

The Doctorate in Clinical Laboratory Sciences: A New Curriculum to Enhance the Connection of the Laboratory to Health Care Providers

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Abstract

This report discusses the need for a Doctorate in Clinical Laboratory Sciences program and describes a curriculum to train Doctorate in Clinical Laboratory Sciences students. The Doctorate in Clinical Laboratory Sciences program was developed to help reduce diagnostic errors in patient care by enhancing connections between the clinical laboratory and health care providers. Data are presented from program implementation in 2016 to 2017 academic year to 2019 to 2020 regarding the faculty and student demographics, program statistics (eg, admissions and attrition rates), and effectiveness. Perceptions of program effectiveness were obtained via surveys from 28 faculty physicians who supervised Doctorate in Clinical Laboratory Sciences students during clinical service rotations. Another survey assessed the preferred type of practice after graduation of 33 students. Over the 4-year period, the program had a 50% rate of admission and a 21.8% attrition rate. As of December 2020, 15 students graduated from the program. The majority (69%-82%) of physician faculty who completed the survey agreed that Doctorate in Clinical Laboratory Sciences students contributed positively at clinical rounds. Approximately two-thirds of students reported a preference to lead a Diagnostic Management Team or serve as an advanced practice provider in a Diagnostic Management Team with leadership provided by an MD/DO or PhD. This report provides useful information for other institutions that may want to establish similar Doctorate in Clinical Laboratory Sciences programs. Early data suggest that our program effectively trains doctoral-level advanced practice medical laboratory scientists, who may play an important role in improving patient safety by reducing diagnostic errors and providing value-based, optimal patient care.

Keywords

clinical laboratory doctorate, curriculum, Doctorate in Clinical Laboratory Sciences, diagnostic error, diagnostic management team

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Introduction

Over the past several decades, advanced practice providers have played increasingly important roles in many areas of medicine. At this time, it would be difficult for most physicians to imagine working without the partnership of a physician assistant or nurse practitioner, especially those in academic medical centers, where multidisciplinary health care teams are the norm. Advanced practice providers also help fill the critical need for health care providers in rural and underserved areas.

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With the substantial increase in number, complexity, and costs of laboratory tests in recent years, there is a growing need for input from experts to provide recommendations for appropriate selection and evaluation of these tests and to aid in interpreting their results. The rapid growth in laboratory testing has produced complex issues in test selection and interpretation, time and effort challenges, financial concerns, and increased potential for error, all of which have created a demand for more advanced training of medical laboratory scientists in the field of clinical pathology.

Pathologist assistants have become important components of the team in many pathology practices. Although pathologist assistants are well trained to assist in specimen preparation and processing, they are not trained to analyze and review medical records to provide recommendations for test selection or to provide interpretation of laboratory results. To create expert-driven, patient-specific interpretations of complex clinical laboratory evaluations, it is necessary to review medical records for all information related to a patient's medical conditions. In academic medical centers, pathology residents and fellows often serve in an advanced practice role to perform initial reviews of medical records and prepare preliminary interpretations and recommendations for providers who ordered the tests. However, residents and fellows are not available in all medical practice settings, and pathology assistants have a restricted scope of practice. Therefore, the need to create a program to produce doctoral-level advanced practice medical laboratory scientists (APMLS) was recognized.

The need for APMLS to participate in generating narrative reports of complex clinical laboratory evaluations is especially compelling at this time. For the past 3 to 4 decades, the vast majority of pathologists have not had adequate professional support to help guide fellow physicians in test selection and interpretation of complex clinical laboratory evaluations because payments are substantially higher for anatomic pathology activities than for professional activities in laboratory medicine.¹⁻³ Further, current payment systems provide no reimbursement to expert laboratory directors with a doctoral degree other than an MD or DO degree for advising colleagues on test selection and result interpretation.

Along with the rising complexity of test options, diagnostic errors are increasing at an alarming rate. The concept of diagnostic error emerged prominently with a 2015 report by the National Academy of Medicine¹ indicating that at least 1 error in diagnosis is experienced by every adult American. The consequences of these errors can be life-threatening. A major contributor to diagnostic error is the rapid expansion of available laboratory tests, many of which are extremely costly.⁴⁻⁶

To circumvent diagnostic errors, Diagnostic Management Teams (DMTs) have been implemented by many institutions in a number of areas, including coagulation, transfusion medicine, toxicology, autoimmunity, liver disease, and anemia. They have even been used to review cases of suspected child abuse.⁵ A DMT is a group of experts who conduct focused meetings to ensure correct selection of laboratory tests and proper interpretation of complex test results within specific

fields or disease groups.⁷ Diagnostic Management Team experts include pathologists, physicians in other specialties, and non-MD/DO laboratory experts. In this report, we show that a doctoral-prepared APMLS can be an effective intermediate care provider.

Methods

This report describes the results of a survey-based Quality Improvement/Quality Assurance project exploring the characteristics and outcomes of the Doctorate in Clinical Laboratory Sciences (DCLS) program at the University of Texas Medical Branch (UTMB) in Galveston, Texas. Because of the nature of this study, the UTMB Human Research Protections Program deemed it exempt from formal review by our institutional review board. Student confidentiality was fully protected.

Data were collected for the UTMB DCLS program from its inception in the 2016 to 2017 academic year to the 2019 to 2020 academic year. The study included all 55 DCLS students admitted to the program during the 4 years. Student demographic, employment, admission, and attrition data were collected through normal operations of the university. Student project information, program curricula, and faculty contributions were obtained from the program leadership.

A total of 28 faculty physicians who were supervisors during the students' clinical service rotations completed an anonymous survey to assess DCLS student contributions as part of the clinical rounding team (which also included medical students and residents). The survey was completed once per faculty physician between May 2020 and August 2020. Respondents used a 5-part Likert scale (from strongly agree to strongly disagree) to rate their agreement with 4 statements covering these domains: (1) service as a clinical laboratory resource, (2) consultation regarding laboratory test selection, (3) consultation regarding interpretation of laboratory tests, and (4) overall benefit to clinical performance.

In total, 33 DCLS students completed an anonymous cross-sectional survey after they completed over half of their clinical rotations to assess the preferred area of employment upon graduation with a DCLS degree. The options were as follows: (1) laboratory consultant and DMT lead, (2) laboratory director but not act as a DMT lead, (3) academic practice but not act as a DMT lead, (4) regulatory setting (CMS, CLIA, etc), or (5) other.

A postgraduation survey was completed by 12 of the 15 DCLS graduates. This anonymous survey was distributed approximately 1 year after graduation. The survey focused on employment outcomes and self-perceived competence.

Results

Program Description

University of Texas Medical Branch is one of 3 institutions in the United States that has organized a DCLS program to help address diagnostic error and incorrect test selection. The DCLS

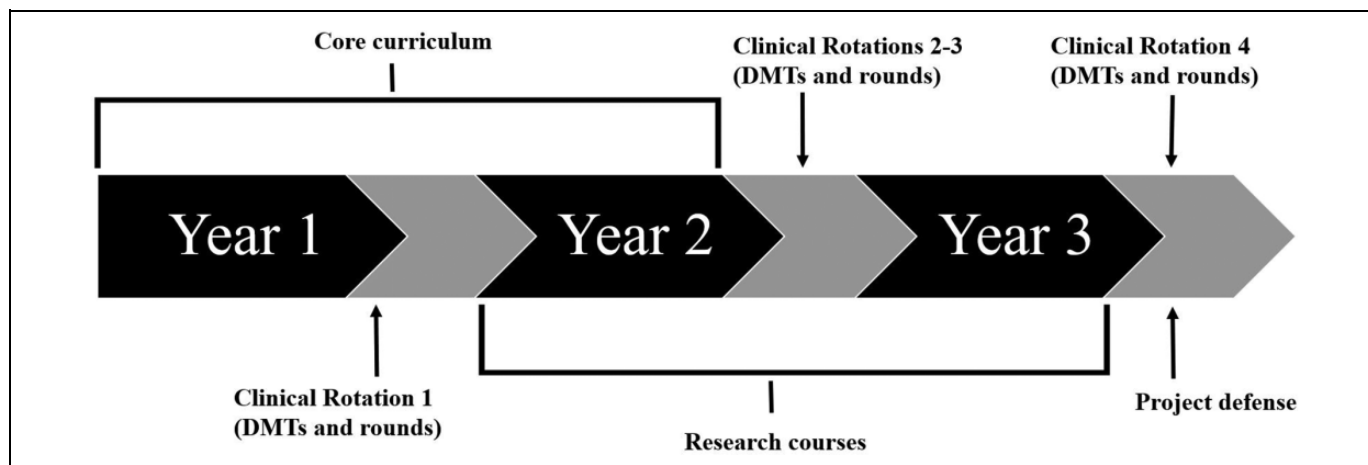


Figure 1. Doctorate in Clinical Laboratory Sciences (DCLS) curriculum sequence.

Table 1. DCLS Curriculum Content.

Courses to Develop Diagnostic Expertise (864 contact hours)

<p>Advanced Clinical Topics: Pathophysiology and Diagnostic Testing</p> <ul style="list-style-type: none"> Cardiovascular Endocrine disorders Gastrointestinal and pancreatic disorders Hepatobiliary disorders Impaired glucose metabolism Renal disorders Reproductive disorders Respiratory disorders Vitamins, trace metals, and nutrition Tumor markers <p>Advanced Microbiology and Infectious Disease</p> <ul style="list-style-type: none"> Host-pathogen interaction Microbial pathogenesis Bacteriology Virology Mycology Antibiotic susceptibility <p>Diagnostic Management Teams (432 contact hours)</p> <ul style="list-style-type: none"> Anemia Autoimmune disease Coagulation Forensics <p>Clinical Service Experiences (288 contact hours)</p> <ul style="list-style-type: none"> Obstetrics and gynecology Internal medicine Forensics <p>Research Courses (144 contact hours)</p> <ul style="list-style-type: none"> DCLS Project 1 DCLS Project 3 	<p>Clinical Immunology and Transfusion Medicine</p> <ul style="list-style-type: none"> Autoimmunity Transfusion reactions Stem cell therapy and immunotherapy <p>Molecular Diagnostics</p> <ul style="list-style-type: none"> Methods in diagnosis of inherited and acquired disorders <p>Hematopathology</p> <ul style="list-style-type: none"> Diseases of red blood cells Diseases of white blood cells Bleeding and thrombotic disorders <p>Introduction to Health Assessment</p> <ul style="list-style-type: none"> Health assessment overview Health systems Professional responsibilities <p>Pharmacology</p> <ul style="list-style-type: none"> Toxicology Pharmacokinetics <p>Liver disease</p> <p>Infectious disease</p> <p>Toxicology</p> <p>Transfusion medicine</p> <p>Geriatrics</p> <p>Surgical intensive care unit</p> <p>Nephrology</p> <p>DCLS Project 2</p>
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Abbreviation: DCLS, Doctorate in Clinical Laboratory Sciences.

degree extends the expertise of the individual beyond that of an entry-level clinical laboratory scientist⁸ and provides a career development opportunity for clinical laboratory scientists seeking a doctoral degree.

Our DCLS curriculum was developed by Clinical Laboratory Sciences (CLS), MD, and PhD faculty and structured to

meet doctoral standards set by the National Accrediting Agency for Clinical Laboratory Sciences. Degree requirements and criteria for awarding the degree include didactic coursework, clinical requirements, and research courses. The program curriculum is taught in 9 semesters over 3 years (Figure 1). The curriculum is summarized in Table 1 and consists of 1728

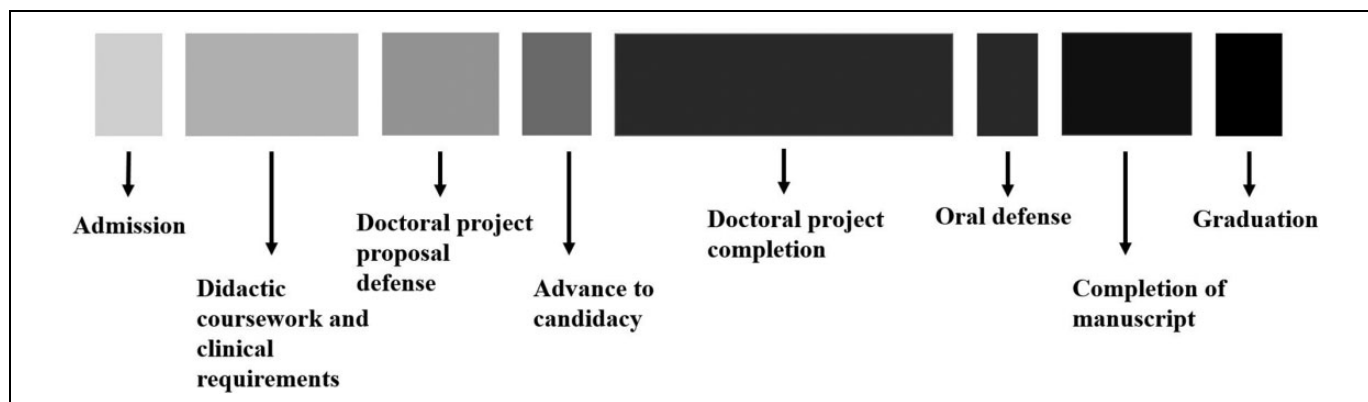


Figure 2. Doctorate in Clinical Laboratory Sciences (DCLS) curriculum milestones.

contact hours organized into 4 sections: (1) courses designed to develop diagnostic expertise (864 hours), (2) DMT rotations (432 hours), (3) clinical service experiences (288 hours), and (4) research courses (144 hours). The courses to develop diagnostic expertise are organized by discipline and consist of online lectures and written assessments. Each student rotates through 8 DMT rotations, ranging from an Anemia DMT to a Toxicology DMT (as shown in Table 1). The clinical service experiences involve participating in direct patient contact (rounds) under the supervision of clinical faculty. Each student rotates through 6 diverse clinical service rotations, including obstetrics and gynecology, psychiatry, geriatrics, and nephrology services, as well as a general internal medicine ward service and the surgical intensive care unit.

The clinical practice experience (sections 2 and 3) allows DCLS students to develop collaborative skills required to properly advise health care providers on test selection and result interpretation in the clinical setting. This experience encompasses a total of 16 weeks on campus, with 8 hours of daily clinical assignments. Before and after attending on-campus clinical sessions, the students receive supplemental classroom instruction on the use of diagnostic tests outside the clinical laboratory.

A doctoral project containing publishable data is also required for graduation. Project work is completed during the last 2 years of the curriculum and is based on original research data derived from clinical projects. The topic of the project is selected by the student, with the aid and approval of the student's doctoral project committee. The committee also supports and supervises the student while conducting the project. Successful oral defense is required for completion of the DCLS degree. Figure 2 depicts the milestones for completing the doctoral project and the overall DCLS curriculum.

Student Admissions and Attrition

Figure 3 is a year-by-year presentation of student admission and attrition rates. The overall acceptance rate for 2016 to 2017 through 2019 to 2020 was 50% (55/110). With an overall 21.8% (12/55) attrition rate, the remaining number of students in the program or who had graduated by the end of 2019 to 2020

was 43. In 2016 to 2017 and 2017 to 2018, approximately two-thirds of the applicants were admitted. In 2017 to 2018, 10 of the 20 admitted students withdrew from the program, representing an attrition rate of 50% for that cohort. Accordingly, we reduced the proportion of applicants who were admitted to less than one-half (46%) the following year. In 2019 to 2020, the admission rate was 33%, and as of December 2020, the attrition rate for students admitted in 2018 to 2019 and 2019 to 2020 is 0%.

Almost twice as many women than men have been admitted to our program since its inception. The most common age range at admission was 35 to 44 years, with 43% of students in this age group. A total of 80% of accepted applicants worked in a clinical laboratory bench setting for more than 6 years. Overall, 68% of admitted candidates identified Texas as their home state, presumably because our institution is in Texas. The remaining 32% of students were from diverse areas of the United States.

Doctoral Project Topics

A total of 15 students graduated from our DCLS program as of December 2020 (8 from the 2016 to 2017 admission cohort and 7 from the 2017 to 2018 cohort). Table 2 lists all doctoral project titles and outcomes for these graduates. Most projects focused on DMT initiation or laboratory test utilization. Six projects examined the use of DMTs for various hematologic and endocrine disorders. The non-DMT projects focused on diagnostic errors attributed to laboratory test utilization (8 projects) and the shortcomings of opioid prescription changes and documentation reconciliation (1 project).

Faculty Characteristics and Clinical Evaluations

Table 3 provides information regarding the faculty of our DCLS program. Although the program is administered by the School of Health Professions, most faculty are not members of the CLS Department. Most teaching is performed in a clinical setting by faculty who hold appointments in the pathology or internal medicine departments and have an MD/DO degree. These faculty include the instructors for the online courses, the DMT leaders (MD pathologists or PhD clinical laboratory directors), and the clinical service MD faculty.

Table 2. Doctoral Projects of Doctorate of Clinical Laboratory Sciences Graduates.*

Project titles	Outcomes [†]
Overutilization and underutilization of autoantibody tests in patients with autoimmune disorders Rajendran R, Salazar JH, Seymour RL, et al. Overutilization and underutilization of autoantibody tests in patients with suspected autoimmune disorders. <i>Diagnosis</i> . 2021. doi:10.1515/dx-2020-0139	Completed August 2019 Published March 5, 2021
Optimizing warfarin therapy in a rural hospital through the use of a diagnostic management team	Completed August 2019 Under review for publication
Impact of an anemia diagnostic management team on primary care providers	Completed August 2019 Under review for publication
Role of a thromboelastography diagnostic management team to diagnose and manage coagulopathies in complex patients	Completed August 2019 Under review for publication
Assessment of narcotic prescription changes and documentation reconciliation in family medicine and pain practitioners	Completed December 2019
Overutilization and underutilization of thyroid function tests in pregnant women with suspected thyroid disorders	Completed August 2020 In Press
Implementation of a metabolic syndrome diagnostic management team in an inpatient psychiatric hospital setting	Completed August 2020
Review of diagnostic errors in platelet refractory patients for a novel implementation of a multicenter platelet refractory diagnostic management team	Completed August 2020
Review of test utilization in patients with recurrent pregnancy losses	Completed August 2020
Stewardship review of reference testing in hospitalized patients	Completed August 2020
Assessing for appropriate test selection and overutilization in vitamin D deficiency	Completed December 2020
Diagnostic errors associated with blood cultures yielding bacteria of indeterminate significance	Completed December 2020
Evaluation of laboratory test utilization in the diagnosis and management of diabetes mellitus type 1 and 2	Completed December 2020
Evaluation of laboratory test utilization in the diagnosis of hepatic disorders associated with hyperbilirubinemia in adult patients	Completed December 2020
Effect of a diagnostic management team on thyroid disorders	Completed December 2020

* n = 15.

† Project outcomes for all 15 students graduating from the program as of December 2020. For all projects, data collection has been finalized, and doctoral project papers have been written and successfully defended.

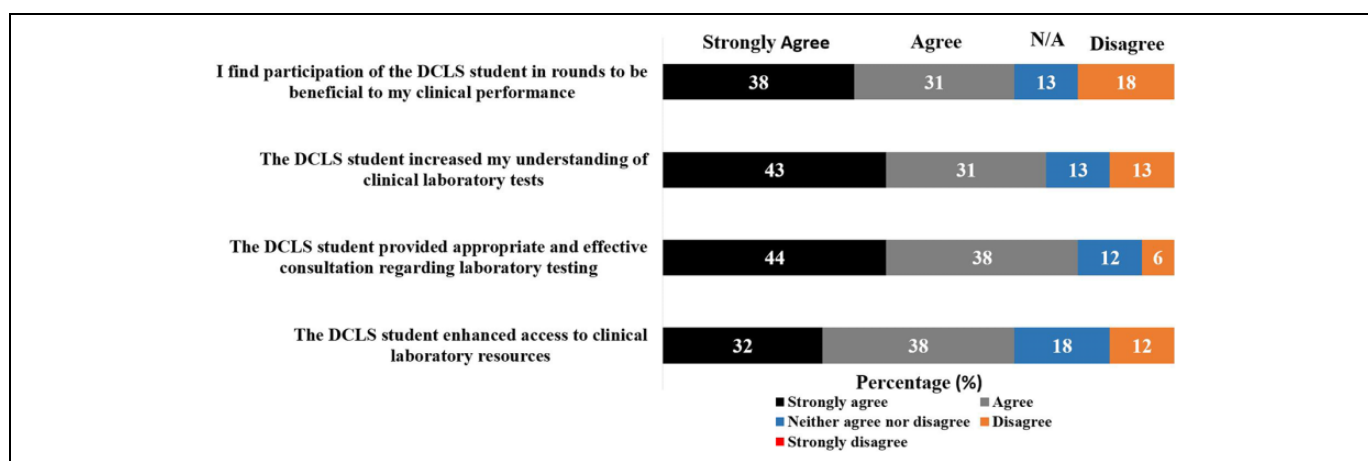
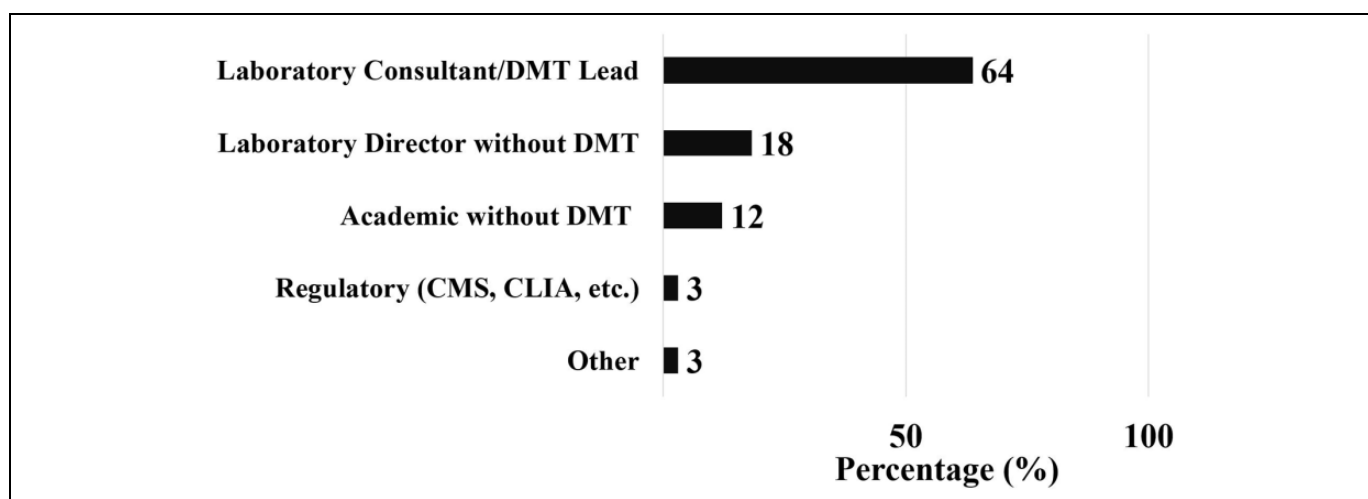
The results of evaluations by MD faculty on the clinical service units are shown in Figure 4. Of the 28 responders, 69% to 82% responded positively to the 4 statements about the presence of DCLS students at clinical rounds (“agree” or “strongly agree” with statements reflecting positive contributions from the students).

Student Employment Preferences

Figure 5 shows responses to the student survey regarding work preferences upon obtaining a DCLS degree. Approximately two-thirds of students reported a preference to lead a DMT or serve as an advanced practice provider in a DMT with

Table 3. Faculty Supervision.

Characteristics	Number of faculty (%)	Average number of teaching hours per year per faculty	
Department		Didactic	Clinical
Clinical Lab Sciences	8 (16)	9	12
Internal Medicine	19 (37)	0	40
Pathology	19 (37)	7	41
Obstetrics and Gynecology	5 (10)	3	20
Highest Earned Degree	Number (%)		
Doctor of Philosophy (PhD)	12 (24)	-	-
Doctor of Allopathic Medicine (MD) or Osteopathic Medicine (DO)	38 (76)	-	-

**Figure 4.** Physician faculty assessments of Doctorate in Clinical Laboratory Sciences (DCLS) students during rounds (n = 28).**Figure 5.** Survey of Doctorate in Clinical Laboratory Sciences (DCLS) student employment preference upon graduation from the program (n = 33). CLIA indicates clinical laboratory improvement amendments; CMS, Centers for Medicare and Medicaid Services. Other includes conducting clinical research.

leadership provided by an MD/DO or PhD. Most of the other students wanted to be a laboratory director or work in an academic setting but not be a DMT leader.

Postgraduation Outcomes

Fifty percent of graduates were offered a new job upon graduation, and 57% of graduates accepted a new job position within 6

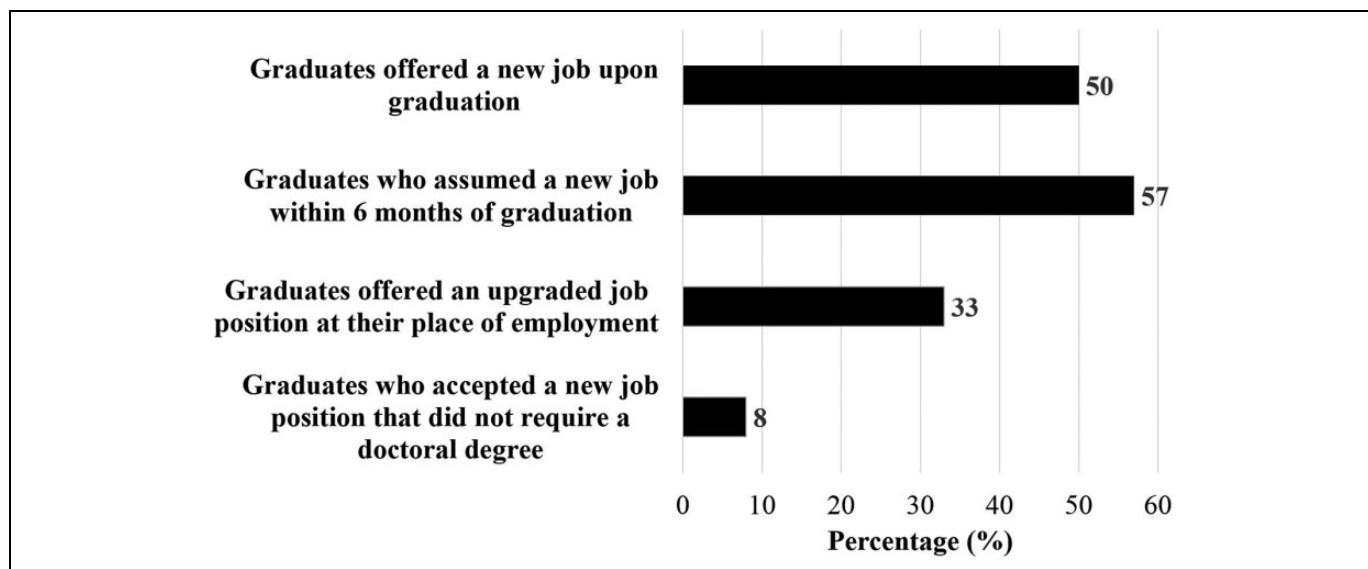


Figure 6. Job opportunities after graduation (n = 12).

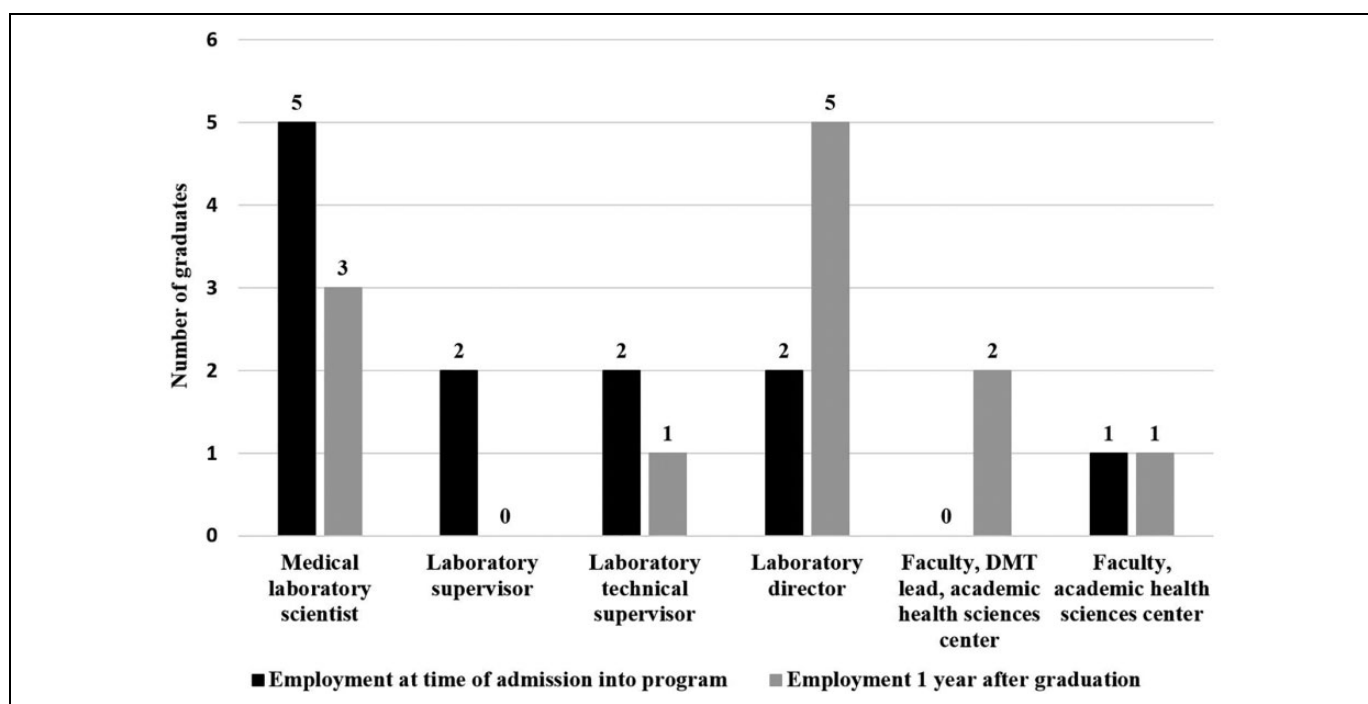


Figure 7. Employment job titles of students at program admission and 1 year after graduation (n = 12).

months of graduation (Figure 6). Thirty-three percent of graduates were offered a job promotion at their current place of employment. Figure 7 shows employment job titles of graduates at the time of admission into the program and 1 year after graduation. Figure 8 shows the results of perceived competence 1 year after completion of the DCLS program. The graduates rated their competence as good or excellent for all 6 items evaluated.

Discussion

In this report, we have described the characteristics and outcomes of the DCLS program at our institution. It provides useful information for other institutions that may want to establish similar programs to educate clinical laboratory scientists at the doctoral level.

The DCLS curriculum is a clinical doctorate program that builds on prior technical knowledge of medical laboratory

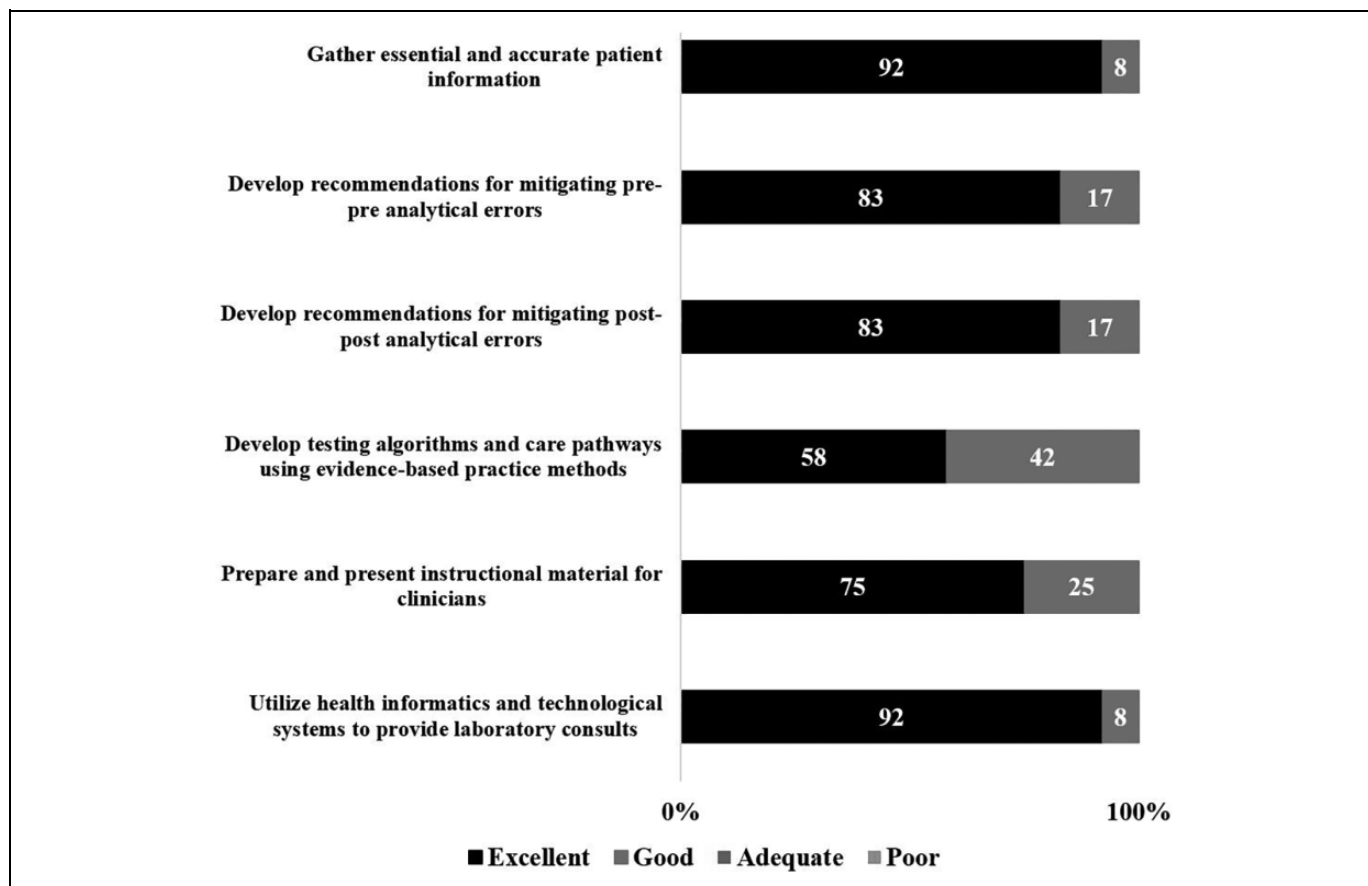


Figure 8. Self-perceived competence 1 year after completion of the Doctorate in Clinical Laboratory Sciences (DCLS) program (n = 12).

scientists. The program leads to a clinical doctorate that differs from a PhD degree. The main difference is a broader focus on clinical training in the DCLS program and an emphasis on DMT leadership. Our students are exposed to a wide variety of clinical settings and receive multispecialty mentorship and instruction from faculty clinicians and educators during the program. The ability to participate as a student APMLS expert in laboratory testing on multiple DMTs and as part of a clinical health care team during direct patient provides our DCLS students with extensive experience in developing and utilizing algorithms both inside and outside the laboratory.

Currently, 3 DCLS programs exist in the United States: our program and programs at Rutgers University, New Jersey, and Kansas University Medical Center. Although admission requirements for these programs vary from institution to institution, the following criteria are the minimum recommended standards for admission into our DCLS program: (1) completion of a National Accrediting Agency for Clinical Laboratory Science-accredited Medical Laboratory Science program (or equivalent international program), (2) a baccalaureate degree, and (3) generalist Medical Laboratory Scientist certification. Some institutions have additional admission criteria, such as a minimum number of years of experience as a practicing clinical laboratory scientist. In our program, the criteria for awarding the DCLS degree are substantial, requiring a total of 1728

contact hours consisting of didactic coursework (derived from asynchronous distance education), clinical experiences, and a doctoral project.

When the DCLS program was initially proposed at UTMB, there were questions about the role of successful graduates in medical practice. One of the major barriers to widespread implementation of DMTs is the lack of individuals with sufficient content knowledge to serve as DMT leaders.⁹ In our experience, our recent DCLS graduates have been able to create interpretive comments and recommendations in DMT team leadership roles that mimic the roles of a resident physician on the DMT. Figure 9 shows an example of a narrative interpretation generated by a Coagulation DMT. The DMT process involves identifying cases, reviewing medical records, preparing brief summaries of the medical history, providing tentative interpretations of the laboratory data in the clinical context of the specific patient, and making recommendations for additional or reduced testing, as appropriate. Our DCLS graduates are well positioned to become leaders of DMT teams. When they assume this role, they should be salaried (similar to PhD DMT leaders), as there is currently no accepted way to bill insurance companies for this interpretive and consultative work.

Importantly, DCLS graduates pay tuition to earn their degree, unlike PhD fellows who receive funding from

Doe, Jane (MRN 123456P)**History:**

Jane Doe is a 65-year-old Caucasian woman who presents with easy bleeding and an elevated PTT. She had a past medical history of intermittent menstrual bleeding and had a hysterectomy when she was 24 years old for heavy menstrual bleeding. She had wisdom teeth extraction at the age of 18 and gave birth in her early 20's without excess bleeding or transfusion. No record of family history of easy bleeding is noted.

Lab:

	Ref. Range	01/01/2020
PT	12.0 - 14.7 sec.	11.9
aPTT	23-38 Sec.	47 (H)
Factor IX	76-158%	158%
Inhibitor screen		negative
VonWillebrand panel		
Factor VIII	47-170%	6 % (L)
vWF antigen (Ag)	52-214%	<10 % (L)
vWF functional (RCF)	51-215%	<10 % (L)
vWF RCF/Ag ratio	<0.7	undetectable
VWF multimers		absence of multimers of all molecular weights

Interpretation:

These values and multimer analyses are all consistent with the very rare form of type 3 von Willebrand disease. This particular patient has a very low value for von Willebrand factor activity and antigen; the value for factor VIII of 6% is a significant deficiency, and a consequence of the absence of von Willebrand factor, which protects factor VIII in the circulation and against degradation.

Recommendation:

Treatment to prevent bleeding requires a blood product derivative that provides both factor VIII and von Willebrand factor.

Figure 9. Example of an interpretation generated by a coagulation Diagnostic Management Teams (DMT).

institutions to complete fellowship training. This is an economic advantage for institutions and could lead to the widespread development of DCLS DMT leaders in multiple areas of diagnostic medicine. Widespread implementation of DMTs may have major impacts on improving patient care by reducing diagnostic errors. The graduation of 5 to 10 individuals each year from multiple institutions over the next 10 years should provide a workforce of hundreds of DCLS graduates.

In our program, the attrition rate decreased over the 4 years since its initiation. This was likely due to changes in our admission rates and the quality of the applicants. In the last 2 admission cycles (2018-2019 and 2019-2020), the admission rates were lower, and the preadmission accomplishments of the applicant pool were greater. Over 50% of graduates accepted new job positions as a result of completing the program. Our graduates have primarily attained positions as laboratory directors or faculty in academic health science centers.

The role of doctoral-level pharmacists as members of multidisciplinary health care teams in patient-facing rounds has become well accepted. The ability to obtain input from a pharmacist during rounds to discuss the appropriateness, dose, frequency, or cost of a drug has proven valuable.¹⁰ An advanced-level practitioner with a DCLS degree can provide

similar input. Nevertheless, not all graduates or students in our program aspire to participate as an advanced practitioner in a DMT or consult on test selection and result interpretation. As more graduates enter the field of laboratory medicine, it is likely that additional roles for DCLS graduates will emerge.

Conclusions

Over the past few decades, a clinical doctoral degree has been created for individuals who obtained nondoctoral degrees in pharmacy with the goal of improving patient outcomes.¹⁰ The concept of a clinical doctoral degree for clinical laboratory scientists arose with similar goals, to improve patient safety by reducing diagnostic errors and to provide value-based, optimal patient care. In its earliest stages, the APMLS service is proving highly useful inside and outside of the clinical laboratory. As DCLS programs continue to evolve, it will be critical to collect and analyze data to obtain evidence of the full impact of DCLS graduates on patient care.

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