addition to medical microbiology, the nation's PHLs provide a wide variety of other analytical services, including environmental chemistry and microbiology, toxicology, and neonatal metabolic screening. Taken together, the 50 state and 1,000 city and county PHLs comprise a laboratory network that provides services directly or indirectly to the entire U.S. population. State PHLs perform tests on over 20 million samples per year.

Throughout their history, PHLs have adapted to changes in public health priorities and private sector laboratory capacity. The role of PHLs varies widely between different locales, but in general they are expected to provide a core set of services which include support of communicable disease clinics in local health departments, plus population-based disease surveillance, environmental monitoring, and response to outbreaks.

The Clinical Laboratory/PHL Partnership

Clearly, then, both clinical laboratories and PHLs are needed to protect and preserve the health of our communities. However, recent changes in health care delivery require that we reexamine our basic assumptions about how public- and private-sector laboratories should work together on behalf of the public's health. Will PHLs continue to occupy their same niche, buffered against the health care market forces swirling around them, or is it time for them to make a major adaptation to their changing environment? Is it realistic to assume that clinical laboratories will continue to play an active role in population-level disease surveillance despite their financial squeeze? If so, how can we best encourage and support them? If not, how will we assure that community outbreaks and newly emerging diseases will be detected promptly? As reported by the Oregon Laboratory Partnership Workgroup: "...public health laboratories must re-examine their role and relationship with other laboratories, as well as the capacity of the entire public-private laboratory infrastructure to support disease prevention and control efforts." To find answers to these questions, we must consider the interaction of managed care and public health in a more general sense.

Managed Care Organizations and Public Health - Partners for Prevention?

Public health programs and managed care organizations (MCOs) would be expected to have a common interest in providing preventive services which improve the health of the populations they serve - for example, immunizations, sexually transmitted disease screening, Pap smears, prenatal care, and other early detection and treatment activities. The CDC Managed Care Working Group reported in 1995 that MCOs could "play a powerful role in prevention" because 1) they are "rapidly becoming a major source of health care for the beneficiaries both of employer-funded care and of the publicly funded programs", 2) they "historically have included prevention", and 3) they "represent organized care systems that take responsibility for defined populations." This optimistic view assumes that an MCO will take the long view toward improving the health of its enrolled members, regardless of whether or not these members will later switch to another MCO. In an ideal future scenario, then, if everyone is covered by either public or private health care insurance, and prevention-oriented managed care is the predominant delivery system, all MCOs will benefit from improving the health of the entire population over time. This sort of "all ships rise with an incoming tide" argument is perfectly consistent with the goals of public health.

Since most large U.S. clinical microbiology laboratories are now part of, or hold contracts with, managed care organizations (MCOs), they are subject to business decisions and policy directions from MCO administrators and payers. Theoretically, then, if MCOs have a genuine interest in population-level prevention services, they would encourage clinical laboratories to participate fully in community health work which goes beyond the needs of individual health care, without a strict emphasis on the financial bottom line for a given individual patient. This might mean that PHLs, especially those in areas with high penetration of managed care, could experience an increase in reference test volume, disease reporting, political support, and perhaps even formal contractual collaborations with MCOs and their clinical laboratories.

However, in reality, just the opposite picture is emerging.

PHLs and Health System Change - The Reality

A second recent study by The Lewin Group, commissioned by U.S. Department of Health and Human Services (DHHS)², found that managed care and other health system changes have actually had negative effects on PHLs and have made it more difficult for them to fulfill their mission. This study was commissioned as part of ongoing research regarding the public health infrastructure by the Office of the Assistant Secretary for Planning and Evaluation, DHHS.

The Lewin Group used several methods to study the effect of health system changes on PHLs. These included: 1) literature review, including peer reviewed journals and other sources; 2) interviews of 54 experts, including clinical laboratory directors, PHL directors, federal officials, state and county epidemiologists, MCO laboratory services directors, organizations of laboratory officials, academic researchers with experience in PHLs, and executives from commercial laboratories and hospitals; 3) a survey of state PHL directors (49 responding); and⁴ 4) formal case studies of three states (Michigan, Tennessee, and Washington). Selected key findings from the study are shown in Table 1.

The Lewin Group confirmed that while PHLs continue to play a vital role in the public health infrastructure, the private sector clinical laboratory services market is "extremely

²This report is available through the DHHS website, at <http://aspe.os.dhhs.gov/health/reports/phlabs/front.htm>.

competitive and focused on efficiency and cost reduction", due to "overcapacity, increased outpatient testing, and intense price pressure from payers." These private sector dynamics were perceived as having changed the relationship between health care systems, clinical laboratories, and PHLs. In fact, the interaction between public and private laboratories and managed care now takes place in a volatile context of government involvement, health care market changes, and rapid advances in information technology (Figure 1).

Among 49 state PHL directors responding to the survey, 27 reported that health care changes were having adverse impacts on their laboratories. Fifteen state PHLs reported a reduction in test volume, mostly attributed to increased involvement of private laboratories in outpatient and public sector testing. Several state PHLs reported an erosion of disease reporting efforts, attributed partly to out-of-state reference laboratories failing to comply with disease reporting laws in the states from which specimens originated.

Several PHL directors reported problems in obtaining payment from MCOs for tests performed by the PHL for MCO members. For example, an MCO client may seek treatment at a local health department, which refers specimens to the PHL. However, when the PHL bills the MCO, payment is refused because the PHL is not the MCO's contract laboratory and there was no prior authorization for "out of plan" services. This is a problem for PHLs because they cannot refuse samples submitted through the public health system, they are unable to bill the local health department or the client for the service, and they are not funded adequately to subsidize the testing of the MCO-enrolled population.

Collaborations and arrangements between PHLs, private laboratories and MCOs could

help mitigate this problem, but the Lewin Group report reveals that very few such relationships exist. Only 15 PHL directors reported any type of contractual or other relationship with MCOs, providers, or private laboratories, and even these were "very limited and specific arrangements." Of these 15, only four had contracts with MCOs, four had contracts with private laboratories, and one had a contract with a provider. A surprising finding was that the probability of a state having collaborations with MCOs or private laboratories was unrelated to the level of managed care penetration in that state. Several PHLs expressed interest in marketing their services to MCOs, but these efforts are still preliminary. Some positive collaborations were reported around specific public health services, such as surveillance for antimicrobial resistance, HIV, prenatal hepatitis B testing, and tuberculosis.

Competition from private laboratories for public health "business" was a concern expressed by many who participated in the Lewin Group study. As financial pressures have forced clinical laboratories to search for testing volume and revenue wherever they can be found, some have naturally looked to local health departments, community health clinics, and other providers who represent the traditional PHL client base. Some of these community providers have chosen to contract with private laboratories because it will reduce their costs (in cases where the PHL is already charging a higher fee for the same testing), or improve their service (e.g., courier pick-up of samples, faster reporting times, electronic transmission of results). This has placed many PHLs in an unfamiliar position - competing for public health workload against private laboratories.

PHL directors understand that their clients must use the highest quality services available at the lowest cost, but they do have some legitimate concerns about private laboratory competition. For example, if the test volume and revenue in PHLs diminish greatly, will they be able to maintain the critical mass of staffing and other resources

needed to support all the population-level testing which is crucial for disease control, but is not billable to anyone (e.g., typing, outbreak investigations, vaccine-preventable disease surveillance, rabies exams, influenza surveillance, etc.)? Because financial pressures will not allow private laboratories to provide "charity care", will uninsured and disenfranchised clients receive the services they need to prevent communicable diseases of public health significance? Will disease reporting and surveillance be fragmented or disrupted by out-of-state laboratories that may not report diseases or refer isolates to PHLs as required by state laws? The Lewin Group report and other studies point to a need to re-conceptualize clinical and public health microbiology services in the U.S. in a different model, with emphasis on collaboration and information sharing.

Toward a National Laboratory System

Clearly, the integrity of the nation's disease surveillance infrastructure depends upon a cooperative network of clinical and public health laboratories. Writing in *U.S. Medicine*, Drs. Joseph McDade and James Hughes of the National Center for Infectious Diseases recently underscored the need for a national laboratory system with "unique and complementary roles" for public health and private clinical laboratories. They warn us that laboratory testing in the U.S. is being undermined by several forces, and that our ability as a nation to acquire essential disease surveillance data could be seriously compromised. They identify these forces as: "the conflict between cost-containment efforts in administering health care and the need for essential laboratory data; a misperception that public and private sector laboratories compete and duplicate efforts; and the lack of a well-defined national laboratory system." Elements of such a system already exist for selected diseases, such as tuberculosis and enteric bacterial

pathogens, but a truly seamless, comprehensive approach is needed to prevent gaps in surveillance for all reportable diseases.

Laboratory services to protect the public's health, whether provided by PHLs or clinical laboratories, are not highly visible to policy makers or the general public. However, our entire framework for controlling communicable diseases is built upon this laboratory foundation. Because health care in the U.S. is being carried out increasingly as a purely business enterprise subject to market forces, this foundation is being eroded by efforts to deliver the minimum care necessary to individual patients, at the lowest cost, often ignoring the secondary impact of a patient's illness on the entire population.

Those of us working in public health and clinical laboratories must build collaborations and relationships which assure that the highest quality services are available to everyone, and that we work together as a system to protect the health of the communities in which we live.

Suggested Reading

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Table 1. Selected key findings of The Lewin Group's report on public health laboratories and health system change

- ▶ **A volatile health care environment for public and private laboratories**
- ▶ **Reduction of testing volume in PHLs**
- ▶ **Reduced reporting of diseases**
- ▶ **Difficulty in obtaining payment for tests with associated fees**
- ▶ **Few examples of contractual or collaborative agreements with MCOs and private laboratories**
- ▶ **Competition from large commercial laboratories**
- ▶ **PHLs adversely affected by managed care and other health system changes**

Source: The Lewin Group, 1997