Practice Levels and Educational Needs for Clinical Laboratory Personnel

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The following white paper was presented to the ASCLS House of Delegates on July 21, 2007. The white paper represents the work of an inter-agency task force commissioned by ASCLS to address issues related to the education and practice roles of clinical laboratory professionals. A white paper is an expository paper to initiate an awareness of an issue and/or to educate regarding the elements of an issue or problem. It does not include a statement of policy or infer action taken by the Society.

The task force was chaired by Mary Briden, a past president of ASCLS. Other task force members were: Susan Beck, ASCLS (CLS educator); Bernie Bekken, ASCLS (immediate past president – ex-officio); Dana Duzan, ASCLS (manager); Paul Epner, industry (Abbott Diagnostics); Linda Fell, ASCP (educator); Frankie Harris-Lyne, ASCLS (CLT educator); Shirlyn McKenzie, ASCLS president (ex-officio); Susan Morris, ASCLS (manager); Bob Newberry, AMT (manager); Rick Panning, ASCLS (facilitator, manager); Elissa Passiment, ASCLS executive vice president (task force staff support); Dana Procsal, CLMA (CEO); Deb Rodahl, ASCLS (manager); and Randy Vandevander, ASCLS (manager).

ABBREVIATIONS: AMT = American Medical Technologists; ASCLS = American Society for Clinical Laboratory Science; ASCP = American Society for Clinical Pathology; CLMA = Clinical Laboratory Management Association; DMAIC = Define, Measure, Analyze, Implement, and Control.

INDEX TERMS: certification; clinical laboratory science; clinical laboratory staffing; education; medical technology; personnel standards; practice levels.

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The following white paper was previously published in Clinical Leadership & Management Review and is available on the ASCLS website, http://www.ascls.org.

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 task force was asked to address issues raised in ongoing, unresolved discussions among laboratory professionals concerning the preparation of students for the current clinical laboratory environment. Laboratory managers expressed frustration with the discrepancy between the skills possessed by graduates of laboratory educational programs and the needs in today's workplaces. Managers further expressed concern that the workforce shortage that existed today was only the tip of the iceberg based on the aging demographics of their current employees. Laboratory employees and educators were discouraged by the lack of well-defined practice roles for technicians and technologists/scientists and by the lack of opportunities for career advancement within the laboratory. With the current workforce shortage in mind, the task force attempted to tackle issues that might help employers use available personnel more effectively and improve recruitment and retention in the clinical laboratory profession.

The task force was a collaborative project that included representatives from ASCLS, Clinical Laboratory Manage-

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ment Association (CLMA), American Medical Technologists (AMT), American Society for Clinical Pathology (ASCP) and industry (Abbott Diagnostics). The task force membership included CLT/MLT and CLS/MT educators and laboratory managers from diverse laboratory environments and geographic locations.

The task force used the 6 Sigma / DMAIC (Define, Measure, Analyze, Implement, and Control) process improvement methodology as a roadmap. In October 2005, the task force met to "Define" the major problems facing the profession and establish the project goals. The task force then began the "Measure" phase of the process which involved collecting data in order to validate the problems defined by the task force, identify additional important problems, and solicit creative ideas for solutions. Measurement included:

- a review of literature related to clinical laboratory levels of practice.
- a review of scopes of practice in several health professions.
- focus groups of laboratory educators and managers conducted at national professional meetings.
- a national survey used to collect quantitative data as well as comments on a proposed model.

In July 2006, the task force met again to review the information from the literature review, the comparisons with other health professions, and the focus groups. The literature review and focus groups confirmed that the current system was not working and did not meet the current needs of the profession.

Problems that were identified include the fact that associate degree and baccalaureate degree personnel are often used interchangeably, that non-certified employees are hired to perform laboratory tests, that employees lack the communication skills needed for today's workplace, and that laboratory practitioners are leaving the profession because there are limited opportunities for advancement. Based on that information, the task force developed a model that defined the educational and certification requirements for laboratory practitioners at each level of practice. The task force designed a web-based survey to collect feedback on the model from as many laboratory professionals as possible. To ensure that the survey data would be meaningful, a pilot version was distributed in early November 2006. Following analysis of the pilot study results, additional changes were made to the survey document. The web-based survey was widely disseminated in January 2007 through the cooperation of laboratory professional associations as well as the National Accrediting Agency for Clinical Laboratory Sciences.

The task force met in February of 2007 and began the "Analyze" phase of the process which included a review of the responses to the survey. Based on this analysis, the model was revised. Following this meeting, the task force met by teleconference to discuss the implications of this new model and to make recommendations for laboratory educators, managers, practitioners, and professional organizations. In this white paper, the task force presents the information collected in the measurement phase of the process, the revised model, and a discussion of the implications of this model for the laboratory profession.

Review of levels of practice literature

The task force reviewed publications on the knowledge and skills expected of clinical laboratory practitioners at different levels of practice and with increasing years of experience. The ASCLS and ASCP Levels of Practice documents and the 2005 report on "The Clinical Laboratory Workforce" by the Bureau of Health Professions were also reviewed. Key findings included:

- There is considerable overlap in the scope of practice between CLT/MLT and CLS/MT practitioners.
- CLS/MT practitioners perform more complex technical tasks, management tasks, and more communication tasks than CLT/MLT practitioners; however many of the CLT/MLT tasks require problem solving and high-level reasoning.
- At entry level, the CLS/MT practitioners perform core tasks more frequently than advanced tasks or management skills. Five years later, the core task responsibilities remain at a high level and advanced technical and management tasks increase (without additional education). These tasks are primarily in laboratory operations and communication/consultation areas.
- Sixty-four percent of CLS/MT practitioners perform routine tests "frequently" and the same percentage reported that they "never or rarely" perform specialized tests.
- The percentage of workers who reported being "very satisfied" with the level of challenge in their jobs declined from 37% to 17% between 1993 and 2002. Job satisfaction does not differ for CLT/MLT or CLS/MT practitioners.
- CLT/ MLT programs have a higher number of new students and a higher attrition rate than CLS/MT programs.

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- Fifty-five percent of educational programs have changed curricula during the past year but only five percent have eliminated any content.

Scope of practice reviews

The task force reviewed the scopes of practice in the professions of pharmacy, physical therapy, and occupational therapy. Information was collected through interviews and from websites. Only occupational therapy has true articulation and a "career ladder" beginning with the assistant level. In each profession, the scope of practice differentiating the entry level and the baccalaureate or masters level is well defined. The difference in the scope of practice between baccalaureate/masters and the doctoral level is not clearly defined in any of these professions. Due to state licensure, the scope of practice for the disciplines varies from state to state. All the disciplines are struggling with many of the same issues as the clinical laboratory profession.

Focus groups

Two focus groups were conducted in the first quarter of 2006. The first was conducted at the Clinical Laboratory Educators' Conference (CLEC) and the second was at the CLMA ThinkLab '06. The former group was largely made up of educators and the latter group was made up of administrators from hospital laboratories. Because the focus groups were small in size (average size of six), and the sample was not random, the task force could not draw conclusions about laboratory practice in all settings. However, the results of the focus groups were used in combination with other data to inform the task force and guide the survey development. Key findings from the focus groups include:

- There is little difference in the scope of practice between associate degree and baccalaureate degree personnel.
- The skill mix in laboratories is driven by a few key factors including state laws, laboratory budgets, CLT/CLS availability, and relationships with educational programs.
- The lack of clear distinctions between levels of practice serves to reduce the externally perceived professionalism of laboratory practitioners.
- The lack of differentiation of job scope combined with unclear career paths, low wages, and increasing alternatives is demoralizing and seems to increase retention problems among younger laboratory professionals.
- Curricula in educational programs are viewed as reflecting "the way it has always been" with some specific additions as a result of new technology.
- More automation and greater use of software with clinical algorithms will increase the need for associate degree level practitioners.
- More baccalaureate degree practitioners will be needed to develop clinical algorithms, for test utilization consultation especially in the area of molecular testing, for troubleshooting automated methods, and for the expanded technological skills for areas such as molecular testing.
- The advanced practitioner or clinical doctorate is seen by some as providing a career ladder beyond the baccalaureate degree.

Survey

The task force determined that it needed to survey a large population of laboratory educators, managers, and laboratory practitioners in order to validate the findings of the literature review and the focus groups and also to provide an opportunity for the profession to comment on the task force's preliminary proposal for a new model. To ensure a robust survey instrument, a pilot survey was first developed, the results of which were used to identify possible ambiguities in the wording of the questions and to identify appropriate choices to include as objective responses to the survey questions. A non-random solicitation to laboratory leaders and select educators occurred. Fifty-two respondents completed the survey. The task force then analyzed the results and modified the survey as deemed appropriate.

The final survey was deployed in January of 2006 and opened for web-based responses for approximately 30 days. Over 2500 responses were received. An analysis of the survey method and responder demographics identified specific limitations on the ability to generalize the data.

Key methodology and respondent demographic limitations:

- Respondents formed a convenience sample (self-selected, not random) which attracted largely CLS/MT certified respondents from metropolitan areas with more than 20 years experience (nearly 11% met all three criteria; CLS/MT respondents were more than six times more common than CLT respondents).
- The CLT respondents were skewed towards smaller facilities (38% were in small hospitals).
- Fifty-eight percent of rural respondents were associated with smaller facilities.

Notwithstanding these limitations, the large number of respondents and the consistency of responses gave the task force confidence that important perspectives were being brought forward. Since this survey was always described as advisory in

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nature, conclusions were drawn based on subgroup analysis as opposed to relying only on analysis of the total sample. Key findings from the survey:

- The consensus was that the current clinical laboratory work environment is not appropriate. More than 95% of respondents indicated that there was a need for change (some need, great need, or critical need) based on the presented rationale and their own experience. Approximately two-thirds of the respondents indicated that there was a great or critical need for change.
- Approximately two-thirds of respondents indicated that neither certification level nor educational attainment level significantly defined job differentiation in practice.
- When asked if the proposed change that would limit microbiology and blood banking skills performed by associate degree practitioners was justified, 30% of the respondents thought that there was minimal or no justification for this change and over 40% thought that there was good or great justification for the change.
- When asked whether or not the model should be adopted, 55.4% of the respondents said yes and 44.6% said no. The percent of respondents who did not want the model implemented was highest in the following groups; respondents with an associate degree (55.6%), educators of that population (78.9%), laboratory managers (50.4%), and laboratory directors (52.15).
- Over 1000 respondents provided written comments describing objections or suggestions for changes in the model.

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 (see Table 1). 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.
- 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, information technology/computer skills, terminology, 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 masters 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.

Definitions used in the model:

- Training = structured instructional program leading to competence in a practice skill prior to independent practice. This could be offered by an employer, formal educational institution, or professional society.
- Additional education = continuing education programs, 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.

IMPLICATIONS AND RECOMMENDATIONS

The proposed model was developed after extensive data collection and analysis to address problems in the laboratory profession identified by educators, managers, and practitioners. The model describes what laboratory practice would look like if the profession were able to start from scratch and design a system that ensured patient safety, encouraged practitioners' professional development, and facilitated the effective use of laboratory personnel at all levels. Of course,

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Table 1. The proposed model for levels of practice in CLS

Level	Practice skills	Education	Relevant experience	Certification
I	Phlebotomy Specimen processing Order entry—accessioning Culture set-up Specimen processing (histo/micro/cyto)	HS/GED + training	No	CLA or certificate
	Waived testing	HS/GED + additional education	Yes	CLA or certificate
II	Automated chemistry, immuno-chemistry, coagulation, hematology, urinalysis Less complex microbiology *(procedure/media selection and culture inoculation; specimen preparation and 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)* Less complex blood banking *(ABO, Rh, antibody screen, crossmatch, direct antigblobulin testing, blood and component release)* Manual differentials with higher review of abnormal results Urine microscopy Less complex body fluids (cell count, automated chemistries, gram stain)	Associate	No	CLT / MLT
III	Body fluid microscopy with higher level review of abnormal results	Associate	Yes	CLT / MLT
IV	Blood bank Body fluids Immunology Microbiology Molecular testing that follows established protocols 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.)	Baccalaureate	No	CLS / MT

(Table 1 continued next page)

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Level	Practice skills	Education	Relevant experience	Certification
V	Infection control/epidemiology Method evaluation/test development Patient education POC oversight Front line supervision Research protocols Safety officer Student/staff education and training oversight Technical consultation Informatics Cellular therapy—stem cell transplantation	Baccalaureate + additional education	Yes	CLS / MT
	Cytogenetics Advanced molecular / PCR *(Modify existing, tests, troubleshooting, method evaluation, research and development)* Advanced flow cytometry Histocompatibility Specialist in (blood bank, chemistry, hematology, coagulation, etc)	Baccalaureate + additional education	Yes	Specialty certification
VI	Compliance/coding/regulatory Quality management 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	Masters degree in relevant area	Yes	CLS / MT plus other relevant certification
VII	Clinical assessment Evidence-based practice/research Grand Rounds Laboratory services clinical consultation Patient counseling Grant-funded research P.I. Test utilization/assessment/protocol development Test ordering	DCLS or PhD	No	CLS / MT plus other relevant certification

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it is not possible to start from scratch, so moving from "what is" to "what should be" will be a complicated and lengthy process. The first step in this process is seeking consensus from laboratory professionals on this model as the vision of "what should be". This will involve discussions on the implications of the model among educators, managers, and practitioners.

Implications for educators and students

The model provides educators with a clear guide for curricula at each level of practice. Using this model as a guide, educators can focus on the theory and technical skills that graduates need to function in their professional careers and avoid teaching topics that will not be needed for entry level practice. Often educators struggle to fit more content into their programs in order to accommodate advances in science and technology. The model can serve as a means to limit the breadth of material covered and allow educators to emphasize the depth of understanding in those areas needed for clinical competence at a given level. Clinical laboratory students should find curricula more meaningful and relevant to the expectations in their entry level jobs. Well defined curricula should also facilitate progression from one educational level to the next.

The model may raise concerns for educators if it is viewed as requiring fewer credits and courses for some programs. However, the model does not necessarily suggest that the length or number of credits in educational programs be reduced, rather that the content of the courses be focused on the specific knowledge, skills, and attitudes needed for competence at that level of practice. It is likely that, by limiting the material that must be covered at a given level, educators could devote more time to higher level skills such as troubleshooting, problem solving, and communication.

This model will only work if there are sufficient educational programs and those programs are accessible to students and meet the needs of rural and/or underserved areas. New programs will be needed and new methods of education will be required to enable practitioners to advance from one level of practice to the next. The model will also require more partnerships between educational institutions and clinical affiliates in order to provide the necessary clinical education.

Implications for laboratory managers

At each level of practice, the proposed model would have an impact on clinical laboratory management. The first level of practice includes new standards for training and certification and this should result in higher skill levels in these important areas of clinical laboratory practice. The ability to advance along a career ladder should also lead to a higher level of professionalism and decreased turnover among Level I practitioners. The educational preparation and practice skills of the Levels II and III practitioners would be appropriate for physician office labs, for most small rural hospitals, and for routine testing in the majority of clinical laboratories. By assigning advanced procedures to the Levels IV and V practitioners, managers can make better use of laboratory professionals with baccalaureate degrees and more clearly distinguish between the CLS/MT and CLT/MLT levels of practice. The fifth level of this model provides new recognition for baccalaureate level practitioners who obtain specialized experience, education, and certification. The requirement for a masters degree for Level VI practitioners recognizes the need for higher degrees for these advanced leadership roles. At the highest level of practice, a new clinical role for laboratory practitioners is defined that would improve laboratory services and patient care through clinical consultation to mid-level practitioners and physicians. Using this model, laboratory managers could assign work responsibilities based on the practice skills that can be expected from a practitioner at each level of practice. Employee morale should improve as a result of the well defined career ladder through which motivated individuals at all levels of practice can advance.

As laboratory managers study this model, they may be concerned about implementing this system in their current laboratories with today's workforce and educational options. The model assumes an adequate supply of practitioners and accessible educational programs and this does not exist today. Recruitment, education, and retention of laboratory professionals are essential, not only for the success of this proposed model, but also for the future of the laboratory profession. A strategy for ensuring an adequate supply of practitioners and educational programs must be included in the implementation plan and will require a commitment of resources from all stakeholders in the laboratory profession.

Implications for laboratory practitioners

In focus groups and surveys conducted by the task force, laboratory practitioners expressed a great deal of frustration with the lack of differentiation between the current levels of practice. This model addresses that concern by providing a well defined career path for laboratory professionals. The model makes it possible for individuals to enter at one level, gain employment, and move up the ladder through additional education, certification, and experience. The emphasis on education and certification should increase laboratory

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practitioners' sense of professionalism and progress in their careers. At the higher levels of practice, the model describes roles for clinical laboratory professionals that recognize their expertise and ability to contribute to the health care system. Young laboratory practitioners may be more likely to stay in the profession when they see opportunities for advancement through education, experience, and advanced certification.

Setting out defined job functions at each level helps differentiate the levels of practice, but it also places limitations on practice at all levels. There are many practitioners who are currently performing laboratory tests that would not be included in their scope of practice in the proposed model. Any strategy of implementation for this new model must recognize the value of current laboratory practitioners and protect their jobs. The transition from current practice to the proposed model will be difficult, but without a vision and a plan for change, the frustrations of the present will continue.

Recommendations

For this model to be successfully implemented, laboratory educators, managers, practitioners, certification agencies, accreditation agencies, and professional organizations will all need to work together to plan the transition from "what is" to "what should be". In order to implement this model, laboratory educators must:

- revise current curricula to match the model.
- develop new educational programs that are accessible and allow for an uncomplicated progression from level to level.
- work with managers to identify mechanisms for Level I training.
- work with certification and accrediting agencies to ensure that the model is reflected in examination content and accreditation standards.

Laboratory managers must:

- educate administrators and human resource departments on the new model and update job descriptions to reflect the new levels of practice.
- work with human resources departments to ensure that pay scales are commensurate with practitioners' education and experience at all levels of practice.
- revise staffing plans based upon the new levels of practice to maximize the use of practitioners at each level of practice.
- ensure that their employees only perform the practice skills that are within their scope of practice.
- support educational programs by providing the clinical affiliations needed for practice skill development.

Laboratory practitioners must:

- plan their careers using the model as a guide.
- seek the education and experience needed to move up the career ladder.
- maintain and document continued clinical competence.

Laboratory certification agencies must:

- revise or develop examinations for all levels described in the model.
- work with their sponsoring organizations and their accrediting agencies (e.g., NCCA) to develop a plan for defensible certification examinations in the transition time between the old and new standards for laboratory practice.
- provide affordable and accessible methods for documenting continued competence.

Laboratory accrediting agencies must:

- work with their sponsoring organizations to develop standards and guidelines based on the model levels of practice.
- educate program directors, paper reviewers, and site visitors on new standards.
- develop standards and guidelines for new programs that may be developed.

Laboratory professional organizations must:

- inform members about the proposed model and provide opportunities for members to be involved in discussions and recommendations.
- identify champions to speak at conferences, publish papers, and promote the new model.
- revise the Body of Knowledge to match the model.
- provide membership opportunities for practitioners at all levels of practice.
- provide the continuing education needed for each level of practice.
- work with educators to develop educational materials and programs for new levels of practice.
- work with certification and accrediting agencies to ensure that the model is reflected in examination content and accreditation standards.
- promote evidence-based research to validate the need for and effectiveness of the model.
- lobby state and national legislative bodies for increased funding for clinical laboratory educational programs and students.

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Next steps

The task force used the 6 Sigma DMAIC (Define, Measure, Analyze, Implement, Control) process to address problems with the current levels of practice in the laboratory profession. The task force proceeded through the "Define" phase in several meetings that resulted in goals, objectives, and a research plan. In the "Measure" phase, the task force collected data from literature, interviews, focus groups, and surveys. The proposed model and recommendations are the result of the "Analyze" phase and it is now time to move to the "Implement" and "Control" phases of the process. This will require a continued commitment from all the organizations represented on this task force and the additional involvement of other stakeholders such as certification agencies and accrediting agencies.

Given the complexity of the laboratory profession, the path forward will not be easy. However, after listening to the concerns of so many, the task force came to believe that a new vision for the laboratory profession is necessary. Without a change in the status quo, problems such as student attrition, blurred lines of responsibility and compensation among laboratory personnel with different education levels, attrition of talented laboratory professionals due to ineffective use of their skills, and lack of advancement opportunities will continue. In addition, the professional status of clinical laboratory practice and laboratory practitioners suffers when professional organizations fail to agree on the common and appropriate scopes of practice for laboratory personnel at all levels. A necessary first step will be to share the proposed model with all members of the laboratory profession for discussion and input. Feedback from these discussions will be used to finalize the model before it is presented to participating organizations for approval. Therefore, the task force recommends the following.

1.The participating organizations should accept the white paper with the proposed model for levels of practice.

2. ASCLS should create a new inter-organizational task force to move the new model through the steps necessary for implementation and validation. This task force should:

- work with participating organizations to develop a process for distribution of the white paper and new model that includes a method for obtaining support from members.
- study the impact of this model on state licensure.
- determine the number of laboratory practitioners needed at each level of practice and determine the ability of the educational programs to meet that demand.
- consider developing a strategy for validating the model through evidence-based research.
- Suggested timeline:
  - January 2008: Develop a plan and process for dissemination that includes a PowerPoint presentation for on-line distribution with accompanying script and Q&A component to promote review, dialogue, and input from all participating organizations' members.
  - February 2008: Present model for discussion at the Clinical Laboratory Educators' Conference.
  - March 2008: Submit the model to all participating organizations.
  - Spring 2008: Seek membership support of new model.
  - Summer 2008: Submit the model to all participating organizations for final review, support, and approval.

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(2) DD BECK". 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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