NAACLS
National Accrediting Agency for Clinical Laboratory Sciences

News

Special Edition

A Clinical Doctorate for the Laboratory

The purpose of this Special Edition of the NAACLS News is to create a transparency of the activities about a current initiative being undertaken by NAACLS in collaboration with NAACLS sponsoring organizations and stakeholders. The NAACLS Board of Directors began by appointing a Graduate Task Force (GTF) charged with determining the feasibility of an advanced practice doctoral degree in the field of clinical laboratory science. The GTF was also to consider whether or not NAACLS should develop standards for such an academic program. With concurrence of the Board, the GTF produced a number of related documents that guided discussions and that are now available to the public.

What follows within this Special Edition charts the course of the GTF efforts beginning with the early planning stages and culminating with input that resulted from an invitational meeting for stakeholders held March 1, 2006 in San Antonio, Texas. Included in this Special Edition is a conceptual definition of the doctorate with broad areas of domains, frequently asked questions plus suggestions for next steps to be taken. Your input in the form of comments, suggestions, questions or critique is invited by the NAACLS Board of Directors and members of the Graduate Task Force. Members of the Task Force include:

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NAACLS, a non-profit organization, is commited to being the premier agency for accreditation and approval of educational programs in the clinical laboratory sciences and related healthcare disciplines through the involvement of expert volunteers and its dedication to public service.

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The Concept of the Clinical Doctorate in Clinical Laboratory Science: Role, Responsibilities and Education

Role

The Clinical Doctorate in Clinical Laboratory Science is intended as the terminal practice degree for the Clinical Laboratory Science profession. This new degree will provide an opportunity for advanced practice in multiple venues including clinical institutions, reference laboratories, physician practices, industry, public health agencies, government facilities, research organizations, and academic institutions. Clinical Laboratory Science professionals holding the Clinical Doctorate will provide a critical interface between practice, research, and health care policy. They will assure the effective and appropriate utilization of laboratory tests and information by eliminating unnecessary tests and ordering tests that should have been ordered but were not. This will result in decreased costs, earlier diagnosis, and improved patient outcomes.

Responsibilities

Individuals holding the Clinical Doctorate in Clinical Laboratory Science will function in many different arenas of practice. These may include but are not limited to such areas as Patient Care Management, Education, Research, and Health Care Policy Development and Services Delivery.

In the practice of Patient Care Management, they will assure cost effective, medically indicated and quality laboratory services by developing/implementing critical paths/laboratory test algorithms, participating in interdisciplinary rounds, managing and ordering diagnostic and therapeutic studies, entering notes into patient records, leading laboratory utilization reviews. They may also provide consultative services through independent practice.

In the practice of Education, they will effectively disseminate laboratory related information as a faculty member in academe, a counselor to patients and families, and a consultant to other health care professionals. They will teach the public and health care professionals about over the counter and point of care laboratory tests and educate other health care professionals about new analytes and tests resulting from the development of new and emerging technologies.

In the practice of Research Applications, they will perform clinical research and outcomes studies applying research findings to clinical practice (to include applied and translational forms).

In practice related to Health Care Policy, they will participate in decision-making teams and provide consultation and input in areas such as services reimbursement, professional advocacy, ethics and human subjects oversight, expert witness testimony.

In practice related to Health Care Services Delivery and Access, the individual will be an integral part of and participate in laboratory resources management (assuring

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access to laboratory testing) laboratory services administration, and laboratory outcomes analysis in multiple practice venues such as direct patient care, industry, public health, government, and clinical and academic administration.

Education

Since individuals holding a Clinical Doctoral Degree in Clinical Laboratory Science will be providing consultation encompassing all areas of clinical laboratory information and testing venues, it is critical that program graduates be broadly educated in all laboratory disciplines. Consequently, individuals pursuing the Clinical Doctorate will need to hold a baccalaureate degree with certification credentials as a generalist with either NCA or ASCP. NAACLS will establish standards (which incorporate minimum competencies developed by the profession) and implement a process for accrediting Clinical Doctorate programs of study. If an academic institution wishes to offer both a PhD and a Clinical Doctorate, NAACLS will accredit only the Clinical Doctorate component of the program.

Graduates will need to demonstrate:

- advanced knowledge in scientific areas that impact on patient care including, but not limited to: Biochemistry and Genetics, Pharmacokinetics, and Pathophysiology.

- medical knowledge necessary to provide and coordinate patient care as impacted upon by laboratory testing. Integral components may include development and application of clinical decision making, development and application of critical paths/test algorithms, utilization review, etc. Acquisition of such knowledge will require participation in clinical internship experiences to include clinical rounding.

- interpersonal and communication skills necessary to function in direct patient care with the patient and family members and with other health care practitioners (physicians, nurses, nurse practitioners, physician assistants, etc.) as an independent provider of health care.

- creation of a capstone experience, applied research, or translational research as required by the degree. Integral components will include research design, statistics, grant writing, protection of human subjects, and research ethics.

- knowledge in development, interpretation, and application of Health Care Policy and legislation to include reimbursement policies, medical liability exposure, licensure, ethics, tort, patient privacy protection, etc.

- knowledge in Health Care Services Delivery and Access through skills developed in resources management, outcomes analysis, analysis of costs relative to benefits, etc.

Background to Development of the Clinical Doctorate Initiative

NAACLS is an independent accrediting agency recognized for accrediting academic programs that prepare graduates in a number of clinical laboratory fields including CLS. Its responsibility is to determine and set educational Standards for the professions it represents. Because development of Standards is a lengthy and laborious process, NAACLS is charged with envisioning the future while considering potential skills required by the workforce.

In 2000 NAACLS held a Futures Conference for stakeholders. The purpose of the conference was to look at possible future health care scenarios and the roles the CLS/MT and CLT/MLT would fulfill in those scenarios. Future skills needed by each profession were delineated. Results of the conference were published and used in development of revised Standards for CLS/MT and CLT/MLT programs in 2002.

Driven by: 1) massive growth in range and complexity of available tests and services; 2) continuing need for increased differentiation between associate and baccalaureate level programs, and 3) the emergence of numerous national studies that called for reshaping of the health care delivery system, a NAACLS Task Force was appointed to study the feasibility of graduate level entry for CLS/MT. The Task Force developed numerous documents and made formal reports to stakeholder organizations. There was no agreement among stakeholders about changing entry level requirement and it was decided to maintain the Standards as they were.

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The NAACLS Board authorized a second Futures Conference for October 2004. Participants at this conference once more met to hear projections of the future and to discuss needed educational changes. They were strongly in favor of maintaining the current entry level for CLS/MT but were now vocal about the need for considering a clinical or advanced practice doctorate in the field.

As a result of evaluations of the conference and further discussion, the Board appointed a new committee, the Graduate Task Force (GTF) to study the possibility of an advanced practice doctoral degree for CLS/MT and to determine if NAACLS should develop Standards for such an academic program.

The Graduate Task Force first met by teleconference late in the winter of 2004 and began to research the issues related to a clinical doctorate. After several teleconference meetings it met face to face with the NAACLS Board in July and September of 2005. At each meeting, extensive information was presented by the GTF. The Board later authorized a March 1, 2006 invitational meeting to obtain stakeholder input on numerous documents produced by the Task Force.

After the September NAACLS Board meeting, the American Society for Clinical Laboratory Sciences (ASCLS) and the American Society of Clinical Pathology (ASCP) were invited to nominate representatives to serve on the Graduate Task Force.

Discussions ensued about how the NAACLS task force might cooperate with a similar ASCLS task force that was also investigating a professional doctorate. At a winter 2006 face to face meeting of the now expanded GTF, it was concluded that there was much overlap between the concept of the professional doctorate being developed by the ASCLS Task Force, the Professional Doctorate Task Force (PDTF), and the concept proposed by the NAACLS GTF. It was determined that after the March 1 meeting the Task Forces would work cooperatively but with differing agendas to develop competencies, curriculum, and Standards for programs preparing to offer a clinical doctorate.

Process and Outcomes of the NAACLS Graduate Task Force

Between December 2004 and March 2006 the Graduate Task Force held several teleconferences of the full membership and a few shorter teleconferences for subcommittees. There were four face to face meetings, two of which were combined with the NAACLS Board of Directors meetings. Much of the work of the Task Force was carried out via email correspondence. Over the tenure of the Task Force, the following documents were developed:

Hard Copy and Electronic Documents

1. Summary Document on Practice Expertise and Requisite Education
2. Hall marks for the CLS Clinical Doctorate vs. CLS PhD
3. Frequently Asked Questions (FAQs)
4. Questions Asked in Other Recent Studies of the Clinical Doctorate (Eight questions with expanded answers)
5. First and Second Draft of possible program Standards
6. "*Clinical Laboratory Science: An Historical Perspective*". NAACLS News, *Vol* 90, Fall 2005 and *Vol* 91, Winter 2005.
7. "*Degree Creep in the Health Professions: A Misunderstood Notion*". NAACLS News, *Vol* 90, Fall 2005.
8. Competencies and Skills of the Clinical Doctorate
9. Statement of Needs, Roles and Benefits of the Clinical Doctorate
10. Draft Research Proposal

Power Point Presentations

1. Envisioning the Future for a CLS Professional Doctorate in the Context of a US Health Care System in Transition.
2. The Value of the Clinical Doctorate
3. The Hallmarks of the Clinical Doctorate
4. Background of the Graduate Task Force
5. Next Steps in Development of Standards for the Clinical Doctorate.

FAQs

What is the benefit to the public? What problems will this doctorate solve?

The public will benefit through improved efficiency and quality of laboratory testing and increased patient safety. Costs associated with inefficient and inappropriate laboratory testing are enormous. Tests that are ordered but not useful or necessary waste health care dollars. Tests that are not ordered but should be delay diagnosis and treatment.

A professional with a clinical doctorate in CLS will have the knowledge and stature to develop, implement and oversee protocols for the appropriate ordering of laboratory tests and the use of laboratory information. Physicians have published the need for experts in the use of laboratory information to support patient diagnosis and treatment. Rapidly evolving technology is constantly producing new procedures for testing old and new analytes. It is impossible for physicians to keep abreast of them. A person with a clinical doctorate will be able to apply the newest tests and technologies to patient diagnosis and treatment and teach other health care practitioners how to use them appropriately. This individual will serve to increase the visibility of pathologists.

What is the relationship between the baccalaureate degree and the Clinical Doctorate? What distinguishes the Clinical Doctorate from the PhD?

The BS entry level degree will continue to be offered using a mixture of didactic and laboratory components. Individuals with the BS degree will continue to staff clinical laboratories performing complex procedures and providing technical knowledge. The clinical doctorate will expand the cognitive knowledge base gained at the BS level to enable the graduate to function as a practitioner. Additional skills include patient assessment, management of laboratory data, patient/family counseling skills, and participation in policy setting bodies (i.e. IRB, DSMB, ethics committees) to name a few.

The individuals with the clinical doctorate will focus on expanded knowledge and the use of laboratory data to enhance patient care and contain costs. They will use research findings to advance clinical practices. A doctor of philosophy degree will provide an individual with the same skills as the clinical doctorate, but go further by preparing the graduate to lead and conduct rigorous research that is competitive with PhD's in other disciplines. The graduate of the PhD program would be expected to serve as faculty, conduct research, and publish in peer reviewed journals.

Must the need to gain new skills and capacities be translated into a doctoral degree?

The clinical laboratory scientist currently lacks a credential to be recognized as an individual who can synthesize the vast amount of laboratory data into a product useful for clinicians, patients and the community. The current CLS baccalaureate degree is jam-packed with a body of knowledge that continues to expand, but that graduate focuses on operations primarily within the laboratory. We cannot expect the BS degree programs to cram more and more knowledge and skills into the curriculum without risking serious dilution of the essential core body of knowledge.

The new practitioner must have a knowledge level that will be recognized by physicians and other health care team members. The new practitioner must incorporate higher order thinking skills attained at the doctoral level. Building upon the essential body of knowledge, the clinical laboratory doctorate will transform laboratory data into an information product that can be used to: a) manage patient education and compliance; b) produce, validate, interpret, evaluate, and communicate diagnostic and therapeutic laboratory information, as well as develop and promote standards for them; and c) synthesize, implement, and communicate decision-making algorithms based on evidence.

How is this viewed from a graduate education perspective? (Professional researcher vs. researching professional, professional scholar vs. scholarly professor, teacher vs. professional, academy vs. industry)

From a graduate education perspective there may not be consensus among various healthcare constituencies and groups as to the role and responsibilities of the clinical doctorate across a number of different professions. Perhaps what is most readily agreed is that the PhD is regarded as the highest degree granted by the academy. Debate and discussion is currently ongoing within various colleges and universities as to whether a clinical doctorate can or should have rank among the professoriate as full faculty or rather that it be on a clinical faculty

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track. Depending upon the type of academic institution (research-doctoral, doctoral, masters, comprehensive, etc.), opinions vary greatly as to what constitutes "Faculty" in higher education.

The clinical doctorate practitioner will be expected to utilize research findings to advance the practices of the laboratory. This individual may participate in research activities, but that is not the principal aim of the clinical doctorate degree.

How much is the changing health model driving change in this profession?

Health Care delivery is undergoing rapid transformation, and the professions that contribute to the overall health care system need to adapt or they will be subsumed and become irrelevant. The health care industry has become highly technological and increasingly information-driven. Some professions have strategically planned and positioned themselves to meet current needs. Issues of access, health care disparities, payer systems and consumer-driven health plans, plus a greater focus on prevention and wellness are all driving system change.

The changing health model affords the clinical laboratory profession with an opportunity to produce a doctoral prepared individual with broad consulting skills who is able to move outside the physical boundaries of the laboratory to function as a more patient-oriented professional. This individual will provide the needed patient advocate in the laboratory, and will contribute to improved patient outcomes and patient safety. Such an individual will be involved with promoting better test utilization and test evaluation.

If the future of health care is based on a team model, how does this contribute? Does it not perpetuate silos? Is this degree creep?

Almost all of the health professions which have or are moving towards a clinical doctorate degree cite numerous multidisciplinary and interdisciplinary reasons that contribute to a rationale for higher degrees. It is evident that there needs to be better communication and interaction within the health care team.

The clinical doctorate will supply a bridge between the laboratory and providers. It will provide for a new practitioner. It neither raises entry level nor is it degree creep but will provide a career ladder and career enhancement, thus supporting a mechanism to retain the best and brightest in the laboratory profession.

Can the value added be clearly defined? Will it translate into better practice?

With the proposed clinical doctorate for CLS being an accredited program of study, minimal competencies will be assured through accreditation Standards. To achieve better practice, it will be critical that the clinical doctorate produce a broadly educated individual who will be able to consult in a manner that encompasses all areas of clinical laboratory testing and is not limited by sub-specialization.

Not all the value associated with the clinical doctorate will be measurable, with some aspects being intrinsic and guided by perception. Value associated with this level of practice may include but is not limited to improved quality of medical care via: improved reflex testing, reduction in medical errors, participation in interpretive rounds, functioning as a clinical consultant, developing of laboratory medicine algorithms and application of them to individual patient cases, process improvement, and consultation on health policy development. Implementation of such interventions to improve the quality of medical care will translate into better practice. It will improve inter-professional interface, foster the team role, and add robustness between the laboratory and clinicians.

Planning for the March 1, 2006 Stakeholder Meeting

Planning the Process

Final plans for the stakeholders meeting were completed in a January 2006 face to face meeting of the Task Force. It was determined that the stakeholder meeting should actively involve participants in discussion of key elements of a clinical doctorate. The focus would be on the summary document prepared by the Graduate Task Force: *Clinical Doctorate in Clinical Laboratory Science: Practice Expertise and Requisite Education Summary Document.* Participants would engage in discussion about several related issues.

The meeting venue was scheduled for the Crown Plaza Riverwalk Hotel in San Antonio. The date set was one day prior to the Clinical Laboratory Educators Conference (CLEC) held at the same hotel. The meeting was to convene at 8:30am and adjourn at 4:30pm.

To effectively initiate conversation, the introductory session would focus on specific hallmarks of the clinical doctorate as well as the more traditional PhD. Both the education and the practice components of each would be clearly identified.

Inviting the Stakeholders

It was believed that a broad spectrum of professionals and other stakeholders should be invited but also program directors of active graduate level CLS/MT programs should attend to provide perspectives on graduate program issues. A total of 28 separate professional organizations/agencies were sent a letter of invitation to the meeting with explanatory information. Eighteen responded affirmatively to the invitation. Several sent regrets but indicated an interest in being kept informed. All 30 program directors of graduate level CLS/MT programs were invited with 19 affirmative responses. Again several were unable to attend but asked to be kept informed.

One month prior to the meeting a follow-up letter was sent to participants with meeting site information and a general overview of meeting plans. Included with the letter were the following:

- March 1, 2006 Meeting Schedule
- Questions Asked and Answered
- Draft Summary Document
- Annotated Bibliography

Participants were encouraged to bring additional questions that they might have with them to the meeting for discussion.

Process Employed at the March 1, 2006 Stakeholder Meeting

At the March meeting, in order to present structural concepts related to the Professional Doctorate, a series of eight questions were developed. They spoke to pivotal decision points in program design and were prepared from the literature describing "lessons learned" in other professions establishing similar programs. The questions, along with "draft" answers supplied by the GTF were sent to attendees prior to the meeting. At the meeting, round tables were designated for discussion of the questions and attendees were assigned seating at a specific table in order to assure a variety of the various stakeholders and educators at each table.

A modified Nominal Group Technique or 'round robin' process was employed to facilitate discussion and elicit responses from participants. GTF members facilitated discussion at each table. The modification to the usual 'round robin' structure was that the facilitators, instead of participants, moved in sequence from one table to another discussing the same question with each table of participants. Members of the NAACLS Board of Directors served as scribes at each table and recorded discussion on a flip chart. These were collated and a summary document developed.

Discussion at each table was timed to last between 15—20 minutes with five minutes for wrap-up and recording. At the end of each discussion period, main themes were summarized and given to NAACLS staff who electronically recorded them for projection during a later summary session.

During the summary session, main themes from answers collated from all groups were presented and discussed by the GTF Members responsible for their specific questions. The summary presentations elicited much spirited general discussion from the floor.

Evaluation of Participant Reactions to Stakeholder Meeting

At the conclusion of the March 1, 2006 meeting participants were asked to evaluate the meeting against eight (8) categorical variables and three (3) qualitative measures using open-ended questions. The following results were obtained.

Sample. The sample was a convenience sample, which cannot be considered random or representative of the population.

Methods. A written questionnaire was administered to participants at the conclusion of the meeting. The questionnaire was anonymous and the first 8 items used Likert scales to measure participant satisfaction. The first six items were:

- scheduling and format;
- printed materials;
- audiovisual materials;
- presenters;
- meeting your objectives; and
- general overall rating.

The scale consisted of excellent, good, fair, and poor with 4 being excellent and 1 being poor. The next item asked "*was the invitational meeting effective in ensuring that your viewpoints were heard and understood*?" This was followed by the question "*was the invitational meeting effective in ensuring that all other viewpoints were heard and understood*?" Both of these items were measured on a scale of 1 to 5 with one being "not effective" and 5 being "very effective." SPSS® was used to analyze the data. Because the data is nonparametric in nature the Kolmogorov-Smirnov test was used. In addition, the data was tested for homogeneity of variance, and robustness of equality of means.

The last three (3) items were analyzed using NUDIST®. The questions for these three items were:

- What additional materials would have been useful to review prior to the meeting?
- What additional areas do you wish had been covered?
- What areas were either not helpful or, perhaps, confusing?

Results. Results show that for the first six variables the range of means was between 3.50 and 3.79 (on a scale of 1-4). The range for variables 7 and 8 was 4.66 to 4.75 (on a range of 1-5). The Kolmogorov-Smirnov Z scores ranged from 2.07 to 2.78 in a normal distribution. In a poisson distribution the range was 1.55 to 1.93 and showed no significant skewness or kurtosis of the data.

The data were also analyzed for homogeneity of variances and the only variable to achieve significance was variable 7. In addition, the data were examined for robustness of equality of means and in this test variables 3, 4, 5, and 6 achieved significance.

The remaining three variables showed a typology consisting of two categories. The first theme may best be described as "needing more information." The second theme to evolve is best described as "curriculum issues."

Conclusions. Analysis of the first six variables indicate that participants were highly satisfied with the structure of the meeting that included:

- scheduling and formatting;
- printed materials;
- audio-visual materials;
- presenters;
- meeting participant objectives; and
- an overall satisfaction.

While the mean of the variables *printed materials* and *audio-visual materials* showed the lowest means (3.50 and 3.55 respectively on a scale of 1-4) they were still relatively high and supported the theme identified in the qualitative question and that was "needing more information."

The questions regarding the expression of individual and other viewpoints achieved a mean of 4.75 and 4.66 respectively (on a scale of 1-5) showing that participants felt viewpoints were solicited and expressed openly. The qualitative questions did not contain any material related to these two questions, which further support the high means.

While there were a number of comments received in response to the qualitative questions, the vast majority fell into the two thematic statements identified by NUDIST®. Given the topic of the conference it seems natural that participants would want additional information on accreditation and curriculum issues. It may be that the conference served to update the field as to what has been considered in developing a clinical doctorate however, it is also apparent that this process is not being conducted in isolation.

Please Note:
Descriptive tables of results are available from the NAACLS office.

Next Steps in Development of Standards

After the Stakeholder meeting it was the responsibility of the GTF to incorporate input obtained from the meeting into documents that had been drafted earlier. A full report is planned to the NAACLS Board of Directors for review in April 2006. If the Board agrees to continue supporting efforts of the GTF, competencies developed by the ASCLS task force will be incorporated into the proposed accreditation Standards.

When approved by the Board, and in accordance with the NAACLS policy and good accreditation practice, the proposed Standards will be released for public comment. Open hearings will be announced and held. The proposed Standards and relevant documents will also be maintained on the NAACLS website. Draft Standards will be revised based upon public comment. The Board will review the comments and the latest version of the proposed Standards prior to determining approval. A protocol or process for review of program applicants will be developed and a review committee formed. After that NAACLS may accept initial applicants.

A Pathologist's Perspective

The Clinical Doctorate: A Boon to Pathologists

By Linda B. Piller, MD, MPH

Work is proceeding through NAACLS on the establishment of a Clinical Doctorate degree in Laboratory Sciences. Based upon a model already in place in pharmacy, these doctoral level professionals would serve as part of the clinical care team on hospital floors, in the outpatient setting, and in the clinical laboratory. In the laboratory the clinical laboratory specialist would function as the liaison between the patients' medical care team (composed of physicians and nurses attending to the patients) and the clinical laboratory, and as such would not only be involved in interpreting and communicating laboratory results but would also facilitate appropriate testing and test preparation. Benefits to patients are clear: they would have an expert in laboratory sciences working with their physicians to determine the most necessary and efficacious laboratory tests to perform, and to appropriately interpret the results vis-à-vis patients' medications and clinical circumstances.

However, how would these clinical laboratory specialists fit in alongside clinical pathologists? Further, how would clinical pathologists perceive and receive these professionals? The overall understanding of the role of the doctoral level laboratory specialist is key to these questions. Pathologists are involved in a myriad of activities and duties. These include obligations to the hospital administration and anatomic pathology laboratory, overseeing the clinical pathology laboratory, conducting molecular and genetic research and applying principles of higher-level molecular and genetics to their practices. The pathologist remains the consultant to clinical colleagues and the teacher of medical students, residents and fellows, and practicing physicians. Indeed, these functions more and more force the pathologist to relinquish valuable time previously spent with physicians as they visit patients on the hospital wards or in discussion with physicians regarding laboratory testing and interpretation. Pathologists cannot continue to answer every call for their expertise: it is time to recognize that which can be shared with well-trained and appropriately credentialed colleagues. The development of a clinical doctorate degree in laboratory sciences will provide a new member to the health care team who can relieve the pathologist of clinical laboratory consultation and patient care duties. Moreover, given the increasing specialization in all medical fields, including pathology, the clinical laboratory specialist would offer an additional measure of knowledge, training, and overall expertise regarding laboratory testing. The specialist would be a member of the medical care team, just as the pharmacist has become on hospital rounds, and would be the physicians' and patients' chief consultant regarding appropriate ordering and interpretation of laboratory test results. The endpoints would be improved patient care, lowered medical costs with the elimination of unnecessary testing and its replacement by the most appropriate laboratory regimen, while relieving the pathologists of patient care burdens relating to the clinical laboratory. Everyone would win and no one would lose.

Will this be accepted by pathologists universally? Probably not in the short-term. But with time and a concerted effort to work side-by-side with, and not against, each other, pathologists and clinical laboratory specialists can improve the quality of care for patients and lower the cost of healthcare.

A Pathologist's Perspective

The Doctorate in Clinical Laboratory Sciences: The Time Has Come

By Larry H. Bernstein, MD

At the March 1 Stakeholder meeting, the purpose was to present a draft proposal for a Doctorate in Clinical Laboratory Sciences (DCLS). Key issues needing full discussion, although not necessarily resolved in the meeting were: 1) the broad scope of the responsibilities of such a graduate; 2) clear differentiation from the narrow scope of the traditional PhD candidate, and 3) financial support for the professional (clinical) services position outlined.

The scope of activities envisioned might vary in postdoctoral settings depending on specific requirements for the individual and the fit to organizations need. Despite the fact that PhD professionals in clinical chemistry or in microbiology may be fully engaged with problems in technical troubleshooting and in a busy consultation schedule, there is little question of how a DCLS would fit into the scheme of things. Organizations have actually been phasing out the positions for some time, and postdoctoral programs in both chemistry and microbiology have traditionally included a clinical orientation that is not part of a traditional PhD programs. This perhaps raises questions about the amount of time needed to complete the DCLS when combined with a PhD degree. However, the main purpose of NAACLS would be to define standards for a clinical profession. I am not interested in dwelling on these concerns here, but observe that the DCLS candidate would be able to integrate clinical and laboratory information much in the way a graduate of a medical institution is expected to perform in postgraduate practice, which distinguishes purely research-based from purely clinical skill-building. The DCLS will create a unique professional who will blend special integrative and research skills who will be qualified to guide the laboratory as a potential OUTCOMES-ENGINE for the organization.

The discussion of activities tied to this position is related to how the activities are reimbursed, the topic on which I focus here. There is a potential for misunderstanding that is based on a perception of erosion of the contribution of the pathologist. That role is defined as the Director of the Laboratory under CLIA'88. Payments for clinical pathology services rendered by pathologists are for services in general and not related to a specific patient specimen. This is based on the CLIA defined oversight of laboratory, supervising laboratory personnel, reviewing abnormal results, discussing with clinicians which is paid to hospitals by Medicare. Hospitals are supposed to pay "reasonable compensation" to pathologists. The professional component assumes billing a component of patient costs in prospective payment for each clinical pathology test/procedure performed based on the pathologist's oversight of the laboratory (regardless of whether the pathologist performs or reviews the test). If we examine this further, the current reality identifies new opportunities and a synergistic relationship between the DCLS and the pathologist.

Medicare policies and hospital choice increasingly restrict the scope of pathologist services that are payable under the rules applicable to physician services. One could ask whether the Medicare provision would continue to compensate the Part A Clinical Pathology as a professional component if it could be identified that a declining portion of a pathologist's time is engaged in Part A Medicare activities. This would also have an effect on other third-parties. Recent changes applying relative value scales have provided an opportunity for national standardization of pathology codes, and have permitted the introduction of clinical pathology interpretations as compensable physician services. However, the pressure to support the practice through a basic level of surgical pathology practice has eroded the availability of the pathologist for other activities, including Part A Clinical Pathology and Part B billable Clinical Pathology interpretations.

Hospital administrations have responded to external pressures by trying to shorten hospital days and increasing admission rates under prospective reimbursement. They have had to meet operating budgets by working with tighter staffing provisions, and even by bundling of

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middle managers (radiology or pharmacy and laboratory), and by going to a core laboratory concept. This has had a direct impact on availability of positions for PhD clinical microbiologists and clinical chemists, as well as for supervisors. The solution is a new model for laboratory leadership that incorporates the DCLS.

The DCLS is well positioned to be the either the Associate Director of Laboratories for Clinical Pathology under the Pathology Chair (just as there might be an Associate Director of AP). The DCLS would oversee the CP quality plan, and would integrate the system and information technology plan for the laboratory. The reimbursement would flow through the Part A payments for services not involving direct patient services. The DCLS would also do the reports for Part B Clinical Pathology that require interpretation, and the reports would be billable under the Chairman of Pathology. The model is workable, and it will lead to high performance and best outcomes. In the current environment the Part A responsibilities may be substantially neglected because there is no incentive for the pathologist's role. The Part B billable portion may likewise be neglected, which leads to no professional reimbursement – the work is most likely sent out. The DCLS could forge strong ties to the Medical Staff, and increase the opportunity for outside laboratory work.

Pathology has three faces. The traditional department of pathology is a lineal descendent of an experimental tradition traced to John Hunter, Carl Freiherr von Rokitansky, Rudolph Virchow, and George H. Whipple. Surgical pathology and billable services have accompanied the success and support for modern surgery. Clinical pathology has emerged with improvements in clinical laboratory sciences and expanding use of diagnostic tests. This has changed the landscape of clinical laboratory science. The science has been divided over time and must be reintegrated in order to serve the primary goals of the health-care organization. The DCLS model being proposed makes everyone a winner.

The CLS clinical doctorate and the pathologist working together to improve the efficiency and quality of laboratory testing and assure patient safety.

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