Growing Our Own: Teaching and Doing Research in CLS

RODNEY E ROHDE, DAVID M FALLEUR, GERALD D REDWINE, THOMAS L PATTERSON

ABSTRACT

The shortage of clinical laboratory scientists (CLS) has been well-documented in the healthcare environment. This growing concern only becomes more critical as we enter the retiring baby boomer era in our society. Concomitantly, the problem of addressing how university CLS programs recruit and retain faculty to teach and satisfy research agendas is not being studied. These two problems, if allowed to collide, will provide a "perfect storm" with serious implications for an ongoing shortage of personnel and overall quality for the profession. CLS faculty, in the university setting, must typically satisfy the three tenets for tenure and promotion – teaching, scholarship, and service. While teaching and service will always be critical, scholarship (research) is an area of expertise that must be "taught" and mentored for future CLS faculty to be successful in the very real arena of "publish or perish". This article provides a commentary with specific details associated with our experience in offering an evolving dedicated CLS clinical research course to purposively "grow our own" students in the art of conducting successful research. It offers a flexible template for adapting or incorporating a lecture and laboratory course to address theoretical and practical knowledge in the realm of clinical research. Additionally, a discussion of other research mentoring activities in our program will be outlined. The long term goal (and hope) of these program objectives is to build a culture of research for current faculty and for CLS graduates. This paper provides an approach to embedding these research ideals in all CLS graduates and, importantly, an intentional attempt to create a mindset for a possible career as a future CLS faculty member who can be successful in both the university and clinical environment.

ABBREVIATIONS: ASCLS = American Society for Clinical Laboratory Science; CITI = Collaborative Institutional Training Initiative; CLS = Clinical Laboratory Science; HIPAA = Health Insurance Portability and Accountability Act; HSP = Human Subjects Protection; IRB = Institutional Review Board; NAACLS = National Accrediting Agency for Clinical Laboratory Science.

INDEX TERMS: CLS faculty; CLS faculty recruitment and retention; education methods; teaching techniques; tenure track requirements; research informed teaching; research methods.

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Rodney E. Rohde, PhD, SV, SM, MB(ASCP)^{CM}, *Texas State University-San Marcos, San Marcos, TX 78666-4616*

David M. Falleur, M.Ed., MT (ASCP), CLS (NCA) *Texas State University-San Marcos, San Marcos, TX 78666-4616*

Gerald D. Redwine, M.Ed., MT (ASCP), *Texas State University-San Marcos, San Marcos, TX 78666-4616*

Thomas L. Patterson, MS, MT (ASCP), *Texas State University-San Marcos, San Marcos, TX 78666-4616*

Address for Correspondence: *Rodney E. Rohde, PhD, SV, SM, MP (ASCP)^{CM}, Texas State University-San Marcos, Clinical Laboratory Science, HPB 361, 601 University Drive, San Marcos, TX 78666-4616, 512-245-2562, 512-245-7860 (fax), rrohde@txstate.edu*

According to the U.S. Bureau of Labor Statistics for the period of 2002 through 2010, 12,400 graduates will be needed annually to staff the nation's clinical

laboratories. Nationwide, less than half the necessary laboratory personnel are graduating from accredited programs. Currently, with 4,200 graduates per year, there is a deficit of about 8,000 laboratory professionals per year.[1] The clinical laboratory scientist (CLS) staffing shortage has been well-documented in a variety of sources.[2-5] While the issue of CLS shortages for the healthcare industry is critical, there is the additional often overlooked problem of recruiting and retaining *successful* CLS faculty in the "publish or perish" tenure-track environment.

There are numerous reasons that are related to attracting and retaining CLS faculty in a university system that can survive in the pressurized arena of satisfying the three tenets of responsibility – teaching, scholarship, and service. In the authors' academic environment, these reasons are typically attributed but not limited to (1) the "type" of terminal degree relating to successful scholarship, (2) the research culture and perceptions of what can be feasibly done, (3) the amount of financial support and time, (4) the requirement of certification, and (5) the mentoring available. It has been the authors' experience that while "good" teaching and experience are a given and expected by the administration, scholarship is the keystone in this three pronged tenure-track archway.

In 2004, Bamberg's survey found many of the faculty in university CLS/MT programs are extending their preparation as scientists to the graduate level. The findings of this survey also found that the doctorate, as opposed to a master's degree, can not be viewed as the 'terminal degree' as less than 50% of the reported faculty held a doctorate. Only 13% of the faculty held master's degrees specifically in CLS. The author concludes that the wide variety of degrees reported and the lack of a substantial number of doctorates in CLS or in primary CLS curriculum areas does not support a doctorate in the teaching field as the standard for faculty teaching in baccalaureate CLS programs.[6] In the authors' experience, a graduate degree that required a thesis or dissertation is a critical part of the "toolset" needed to be successful in the area of research and overall scholarship. The Ph.D. is also being pushed for most academic units in our university.

In a very current and timely review, Mundt and Shanahan conducted a study of American Society for CLS (ASCLS) members to address the problem of how the professional society does not understand how their members perceive the importance of conducting research or their duty to the profession to do so. Briefly, the study found that the majority of participants agreed that the CLS environment offers important opportunities for information to be researched and published. However, the authors also found that a majority of participants felt that there are inadequate resources and time to do so. Finally, only a few (29.2%) are willing to publish research findings on their own.[7] In a survey specifically of CLS faculty, Waller, Clutter, and Karni show an overall increase of faculty obtaining doctorates, promotions, presentations, publications, and grant funding from 1985 to 2008. However, teaching responsibility remains high and the average age of CLS faculty continues to increase.[8] The expectation of scholarship is continually rising in the university setting which can impact faculty recruitment, retention and promotion.

It is within this context that the authors of this paper will discuss their experiences with building a research culture for their students (in a 2+2 university-based program). The following is a review of (1) an evolving dedicated CLS clinical research course to purposively "grow our own" students in the art of conducting successful research, and (2) a discussion of other research mentoring and activities in our program. The CLS course offers a flexible template for adapting or incorporating a lecture and laboratory course to address theoretical and practical knowledge in the realm of clinical research. The long term goal (and hope) of these intentional program objectives is to build a culture of research and a synergistic environment for current faculty and CLS students/graduates. This paper provides an approach for embedding these research ideals in all CLS graduates and, importantly, an *intentional attempt* to create a mindset in CLS students of a possible career as a future CLS faculty member who can be successful in both the university and clinical environment.

EVOLUTION OF RESEARCH IN THE CLS CURRICULUM

Current National Accrediting Agency for Clinical Laboratory Science (NAACLS) standards for accreditation includes research and development as a future responsibility of the CLS practitioner and knowledge of research design/practice sufficient to evaluate published studies as an informed consumer. The standards include principles and practices of applied study design, implementation and dissemination of results.[9-10] With these standards in mind and the current reality of scholarship production in academia, the CLS program at Texas State University – San Marcos (www.txstate.edu/cls) has purposefully attempted to "grow our own" future CLS faculty while also continuing to maintain the high standards set for future CLS practitioners in the hospital and other laboratory areas.

Didactic lectures

While some institutions of higher education may only integrate research topics and laboratories in different CLS courses throughout the curriculum, a dedicated clinical research lecture/laboratory course (originally CLS 4261: Medical Technology Research, but currently CLS 4361: Clinical Research) was introduced at Texas State University in the 1977-78 catalog year. The faculty at Texas State University also take advantage of the opportunity to incorporate appropriate research-building skills (e.g. literature reviews, consent, Institutional Review Board (IRB)) in other courses; however, an *immersion* in a dedicated course is critical to allow for deeper learning, understanding and practice of the research experience. A variety of textbooks has been utilized for this course since its inception and is listed in Table 1. Regardless of the textbook, the topics selected in the lecture have remained fairly stable and are listed in Table 2.

The course begins with an introduction to research design and implementation in the clinical environment. The lecture topics follow with proposal writing, compliance issues in research (e.g. HIPAA, informed consent, IRB), literature searches (database tactics), manuscript writing (components of the manuscript), statistics (review and choosing the right statistical method), and illustration guidelines. The latter topics introduce professional journals, author instructions, manuscript submission troubleshooting and conclude with presentation guidelines. The lectures are supplemented with journal articles associated with clinical research and problem sets requiring student decision making with respect to choice of statistical tests. Additionally, the lectures are supplemented with special guest lectures from a variety of successful researchers from our university and other institutions.

Table 1. Textbook resources for clinical research course.

1. *Introduction to Research: Understanding and Applying Multiple Strategies,* 3rd edition. E. EdPoy & L.N. Gitlin, Mosby Elsevier, St. Louis, Missouri 2005.
2. *Understanding and Interpreting Statistics: A Practical Text for the Health, Behavioral, and Social Sciences,* 1st edition. Corty, E.W., Mosby Elsevier, St. Louis, Missouri 2007.
3. *Designing Clinical Research*, 3rd edition. Hulley S.B., Cummings S.R., Browner W.S., Grady D.G., & Newman T.B., Lippincott, Williams & Wilkins, Philadelphia, PA 2006.
4. *Clinical Diagnosis and Management by Laboratory Methods,* 21th edition. John Bernard Henry, MD., W.B. Saunders Company, Philadelphia, PA 2007.
5. *Publishing and Presenting Clinical Research,* 2nd edition. Browner, W.S., Lippincott, Williams & Wilkins, Philadelphia, PA 2006.
6. *High Yield™ Biostatistics,* 3rd edition. Glaser, A.N., Lippincott, Williams & Wilkins, Philadelphia, PA 2004.
7. *Spring into: Technical Writing for Engineers and Scientists.* Rosenberg, B.J., Pearson Education, Inc., Addison-Wesley, Upper Saddle River, NJ 2005.
8. *Clinical Laboratory Science* journal, Fowler, D.G., Executive Editor, American Society for Clinical Laboratory Scientists, Access at www.ascls.org, Bethesda, Maryland 20817.

Table 2. Topics for clinical research lectures.

Unit	Topics
1.	Research Design and implementation
2.	How to write a winning proposal
3.	HIPAA – IRB / Compliance with Research
4.	Database searches
5.	How to write a good research paper
6.	Statistics Review
7.	Illustration guidelines
8.	Professional journals
9.	Instructions to authors
10.	Journal submission troubleshooting
11.	Presentation guidelines
12.	Sharing your research / Grant process

Students are evaluated on the material based on written assignments including a proposal, IRB application, a final manuscript that must adhere to the guidelines of our professional journal, *Clinical Laboratory Science*, a final presentation of their research and a final comprehensive examination. The course is taken in the final semester in the CLS program (2nd year, summer semester); however, students are introduced to research project requirements for this course in the fall semester of the final year. In this way, the faculty can introduce content in other courses that will initiate the student towards a successful outcome in the subsequent clinical research course. For instance, the topic of compliance is discussed and modules are completed in a clinical seminar course in the final fall semester. Likewise, in the final spring semester, students begin clinical rotations at local hospitals and reference laboratories. The clinical rotations are accompanied by a clinical rotation course in which faculty assign journal article reviews while students are on campus. Each student is required to "dissect" CLS research journal articles that might be repeated in a research project. Students present journal findings to the entire class and faculty to augment the "research process" that occurs in the writing of a typical manuscript. The students are required to identify research projects at a clinical site that they will help design and conduct, such as a method comparison or validation of equipment or assays. Students may also design more elaborate research projects with a faculty advisor such as the recent publication of MRSA prevalence and characterization of a Texas university.[11] The authors' experience has been that a handful of CLS students become excited and motivated to work toward a possible publication and presentation of their research project in the clinical research course. The recent MRSA study by two of our students has received awards in our College of Health Professions Faculty-Student Research Forum, our University Undergraduate Research and Honors event, and the Texas Association for CLS state conference. It was also presented at the 2009 ASCLS national conference in Chicago, and ultimately, led to a publication in the journal, *Clinical Laboratory Science*.[11] It is the authors' belief that this type of mentoring will ultimately lead to potential future CLS faculty who will be successful in the realm of academic rigor with regards to tenure-track expectations.

The major limitation of the lecture format is that students are at different stages of understanding research concepts. Due to this concern, the Texas State University CLS program requires a prerequisite statistics course. However, students still can be at different "levels" of understanding due to the prerequisite being satisfied at different institutions and by different instructors. For example, some instructors focus on classic statistics and/or research design without including clinical or applied research. Other courses are lecture-based only without offering the student any laboratory experience. Another limitation is in the area of calculations and software such as SPSS that is often associated with clinical research. Some students struggle with calculations due to differences in their backgrounds and cognitive skills in math and statistics. This is especially noticeable with students who have not taken these types of courses recently. Texas State University, like others, has seen this issue with courses that require method validation and correlation cognitive skills.[12] To help the students master the material, the instructor (and other CLS faculty) will meet with students independently or in small groups to review or practice these topics.

It should be noted that this type of research skill-building requires constant feedback, modeling, and examples of "how research is really done" in the university and in the clinical setting. The research course also has laboratory components and special guest "content area" lectures to review and build research skills.

Laboratory component

The laboratory component of the clinical research course is taught concurrently with the didactic component. Concurrent lecture and laboratory sessions allow the student to be involved in the actual generation of data using clinically relevant research tools and techniques. Senior students are also completing their clinical rotations in various community clinical laboratories during enrollment in the research course which permits possible observation and experience with clinical equipment and methods in the hospital and reference laboratory setting which apply to possible research projects. Finally, the concurrent clinical research laboratory helps reduce the problem of lecture

topics becoming abstract or distant before the student has an opportunity to "practice" what's being covered in the didactic lecture.

During the initiation of the course in 1977, the laboratory component was a mixture of literature reviews, statistics applications, method comparison studies, and poster development and presentation by students. In 2002, an opportunity to revisit and revamp the course occurred due to the retirement of one faculty member and the subsequent employment of a new tenure-track faculty member. The laboratory experience for this course was adapted for the student(s) to successfully complete a "start to finish" research project. Students begin to identify possible research projects in the spring semester of their final year. Thus, when students enroll in the actual clinical research course for their final semester in the program they are ready to begin specific research "steps" that will result in the culmination of a final, polished manuscript ready for submission to *Clinical Laboratory Science*, if applicable.

Briefly, the students are required to complete the following steps chronologically in the course: (1) a proposal of their study which includes at a minimum the study title, problem description/hypothesis, clinical location, sample size, experimental design, IRB status, and clinical supervisor(s), (2) the completion of a Human Subjects Protection (HSP) course and subsequent electronic submission of an IRB application (exempt, expedited or full IRB), (3) attendance at an advanced database search and electronic bibliography software workshop with a research librarian at our institution, (4) attendance at a statistics review adapted by an institutional expert for an interactive session directed at "how to pick the right statistical method" for their clinical research projects, and examples of SPSS application of data, (5) completion of problem sets that have been "pulled" from published method validation articles (e.g. linear regression and correlation) and other types of research articles that include nominal data analysis (e.g. risk analysis via Chi Square and Odds ratio), (6) attendance at a "How to use SPSS" workshop adapted for our program by an institutional expert, (7) submission to the instructor of a "rough draft" at mid-semester to include the basic components of a manuscript for *Clinical Laboratory Science* and the subsequent "mock reviewers" comments from the instructor or other faculty in our program, (8) practice presentation of research projects with instructor and peer feedback, (9) attendance at a "How to submit a grant" workshop with a member from Texas State University Office of Sponsored Projects, (10) electronic submission of the final manuscript to the mock editor (instructor) including all accompanying paperwork (e.g. author checklist, financial conflicts, etc. found at http://www.ascls.org/leadership/cls/index.asp#Authors), and (11) a final presentation before student peers, CLS faculty, and guest clinical faculty.

It is important to mention that Texas State University's Assurance with the federal Office of Human Research Protections requires that the University provide an education program in HSP. Completion of the basic HSP course is required for Texas State faculty and students submitting an application to the IRB, and for faculty supervising student applicants. Beginning November 17, 2006, the nationally recognized training program by Collaborative Institutional Training Initiative (CITI) was implemented at Texas State to fulfill the federal training mandate. More than 600 other institutions utilize this web-based program. Curriculum content is provided by well-known experts and is updated regularly. For more information, please see: (http://www.txstate.edu/research/orc/humans-in-research/training.html).

This laboratory component is critical to the students' overall understanding of "how research is conducted" in a real world approach and clinical setting. The step by step process augments the ability of a student to integrate all pieces of the research puzzle, builds critical thinking skills, and improves writing skills with respect to peer-reviewed manuscript production. The individual assignments also improve understanding of mathematical operations and interpretation of data. Students are evaluated during the entire semester and are given a comprehensive final exam. The final exam includes theory of basic research concepts and synthesis/critical problem solving of data interpretation (Table 3).

Research Activities

A variety of other research intensive experiences and assignments are provided by the Texas State CLS program. Students in their first year of the program are required to complete Health Insurance Portability and Accountability Act (HIPAA) training at the university's student health center. Students review HIPAA and related confidentiality issues (informed consent, electronic health records, CLS related law suits, and IRB) in their final year during a seminar course. Instructors integrate literature reviews, case studies, and writing intensive coursework in most of the CLS curriculum/coursework.

Table 3. Topics for clinical research laboratory.

1. Proposal design: An overview
   - Identifying topic / Framing research problem
   - Literature review
   - Common elements
   - Example proposals
2. Principles for protecting human subjects
   - Disclosure / Confidentiality / Participation
   - Belmont Report / Institutional Review Board
   - Informed consent process / Developing documents
3. Advanced database searches / Electronic bibliography building software
4. Statistics
   - Research design approaches
   - General review
   - Advanced data analysis / SPSS
5. Preparing and organizing data
   - Text
   - Tables / Figures
6. Manuscript preparation and submission
   - Instructions to authors
   - Publishing your manuscript
   - Research sharing
7. Formal presentation of research
   - Guidelines for components of research

In the clinical immunology course (first year) and molecular diagnostics course (final year),[13] students are required to complete a literature review for a class grade to include submission to the Texas State College of Health Professions Faculty-Student Research Forum. The Research Forum introduces the students to the process of abstract writing, synthesis and integration of literature as it applies to an advanced course content area (e.g. flow cytometry in cancer diagnosis, microarrays in genetic disorders), and the peer-review method for abstract acceptance to present findings at a scientific meeting. Tours of specific research laboratories (e.g. The Virginia Harris Cockrell Cancer Research Center at The University of Texas M. D. Anderson Cancer Center, Science Park – Research Division) are conducted specifically in the research course to identify research in clinical and related disciplines and to introduce students to graduate school opportunities. The Science Park - Research Division is located in the Lost Pines region near Smithville, Texas. The mission of Science Park is to investigate the molecular biology of cancer and to develop means for cancer prevention and detection (see http://sciencepark.mdanderson.org/). Students are also encouraged to attend the annual state TACLS conference (see http://www.tacls.org/) and, if possible, the national ASCLS conference (see http://www.ascls.org/). These efforts have led to recent increased attendance and posters at the state level and submission of research papers for student award opportunities at the national level.[11]

The CLS faculty at Texas State University attempt to incorporate their students into various research projects that they are conducting throughout the academic year. For example, two recent projects incorporated student immersion into a MRSA prevalence, risk analysis, and genetic characterization study in a Texas correctional facility[14] and in a Texas university.[11] Student cohorts were involved at various stages of the projects as the research progressed. For instance, some students performed the actual bench level microbiological testing while others were involved in data analysis and other post-analytical steps. Participation with a faculty research project is strictly voluntary; however, the students that do participate usually become "hooked" on the research experience and offer a mechanism for peer-to-peer sharing of their efforts. These types of student initiated research opportunities are far more powerful than a top-down approach from a faculty member.[15-16]

SUMMARY

As many CLS programs in the U.S. can attest to, it is often difficult if not impossible to fill CLS tenure-track positions with "research-prepared" faculty that can succeed in this environment. Many CLS programs are

faced with the very real problem of needing competent and qualified "teachers" to prepare future CLS for the workforce. Historically, these faculty have a master's degree (46%) or a BS in CLS (11%), with the remainder being doctorates (43%)[6] and usually all of these are most likely recruited from the clinical environment. All of these degree holders are probably outstanding teachers of the CLS curriculum. However, the profession should not overlook the equally important issue of ensuring that faculty can be successful in the 21st century academic environment of scholarship production. Universities are continually raising the bar for faculty, including CLS faculty, in the realm of research and publish/perish viewpoints. As Mundt and Shanahan recently reported, "though the percentage of the reported faculty holding a doctorate was not higher than previous assessments of such faculty, these data indicate that almost half of the reported CLS faculty in the U.S. universities are preparing themselves as scientists for their roles in teaching and, increasingly, in research."[7]

By including a dedicated clinical research course in the CLS curriculum alongside other intentional research activities, the CLS program at Texas State is attempting to prepare students with the knowledge and background they need to be competent in applying this skill set in the clinical workforce and academic arenas. The course has strengthened our student's "job attractiveness" in clinical, reference, research, and public health laboratories. Importantly, the course also has had the added effect of stimulating student's interest in research and the likelihood of pursuing a graduate degree, and ultimately, attracting future CLS faculty that will be better equipped to be successful in the academic research world. These activities have also enhanced a synergistic relationship between the scholarship activities of our current CLS program with students and increased the collaboration across other allied health programs in our college.

Expectations on how and where to publish research offers an opportunity for faculty to become comfortable with the journals in CLS while also showing venues for published writing to the student. This approach can be quite effective for programs with limited time and schedules available for expanding coursework because research standards could be added to existing courses. It could also be effective for a CLS designated research course. Critical components for faculty would be knowledge of principles of basic research design for successful integration of research skills into curricula. Universities and the healthcare arena have research personnel who can help faculty with the design of course related research exercises if faculty are not accomplished in research.

It is important to mention the challenges associated with the endeavor of pursuing this type of course in the CLS curriculum. The major obstacles that the Texas State CLS program encountered were (1) faculty expertise, (2) time of placement within CLS curriculum, and (3) student preparation for course rigor (e.g. prerequisites and advanced research skills).

These obstacles were addressed in a variety of ways. Faculty expertise is continually being met by a renewed commitment to a research culture within our program, college and university. The faculty spends time in special workshops and informal mentoring with experts in the areas of statistical methodology, proposal development, grant development, and peer-reviewed publication. Additionally, one current CLS faculty member has successfully defended his Ph.D. dissertation and one other recently hired faculty has been accepted into a Ph.D. program. The placement of the research course in the curriculum and student preparation will be different for each CLS program. In the authors' experience, the course was best placed in the final year so that students would have the opportunity to finish prerequisites and build their skills in critical areas (e.g. statistics, software, and writing). Finally, students can become frustrated with the challenge that research courses and projects present in an undergraduate program. This challenge is being met by consistent mentoring, feedback, tutoring, and "modeling the research environment" for a clinical laboratory scientist.

A dedicated course in clinical research provides CLS programs with the unique opportunity to become flexible in the face of growing clinical shortages in the workforce and in the continuing decline of finding research-prepared faculty for the tenure-track environment in academia. Furthermore, CLS programs

must begin to build a synergistic research environment between faculty and students to encourage the future possibility of a career in academia. While research is taught and practiced in a variety of university and college departments at the master's and doctoral degree level, CLS programs can begin to develop future academicians at the undergraduate level by preparing clinically competent and research-oriented CLS professionals.

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