

Laboratory Medicine in the 21st Century

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At the end of the 19th century, medical problem solving relied almost entirely on history taking and physical examination. The enormous advances in science and technology that have characterized the 20th century have so transformed the practice of clinical medicine that now, as we approach the next millennium, history taking and physical examination have increasingly given way to a practice of medicine dominated by the use of medical technology—in particular, laboratory testing. There is every reason to believe that this trend will continue into the 21st century. Moreover, it will continue against a background of continuing advances in information technology and computer-based electronic communications—advances that could revolutionize the provision of medical care through online dialogue among patients, databases, clinicians, pathologists, and other laboratory professionals. These changes in the provision of health care are likely to have profound effects on the practice of laboratory medicine—effects that will be determined by the competing demands of cost containment, assurance of quality, and financial support of education and research.

Laboratory Medicine: Origins and Historic Development

The term used most commonly throughout the world to describe the use of laboratory tests in clinical problem-solving is *laboratory medicine*.¹ In the United States, laboratory medicine often is considered synonymous with *clinical pathology*, and the terms frequently are used interchangeably. They derive, however, from 2 distinctly different traditions.² Clinical pathology may be unique among medical specialties in that it originated not in the academic medical center but

in the community hospital.³ As a result, clinical pathology has been a service-oriented discipline devoted primarily to the solution of practical clinical problems. Its origins may be traced to those early 19th century French “patho-clinicians,” so called because they were the first to put the practice of medicine on a rational basis by correlating clinical with autopsy findings.⁴ The practice of physicians performing autopsies and conducting bacteriologic analyses on body fluids as aids to solving clinical problems spread from Paris to London, Dublin, and Edinburgh and later to the United States.⁵

With the discovery of blood groups and the development of chemical analyses of body fluids in the 1920s, the demand for laboratory tests by community physicians grew to the extent that hospitals needed a full-time laboratory physician.⁶ Since pathologists were needed to perform autopsies, they became the natural choice to assume responsibility for centralized laboratory work. With the increasing reliance on laboratory testing that began in the 1960s, clinical pathology grew in importance, and clinical pathologists developed strengths primarily in clinical consultation and management of laboratory resources.⁶ In the academic medical center, with its high concentration of medical specialists and emphasis on basic and applied research, demand for the interpretive skills of the clinical pathologist was less than in the community hospital. More often than not, clinical laboratories in academic medical centers developed as service components of research laboratories with little emphasis on consultation and management.^{2,7}

Laboratory medicine, on the other hand, developed in the academic setting with an emphasis on science as a basis for laboratory practice and with contributions from medicine and pediatrics, as well as biochemistry and microbiology.² Its

emphasis on science is traceable to the influence of Claude Bernard (1813-1878) and Rudolph Virchow (1821-1902).^{2,5,8-10} Bernard was one of the first investigators to use experimental animals,⁸ and Virchow—contrary to popular opinion—was more interested in microscopic histopathology as a research tool than as a diagnostic aid. To quote Juan Rosai, "...if Rudolph Virchow were alive today he would be a committed molecular biologist."¹¹ In 1893, William H. Welch (1850-1934) was appointed the professor of pathology at Johns Hopkins Medical School, Baltimore, MD. He had trained in experimental medicine in Leipzig where he came under the influence of Virchow's teachings. Welch is credited with establishing the scientific approach to medicine in the United States and was influential in the early development of laboratory medicine.¹⁰ By the 1960s, the discipline had gained strength with the development of strong academic departments of laboratory medicine at several medical schools. By the 1980s, many of these departments had become integrated with pathology and were designated departments of pathology and laboratory medicine.²

The Changing Environment

Before World War II, physicians tended to confine their use of laboratory tests to confirming clinical diagnoses rather than to the detection of clinically inapparent disease. With the steady growth in the numbers of insured that began in the 1950s, the demand for laboratory tests increased, providing an impetus for technical innovation and creating a need for increased numbers of clinical pathologists and laboratory medicine faculty.⁶ Between 1970 and 1990, with the help of automation, computerization, and immunoassay and molecular probe techniques, the number of laboratory tests performed annually in the United States grew at an annual rate of more than 12% and accounted for more than 10% of overall health care expenditures—expenditures that had been doubling until recently.¹²

Now, after almost a century of enormously successful growth and development, laboratory medicine faces serious challenges. Managed care and fixed capitation payments are changing the economics of health care provision, and the effects on laboratory medicine and clinical pathology are likely to be profound.^{7,13,14} Hospital laboratories have become cost centers, and clinical pathology is no longer considered a professional medical service to the individual patient but a service of benefit to patients generally and payable to the hospital rather than the pathologist.¹⁵ Clinical laboratory consultation, a major component of community hospital clinical pathology practice in the past, has declined in the wake of managed care systems' discouragement of consultation on the part of the primary care physician.¹⁵

The growth of managed care presents particular problems for academic laboratory medicine as medical centers are forced to reexamine their traditional roles as centers of teaching and research.¹⁶⁻¹⁸ As competition for research funds intensifies and academic departments become increasingly dependent on clinical income with its decreasing reimbursement rates, survival may depend on choosing to emphasize reimbursable pathology and laboratory services at the expense of research and service in a cost center such as hospital laboratory medicine.¹⁸ Choices such as this are made all the more difficult by the realization that, despite the emphasis on cost containment, continued advances in diagnosis and treatment demand investment in new and often expensive technologies. Moreover, with the realization that health care could learn much about patient safety from other industries, an increasingly consumer-oriented public is holding physicians and other health care workers more accountable for errors.¹⁹ In the case of laboratory medicine, this concern translates to a need for a greater emphasis on continued quality improvement and an awareness that in today's clinical laboratory, most mistakes are preanalytic and postanalytic.

Reactions to Change

Reaction on the part of clinical laboratories to decreased reimbursement has begun on several fronts. Traditionally, hospital laboratories have been organized on a departmental basis with separate sections, such as hematology, chemistry, and immunology. In the larger institutions in particular, little or no cross-training between departments has created inevitable inefficiencies in productivity. Cost savings are being realized by consolidation of laboratory sections with the creation of central core laboratories.²⁰ Further savings are likely to be achieved in the future by the addition of automated preanalytic specimen handling using robotic systems.²¹ The development of reliable point-of-care testing instrumentation has facilitated decentralization of testing well beyond the traditional boundaries of the hospital setting.^{22,23} The expectation is that such testing, while not affecting laboratory costs directly, may decrease the overall cost of care.²⁴ Further economies of scale are being sought through regionalization of laboratory services with the creation of core laboratories serving networks of health care facilities.

Economic survival in this managed care environment will depend not merely on decreasing costs but rather on the ability to provide the best care at the least cost. In the case of laboratory medicine, this means ensuring that cost-saving reductions in the utilization of tests apply only to tests that are inappropriate.⁷ Studies of interventions to modify test ordering behavior—including education, feedback, and

guidelines or reward systems—have not been uniformly successful.^{25,26} Recent evidence, however, suggests that, when carefully chosen, administrative intervention was effective, and combinations of interventions targeted at several behavioral factors were most likely to succeed.²⁷⁻²⁹

A 1992 Academy of Clinical Laboratory Physicians and Scientists survey of US medical schools found that only about two thirds of the schools surveyed offered courses in laboratory medicine.³⁰ It is not too surprising, therefore, that physicians seem to have a limited understanding of the test characteristics that determine appropriate use. As a remedy, a laboratory rotation for house officers has been suggested.³¹ Other approaches include pathologist participation in the formulation of evidence-based clinical pathways and reform of clinical pathology residency training and that of clinical laboratory PhD scientists. The 1995 Graylyn Conference Report, representing the conjoint efforts of several laboratory medicine and pathology societies, recommended that residency training emphasize the role of the pathologist as a consultant on cost-effective test strategies, the management of laboratory resources, and the use of information technology to manage and translate data to clinically useful information.³²

In 1996, when 75 California community hospital pathologists were surveyed about the skills and knowledge required for successful community pathology practice, knowledge of test interpretation and test strategies was considered essential or useful by all respondents, with 60% considering it essential and 40% useful.³³ The same group considered management and information technology essential (41%) or useful (55%).³³ In recommending reform of clinical laboratory PhD scientist training, McDonald³⁴ made similar recommendations for reform of their training.

Before the 1990s, several workforce studies predicted—based on fee-for-service practice patterns—that there would be a shortage of pathologists by the turn of the century.³⁵ Managed care has drastically altered these predictions. A survey of the heads of community hospital pathology practice groups indicated that, compared with 1994, in 1995 the number of retirements had decreased by 15% and the number of resignations by 65%.³⁶ In the same time frame, hospital mergers increased 6-fold, and the total demand for pathologists decreased by 40%, owing mainly to a 60% decrease in filled vacancies.³⁶ In 1995, the supply of pathologists in the United States was 4.2 per 100,000 covered lives compared with managed care demand ratios of from 1.7 to 3.1 per 100,000 covered lives.³⁶

Predictions for the Future

Despite the profound changes already under way in the nation's health care system, advances in science and

technology will ensure that laboratory investigation dominates the practice of medicine in the 21st century.⁷ Less clear is how the 2 traditions—academic laboratory medicine, with its emphasis on teaching and research, and clinical pathology, with strengths in test strategy and interpretation of results—will fare in an environment dominated by cost containment and a public increasingly concerned with avoidance of error and the assurance of quality. The survival of both in such an environment depends on the ability to add value.⁷ That ability depends in turn on how effectively academic laboratory medicine and clinical pathology exploit advances in science and technology—particularly advances in computer-based electronic communications and information technology—to add value to the care of patients.⁷

The 21st century will witness changes in the environment of health care, in the nature of medical practice, in the development of new technology, and in the practice of laboratory medicine **Table 1**.

The Health Care Environment

Although managed care has been successful in reducing the rate of increase in health care costs, the emphasis on cost containment, and less so on quality, has patients and providers complaining. Because health care costs will continue to increase, the likelihood is that, for the near future at least, managed care—albeit in more regulated form—is here to stay. It may not survive the long run, however, unless patients and providers are satisfied and unless the number of

Table 1
Laboratory Medicine: Predictions for the 21st Century

Health care environment
Single-payer health care reform
Continued advances in science and technology
Integrated regional health care networks
Integrated regional laboratory services
Emphasis on point-of-care testing
Telemedicine and online medical practice
Emphasis on cost containment
Practice of medicine
Emphasis on preventive medicine
Primary care nursing practice
Evidence-based disease management
Laboratory technology
Automated molecular technology
Integrated testing platforms
Regional laboratory full-scale automation
Modular robotic automation
Practice of laboratory medicine
Comprehensive laboratory consultation services
Management of information technology
Management of evidence-based disease programs
Direct patient access to laboratory services
Emphasis on subspecialty practice
One specialty: laboratory medicine (or pathology)

uninsured people decreases.¹²⁻¹⁴ Ultimately, a single-payer system³⁷ may prevail.

The merging of hospitals and the vertical integration of health care delivery systems, already well under way,³⁸ will culminate in the regionalization of medical care. Laboratory medicine also will regionalize and integrate. Horizontal integration with testing performed in fully automated core laboratories will be combined with a vertically integrated laboratory system that will include testing at the point-of-care, eg, physician's office, bedside, home, free-standing laboratory, long-term care facility, school, and airline terminal.²⁰

These changes will come about largely because of developments in computer-based electronic communication and information technology.^{39,40} Ten years ago, the Internet was used by a small group of scientists and engineers.⁴¹ In 1997, more than 40 million US adults were users.⁴¹ For those users, health care information is more readily available than at any time in history.

These developments will lead to a demystification of medical care. The implications are far-reaching and include online communication among physicians, patients, and databases, thereby facilitating the inclusion of patients as more informed participants in the medical decision-making process.⁴² Implications for laboratory medicine are no less profound and include the development of integrated databases to lessen the fragmentation of laboratory information occasioned by decentralized clinical laboratory activities within institutions and across networks.³⁹ Moreover, further developments in satellite telecommunications will facilitate wide use of remote consultation and transmission of real-time imagery to regional centers for expert interpretation.^{43,44}

Medical Practice

The emphasis on cost containment has set in motion changes in the practice of medicine that will continue irrespective of the future of managed care. These changes include an emphasis on primary care and preventive medicine, as well as an increasing reliance on evidence-based disease management.⁴⁵⁻⁴⁷ Nurse practitioners will have an increasingly prominent role in primary care, not only in collaborative-practice settings with specialists but also as independent practitioners at the point of care.⁴⁵ Disease management emphasizing coordinated comprehensive care along the continuum of disease and across health care delivery systems will largely replace the traditional focus on treating patients during discrete illnesses.⁴⁶ Management will be evidence based in the sense that it will involve integrating pathophysiologic rationale, caregiver experience, and patient preferences with valid and up-to-date clinical research evidence.⁴⁷ Use of evidence-based practice guidelines, clinical pathways, and algorithms, supported by

computerized clinical information and reminder systems, will be the norm.

Technology

Molecular techniques will dominate. At present, molecular testing is manual, labor-intensive, and expensive. In the future, molecular testing will be automated—including specimen preparation, amplification, and detection—using microarray probe technology.⁴⁸⁻⁵⁰ Microarray or biological chip (biochip) technology will allow thousands of biologic reactions to take place at once, analogous to computer chips simultaneously performing thousands of mathematical calculations.⁵⁰ Applications will include screening for genetic indicators of disease, infectious disease detection, and the determination of cellular gene and protein expression profiles for the diagnosis and management of malignant neoplasms.⁴⁸⁻⁵¹ Integrated testing platforms suitable for core or satellite facilities with the capability of performing hundreds of assays will be developed.⁵² Building on the pioneering work of Masahide Sasaki at the Kochi Medical School, Kochi, Japan,²¹ full-scale automation of regional core laboratories will be further refined. The next century will see further development of more versatile point-of-care instrumentation with emphasis on modular robotic automation.⁵²

Practice of Laboratory Medicine

Emphasis will be on the provision of comprehensive laboratory consultation services. As a matter of routine, most laboratory data will be translated to information understandable to the clinician. This will come about for several reasons: the complexity of future medical technology will demand it, advances in information technology will facilitate it, and the primary care clinician of the future will need it.⁵³ Pathologists will direct these services, but laboratory scientists and medical technologists also will have major consultative roles.^{54,55} The likelihood is that the pathologist's consultative role will extend beyond the diagnostic phase of clinical decision making to include the management of disease. There seems little doubt that responsibility for laboratory utilization will fall to the pathologist,⁵⁶ but pathologists also may have major managerial roles in information technology⁵⁷ and evidence-based disease management.^{36,47,58} These expanded roles for pathologists in a medical practice environment dominated by online communication among patients, physicians, and databases make it likely that patient-initiated laboratory testing with direct access to pathologists' consultation services will be the norm.⁵⁹ Pathology residency training will emphasize molecular genetics, information technology, clinical consultation, and laboratory management. Pathologists will subspecialize and

practice in the core laboratory facilities of regional health care systems.

The distinction between anatomic and clinical pathology, already blurred to some extent, will disappear. There will be one laboratory service. Whether the unified laboratory service will be termed *pathology* or *laboratory medicine* remains to be seen.

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