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

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

eJIFCC

Education & training in laboratory medicine in the United States

Guest Editor

Stacy E. Walz, PhD, MS, MT (ASCP)
Assistant Professor, Department Chair, Clinical Laboratory Science Department, Arkansas State University- Jonesboro
P.O. Box 910 - State University, AR 72467
Tel: (870) 680-8596
e-mail: swalz@astate.edu

Disclosure: The author has no financial conflicts of interest to disclose.

The clinical laboratory world in the United States is an exciting, fast-paced, and rewarding world for those who choose to engage it. The educational and training paths that lead to work in this world are varied in length, curriculum, scope and opportunity. This special issue of the Journal of the International Federation of Clinical Chemistry and Laboratory Medicine will describe the common paths individuals may take to work in the clinical laboratory. As an introduction to the edition, a brief history of formal laboratory education is provided, along with a synopsis of the governmental regulations that dictate personnel requirements in the laboratory. The levels of practice, as defined by one of the major laboratory professional organizations, the American Society for Clinical Laboratory Science, is summarized, and the expert authors and their respective contributions to this edition are introduced.

HISTORICAL PERSPECTIVE

In the late 1800's and early 1900's, laboratory education occurred within hospital laboratories, where young women (typically) were taught how to perform basic laboratory tests under the direct tutelage of a pathologist (1). More formalized education programs began to appear after World War I, however, there was no professional recognition or oversight of these programs at the time. These early programs only required a high school diploma or less for acceptance, and the quality of training was widely variable. A few college-level laboratory instructional programs arose in 1918 in response to an increase in both the number of clinical laboratories and the number laboratory tests being developed and offered (2).

A group of pathologists established the American Society for Clinical Pathology (ASCP) in 1922, in part to oversee and standardize the training programs for laboratory technicians. Shortly thereafter, a subcommittee was charged with formally defining the profession and creating a registry of those trained according to the standards set forth by the Society. This subcommittee became the ASCP's Board of Registry in 1928, and two years later, the first certificates were awarded to more than 400 laboratory technicians (3).

Initially, laboratory professionals were divided into "technicians" and "technologists". Technicians must have graduated from high school and received approximately 18 months' worth of didactic and clinical training in the laboratory. Technologists possessed a degree from a university with at least one year of basic sciences and a year of hands-on clinical training in a recognized laboratory (3). To this day, the professionals performing the bulk of the testing in laboratories in the U.S. are classified as "technicians" with associate's degrees, or "technologists" with bachelor's degrees.

During the 1930's and 1940's, the ASCP Board of Registry (BOR) performed a number of important tasks that further formalized laboratory training programs. They surveyed existing training programs, using the gathered data to develop recommendations for curricula (didactic and clinical), program length, and qualifications of teaching faculty in both hospital-based and university-based training programs. The BOR raised the criteria for applying for registration, and generated a list of "approved" schools (3). The work of the ASCP, the BOR, and a newly established professional organization for the "bench-level" laboratorian (the American Society of Clinical Laboratory Technicians- ASCLT), all helped to elevate the status of the laboratory "technician" in

the early to mid-1900s. World War II impacted the profession by increasing the need for technicians in the public health realm and in military hospitals. Another type of training subsequently arose: that which occurred within a U.S. Armed Forces (i.e. Army, Navy) environment (4).

The ASCP continued to oversee U.S. education programs in laboratory medicine until the early 1970's. At that time, more autonomy was desired by laboratory professionals, and the professional organization, American Society for Medical Technologists (ASMT, formerly ASCLT), helped develop an independently operated and governed board to oversee laboratory education (5). The ASCP relinquished their oversight of laboratory education programs. The National Accrediting Agency for Clinical Laboratory Science (NAACLS) was established in 1973, and remains the premier accrediting body for laboratory education programs in the U.S., both within hospitals and universities. Although other organizations have entered the realm of registering or certifying laboratory professionals over the years, only three remain (ASCP, American Association of Bioanalysts- AAB, and American Medical Technology- AMT), with the ASCP continuing as the primary source of independent, professional certification of laboratorians.

Professional certification is a distinct activity from professional licensing, and needs to be briefly discussed here for clarity. Certification, such as what is offered through the ASCP, involves taking a written examination covering all related topics specific to the practice. One must achieve a certain level of knowledge before being able to pass the certification exam, but once the exam is passed, the certification is equivalently recognized in all 50 states in the U.S. Professional licensing, on the other hand, is a state-specific activity that is not currently required in all 50 states; surprisingly only 12 states in the U.S. require a license to practice as a laboratory professional. The results of a certification exam are often submitted to a licensed state as initial "proof" of competency in the profession, and in subsequent years, documentation of appropriate continuing education is submitted to maintain the license.

Today, the individuals who perform the majority of the testing in a typical medical laboratory in the U.S. possess the equivalent of an associate's degree (usually 2 years, 60 credit hours) or a baccalaureate degree (usually 4 years, 120 credit hours). Those within supervisory roles, such as section heads, shift supervisors, and managers, usually have some type of post-baccalaureate education or certification, whether it be specialist certification, a graduate certificate, or a master's degree in laboratory, science, business, or related fields. Laboratory directors possess a PhD or MD degree, with specialized board certifications in laboratory disciplines or pathology.

CLIA

All laboratories that provide testing for the purposes of diagnosis and treatment of disease in humans in the United States must possess a certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), appropriate to the level of complexity of the testing performed (6). Laboratories may additionally be accredited and inspected by other entities, such as the College of American Pathologists (CAP), the Joint Commission (TJC), or the Commission on Laboratory Accreditation (COLA), however, CLIA is the only universal, federally-required inspection and laboratory certification agency.

CLIA regulations (7) define the personnel requirements for all levels of work in the laboratory, according to the level of complexity of tests being performed. Four levels of complexity exist: provider-performed microscopy (PPM), waived, moderate, and high. The typical hospital-based laboratory in the U.S. is usually at a moderate or high complexity level. The testing personnel (i.e. the typical bench laboratorian) requirements for a moderate complexity laboratory are "a high school diploma or equivalent and training for the testing performed" (8).

The laboratory professional community generally considers the CLIA requirements for laboratory testing personnel to be inadequate, and many feel CLIA's low standards have contributed to a "dumbing-down" of the profession. An uphill battle for equivalent recognition of laboratory professionals and their contributions to quality patient care, as compared to more visible healthcare professionals such as nurses, has ensued. Thankfully, most laboratory directors realize that a high school diploma coupled with some training is usually not sufficient to produce a competent, high-quality laboratory professional, and therefore hire only those who graduate from accredited training programs.

Levels of practice

Despite CLIA's minimal personnel requirements for laboratorians, professional organizations and educators continue to work on defining the career ladder and levels of practice of the clinical laboratory profession. In 2005, a task force was commissioned by the American Society for Clinical Laboratory Science (ASCLS, formerly ASMT) to explore the practice levels and educational needs for laboratory professionals (9). This work was in response to laboratory directors' frustration with the discrepancies that existed between the skills new graduates possessed versus what the laboratory work required in the "real world". The task force's work culminated in a position paper adopted by ASCLS in 2009 (10).

The levels of practice as adopted by ASCLS are designed to guide corresponding educational curricula and create a career ladder for those choosing to enter the profession. They provide an excellent outline to this special edition of the eJIFCC, and are summarized in Table 1 (10).

Table 1
Levels of Practice in Clinical Laboratory Science

Practice Skills	Education	Certification
Phlebotomy, specimen processing	High school diploma or equivalent + training	Educational certificate
Waived testing	High school diploma or equivalent + training	
Automated chemistry, coagulation, hematology, urinalysis, less complex microbiology & blood bank	Associate's degree	Medical laboratory technician (MLT)
Advanced techniques in chemistry, coagulation, hematology, urinalysis, microbiology & blood bank	Baccalaureate degree	Medical laboratory scientist (MLS)
Infection control, method evaluation, point-of-care oversight, technical supervision, advanced molecular, specialist	Baccalaureate degree + additional education	MLS or MLS + specialty certification (such as SBB)
Quality management oversight, risk management, operations or technical management	Master's degree in relevant area	MLS + other relevant certification
Evidence-based research, grand rounds, clinical consultation, laboratory director	Medical Doctor, Doctor of Osteopathy, PhD, Doctorate in CLS	MLS + board certification (such as CP or DABCC)

A number of clinical laboratory education experts contributed to this special edition. Dr. Perry M. Scanlan details the educational requirements of the baccalaureate degree, which is widely considered the most versatile and most common of the entries into the clinical laboratory profession. Phyllis Kirchner and Susan T. Johnson discuss post-baccalaureate degree options at the laboratory specialist and master's degree levels. Dr. Joely Straseski highlights the opportunities for post-doctoral fellowships in laboratory medicine. Dr. Jonathan Genzen explains the routes medical doctors may take to become board certified as clinical pathologists. And Dr. Teresa Nadder presents an exciting new degree for laboratory professionals that is only just starting to take off: the doctorate in clinical laboratory science.

In conclusion, this special edition of the eJIFCC serves to provide an overview of clinical laboratory education and training in the United States, with some background on the history of the profession and the regulatory world in which U.S. laboratories operate to "set the stage". Because the practice of medicine and the laboratory world are rapidly changing, educators and healthcare professionals continually need to communicate with one another to ensure that laboratory education is meeting the needs of healthcare. Many others, in addition to those who contributed to this special edition, are passionate about the education and training of competent, high-quality laboratory professionals, and those necessary conversations and assessments will continue to happen, guaranteed.

References

1. Kotlarz, VR, Tracing Our Roots: Origins of Clinical Laboratory Science, Clin Lab Sci 1998; 11(1): 5-7.
2. Kotlarz, VR, Tracing Our Roots: The First Clinical Laboratory Scientist, Clin Lab Sci 1998; 11(2): 97-100.
3. Kotlarz, VR, Tracing Our Roots: The Beginnings of a Profession, Clin Lab Sci 1998; 11(3): 161-166.
4. Kotlarz, VR, Tracing Our Roots: Early Clinical Laboratory Scientists and Their Work – Myth and Reality, Clin Lab Sci 1998; 11(4): 209-213.
5. Delwiche, FA, Mapping the Literature of Clinical Laboratory Science, J Med Libr Assoc 91(3) July 2003, 303-310.
6. Public Health Service Act, Sec. 353, Subpart 2 – Clinical Laboratories, found at http://wwwn.cdc.gov/clia/pdf/PHSA_353.pdf, last accessed 3 March 2013.
7. Current CLIA Regulations, found at http://wwwn.cdc.gov/clia/regs/toc.aspx, last accessed 3 March 2013.
8. CLIA Moderate Complexity Testing Overview, found at http://wwwn.cdc.gov/clia/moderate.aspx, last accessed 3 March 2013.
9. Beck, SJ, MF Briden, PL Epner, Practice Levels and Educational Needs for Clinical Laboratory Personnel, Clin Lab Sci 2008; 21(2): 68-77.
10. Practice Levels and Educational Needs for Clinical Laboratory Personnel Position Paper, ASCLS, Approved 25 June 2009, found at http://www.ascls.org/about-us/voice-your-opinion/position-papers/173-levels-of-practice, last accessed 4 March 2013.