

The Doctorate in Clinical Laboratory Science: An Executive Summary

ELIZABETH KENIMER LEIBACH

This article describes, in informational bullets, the concept of the doctorate in clinical laboratory science. The intent of the article is to support the marketing of these new practitioners and to provide the conceptual frame and links to data for proposals required to implement educational programs for them.

ABBREVIATIONS: ASCLS = American Society for Clinical Laboratory Science; CLS = clinical laboratory science; DCLS = doctorate in clinical laboratory science; NAACLS = National Accrediting Agency for Clinical Laboratory Sciences; PDTF = Professional Doctorate Task Force.

INDEX TERMS: clinical doctorate; clinical laboratory science; evidence-based practice; professional doctorate.

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Elizabeth Kenimer Leibach is professor and chair in the Department of Biomedical and Radiological Technologies, Medical College of Georgia, Augusta GA.

Address for correspondence: Elizabeth Kenimer Leibach EdD MS CLS MT(SBB), professor and chair, Department of Biomedical and Radiological Technologies, EC 2437 Medical College of Georgia, Augusta GA 30912-0500. (706) 721-3046, (706) 721-7631 (fax). ekenimer@mccg.edu.

DCLS PURPOSE

The aim of the profession, as expressed in the position statement of the American Society for Clinical Laboratory Science (ASCLS) and the National Accrediting Agency for Clinical Laboratory Sciences, is the “creation and implementation

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of a doctorate in clinical laboratory science (DCLS), an advanced degree that requires comprehensive knowledge of test methodologies, their limitations, pre- and post-analytical and patient circumstances that could invalidate test results; and knowledge of healthcare policy and delivery systems, principles of education, research and management.”¹

The position statement regarding the doctorate in clinical laboratory science (DCLS) continues:

Missing within the continuity of healthcare are enough scientists and physicians within the clinical laboratory or elsewhere on the healthcare team who are totally dedicated to and who have the breadth of knowledge and assigned authority essential to the ordering of appropriate laboratory tests, the effective use of laboratory test information, effective consultation with other healthcare team members, direct communication with patients, review of patient records, and interpretation/application of laboratory generated information in reference to clinical signs and symptoms. A clinical laboratory science professional holding a doctoral degree (DCLS) is needed to provide the critical interface across the healthcare system in order to assure improved patient outcomes and cost effective patient care.¹

DCLS ROLE

The role of the DCLS in healthcare delivery is supported by the following:

- The need for an individual from the clinical laboratory to function in our healthcare system “to provide the critical interface across the healthcare system in order to assure improved patient outcomes and cost effective patient care” is recognized and documented.^{1,2}
- The Institute of Medicine (*Crossing the Quality Chasm*, <http://www.iom.edu/CMS/8089.aspx>) has challenged the healthcare delivery system to refocus on appropriate use of healthcare services. Following from this, accreditors of clinical laboratories have taken up the challenge and are actively reviewing progress toward this “new quality” of appropriate use of clinical laboratory information relative to an increase in patient safety and decrease in medical errors (JCAHO, <http://www.jointcommission.org/>).
- The clinical laboratory by every cost, revenue, and

quality measure is foundational to any consideration of healthcare efficiency and effectiveness given that as much as 93% of the objective data in the clinical record is contributed by the laboratory.²

- Inefficiencies involving the generation of orders (pre-analytical processing) and utilization of laboratory data (post-analytical processing) increase the possibility of inappropriate resource utilization. An estimated 50%-60% of all laboratory orders may be inappropriate³ and most (68%-87%) of laboratory errors are non-analytical.⁴
- To identify, describe, measure, provide for, and improve the ordering, dissemination, and utilization of medically effective and cost-efficient clinical laboratory information defines the objectives of quality in clinical laboratory science as well as the focus of CLS evidence-based practice.¹¹
- The need for interpretation of laboratory information related to appropriate patient assessment is a growing concern worldwide.⁵
- With the design and implementation of the DCLS, the clinical laboratory science profession has claimed and accepted responsibility for the quality of the information provided by the clinical laboratory and for assuring its effective use in patient care.⁶
- With the creation and integration of the DCLS, the profession has also completed its "career ladder" with positions identified to address all areas of the laboratory industry including its leadership.^{7,8}

DCLS PRACTICE

The functions of the DCLS in healthcare delivery are defined by the following:

- The clinical laboratory is a huge and expanding sector of the healthcare system. According to the Bureau of Labor Statistics (<http://www.bls.gov/oco/ocos096.htm#outlook>), there were 319,000 positions for clinical laboratory professionals in 2006. In 10 years, this number is projected to grow by 14% thus expanding available positions to 362,000 by 2016.
- Work in the clinical laboratory is performed by non-physician scientists who then report diagnostic information directly to other healthcare providers. These healthcare providers then interpret this information relative to their patients. These patient care providers express a growing need for consultation in narrative interpretations of complex and diverse laboratory test options and results.⁹
- The interpretive role needed to accompany diagnostic laboratory information (that other healthcare providers

increasingly expect) is not currently being fulfilled consistently and will be addressed by the DCLS. Literature suggests that doctorate-trained laboratory professionals improve the quality of medical care, reduce medical errors, and help to contain costs.¹⁰

- DCLS practice will be focused by demand for patient and provider consultative services. There is growing evidence of physicians' need for advice on laboratory test selection and interpretation of test results. The DCLS will function as a key resource in disease prevention and management.
- The generalist DCLS' practice will supplement and support (not replace) the focused knowledge of clinical laboratory PhD specialty scientists as well as the practice of medical doctors in fulfilling quality responsibilities in the clinical laboratory. Most likely, rules regulating the practice of specialty scientists in the clinical laboratory (e.g., CLIA, state-specific licensure laws) will apply to these new DCLS degrees.¹¹ Thus, the DCLS will be qualified to fill traditional administrative positions in the clinical laboratory and will bring the consultative functions currently missing from clinical laboratory services delivery to these traditional positions.
- The DCLS will also consult in a variety of new, non-traditional practice venues (e.g., rounding, auditing medical records, interviewing patients and healthcare providers, charting clinical laboratory information and interpretations, recommending test selection, and participating in medical decision-making) with healthcare providers to assist in the selection and ordering of tests, and interpretation of clinical laboratory information. The practitioner will also assist patients directly in understanding laboratory information related to managing disease, preparing for laboratory tests, and performing tests at home.¹
- The most unique aspect of DCLS practice is defined by the development and utilization of evidence. On a patient by patient basis, the DCLS will be involved in the development and interpretation of practice guidelines and the collection and utilization of outcomes data. On a daily basis, the DCLS will establish relationships with other healthcare providers and re-define existing relationships of these other healthcare providers to CLS and clinical pathology.¹³
- The DCLS will be positioned to suggest algorithmic approaches to the evaluation of laboratory information utilization across provider settings. Having a DCLS placed in all provider settings will favor the development of industry-wide utilization guidelines which will, in turn,

decrease errors, decrease costs, and increase the number of good patient outcomes in all service venues.¹³

- The role of the DCLS will impact the roles of the CLS (baccalaureate degree clinical laboratory scientist) and CLT (associate degree clinical laboratory technician) as application of evidence (downstream effects of laboratory information) suggests more efficient use of skills at each practitioner level.¹³
- A recent survey of 299 randomly selected early career clinical laboratory scientists indicated that 65% would be interested in pursuing the DCLS for career advancement.¹²

DCLS EDUCATION

- The DCLS represents a new healthcare practitioner. The competencies of DCLS practice, based on the CLS generalist scope of practice, were designed to address existing specific needs in the clinical laboratory industry and the CLS profession.
- The responsibility of quality oversight within the profession, e.g., education, research, clinical practice, manufacturing, informatics, etc., will require education of clinical laboratory scientists (CLS) at the doctoral level resulting in the conferral of either the Doctor of CLS (DCLS, clinical practice curriculum and clinical project) or the Doctor of Philosophy in CLS, (PhD-CLS, clinical practice curriculum and dissertation).¹¹
- The role of the DCLS, in educational programs as well as in practice, is to participate in the generation, interpretation, and utilization of translational research, e.g., research that transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical or population-based applications to improve health by reducing disease incidence, morbidity, and mortality.¹⁴ Institutions offering the PhD-CLS option will require new knowledge generation and the rigor of the dissertation.
- DCLS competencies were developed by the ASCLS Professional Doctorate Task Force (PDTF) in an iterative process referencing an extensive review of competency requirements of other doctoral-level healthcare practitioners. These competencies were validated by a qualitative process involving thematic analysis of interviews with current practitioners self-identifying as “advanced practitioners” functioning in patient care roles for which they were prepared by experience and formal education.⁶
- The scope of the DCLS competencies, as well as doctoral curricula from other healthcare disciplines and biomedical science programs of comparable rigor, were considered in setting the DCLS program of study at a

minimum 90 semester credit hours beyond the baccalaureate CLS degree. Additional admissions requirements, e.g., minimum scores on standardized proficiency examinations, minimum grade point averages, and prerequisite course work, are not specified, but are to be addressed by individual institutions and their program admissions committees.⁶

- The DCLS curriculum is not technical in the traditional CLS interpretation. Rather, the doctoral curriculum is based on new competencies related to postgraduate biomedical sciences; patient interactions, communication, and patient case management; CLS diagnosis and therapies; evidence based practice; and clinical services delivery.⁶
- Model curriculum materials (course descriptions and objectives) developed by the PDTF were disseminated for review and comment by a sample of individuals in other healthcare professions with knowledge of clinical laboratory science responsibilities in healthcare delivery, interest in furthering the quality of the clinical laboratory, and expertise in clinical healthcare education. A total of 22 sets of curricular materials were distributed with a response from 12 reviewers (55% response rate).⁶
- From the programmatic perspective, a cooperative, national (distance or “blended” delivery) approach to DCLS practitioner education is envisioned that will assure access to common educational content related to the current complex regulatory and financial environment of healthcare delivery. Academic institutions and clinical facilities will partner to provide curriculum, so that regardless of the limitations of the local educational environment, DCLS students can develop competency in all areas considered to be pivotal in evidence-based practice including regional and national assessment of health risk. Not only does this educational approach speak to the development of a national workforce, but it favors the emergence of common DCLS job responsibilities later in practice, thus hastening the availability of job analysis-based DCLS certification.¹³
- A national, collaborative approach to DCLS program delivery will provide an opportunity to benchmark best practices related to these competencies and assure students’ exposure to interpretation of competency in multiple practice settings.¹³
- Having the obligation to provide wide access to the DCLS in healthcare delivery, institutions interested in implementing DCLS programs are exploring consortia development that would allow multiple institutions to share some or all of their collective resources in program delivery.¹³

DIALOGUE AND DISCUSSION

- The DCLS clinical competencies in the curriculum will be addressed within the clinical laboratory in preparation for administrative practice roles and outside the clinical laboratory in preparation for consultative functions by shadowing healthcare providers, rounding, auditing medical records, interviewing patients and healthcare providers, charting clinical laboratory information and interpretations, recommending test selection, and participating in medical decision-making.¹⁵

Continue to monitor our professional literature and the ASCLS website (www.ascls.org) for progress updates. Please post general comments to the ASCLS Forums. (You can find the Forums from the "About" link on the title bar of the ASCLS homepage). Your comments regarding the DCLS continue to shape the future of our profession!

Clin Lab Sci encourages readers to respond with thoughts, questions, or comments regarding this article. Email responses to ic.ink@mchsi.com. In the subject line, please type "CLIN LAB SCI 21(3) DD LEIBACH". Selected responses will appear in the Dialogue and Discussion section in a future issue. Responses may be edited for length and clarity. We look forward to hearing from you.

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2009 Annual Meeting Abstract Deadline

The deadline for abstracts for oral or poster presentations of research or case studies at the 2009 ASCLS Annual Meeting is January 15, 2009. Submission instructions and the proposal form may be found at www.ascls.org/conferences. The completed proposal form and abstract must be submitted electronically by the deadline.

The 2009 Annual Meeting will be held July 21-25 in Chicago, IL. Additional meeting information will be available at the ASCLS Conferences webpage.