Practice Levels and Educational Needs for Clinical Laboratory Personnel

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Definition of a Position Paper: A detailed policy report that explains, justifies, or recommends a particular course of action.

I. INTRODUCTION

The provision of laboratory services requires the coordinated efforts of a variety of personnel. These personnel span the education continuum from high school through medical school and acquire degrees and certifications with which to appropriately deliver services. There currently is a lack of well-defined criteria for that education and certification at each level of practice that would ensure that the right person with the right qualifications is providing quality health care and guaranteeing the safety of patients.

The existing employment system does not provide for the efficient use of each level of personnel and has led to practices that include: individuals with disparate levels of practice and education that earn similar compensation, the lack of a well-defined career ladder, the use of inadequately educated/trained individuals in the practice setting, and the underutilization of the CLS's skills and education in the workplace.

Our colleagues in other healthcare professions have clearly defined their scope of practice and levels of education for practice and routinely defend these against those who seek to limit or alter them. This is not a new realization for our profession. Over the years the ASCLS House of Delegates has passed a number of position papers that address the issues of level and scope of practice.

- 1995 and 2001 – Scope of Practice
- 2004 – Model career Ladder
- 2005 – Value of Clinical Laboratory Science in Health Care

These papers described our beliefs about appropriate use of personnel, our distinct profession and professional Body of Knowledge, our scope of practice, the utilization of laboratory services, our

impact on diagnosis and changes in patient management, patient safety, and contribution to cost-effective delivery of care. We have not however, outlined an implementation plan or developed consensus among the diverse groups within the profession to support these and to take measures to defend the profession.

It is the duty of the profession to routinely examine the levels and scope of practice and, if necessary to alter them and the corresponding education, program accreditation, and personnel certification requirements. This is necessary not only for the continued existence of the profession but also for its growth. Over the past several years, the leaders within ASCLS and across several laboratory organizations (CLMA, ASCP, AMT, NCA, NAACLS, BOR) have recognized that these issues must be addressed and that a comprehensive look at the profession from education to practice by both managers and educators is necessary. The process is time-consuming, and not without difficulty. It presents a challenge for the profession and will result in change in education and practice. This Position Paper provides a summary of the process, the rationale for change, ASCLS position on Levels of Practice and Educational Needs, the proposed model implementation considerations, and a summary of the business case findings.

II. BACKGROUND

In July 2005, the American Society for Clinical Laboratory Science (ASCLS) Board of Directors commissioned a task force entitled “Practice Levels and Educational Needs for Clinical Laboratory Personnel”. This inter-organizational task force was charged with the following goals:

- Define levels of practice to include knowledge, skills, competencies and attributes.
- Evaluate titles for all levels of practice and rename them if appropriate/needed.
- Develop a comprehensive career ladder.
- Match educational curriculum to practice needs.
- Develop a process to evaluate changing practice needs and adapt education curriculum.
- Develop measures to monitor outcomes of the process.
- Build consensus, within the profession, related to levels of practice.

The first Task Force utilized a Six-Sigma approach to their task and conducted literature review, held focus groups, and ultimately developed a “Model” for levels of practice in the clinical laboratory profession. A survey of clinical laboratory professionals was conducted in January 2007 to obtain feedback on the proposed model. The survey was distributed via e-mail to ASCLS, ASCP, AMT, and CLMA members. Over 2,500 responses were received and reviewed, which although not random nor representative of the total workforce, has provided great information from a broad variety of individuals. Adjustments were made to the model based on the survey input and a White Paper was drafted summarizing the work of the task force and providing rationale for the model. The White Paper and Model were forwarded to all of the participating organizations for review and input. The

model has been presented at numerous state and regional meetings for additional feedback from practitioners in the profession.

In January 2008, the American Society for Clinical Laboratory Science (ASCLS) Board of Directors commissioned a second task to continue the work of the first group. Specifically, Task Force II updated the model based on the additional feedback (see section IV), developed a plan for implementing the model, and developed a business case for why the model can and should be implemented. The Implementation Plan and Business Case documents are on file in the ASCLS office and available on the ASCLS Web site.

III. RATIONALE:

The Institute of Medicine (IOM) report on medical errors (*To Err is Human*) highlighted an unacceptably high rate, stating that between 44,000 and 98,000 hospitalized Americans die each year as a result of preventable medical errors.[1] This created an intense public response, and reduction of medical errors became a top agenda item for virtually every part of the U.S. health care system. However the supporting data and methods for these estimates along with the assertion that about half of these adverse events are preventable were never well substantiated[2]. Medical errors are not random events but have associations between human error and system faults that result in patient injuries. The understanding and analysis of causal factors can reduce the rates of adverse outcomes.[3]

While pathologists and the field of laboratory medicine took up the call of the IOM *To Err is Human* report to reduce medical errors,[4,5] little progress can be claimed given the lack of standardized, consistent, and meaningful measurement, and that most measurement efforts have not been linked to patient-related outcomes. [6,7,8,9,10,11,12] Currently available error measurement is related to laboratory processes rather than its potential impact on medical care and patients .[10, 12, 13] There has been some progress in classifying laboratory errors and their impact on patient outcomes,[14, 15, 16, 7, 18] however this work remains at a very early developmental stage as the studies and initiatives are on a limited scale and are uncoordinated. These studies still require considerably more effort to develop and achieve a standardized and broadly implemented taxonomy, methodology, and associated measures that identify errors related to patient outcomes.[6, 8, 10, 14, 19, 20, 11]

In lieu of data and studies on laboratory errors, the field has focused on, among other factors, laboratory personnel standards including education, training, certification, and competency. Although competency assessment is mandated by the Clinical Laboratory Improvement Amendments (CLIA) of 1988, no consistent methods or tools have been adopted to assess worker competence. The available evidence is that most laboratories rely on direct observation of performance.[21, 23, 24] It is therefore difficult to make the connection between clinical laboratory education and/or workforce

shortages and their impact on the health care system, or the connection between quality, staffing levels, and outcomes.[25] Sufficient data on errors are not available.

The only existing study on the accuracy of laboratory test results evaluates the effect on accuracy of having ASCP-certified MTs versus non-ASCP-certified MTs in the laboratory was published in 1987.[26] The study compared laboratories with all ASCP-certified MTs to those with no ASCP-certified MTs, and also compared laboratories based on the proportion of ASCP-certified to non-ASCP-certified MTs. It found that laboratories with all ASCP-certified MT staff had significantly higher accuracy in their test results compared with laboratories having no ASCP-certified MTs on staff. The study also found that, among laboratories having some ASCP-certified and some non-ASCP-certified MTs, accuracy of test results was positively related to the proportion of ASCP-certified MTs on staff.

IV. POSITION:

ASCLS recognizes and accepts the responsibility of a professional organization to define the duties, responsibilities, education, and certification requirements of practitioners at every level of practice.

1. ASCLS believes that personnel standards should be defined and prescribed for all levels of practice in order to ensure the validity of laboratory tests and the safety of patients.
2. ASCLS supports defined and differentiated levels of practice that guide educational curricula and employment decisions.
3. ASCLS supports and promotes a career ladder for laboratory professionals as described in the model (see section V).
4. ASCLS adopts the Levels of Practice model as proposed.
5. ASCLS endorses the need for, and will develop an ongoing process to refine the model based on factors such as input from stakeholders, published evidence, and changes in the practice field.

In summary, ASCLS recognizes the need for implementation of the model in the workplace with documentation of the successes, challenges, and outcomes. This will require the communication, coordination, and cooperation of both educators and managers for ultimate success.

V. THE PROPOSED MODEL FOR LEVELS OF PRACTICE IN CLS.

Based on the data collected in the literature review, focus groups, and national surveys, the task force revised the model to reflect a new vision and new standards for the levels of practice in the clinical laboratory science. The model attempts to make the educational process more realistic, attainable, and differentiated. The model represents "**what should be**" rather than "what is". It differs from "what is" in several important ways. First, the model more clearly differentiates levels of practice based on education, certification, and experience. Second, the model affirms the importance of certification and verified competency at all levels of practice. Third, the model defines the practice skills that should be taught and can be expected of new practitioners at each level. In some areas that are not currently well differentiated, the model includes a description of specific practice skills to better differentiate the levels (e.g. associate degree practice skills in blood bank and microbiology). Finally, the model represents a true career ladder from entry level positions through the clinical doctorate. This model will not work with today's curriculum, availability of certificate and associate degree candidates, and possibly some state licensure requirements. However, the model is compliant with and exceeds the current CLIA requirements.

The model assumes that:

- Practitioners receive national certification at each level.
- Practitioners at each level are responsible for performing and/or supervising the duties performed at lower levels.
- Practitioners at each level are responsible for training at their level or at lower levels.
- Skills needed at all levels include, but are not limited to: Communication, Troubleshooting, Quality Control, Patient Safety, Basic Laboratory Safety (OSHA/EPA), Ethics, Interpersonal Skills, Cultural Awareness, IT /Computer Skills, Terminology, Quality / Process Improvement, Basic Laboratory Operations.
- Competency must be verified at all levels of practice.
- Systems for documenting continued competence and recertification would be available at each level of practice.
- An individual could enter at the certificate, associate degree level, baccalaureate degree, or master's degree level.
- Once graduates of educational programs enter the workforce, additional education would be available and required for those who wish to advance their knowledge, skills, and level of practice.
- All <u>new employees</u> complete training and demonstrated competency.

Definitions:

- **Training** = structured instructional program leading to competence in a practice skill prior to independent practice. This could be offered by an employer, as a continuing education program, formal educational institution, or professional society.
- **Additional education** = formal coursework or programs leading to additional certification or an advanced degree.
- **Certificate** = Certificate indicating completion of a structured or defined educational program.
- **Relevant experience** = Supervised experience in the practice skill.
- **Entry Level** = Skills expected at career entry. After competency is documented, practitioners can perform the skills without additional experience.

Proposed Model for Levels of Practice in CLS

Level	Practice Skills:	*Education*	Relevant Experience	Certification
I	Phlebotomy	HS/GED + Training	Entry Level	CLA or Educational Certificate
	Specimen Processing			
	Order Entry – Accessioning			
II	Waived Testing Assisting Duties: • *Loading Analyzers* • *Culture set-up*	HS/GED + Training	Yes	
III	Automated Chemistry, Immuno-Chemistry, Coagulation, Hematology, Urinalysis	Associate	Entry Level	CLT / MLT
	Less complex Microbiology • *Procedure/media selection* • *Culture inoculation* • *Specimen preparation* • *Inoculation/loading of automated ID/Sensitivity instrumentation* • *Direct microscopic procedures, i.e. gram stain* • *Recognition of potential organisms likely sources and significance of culture findings* • *Confirmatory testing and sub-culturing* • *Non-waived antigen kit tests* • *Macroscopic screening for parasites* • *Urine cultures or other single organism cultures*			
	Less complex Blood Banking • *ABO* • *Rh* • *Antibody screen* • *Crossmatch* • *Direct antigblobulin testing* • *Blood and component release*			
	Manual Differentials with higher level review of abnormal results			
	Urine Microscopy			
	Less complex Body Fluid procedures • cell count • automated chemistries • gram stain			
IV	Micro ID including aerobes, anaerobes, or mixed cultures	Associate (plus training)	Yes	CLT / MLT
	Blood Bank antibody identification			
	Manual differential with the potential for higher level review			
	Body Fluid differential with higher level review of abnormal results			

	Simple molecular testing that follows established protocols including DNA Probes			
Level	**Practice Skills:**	***Education***	**Relevant Experience**	**Certification**
V	Advanced Techniques in Blood Bank	Baccalaureate	Entry Level	CLS / MT
	Body Fluid Differential without Higher Level Review			
	Immunology			
	Advanced Techniques Microbiology			
	Advanced molecular testing that follows established protocols including DNA Probes			
	Advanced Techniques in Hematology / Bone Marrows			
	Advanced Techniques in Coagulation			
	Advanced Techniques in Chemistry (Electrophoresis, etc.)			
	Advanced Techniques in Immunochemistry and Drug Testing (HPLC, etc.)			
VI	Advanced Techniques in Body Fluids • *Micro Array* • *Flow Cytometry* • *PCR*	Baccalaureate + Additional education	Yes	CLS / MT
	Infection Control/Epidemiology			
	Method Evaluation/Test Development			
	Patient Education			
	POC Oversight			
	Technical Supervision • *Discipline Specific* • *Employee Supervision* • *Daily Operations, QC Review, etc.*			
	Research Protocols			
	Safety Officer			
	Oversight of Student/Staff Education and Training			
	Technical Consultation			
	Informatics			
	Cellular Therapy - Stem Cell Transplantation			
	Educators: • *Develop and teach didactic and laboratory sessions to reflect current practice* • *Assess student performance* • *Available to students for counseling* • *Engage in service and scholarly activities.*			
	Cytogenetics	Baccalaureate + Additional education	Yes	Specialty Certification
	Advanced Molecular / PCR • *Modify existing tests* • *Troubleshooting* • *Method evaluation* • *Research and development*			
	Advanced Flow Cytometry (anything beyond a routine hematology analyzer)			
	Histocompatibility			
	Specialist in (BB, Chem, Heme, Coag, etc)			

Level	Practice Skills:	*Education*	Relevant Experience	Certification
VII	Compliance/Coding/Regulatory Management	Masters Degree in relevant area	Yes	CLS / MT plus other relevant certification
	Quality Management Oversight			
	Risk/Patient Safety Management			
	Operations/Business Management • *Overall management of the laboratory* • *Regulatory Affairs / Compliance* • *Quality Assurance* • *Process Improvement* • *Information Management* • *Personnel Management* • *Productivity and Performance Monitoring* • *Inter and Intra disciplinary management* • *Financial Management (capital, operating, and personnel)* • *Projecting and Monitoring* • *Contractual Agreements/Business Planning*			
	Technical Management • *Coordinates* • *Plans* • *Manages and monitors testing activities and R & D* • *Data Management and Problem Solving* • *Instrument Selection* • *Test Development and Method Evaluation*			
	Educational Program Director • *Manage human and financial resources* • *Recruit and mentor faculty and students* • *Assure program meets accreditation standards (responsible for organization, administration, periodic review, planning, development, evaluation, and general effectiveness of the program)* • *Engage in service and scholarly activities* • *Engage in strategic planning and set priorities for the program*			
VIII	Clinical Assessment	DCLS or PhD	Entry Level	CLS / MT plus other relevant certification
	Evidence based practice/research			
	Grand Rounds			
	Laboratory Services Clinical Consultation			
	Patient Counseling			
	Grant-funded Research P.I.			
	Test Utilization/Assessment/Protocol Development			

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