Laboratory Performance and Director Qualifications

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Since 1971, federal laboratory regulations have required that directors of approved laboratories possess earned doctorates. Private accrediting agencies and some states also require doctoral directorship of accredited laboratories. No empirical studies have demonstrated that a director’s earned doctorate is necessary to assure laboratory quality. Laboratories in physicians’ offices (POLs) are exempt from federal regulation but receive federal reimbursement on the basis of the physicians’ medical degree. No empirical studies have demonstrated that unregulated laboratories perform comparably with regulated laboratories. This investigation found no statistically discernible differences in quality when 1983 proficiency test data were used to compare statistically the performance of doctoral- and non-doctoral-directed Medicare-certified independent laboratories in California. When regulated non-doctoral-directed full-service laboratories were statistically compared with unregulated limited service POLs, regulated non-doctoral-directed laboratories consistently demonstrated superior performance to POLs. Evidently a director’s earned doctorate is neither necessary nor a sufficient condition to assure laboratory performance. Government regulation appears to provide substantial quality assurance in the clinical laboratory field.

The federal government regulates clinical laboratories under the Medicare program (1) and the Clinical Laboratory Improvement Act (CLIA) (2). As a condition for participation in the Medicare program (e.g., for reimbursement for laboratory services), and as a requirement for receiving a CLIA license to provide laboratory services in interstate commerce (3), approved laboratories must be directed by persons with earned doctorates.1,2 Conditions for participation in Medicare were “... intended to provide assurance of the quality and adequacy of the services and facilities participating in independent laboratories” (4).

The federal doctoral director requirements parallel standards used by professional societies that accredit clinical laboratories under voluntary accreditation programs. Laboratories in hospitals that are accredited by the Joint Commission on Accreditation of Hospitals (JCAH) and the American Osteopathic Association (AOA) are deemed under Medicare regulations to be in compliance with Medicare standards and are therefore exempt from direct Medicare regulation. Laboratories accredited by the College of American Pathologists are deemed by the Health Care Financing Administration (HCFA), which administers both the Medicare and CLIA regulatory programs for clinical laboratories, to be in compliance with CLIA regulations and are exempt from direct federal regulation.

The JCAH, AOA, and CAP accreditation programs require that accredited laboratories be directed by persons with earned doctorates. Several states regulate clinical laboratories. Most require that laboratory directors have earned doctorates. The JCAH and CAP programs emphasize that laboratory directors should be medical doctors, preferably pathologists.

The similarity of the mandatory federal requirements and voluntary professional standards with respect to clinical laboratory director requirements (and most other requirements) reflects decisions by the then Department of Health, Education and Welfare to incorporate existing private voluntary standards, with some modifications, into the new Medicare and CLIA regulations in the mid-1960s. JCAH standards formed the basis of Medicare regulations (5); the similar CAP standards formed the basis of CLIA regulations. Both sets of voluntary accreditation requirements were based on professional consensus (6) rather than on rigorous testing of the proposed standards by use of inferential statistical testing techniques.

The federal government based mandatory regulations on the voluntary standards also, without empirically testing their efficacy or appropriateness. The assumption that doctoral directorship of clinical laboratories is a necessary condition to assure acceptable laboratory performance was not empirically tested before adoption of the doctoral directorship requirement by Medicare and CLIA. Indeed, very few studies had been reported in the professional literature that attempted to link directors’ or supervisors’ formal education with laboratory performance. Those studies that had either focused on the question of director education levels and laboratory performance or had addressed the question tangentially found no evidence to support the vision to mean that the director of the hospital laboratory must be a physician (telephone interview of May 13, 1985, with Dr. Stanley Edinger, HCFA).

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