

The impact of regulations, accreditation standards, and 'healthcare reform' on laboratory practice in the United States

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Abstract

Professional standards of laboratory practice are partially derived from regulatory and accreditation standards of the federal government as well as those of non-government organizations and professional societies. These standards are monitored by on-site inspection and encompass personnel standards, patient test management requirements, quality control and assurance standards and proficiency testing stipulations. Problems related to these standards are reviewed and the impact of the volatile changes in the provision and financing of healthcare ("healthcare reform") on the organization and functioning of clinical laboratories are discussed.

Professional standards of practice for laboratories in the United States(US) arise from a complex matrix that includes (1) regulations of Federal, state and local government, and (2) the accreditation standards of the Joint Commission on Accreditation of Healthcare Organizations(JCAHO) and the College of American Pathologists(CAP). The history of the evolution of laboratory regulations in the United States¹ reflects the complex relationship between local, state and federal authority, as well as the uneven geographic pattern of regulatory enforcement, only recently standardized on a national basis by the passage of the Clinical Laboratory Improvement Amendments of 1988(CLIA88).² Regulations established by federal, state or local government are supplemented by standards established by other professional organizations as well as commonly-accepted "standards of care" that are recognized by custom and partially enforced by medical liability considerations.³ Implementation and enforcement of standards are dependent on an inter-related system of mandatory and voluntary inspection of laboratories by external teams composed of professional and peer-group inspectors. In addition, payment to laboratories, hospitals, and other providers of laboratory services is linked to documentation of compliance with regulatory and professional standards.

The most important standards that determine daily practice in US laboratories are those of the Federal Government (Clinical Laboratory Amendments of 1988, or CLIA88),⁴ the JCAHO⁵ and the CAP.⁶ Hospital and laboratory inspection and accreditation programs of the latter two organizations are recognized separately by the Federal Government through an arrangement known as "deemed status." Deemed status confers upon these two organizations, as well as several other state and private sector organizations, the authority to inspect and accredit laboratories on behalf of the federal government subsequent to demonstration that their standards are equivalent to or more stringent than those of the CLIA88 regulations. The JCAHO, whose accreditation standards for all aspects of performance for hospitals and other organizations are very widely recognized, accepts CAP accreditation as equivalent to their own laboratory accreditation process. In fact, the CAP Laboratory Accreditation Program is widely recognized as the unofficial benchmark for laboratory inspection and accreditation; many of the other programs for laboratory inspection utilize key concepts and practices that have been developed by the CAP. Recently, a new organization -- the Commission on Office Laboratory Accreditation (COLA) -- has implemented a program for accreditation of physicians office laboratories that has achieved deemed status and has become widely-recognized as a source of accreditation for these laboratories.

Although there are procedural and programmatic differences between the various inspection and accreditation options, common elements include education, experience and "responsibility" requirements for the laboratory director, standards for testing personnel, requirements for patient test management (the audit trail), quality control and quality assurance standards, and proficiency testing stipulations. The implementation of the CLIA88 regulations has had a profound impact on laboratory practice in the United States and has forced the voluntary private-sector organizations such as the CAP and the JCAHO to revise their standards and modify their practice to achieve equivalency. Continuing controversy surrounds the CLIA88 regulations, particularly in regard to personnel standards, stringency of quality control requirements, the critical requirement for "correct" performance in mandated external quality control (proficiency testing), and the role of CLIA88 in physician office laboratories and in the provision of cytology services.

The hospital and diagnostic manufacturing industry have, on the whole, favored the relatively less stringent personnel standards of CLIA88 compared to the previous federal standard that only applied to Medicare and Medicaid (the federal health insurance programs for the elderly, poor and disabled). On the other hand, most professional laboratory organizations have viewed the new regulations as a de facto "deregulation" that has opened the door for the employment of less-qualified individuals by cost-conscious hospitals and independent laboratories.

There has been general agreement on the part of hospitals, professional organizations, and, of course, the diagnostic equipment manufacturing industry, that the quality control and quality assurance requirements of CLIA88 are overly prescriptive and detailed with considerable potential to impede and discourage the development and introduction of new technology that could be safely deployed using alternative quality control techniques. Although strict enforcement of CLIA88 would require imposition of sanctions (usually restriction of testing) for proficiency testing "failures" by laboratories, actual practice has been less onerous than initially feared and recent statements by federal authorities suggest that a more educational approach will be taken.

Perhaps the two most controversial elements of the CLIA88 regulations have concerned physician office laboratories (POL) and cytology laboratories. Although indications are that POL have shown improvement in proficiency testing and regulatory compliance, organized medicine remains strongly opposed to the federal oversight of POL created by CLIA88 and are actively seeking legislative exemption from the current anti-regulatory Congress. It is of considerable interest and somewhat ironic that although the CLIA88 regulations were drafted largely in response to allegations of improper performance of cytology testing, the promised implementation of cytology "proficiency" testing has not taken place, largely because of the difficulty in implementation of such programs and because of widespread opposition on the part of the professional cytology community to certain aspects of the regulations.

Within the past decade, immense changes in the financing, organization and delivery of medical and laboratory services have been implemented and continue to change traditional practices. Very high and increasing costs of healthcare have given rise to a major initiative on the part of government and private industry - the latter the source of most health insurance funding for American workers - towards "healthcare reform." This process consists of a plethora of government and private sector initiatives that include major reductions in payment to healthcare providers including laboratories, limitations on coverage and availability of services including laboratory tests, and other "carrot and stick" measures designed to reduce utilization of services. These changes are linked to the industrialization of medical care and the emergence of managed care and capitated payment. The rapid growth of managed care⁷ - a system under which the financing and delivery of healthcare services are combined in a single non-profit or for-profit organization that has broad latitude to "manage" and control the utilization of resources (including laboratory testing), has accelerated what many fear to be the "deprofessionalization" of the practice of medicine and laboratory medicine⁸ and is seen as a significant threat to the viability of academic medical centers⁹ and medical research.¹⁰

The magnitude of these changes is such that despite historical opposition by physicians and laboratory scientists to prescriptive regulations, liability concerns and regulatory interventions may play an increasingly important role in supporting standards of professional practice. Although quality assurance efforts have for some time been driven primarily by regulatory concerns and centered around common managerial and administrative themes, a new emphasis on “outcomes” research is emerging¹¹ and pathology and laboratory organizations are producing practice guidelines¹² and inter-institutional studies¹³ designed to generate practice data that may be used for “benchmarking” surrogate standards of care.

Related phenomena that will continue to change laboratory standards and practice are the direct results of the rapid change in modes of laboratory organization and service delivery. These include the paradoxical growth of interest in “point-of-care testing”¹⁴ that has occurred in conjunction with increasing automation, centralization, consolidation and increase in size of both commercial and hospital laboratories, the latter often providing services to newly- integrated healthcare delivery systems.¹⁵

This review has attempted to demonstrate that regulatory and accreditation standards and practices in the United States are in a state of considerable flux due to volatile changes in the financing and delivery of healthcare services. Nevertheless, I strongly advocate continuing efforts on the part of laboratory professionals and organizations to ensure that professional standards shall be consensual and formulated by professional medical, scientific and laboratory-based organizations. Initially, provisional standards should be data-based and referenced to patient-care outcomes as defined by physicians and other “clients” of the laboratory, including patients. “Final” working standards should be consensual and subject to continual review and modification based upon the ease and practicality of “real world” implementation in a wide variety of settings.

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