Training Technologists for the Genomic Age

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Molecular techniques are playing an ever-increasing role in all areas of anatomic and clinical pathology. The field is currently in need of well-trained technologists in this area of the clinical laboratory who are situated to bridge the current state of practice and the continuing developments in high complexity testing. For the close term, use of "home-brew" and analyte specific reagents (ASR)-based tests will require well-trained personnel with strong biomedical science backgrounds and a thorough understanding of technologies used in assay development. Here, we discuss the selection and evaluation of molecular diagnostic training preceptor sites and tasks indicated for trainees that most meet the needs of the newest facet of the laboratory. We present evaluation tools developed over the course of four years of clinical education used to assess practical performance of trainees in a molecular diagnostic pathology laboratory and conclude with considerations for future training of laboratory technologists.

ABBREVIATIONS: ASR = analyte specific reagents; BMC = below minimum competency; DMS = diagnostic molecular scientist; MSMP = Master of Science Program in Molecular Pathology; NAACLS = National Accrediting Agency for Clinical Laboratory Sciences; PAS = performs above standards; PCR = polymerase chain reaction; TTUHSC = Texas Tech University Health Sciences Center.

INDEX TERMS: clinical education; molecular; training.

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Over the past few years, the clinical laboratory has seen an explosion in the number of tests based upon DNA and RNA analysis. For the first time in the history of the diagnostic laboratory, molecular pathology is extending the range of information available to physicians, research scientists, and other health professionals. The completion of a draft sequence of the human genome and the wealth of technology to arise out of that effort has moved from the research bench to the clinical laboratory bench with swift success. It is now commonplace for a molecular diagnostics laboratory to have the capability to provide diagnostic services ranging from the analysis of the fundamental genetic makeup of an individual which indicates the development of a pathology later in life[1-3] to the ability of a physician to monitor the response of an individual to therapy,[4] to the determination of viral load[5] or a nascent public health concern.[6]

A problem unique to this area of practice is the paucity of FDA-approved assays currently on the market. The majority of molecular diagnostic assays currently exist as ASRs or as in-house developed "home-brew" tests, original and unique to a facility. The complex nature of molecular diagnostic testing and the nature by which testing is brought to fruition therefore requires that technologists have not only well-developed clinical laboratory skills, but also a strong background in basic molecular biology and genetics. Individuals trained specifically in molecular diagnostic testing are uniquely situated to bridge the gap between the current state of practice in the clinical laboratory and an area expected to continue rapid growth over the next few years. The goal of molecular diagnostic practice is to enhance the value of clinical laboratory services by providing an environment in which new tests can be developed, validated, and implemented in practice based on the application of knowledge and new techniques at the most basic biological level.

To address this particular need, a graduate-level Master of Science Program in Molecular Pathology (MSMP) was devel-

oped in the Spring of 2001 within the Department of Laboratory Sciences and Primary Care at the Texas Tech University Health Sciences Center (TTUHSC) School of Allied Health Sciences. The program was developed with a focus on training technologists who are well-prepared to step into bench- and higher-level roles in a molecular diagnostics laboratory, with a strong emphasis on clinical skills. The curriculum was developed to meet the standards set forth by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) for the diagnostic molecular scientist (DMS).[7] To date, the MSMP program at TTUHSC remains the only graduate program to have been granted accreditation by this body (2004). Briefly, the didactic portion of the curriculum consists of courses in cell biology, biomedical ethics, pathophysiology and human molecular genetics, and training in high complexity molecular biology methods specific to the diagnostic environment.[8] Students receive hands-on training in molecular diagnostic methods and clinical assays in a functioning clinical molecular pathology laboratory at TTUHSC during the entirety of the program as a complement to classroom instruction. The program concludes with clinical training at one of ten affiliated institutions performing molecular diagnostic testing in a Clinical Laboratory Improvements Act and College of American Pathologists-accredited facility (the exception is a combined rotation at two sites). The purpose of this article is to present tools that may be used for evaluation of student performance at clinical training sites.

The MSMP program currently enrolls a maximum of 16 students per year. To date, a total of 33 students have graduated from the program and 16 are enrolled for 2005-2006. This is hardly adequate to address the shortage of well-trained personnel and projected shortfalls in the laboratory sciences.[9] However, a small class size does ensure a very high level of technical training and depth of understanding of basic biomedical concepts upon graduation. The ultimate goal of the program is the production of individuals who are capable of stepping into, at the very least, a bench position and more likely, a supervisory position in the laboratory upon graduation.

With the exception of reference laboratories and very large hospital systems, it is not common for a molecular diagnostics laboratory to offer a menu of services that spans the range of services commonly regarded as the scope of molecular diagnostics and pathology. Briefly, this includes human identity testing, hematology/ oncology, genetics, and infectious disease/microbiology, and the associated technologies of each. The scope of molecular diagnostic practice coupled with the ever-changing technological innovations initially made selection of training sites a challenging task. During the first two years of the MSMP program, every effort was made to select sites that had a comprehensive test menu, including at least one test from each of the previously mentioned areas of practice. It was decided that this strategy was largely ineffective, primarily because the test volume of an individual laboratory was not high enough in any one area to adequately train students beyond the level of a bench technologist. We found that an assay may have only been run one time in an eight week period and rarely led to the discussion of higher-level considerations of a technology or the special clinical considerations unique to the test.

Table 1. Molecular pathology student task list: basic competencies

TASK	BMC*	PAS†	N/A‡	Comments	Instructor initials
DNA extraction					
DNA quantification					
RNA extraction					
Reagent preparation					
Gel preparation					
Master mix set up					
Primer dilution					
Probe preparation					
Assay QC					
Other					

Legend for Tables 1, 2, 4:
* performs below minimal competency
† performs at or above minimal competency/above standards
‡ not applicable

Not surprisingly, it was found that at sites specializing in only one type of testing (e.g., infectious disease), the depth of knowledge gained by students far exceeded that of their peers. Because the profession is highly technology-oriented, it has been most effective to train technologists with this in mind, regardless of the clinical condition being assayed. The nature of molecular diagnostics laboratories across the nation is varied with regards to the areas of testing offered by a given facility. However, the technology platforms used in testing are relatively constant, regardless of clinical condition. Currently four of our affiliates offer a comprehensive test menu, i.e., one that spans the spectrum of disease. We therefore found it important to develop standardized tools that would provide a comprehensive assessment of the training provided and student performance during the clinical rotation. This unique perspective on training has allowed us to better resolve the difficulty associated with the diverse climate of molecular diagnostic training and ensure that all students acquire the same level of competency upon graduation. This is a philosophy shared by NAACLS, as reflected in the July 2005 revision to standard 9B2 in the DMS training criteria.

Each student is evaluated on performance and professional skills by the clinical training site. In turn, the students provide feedback on their experience. Together, this information is used to assess the clinical competency of each student and to further refine the MSMP program. All students are evaluated on areas of basic competency in molecular diagnostic practice: nucleic acid extraction and quantification, reagent preparation, gel preparation, polymerase chain reaction (PCR) preparation, probe preparation, and assay quality control. It is required that all students perform these tasks during the course of testing (Table 1). Additional required tasks are enumerated in Table 2. These skills are evaluated as they relate to specific areas of practice – genetics, oncology and/or microbiology/infectious disease.

A score of "performs above standards" (PAS) or "below minimum competency" (BMC) is assigned in each category and comments are solicited from the clinical instructor, as appropriate. These task lists refer back to the objectives set forth in the NAACLS DMS standard and by those developed specifically in the MSMP program relating to clinical training with criteria for evaluation of performance. Table 3 contains our current training sites and the areas of testing provided at each. Tables 1 and 2 describe the areas of laboratory competency assessed at the training site for each student.

Overall, student performance evaluations indicate a high level of affiliate satisfaction with student training upon completion of formal coursework and upon completion of clinical training. To date, the external certification rate for all graduates taking either the CLSp(MB) or (MP)ASCP exam is 100%. All training sites evaluated trainees using the worksheets represented in Tables 1

Table 2. Molecular pathology student task list: specific discipline

TASK	BMC*	PAS†	N/A‡	Methodology instrument	Disease	Comments	Instructor initials
PCR§							
Reverse Transcriptase PCR							
Quantitative/ real time PCR							
Sequencing							
Fragment analysis							
Southern							
Florescent genotyping							
Viral load							
Result analysis							

§ polymerase chain reaction

and 2. In 2005, all students (100%) were scored as PAS at all sites. In addition to evaluation of individual trainees and certification rate, affiliate satisfaction can be inferred from offers of employment to graduates upon program completion. In 2005, students were made offers of employment at 66% of affiliated laboratories. Initial selection of affiliates included laboratories in Texas and outside of the state. While the employment outlook for molecular technologists within the state is expected to be positive for the next several years, diverse opportunities for employment within the field are available across the nation. Seeking affiliates at distant sites has also increased awareness of the program among out-of-state laboratory directors and medical centers.

As mentioned previously, the philosophy of the MSMP program emphasizes a focus on technology platform secondary to clinical condition to ensure appropriate training for all students. Provided an affiliate covers all areas of appropriate technology, it is not necessary for all students to receive the same training experience to receive an equivalent training experience. Note that the characteristic common to all sites is an active program of research and the development of new assays and validation of new assay platforms. The business climate and very nature of molecular diagnostic testing requires that laboratories investigate the design and validation of novel "home-brew" assays and analyte specific reagents. It was this need for individuals prepared to participate in research and development activities that guided the development of new performance evaluation tools used within the MSMP program. In response to strategic needs of clinical laboratories, we are currently constructing an additional skills assessment checklist to be used for evaluation of research and development tasks. This list will include "home-brew" assay design and validation, crossover study data analysis, and other skills required for implementation of novel testing platforms.

In the first two years of the MSMP program, additional tasks were included for evaluation of students with a focus on Southern blotting and hybridization and PCR. Other technologies were to be enumerated by the affiliate and a pass/fail grade assigned as appropriate. For purposes of evaluating student performance, a brief listing of additional tests performed in a laboratory was adequate. However, we were often unable to determine the specifics of the training provided. We felt that such information would be helpful in refining our clinical training, as well as in making initial assignments of students to sites in future classes that would best "round out" their technical training. Keeping in mind that clinical instructors often have additional job responsibilities and that students may rotate through several instructors in a laboratory, an evaluation task list was constructed to obtain more specifics with a minimal amount of required narrative.

We prepared a separate table of tasks for each practice area: infectious disease, oncology/hematology, and genetics. The skills to be evaluated were common amongst all three areas and now include an area for the instructor to provide the methodology (instrument) and disease tested for each skill, as well as a section for brief comments. An example of this worksheet is provided in Table 2. In the first year of implementation, from these worksheets we were better able to determine the scope of testing in which each student actually participated, areas for remediation and additional study before certification, and the trends of technologies currently utilized in the laboratory. This last point has proven particularly helpful in curriculum development and in strategic planning.

Table 3. MSMP training sites and areas of testing

Clinical affiliate	Genetics	HID*	Oncology	Microbiology	R&D†; new assays
Affiliate 1	X	X	X	X	X
Affiliate 2	X			X	X
Affiliate 3	X				X
Affiliate 4	X		X	X	X
Affiliate 5	X	X	X	X	X
Affiliate 6				X	X
Affiliate 7	X		X	X	X
Affiliate 8	X				X
Affiliate 9			X		X
Affiliate 10				X	X

* Human identity testing
† Research and development

Areas of service provided at each laboratory are indicated by an "X"

Because graduates may seek or be expected to step into a supervisory position, additional training in laboratory management was added to the task list in the second year of the MSMP program (2003). The expectation of this training experience is for students to be given an overview of human resources management for the organization, quality assurance and management, laboratory accreditation, and any other supervisory issues the affiliate finds appropriate to discuss. In the first year of implementation in the clinical curriculum, we observed that no clinical training sites addressed management tasks as described in the task list in 2004. This may have merely been due to their position on the task list – they were added at the end of a large table of items. In the most recent revision of evaluation criteria, these competencies were expanded and included as a separate, freestanding worksheet (Table 4). In 2005, 33% of students were evaluated for performance/training in management tasks and 100% were scored as PAS. Emphasizing these tasks as a separate area of focus increased the number of affiliates that addressed these tasks with trainees. It is expected that this number will further increase in subsequent years as we pursue improvements through personal communication with clinical educators.

In summary, narrative commentary from clinical educators has been overwhelmingly positive as it relates to both student performance and structure of evaluation tools (e.g., task lists). Students are demonstrating mastery of laboratory tasks and in most cases exceeding initial expectations. Continuous refinement and utilization of appropriate evaluation criteria are critical to the development of excellence in clinical laboratory education. The implementation of these task lists has provided us valuable data that will allow us to evaluate the quality of student training and plan for future developments in the field of molecular diagnostics.

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Table 4. Molecular pathology student task list: management

TASK	BMC*	PAS†	N/A‡	Comments	Instructor initials
Applicant hiring process					
Employee performance appraisal					
Ordering and purchasing for lab					
Sit in on supervisory meeting					
Understand quality management program					
Maintenance of laboratory accreditation					
Marketing strategies					
Participation in laboratory meetings					
Other					