

Integration of the CLS Doctorate into the Healthcare Organization

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OBJECTIVE: A review of how the doctorally prepared CLS fits into the healthcare organization.

DESIGN: Literature review.

BACKGROUND: Numerous national studies have called for a reshaping of the health care delivery system and the need to improve patient outcomes. Because of unprecedented advances in laboratory related technology as well as the need for economic retrenchment strategies in health care, with its significant influence on patient care, the laboratory has become the subject of intensive study. It has been concluded that the traditional organizational structure of the laboratory information process and the required personnel skills both need rethinking. In order to foster change in the laboratory, an advanced degreed CLS laboratory professional is needed, one already equipped with a broad scientific base developed via a baccalaureate/masters level of education.

CONCLUSION: With the addition of advanced technical expertise, basic medical skills, data interpretation skills and patient interaction abilities, and medical research experience, this laboratory professional can enhance the effective and efficient use of laboratory information and ultimately improve patient care. The clinical doctorates in CLS are educationally and experientially prepared to recommend support and enhance appropriate testing. They translate and transform complex laboratory data into an understandable product necessary for clinicians to be able to assess the validity of current and new assays to ensure better patient care. In addition, they assist in reducing questionable test usage, thereby reducing costs for both the patient and the laboratory.

The peer-reviewed Clinical Practice Section seeks to publish case studies, reports, and articles that are immediately useful, are of a practical nature, or contain information that could lead to improvement in the quality of the clinical laboratory's contribution to patient care, including brief reviews of books, computer programs, audiovisual materials, or other materials of interest to readers. Direct all inquiries to Bernadette Rodak MS CLS(NCA), Clin Lab Sci Clinical Practice Editor, Clinical Laboratory Science Program, Indiana University, Clarian Pathology Laboratory, 350 West 11th Street, 6002F, Indianapolis IN 46202. brodak@iupui.edu

INDEX TERMS: Clinical Doctorate, Clinical Laboratory Scientist, Pathologist

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INTRODUCTION

The velocity of change in health care has increased and there is a growing need to shift the emphasis from how laboratory information services are delivered (i.e. test results) to a focus on their direct contribution to patient care.¹ Without a significant change in the way that these services are rendered, the increasing personnel shortages at all levels may foster the factory mentality in the laboratory to the detriment of patient care.² Further, without additional understanding of new testing capabilities and constraints, it may be left to clinicians to rely on outdated and incomplete information when ordering tests. This would increase the use of inappropriate and multiple tests, thus increasing costs.

Addressing these laboratory issues is paramount to improving patient care and is critically important to economic considerations. It is evident that there is no organizational model that previously worked and that now works effectively and efficiently.³ The breadth and depth of laboratory services have dramatically expanded to the point that the need for a new professional with additional professional skills has been demonstrated.⁴

Laboratory professionals at all levels must be able to provide assurance that the correct test is performed on

the right person, at the right time, as well as that the test produces accurate and timely results. This chain of events enables clinicians to make correct diagnostic and therapeutic decisions using the appropriate level of health care resources.⁵ Repeated studies have shown that clinicians and patients may not always be receiving optimal laboratory services because of a significant gap in the provision of these services within the profession.⁶ The gap lies between the increasing number of scientific tests available and the lack of expertise to clinically manage the data emanating from these tests.

Because of this gap, the organizational structure of laboratory services and how these services are provided are changing.⁷ A perspective of how the doctorate in clinical laboratory science provides a vehicle for this change follows.

BACKGROUND

Traditionally, the laboratory has been recognized as a critical component in the provision of information to clinicians as they assess patient health status. Early on, the pathologist was the singular laboratory professional who provided information to clinicians. More recently, however, the increasing numbers and sophistication of complex tests fostered the need for development of additional professionals who could augment the pathologist's capability. Now most laboratories of any size have a rich mix of necessary staff at many professional levels.⁸ These include technicians, technologists, and scientists at a variety of educational levels. The non doctoral clinical laboratory scientists are the most broadly educated in depth within the laboratory fields and are not confined to addressing one specific discipline. These scientists are prepared to rotate through the many scientific testing fields within the laboratory. They have experience and understand testing protocols for blood bank, chemistry, genetics, hematology, immunology, microbiology, molecular diagnostics and virology. They can assure that the correct test is preformed at the right time producing the best information.⁹ However, their expertise is not always requested and clinicians may look only to the data on paper and not appropriately use their professional interpretive capabilities.

The clinical pathologist most often remains the final authority for laboratory test interpretation and, when available is clearly needed for consultation and interpretation. However, as critical as this professional is to laboratory medicine, they are drastically diminishing in numbers at a time when the responsibilities within the laboratory are

increasing in complexity.⁷ Given a conservative estimate of 2,000 or more possible laboratory tests available to clinicians for interpretation, it is now obvious that clinicians, and to an increasing extent even clinical pathologists, cannot be versed in all tests. While it is reported that 60 – 70% of objective medical decisions are based on laboratory data, inappropriate utilization of testing can range from 10 – 50% of test volume at any given time.¹⁰ This is due in large part to the lack of appropriate laboratory consultation available to clinicians before, during and after testing.

Professional organizations related to the laboratory have been monitoring these issues over time and have developed initiatives to counteract the negative effects projected for patient care. The American Society for Clinical Laboratory Science (ASCLS) developed position papers that proposed a clinical doctorate in CLS to address the future need.¹¹ The National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) promoted extensive discussion of the changing laboratory roles at several national conferences and invited broad professional input.¹² In 2005 ASCLS appointed a task force to determine the feasibility of such a doctorate. When, after numerous broad based debates, it appeared that the doctorate was needed and generally accepted, NAACLS developed accreditation *Standards* to be used to carefully evaluate programs producing graduates with these appropriate skills.¹³ An exploration of who these doctorally prepared individuals are and how they fit into the clinical laboratory and health care system follows.

Structure and Integration of the Clinical Doctorate

Fitting into the Organizational Structure

Pathologists and other doctorally prepared individuals (e.g. Ph.D. microbiologist, clinical chemist) in the laboratory are engaged in a myriad of focused activities. For pathologists, these include obligations to hospital administration as well as serving on numerous organizational committees. They also include conducting research in addition to their consultation responsibilities in clinical pathology and the overall testing operations within the laboratory.

However, while the Ph.D. prepared individuals are helpful as specialists, they have doctoral education in the specific field and may not have a generalist background to enable them to provide for broad based consultation beyond their field.¹⁴

The CLS doctorate, prepared with broad generalist education plus the additional medical and information skills, can be

available as the physician's 24/7 consultant. This doctoral graduate is knowledgeable regarding appropriate ordering, carrying out and interpreting tests. It is timely that pathologists recognize what can be shared with well-trained and appropriately credentialed colleagues.¹⁴

The doctorally prepared CLS can fit into a number of roles within the organizational structure. In the laboratory, the individual may serve as director of laboratories, as the head of a specialty laboratory, or other roles that utilize their expertise (e.g. director of clinical trials testing, director of community education & screening programs, director of new testing methods). Within the healthcare organization, but beyond the laboratory, the individual may:

- serve as infectious disease officer;
- serve with clinical teams conducting grand rounds;
- develop specialty practices such as newborn ICU, surgical ICU, burn units, trauma;
- serve as an academic officer;
- serve on organizational committees.

Within the community, the CLS doctorate can function in numerous settings such as:

- a reference laboratory;
- a public health department at the local or state level;
- a federal agency (e.g. CDC, FDA, NIH);
- an academic setting;
- private industry;
- a veterinary setting.

The CLS Doctorate Education

Entry Requirements - Applicants to programs providing education for the CLS doctorate are required by accreditation Standards to be certified and experienced at the generalist level via appropriate certifying agencies. They must have licensure in any state that licenses the clinical laboratory scientist at the baccalaureate or masters level. Applicants must demonstrate proficiency in all major areas of the clinical laboratory as outlined in the Standards.¹³

Technical Expertise - At the doctoral level, technical expertise is based upon advanced scientific areas that directly impact patient care. These professionals have expertise to assess the validity of current and future laboratory assays and to institute corrective measures when problems arise. This requires an understanding of 1) principles of test methodology, 2) evaluation of new instrumentation and

techniques, and 3) knowledge of appropriate specimen collection and processing.¹⁵

Medical Knowledge - Medicine may best be described as the art and science of healing. The mission of medicine supports a wide range of health care practices aimed to maintain and restore individual and community health through the prevention [http://en.wikipedia.org/wiki/Prevention_\(medical\)](http://en.wikipedia.org/wiki/Prevention_(medical)) and treatment http://en.wikipedia.org/wiki/Treatment_of_illness. The practice of today's medicine integrates both science <http://en.wikipedia.org/wiki/Science> (as the evidence base) and art <http://en.wikipedia.org/wiki/Art> (the application of this medical knowledge) in combination with scientific intuition <http://en.wikipedia.org/wiki/Intuition> and clinical judgment to determine the best treatment plan.

Central to medicine is the patient-physician relationship that is established when a person seeks a physician's help. Other health professionals similarly establish a relationship with a patient and may perform various interventions (e.g. clinical laboratory scientists, nurses, pharmacists, and therapists). Working together as a team, many highly-trained healthcare professionals besides physicians are involved in the delivery of modern health care. Examples include but are not limited to nurses, pharmacists, paramedics, speech language pathologists, physical therapists, radiographers, and bioengineers. The scope and sciences underpinning medicine overlap many other fields. For example, dentistry while a separate discipline from medicine, is considered a medical field. Veterinary medicine has also adopted a very similar model of medicine, including using some of the various health professionals described above.

When a patient is admitted to hospital, it is usually under the care of a specific physician or team based on the patient's primary presenting problem, (e.g. internal medicine, cardiovascular, surgery). These physicians may then interact with other specialties, (e.g. radiology, infectious diseases, hematology) to help diagnose or treat the medical issues and any subsequent complications / developments. Two of the specialties that physicians, nurses and others consult with are the clinical laboratory scientist and the pathologist and often their specific expertise may be confused. Their expertise may best be described as:

Clinical laboratory scientists provide the clinical diagnostic services which apply laboratory techniques to the diagnosis and management of patients. The personnel that work in the clinical laboratory are educated in clinical laboratory

sciences. These are the individuals who actually perform the tests, assays, and procedures needed for providing the specific services. Subspecialties include transfusion medicine, clinical chemistry, hematology, clinical microbiology, clinical immunology, virology and molecular genetics. These individuals consult on the appropriate use and interpretation of laboratory test.

Pathology is a medical specialty and is the branch of medicine that deals with the study of diseases and the morphologic and physiologic changes produced by them. As a diagnostic specialty, pathology can be considered the basis of modern scientific medical knowledge and plays a large role in evidence-based medicine.

Since clinical laboratory doctoral graduates function as liaisons between clinicians and the laboratory and can assist in patient assessment, in addition to their basic science understanding, doctoral graduates have considerable exposure to clinical medicine. This is obtained through service on grand rounds as a member of the medical team as well as access to the literature on pertinent laboratory issues related to patient management.¹⁵

Health Services Research - Health services researchers examine health care quality, effectiveness, efficiency, patient outcomes, access to care, health care costs, financing, primary and managed care, new technologies, and other critical topics. Health services researchers are employed in many settings, including academia, professional organizations, health policy groups, clinical settings, and in Federal, State, and local agencies.

Clinical laboratory scientists may be employed as health services researchers who focus on some of the most complex and challenging issues currently affecting health care in the world. Findings from health services research inform the health care policymaking process, lead to improvements in clinical practice, and help shape the manner in which health care is to be delivered and paid for in the future.

Structured education in basic science, clinical care, and research methods are fundamental educational components of the doctoral graduate in clinical laboratory science and prepare the individual to integrate these skills into clinical trials and other types of research. The graduates' strength in research design, statistics, grant writing, as well as knowledge of the protection of human subjects and research ethics are added benefits to managing clinical laboratory data.¹⁶

Communication and Policy Development - A variety of opportunities for teaching experiences are required in the education programs for the doctoral CLS. These experiences provide for skills necessary to function in direct patient care with diverse communities of patients and family members as well as with other health care practitioners. There are opportunities to enhance presentations skills and present clinical cases to professional groups.¹⁵

In addition, the doctoral CLS will have documented experience in policy development. That includes knowledge in development, interpretation and application of overall health care policy and legislation as they apply to the laboratory and patient care. These would include reimbursement policies, medical liability exposure, licensure, ethics, tort, and patient privacy protection.¹⁷

The CLS Doctorates Responsibilities and Relationships

As the presence and understanding of the CLS Doctorate becomes more evident, increasing communication with clinicians must occur. For example, blood bank requires communication with anesthesiologist, blood donors, patients and clinicians. CLS doctorates will follow patients to investigate transfusion reactions and/or screen patients for aphaeresis. In microbiology and hematology, CLS doctorates will attend 'grand rounds' with physicians. Since every patient is managed with data from clinical chemistry, there is the potential for a large number of questions and interpretations that CLS doctorates will be able to address in a succinct and professional way.¹⁴

For the Pathologists the CLS doctorate fills the gap between the clinician concerned about what tests to order given the patient's status, and interpretation of results of the test for the clinician. As such they provide significant consultant and educator expertise for the physician. To the undergraduate and masters level CLS professionals they can be mentors and colleagues and serve once again as in-house consultants. For other health professionals (specialty doctorates in the laboratory, nurse practitioners, physician's assistants, etc.) they can serve as colleagues, educators and consultants. To patients and the general public they are educators and consultants plus givers of care in the broadest sense.⁷

CONCLUSIONS

The CLS clinical doctorate provides for an individual with a broad generalist's understanding of the total laboratory assay

functions and impact but with added skills. This emerging professional has broad consulting and teaching skills and the ability to move outside the physical boundaries of the laboratory to function knowledgeably as an integral part of a patient-oriented professional team. They are actively involved in promoting better test ordering, test utilization and test evaluation. All of these are critical components of quality health care. The CLS doctorate's capabilities can significantly improve patient outcomes and patient safety. In addition they can significantly reduce the overall costs of health care^{3, 16}.

Clin Lab Sci encourages readers to respond with thoughts, questions, or comments regarding this article. Email responses to westminsterpublishers@comcast.net. In the subject line, please type "CLIN LAB SCI 22(3) I MONTROYA". 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.

REFERENCES

1. Institute of Medicine. To Err is Human: Building a safer health care system. Washington, D.C. National Academy Press. 1999.
2. Epner PL. Laboratory Workforce Shortage: Implications for the Future. Clin Leadersh Manag Rev 2007;21(6):E1-7.
3. The Lewin Group, Inc. The Value of diagnostics: innovation, adoption and diffusion into health care. Washington System, Washington D.C. 2005. 209 -12
4. Dighe AS, Soderberg BL, Laposata M. Narrative interpretations for clinical laboratory evaluations; an overview. Am J Clin Pathol 2001; Dec; 116 Suppl; S123-8
5. Mechanic D. Physician discontent: Challenges and opportunities. JAMA 2003; 290: 941-6.
6. Kratz A, Laposata M. Enhanced clinical consulting – moving toward the core competencies of laboratory professionals. Clin Chim Acta 2002;319:117-25
7. Bernstein L. The Doctorate in Clinical Laboratory Sciences: The Time Has Come, NAACLS News, Special Edition Volume 92: 10-11, 2006
8. Laposata M. Patient-specific narrative interpretations of complex clinical laboratory evaluations; who is competent to provide them? ClinChem 2004; 50:471-2.
9. ASCLS Position Paper: Doctoral Education in Clinical Laboratory Science. Approved by the ASCLS House of Delegates June, 1989.
10. Forsman R W: Why is the laboratory an afterthought for managed care organizations? Clin Chem. 1996; 42(5):813-6
11. ASCLS Position Paper: Advanced Practice: Doctorate in clinical Laboratory Science. Approved by the ASCLS House of Delegates July 2005.
12. NAACLS NEWS: A Clinical Doctorate for the Laboratory. Special Edition 92, 1-11, Spring 2006
13. NAACLS Standards for Clinical Laboratory Science Doctorates. 2005
14. Piller L. The Clinical Doctorate: A boon to pathologists. NAACLS News, Special Edition 92: 9, 2006
15. Beck SJ, Briden ME, Epner PL. Practice levels and educational needs for Clinical Laboratory Personnel. Clin Lab Sci 2008;21: 68-77.
16. National Cancer Institute. Report of the Translational Research Work Group of the National Cancer Advisory Board. Transforming Translation- Harnessing Discovery for Patient and Public Benefit. Accessed November 15, 2008 at www.cancer.gov/aboutnci/trwg/executive-summary.pdf.
17. American Society for Clinical Laboratory Science. Educational statement related to the doctoral level clinical laboratory scientist. Advanced Practice: Doctorate in Clinical Laboratory Science. Accessed December 12, 2008 at <http://www.ascls.org/position/AdvPractice.asp>

ERRATA: The Spring 2009 volume of Clinical Laboratory Science was published with some misspellings in several locations of the journal. ASCLS and Clinical Laboratory Science regret this oversight in proofing the journal. It is our intent to provide the most professional journal possible for the profession and we apologize to the authors and readership.