

*In this issue: EDUCATION & TRAINING IN LABORATORY MEDICINE IN THE UNITED STATES*

The Journal of the International Federation of Clinical Chemistry  
and Laboratory Medicine



## THE DEVELOPMENT OF THE DOCTORATE IN CLINICAL LABORATORY SCIENCE IN THE U.S.

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Key words: clinical doctorate, Clinical Laboratory Science, DCLS, advanced practice, education

### **ABSTRACT**

In the United States, a new post-baccalaureate degree has been introduced in the medical laboratory sciences profession whose hallmark is advanced clinical practice beyond that of the entry level generalist. After more than a decade of exploring the most appropriate level of education and training in laboratory medicine to meet the demands of a changing health care system, the first Doctorate of Clinical Laboratory Science (DCLS) program is now offered. This article discusses the collaborative effort among professional organizations and stakeholders to develop the framework for the DCLS degree. In addition, the roles, responsibilities and justification for need of the DCLS are presented along with accreditation standards for DCLS programs and future challenges for this new member of the health care delivery team.

### **INTRODUCTION**

The development of the Doctorate in Clinical Laboratory Science (DCLS) in the United States as the terminal advanced practice degree in the profession of medical laboratory sciences is the result of a systematic and thorough process initiated by the profession's accreditation agency and its sponsoring organizations and stakeholders from various venues. Like other health professions who have incorporated the professional or clinical doctorate in their career ladders, the progression has been slow but deliberate, evolving over the past decade. The purpose of this article is to share the history of the development, justification, and educational requirements for the new degree.

### **BACKGROUND**

At the turn of the century, several factors propelled the discussion of introducing a new graduate level degree in the profession of medical laboratory sciences. Historically, academic offerings included the associate and baccalaureate degrees for entry in to the profession, providing eligibility for separate certification examinations. Master degrees were offered by fewer higher educational institutions for professionals pursuing career advancement in management or academe, and only a handful offered PhD degrees specializing in clinical laboratory science. However, the need for professionals with an advanced base knowledge of the sciences and clinical practice was realized with the near completion of the Human Genome Project. A rapid explosion of technology ensued, which led to an expansion of the range of clinical laboratory test offerings and laboratory services. The increase in complexity of testing and laboratory services also prompted the need for consultation services for test result

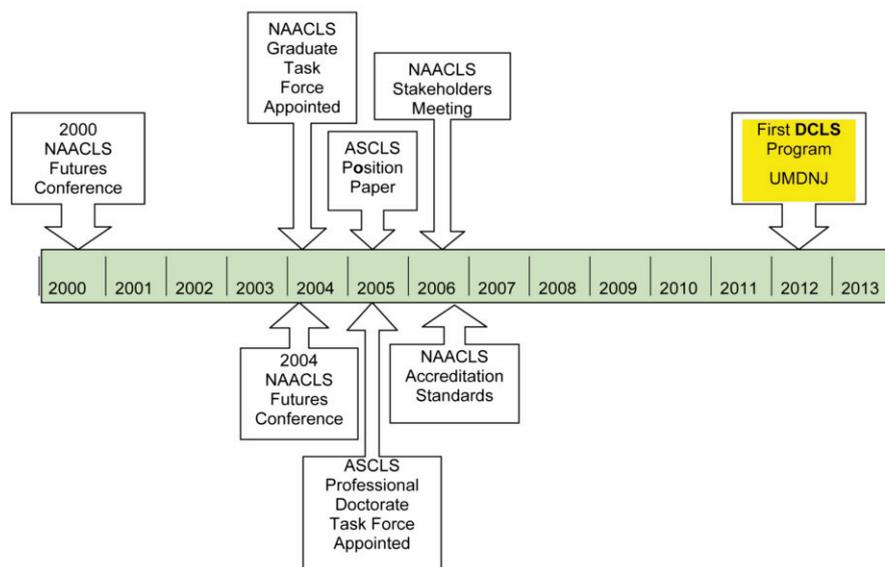
interpretation, test utilization, and informatics.<sup>1</sup>

As clinical laboratory services were expanding, demands were also being made on the health care system as a whole in the U.S. to improve patient safety and quality and resource utilization.<sup>2,3</sup> In its recommendations for transformation of the health care system, the Institute of Medicine (IOM) in its report *Crossing the Quality Chasm* emphasized patient-centered care, evidence-based practice, and information technology.<sup>3</sup> Further, the report states that one approach to accomplishing these goals is to restructure the training of health professionals and to provide more opportunities for interprofessional training. Echoed in a subsequent report, *Health Professions Education: A Bridge to Quality* is the emphasis on educating all health professionals to be trained in applying evidence-based practice and quality improvement in an interdisciplinary approach to patient-centered care.<sup>4</sup> These demands directly impact and highlight the clinical laboratorians' role in diagnostics, health and treatment monitoring, and disease prevention and early detection.

Thus, the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) held a Futures Conference in 2000 followed by one in 2004 to explore the level of education most appropriate to meet the demands of a health care system in transition. Stakeholders were strongly in favor of maintaining the baccalaureate degree requirement for entry level and developing a new advanced practice degree.<sup>5</sup> NAACLS appointed members to the Graduate Task Force including representatives from the national professional organization, the American Society for Clinical Laboratory Science (ASCLS), and the certifying agency, the American Society of Clinical Pathology (ASCP), to research the key elements related to the clinical doctorate and develop accreditation standards for degree programs. Working cooperatively with NAACLS, ASCLS appointed a separate task force to develop a needs assessment plan, competencies, and a model curriculum for the advanced practice degree. The ASCLS Professional Doctorate Task Force (PDTF) developed competencies expected of the DCLS in the workforce utilizing and referencing a thorough review of competency requirements of other health care professional doctorates and validated by advanced practitioners with patient care responsibilities. Further, the model curriculum developed by the PDTF in a two-year period was disseminated for external review by stakeholders including pathologists.<sup>1</sup> In July 2005, ASCLS adopted a position paper advocating for the development of an advanced practice Doctorate of Clinical Laboratory Science (DCLS).<sup>6</sup> An invitational Stakeholders Meeting sponsored by NAACLS was held in 2006 to ensure input was received from a broad perspective. Later that year, the NAACLS Board of Directors approved the Standards for Accredited Educational Programs for the Clinical Doctorate in Clinical Laboratory Science (DCLS), which have since been revised.<sup>7</sup> Figure 1 depicts the timeline for the development of the first DCLS program in the U.S.

**DEFINING THE ROLES AND RESPONSIBILITIES OF THE DCLS**

With advanced practice training, what new roles and responsibilities will the laboratory practitioner assume in a health care system that emphasizes patient-centered care and improved patient safety and quality improvement and cost-effective health care? Is there evidence that these roles are needed? The DCLS will be integrated as a new member of the health care delivery team in a variety of settings that are currently populated with medical laboratory scientists including clinical and reference laboratories, physician offices, industry, public health and government agencies, and academe.<sup>5</sup> However, in these settings, the DCLS will assume roles as consultants, educators, and/or administrators to contribute to the common goals of decreasing medical



**Figure 1**  
Timeline for Development of First DCLS Program

errors, reducing health care costs, and improving patient outcomes.<sup>8</sup> NAACLS categorizes the responsibilities of the DCLS into four areas in which these roles are utilized: patient care management, education, research applications, health care policy development, and health care services delivery and access.<sup>5</sup>

In the area of patient care management, the DCLS will play a vital role in cost-effective laboratory test utilization to include providing input during clinical rounds with other health professionals and developing and disseminating algorithms to optimize testing. A survey of the literature indicates a growing concern for inappropriate laboratory test utilization with various types of proposed solutions or interventions, including peer management, development of guidelines for test utilization in a coronary care unit, and the use of intelligent computer information systems to reduce unnecessary repeat testing in an immunology laboratory.<sup>9-11</sup>

With the increase in complexity testing, especially in the field of molecular diagnostics, providing interpretation of test results to other health care professions as well as patients is essential in a patient-centered health care system. Patient specific narrative interpretation in laboratory reports has been advocated.<sup>12</sup> Based on a review of previous studies, Dighe, Soderberg and Laposata cited the inadequacies of current laboratory advisory systems which include curbside consultations, computer information systems, algorithms, and web-based medical information.<sup>13</sup> Using the results of a five year intervention in which daily interpretative rounds were utilized to evaluate coagulation cases, Dighe et al. suggest that physicians need expert advice from the clinical laboratory staff on the selection of laboratory tests and interpretation of test results on a case by case basis. The provider of such services was further characterized as an expert in all areas of the clinical laboratory who is readily available for consultation when needed. To provide quality of services equivalent to that of anatomical pathology and radiology, the authors also recommended that interpretative services should include narratives to accompany complex evaluations. In a later study in which physicians were surveyed regarding the outcome of utilizing their health system's laboratory medicine interpretation service for complex laboratory panels, 70% reported that the interpretation reports prevented misdiagnoses and 60% reported reduced time to diagnosis.<sup>8</sup> The DCLS can assist the pathologists with these important tasks, especially in rural communities where the number of pathologists may be scarce.

Key informants surveyed for the report *The Clinical Laboratory Workforce: The Changing Picture of Supply, Demand, Education, and Practice* endorse the new role for laboratory practitioners as consultants on the health care team.<sup>14</sup> The need for such an advisor is also supported by reports from primary care physicians that their increased scope of care is difficult to handle and may affect the quality of care provided to their patients.<sup>15</sup> In addition, an emphasis has been placed on the need for improvement in the treatment and monitoring of chronic illness and preventative services. The DCLS can be a key resource in disease prevention and management for these patients, subsequently reducing the burden of practice among the primary care physicians.<sup>16-17</sup>

The DCLS responsibilities also fall in the realm of education, which ultimately affects the quality of patient care. Educating other health professionals with regards to quality of specimen collections, point of care testing, new test offerings and emerging technologies will be an important responsibility for the DCLS. As the interface between the clinical laboratory and the clinician, the DCLS would be an ideal candidate for instructing patients on point of care devices and home testing kits.

The DCLS is also expected to make significant contributions to research related to quality improvement and patient outcomes. Most errors in the total laboratory process are due to pre-analytical factors (up to 68%) and post-analytical factors (up to 47%).<sup>18</sup> Thus to increase the quality of laboratory medicine and increase patient safety, efforts addressing these pre-and post- analytic errors have been made through systematic evidence review methods. The Laboratory Medicine Best Practice (LMBPTM) initiative, created in 2006 by the US Center for Disease Control and Prevention (CDC) Laboratory Science, Policy and Practice Office in collaboration with the Battelle Memorial Institute utilized this approach for analyzing critical value reporting, reducing blood sample hemolysis, the effectiveness of barcoding to reduce patient specimen errors, and effectiveness of practice to reduce blood culture contamination.<sup>19-23</sup> Indeed, one objective of the LMBPTM initiative is to increase the participation of laboratory professionals in clinical research. As a generalist with advance practice experience, the DCLS will have the training to conduct such studies. Engaging in clinical research to benefit the the quality of laboratory medicine will also well position the DCLS as invaluable participants in health care policy debates and in decision making associated with laboratory services.

## ASSESSING INTEREST IN DCLS PROGRAMS

In addition to providing evidence of a need within the community for the skills set afforded by the degree, approval at university and state levels for a new doctorate level degree program usually requires data on the level of interest in the degree from potential applicants. Empirical data that would reveal numbers of potential applicants for a DCLS program are needed to construct proposals for new programs. The results of the 2008 survey of 299 randomly selected early career clinical laboratory scientists in the U.S. was encouraging in that 65% of the responders indicated interest in pursuing the DCLS for career advancement.<sup>24</sup>

In 2009, the ASCLS DCLS ad hoc Committee (renamed the ASCLS DCLS Oversight Committee) conducted a larger national study to assess interest in a new doctoral level degree program for medical laboratory scientists.<sup>25</sup> This electronic survey was emailed

to ASCLS members and directors of educational CLS programs who were asked to disseminate the survey to their students. The results of the survey were not only informative in regards to interest but also with respect to the characteristics of potential applicants for future DCLS programs. Of the 1,452 respondents, 849 (61%) were very interested or interested in completing a DCLS program and 23% envisioned starting a program as soon as one is offered. The majority of the respondents worked in a hospital setting (51.0%). When asked which type of degree program would be most advantageous to meet their professional goals, 23% responded the clinical doctorate, 7% the Ph.D., and 34% a combined clinical doctorate/Ph.D. degree program. A majority (57%) of the respondents indicated that the time that can be devoted to completing a DCLS educational program including the clinical rotation was less than 4 years while 37% responded 4-5 years. In addition, half of the respondents indicated that they were unable to relocate; but 93.6% would be interested in enrolling in online courses. With regards to important factors for consideration in decisions to attend a DCLS program, the majority of the respondents cited cost or financial support and length of program. Lastly, life stage was identified most often as the reason for little or no interest in the program. The large number of survey respondents and the high interest in a DCLS program strongly suggests that new programs will attract applicants and meet enrollment projections. Curricula delivered through distance learning formats will be beneficial since relocation would be challenging for the majority. Though a third of the applicants who aspire to earn a DCLS would prefer a program that offered a dual clinical doctorate/Ph.D. degree, it may be difficult to complete such a curriculum in the time frame desired by the majority of the respondents. Financial support will be a necessity for most potential applicants, especially while completing the clinical practicum component of the program. Training grants, therefore, should be explored such as those offered in the doctoral programs of the nursing profession. Notably, the majority of respondents are employed in hospital laboratories. Perhaps it is in this setting that the value of advanced clinical practice is most often recognized due to the inadequacies of current laboratory advisory systems and the growing concern for inappropriate laboratory test utilization.

### **ACCREDITATION STANDARDS FOR DCLS PROGRAMS**

NAACLS Accreditation Guide for Doctoral Programs in Clinical Laboratory Science defines the DCLS as a clinical doctorate who has completed a curriculum comprised of advanced generalist practice.<sup>7</sup> The document further describes the requirements for potential candidates of such a program to include an entry level degree (either a baccalaureate or masters degree) and national certification as a laboratory generalist (e.g. MLS, MT, CLS). The curriculum of a DCLS program must include a mix of didactic and practice experience and requires a research or capstone project as well as teaching and consulting opportunities. In order to maintain flexibility, the length of the program to completion is not specified, though it is stated that three years of full-time study is typical for clinical doctorate programs. Innovative modes of instruction, including distance education are endorsed. The instructional areas that must be included in the curriculum are found in Table 1.

### **ADDITIONAL BENEFITS OF THE DCLS**

In addition to improving patient care and outcomes and reducing the health care costs, it is anticipated that the addition of DCLS to the career ladder will not only enhance recruitment and retention of laboratory practitioners but also raise awareness among other clinicians and the served community of the critical role of clinical laboratory scientists in delivery of quality health care. However, in assessing the need for the DCLS, one must also consider the effect of implementation of such a degree program on the current shortage of the clinical laboratory workforce. HRSA's 2005 report, *The Clinical Laboratory Workforce: The Changing Picture of Supply, Demand, Education, and Practice*, reveals that the shortage is due in part to the lack of career development opportunities for laboratory practitioners.<sup>14</sup> Not only is the profession challenged to recruit high quality students, but retention is reduced when laboratorians seek other professions to find "meaningful work", more respect, and greater visibility.<sup>26</sup>

### **CHALLENGES TO PROGRAM DEVELOPMENT**

With current economic constraints, institutions are cautious about funding new programs; however, distance education and inter-institutional collaboration could facilitate the growth and delivery of DCLS programs. During the last decade, several institutions of higher learning expressed interest in offering a DCLS program culminating in either a professional doctorate degree or in combination with a PhD. Distance education will be utilized to deliver the didactic courses in the DCLS program at The University of Medicine and Dentistry of New Jersey (UMDNJ), the first and only institution thus far in the U.S. to receive approval to offer the DCLS. Its curriculum includes 80 post-baccalaureate credits and is designed to be completed in four years including one year of clinical experience. Hybrid learning formats in which distance education is a major component of the curriculum is one means of consolidating efforts of doctoral faculty while providing an attractive way for students who cannot relocate to obtain an advanced degree. Inter-institutional collaboration in degree offerings is another means of combining talent among programs with limited resources or faculty. Two institutions within the University of Texas System have created a proposal to offer one DCLS program and waiting to receive approval to begin planning. It is imperative for the medical laboratory science

**Table 1**  
Instructional areas in a DCLS curriculum as specified by NAACLS

- 1) Scientific (post-entry level) areas that impact patient care:
  - epidemiology
  - pharmacology
  - pathophysiology
- 2) Health care:
  - development and application of clinical decision making,
  - development and application of critical paths/test algorithms,
  - utilization review,
  - patient and provider safety,
  - quality systems, and
  - medical error prevention.
- 3) Clinical experiences to include rounds and patient assessment.
- 4) Informatics utilizing patient records.
- 5) Interpersonal and communication skills necessary for interactions with patients, their family members from diverse populations and other health care practitioners.
- 6) Capstone experience, applied research, or translational research to include:
  - research design,
  - statistics,
  - grant writing, and
  - protection of human subjects, and research ethics.
- 7) Health care policy and legislation development, interpretation and application.
- 8) Health care services delivery and access to include:
  - resources management,
  - outcomes analysis,
  - analysis of costs relative to benefits

profession to continue inter-institutional collaborative efforts to develop DCLS programs and to locate sources of funding for resources and student stipends.

## FUTURE CHALLENGES

Though the role of the DCLS as a new member of the health care delivery team has been well articulated by the medical laboratory science professional organizations and the need for an advanced generalist practitioner justified, active assessment of job opportunities, the effect on the workforce, and the cost-savings to institutions and patients will determine the future of the DCLS. Support from pathologists and hospital administrators will need to be garnered especially in the event that no or little reimbursement may be received for services. In addition, national certification and state licensure credentials would add value to the position.

## CONCLUSION

As DCLS programs slowly evolve, the medical laboratory professional community will need to be vigilant in collecting and analyzing data related to DCLS student and program outcomes.<sup>27</sup> This data in turn will provide evidence to institutions of higher education and laboratory administrators of the value of the DCLS and the potential impact on quality and cost-effective health care.

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