

## GUEST COMMENTARY

# Modernization of Public Health Laboratories in a Privatization Atmosphere

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### INTRODUCTION

Public health laboratories are essential components of the nation's public health infrastructure. Unfortunately, the important role of such laboratories is not well recognized (4, 5). Views of the contemporary role of public health laboratories vary greatly, depending on the perspective of the observer. Advocates argue that such laboratories have experienced serious erosion and need strengthening. They cite the many historical and continuing contributions of public health laboratories, e.g., helping to improve the sanitation of food and water and to control infectious diseases, as testimony of their enduring value. Proponents of privatization recommend that some or all of the traditional public health laboratory functions be transferred to the private sector because laboratory technology is broadly available and to reduce public-sector spending. Legislatures may view public health laboratories as a commodity of increased or diminished value in an era of health reform and budgetary shortfalls. These issues are further complicated because there is no single model of a typical public health laboratory. All state health departments have laboratories, and a survey conducted in 1992 and 1993 indicated that approximately 1,700 (60%) of 2,888 local health departments perform some form of laboratory testing (2a). However, the sizes of laboratories and the scopes of their activities vary enormously (4).

The public and private sectors have distinct niches and overlapping responsibilities in meeting the nation's health needs. However, because of changing roles and responsibilities, new arrangements are needed to identify the specific functions of public- and private-sector laboratories, facilitate collaboration in areas of shared responsibility, and prevent unnecessary duplication of services. We propose that local public health institutes be formed, with public health laboratories as founding members, to improve strategic planning for public health.

### ROLE OF THE PUBLIC AND PRIVATE SECTORS IN ENSURING THE NATION'S HEALTH: A CONTINUUM OF RESPONSIBILITIES

In 1986, because of growing concern that the nation had lost sight of its public health goals, the Institute of Medicine of the U.S. National Academy of Sciences commissioned a committee of experts from government, academia, and industry to conduct a comprehensive analysis of public health. The conclusions and recommendations of that expert com-

mittee were summarized in *The Future of Public Health* (7). That report described public health as "what we, as a society, do collectively to assure the conditions in which people can be healthy" (7, p. 1). It concluded that although concerned groups nationwide generally agree on the mission of public health, few parties agree on how to translate this mission into action.

*The Future of Public Health* affirmed the role of government in fulfilling the mission of public health; states were considered "the central force in public health" (7, p. 8). Notably, the report also clarified the respective roles of the public and private sectors: as the mission of public health is addressed in part by individuals and private organizations, public health agencies are responsible for ensuring that all vital elements of these programs are in place and that the mission is adequately addressed. The core functions of public health agencies at all levels of government were given as assessment (identification of problems), policy development, and assurance (that necessary services are provided by the private or public sectors) (7).

In Table 1 we propose a list of unique and shared functions of the public and private sectors in providing for the nation's health. The list is based in part on earlier publications on related topics (1, 4, 5, 11, 12). The functions listed in Table 1 for the public health sector are consistent with the traditional roles of assessment, policy development, and assurance, whereas private-sector functions reflect responsibility for health care for individuals. The shared functions in Table 1 are truly a blend of responsibilities and activities, and collaborations exist in many areas. For example, local and state health departments, and frequently the Centers for Disease Control and Prevention, are responsible for responding to disease outbreaks in the community, but individual physicians, hospitals, and clinical laboratories are invaluable sentinels for the early detection of unusual disease trends. Industry is a significant contributor to vaccine development and production, but research sponsored by universities, institutes, and government agencies contributes significantly to the development, evaluation, and quality assurance of vaccines. However, although collaborations may assist the public and private sectors in meeting their respective functions, they do not relieve either sector of their specific responsibilities.

Confusion about the public sector's and the private sector's functions persists and presents a major impediment to effective public health action. *The Future of Public Health* notes that "decision making in public health, as in other areas, is driven by crises, hot issues, and the concerns of organized interest groups. Decisions are made largely on the basis of competition, bargaining, and influence, rather than comprehensive analysis"

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TABLE 1. Functions of the public and private sectors in maintaining the health of the nation

Sector with responsibility	Function
Public health sector	Conduct population-based disease surveillance Conduct epidemiologic investigations of new diseases and syndromes Establish national and local health goals and priorities Conduct environmental assessments (air, soil, food, water, vectors) Assess health status of and disease risk for populations Establish the national research agenda; fund and conduct research Ensure the quality of public and private laboratories Perform mandated laboratory testing, including neonatal and forensic testing Establish standards, codes, and regulations; license laboratories or products Develop disaster response plans
Public and private sectors	Investigate disease outbreaks Trace contacts of persons with infectious diseases Provide care and services for indigent and hard-to-reach people Develop and standardize health-related databases Develop communications networks Conduct cost-benefit and cost-effectiveness evaluations Develop and evaluate vaccines Develop and evaluate diagnostic reagents and techniques Conduct immunization programs Evaluate the effectiveness of prevention strategies Conduct health promotion and public education programs Perform professional education and training
Private sector	Deliver health care Perform clinical diagnostic testing Report cases of disease to public health agencies Determine health status or provide disease assessment of insured populations Establish organizational research goals; conduct research Develop drugs Perform quality assurance of respective organizational laboratories

(7, p. 4). Providing clinical laboratory services related to patient care for indigent individuals is a good example. Many state public health laboratories have been designated by their governing bodies as the providers of such services. Proponents of privatization argue that such testing can and should be done by private-sector laboratories. In our view, clinical laboratory testing for indigent people remains a shared responsibility. Privatization of this service should be a local decision that considers the capabilities of public- and private-sector laboratories and how best to meet local health goals.

#### CLINICAL VERSUS PUBLIC HEALTH LABORATORY TESTING

Testing is considered clinical when it is done for the care and management of individual patients; the private sector should take the lead in clinical laboratory testing. Situations in which public health laboratories could justifiably perform clinical tests include the following: (i) when mandated by statute (e.g., screening neonates for metabolic disorders), (ii) unusual or rare diseases, when public health laboratories have a laboratory diagnostic capability that is not available in commercial laboratories, (iii) when a diagnosis can be made only by a new technology that needs controlled evaluation (e.g., testing for hantavirus during the early stages of its identification as an etiologic agent in the United States), (iv) in emergency situations (e.g., communitywide disease outbreaks, when coordination of testing requires that a large number of specimens be sent to a central laboratory to test for a wide variety of possible infectious and noninfectious causes), and (v) as part of special clinical or epidemiologic studies of a given disease or condition.

Some examples of public health laboratory testing include the following: (i) tests for microorganisms, toxicants, or pollutants in air, food, soil, or water; (ii) confirmatory or reference diagnostic testing for diseases of potential public health importance; (iii) subtyping of microorganisms for epidemiologic purposes; (iv) assessment of antibiotic resistance patterns of locally circulating strains of bacteria; and (v) development, standardization, and distribution of "orphan" reagents and products.

The scope and purpose of clinical and public health laboratory testing are quite different, and neither type of testing alone is capable of addressing the health needs of the nation. A given test can usually be done equally well in either a public health or a private-sector laboratory. The real difference is the objective of the testing, which is unique to each sector, and the needs of the consumer for the information that is obtained. The principal purpose of clinical laboratory testing is to diagnose active disease; public health laboratory testing is designed primarily to assess the health status of the community and to prevent illness.

Testing for enteric pathogens illustrates the difference in responsibilities. Stool specimens from a person with an enteric illness may be cultured for pathogenic bacteria in a clinical laboratory and a given species may be recovered. Such test results are usually considered sufficient for patient management, and empiric therapy is administered. In contrast, state public health laboratories subtype *Salmonella* isolates serologically and characterize isolates of *Escherichia coli* O157:H7 by molecular biology-based techniques to determine whether the patient's illness is sporadic or if other persons in the community have been infected with the same strain. Subtyping information is transmitted electronically to a common database.

These surveillance systems can detect an outbreak caused by a particular strain, even if it occurs simultaneously in several states. For example, pulsed-field gel electrophoretic (PFGE) analysis of *E. coli* O157:H7 isolates by the Colorado Department of Public Health and Environment allowed the prompt identification of contaminated beef patties that had been distributed nationwide. Twenty-five million pounds of frozen patties were recalled and hundreds of additional cases of illness were prevented (3). *Salmonella* serotyping by public health laboratories has detected many outbreaks of enteric illness involving thousands of persons and has ultimately led to the detection and elimination of the source of infection (6, 9). A partnership should exist in which clinical laboratories provide a representative sample of isolates to state public health laboratories for subtyping for public health purposes.

PFGE analysis of *E. coli* O157:H7 isolates by state health laboratories began as a regionalized activity: the Centers for Disease Control and Prevention transferred the technology to four state health laboratories, which offered testing as a service to other laboratories (16). No consensus criteria for determining the types of public health laboratory testing that should be performed at the local, state, regional, or federal level exist, but criteria might include the utility of the technique; the demand for testing; the availability of technology, facilities, and expertise; the availability of resources to ensure the timely testing and reporting of data; the minimum throughput necessary to ensure expertise; the degree of centralization needed to provide adequate aggregation of data, both temporarily and geographically; and cost-effectiveness. Because of its public health utility and demand for testing, PFGE testing is now available in more than 20 state health laboratories, and additional states plan to add this capability.

Although regionalization of certain specialized testing has been implemented successfully, consolidation of the 54 state and territorial public health laboratories into a smaller number of regional laboratories seems an impractical task. Each state has the prerogative to organize its public health system as it chooses, and the formation of regional laboratories would require multiple interstate compacts or treaties. Agreement on the regionalization of certain services is a more practical approach.

Just as there are exceptions in which clinical testing can justifiably be performed in a public health laboratory, situations in which it is desirable to have commercial laboratories perform tests in support of population-based public health programs may develop. For example, a state public health laboratory conducting an environmental assessment program or performing serotyping might decide to contract with the private sector for certain tests, provided that the commercial laboratories meet certain criteria for performance. However, under the contracting arrangement, full responsibility for the assessment program appropriately remains with the state health laboratory. As indicated in *The Future of Public Health*, "this basic function of public health (assessment) cannot be delegated" (7, p. 7).

Public health laboratories also provide assurance functions that are essential for maintaining the nation's laboratory capabilities. For example, state laboratories can provide continuous assurance of the competency of local laboratories (2) and a reliable source for nonstandard, nonroutine laboratory testing (specialty or orphan testing). State health laboratories can also ensure adequate follow-up testing during disease outbreaks when routine testing fails to identify a cause. Nonstandard diagnostic algorithms and techniques are usually required in outbreaks with unknown etiologies; sometimes, the techniques are still experimental and are not yet approved for use in the

private sector. Moreover, the choice of the next test to be performed with patient specimens frequently depends on the outcomes of current tests and cannot be anticipated. In these outbreaks state health laboratories generally provide a better source of laboratory testing than commercial laboratories; state laboratories maintain nonstandard capabilities for laboratory testing and are not encumbered by legal or regulatory requirements in such situations, factors that could limit testing by the commercial sector. Without this capability, new infectious diseases or etiologic agents and newly recognized associations with known microorganisms might not be detected.

State health laboratories also ensure that a backup capability for clinical and other public health laboratories will always be available in the event of unanticipated failures to perform tests, e.g., because of disasters, loss of critical personnel, default of contractors, withdrawal of a commercial diagnostic reagent from the marketplace because its performance was unsatisfactory, or failure of critical instruments. Backup capabilities need not be on-site at the state laboratory but can be made available by other laboratories that comprise the state public health laboratory network. Many examples of extensive assistance during major disasters are available.

Maintaining a strong network of state public health laboratories also militates against a marketing strategy that attempts to create a laboratory testing monopoly and to control the costs of testing.

## PRIVATIZATION INQUIRIES

During the last 5 years, many states have undertaken reviews of government programs to determine whether certain functions might be performed better in the private sector; state public health laboratories have been included in these evaluations. In a survey of state public health laboratory directors conducted in 1996, 19 of 32 respondents indicated that a review of their programs had already been undertaken or was planned (3a). For example, boards or commissions were established in Illinois, Michigan, and Kansas to review government programs. Each advisory group had at least two features in common: (i) they were composed of representatives of the public and private sectors, and (ii) their goal was to provide quality service to citizens in the most cost-effective manner, regardless of the provider. Criteria for privatization decisions for the Michigan Commission are shown in Table 2. Possible outcomes included the following: privatization, elimination, retention as a government function, or modification of the program. Michigan's public health laboratory retained all of its programs when they were evaluated by these criteria. We believe that state laboratories will uniformly fare well when they are evaluated by relevant criteria, such as general characteristics of the activity, accountability in terms of process or outcome, achievement of higher dependability of services, providing services not otherwise available, continuing need for programs, and level and quality of services needed (Table 2).

Cost-effectiveness has been the driving force for most privatization reviews. However, we note that the Kansas Council on Privatization was asked to "identify methods by which members of the public and private sectors can work together to accomplish desirable public policy objectives" (Kansas Senate Concurrent Resolution 1626, 1994). Thus, privatization reviews are also manifestations of the continuing need for more effective integration of public- and private-sector programs.

TABLE 2. Criteria for privatization decisions by the Michigan Commission on Total Quality Government<sup>a</sup>

Criterion
1. Ability to specify the requirements of the service in advance of production
2. Ability to switch from one producer to another without serious disruption in service delivery
3. Achievement of tangible benefits, such as operating or capital cost savings, higher-quality services, providing services not otherwise available, risk sharing, shorter implementation time, and solving political problems
4. Accountability in terms of process or outcome
5. Amount of efficiency gain
6. Availability or potential availability of competitive private-sector producers
7. Characteristics of the activity (those concerning policy management, regulation, objectives related to equity, discrimination, stability of services, and social cohesion)
8. Continuing need (if a program is not needed, it should be eliminated)
9. Control of program or activity (necessary participation of the universities, State Board of Education, and the legislature)
10. Costs of resuming government production if privatization or elimination options do not materialize as planned
11. Independence between the nature of the final product and the methods used in its production (if hands-on control of the production process is necessary, privatization may not be a viable alternative)
12. Legal constraints that may impede privatization efforts
13. Determination of the level and quality of services needed
14. Monitoring the costs of government agencies if privatization is the selected option
15. Transition costs associated with shifting public-sector service delivery to private-sector service delivery.

<sup>a</sup> Derived from Executive Order 1994-5 from the governor of Michigan in 1994.

### THE PUBLIC HEALTH INSTITUTE

The public and private sectors must develop better mechanisms to ensure effective strategic planning and resource allocation, especially in areas of shared responsibility. Public health institutes can provide such a forum. For example, the Michigan Public Health Institute (MPHI), founded as a non-profit organization in 1989, is a consortium of government agencies, researchers from Michigan universities, and other organizations that addresses local health issues. Founding members include the Michigan Department of Community Health, Wayne State University, Michigan State University, and the University of Michigan. The mission of MPHI is to contribute to the improvement of the public's health through increased collaboration among the partners and other interested organizations. Core program areas include, among others, health care systems, policy, and financing; laboratory services and infectious diseases; data systems, evaluation, and training; health promotion and chronic disease prevention; substance abuse prevention; and violence and injury prevention. The day-to-day operations of MPHI are administered by an executive director. The head of the Michigan Department of Community Health serves as president of a 12-member board of directors; the three universities each have two members on the board, and Michigan's government appoints five other members, representing local public health agencies, foundations, and health systems. MPHI may bid for grants as a single entity on behalf of its members. In 1996, funding for MPHI exceeded \$10 million from 29 sources; about 40% of this amount supported community-based programs (10). The development of detailed community health profiles was one of the MPHI's initial projects and provides the basis for future health programs (13).

Most importantly, the consortium creates a neutral zone for collaborators, where all participants are equal partners. From the perspective of the public health laboratory, membership in a nonprofit institute provides an ability to compete for grants from funding sources that usually do not fund government agencies. Other advantages include the ability to generate fee-for-service income from small-scale, one-time services; undertaking new projects in a timely manner, including hiring temporary staff and purchasing supplementary supplies and equipment; termination of completed projects in a timely man-

ner to ensure streamlined staffing; and preferential procurement contracts associated with bulk purchases.

Assuming appropriate representation of public- and private-sector components, public health institutes could be an invaluable source of advice for legislatures as they consider policies that would affect both sectors. Combining the expertise of public health and university laboratories could also provide enormous surge capacity in the event of unexpected demands for laboratory testing.

### THE PUBLIC HEALTH INSTITUTE AND EMERGENCY RESPONSE TEAMS

Public health institutes could also provide the framework for emergency response teams, analogous to the National Guard, that could be activated during public health emergencies to ensure an adequate response. Is this idea too far-fetched? We think not.

Emergency response teams, composed of medical, epidemiologic, laboratory, and other units necessary to address major medical emergencies, could be formed for each state and could provide essential expertise that would otherwise be unavailable. A member of the governor's staff or the head of the state health department could serve as director of the team. The laboratory unit would be composed of appropriate members of the public health institute, i.e., staff of state public health laboratories and employees of state-supported university laboratories and research facilities with specialized expertise. Member laboratories would be upgraded to meet continually evolving needs. To become familiarized with state public health activities, academic researchers could become visiting scientists at the state health department laboratory and could collaborate on relevant programs. Support for visiting scientists might be provided by the state public health laboratory or through the local public health institute.

Emergency response syllabi could be developed and exercises could be conducted periodically. In the event of a statewide medical emergency, the governor could activate the team. Activated employees from academia could work on emergency projects in their own laboratories or at the state health laboratory, as indicated. In the event of a national emergency, the U.S. Public Health Service could coordinate activities overall,

but members of the state team would remain under the immediate supervision of their local directors.

Obviously, the mechanics of such a system need the expert assistance of planners, but such a system is a distinct possibility. The need for improved emergency response capability is apparent. New and reemerging infectious diseases pose serious threats to the nation because of current inadequacies in the public health infrastructure (8); potential threats of bioterrorism underscore the need for surge capability (15).

### ENSURING ESSENTIAL LABORATORY INFRASTRUCTURE

In her analysis of the implications of health reform in Minnesota, O'Brien concluded, "It is clear that public health reform must occur as part of health reform. It is also clear that the public health subsystem has an important role to play in a reconfigured health system" (12, p. 34). Like all government activities, state public health laboratory programs should be continually assessed to ensure that they stay competent to respond to the evolving needs of the communities they serve. Undoubtedly, new or modified programs—brought about by scientific advances, newly recognized diseases, or greater awareness of disease—will be needed. This does not mean that the state health laboratory alone must meet all testing needs; however, the responsibility for fulfilling functions of the public health laboratory does rest with the state laboratory.

Improving the cost-effectiveness of health care delivery and public health programs must become national goals. Frequently, direct cost comparisons of public- and private-sector laboratory programs are difficult because the scope and purpose of laboratory testing by the two sectors differ considerably. Moreover, as indicated by economist Donald Ratajczak, "Unfortunately, the value of public activity is difficult to measure precisely because some public goods provide value even to people who do not pay for them. A good health program will reduce the spread of disease even to some people who may choose not to pay for the program. If only government programs that people individually chose to buy were enacted, public parks, health programs and basic research support would be under funded or not funded at all. Some people gaining value would realize they could benefit without paying, and therefore would not" (14). Ratajczak also concludes that "Efficient government programs are likely to provide more value than the private sector" (14). We concur with this assessment: the goal should not be

to eliminate valuable public health laboratories but to ensure that they remain efficient partners in national health programs.

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### REFERENCES

1. Baker, E. L., R. J. Melton, P. V. Stange, M. L. Fields, J. P. Koplan, F. A. Guerra, and D. Satcher. 1994. Health reform and the health of the public. *JAMA* 272:1276-1282.
2. Bourdeau, N., D. Mueller, S. Inhorn, and D. Hassemer. 1996. The Wisconsin state laboratory of hygiene proficiency testing (external quality assessment) programs in microbiology. *Med. Microbiol. Lett.* 5:98-104.
- 2a. Brown, C. (National Association of City and County Health Officials). Personal communication.
3. Centers for Disease Control and Prevention. 1997. *Escherichia coli* O157:H7 infections associated with eating a nationally distributed commercial brand of frozen ground beef patties and burgers—Colorado 1997. *Morbidity and Mortality Weekly Report* 46:777-778.
- 3a. Cordts, J. (Association of State and Territorial Public Health Laboratory Directors). Personal communication.
4. Dowdle, W. R. 1993. The future of the public health laboratory. *Annu. Rev. Public Health* 14:649-694.
5. Dowdle, W. R. 1995. The public health laboratory: does it have a role in the future. *Curr. Issues Public Health* 1:25-29.
6. Hennessey, T. W., C. W. Hedberg, L. Slutsker, K. E. White, J. M. Besser-Wiek, M. E. Moen, J. Feldman, W. W. Coleman, L. M. Edmonson, K. L. MacDonald, M. T. Osterholm, and the Investigative Team. 1996. A national outbreak of *Salmonella enteritidis* infections from ice cream. *N. Engl. J. Med.* 334:1281-1286.
7. Institute of Medicine. 1988. *The future of public health*. National Academy Press, Washington, D.C.
8. Institute of Medicine. 1992. *Emerging infections: microbial threats to health in the United States*. National Academy Press, Washington, D.C.
9. Mahon, B. E., D. D. Rohn, S. R. Pack, and R. V. Tauxe. 1995. Electronic communication facilitates investigation of a highly dispersed foodborne outbreak: *Salmonella* on the superhighway. *Emerg. Infect. Dis.* 1:94-95.
10. Michigan Public Health Institute. 1996. Annual report. Michigan Public Health Institute, Okemos, Mich.
11. Oberle, M. W., E. L. Baker, and M. J. Magenheimer. 1994. Health people 2000 and community health planning. *Annu. Rev. Public Health* 15:259-275.
12. O'Brien, M. J. 1995. Building a new health system: implications for public health management and practice. *J. Public Health Management Pract.* 1:29-34.
13. Paul-Shaheen, P. A., B. A. Schilla, G. E. Beane, and E. F. Kleinau. 1997. The challenge of developing community profiles for use in community health assessment; lessons from Michigan's experience. *J. Public Health Management Pract.* 3:16-28.
14. Ratajczak, D. 1995. Taxpayers should push for more efficient government, March 5, p. G-6. *In Atlanta Journal and Constitution*.
15. Simon, J. D. 1997. Biological terrorism: preparing to meet the threat. *JAMA* 278:428-430.
16. Stephenson, J. 1997. New approaches for detecting and curtailing foodborne microbial infections. *JAMA* 277:1337, 1339-1340.

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