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Advanced Practice: Doctorate in Clinical Laboratory Science

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Introduction:

The concept of interprofessional patient care teams to provide more effective medical care for patients has been promoted for decades.~~[1,2]~~[1-5] These teams usually consist of the admitting physician, hospitalist physicians, nurses, doctoral pharmacists, health profession therapists, and social workers. Professionals from the clinical laboratory are conspicuously absent from these teams, yet ~~the majority of~~ many medical decisions (diagnosis, therapy, discharge, etc.) rely on laboratory test results.~~[3,4,5]~~[6] With a plethora of clinical laboratory tests and new molecular methodologies being added to the clinical laboratory test menu, clinicians are challenged with keeping abreast of the latest in laboratory services.[7,8] Technological advancements in laboratory informatics, patients' ready access to laboratory test results, and personalized/precision medicine place the clinical laboratory in the center of patient-centered care.[9-13] ~~The~~ Thus medical laboratory ~~scientist~~ professionals can be ~~a~~ key members of the interprofessional health care team. Development of ~~the~~ certified M~~m~~edical L~~l~~aboratory Sscientists to assume a role as a member of the interprofessional health care team requires additional education to acquire advanced knowledge and ~~clinical training~~ skills.

Background:

In 1999, the Institute of Medicine (IOM) reported that an estimated 44,000 to 98,000 hospitalized Americans die each year from preventable medical errors in a health care system that is fragmented with inadequate systems to protect patients.~~[6]~~[14] An evidence-based analysis of more recent data increased the estimate of preventable patient deaths in U.S. hospitals from 210,000 to over 400,000 each year.[15] In addition to this tragic human toll, medical errors waste billions of health care dollars annually.[14] In a follow-up publication in 2001, the IOM specified six aims to improve the delivery of health care so that it is safe, timely, efficient, equitable, patient-centered, and effective based on scientific knowledge.[2] In 2003, the IOM specified five core competencies for health care professionals, namely, the ability to provide patient-centered care, work in interdisciplinary teams, employ evidence-based practice, apply quality improvement, and utilize informatics.[3] The IOM further expanded recommendations in 2015 concentrating on the diagnostic process to reduce diagnostic errors.[16] Recommendations included promoting teamwork with health care professionals, patients, and families; better use of information technologies; developing processes to detect and reduce diagnostic errors; and providing more funding for research on the diagnostic process.[16]

The American Society for Clinical Laboratory Science (ASCLS) strongly supports the IOM's recommendations to improve patient safety.[17] Although initiatives in clinical laboratory quality improvement, informatics, and evidence-based practice continue to be addressed to improve health care quality and safety, these efforts need to be expanded, coordinated, standardized, and linked to patient outcomes.[11,18-24] ASCLS particularly supports a new role for clinical laboratory practitioners in ~~for healthcare~~ interprofessional collaboration, ~~and promotion of~~ effective health care teams, and patient-centered care.[~~7,8~~ 17,18,25,26] Inclusion of a clinical laboratory practitioner in the interprofessional health care team ~~approach~~ would have a positive impact on patient outcomes and safety. It would also result in cost savings to the health care system by providing valuable and reliable clinical-based knowledge regarding laboratory testing that fosters accurate and timely diagnoses and treatment, thus supporting the IOM's recommendations.[2] . ~~The addition of medical laboratory professionals further supports the IOM's report suggesting that improved access to accurate and timely information is a way to prevent errors and improve patient safety.[6]~~

The Centers for Disease Control and Prevention (CDC), Division of Laboratory Systems convened a professionally facilitated meeting "The 2007 Institute: Managing for Better Health." This Institute addressed the wide-ranging goal of improving the integration of laboratory medicine within the health care system. Four main goals were identified at this meeting.[27] One of the goals identified was:

> *"to institutionalize new models of clinical consultation provided by ~~the~~ laboratory medicine professionals to clinicians to guide their decisions about utilization of laboratory tests or services."*[27]

This goal addresses the CDC's vision of a collaborative, consultative relationship between medical laboratory professionals and clinicians, thus integrating laboratory medicine into patient care. ~~Since the meeting, CDC has modified the initial four goals down to two. However, this goal has been maintained, emphasizing its importance.[9]~~

The advanced practice clinical laboratory practitioner ~~may~~ can increase efficiency, facilitate patient management outcomes, and improve timely access to accurate and appropriate laboratory information by participating directly in patient care decisions, monitoring laboratory utilization, and conducting research on the diagnostic process.[3,16,28] Medical L~~l~~aboratory S~~s~~cientists have extensive knowledge regarding laboratory tests and data, and with advanced ~~training~~education can: ~~assist in appropriate laboratory test selection based on physiological and clinical situations. Working along with the healthcare team, the advanced practice clinical laboratory practitioner can~~

- ~~participate in rounds, contributing expertise related to test ordering as well as provide day-to-day consultation~~
- ~~consult with healthcare providers in a variety of healthcare settings about selecting the most appropriate laboratory tests~~
- ~~customize the testing needs of patients, particularly those in a critical care setting~~
- ~~provide support to the patient during pre-analytical phase of testing (test preparation)~~
- ~~assist with interpretation of tests, and provide patient specific analysis of the test results~~
- ~~explain test results specific to a patient's medical status in relation to physiological conditions and/or possible interfering substances~~
- ~~educate patients to perform home/self-testing~~
- Provide patient-centered, customized consultation services on appropriate test selection and interpretation for the purpose of clinical decision making among the interprofessional health care team and for the patient.
- Monitor laboratory data, test utilization, and diagnostic testing processes in individual patients and populations using informatics and analytics to reduce diagnostic errors, improve efficiency, and reduce costs.

- Conduct research and apply evidence to demonstrate clinical utility of laboratory tests and algorithms and to improve the quality, efficiency, and safety of the overall diagnostic testing process.
- Educate health care providers, patients, their families, and the general public about the indications, best evidence, patient preparation, and interpretation of clinical laboratory testing, including home self-testing.
- Direct laboratory operations to comply with all state and federal laws and regulations, as well as guidelines determined by professional boards of licensure, and certification/accreditation agencies
- Participate in public and private health policy decision making at all organization and government levels using best evidence.

Pathologists and other health care providers recognize the need for greater clinician access to laboratory consultants for clinical decision support and appropriate utilization of laboratory services.[7,29] The advanced clinical laboratory practitioner would be in a unique position to improve patient outcomes while developing and strengthening collaborative relationships among laboratory professionals and other health care providers. Improper test selection and patient preparation, and misinterpretation of laboratory tests cost patients in time, treatment, and money, and jeopardize their safety.[20] The advanced clinical laboratory practitioner would also be instrumental in coordinating utilization of laboratory test data to actionable outcomes that can improve patient care and reduce medical errors. ~~Pathologists recognize the need for improved utilization of laboratory services.[10]~~

ASCLS has advocated for the role of advanced practice non-physician laboratory scientists in promoting improved patient outcomes. In July 2004 the ASCLS House of Delegates accepted a model career ladder for the profession.[8,25] The highest practice level (Advanced Practice Scientist III) ~~level represents the professional doctorate degree in clinical laboratory science~~requires a doctorate degree with skills in consulting, evaluating laboratory testing outcomes, and evaluating research designs. ~~At this level of practice, the medical laboratory scientist is expected to serve in consultant roles, interpret patient assessments to determine clinical status of the patient, and manage patient laboratory data as part of the healthcare team.~~ In July 2009, the ASCLS House of Delegates approved a position paper which expanded the practice levels and educational requirements.[18] In that paper, the highest level of practice (Level VIII) specified a requirement for a doctorally-prepared clinical laboratory practitioner (Doctor of Clinical Laboratory Science or PhD), with practice skills in clinical assessment, evidence-based practice/research, laboratory services clinical consultation, patient counseling, grant-funded research as principal investigator, and test utilization/assessment/protocol development.[18] The following represents the most recent position of ASCLS on the Doctorate in Clinical Laboratory Science.

POSITION

ASCLS supports the development and implementation of a professional Doctorate ~~of~~ in Clinical Laboratory Science degree in institutions of higher learning. The professional doctorate would not be viewed as an entry level for the profession, but instead will provide an additional level of education to afford advanced career opportunities for ~~the~~ M~~m~~edical L~~l~~aboratory S~~s~~cientist~~s~~. ASCLS recommends that the professional be designated Doctor ~~in~~ of Clinical Laboratory Science, and the degree be designated a Doctorate in Clinical Laboratory Science (DCLS).

ASCLS believes that formal education leading to certification as a generalist Medical Laboratory Scientist provides an essential foundation for success in the graduate curriculum and for building the advanced DCLS competencies. Therefore ASCLS believes that the minimum prerequisites for entry into a DCLS Program include 1) completion of a NAACLS-accredited Medical Laboratory Science Program (or equivalent international program), 2) a baccalaureate degree, and 3) generalist Medical Laboratory Scientist certification. For individuals with clinical laboratory experience or relevant advanced degrees who do not have all three prerequisites, ASCLS believes that advanced placement mechanisms could be made available in NAACLS-accredited Medical Laboratory Science programs to enable these individuals to meet these prerequisites and become eligible for entry into a DCLS program.

ASCLS supports the concept of designing a common education model for this professional degree and implementing programs in a collaborative manner where feasible and desirable. Consortia or other collaborative models that rely on distance delivery options, and emphasize the relative strengths of the participating institutions are encouraged.

ASCLS supports the curriculum model developed by the ASCLS DCLS Task Force. This curriculum serves as a guide for program development. It includes the core competencies of basic science, and clinical laboratory science that provide the knowledge, clinical skills, and interpersonal skills needed for competency at this advanced level of practice.

ASCLS supports and encourages development of interprofessional health care teams that include the ~~professional doctorate prepared medical laboratory scientist~~ Doctor of Clinical Laboratory Science (DCLS).

ASCLS supports a continuous dialogue with the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) in the process of developing and revising accreditation standards for the Doctorate in Clinical Laboratory Science ~~level~~ programs.

~~ASCLS believes that practitioners at the DCLS level should hold active certification and/or licensure. ASCLS supports a continuous dialogue with the Board of Certification (ASCP) in the process of developing a DCLS Certification~~.

ASCLS believes that DCLS practitioners must earn doctoral-level board certification comparable to the certifications held by individuals with whom they will consult such as medical doctors (MDs, DOs), pharmacists (PharmDs), nurses (DNP), etc. Therefore a single board certification specific to the unique scope of practice of the DCLS should be developed. Further, that certification agency should seek approval from the U.S. Department of Health and Human Services for its DCLS certificants to qualify as laboratory directors under the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

ASCLS believes that state licensing boards, ideally with nationwide reciprocity, should be created in all states to regulate the practice of DCLS practitioners and protect the public.

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