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VALUE PERCEPTIONS OF BASIC CLINICAL LABORATORY ASSISTANT TRAINING

WITH CERTIFICATION

By

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MS Rutgers University MS, BS, BA Seton Hall University

A DISSERTATION

Presented to the Affiliated Faculty of

The College of Graduate and Professional Studies at the University of New England

In Partial Fulfillment of Requirements

For the degree of Doctor of Education

Portland & Biddeford, Maine

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VALUE PERCEPTIONS OF BASIC CLINICAL LABORATORY ASSISTANT TRAINING WITH CERTIFICATION

ABSTRACT

This study examined the perception of the value of medical laboratory science (MLS) program training and validation of that training with respect to entry-level clinical laboratory professionals. The demand for clinical laboratory professionals is increasing due to the number of retirees expected to peak by 2024 and is expected to yield a two to one job vacancy gap, mainly in entry-level positions. The study examined the perceived value of such traditional educational clinical laboratory programs from the viewpoints of the MLS educators and employers to effect change efforts to better match these programs with what is required within the career path and respective employment field. Research questions asked were: how do MLS program educators describe their understanding of how traditional MLS programs of study prepare students for work in the clinical laboratory and how do clinical laboratory employees for work in their clinical laboratory?

A balanced mix of ten MLS program educators and clinical laboratory employers were purposively selected for 30 minute audio interviews in which Interpretative Phenomenological Analysis (IPA) was used to code themes from their verbatim interview transcripts. Study participants noted an awareness of laboratory staff shortages, limited student internships and MLS training programs in existence, the negatives of increased instrumentation within the laboratory and developmental soft skills needed to promote success of the clinical laboratorian

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graduate from either traditional or alternative education programs. A need for better marketing and recruitment of new students to backfill mainly the retiring staff was a paramount concern, plus additions of more mentors and trainers within internships. The prerequisite employment soft skills of communication, troubleshooting, problem solving and teamwork can be developed within intra-educational events with other clinicians within both the academic and workplace environments.

Keywords: Accreditation, ASCLS, ASCP, CMS, Core Laboratory, Credentialing, Exchange Theory of Value, Medical Laboratory Assistant (MLA), MLS, MLT, MT, Send-out, Specimen Accessioning, Subjective Theory of Value, STEM. University of New England

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CHAPTER 1

INTRODUCTION

Medical laboratory workers serve the patient population as clinicians on whom other healthcare professionals depend for help. These laboratory members with doctors, nurses and their assistants provide the objective laboratory data needed to properly deliver quality healthcare to today's patient population (Garcia et al., 2020). However, this population of professionals has continued to decrease in size over the past 30 years. While attrition attributes to part of the decline, the paramount reason is that the current aging laboratory workforce is nearing retirement by 2024, creating a two to one vacancy gap apex within the clinical laboratory (Garcia et al., 2019).

Growth rates for entry-laboratory assistant level positions are projected to increase from 18% to 23% within the same three-year time frame, but the number of traditional medical laboratory science (MLS) educational programs and their requisite post classroom hospital internships have declined (Bureau of Labor Statistics, 2019). This is partly due to economic downturns linked to rising healthcare costs of operation that have pressured hospitals to consolidate into and affiliate with larger healthcare organizations; this has contributed to the closure of 70% of accredited MLS programs since 1970 (US Department of Health and Human Services, 2019). Hence, there exists the paradox of cost cutting efforts to be economically more efficient while actually limiting the effectiveness of the clinical laboratory having to work with a decreased workforce.

The need to complete a greater number of tests at a faster rate and to keep pace with new technological innovations persists for the compassionate goal of increasing quality healthcare delivery to the patients in the communities that the healthcare systems serve (Center for

Medicare and Medicaid Services, 2019). The Center for Medicare and Medicaid Services (CMS) is encouraging healthcare providers to shift away from a pay for services model to one of a pay for treatment outcomes as an effort to promote increased quality economical care for the patient community (CMS, 2019). Clinical laboratory professionals participate in treatment outcomes by assisting the clinicians delivering the primary care, since they are participating in the pre-analytical, analytical and post analytical testing phases of patient samples, which are provided by these clinicians. The outcomes of these tests help these clinicians treat their patients.

The Study Topic, Context

This study examined the perception of the value of training and validation of that training with respect to entry-level clinical laboratory professionals. Menger's (1976) subjective theory of value in economics and the concept of exchange theory of value can be applied to entry-level basic training and credential verification by looking at the two as consumer products. These theories of value believe that an item's value depends on the consumer. Hence, if an employer values such training and/or credentials of a potential entry-level laboratory candidate, she or he should be more inclined to hire that individual via the exchange theory of value. The exchange theory of value proposed in Marxian economics by Rubin (1927/1978) describes how a commodity has both subjective value and an objective exchange value or social marginal utility value. Logic may follow that if the same individual becomes employed, they should then more easily become part of the staff if the veteran staff members recognize that same subjective value. Key sample populations are employers, clinical laboratory workers, students and training program educators. In the past, the skill sets of advanced level associate and bachelor level degreed scientists and technicians were needed to conduct many manual tests in the clinical laboratory, but the advent of automation has contributed to shifting this need (Richards, 2018).

Medical Laboratory Science Education

The educational process of pedagogy has changed from a lecture-based practice to a dialogue between students and educators; this has happened by shifts in the manner of instruction within three eras of education: apprenticeship, universal schooling and now life-long learning (Collins & Halverson, 2009). Learning has now progressed even further using new technologies for educational gaming, home schooling, adult learning and on the job training with a throwback to apprenticeships within workforce readiness programs preparing those ahead of employment. There are several alternatives today besides standardized private and public school live in-class educational learning. Collins and Halverson (2009) discuss home schooling, workplace learning, distance and adult education, plus learning centers, educational television, videos, software, together with lifelong learning, coupled with certifications of achievement along the way. Society is no longer limited to using standardized school systems.

A shift from a static traditional didactic approach from a lectern to multi-modal approaches of group discussions, virtual and on-line learning, use of artificial intelligence and technological gaming, all serve to incite interest with educators; these formats give more individual guidance per student especially for socioeconomically disadvantaged students and those of neurodiversity (Collins et al., 2009). Thus, a study to examine how educators view traditional MLS programs as a way to prepare their students for today's real world clinical laboratory as well as how clinical laboratory employers perceive the same for these educational programs was warranted. It is relevant to ask if these two- and four-year programs align with today's workplace tasks or if there should be change efforts to improve or modify them for a better fit with the demanding needs of the shrinking clinical laboratory workforce.

Certification

Traditional MLS students spend two to four years within an educational professional program in preparation for a career within the clinical laboratory. Post-graduation of these programs, two years for a Medical Technician (MT) or four years for a Medical Laboratory Technologist (MLT), also known as Medical Laboratory Scientist (MLS), students then validate their education by becoming certified via written examination by professional organizations such as the American Society for Clinical Pathology (ASCP). Certification is a voluntary process through an international recognized agency as the ASCP, while licensing is a requirement only in 13 states and territories of the United States. However, certification may not only lead the student on an accelerated career interest pathway but it is a prerequisite for any U.S. state or territory that mandates that the laboratory professional test to gain and hold a license before being employed (American Society for Clinical Laboratory Science, 2019). Certification is then a way to provide validation of education within a specific field.

Statement of the Problem

This study has examined MLS educators and clinical laboratory employer perceptions of the value of traditional MLS program clinical medical laboratory workers' training. Various credentials are gained via the fulfillment of requirements of professional agencies. For example, the ASCP is a professional association based in Chicago, Illinois, encompassing 130,000 pathologists and laboratory professionals. It has been providing programs in education, certification and advocacy on behalf of patients, pathologists and laboratory professionals since 1922. Individuals and organizations that hold specific credentials are then deemed to be accredited. Credentials are linked with both external and internal organizational status, the esteem of the individuals holding them and additionally enhance initial trust, within the collective of internal colleagues (Gupta, 2016). Twelve states in the United States and the territory of Puerto Rico require clinical laboratory workers to be state licensed; as a prerequisite to take the licensing exam one first has to hold a nationally recognized credential (ACLS, 2019).

Aging of the current clinical laboratory population has led to continued retirements, which cumulatively have resulted in the number of vacancies of needed qualified individuals compared to the number of retirees in clinical laboratories to accelerate at the rate of two to one (Garcia, Kundu, Ali & Soles, 2018). As a result, more openings for entry-level clinical laboratory assistants are available than for those of the four-year baccalaureate and higher degreed advanced medical technologists. When today's current retirees first entered the clinical laboratory many tests were manually done and hence more academic education was needed to complete them. Many more tests are now completed by automation at ten or more times the rate than analyzed in the past (Garcia et al., 2020). Higher demands in the areas of specimen accessioning (14.69%), the core laboratory (20.72%), and reference laboratory send outs (18.23%) all contribute to a need for a greater number of work-ready trained entry-level laboratory assistants to back fill the vacancies left by retiring veteran workers (Garcia et al., 2019).

Purpose of the Study

The purpose of this study was to examine the value perceptions of both educators and employers within the clinical laboratory professional field by their lived experiences in an effort to collect their impressions of how the current MLS educational programs act as a prerequisite for executing various activities required of the entry-level clinical laboratory assistant. The term entry-level laboratory assistant is used as a general term to include students within all levels of any medical laboratory science education. The study also provides insight into what participants value about the instruction and how well their MLS pedagogy programs have prepared them for specific activities in the clinical laboratory workplace. As previously noted, deficiencies within the areas of specimen processing, reference laboratory send-outs, and the general core chemistry laboratories, are specific areas where there are not enough of these entry-level workers (Garcia et al., 2018).

Since many tests are now automated, an ability to troubleshoot equipment by association of the practical with theoretical knowledge is logically more important than learning an allencompassing scope of textbook knowledge. Hence, some four-year Medical Laboratory Technologist (MLT) graduates may be disillusioned to learn that their school knowledge is not comparable to what it was in the past when many of the same automated tests had to be done manually using that additional knowledge; higher supervisory salaries of 20 to 30 years past may not be offered to entry-level MLTs due to their lack of experience and hence they are placed in entry-level lower wage positions (McClure, 2009; Rhode, 2014). Lab workers who do move up within their careers sometimes have a greater educational foundation, but also possess sufficient clinical experience to demonstrate advanced technical and communication skills.

Research Questions

Central research questions sought to record the lived experiences of a specific population that could affect change efforts on the educational preparedness of entering clinical laboratory workers.

• How do MLS program educators describe their understanding of how traditional MLS programs of study prepare their students for work in the clinical laboratory?

 How do clinical laboratory employers describe their understanding of how traditional MLS programs of study prepare potential employees for work in their clinical laboratory?

The Organization

The setting for this study was a large network healthcare system within the eastern U.S. It consists of over 20 hospitals and near 400 patient care centers. This researcher focused on a very small number of its employees as sample participants who either work as clinical laboratory supervisors within the system or who are clinical laboratory educators within the healthcare system. Three key geographical beachhead (core) hospitals, which operate internal on-site clinical laboratories, were chosen to purposefully select sample participants for this study. One of these hospitals regularly hosts MLS students for internships in association with various colleges and universities within the state. Key MLS program educators were selected from this site. At the other two hospital sites, those in key supervisory and management roles were selected, however, some of these individuals also work within a training capacity of their employees and hence may also be considered as part of the education population in a dual role.

Entry-level laboratory assistants trained in basic vocational skills for the job are in demand as replacements as they are the most economically feasible to organizations as this healthcare system, yet there are still not enough candidates to fill this entry level step that offers a great career ladder, although many of the same organizations are willing to support them with paid additional training and benefits; the world population is aging, there is an ever-increasing need in healthcare for more laboratory testing of patients by both clinicians and insurance payers (ACLS, 2019, 2019). There is a positive growing outlook for employment in the clinical laboratory at a rate of 18 to 22 percent (Bureau of Labor Statistics, 2019). On the negative side,

there has been greater consolidation of hospitals into larger healthcare systems resulting in the closing of independent laboratories in favor of network laboratories (Scott et al., 2015). In addition, fewer students are now enrolling in medical laboratory science (MLS/CLS) bachelor programs as employment, wages, and career advancement for these more highly trained graduates are limited due to the fact that the higher-level senior and supervisory roles with which they were once matched have declined with the influx of automation and cheaper labor (ACLS, 2019, 2018). The current graduation rate of MLS students from NAACLS-accredited academic programs is insufficient. This is partially due to the closure of 70% of NAACLS-accredited clinical laboratory science academic programs since 1970 (US Department of Health and Human Services, 2019).

Conceptual Framework

Educational achievement of a graduate from a professional healthcare program can elevate individual self-worth. The necessary link between certification and course accreditation should also be considered if courses are to provide an adequate number of work-ready MLS students to ensure the workforce can provide the necessary professional values and skills for the protection of the public (Badrick et al., 2018). Thus, these new achievement values are further increased by linking some validation of that educational knowledge learned via recognized and respected certification credentials. An individual then has a basis of some increased self-worth or value attached to successfully completing an education program. This study examined the perception of the value of traditional MLS educational programs from the lens of MLS educators and employers. Hence the ADDIE model of instructional design which generically structures the curriculum with respect to Analyze, Design, Develop, Implement and Evaluate was used as an overall conceptual framework (CF) for this study since MLS preparation via curriculum studied is in question as to how it prepares an MLS graduate for work in the clinical laboratory (Branson et al., 1975). More about this CF will be discussed in chapter two. The specific Backward Design model of McTighe and Thomas (2003) together with the theoretical framework previously presented was used to give perspective to the study. The Backward Design Model of Wiggins and McTighe (2005) focuses on the end goal and then works backward to develop a curriculum that teaches to the test of achieving that goal. MLS can be viewed as technical programs in which the end goal is to place graduates into a clinical laboratory job. The graduate can also be seen as an economic commodity when they seek out employment in the world. This can be aligned to Menger's Subjective Theory of Value, which states the idea that an object's value is not inherent and is instead worth more to different people based on how much they desire or need the object (Menger, 1976).

The Subjective Theory of Value places value on how scarce and useful an item is, rather than basing the value of the object on how many resources and hours of labor went in to creating it (Menger. 1976). Inside of the corporate circle, the employer views the graduate, who is now a job candidate, as an economic commodity. The employer views these job candidates as economic commodities who hold specific educational degrees, certifications and skills and will be making financial investments in them based on their own value perceptions of those individuals. This is why the Subjective Value Theory of Menger must be considered in concert with the Exchange Theory of Value. The Exchange Theory of Value, proposed by Rubin (1927/1978), describes the dual contrary nature of the labor contained in a specific commodity, which has at the same time, both a subjective material use value and an objective exchange value or social value. If the subjective value of the individual job candidate aligns with the employer's subjective value of that candidate, a job offer is made and the Exchange Theory of Value comes into play.

One can apply the economic basics of supply and demand theory and the theory of investment in human capital when reviewing the Exchange Theory of Value. This second adjacent economic theory has many elements in common with the theory of investment in physical capital since in both cases investments now produce benefits in the future, but marked differences include the crucial significance of the time of investors, such as college students, in the creation of human capital (Becker, 2017). These economic related facts are important since the clinical laboratory workforce is declining due to increasing retirees in the next three to five years of a more than two to one vacancy gap at the entry worker level; job candidates having knowledge of the field as graduates of MLS programs should then logically have a higher commodity worth to the employer with an increased chance of hireability.

Assumptions, Limitations, and Scope

Assumptions are made that the lived experiences from the sample population will record that traditional MLS education received even when validated via certification either aligns or does not align with what is needed for the proper performance of the laboratory professional within the working clinical laboratory. If education is deficient or over-efficient then the two value theories will not reach a point for a hiring to happen. A prerequisite assumption of the sample population in this study is that each participant must satisfy the requirement that they have successfully completed a MLS program in the past before they had entered into the clinical laboratory as an entry-level employee. In addition, they each should have advanced to their current position gaining at least five years or more of work experience in the field. The study is limited in scope to focusing only on a group of ten MLS program educators and clinical laboratory employers within management. However, using a qualitative research design within Interpretative Phenomenological Analysis (IPA), the sample size is acceptable (Smith, Flowers & Larkin, 2009). Semi-structured open ended question interviews yielded sufficient data for saturation. The purposive sample of participants was selected from within three hospital clinical laboratories of a large eastern U.S. healthcare system where this author is employed.

This author is not an educator of a traditional MLS program nor an employer of clinical laboratory professionals and has not completed nor has been a student of a traditional MLS program, hence personal bias is minimal. However, the sample participants selected were individuals that this author has been associated with on a limited basis within the course of employment as an educator of a non-traditional entry-level laboratory assistant program for special students. Hence, sample participants may have given comments regarding the author's own non-traditional MLS educational program as a possible improvement over traditional MLS programs. But an effort was made by this researcher to generalize these types of comments.

Rationale and Significance

This study is important as it documents how MLS program educators and employers of clinical laboratory personnel perceive how traditional MLS training programs prepare graduates for employment in the clinical laboratory. From this research one may gather insight about how well these MLS programs prepare students as entry-level clinical laboratory personnel and also how current MLS training programs may be modified or how new programs in the future may better align with the needs of a clinical laboratory employer. The reason why MLS program educators were purposively targeted for this study is that these individuals are the influencers

that can affect any significant change effort with respect to current traditional MLS programs as a way to better align what is taught in the pedagogy to what is required to perform an entry-level clinical laboratory assistant position in the workforce.

Clinical laboratory management with the responsibilities of hiring the best suitable personnel as entry-level laboratory assistants and who draft the employment and specific job requirements are another group of influencers. In this author's opinion, they can initiate a change effort within their circles with respect to answering the same question of the level of preparedness for the job as MLS program graduates. Modifications of educational requirements for the entry-level laboratory assistant job can be made by them with substitution of either internal or external shorter in length educational programs or no training at all.

The use of an Interpretive Phenomenological Analysis (IPA) design was shown to be one of the best ways to explore the individual lived experiences narratives in an effort to gather information about the extent to which traditional MLS programs prepare students for the clinical laboratory workforce. The interpretative outcomes of this study will be relevant to various stakeholders. The value perceptions of traditional MLS programs relative to the job preparedness of graduates affect stakeholders within both the educational and the healthcare working communities. Populations include students beginning career explorations as early as the high school years, MLS program educators, and graduates of these courses of study that become job seekers for employment within the clinical laboratory. On the corporate employer side influence over these graduates can arise from a reshaping of employer job requirements for the clinical laboratory professional regarding education, requirements for certification to validate any education, and the need for previous hands on experience as provided now by hospital internships within traditional MLS educational programs. In both the educational and employment circles these key influencers of educators and employers will be able to either raise their transformative leadership skills within their own organizations or lower them based upon any change efforts they advance forward or reverse relative to their educational programs or job requirements in which they have debating voice. Their decisions can either serve to benefit the entire team or be a deficit to the group.

Definition of Terms

ACA: Affordable Care Act – US governmental act of Congress (US Dept. of HHS, 2018) which expanded healthcare access in the US, hence creating the need for greater clinical laboratory testing and more clinical laboratory personnel

ACCN: American Association of Critical Care Nurses – professional agency for continuing education of nurses (Stahl, 2011)

Accreditation: The action or process of officially recognizing someone as having a particular status or holding a credential such as to be qualified to perform a particular activity.

ASCLS: American Society for Clinical Laboratory Science- professional agency for continuing education of clinical laboratory personnel (ASCLS, 2019)

ASCP: American Society for Clinical Pathology (Garcia et al, 2018)
BOC: Board of Certification – part of ASCP credentialing team (Berger, 1999)
BOR: Board of Registry - part of ASCP credentialing team (Berger, 1999)

Bureau of Labor Statistics: The Bureau of Labor Statistics measures labor market activity, working conditions, price changes, and productivity in the U.S. economy to support public and private decision making (Bureau of Labor Statistics website, 2019) *CMS:* Centers for Medicare & Medicaid Services –agency to serve Medicare & Medicaid beneficiaries to strengthen the health care services & information available to these beneficiaries and the health care providers who serve them. (CMS, 2019)

CHA: Certified Health Aide (Merriam-Webster. (n.d.). 2020)

CMP: Certification Maintenance Program – continuing educational program to retain a credential (ASCP, 2019)

CLIA: Clinical Laboratory Improvement Amendments (CLIA, 2018)

CLS: Clinical Laboratory Scientist aka MLS or MLT (ASCP, 2019)

CLT: Clinical Laboratory Technician aka MT (ASCP, 2019)

CNA: Certified Nurse's Aide (Merriam-Webster. (n.d.).2020.

Core Laboratory: where a variety of chemical tests can be performed in the clinical laboratory depending on the organizational structure (Garcia et al., 2019)

Credentialing: the process of establishing the qualifications of licensed medical professionals and assessing their background and legitimacy (ASCLS, 2018; ASCP, 2018)

EPTL: Eligible Training Provider List - The Workforce Innovation and Opportunity Act (WIOA) requires states to maintain a list of providers approved to offer training to individuals eligible to receive WIOA funds. Federal law calls this list the Eligible Training Provider List (ETPL). (DC Works, 2020)

Exchange Theory of Value: describes the dual contrary nature of the labor contained in a specific commodity, which has at the same time, both a subjective material use value and an objective exchange value or social value (Menger, 1976; Rubin, 1927/1978)

High Complexity Testing: tests that are most difficult to perform or are most subject to error. They are usually performed only by large clinical laboratories and require quality control,

quality assurance, proficiency testing and stricter personnel requirements. Minimum requirement is an Associate degree, including 24 semester hours in science, and completion of either: (1) an accredited or approved clinical laboratory training program, or (2) three months laboratory training in the specialty in which the individual performs the specific testing (CFR, 2019)

"Medical Assistant" Terminology (ASCP Board of Registry, 2020):

Medical Assistant: an allied health professional who supports the work of physicians and other health professionals in patient care centers

Medical Laboratory Assistant: entry-level clinical laboratory assistant

MLA (ASCP): Medical Laboratory Assistant American Society for Clinical Pathology credential

MLA: Medical Laboratory Assistant. An entry-level clinical laboratory professional certified as such via examination from the ASCP.

MLS: Medical Laboratory Science or Scientist – 4 year bachelor degreed clinical laboratory professional

MLT: Medical Laboratory Technologist – aka MLS

MT: Medical Laboratory Technician-2 year associate degreed clinical lab professional *Moderate Complexity Testing:* Tests that are more complex than waived tests and much of the testing performed in clinical laboratories falls into this category. There are requirements for quality control, quality assurance, proficiency testing and limited personnel requirements (CFR, 2019)

Send-out: specimens that are sent to other laboratories as reference laboratories for specific testing

Specimen accessioning/Specimen processing: The process of accepting samples into the lab and entering sample data into a laboratory computer system so that each sample can receive a unique identification number for tracking purposes (Turgeon et al, 2019).

STEM: Education which is an interdisciplinary approach to learning where rigorous academic concepts are coupled with real-world lessons as students apply science, technology, engineering, and mathematics in contexts that make connections between school, community, work, and the global enterprise enabling the development of STEM literacy and with it the ability to compete in the new economy (Tsupros, 2009).

Subjective Theory of Value: the idea that an object's value is not inherent and is instead worth more to different people based on how much they desire or need the object (Menger, 1976).

US Department of Health and Human Services: US agency to enhance and protect the health and well-being of all Americans (USDHHS, 2019)

Waived Testing: laboratory testing that employs specific test methods designated under the Clinical Laboratory Improvement Amendments (CLIA) of the Food and Drug Administration (FDA) as "waived;" designated by CLIA as simple tests that carry a low risk for an incorrect result (CFR, 2019)

Conclusion

Maintenance of a sufficient population of properly trained clinical laboratory workers is essential to today's healthcare systems. These clinical laboratory workers aid the clinicians in providing needed information to diagnosis and treat an ever-aging population. A greater number of laboratory tests are needed to validate these diagnoses, to satisfy insurance providers and government agencies, such as the CMS, within a world of continuing rising healthcare costs. Faster turnaround times for results with the need to learn and implement ever changing innovative new technologies, challenge the dwindling clinical laboratory workforce. This is happening due to attrition of the staff primarily due to retirement of older laboratory workers leaving a two to one vacancy gap at the entry level into the laboratory. Traditional two- and fouryear MLS programs are not keeping pace with these shortages for various reasons, such as downsizing requisite hospital internship tours and consolidation and elimination of independent hospitals in favor of larger more cost efficient healthcare systems.

There was a need to examine if the current educational MLS programs sufficiently prepare graduates for work in the clinical laboratory. This study targeted two groups of influencers who could affect change efforts within these programs or the requirements for employment in the field. The educators of the programs and the employers' management team hiring officials both can then become transformative leaders if they can develop and sustain needed positive changes which would contribute to the enhanced development of MLS students and potential employee candidates from that same MLS student population.

CHAPTER 2

LITERATURE REVIEW

A vital component of the complex and changing healthcare system in the United States is the medical laboratory worker. Medical laboratory workers act as a hidden population to many since they serve the patient population indirectly, because physicians, nurse practitioners and physicians' assistants depend on them for accurate reporting of an increasing number of required laboratory tests to construct their diagnoses of patient ailments. There is a growing shortage of these workers due to various reasons: retirement of an aging workforce from clinical laboratories, an increasing demand for more tests to be completed at a faster pace, increased automation technology affecting practices, demographics and operations within the laboratory and a decreasing number of training programs and graduates from these remaining programs. This is especially true at the traditional advanced degree Medical Laboratory Scientist or Technologist (MLS, MLT)/Clinical Laboratory Scientist (CLS) and Medical Laboratory Technician (MLT)/Clinical Laboratory Technician (CLT) levels (American Society for Clinical Laboratory Science [ASCLS] 2019).

The clinical laboratory professionals came about in the twentieth century necessitated by practitioners looking for help. The ASCP in 1928 established its Board of Registry (BOR) who then certified 350 applicants for ASCP medical technologist (MT) of which 80% were women (Berger, 1999). As noted by Berger (1999), the ethical code for technicians and technologists is for them to always work within the supervision of a physician and not make any written or oral diagnoses or advise physicians on treatment options without any supervisory directive. There are several professional agencies that provide certification for laboratory professionals but the most widely known and accepted are the American Society for Clinical Pathology (ASCP) Board of

Registry (BOR) and the National Credentialing Agency (NCA) for Laboratory Personnel. Simplification for a trained individual clinical laboratory worker to become certified occurred when it was decided to create a single certification agency for medical laboratory professionals from these two, effective October 23, 2009. An agreement was reached between the American Society for Clinical Pathology Board of Registry (BOR) and the National Credentialing Agency for Laboratory Personnel (NCA) to consolidate credentialing solely within the ASCP Board of Certification (BOC) with the ASCP BOC now serving as the certification body for medical laboratory professionals, hence dissolving the NCA.

In the allied health field of nursing, the American Association of Critical Care Nurses (ACCN) advancing credentialing values for continued education of nurses noted links to greater efficiency and lower error rates on the job (Stahl, 2011). Hospital errors are the third cause of all deaths today in the United States behind heart disease and cancer (Makary & Daniel, 2016). The mission of ACCN focuses on providing nurses with expert knowledge to deliver excellent, safe, quality care to acutely and critically ill patients and their families. The ACCN promotes strategies that can be implemented by local chapters to facilitate and support certification and emphasize the value of certification and continuing education. Following in a parallel track the same standards can be advanced within the clinical laboratory arena as a way of marketing the field to new students, who could fill the need for more trained clinical laboratory personnel.

The Clinical Laboratory Improvement Amendments (CLIA, 2018) program was passed by Congress in 1988 to improve the quality of testing in all laboratories nationwide. These health assessment tests examine diagnoses and the prevention and treatment of disease in the human body. The basis of the complexity of CLIA (2019) tests are categorized into three levels: waived tests, moderate and high complexity. These standards focus on the laboratory operations but not on the individual workers. Quality standards are assessed for laboratory testing to ensure the accuracy, reliability and timeliness of patient test results. CLIA requires that any facility examining human specimens for diagnosis, prevention, and treatment of a disease or for assessment of health must register with the Centers for Medicare & Medicaid Services (CMS) and obtain CLIA certification (CLIA, 2019).

The problem of practice examines the value perception of clinical medical laboratory workers' training and accreditation credentials. Credentials are linked with both external and internal organizational status and the esteem of the individuals holding them additionally enhancing initial trust, especially within the collective of internal colleagues (Gupta, 2016). Twelve states in the United States and the territory of Puerto Rico require clinical laboratory workers to be state licensed. In order to take the licensing exam, one first has to hold a nationally recognized credential. Some hospital healthcare systems require a credential for a candidate to be employed or they have thought about imposing such a requirement in the future (ASCLS, 2019).

Due to aging of the current clinical laboratory population, the number of vacancies for qualified individuals compared to the number of retirees in clinical laboratories is accelerating at the rate of two to one (Garcia, Kundu, Ali & Soles, 2018). On the plus side there are more openings for the entry-level clinical laboratory assistant than for those of the four-year baccalaureate and higher degreed advanced medical technologists who are also retiring. This is because 30 or more years ago, when these now retirees first entered the clinical laboratory, many tests were done manually and hence more academic education was needed to complete them. Many tests are completed by automation at ten or more times the rate than were analyzed in the past. Higher demands in the areas of specimen accessioning, the core laboratory, reference laboratory send outs and phlebotomy all contribute to a need for a greater number of work-ready trained entry-level laboratory assistants to backfill the vacancies left by retiring veteran workers.

Conceptual Framework

There are many ways the idea of a conceptual framework is defined, which Ravitch and Riggan (2016) have discussed extensively. Some think of it simply as a representation of a study's organization as a stand-alone figure, while a second view treats both the conceptual framework and the theoretical framework as essentially one and the same with a third discourse defining a conceptual framework as a chain that holds everything together in an evolving process of the researcher's interests and goals, positions, and context as a setting for the informal theory and the methods used. Ravitch and Riggan (2016) find that the conceptual framework is not of a static nature, nor is it able to be constructed before a study begins or even after the start of a study, but instead, a conceptual framework must evolve throughout the duration of the research; it underpins and glues together all of the parts that comprise the study. Furthermore, a conceptual framework connects three main parts: the personal interests of the researcher, topical research in the literature review and the theoretical framework(s) selected to support the arguments for the study. In the process of holding it all together, a driving force emerges that influences the appropriateness and the rigor of treatment with respect to selection of the proper research questions to pose. These questions are then matched with suitable data collection and modes of analysis, such as qualitative and/or quantitative techniques.

Hence, the conceptual framework can be seen as a creative building process without a clear blueprint. It begins with personal interests and ideas for an argument as to why something is important to look at but evolves along the way with a literature review to substantiate a

plausible theoretical framework(s) chosen in line with topical research of importance within a central theme of the work.

Selection of a conceptual framework (CF) for this researcher's study was made after examining what purpose a traditional medical laboratory science program curriculum serves: to have a graduate gain entry into the employment of a clinical laboratory. While advanced degree programs as such are not entirely considered vocational programs, they are technical programs in which specific tasks are required to be studied for a graduate to perform successfully within the clinical laboratory. Within these technical programs the science behind the tasks required to perform the job is also included. Hence, the end goal of each graduate to attain employment within the clinical laboratory is paramount within these programs. The Analyze Design Develop Implement and Evaluate (ADDIE) Model of instructional design by Branson et al. (1975), is a general model which can be used regarding a CF. There are several specific models based upon the ADDIE model. Some of these focus on the motivation of the student/learner as ARCS (Keller, 1983) ASSURE, Cognitive Apprenticeship and the Dick and Carey (2005) models (Gustafson et al., 1997). The ARCS model highlights the motivational aspects of the learning environment. The ASSURE model analyzes the learners and builds the learning structure around them, while the Dick and Carey approach focuses on identification of instructional goals with entry behaviors and learner characteristics. This is only a sample of ADDIE-type instructional design models. One of the many specific ADDIE-based model designs was chosen by this author as a suitable CF, the Backward Design Model (Wiggins and McTighe, 2005; McTighe and Thomas, 2003).

The Wiggins and McTighe (2005) Backward Design Model of instructional design centers the design and development of the instructional curriculum based upon the intended end goals of that instruction. There are generally three stages of developing this type of curriculum: 1) identification of the desired results of what the students should know with respect to the goals, 2) creation of acceptable assessment tasks which support understanding of the overall goals and 3) formulation of learning activities that will develop skills the students need to reach the end goals (Wiggins and McTighe, 2005). In this type of design, the educator starts with what is required as an outcome for the student and then aligns the instructional plan to guide the students to successfully achieve those goals. This is backwards to forward traditional learning in which a content curriculum is chosen and then what will be taught is created or selected. The backward design model teaches to the end game or teaches to the test, rather than testing what is taught. The focus remains organized and focused upon the outcome of that educational program.

Students within Medial Laboratory Science (MLS) programs seek to gain employment within the clinical laboratory as their end goal at graduation. In this way these technical programs have a vocational approach purpose. The positive aspects of the backward design approach, as per Doug Buehl (2000), support that the students not lose focus by studying factual topic details but continually focus on the larger program outcome since their daily lessons are constructed on the overall goals with assessments created before lesson planning, all driving students to what they need to know. Further evidence to support this teach to the test design is the fact that certification exams following MLS graduation are usually either preferred or required for employment within the clinical laboratory. Hence, these backward design MLS programs intend to create graduates who not only can perform the required skills needed within the clinical laboratory but also intend to demonstrate that each graduate can validate their skills by successful passing a standardized certification exam as one from the ASCP. This research study sought to gain information from MLS educators and MLS employers about how well traditional MLS curriculum programs prepare students to work in the clinical laboratory.

The Changing U.S. Healthcare System

The same shortages occur on a global scale in Canada, Europe, and the Middle East; and according to the statistics of the most recent American Society for Clinical Pathology (ASCP) job vacancy survey, the number of retirees from the profession in the U.S. will outpace the job vacancies by two to one by the year 2024 (Garcia et al., 2018). Medical technicians and technologists of yesteryear, skilled in running manual tests that have been greatly reduced today by the advent of automation, are now becoming anachronisms. Their former two- and four-year degree college and university training should command a higher salary, but their skills often do not align with the current automated testing chains. Employers are pressed to fill vacancies within three to six months and cannot wait for a two- to four-year graduate, who will not economically fill the needs of today's automated laboratory (Garcia et al., 2018).

The number of clinical laboratory technologists and technicians employed in the US as of 2019 was estimated at 335,700 by the Bureau of Labor Statistics (2019). These numbers are a best guess, because without all states in the U.S. requiring licensure, it is difficult to be specific. Based on these projections by the same Bureau of Labor Statistics (2019), there exists a 13% average increase in the need for these professionals from the year 2016 through 2026. However, the US Department of Health and Human Services (2019) shows an outlook of a 22% rise over the years 2012 to 2025. The job of the clinical laboratory worker is rated as one of the most critically needed by the Veteran's Administration, which can no longer hire these technicians due to budgetary cuts not in line with current compensation for these specific positions (U.S. Department of Veterans Affairs, 2017).

Average hourly wage by occupational title as reported by the ASCP Wage and Salary Survey is as follows:

- Medical Laboratory Scientist/Medical Technologist/Clinical Laboratory Scientist \$30.49,
- Medical Laboratory Technician/Clinical Laboratory Technician \$22.38,
- Clinical Laboratory Assistant/Medical Laboratory Assistant (MLA) \$18.49 (Garcia et al., 2019).

From these survey statistics by Garcia et al. (2019), it is evident that there is an hourly savings for employers of \$3.89 to \$12 per each paid work hour cost by a hire of the MLA; this equates to an annual savings maximum of \$15,000 to \$23,000 on salaries alone, using the following reported annual rates in the calculations: \$61,112.31 for MT/MLS/CLS technologists, \$45,715.29 for MLT/CLT technicians and \$37,772.51 for CLA/MLA entry level clinical laboratory assistants.

The Medical Laboratory Assistant (MLA) (ASCP) credential, created in 2016, is unique and specific to the clinical laboratory, unlike the colloquial physician's office medical assistant degree/certificate. This credential validates graduates' training by an acclaimed international professional agency, the American Society for Clinical Pathology (ASCP). After the completion of an ASCP acceptable academic program of clinical laboratory study which includes a clinical internship followed by six months of fulltime employment as a medical laboratory assistant, the graduate is eligible to register to take the MLA (ASCP) exam; successful passing of the exam awards the graduate with the MLA (ASCP) certification. Such a certification then further validates the graduate's training within the employment of the clinical laboratory.

Citing examination statistics for ASCP credentials in 2019, the exam pass rate for first time test takers differs regarding the MLS, MLT and MLA credentials. For the MLS and MLT,

examinees post traditional two and four year advanced college level programs of study, the pass rate was 75 to 77% overall and specifically 83 to 85% for the Commission on Accreditation of Allied Health Education Programs (CAAHEP) or the National Accrediting Agency for Clinical Laboratory Science (NAACLS) programs; in contrast, first time pass rates for examinees of the MLA was less than half (49% overall and 40% for those trained within various CAAHEP/ NAACLS programs) (ASCP BOC 2019). These statistics illustrate that the MLA test takers have a lower pass rate than the MLS/MLT population. Modification of current MLS programs and alternative MLS education programs tailored to these entry-level medical laboratory assistants who are currently in great demand may better serve this student population. The entry-level MLA population having no college degree requirement have no standardized training programs to attend as the two- and four-year college-level advanced MLS/MLT students.

Reviewing the past literature, no study has been completed with respect to this specific type of program. However, there are value-based perception-related studies regarding the importance of alleviating the shortages of various healthcare personnel, including not only laboratory staff such as medical technicians and technologists, but also nurses, nurse practitioners, physicians and other clinicians in the U.S. and globally (ASCLS, 2019; Baumann, et al., 2012).

Research within these areas is examined to support the argument for a better educational program to train entry-level laboratory assistants with respect to economics for both employer and student, increasing its attractiveness for enrollment from the prospective students' view with respect to career outlook and job security. In addition, this approach could provide a way to backfill the vacant positions left behind by attrition of older staff and thus increase quality care for the patient.

Various studies have addressed the ongoing shortage of clinicians within the healthcare industry around the world and in the United States. Researchers have examined the global shortage problem from the view of declining enrollments in training programs, lack of essential clinical internships, hospital consolidations for economic survival, and elevation of community patient care (Bashawri, Ahmed, Bahnassy & Al-Salim, 2006; Bennett, Garcia, Schmize, Bailey, Doyle, & Zaleski2014; McClure, 2009). Exploration attempts have examined the need for validation of training with respect to ongoing certifications of study and continuous maintenance certification programs, as well as how students view the value of various healthcare education programs with respect to career possibilities and advancement in the ever-changing world of healthcare (Badrick & Wilson, 2014; Gupta, 2016; Hansen-Turton, Ware, Bond, Doria & Cunningham, 2013; Rohde et al., 2014; Stahl, 2011).

Yet, there are still gaps in addressing specialized vocationally-directed programs that provide a more intense study on a faster track, but with the same or broader depth into the real world of the employer's clinical laboratory. Healthcare costs continue to rise on a global scale; however, increased costs are especially apparent in the U.S. as a result of government policies, costs of new treatments, diagnostic testing and research; the U.S. capitalistic medical system has a basic goal to increase profits (Bearce, Spiegal & Hulse, 2017). Further, new Medicare and Medicaid policies from the Center for Medicare and Medicaid Services (CMS) seek to change the current pay-for-service model to a pay-for-treatment outcome model; however, the healthcare system has yet to get there (CMS, 2019). Recruitment competition in parallel healthcare career ladders makes it difficult for a prospective student to choose an educational path. Many of these other clinical training pathways for doctors, nurses, nurse practitioners plus various surgical and staff technicians face the same healthcare personnel shortage dilemma (Bearce et al., 2017; Delwiche, 2003).

Perception studies of clinical laboratory students' views of the clinical laboratory with respect to education preparedness curriculum and future career advancement have been done (Butina, 2010; Funnye-Doby, 2016; McCauley, 2008). Early work by McClure (2009) determined that students view a Medical Laboratory Science (MLS) curriculum as a steppingstone to more promising careers in healthcare providing greater advancement potential, but they have a lack of knowledge about the clinical laboratory professions, which lack government support in the way of new grant funds as in the STEM educational arena. These perceptions still hold true today, as the ASCLS (2019) and Funnye-Doby (2016) noted that both high school and college students knew little about the Clinical Laboratory Sciences (CLS) profession as a career choice although their interests were in science, healthcare, and family. CLS employed professionals had interests in science and an optimistic job outlook in the workforce due to increasing medical service demands. Complacency about the shortages of clinical laboratory workers over the past 30 years indicate a need for a greater awareness, recruitment and marketing of these programs in order to attract prospective students (Castillo, 2000; Garcia et. al, 2011, 2013, 2018).

Consolidation of hospitals into larger healthcare systems have decreased many of the clinical laboratory training programs especially with respect to once thriving MLS programs, which trained medical technicians and technologists at hospitals in association with two-year community colleges and four-year universities (ASCLS, 2018). Together with the lack of interest from prospective students and the decline in financial support to keep these programs in existence they have declined. An essential part of these programs were hands-on clinical

internships in the clinical laboratory, which have been reduced along with the program funds. MLS graduating students and educators agree that these internships are an integral part of these programs (Bashawri et al. 2006). These internships not only provide the students with real world experiences of the workplace, but they foster a mentorship in behavioral leadership and set a path-to-goal leadership track for them.

Laboratory professionals may provide up to 70% of patients' laboratory testing to physicians; although some prospective clinical laboratory job applicants may already have a BS, MS or PhD degree, they find that they are restricted from working in the clinical laboratory without proper certification (Rohde, 2014). Twelve states in the U.S. plus the territory of Puerto Rico currently require clinical laboratory technicians and technologists to be licensed for work. Before licensing, they must earn a credential from a recognized professional society, such as the ASCP. Because a professional society such as the ASCP requires a continuous maintenance program of continued study to validate such a credential, as in other clinician fields such as nursing, it follows that a path-to-goal track proves more valuable to validate education completed. Countries outside the U.S., such as Australia have considered adoption of a selfmanaged certification validation system (Badrick et al., 2018).

There is collaboration between the laboratory personnel and the clinicians even though they do not usually get the recognition that doctors and nurses receive. Physicians originally established professional societies such as the ASCP to give recognition and stature to their colleagues in the laboratory. These colleagues help curtail some of the shortages of personnel in healthcare. Nurse practitioners for example, have helped to ease the crisis; 74% of insurance provider HMOs have on-boarded credentialed nurse practitioners (NPs) as primary care providers (Hansen-Turton et al., 2013). Most critical care nurses work with medical school internists and they have a voice in how internists are trained; both the ACCP and AACN agree that this is a mutually beneficial relationship (Baumann et al., 2012).

Theoretical Framework

The value perceptions of basic laboratory training for an entry level laboratory assistant plus the addition of a validation credential for that training can be studied in several ways. The training itself can be seen through the lens of behavioral leadership as providing a mentor to the student and a path-to-goal approach can be used to highlight a student's view of what they want to achieve by completing the training and attaining the certification credential (Northouse, 2015). The teaching environment, whether it in a college, university, vocational school, hospital or corporate laboratory processing site aligns with a situational leadership stance. Because the laboratory training program is part of a vocational rehabilitation effort with an end goal of placing every graduate in a position of gainful employment, the training and the credential may be viewed as a coveted consumer commodity from not only the point of view of the student, who later becomes a graduate and then a job seeker, but in the eyes of a potential employer. Therefore, theoretical frameworks that make the most sense seem to come from an economic point of view: Carl Menger's (1976) Subjective Value Theory.

The development of the subjective theory of value was partly motivated by the need to solve the value-paradox referred to as the diamond-water paradox: which of the two is of greater value? This paradox is the apparent contradiction that, although water is on the whole more useful in terms of survival than diamonds, diamonds command a higher price in the market. One can argue that value is then influenced by the context in which it is being considered, in this case the surrounding environmental influences. For example, near a reservoir the diamond may be worth more, while in a desert, the water may be worth more. This can be applied when considering the education of a clinical laboratory worker when evaluating a two-year or fouryear college degree program versus a more basic quick-start internal employer-based or external academic vocationally geared training program.

The Subjective Value Theory of Menger must be considered in concert with the Exchange Theory of Value proposed by Rubin (1927/1978) which notes the dual contrary nature of the labor contained in a specific commodity, which simultaneously has a subjective material use value and an objective exchange value or social value. If the subjective value of the individual job candidate aligns with the employer's subjective value of that candidate, a job offer is made and the Exchange Theory of Value comes into play. The economic basics of supply and demand theory and the theory of investment in human capital also need to be considered as variables when projecting the outcomes of the Exchange Theory of Value (Becker, 2017).

Two and four-year traditional training programs yield Clinical Laboratory Technicians and Clinical Laboratory Technologists (formerly known as Medical Laboratory Technicians (MLT's and Medical Laboratory Technologists, MTs). Some of these graduates expect a higher salary in compensation for more years of study and they look for greater responsibilities today mainly as managers and supervisors. These upper-level positions are limited, pushing some graduates into lower entry-level ones. Thus, as rank-and-file job candidates, they may be seen as overpriced for work that is now done by extensive automation, not requiring their greater knowledge base. Basic training and ingenuity as how to organize, schedule, communicate, problem solve, troubleshoot instrumentation, data analytics, social media literacy, creativity, resiliency, good business sense, willingness to learn, and proving one's worth from the start, are all skills needed in todays' job market (Bortz, 2018). These same skills are stressed in vocationally guided programs that have the end goal of placing students in gainful positions in the field.

The above paradox illustrates that the subjective theory of value places the cost of an item on both. It focuses on how scarce and useful it is, rather than equating the value of the object on how many resources and hours went into creating it. This theory of Menger (1976) states that an object's value is not inherent and is instead valued differently by different people based on how much they desire or need the object.

Much of the public are not aware of who conducts their medical laboratory tests when they become patients and their physician needs laboratory tests to confirm any health conditions. Most clinical laboratory workers in the U.S. act as the middlemen between the patient and the clinician. Clinical laboratory workers may or may not be required to be licensed professionals depending on their location in the U.S. Currently, Puerto Rico and 12 states require licensing: California, Florida, Georgia, Hawaii, Louisiana, Montana, Nevada, New York, North Dakota, Rohde Island, Tennessee and West Virginia (ASCP, 2019). Licensure and certification programs set the minimum standards for clinical laboratory personnel workers which help ensure quality laboratory testing and proper patient care and in turn link to overall healthcare quality by an institutional provider (ASCLS, 2019). Licensing eligibility in these states requires that an individual clinical laboratory worker must first have earned a credential from a recognized accrediting agency as the American Society for Clinical Pathology (ASCP).

Accreditation credentials are linked with both external and internal organizational status plus esteem of the individuals holding them with addition of enhancing initial trust, especially within the collective of internal colleagues (Gupta, 2016). The American Society for Clinical Pathology (ASCP) believes that states should license laboratory personnel. The specific state licensure legislation should ensure that laboratory personnel possess appropriate academic and clinical training, pass competency-based examinations conducted by an approved national certifying organization and participate in continuing education programs (ASCP, 2019).

There is little research that examines entry-level clinical laboratory worker basic training programs coupled with professional certification as a consumer product that should be valued by educators, students, laboratory managers and laboratory workers. The changing demographics of the overall healthcare field and the delivery of healthcare present the need to study credentialing as a way to fill the gap of needed healthcare personnel. Greater technology usage in medicine and a rising number of retiring clinical laboratory workers is increasing the vacancy rates within those laboratories. Twelve thousand program graduates are needed annually while only roughly five thousand people are slated to enter this workforce in the next several years (Bureau of Labor Statistics, 2019).

Students' View of the Clinical Laboratory

Some clinical laboratory students in advanced degree programs for Clinical Laboratory Scientist/Clinical Laboratory Technician (CLS/CLT), in the past known as Medical Technologist and Medical Technician training programs, have a new perception of the value of their training. Implications for social change include improving professional-development programs for student awareness of allied health professions and mitigating the shortage of clinical laboratory scientists.

A qualitative study by McClure (2009) that included exploratory discovery and inductive logic regarding the attitudes of four focus groups of such students, describes the attitudes and perceptions among college biology and CLS/CLT students. Specific factors that influenced their choice of field of study and career expectations were noted of the students surveyed who viewed

their clinical laboratory positions after their CLS/CLT training as only a stepping-stone to more promising carriers in healthcare with greater advancement potential. Butina (2010) found identity issues with clinical laboratory workers as not only was there a lack of awareness on the part of healthcare professionals and the public regarding their place within the healthcare field, but there were job retention issues due to the perceived role and value of the clinical laboratory practitioner. There is a clear lack of knowledge about the clinical laboratory professions and lack of economic government support (ASCLS, 2019). There is a decreased need for advanced degreed CLS/CLTs due to increased automation and a greater need for trainable entry-level laboratory workers (Bennett et al., 2014). Regarding job stability concerns by clinical laboratory workers, the occupational outlook is excellent for clinical laboratory staff according to the latest ASCP Vacancy Survey statistics (Garcia et al., 2018):

- 95.70% of supervisors had no laboratory worker layoffs in the past 6 months and 88.23% of them do not anticipate any layoffs in the next 6 months
- 45.98% of budgets are allocated to laboratory staff labor/personnel
- Most layoffs are performance-based at 11.77% budget cuts at 9.09% and restructuring at 9.08%; numbers that are less than many other industries
- Unfilled positions are temporarily assigned to current staff (49.81%), left open (45.00%), or reposted (27.97%)

Need for Certification /Licensing for Clinical Laboratory Professionals

Although an individual may hold an advanced scientific degree, employment requirements exist within many U.S. clinical laboratories for certification or licensing. The clinical laboratory is a key component of today's healthcare system where collaboration between its laboratory staff and all the clinicians involved in a patient's care is essential to achieving quality care outcomes (Perrone, 2016). Including credentialed clinical laboratory professionals within the medical consultation circle elevates the laboratory team's rigor to a higher extent. Although today's patients can access their own results via on-line portals of these laboratories, they usually receive limited information about the meaning of their tests from their clinicians, (ASCLS, 2019).

Rohde (2014) noted that those with advanced degrees comprise 40 to 50% of the current clinical laboratory workers' population, but many are still required to have recognized independent certification from accredited agencies as ASCP. From the personal view-point as a past clinical laboratory worker and student, Rhode (2014) found that certification was needed before gaining employment in a clinical laboratory. Rohde (2014) had chosen an educational route to obtain a microbiology and virology advanced scientific degree instead of a clinical certification which led to disappointment in the career choice made.

There is a difference between licensure and certification - the earning of a credential from a professional agency (ASCP, 2019). While licensure is mostly understood by the general population as a requirement by a government agency for an individual to work, the idea of certification and credentialing are misunderstood. While licensure is mandatory for twelve states in the United States and Puerto Rico for a clinical laboratory worker to be employed in those regions, certification is a voluntary process in which an individual satisfies training and educational requirements of a selected professional organization as the ASCP and then sits for their current exam for a specific certification credential. After passing this exam in which the material tested is updated with the latest regulations and technical advances in the field, the individual is deemed by that agency to be competent within the scope of that credential earned (ASCLS, 2019; ASCP, 2019). Justification of all medical laboratory workers to be licensed is that the federal Centers for Medicare and Medicaid Services (CMS) regulate all laboratory testing (except research) performed on patients in the United States through CLIA (ASCP, 2019). A major difference involves the consequences of engaging in practice without each credential: licensing is required to practice a profession in a state, making it unlawful to engage in the work without a license without serious consequences; whereas not holding a certified credential may make it more difficult to get a job, it is not unlawful for an individual to work without it (ASCLS, 2019).

Continuous Education Certification Maintenance Programs

Continuous education certification maintenance programs (CMPs) to update the skills of the original earned credential holder are essential in the clinical laboratory as each worker needs to keep current with the latest regulations, research, and technological developments in the clinical laboratory science field. ASCP continuous maintenance update credentialing programs are in effect part of their Board of Certification (BOC) (ASCP, 2019). The American Society for Clinical Laboratory Science's (ACLS's) original certification program was created without CMPs (ASCP, 2019).

Physicians have always played a large role in the status of clinical laboratory professionals. The founding doctors of healthcare organizations in an effort to maintain their own autonomy delegated the work of time-consuming repetitive tasks to other healthcare professionals such as the CLS and CLTs of today. These doctors encouraged professionalism within the ranks and were one of the earliest groups to employ mainly women in the field of laboratory work as at that time their roles were seen as ancillary ones in which they would not challenge the authority or economic position of the doctor. Clinical pathologists wanted professional recognition in the medical field so the American Society for Clinical Pathology was founded in 1922 with a mission of maintaining their status but encouraging collaboration between them as practitioners and their laboratory teams. Physicians needed technical assistants to use hospitals and laboratories without them becoming employees of these facilities. This was in an effort to maintain their autonomy.

Requirements for the submission and handling, specimen referral, test applications, test records and reports are stipulated by CLIA (2018) regulations. Therefore, patient test management must establish and maintain a system to ensure identification and reliable handling of specimens during the testing process and correct reporting of the results. Quality assurance and control ensures that every laboratory create quality control procedures that oversee and assess every test technique to guarantee precise and dependable results; each laboratory must set written policies and procedures for a quality assurance (QA) program intended to oversee and assess the complete testing process (Turgeon, 2019). Entry-level laboratory assistants qualify to run waived tests and some moderate tests; performing high complexity laboratory analyses requires additional training and proficiency testing (CLIA, 2018). The CLIA personnel qualifications for the three categories of tests summarized from the Code of Federal Regulations (CFR) (2019) are:

- Waived Testing: Standards: None.
- Moderate Complexity Testing: Standards: Minimum requirement is a high school diploma or equivalent and documented training for the testing performed.
- High Complexity Testing: Standards: Minimum requirement is an Associate degree, including 24 semester hours in science, and completion of either: (1) an accredited or approved clinical laboratory training program, or (2) three months

laboratory training in the specialty in which the individual performs the specific testing.

Need for Hands-on Clinical Laboratory Training Experience

For many of the recognized certification agencies there is a hands-on clinical laboratory requirement so that every individual student can demonstrate his or her ability to apply the theoretical classroom education (ASCP, 2019; NAACLS, 2019). Each professional agency outlines specific standards that must be included in a clinical training component. Findings from Funnye-Doby (2016) revealed that both high school and college students knew little about the CLS profession. Factors influencing CLS/MLS as a career choice were their interests in science, health care, and family; CLS-employed professionals had interests in science and an optimistic job outlook in the workforce due to increasing medical service demands.

Bashawri et al. (2006) explored the attitudes of medical laboratory technology graduates towards their clinical internship training by using self-administered questionnaires. Questionnaires were completed by 115 out of 200 MLT students. Survey results agreed that such an internship was essential to the training and that the importance and necessity of the length of that internship period should not be reduced or eliminated. Microbiology and safety were perceived paramount as the most important topics of the hands-on internship. Bashawri et al. (2006) conducted the study due to initial concerns over whether to reduce or eliminate the internship period perhaps in an effort to accelerate the students into the marketplace at a faster rate to fill needed shortages.

The graduation of clinical laboratory worker professionals from university, college and vocational programs is not keeping pace with demand and they educate only about half of what is needed in the near future; this fact is due to threats of many closures of such training programs

for MLS, MLT and allied health professions because of the high costs of operating these programs (NAACLS, 2019). Part of the cost is for the educational training programs in collaborating with the hospital sector so that students can have access to the needed hands-on clinical laboratory internship experience. There has been limited availability of clinical training sites and many hospital laboratory supervisors refuse to take on interns due to limited capacity. This in turn is leading to burn-out among their overworked staffs (Garcia et al., 2020; Landro, 2009).

The Changing Face of Healthcare Delivery

The changing face of healthcare delivery from a pay-per-individual service model to a value-based model of pay for overall outcomes with respect to patient treatment and care has uprooted the long-time status quo of the clinical laboratory professional (Eastman, 2016). Healthcare in the U.S. is undergoing a dramatic transformation. Costs continue to rise, delivery service changes with the influx of new technology, patient self-care products come on the market, there is a demand for greater services and at the same time there is a shortage of qualified medical laboratory professionals entering the field. Bennet et al. (2014) conducted a comprehensive review of factors affecting recruitment and retention of laboratory professionals. Their recommendations outlined a multifaceted approach to increase the number of candidates for the profession as well as leadership in health care. There was a focus to analyze the demand for services from the nation's medical laboratories, which are predicted to dramatically increase as our citizens age (about 84 million of age 65 years or greater) and millions more receive insurance coverage through the Affordable Care Act.

Increased clinical laboratory testing, laboratory consolidations, outsourcing of services and hostile takeovers of hospital laboratories by commercial companies were common occurrences in the U.S. in the mid-1990s (Mitchell et al., 2015). Near the top of the career ladder in the medical laboratory were mainly scientists with advanced degrees. The consequences of this consolidation led to fewer positions for clinical laboratory directors, the closing of many medical technology schools, and the downsizing of postdoctoral training programs. Compounding the problem, regulatory requirements, quality assessment programs, compliance issues and general administrative responsibilities of laboratory directors have significantly increased over the past decade (Currie, 2019).

Possible solutions to the shortage problems have been brainstormed by some researchers. Baumann et al. (2012) made suggestions to help transform the healthcare system in the United States and to improve upon the inadequacies and deficiencies of the current model. The Robert Wood Johnson Foundation and the Institute of Medicine created a collaborative partnership to spell out what aspects of our healthcare system need to be remodeled. Because critical care nurses work with internists, they felt they should have a say in how internists are trained as they are essential members of the patient care team. Both the ACCP and AACN have agreed with these findings (Baumann et al., 2012). Hansen-Turton (2013) looked at the influence of the ACA and found that more patients are waiting to see fewer doctors; they noted 16 million newly insured people with an estimated shortage of over 60,000 primary care physicians. These results were gathered by a telephone survey that was administered to 258 of the largest health maintenance organizations (HMOs) in the United States, operated by 98 different managed care organizations (MCOs).

Regarding the assessment of current credentialing practices of health plans in nursing across the United States, credentialing nurse practitioners (NPs) can help to ease this crisis as 74% of these HMOs currently credential NPs as primary care providers (Hansen-Turton, 2013).

Looking at the shortage of physicians, a new credentialing system was introduced for advanced clinical practitioners (ACPs) by the Royal College of Emergency Medicine (RCEM) in England addressing emergency care patients. This gives possible solutions for increasing the number of trainees, adding the role of physician's associate and further developing the role of advanced practitioners (Emergency Nurse, 2017).

Mainly since the beginning of the twenty-first century, a consolidation of hospitals and laboratories has resulted in decreased community reach and less funding for new technologies. A lack of evidence to connect laboratory tests, clinical decision-making and patient outcomes coupled with fewer economic resources have stressed healthcare systems on their delivery of laboratory services forcing consolidation, merger and downsizing, while increased productivity is demanded (Delwiche, 2003). Developments in the clinical laboratory and their effects have been driven by: regulations, staff education, new technology, automation and advances in research and development and clinical care (Scott et al., 2015). One suggestion is to align advances in the tests to modified payment models in an effort to continue the existence of laboratory medicine and hence provide the best care to all patients. There has been a decrease in academic CLT/CLS advanced degree training programs; joint ventures of academic laboratories with corporate and hospital laboratory systems can perpetuate the survival of some waning academic laboratories and educational programs (Strom, 2012).

Parallel Career Ladders - Competition with the Clinical Laboratory Worker

The clinical laboratory has changed with a move to centralization versus decentralization of the various testing laboratories, plus increased focus on the debate over the preferred use of either hospital or commercial laboratories (Scott et al., 2015). The realization of personalized medicine and patient awareness do-it-yourself self-healthcare have changed the face of healthcare (Plebani & Lippi, 2013). There are competitive parallel career ladders for the clinical laboratory worker such as Medical Assistants of physicians' offices confused with the Medical Laboratory Assistant (ASCP) of the clinical laboratory, medical transcriptionists, electronic records clerks and analysts, registrars and allied healthcare fields of the Patient Care Technician (PCT), Certified Health and/or Nurse's Aide (CHA and CNA), sonographers and nursing (including nursing practitioners and educators) (U.S. Department of Labor Bureau Statistics, 2019). With so many competitive choices embarking on a laboratory professional career is not that clear a choice as it was in the past.

Need for Entry-Level Clinical Laboratory Workers

A definite need exists for entry-level clinical laboratory workers as shown in the data produced within the ASCP's vacancy surveys of recent years (Garcia et al., 2010, 2013, 2018). The confidential survey has been administered every two years since 1988 and serves as the primary source of information for academic, government and industry labor analysts. Vacancy rates in clinical laboratories will rise due to the number of retirees in the next few years, while there will be greater future demands on clinical laboratory services for the aging population needing more laboratory tests for substantiation of insurance claims (Garcia et al, 2018). These factors coupled with greater automation and technological advances, all necessitate training an entry-level worker base as opposed to hiring a more advanced level CLS/CLS worker which would increase cost (Garcia et al., 2018).

As clinical laboratory worker retirement rates continue to rise, the field needs to increase its efforts to recruit the next-generation of students, enroll them in accredited programs and then retain these new graduates. Qualifications and certification status of these laboratory professionals are crucial factors in addressing the current needs of the laboratory workforce. Marketing efforts need to increase for specific entry-level laboratory assistant programs currently being offered with declining enrollments. These are all valid recommendations of the ASCLS (2019).

Clinical laboratory hiring managers' main concerns are in staffing the laboratory with qualified laboratory professionals (24.22%), certification in specimen processing (34.82%), and increasing workloads contributing to employee burnout and lack of retention (39.52%). Supervisors are compelled to hire entry-level applicants not trained in a laboratory training program as they are pressured to fill staff shortages within three to six months (Garcia, et al., 2018).

Included in the latest ASCP vacancy rate survey from Garcia et al. (2018) statistical data collected on the workforce of the current clinical laboratory from 1,340 survey respondents representing 51,586 laboratory worker employees map the specific laboratory departments in the clinical laboratory where the retirement rate outpaces the vacancy rates. Key areas hiring entry-level laboratory assistants have anticipated retirement rate percentages which outpace the vacancy rates by more than two to one within the next five years. Typical areas in which entry-level clinical laboratory assistants are hired and work will be impacted include: the core laboratory (20.72%), send-out (18.23%), and specimen processing (14.69%) (Garcia et al., 2018). There is also concern about the phlebotomy sections of the laboratory with a retirement rate near ten percent as this field is an alternative on the career ladders for some entry-level laboratory assistants (Garcia et al, 2018). All geographic areas of the United States are currently experiencing shortages of clinical laboratory workers, and the numbers will increase in various regions with a high vacancy rate in the Northeast where the number is approaching 10 percent. However, the other underlying perceptual reasons for shortages such as the decline of training

programs, changes in healthcare delivery systems and patient demographics are harder to define. There is a lack of perception of values for credentialing with no clear future plan to stem deficits in healthcare personnel numbers, and very little data on new credentials, such as the Medical Laboratory Assistant, MLA (ASCP) geared to the newly trained entry-level clinical laboratory worker (ASCP, 2019). This entry-level worker is the one who will fill these retirement vacancies in the near future.

The number of clinical laboratory tests ordered by clinicians has increased over the years. Thirty years ago, advanced degreed hospital medical technologists may have completed hundreds of clinical laboratory tests in a day, while today they may complete thousands daily by way of automation. A large corporate clinical laboratory as Laboratory Corporation of America (LabCorp) provides support for more than 160 million patient encounters annually and typically processes tests on more than 3 million patient specimens weekly while supporting clinical trial activity in approximately 100 countries (https://www.labcorp.com/about-us, n.d.). Many hospitals use such outsourced vendors while downsizing their own laboratories. As an attempt at some solution to this problem, non-traditional approaches to expand clinical laboratory training have been put forth such as off-shift internships, augmented reality (AR), virtual or simulation laboratory training, and a proposal to certify only in specific laboratory specialties such as microbiology and immunology which have been consolidated into core laboratories (ASCLS, 2018).

The advent of the core laboratory model, which consolidated chemistry and hematology laboratory operations, merged chemical analytical testing and immunoassay platforms with expanded menus and sample in-and-out automation-played a key role in the success of the core laboratory's evolution (McCune, 2016). However, although a greater number of tests can be completed in a shorter amount of time, the net impact of these factors significantly reduced operating efficiency in optimization of staff. Many advanced scientists were assigned to running automated tests instead of completing complex tests that required their attention due to the shortage of entry-level staff that required only basic training programs for employment (Richards, 2018).

Using highly trained technologists for routine tasks such as specimen accessioning, preparation and transport, archived sample retrieval and data entry can negatively impact laboratory efficiency, staff engagement, retention and, potentially, patient care. These are areas in the clinical laboratory that now demand a need for entry-level basically trained laboratory workers so that that advanced level staff can focus on leadership at the supervisory level and on the resolution of the CLIA complex testing components of required analytical work to be completed. McCune (2016) notes a lack of automation in this more difficult field such as molecular biology testing.

Categorical certification within microbiology and immunology by themselves may serve some value as agencies as the ASCP certify other specialties of histology and phlebotomy at the technician level. Any ASCP certification requires an acceptable classroom and hands-on laboratory training component plus a clinical internship with some work experience. Medical Laboratory Assistant (MLA) certification created by the ASCP in 2017 follows these requirements.

Conclusion

Increasing shortages of workers in the clinical laboratory are statistically noted within the past 30 years, but no definitive solutions have been advanced to resolve the problem. The lack of adequately trained staff continues to impact patient wait times for laboratory services and poses a

potential threat to the safety and quality of healthcare (Landro, 2009). Proper basic clinical laboratory training validated by updated certification with recognized continuous education is the benchmark for appropriately educated and adequately trained staff (ASCLS, 2019). Promotion of the clinical laboratory sciences early in secondary education could increase awareness of the profession to potential new training program applicants and recruit more students into these programs, while establishment of employer career ladders can support staff recruitment and retention in the field. Greater collaboration between clinical laboratories and training programs needs to occur so that students in laboratory professional training can experience the required, but now decreasing hands-on field internships. Making clinical laboratory professionals welcome members of the clinical patient care team will foster a more collaborative atmosphere rather than one of isolation that some current laboratory workers experience.

CHAPTER 3

METHODOLOGY

The clinical laboratory professional is an important individual within the diagnostic chain of healthcare (ASCLS, 2019). At a time of the highest levels of increasing healthcare costs, more laboratory testing is required for each patient in part to satisfy insurance providers. However, there is a declining population of clinical laboratory professionals to operate greater amounts of diagnostic technology instrumentation. The decline arises from the fact that the retirement rate in today's clinical laboratory is outpacing the number of vacancies in the same sector by a two to one margin (Garcia et al., 2018). At the same time, traditional two-year medical laboratory technician and four-year medical laboratory science (MLS) technology programs are enrolling fewer students. The decreasing enrollments are a result of waning candidate interest within the field and fewer hospital-hosted internship sites post cost reductions and consolidations within healthcare networks. In 2000, there were 263 MLS programs and 248 MLT programs, while in 2017, there were fewer accredited MLS (234) and MLT (244) programs (ASCLS, 2019).

The problem of practice looked at the perception of the value of clinical medical laboratory workers' training with accreditation credentials. This study examined the perception of the value of training and validation of that training with respect to entry-level clinical laboratory professionals. These professionals are now in high demand.

There was a need to examine the perceived value of such traditional educational clinical laboratory programs from the viewpoints of the influencers that could affect change efforts to better match these programs with what is required within the career path and respective employment field. Lived experiences from those who were previous students in these programs but are now in positions to influence institutions to make positive changes were studied using Interpretative Phenomenological Analysis (IPA).

The key influencers this researcher focused on were select educators involved in traditional MLS program instruction and employers who are currently supervising clinical laboratory staff within a management role. This researcher is an educator of entry-level laboratory professionals within a non-traditional vocational program but has not ever been a student within a traditional MLS training program, hence bias along those lines is negated. Any bias toward such traditional programs in favor of non-traditional ones was tempered using correctly worded open ended interview questions and probes. The researcher has gained the Phlebotomy (PBT) certification from the American Society for Clinical Pathology (ASCP) and a Medical Laboratory Assistant (MLA) certification; however, the researcher's main science background is as an empirical quantitative life scientist. The clinical education and clinical laboratory management lived experiences of the sample population studied in this qualitative IPA is different than those of the researcher; these dialogues provided a new evaluation lens. A small group of educators and employers was selected from within the large parent healthcare organization which the author is employed.

Purpose

This study examined the perception of the value of training and validation of that training with respect to all entry-level clinical laboratory professionals. The lived experiences of key influencers in the field provided narratives incorporating their own learning experience with what is now expected in employment of the newly hired entry-level laboratory assistant. Using this information, the researcher may suggest within the parent healthcare organization of his employ ways to evaluate and tailor alternate education pathways of training for these generalist

laboratory professionals rather than the traditional two- and four-year college medical laboratory science (MLS) programs at the technician and technologist levels.

Central Research Questions and Design

Using a semi-structured open-ended interview design the following research questions were explored:

- How do MLS program educators describe their understanding of how traditional MLS programs of study prepare one for work in the clinical laboratory?
- How do clinical laboratory employers describe their understanding of how traditional MLS programs of study prepare one for work in their clinical laboratory?

Site Information and Participants

Even though the sample population was small with ten participants, they were all key influencers with respect to experience with a traditional medical technology education and each had at least five years or greater of career/educational experience. The mix of participants was from three hospital sites within a large healthcare system network in the eastern U.S. One site participates with associated academic institutions in hosting clinical internships for their MLA programs of study while the other two operate internal clinical laboratories for their patient communities they serve. There were five educators of MLS programs and five hospital laboratory employers.

Potential participants were initially contacted by email with details in a follow up telephone conversation to each outlining the study to be conducted, the reasoning behind it and how they each could contribute to advancing education within the clinical laboratory field especially for new entry-level laboratory assistants. All University of New England (UNE) protocols and those of the healthcare system network sites were followed with regard to written

informed consent for the participants within the study. Written informed consent forms were provided via email to each participant before the study began and any explanation of the details within that informed consent was clarified by the researcher. After signed copies by participants of the informed consents were scanned and returned via email to the researcher suitable telephone interview scheduling began.

Each participant was asked to give their informed consent and be involved in a two way transparent dialogue with the researcher about how the data will be collected and used. As per the Institutional Review Boards (IRB) of the University of New England and the healthcare system network, they had the ability to withdraw at any time from the study and all data collected and any personal or corporate identifiers would then be kept confidential but not guaranteed and revealed only if necessary to this researcher's committee and the IRBs of the university and/or healthcare system network. No one withdrew. Any unintentional harm that could be inflicted on the sample population was noted; there was none. In an effort to increase credibility, dependability, confirmability and validity, each participant was able to review their recorded verbatim transcripts as a member check post their transcription. No revisions were needed.

Sampling Methods

The use of purposive homogeneous sampling in line with IPA was used by this author; this sampling is theoretically consistent with the qualitative design (Patton. 2002). The participants are selected purposively since they would offer insight into the particular experience of both being a clinical laboratory student and later an employee within the field. Using a fairly homogeneous sample tends to focus the research questions as meaningful toward a similar group (Smith, Flowers & Larkin 2009). Qualification for participation will be having graduated from either a traditional MLS four-year bachelor degree medical technology program or a traditional MLS two year associate degree medical technician program; they each also have to have been in a position as either an educator or employer (supervisors and managers included) for at least five years. Participants were chosen on the basis that they can give one a rich view in the phenomenon of study. In this study the subjective phenomenon of value perceptions of current educational training for the entry-level clinical laboratory worker from both educators and managers was noted (Smith, Flowers & Larkin 2009).

For the purpose of this study, a total group of individuals who have had their own personal experiences as a student within a traditional medical technician or medical technology program within an MLS program then working as an employee within the same educational system or a manager within a clinical laboratory were invited to this study. Both of these groups have lived experiences of studentship versus management. The essence of conducting an IPA research study with homogenous participants as such is to get a better understanding of the overall perceptions among the participants based on their lived experiences.

There is no right or wrong answer as to the chosen sample size (Smith et al., 2009). Accounts are usually drawn from of a relatively small number of people, six has been suggested in the past as a good number, although anywhere between three and fifteen participants for a group study can be acceptable, yet in either case 10 to 20 may be better; participants are invited to take part because they can offer the researcher some meaningful insight into the topic of the study defined as purposive sampling (Reid et al., 2005). The rule in qualitative sampling is to continue incorporating new interviewees until one reaches the saturation point, where there are no new categories or new themes related to the research problem (Saunders, Sim and Kingstone, 2018). Therefore, after an initial sampling, data analysis must begin and a decision has to be made to either continue to expand the sample pool. However, using focused semi-structured interview questions within relatively rich sessions, saturation should come sooner. Thus, the projected ten participants proved to be enough to reach thematic saturation and begin data analysis.

Each subject was chosen for their known credentials within the field and their career experience. All members of this sample population are interrelated as professional colleagues within the same healthcare organization of which this author is employed They each are an individual that either provided a student tour of their laboratory facilities, an internship for class students or had a collaborative healthcare discussion within the last three years.

Thus, Transcendental Phenomenological Analysis (TPA) was dismissed in favor of IPA since the author was a detached observer of the interviewees. Rich experiences were gathered from each of them by an approximate 30 minute personal interview via telephone by the researcher as the instrument. A second follow up interview using the same media was not needed to gain more narrative details. A final review of a verbatim transcript by each interviewee as a form of validation of what they had described to during the interview allowed the researcher to conclude the data collection process. There were no revisions from the participants. Creswell (2013) stated that the participants' 'lived experiences' are what helps and guides many qualitative approaches to make sense of their research analysis.

Instrumentation

IPA is a design of qualitative research with an idiographic focus that aims to offer insights into how a given person, in a given context, makes sense of a given phenomenon. The general inductive approach has been described as a qualitative research tradition that has the ability to analyze raw data to the objectives of the researcher. Thomas (2006) asserted that "The primary purpose of the inductive approach is to allow research findings to emerge from the frequent, dominant, or significant themes inherent in raw data, without the restraints imposed by structured methodologies" (p. 238). Creswell (2012) argues that, "The purpose of a proposal is to help an investigator think through all aspects of the study and anticipate problems" (p. 268). As for an IPA approach, the essence of the approach is to understand and amplify the lived experiences of the research participants that the research project is investigating.

Using semi-structured interviews, this researcher used the set of research questions previously discussed on an interview schedule, but the interview was guided by the schedule rather than dictated by it. There is an attempt to establish rapport with the respondent, the ordering of questions is less important, probing questions can be added to clarify dialogue and the interview can follow the respondent's interests or concerns (Smith et al., 2009). No questions require any answer in which any participant personal, protected health information (PHI) or Health Insurance Portability and Accountability Act (HIPAA) information was divulged.

Data Collection

Qualitative data is collected from research participants in IPA by the use of interview, diaries, or focus groups. This author focused on the use of the in depth interview process of an initial interview of individuals within the field affiliated with the same health care organization. The health care system chosen is an organization of 20 hospitals and 400 patient care centers on the east coast of the U.S. Each participant afterward was provided with a professionally transcribed verbatim transcript by rev.com of their own interview to satisfy member checking. All participants were provided pseudonyms that were stated at the start of each interview and participants were instructed to not name anyone directly in their interview and only use either a pseudonym or a person's initials. In this manner only the researcher, the committee, university and IRB members were the only entities aware of any actual identities of the study participants.

A flexible and open-ended inquiry that is facilitative was adopted by the researcher. This author concentrated on the semi-structured open-ended question interview format, due to having a background within using similar techniques from a past sales career and for the fact that limited public data is available about the lived experiences to be studied of the participants being selected. Written material as diaries and focus group are not likely due to the conflict of proprietary information that would have to be shared between the groups within the healthcare system and logistical problems of face-to-face focus groups due to the current presence of a pandemic. Public website information of the institution's individual hospitals involved and social media accounts of the participants as LinkedIn were available to supplement participant, program and site backgrounds.

In person interviews within the participants' own work setting or their site choice were not possible due to a national emergency pandemic. Hence phone interviews were used. Audio was recorded with a digital voice recorder and on an Apple iPhone 7, while hand scribed memo notes were also written by this author. The formal three interviews recommended within the IPA process was modified due to challenges of a national health crisis and its later repercussions. As per Seidman (2019), a first interview should focus on lived history, a second on details of that lived experience, while the third, a reflection on the meaning of the recorded text, which can be a review of the verbatim transcripts by the participants and researcher (Seidman, 2019). But, the goal of documenting participants' life history, reconstruction of their lived experiences and meaning of that experience may be able to be conducted all in the same day or in one interview (Seidman, 2019). At the time all study participants being health care workers had limited time to be interviewed; an in-depth approximately one-half hour interview with the procedures described followed by a participant member check of their verbatim professionally transcribed transcript by rev.com sufficed to align with current demands of the participants during the health crisis.

In-depth interviews served as open conversations with the purpose of contributing to each of the research questions. In a way this conversation is an artificial construct for the participants to tell their own narrative but not in a completely unstructured way of their own choosing. As previously noted, a schedule for semi-structured interviews was constructed. Open and expansive questions were used with various possible probe points along the way. Smith et al. (2009) noted that a schedule with between six and ten open questions, along with possible prompts will tend to occupy between 45 and 90 minutes of conversation depending on the topic. Time restrictions during the pandemic crisis was critical for some of the participants and hence the researcher had to work with them to collect the data needed within single interviews of approximately 30 minutes each.

Data Analysis

This author followed the tenets of IPA by using inductive reasoning in the way of a bottom up analysis. Data collection is not a path set out to test a hypothesis as in deductive empirical reasoning but a journey for the researcher to put aside any preconceptions about the data in order to analyze the world presented by each participant. There are several steps within a structured IPA protocol to be used: beginning with reading and rereading of the verbatim interview transcript of each participant, then initial noting via memo of anything of key interest with descriptive, conceptual and linguistic comments, followed by identifying development of emergent themes within each interview and then looking for connections across those themes before finally formulating interpretation of the themes that were found (Smith, Flowers &

Larkin, 2009). Of course, within IPA as opposed to TPA, the author and each participant acted in a collaborative approach to the data collection and analysis as opposed to a detached one; an open-ended dialogue between the researcher and participants is encouraged (Larkin, Watts & Clifton, 2006).

Following the inductive approach this researcher generated codes from the data rather than using the theoretical to identify codes that may apply. After professional verbatim transcription of each interview the author annotated with codes applicable to the data which was collected. Manual coding was done on this projected sample size. This study is an IPA study in which semi-structured interviews are the basis for developing a data record of the lived experiences of the participants.

Hence, as per Saldana, (2016), three rounds of coding were executed: a first cycle of attribute, structural, descriptive and in vivo, process and values coding, followed by a second cycle coding of eclectic and patterned and/or focused coding concluding with a final round of post coding and prewriting transitions as a way to align the conceptual and theoretical within the study results. At the point of saturation recurring codes should be evident to form recurring patterns or themes related to perceptions, thoughts and feelings from the participants' lived experiences. Themes were then grouped together as main themes and subordinate subset themes. A rich IPA analysis has to be a balance of the participants' descriptions of their lived experiences with insightful interpretation from the researcher as a way to focus and bind the two together.

Limitations of the Research Design

Qualitative research, when compared to quantitative research, can be more subjective on the part of the researcher. Within IPA especially the data can have various interpretations. One has to carefully consider and note the limitations of the design of any proposed study. This study focused on one small sample of a large eastern U.S. healthcare system and is spotlighting only three hospital clinical laboratories within that healthcare system.

Member Checking Procedures

In qualitative research a member check, known as informant feedback or respondent validation, is a technique used by researchers to help improve credibility, transferability, dependability, validity and confirmability of a study (Creswell, 1994). There are many subcategories of member checks, including: narrative accuracy checks, interpretive validity, descriptive validity, theoretical validity, and evaluative validity. Regarding member checks for this study, the professionally transcribed verbatim transcripts of each interview were given to participants in the sample population to check the authenticity and the accuracy of the work for their interview sessions, with their comments serving as a check on the viability of the interpretation of their dialogues. No comments for revisions were made by the participants.

Member checking in phenomenology known as participant or respondent validation, is a technique for exploring the credibility of results (Birt et al., 2016). Data or results are returned to participants to check for accuracy about their semi-structured interview recorded experiences. Member checking is one validation technique in qualitative research, used by researchers to help improve the accuracy, credibility, validity, and transferability of a study. The member checking process adds to the trustworthiness of the data collected. This process allows the study participants to verify their statements and backfill any deficiencies in their own narratives and hence promotes increased trust between the participants and the researchers which in turn heightens a greater two-way rapport. A possible second follow up interview and the following verbatim transcript review are part of the overall member checking procedures.

Positive aspects of member checking procedures include the ability of participants to volunteer additional information, correct errors and to review and summarize preliminary results (Birt et al., 2016). However, member checking assumes that there is a fixed truth or reality that can be accounted to by a researcher and confirmed by a respondent which may not be true (Bryman, 2012). Member checks are usually conducted at the end of the interview process via participants reading their verbatim transcripts; however, this author paraphrased and summarized during the interview sessions for clarification of what the participant had voiced. The necessity for member checking is warranted in such an IPA study by this researcher since this type of study involves interpretation. The process avoids the pitfall of being one-sided or slanted toward the researcher (Birt et al., 2016). Participant demographics and relationships to the interviewer are checked and interpreted as to what is in agreement or not.

There are extensive demands on the participants for a standard three-prong process of initial interview, a follow up interview and then a verbatim transcript review which was facilitated via email. Interviews are preferred to be conducted as face-to-face in IPA but video conference or telephony can be used as a second or third choice if more accommodating to a participant. Different members may have different views of the same themes within the total data collected from a study. Such a member check of overall thematic interpretations can lessen the impact of the lived experience description via the analysis and writing process. Member checks can then be viewed as tools for error reduction rather than a true definitive verification protocol when used in interpretative analysis. As already stated, since in-person interviews were not possible due to a pandemic outbreak and limited availability of the sample participants, single phone interviews with each participant were later followed by the delivery of their conversational transcript provided via email for their review.

Credibility

Interpretive research can be considered credible if readers find its inferences to be believable. This concept is similar to internal validity in functionalistic research. The credibility of interpretive research can be improved by providing evidence of the researcher's extended engagement in the field, by maintaining organized data management and analytic procedures, such as verbatim transcription of interviews, accurate records of contacts and interviews, and clear notes on theoretical and methodological decisions that can allow an independent audit of data collection and analysis if needed (Korstjens & Albine Moser, 2018). Verbatim transcription was completed by a professional external transcription service and all data, completed informed consent forms and records were secured in a safe deposit box for this study by the researcher, while audio file recordings was secured by computer password protection. All of these materials will be kept until deletion or destruction as deemed afterward by the university and healthcare system.

Transferability

Transferability refers to the extent to which the findings can be generalized to other settings. It relates to external validity and refers to the specific qualitative research design, in this case, IPA. In plainer terms, transferability refers to whether results transfer to situations with similar characteristics. Transferability is synonymous with applicability, internal validity, or fitness; this idea is similar to that of external validity in functionalistic sociological research where each aspect of society is interdependent and contributes to society's stability and functioning as a whole (Korstjens, & Albine Moser (2018). The researcher provided rich, detailed descriptions of the research context and thoroughly described the structures,

assumptions, and processes revealed from the data so that readers could independently assess whether and to what extent the reported findings were transferable to other settings.

Dependability and validity

Dependability in qualitative research can be defined as the stability of data over time and over various conditions (Given, 2008; Lincoln & Gupta, 1985). In quantitative studies it is noted as reliability. External validity refers to how well the outcome of a study can be expected to apply to other settings. Interpretive research as in IPA design can be viewed as dependable or authentic if two researchers assessing the same phenomenon using the same set of evidence independently arrive at the same conclusions or the same researcher observing the same or a similar phenomenon at different times arrives at similar conclusions (Bhattacherjee, 2012). This is a positivist research idea where agreement between two independent researchers of observations of the same phenomenon by the study researcher aligns to test reliability. To ensure dependability, interpretive researchers must provide adequate details about their phenomenon of interest and the social context of which it is a part to allow readers to independently authenticate their interpretive inferences. In this case, the purpose and rationale of the study has already been described in this chapter with respect to the research questions.

Confirmability

Confirmability refers to the extent to which the findings reported in interpretive research can be independently confirmed by others, usually the participants (Given, 2008; Lincoln & Gupta, 1985). This aligns with the concept of objectivity in functionalistic research. Since interpretive research rejects the notion of an objective reality, confirmability is demonstrated in terms of "inter-subjectivity", i.e., if the study's participants agree with the inferences derived by the researcher (Bhattacherjee, 2012). For instance, if a study's participants generally agree with the inferences drawn by a researcher about a phenomenon of interest based on a review of the research paper or report, then the findings can be viewed as confirmable. The study participants will know the inferences drawn by the author in a final publication of the results.

Participant Rights and Ethical Concerns

Five main ethical considerations in sociological research are respect for participants' rights, dignity, and diversity, social responsibility, professional competence, integrity and scientific responsibility. In order to uphold these tenets, the processes of informed consent, use of an institutional review board (IRB) and the following of a professional code of ethics drafted by that IRB will satisfy most participants and researchers. Hence, the IRB and the informed consent process protect the individual participants' rights and liability of the researcher since no participants or the organization were named within the study. IRBs from both the university and the healthcare system in this study reviewed the study proposal and processes.

Informed consent

Voluntary participation of all participants and harmlessness to them has to be upheld. Subjects in a research project must be aware that their participation in the study is voluntary, with the right to withdraw from the study at any time without any repercussions or negative consequences, the right not to be harmed as a consequence of their project participation or lack thereof. All participants must receive and sign an informed consent form that clearly describes these rights to not participate or withdraw, before any of their responses in the study can be recorded. Researchers must retain these informed consent forms for a designated period of time after the completion of the data collection process in order comply with the norms of scientific conduct within the discipline or workplace. A form drafted by the university which includes the specifics of the study is included. The researcher needs to understand the concepts of anonymity and confidentiality. To protect subjects' interests and future well-being, their identity will be protected in such a qualitative study by this author. This is usually accomplished by using the two principles of anonymity and confidentiality. Anonymity implies that the researcher or readers of the final research report or paper cannot identify a given response with a specific respondent. In research designs such as face-to-face, video and phone interviews, anonymity is not possible. But in such cases, subjects will be granted confidentiality, in which the researcher can identify a person's responses, but promises not to divulge that person's identity in any report, paper, or public forum. Confidentiality is a weaker form of protection than anonymity and not always guaranteed, because social research data do not enjoy the "privileged communication" status in United States' courts as do communication with priests or attorneys (Bhattacherjee, 2012). There are no certificates of confidentiality within this study.

Disclosure

Researchers have an obligation to provide some information about their study to potential subjects before data collection to help them make the decision of whether or not they want to take part in the study. They should be informed as to who is conducting the study, for what purpose, expected outcomes, and who will benefit from the results. However, in some cases, disclosing such information may potentially bias subjects' responses. Under such circumstances, even if the study's purpose cannot be revealed before the study, it should be revealed in a debriefing session immediately following the data collection process, with a list of potential risks or harm borne by the participant during the experiment. Full disclosure to participants is possible within this study.

Institutional review boards

Research ethics in studies involving human subjects is governed in the United States by federal law. Institutions, including the University of New England (UNE) that want to continue to apply for federal funding to support its research projects must establish that they are in compliance with federal laws governing the rights and protection of human subjects. This process is overseen by a panel of experts in that agency called an Institutional Review Board (IRB). The IRB reviews all research proposals involving human subjects to ensure that the principles of voluntary participation, harmlessness, anonymity and confidentiality are upheld, and that any risks to human subjects are ranked as minimal. These same standards and procedures are applied to non-federally-funded studies and student projects. The UNE university IRB website was used by the author as a repository for research and scholarship needs. Policies as HIPAA or human subject protection topics are noted with the downloadable forms on the UNE website to facilitate an IRB application.

The IRB approval process requires the researcher to complete such a structured application by providing specific detailed information about the project especially about how the subjects' rights will be protected. The informed consent form, research questionnaire or interview protocol may be required within the application. The researcher will demonstrate knowledge of the ethical research principles by providing certification of participation in a research ethics course. The appropriate courses required by University of New England and the healthcare institution in which the study's sample participants and researcher are employed was completed by this researcher within the Collaborative Institutional Training Initiative (CITI Program) before the commencement of the research project. The process of data collection began after the project was reviewed and authorized by the IRB review committees of both the university and the healthcare system.

Professional code of ethics

Most professional associations of researchers have established and published formal codes of conduct describing what constitute acceptable and unacceptable professional behavior of their member researchers. Primary infractions usually include serious transgressions such as plagiarism and falsification of data, research procedures, or data analysis, which may lead to expulsion from the association, dismissal from employment, legal action, and fatal damage to professional reputation. Secondary infractions usually include less serious offenses such as not respecting the rights of research subjects, misrepresenting the originality of research projects, and using data published by others without proper citation for acknowledgement, which may lead to professional reputation damage or sanctions from journals who had published the data. This code provides guidance on good research behaviors, what to do when ethical transgressions are detected and the process to be followed dealing with ethical violation cases. Though codes of ethics such as this have not completely eliminated unethical behavior, they have certainly helped clarify the boundaries of ethical behavior in the scientific community and reduced instances of ethical transgressions.

Conflict of interest and bias

If one is faced with two competing interests there can be the perception that there is an increased risk of bias or poor judgement. Financial conflicts are most familiar to society but there are other possible conflicts whether being intentional or not. In order to stem off these conflicts the researcher will comply with regulations, avoid and minimize conflict by recognizing them and taking any steps to resolve them, disclose interest, in this case primarily to complete a

dissertation to gain a doctoral degree, manage any conflicts during the process of the research study by isolating the conflicted individuals from all negative decision functions, and to keep learning by review within the research process (Kalichman et al., 2016).

There is no financial remuneration to this author for this study or contingent career advancement from the employer. A conflict of interest form was completed by this researcher for the healthcare system before the onset of this study. Renewal of this form is required annually by the same system. There is no intentional conflict of interest especially regarding a financial nature, but unintentional conflict of interest has to be considered: the choice of topic, design of experiment, collection of data and its analysis as was outlined earlier in this chapter. Unintentional bias of this author may be evident since the author is an educator in the field, teaching clinical laboratory science but this bias can be negated since the author does not teach within any traditional MLS programs of study on which the participants focused when describing their lived experience understandings; since the author never completed a formal complete MLS program as a student, the researcher's career background path is in contrast to the study's participants who have done so. The participants of this study have been known work acquaintances of the author but were never supervised or managed by this author.

Conclusion and Summary

Healthcare costs in the United States of America continue to rise at an alarming rate: national health expenditures are projected to grow at an average annual rate of 5.5 percent for 2018–27 and will represent 19.4 percent of gross domestic product in 2027 (CMS, 2019; Sisko et al. 2018). This is due to various factors. With these increasing costs come an increasing number of laboratory tests being required to be performed by clinicians in order to properly diagnose and treat their patients. At the same time the clinical laboratory professional's population who analyzes the samples and reports their results back to the clinicians have been declining over the past 20 to 30 years. In addition to this, the number of vacancies within the clinical laboratory with respect to these professionals will increase at a rate of two to one within the next three to five years due to the retirees from these laboratories outnumbering the new clinical entry laboratory professionals (Garcia, et al., 2018). Declining Medical Laboratory Science (MLS) education programs and their required hospital internships are one reason for this vacancy gap. In an attempt to understand how MLS education programs prepare students to work in the clinical laboratory this study focused on narratives from educators and managers within the field.

This author sought to answer the research question of how MLS program educators and clinical laboratory managers describe their understanding of how traditional MLS programs prepare individuals to perform the tasks required as part of the clinical laboratory workforce. The traditional MLS programs have not significantly changed over the past 20 to 30 years with respect to theoretical content to be taught. An Interpretive Phenomenological Analysis (IPA) was chosen to record the lived experiences of each of the ten participants, each having lived through the preparation as a student of a traditional MLS program but who are now in positions of influence. These influencers are program educators and clinical laboratory managers with the power to effect change efforts within these educational programs or with regard to employment requirements that may better match with today's healthcare laboratory needs rather than of the past.

A semi-structured phone interview approach was used in which one interview session was conducted by this author. Any follow up interviews would have included further member checking procedures to correct errors or add any participant information volunteered. No follow up phone interviews were needed. Final reviews of verbatim professionally recorded and transcribed transcripts were given to each participant for a further review. No revisions were made. The IPA approach noted by Smith, Flowers & Larkin (2019) is akin to recording of perceptions and opinions of respondents via a relaxed narrative dialogue between the interviewer and the interviewees, who described their lived experiences of the phenomenon of their views of how such MLS education contributed to the preparation of someone transitioning as a student to the clinical laboratory as a new entry-level worker.

Value perception data from those in control of education and the employment field may add to the gap as to why little has been done to change training programs for entry-level clinical laboratory professionals with the pedagogy mainly remaining traditionally the same for the past 30 or more years even though the demographics and equipment with procedures in the clinical laboratory have advanced through the years. The IPA methodology outlined focused on these MLS program educators and clinical laboratory managers' lived experiences could help to fill in the knowledge gap, but also shape and change the education curriculum and/or job requirements for specific future laboratory professionals, resulting in improvements to existing MLS programs or the creation of new ones.

CHAPTER 4

RESULTS

The purpose of this study was to examine the value perceptions of both educators and employers within the clinical laboratory professional field by their lived experiences in an effort to collect their impressions of how current traditional medical laboratory science (MLS) educational programs act as a prerequisite for executing various activities required of the entrylevel clinical laboratory assistant. The term entry-level laboratory assistant is used as a general term to include students within all levels of any traditional or alternative MLS education programs. The study also provided insight into what participants value about the instruction and how well their MLS pedagogy programs have prepared them for specific activities in the clinical laboratory workplace. Interview questions were focused on traditional MLS programs (i.e. medical laboratory technician and medical laboratory technologist/scientist) rather than alternative ones. The reasoning was that first, there are very few alternative programs in existence for extensive analysis and second, this researcher did not want to bias study participants since they were aware that the researcher/interviewer teaches an alternative MLS program which is the only one in the home state of the healthcare organization. However, additional questions were asked of the participants regarding their views of the creation and use of alternative MLS training programs as options for prospective students rather than the current traditional MLS programs. Central research questions sought to record the lived experiences of a specific population that can affect change efforts on the educational preparedness of entering clinical laboratory workers.

• How do MLS program educators describe their understanding of how traditional MLS programs of study prepare their students for work in the clinical laboratory?

 How do clinical laboratory employers describe their understanding of how traditional MLS programs of study prepare potential employees for work in their clinical laboratory?

Data were collected from ten participants working at three hospitals within a large eastern U.S. healthcare organization. The interviews were conducted over an eight week period via phone with audio recordings made on a digital tape recorder and an iPhone7. Participants were selected purposively and were invited to join the study by an emailed invitation noted in Appendix A, followed by an approved IRB consent form depicted in Appendix B for those who chose to participate. All interviews were only approximately 30 minutes in length due to time constraints of the laboratory staffers being interviewed busy with work throughout the COVID 19 pandemic of 2020. Verbatim transcripts were completed by rev.com and were emailed back to each representative study participant after their interview for member checking. No revisions were needed.

Three detailed manual reviews of each participant's transcript were completed by this researcher following the tenets of Smith, Flowers and Larkin (2009) to create coding via the rules of Saldana (2016). Resultant themes and subthemes were then noted from each of the participant's transcripts as described in the text that follows.

Participants

There were ten participants purposively selected to be interviewed via audio recorded phone conversations of approximately 30 minutes each. Each participant was given a pseudonym to maintain confidentiality, plus an effort was made also not to report any specific participant job titles. Actual interview times are noted in Table 1. Due to COVID-19 pandemic conditions, interviews were single sessions and audio recorded only via phone. Interview verbatim transcripts were provided for member checking following their interviews: there were no revisions. Each of the participant employers and educators, being clinical laboratory professionals, had increased work duties at this time either in the laboratory or administratively during the pandemic. Participants were either classified as Educators or Employers. Within the Employer classification some may have had some educator experience with respect to adjunct teaching or training within their work environment. A snapshot of the participants appears in Table 1 below with further detailed descriptions following in the text.

Table 1

Participant Pseudonym	Employer (EM) or Educator (ED)	Approximate Age and Career Stage	Gender	Interview Length (Minutes)
Dan	EM	60s late career	М	33:13:00
Greg	EM	60s late career	Μ	42:43:00
Joanne	ED	20s early career	F	41:57:00
Karen	EM	40s mid-career	F	38:02:00
Nicole	ED	40s mid-career	F	29:49:00
Pam	ED	60s late career	F	29:49:00
Patricia	EM	60s late career	F	41:32:00
Sally	EM	40s mid-career	F	40:43:00
Sarah	ED	50s late career	F	34:17:00
Susan	ED	50s late career	F	37:55:00

Interviewed Sample Participants' Demographics

Dan

Dan is a late career professional who, after leaving the military, enrolled in a community college medical technician program to earn his associate degree since it was a better economic choice than a commitment to a four-year program. He interned at the hospital where he is now employed and was hired part-time. He transitioned to a full-time night shift lone medical technician position while attending another college to earn his bachelor's degree in biology. Within his early hospital tenure, he also enrolled in and graduated from an allied clinical

professional school because he wanted to do more. He kept his clinical hospital laboratory job at least part-time, maintaining his laboratory certifications. He advanced to become a senior technician and later section head within the same hospital laboratory. After retirement from his other clinician position, he is now involved with financial laboratory management.

Greg

Greg is a late career professional who began his education within animal science and then transitioned to clinical laboratory medicine. While he furthered his education from undergraduate through graduate school within the life sciences, he moonlighted as a laboratory technician to earn money. He advanced within education and in the clinical laboratory to management within a division within a hospital laboratory.

Joanne

Joanne is an eager early career professional who is now working within the core laboratory at her hospital, but as an alumna of her medical technology program also devotes time to intra-educational events to promote the program and may want to get back into the education side of clinical laboratory science after she earns a higher degree.

Karen

Karen is a mid-career professional who began with an undergraduate biology degree and then continued within a medical technology program. Most of her experience has been within the hospital clinical laboratory. She has had the experience of a small specialty lab, a medium-sized lab and a full-sized laboratory. After working for several years as a technologist she earned an MBA and gained experience within the corporate compliance side of the clinical laboratory within the hospital.

Nicole

Nicole is mid-career professional who graduated 20 years back or so with a bachelor of science in medical technology and who has worked at two major hospitals and now is part of the management of a hospital medical technology program. She is pursuing a Master in Education degree to further her career as an educator.

Pam

Pam is a late career professional who was involved within her hospital medical technology program from its start within various positions: student, medical technologist, supervisor and management. She also taught within the two-year associate degree medical technician affiliated program in conjunction with the affiliated community college academic program. She was an accreditation site inspector for hospital–based programs and has been active in the ASCLS as a proponent to advance MLS programs.

Patricia

Patricia is a late career professional who earned a two-year degree as a medical technician and then moved on to complete a medical technology program bachelor's degree. After a one-year internship at a community hospital she was hired there and worked almost ten years until moving to a larger healthcare network affiliated hospital where she is today. Concurrently she was as an adjunct community college instructor for phlebotomy and Licensed Practical Nursing (LPN) programs and served within management of the clinical laboratory as a supervisor and trainer.

Sally

Sally is a mid-career professional with about 25 years of experience who graduated from a university medical technology program. She worked at the laboratory bench as a medical technologist, in supervisory roles as a section head and within quality clinical laboratory management at a hospital within the healthcare system, and as an adjunct community college instructor.

Sarah

Sarah is a late career professional who works within the management of her hospital medical technology program. She began as a chemistry technician and teacher and then transitioned into the current school program. She has worked with two-year medical technician and four-year medical technology program students.

Susan

Susan is a late career professional who chose a Medical Laboratory Technician (MLT) program as her educational beginning to work as an MLT to earn and pay her way through a later medical technology four year program to become a Medical Technologist. She was able to work as an MLT for a couple of years and then once she finished her bachelor's degree, took the ASCP certification exam and then went on to become a Medical Technologist (MT) where she worked for many years in the clinical hospital laboratory; she then moved on to academia as an educator to manage both MLT and MT educational programs of today.

Presentation of Themes

Theme 1: Awareness of Laboratory Professional Staff Shortages

All of the participants noted an awareness of increasing staff shortages in the clinical laboratory within their tenures. It is a complex problem to solve. As Karen noted, "There are multiple factors that are driving the shortage up." Two participants reported one reason as increasing retirements/attrition of older workers; four highlighted poor recruitment of new medical laboratory science (MLS) students and lack of awareness of training programs, while half of the participants noticed a lack of job appreciation, recognition and compensation within

the field which could lead to worker burnout. All participants were for greater certification of laboratory workers with six in favor of continuous maintenance programs (CMPs), while the topic of universal licensing drew mixed reviews from the group.

Subtheme 1: Increasing retirement of older workers

Dan noted that in his age group, they're all getting ready to retire and there are no programs to backfill their vacant positions with new graduates. Dan stated, "there's a shortage now because I believe there's only one or two programs left in the state for medical lab technologists (and) technicians and it's a great steppingstone on to especially other clinical professions." A lot of them go right to nursing because it's a good solid profession and it pays much better than the lab. They also had some medical doctors come out of their lab. Nicole commented that, "I just hope that the public continues to recognize us as laboratorians ...we will have many people retiring and we need to fill those spots and that's the reason why we want to keep the schools open in order to graduate more people to come out into the workforce." Karen noted that, "I think it's a supply-demand issue," while Greg had a positive comment, "…in a shortage, trained individuals probably have more choice," with reference to what clinical laboratory area they wish to work in.

Subtheme 2: Poor recruitment and marketing of MLS programs

Dan mentioned that they "used to do (marketing) programs at high school (and) career days...I don't even think that goes on anymore." Today there is little time for the staff to do so. Pam is in favor of more intra-professional events; "I wanted to expose our students (to) participate in ...intra-professional events once a year." In this way, medical laboratory science students mingle with other professionals within the university, so they hone their skills of mingling with other people plus it also increases awareness of MLS programs and laboratory professionals. Sarah commented, "it's amazing, even within a hospital, they do not know we have a school of medical laboratory science."

Joanne was proactive to find information about her own MLS educational program on her own. She noted that most people are unaware of these programs since she has found that many people in her life "have no idea what it means or what we do on a daily basis." Even though she is employed in a hospital laboratory now she is now taking an active part on the educational side of the MLS program that she graduated from. She wants to be more involved in the school since they were not getting the number of applicants that they had seen in past years. She said it would be a beneficial task for her and others to go "out to the local high schools...(and) local colleges and ...spread the word about what we do and what this is because it's so up in the shadows of healthcare." Nicole mentioned that more marketing and recruitment of students is "something that we continuously work on," but occasionally students had to research the career on their own due to the lack of awareness of the programs.

Nicole notes that a reason why 4+1 students enroll, those with a bachelor's degree and opting to complete an additional clinical internship year to earn a medical technology certificate, is because perhaps "they didn't initially think what kind of job they could get with that bachelor of biology or chemistry degree." Some of them were previously seeking a nursing track but decided that they didn't want to have that much patient interaction.

When Patricia went to school years back, there were a lot of different academic entities like universities and colleges, that offered MLS programs, but now there's hardly any. There are no more than two or three programs in our state, so this may be a reason that she hasn't encountered any students in her local hospital lab in a while. Patricia noted, "We're going to be retiring and I don't know what's going to happen then with the supply of people." Sally suggests the idea "to gear that marketing towards the education" noting that "there are multiple levels available in the lab." This would be an effort to align that with what truly is available for hiring and positions in a real-world lab and what the industry wants as far as who they're hiring, where they're hiring, and how they're hiring. She stated that it is "critical that we get the (two camps of educator and employer goals aligned well) so that students have a realistic view of what they can actually do (in the clinical lab) when they get out of college" or what they can do without a college education program.

Sarah states regarding the profession, "I don't think we have very good marketing right now." This profession is not promoted on the college level, resulting in decreased applicants in the past. Hence, there is a need to go back to promoting programs within the high schools especially with the guidance counselors there as they did previously and speak at career days and even take the marketing efforts into the middle schools because many seventh and eighth graders today are already thinking of what they would like to do with their lives even at that early age. She is part of a medical laboratory professionals group, where they promote awareness of the profession. In order to have successful recruitment, people are needed to act as recruiters, but laboratory staff is usually too lean. The COVID-19 pandemic may have influenced the unusual increase in the number of applicants for Sarah's upcoming class this year. It brought awareness to the field and medical laboratory professionals. Greg also notes that surges in disease outbreaks and even flu seem to bring awareness to the field of laboratory professionals who are usually seen as hidden figures to the public most of the time, that possess "a unique skill that's underappreciated." Awareness and knowledge from professional groups as Sarah's helps recruitment but we need also to consider retention by preventing burnout from these new graduates who have achieved their educational goals and want to further their career aspirations within the clinical laboratory.

Subtheme 3: Declining retention of employees – no clear career pathway, poor job recognition, recognition, rewards and compensation

Retention of employees at least at Dan's local hospital has decreased with some moving on to other clinical professions for better compensation and recognition. The hospitals treat their lab professionals just as regular employees and do not give them the professional respect that they should be earning. From Dan, "the younger generation considering an MLS career, look at it more as a job, rather than a profession and focus on where they can make the most money, there or somewhere else." A medical technologist today has to start at an entry level and work their way up the career ladder which is hard to define; "You don't want to feel that you need to keep working endlessly without some rewards," Greg noted.

Greg commented that there should be a staffing appropriateness to manage workflows; "That's a deficit in industry because we turn things into factories." There's a need for a greater respect and rewards for the clinical staff. Respect, reward, and recognition are warranted. "Two years of experience as a lab professional is enough to have a resume for someone to go somewhere else."

Joanne expressed that "people forget in the lab that there's a patient behind the result." That's something she never loses sight of since she has seen how lab tests and their turn-around time can be critical to patients even within her own family. She sees "much more drive in the younger crowd" as that new graduates versus older veterans have a better appreciation for the turn-around time and why it's important to get accurate results out while veteran employees have a more "lackadaisical mindset sometimes." Joanne said, "there's definitely some burnout going on, because I think they keep increasing the amount of work without increasing the number of techs (which) can get frustrating. There should be analysis done about the tech to test ratio."

Karen noted challenges that the industry has of "providing the right compensation that the staff sees in other areas like pharmacy or nursing;" higher education appears to align with higher compensation. They have a lot of new enthusiastic graduates who come into their laboratory to work, but in two years or so they're leaving the area because there is "no appropriate compensation for their four-year degree." They're not getting the appropriate compensation or return on their investment in education and time for their four degree, but yet the testing is becoming more sophisticated and there continues to be a need for higher education and continuous learning.

Patricia noted the changing attitudes of new student candidates and graduates who, see a lab professional as not really recognized that much, but in the background with no glory or rewards/recognition; plus, the med tech profession has been traditionally seen as a female profession with less pay. In the past everybody always performed professionally but worker participants interviewed who are at different points in their careers presented different points of view with respect to new grad attitudes. A veteran lab worker as Patricia views "the next generation of people (that) they're so soft," and not hard workers but only looking for big payout jobs, while Joanne, an early career worker, sees the new generation of grads as go-getters willing to learn all that they can on the job to advance their careers.

Sally does think that MLS school graduates do expect more return on their investment from their education and do expect to be placed in higher positions earlier. Even though one has earned that knowledge to advance to a higher level, within the field of medical technology in the laboratory, the entry level one starts out at is on the bench with every other entry-level employee. Sally states, "It would be beneficial if they can get in and see how a laboratory and a medical environment works before they spend a lot of investment in time in learning the skills necessary to really be a productive member of the laboratory team..." Hence, she promotes support of quick-start laboratory assistant entry programs which would accomplish this, noting "It's important to have the right career pathway in sight for one to be able to see what one can make of it and how far they can advance."

Subtheme 4: Pluses/Minuses of certification with CMPs and licensing

Dan commented: "It's just so much information...I think the best thing that could happen, at least in this state, would be to have the med techs, like technicians, scientists, whatever, licensed by the state, the pay would be more, your opportunities would be better, you'd have to continue ed." Currently there is continuing education available, but a lot of people just don't have the time or the will to do it because they don't have to. Most employers are against it for the most part and most of the workers are for it.

From an organizational supervisory view, Greg stated that, "I believe everyone should be competency-evaluated for every function that they do to show proficiency and understanding, whether it be formalized in a certificate or continued education." Continuous learning throughout one's career shouldn't be just for a certification. CMPs should really keep up with everything because changes with instrumentation and technology are so fast-paced.

Joanne supports certification continuous maintenance programs as important since they give one an "incentive to keep up with what's going on especially for someone who works a core lab" like her where there is a variety of different tests being done and developed. Licensing is seen as a plus and minus for her. On the plus side it is "an extra barrier to keep unqualified people getting into the position which can have detrimental effects on the work-flow" and the treatment outcomes that patients get, but on the negative side, different jurisdictions (states, territories) may have different requirements for educational courses and experience which may be restrictive to an excellent lab professional, hence, "using that licensure...to bar people from outside states from getting in." Nicole agreed that certification will help on the side of the student and on the side of the employer being more comfortable with that person. While Pam supports that "it is important to have certifications that are basically your way of knowing whether or not the person has the necessary knowledge and possibly skills to do their job." It is a job which directly affects human lives. She was always proactive with continuous learning even though she had earned a grandfathered certificate that did not require CMP course credits and feels that that a laboratory professional should be of the same mindset since technology is so fast paced today and one must keep pace to do the job. She's always kept up with new instrumentations and knowledge since she taught both at the bench and in the classroom and any seminars she attended were always enlightening.

Patricia noted that, "If a laboratory requires people to have ASCP certification depends on the laboratory; it may be if a person who does not have a degree in medical technology but might take a specialty exam" in which then they can work for a certain amount of time within that particular discipline. She supports CMPS because there's always new technology and testing coming out to keep abreast of further learning.

Sally "personally (does) like certification (and) think it plays a big role." Individuals that take CME courses are "more engaged in the field and continue their process and learning." The certification process really helps hone what's expected from the clinical laboratory perspective. She has interviewed non-certified job candidates who came from other countries and while they have more of a general biology life science background they really did not have the breath and scope needed even though their resumes indicated to her that they did.

Sarah, even though supportive of certification, noted the downside of CMPs as they take time away from the MLS program educator or hospital lab's staffer workday to complete educational courses. But there is definitely a role for people coming in at a Medical Laboratory Assistant (ASCP), MLA level. The MLA (ASCP) certification has opened the door to a new career ladder. Some potential students' economic status may be such that they can't afford the college tuition so they need something faster rather than later to earn the credential. If they can get into a program like the one at her hospital, the education tuition can be paid for after a while. There are a lot of pluses for coming in at a lower level without an associate or bachelor's degree, since there are a lot of opportunities to advance within either a hospital clinical organization or a corporate organization with continued education once one gets in the door. Sarah supports licensing since, as she said, "I think considering the fact that the person who does my fingernails needs to be licensed, I would think that someone who's analyzing my blood should have a license."

Susan commented that today certification is "extremely important", but because of "such a great demand, some of those that have not been certified do still get jobs" with the stipulation that they will go through the process to get certified while employed. In the past it was a requirement for students to get the certification before being employed and most places today follow suit with some hospitals that will still require the intention of getting certification as a prerequisite of employment in their clinical laboratories. Depending on the state jurisdiction one may not be permitted to work without passing a licensing exam which requires a prerequisite certification. There is value even in the MLA entry-level ASCP certification since as Susan noted, it adds an extra "notch in your belt" and management will look at that during hiring, preferring somebody that has the board-certified notch over someone that does not. Board certification as with the ASCP can place some job candidates ahead of the non-cert competition. New entry-level laboratory employees have to be able to adjust to change, be willing to learn and even continue their education within CMPs which are now required to hold an ASCP certification. Beyond that, there's tuition reimbursement programs that a lot of hospitals also offer to encourage higher education, no matter what type of continuing education it is even to earn an MLA (ASCP) certification.

Theme 2: Limited Clinical Student Internships and MLS Training Programs

Half of the participants emphasized a decline in student internships with two noting the current lack of space for students in the laboratory since it is taken up by greater instrumentation; three pointed out that due to a decreased amount of staff and a greater workload, less staff have the willingness and time to train and mentor new students. Three of them focused on the changing economics of healthcare delivery moving from the fee for service model to a fee for treatment outcome, plus the general cost containment consciousness of hospitals to join together in networks with outsourcing of some services to defer rising costs. Joanne stated with regard to student internship programs that, "I definitely think that it's necessary...you wouldn't gain those basic skills that you have to take into the lab." She views both the didactic classroom and clinical internship as important needed allied components within the MLS education curriculum. Her program may be transformed moving forward so that increased focused changes within automation and technology are placed more at the forefront in the classroom, which is now only experienced as hands-on within the internship portion of the program. Joanne further commented

that "...being in the lab part...in an actual hospital...you understand the work flow... (and instrument) quality control and calibration."

Subtheme 1: Lack of physical space to train

Pam comments that "...in the past we had a lot more (tech) hands in the laboratories, because there was less instrumentation" on the floor and a lab could handle more students. "With the advance of sophisticated instrumentation taking up two or three benches all at once, that's reduced the number of people that are actually running that sophisticated instrument to maybe two instead of five" previously at manual testing benches. Since these techs are running very sophisticated instrumentation that sometimes requires their undivided attention, they dislike being distracted by students asking questions.

Subtheme 2: Decreased staff resulting in less student mentors and trainers

Greg noted that the problem with mentoring today is that "the new employee has so many questions that the veteran doesn't know how to answer anymore," so it is better if one teaches from the standard operating procedure (SOP), having the trainee read along noting important points on their own rather than having somebody who may explain it to them but may leave out key words or concepts.

Within her hospital, Karen notes that they had affiliations, with "at least about four or five academic institutions where we had medical technology interns come for training, (but) in order to train ...any student...takes resources...a lot of time and effort...we're always doing more with less." The staff whose employer has allocated their time to perform diagnostic patient testing that they're assigned are not a team of laboratorians who can focus on education of trainees. Taking in to account the limited staff, time, resources and physical space for students, leaves no one in the lab available dedicated to teaching. "We just don't have enough FTEs (Full-

time Equivalents) to support both the clinical and the educational need in the field that's required," said Karen.

Hospital hands-on internships are a critical component of MLS programs. But Sally notes "that staffing levels are so much leaner that we don't have that opportunity...to teach (students) and really mentor them; ...12 to 15 years ago my students had much better teacher-student ratios and much more of a mentorship than they have today where we don't have as many people on the bench because of automation." Automation is this case has led to "streamlining" of staff, resulting in fewer overall people and hence fewer people available to teach.

Subtheme 3: Consequences of economics – hospital consolidations and changing models of payment

Dan now being more in tune with the financial side of the health organization business later in his career pointed out that healthcare organizations' financial goals are shifting their focus more on outpatients and outsourcing rather than inpatients. He noted that, "you want less testing on hospital inpatients because they're getting paid by the diagnosis, not by what (services) they do, and you want more testing to shift to outpatients because that's where you get paid (for services)." He commented on outsourcing of laboratory outpatient services since his hospital will be undergoing the change soon. An outsourced company provides routine daily "factory work" whereas a hospital environment provides challenging varied work each day which Dan prefers, resulting in two different mentalities for two different types of new workers.

Karen commented that it is important to understand a hospital's primary goal is overall patient care, "but with patient care, you also have to evaluate ...your spending both from technology, equipment, the infrastructure ...services...tests you would provide." Healthcare

organizations moving from a service based payment model to an outcome based one need to think carefully and make sure resources are allocated in the right areas.

Pam remembers, "we had dozens of programs at hospitals with their own (internship) programs back in the '70s and '80s...(but) because of economics, government" cost containment and changing the CMS model from fee for service to fee for outcomes of treatment to advance personalized medicine they began to decrease to the very few we have today.

Sarah commented that when she first started in the field, "there were 16 affiliates in the state...and now we are down to three." She remembered "some years ago someone did an analysis, they figured it was \$50,000 or \$60,000 to educate someone for one year...it's gone up much more since then." She views this as a big economic outlay for a hospital MLS program, but while there's some reimbursement from Medicare and altruistic funds to help, both areas have been reduced over the years.

Theme 3: Consequences of Increased Laboratory Instrumentation

There have been pluses and minuses of increased laboratory instrumentation over the past 30 years. Two participants noted the positive of increased work output with instrumentation but also noted the negative side of the staff having a greater focus on the time-to-resolution (TTR) and metrics of the QA and QC maintenance metrics of that instrumentation rather than a focus on training and mentoring new employees and students. Two commented on the simple fact that instrumentation also takes up physical space in the laboratory, resulting in the laboratory accepting less student interns at a time to be trained. Greg commented that "(instrumentation) doesn't replace a person" since from an individual's learned "knowledge comes troubleshooting" of instrumentation and its critical patient test results produced.

Subtheme 1: Increased work output with focus on proficiencies and test outcome metrics

There's are so many different pieces of equipment available and depending on where one works, having the basic background, one can learn to operate anything, but it's a challenge to find those people who want to and keep learning to understand more of what instrumentation they are using. Sally commented that instrumentation "has taken a lot of the work away …streamlining many processes, but …instruments can't run in a vacuum…you have to understand what's happening behind the scenes to know if you have a problem."

Sarah commented about the mindset of MLS students with regard to increased instrumentation: "If they are a person who always look for knowledge then the technology is certainly going to be advantageous to them. If they're someone who puts it aside, then no, they'll probably never get any further or they'll never learn anymore."

Subtheme 2: Fewer staff now focused on instrumentation QA/QC rather than training new employees and graduates

Instrumentation today is probably beyond the technical knowledge of the techs that are running the instrument; their time with the technology is taken up to do the maintenance checks, maintaining the validation and the integrity of that machine. Pam, together with Karen and Greg all agree as noted previously, that these processes leave very little time for an experienced laboratorian that can be devoted to teaching a student or training a new employee. Pam notes that "right now we are permitted to train someone...say a high school graduate...in a particular area then (have them) work in that area." But on the downside, one is then limited to a specific area, but could advance into other areas as long as there is supervision by a medical technologist. Such students or techs can then add their knowledge in other areas as they work in that particular area elevating them to have knowledge later in multiple areas instead of just one.

Susan discussed that training is different today via internships since "we have to look at how we have progressed over the years, especially in technology. We needed more techs at the bench (in the past), so it required a lot more hands on skills." When you have the type of stateof-the-art instrumentation we do today where technology has been rapidly increasing there is a need to teach the theory behind the instrumentation paired with the use of any new technology. Along with the advent of Six Sigma process improvements of the 80s "came this new engineering of instrumentation and fewer med techs," contributing to the shortage of lab professionals who are now in great demand. Hence, today's lab professionals now have to focus on operation, maintenance and troubleshooting of instrumentation for its accuracy and precision. As Susan states, "It's almost like not just driving a car, you're really learning the engine of the car to a point where you can troubleshoot it and perhaps even fix it." Pam even had one clinical laboratory student that "was a (lab) supervisor for a while, and then went for the corporate instrument (service tech repair job)."

Theme 4: Developmental Soft Skills Needed for Success and Career Advancement

All participants strongly agreed that various soft skills were needed for a new MLS program student to be successful within the clinical laboratory and within their career. Even though many of these skills are highlighted within training programs, many of the study participants believe that they can only be further developed by putting them into practice after graduation. Half of them emphasized communication, general problem solving, troubleshooting instrumentation and team work to be paramount. A third of the group were more specific noting the values of writing and telephone etiquette as an extension of communication with a flexibility and openness to change and acceptance of transformative change. Intra-educational teamwork between laboratory professionals and other clinicians was noted from two of the participants to

greater foster teamwork. Seven participants were in favor of more alternative MLS programs and pathways for a greater variety of new trained students to enter the laboratory rather than just twoor four-year college degreed medical technicians and medical technologists. Defined career paths are needed by internship hosts and employers so students can see the career road ahead. From Sarah: "Communication, flexibility, team building, critical thinking. I think those are some of the very important soft skills." She stated that in recent years "lab personnel are getting out of the lab, getting involved in all kinds of hospital committees (and) doing presentations, so the ability to speak and stand on your own is something very important."

Subtheme 1: Communication, troubleshooting, problem solving, critical thinking

Patricia sees communication skills with proper phone etiquette, teamwork, and problem solving as important but thinks that they are being developed in the internship. "We teach them how to communicate with each other, but communication with other departments is lacking so more intradepartmental events and training is needed." According to Susan, "with regard to soft skills I believe a lot of them are something that we learn as we grow older, (especially) computer skills, strong communication skills, problem-solving...critical thinking, time management and team building." The biggest background that she teaches is that they become, as she describes, "mini me's of a pathologist" because they have to know the pathogenesis of disease and be able to answer specific questions on the phone for doctors and nurses that might be inquiring about critical patient test results.

Karen noted that communication, teamwork, problem solving and critical thinking aligned with instrumentation and technology are important since many basic skills are now completed via technology. "But the value of medical technology training will come actually with higher learning...because you really need to make critical thinking. The person on that instrument needs to be the one who can really assess the value that is coming out."

Nicole noted the importance of students learning telephone etiquette. "That's something they need to know for speaking with other medical personnel from the laboratory and beyond." Consultative conferences among clinicians and the laboratory can be very important to patient care. Sally has seen her share of new hires and she does see a difference with people who have finished a Med Lab Technician (MLT) two-year program versus a Med Technologist (MT) fouryear program. "MTs tend to have a little bit more of critical thinking skills than MLTs. The MLTs learn the nuts and bolts, but not necessarily all of the whys when they're coming into the job, but yet they all have the ability to learn the job, do the job, perform the tasks and most want to learn more and continue their education in the field." She feels like MLTs have just as much a knowledge base as an MT after time on the job as long as they have people who are helping them and mentoring them along the way.

Subtheme 2: Teamwork with intra-educational events

In Pam's early medical technology training programs, "We didn't teach our students of those skills to mingle with the others, because they were specifically told to work in the laboratory with this instrument and that instrument." They only started to go out and meet other members of the laboratory and hospital staff when they established their Point-of-Care department. This team required the laboratory staff to go out to the unit floors and see the inpatients to conduct Point-of-Care testing face-to-face while collaborating with other hospital staff.

Subtheme 3: Flexibility with an openness to accept and adapt to change

Nicole is open to change as an educator since see has seen every year things change from a new piece of instrumentation that the core laboratory is no longer using or new tests developed. She expects her students to be flexible and open to transformative change to be successful within their future employment positions. "I teach the majority of the student labs and every year things change. We're always making improvements." It is also very beneficial to have her classroom on site next to a hospital to secure resources when they are needed. Also, they are much different from the student labs that the academic institution undergraduates work in because they "actually do have the students working with real patients and real biohazardous materials" rather than using simulations.

Subtheme 4: Development of alternative programs and defined career pathways

Dan noted "there is a difference between technicians and technologists and it's mainly a procedural thing in my mind...a technologist could be in charge, whereas a technician is just basically doing the work." Hence, a technician probably won't be able to rise to the supervisor's level, where a technologist can. He together with Greg, Susan and Patricia, all started out in their careers with alternate routes of entry into the clinical laboratory. Greg began in animal science and worked up the educational ladder with advanced degrees in science while working as a technician in a laboratory in the evening to earn more. Dan and Susan both chose community college to start out since it was more economically feasible for them rather than a greater outlay of funds for a four-year program at the beginning. Some internships were unpaid at the time so Dan worked as a Medical Laboratory Technician at night while he studied in the day to advance to earn his four year degree. Susan had a similar pathway to success. Patricia also started out in

community college changing majors a few times to finally pick a medical technician program to go on for a medical technology education.

"An entry level that has an infinite possibility is a journey that's worth embarking on" according to Greg, but one can hit a dead end early in one's career choice. They may not be able to see beyond that, unless there's room to grow with an organization; hence, most do not see the lab professional ladder upon entry into the job. There are also different entry points other than formal schooling that introduces one to the profession. Greg said, "that's where academics or training can happen by partnering with those opportunities."

Joanne commented she "wanted to advance whereas some people are comfortable staying in their position which is okay for some, too." She aspires to earn a master's degree in healthcare administration with the hopes of either becoming more involved in the MLS school or taking on a more managerial position. Quick-start alternative programs have a lot of value, but in Karen's opinion those values are for very limited or point of care testing. These shorter in length programs are good to give one a taste of what the laboratory sector is all about to see if that is the right area in which one wants a career. Karen also notes that "foreign graduates, as long as they did their clinical training in the United States, the basic education...regardless of where you received it, is fine because the basic education and science education are practically the same." However, matching this education with certification is important. Having even an ASCP Medical Laboratory Assistant MLA certification from an entry-level person going into a seasoned veteran lab means something to the extent of the knowledge they have learned, maybe because that individual has been tested by an internationally global agency as the ASCP. Shorter entry level laboratory assistant programs are "a great way to introduce someone through the laboratory area." These shorter programs can provide a kind of steppingstone on the career ladder by being

initially more economically feasible to the graduate and to the employer. There are strengths in all levels of the programs: medical technologist, medical technician, or alternate shorter or even online programs. Karen notes, "It takes a village to run a lab so all levels are really important." She noted that the one thing that made a difference was the amount of time that the student spent during their clinical internship rotation.

Nicole voiced her view of alternative quick-start programs saying that, "If some of them (educators) were willing to open such a program, then surely that would be beneficial." However, her experience with conducting alternative remote learning during the pandemic proved to be difficult since the didactic classroom for the study of medical technology is better suited as a hands-on endeavor. Pam commented that, "I think we can (teach) many students online; our capacity can be doubled, even tripled, but the problem always is the clinical areas where they eventually would have to be trained and the internship that they have."

Pam noted that "there (are) requirements that supervisors in the laboratory (have) to have a bachelor's degree." It's necessary that the medical laboratory science technologist programs, which are four-year bachelor's degree programs, continue to be maintained for the supervisory positions. However, for the workers, medical laboratory science programs granting lesser degrees or certificates are fine whether they are one year, two year or six months training. Perhaps from these hospital-based program graduates, more employees can be hired at a quicker pace than the four-year degree programs. Pam stated: "We are hiring Cadillacs. We don't have to hire Cadillacs." For workers, we can work with people with a lesser degree or certificates. Shorter programs can be a nice stepping career stone for people that are unsure of where they want to go. Sally holds that entry level and quick-start training programs have their place in MLS education. She stated, "I think that entry level and that quick ability to get someone in and training is important." The employer then has the ability to hire someone with some training earlier to fill their staffing needs, but formal education MLT and MT programs should never go away since, to advance up the ranks, a broad knowledge base is critical. Also, before one markets quick-start programs for the entry-level lab assistant, one has to make sure those positions are available since not every job in a laboratory is an entry level one. She sometimes needs those who are experienced, can work independently, and step up for any task.

Comparing and contrasting medical laboratory technicians (MLTs) versus medical technologists (MTs), Susan stated that these two-year and four-year students "both learn the same material at the same levels" since they both enroll in the same 11 month hospital training period in her program. It's the previous prerequisite academic university or college education that they happen to be exposed to at different levels which may make a difference. Over the past three or four years she has changed and updated her curriculum as a transformative change leader, so she is confident that the latest curriculum sets the stage for new student preparation heightened tenfold.

Advancing into a management role was another story for both Pam and Susan. The first had no clear management training path in place while the second had too many requirement hoops to jump through for her role. But then again, Patricia stepped into a management role during her advancement up her laboratory career ladder, but then opted out to become just a worker again as personal choice as she got older. Sarah has seen for medical technologist graduates that if one is in school for two or four years, that individual would certainly get more theory than if they had only been in school for six months and that added knowledge is needed to progress up through the career ladder.

Conclusion

Results obtained from this study's participants are representative of what was researched in the literature review section. Participants noted definitive statistical evidence of the increasing shortage of clinical laboratory professionals happening within the last 20 to 30 years without any actions taken to halt the decline. They each presented different key points from their own lived experiences as educators or employers as to why this was the case. The main noted causative effects seem to stem from the fact that clinical laboratory professionals are retiring at a rate outpacing the needed staff at the entry level, poor recruitment and marketing of existing MLS programs with limited internships and MLS training programs due to cost saving economics. Participants also provided commentary about what is needed with respect to developmental soft skills for MLS students and creation of new programs to entice new potential student candidates to train to become future laboratory professionals. An overall analysis of the participant data collected for this study follows in the next chapter.

CHAPTER 5

CONCLUSIONS

Following the data analysis of this study's participants within the previous chapter, this researcher presents to the reader the implications of what each of the themes mean to the health of the clinical laboratory workforce. Together with these discussions are recommendations to improve the current situation of a continually declining clinical laboratory professional workforce.

On the student side, backfilling retiring vacancies with quick-start program graduates and second career retirees, increasing recruitment of new students by greater marketing of traditional MLS programs plus more new affiliations with internship sites, and creation and promotion of new MLS fast track programs to entice students with shorter matriculation times and less of an economic burden, are presented. Within the workplace clinical laboratory, more recognition and rewards are needed to be given to the staff with an encouragement for continuous learning so that they can perform better in their own positions and mentor student and new entry-level workers as part of a clinical consultative intra-educational team.

Theme I: Awareness of Laboratory Professional Staff Shortages

Noted by all the participants within this study was the realization that the clinical laboratory workforce has been declining for many years, as documented within the latest ASCP vacancy surveys which have been conducted every two years since 1988 (Garcia et al., 2010, 2013, 2018). Growth rates for entry-laboratory assistant level positions are projected to increase from 18% to 23% through 2024, but the number of traditional medical laboratory science (MLS) educational programs and their requisite post-classroom hospital internships have declined (Bureau of Labor Statistics, 2019).

One prime reason the clinical laboratory workforce is declining is the increasing number of retirees in the next three to five years, leading to a more than two to one vacancy gap at the entry worker level. Most study participants noted this fact within the clinical laboratories where they are currently employed. However, this is not the only reason for a declining clinical laboratory workforce. Both study educators and employers commented on the decline in available MLS programs within their state; they noted that contributing factors to this consequence is poorer recruitment of new MLS program students in conjunction with poor lackluster marketing of these programs to the right targeted educational audiences.

Within the current clinical laboratory workforce, participants noted declining retention rates due to lack of recognition, rewards and compensation. Some stated that MLS students may have high expectations of where they will work after graduation, but then are disillusioned when the facts prove out that other clinicians gain a higher respect and compensation from their employers. The primary concerns of employers are in staffing the laboratory with qualified laboratory professionals (24.22%), certification in specimen processing (34.82%), increasing workloads contributing to employee burnout and lack of retention (39.52%) (Garcia et al., 2018).

All of the participants supported certification from an accreditation agency as the ASCP to validate one's educational knowledge, while support for universal licensing was mixed. They also felt that certification would make it easier for veteran laboratory workers to accept them into the clinical laboratory as being able to support them and do the work needed. Some participants viewed licensing as a positive to keep out unqualified laboratorians while others saw it as a barrier to letting some excellent laboratorians into the field. The problem stems from different requirements for different U.S. states and territories. There are no universal federal U.S. licensing requirements established; hence, an excellent medical technologist licensed in one state

may have to complete additional educational courses in order to qualify to take the licensing exam in another state (ASCLS, 2019).

Implications

Many statistics have been recorded documenting the increasing shortages of clinical laboratory personnel over the past 20 to 30 years, but little has been done to improve the situation. The ASCP has been recording the decline in detailed vacancy survey reports every two years since 1988. Accounting for the decline in the workforce creates the overlooked problems with healthcare organizations then failing to deliver fully on their mission statements of delivering the best quality patient care. There is an ever-increasing demand for more laboratory services, expanding new automated platforms as rapid PCR testing for viruses as COVID-19 and manual platforms as molecular-based and esoteric tests. All of these tests require a staff of laboratorians to either conduct them or monitor them.

The ASCP vacancy rates reported are those where there is a two to one gap between the numbers of retirees leaving in the next four to five years with the number of clinical laboratory positions needed at the entry level to backfill (Garcia et al., 2019). There are not enough MLS program students graduating to fill these open positions due to poor recruitment and marketing of the various clinical laboratory training programs. The educators are only training less than half of the laboratory professionals needed (ASCLS, 2019).

As noted by this study's participants, the clinical laboratory professional has always lagged behind other clinicians such as nurses with respect to compensation, recognition, rewards and respect for the work they do. Laboratorians are key professionals that these other clinicians need to form their patient prognoses to treat and resolve disease outcomes. The laboratory results produced by them are used by advanced practitioners to make very difficult life and death treatment decisions for their patients. Without the clinical laboratory and its laboratorians, patient treatments and outcomes could not rationally be justified by insurance providers, who in turn require the data for any payment of services performed under the current pay for services model of the CMS (2019).

Certifications of laboratory professionals have increased within the years 2000 and 2017 from 1,370 to 2,484, for Medical Laboratory Technicians (MLTs), an 81% increase, and from 1,990 to 3,619 for Medical Technologists (MTs) reflecting an 82% increase (ASCLS, 2019). However, these numbers do not truly reflect the actual number of new MLS program graduates. A significant number of these certificates were issued to MLT certificate holders already employed who wanted to advance their careers onto the MT rank. Thus, while certification does provide validation of previous knowledge, the statistical numbers of new certifications are amiss when it comes to justifying an increased number of clinical laboratory professionals needed to backfill positions of those retiring and leaving the profession.

Recommendations

The overall problem of stemming the declining clinical laboratory professionals is a complex one, hence, requiring a look at many different types of solutions all working together. The shortages mainly have gone unnoticed outside the laboratory until a crisis of a new outbreak of a flu or a virus like COVID-19 causes the media to spotlight the high volumes of work that these laboratorians do for the patient community. One has to address not only backfilling the retiring workers, but increasing graduates of MLS programs by greater marketing, awareness and recruitment of these programs with avenues to greater motivate MLS students and those employed. Certification and licensing could also help in ways to elevate recognition of laboratorians and can be used as a screening education validation tool to make sure that an

individual within the laboratory has the needed knowledge to conduct and/or supervise various tests.

There are some various overall solutions to filling the gap to be filled by retiring workers. Some of these older workers considering retirement can be offered part-time positions to continue their work in the laboratory or become educators as mentors and trainers for new student interns and employees. Using a proper compensation incentive this can be offered. Within high demand areas as noted by the ASCP vacancy surveys, retired workers from other fields can train and become part-time phlebotomists or specimen accessioners. This researcher has had personal experience with noting that some retired public school teachers worked within an area hospital after they opted to get trained as phlebotomists as a way to earn extra income in their golden years. There are also retired pools of individuals from the scientific community that could also opt to scale back their careers to become consultants within the laboratory to perform various activities to help out the existing staff.

Bringing in more individuals to help in the laboratory is a start but there is another source of the problem of a declining clinical laboratory staff. On the education front many middle school, high school and college students are not aware of the clinical laboratory profession. This is a field that has been documented by the Bureau of Labor Statistics with a projected growth rate of 13% from 2016 through 2026, while the Department of Health and Human Service Administration (HRSA) predicts a 22% increase in the same medical and clinical laboratory technologists and technicians between 2012 and 2025. (BLS, 2019; HRSA, 2019). Recruiters are needed to market the MLS programs to students, while academic institutions and their educators need to expand their programs offering more enrollment dates. Current MLS students with alumni, together with the academic science faculty of a higher learning institution together with either paid or volunteer retired clinical laboratory workers can serve as the promoting salesmen of MLS programs. ASCLS supports expanding the Title VII health professions program to include clinical laboratory science, together with including them in the STEM (science, technology, engineering, and math) designation so that greater funding can be available especially via grants (ASCLS, 2019). Development of shorter time frame quick-start laboratory entry-level assistant training programs can also help both students and employers. Students would spend less time and at a lower cost than traditional two- and four-year medical technician and technologist programs and be able to test out whether they are right for a clinical laboratory workforce position before committing to a longer-term career. Employers will get knowledgeable basic trained laboratory professionals that they can put to work faster to fill specific niches in their labs rather than waiting for the two or four year traditional MLS program graduates.

Addressing issues of retention of employees in the clinical laboratory focuses on compensation paid, but also recognition of a job well done, rewards, whether they be monetary or not, gifts, paid time off earned, or group or individual team events are factors. There are also no clear pathways defined for the new entry-level clinical laboratory employee. There are work task proficiency reviews included within performance reviews, but these are poor individual motivators which could contribute to burnout. Motivation at a simple level is illustrated by Maslow's Hierarchy of Needs and its five levels of those needs: physiological, safety, social, self-esteem and self-actualization, in which the lower basal needs must be satisfied first before moving up higher on the pyramid (Marion and Gonzalez, 2014). But those within the leadership of an organization can also elevate or deflate the ambitions of a student or worker. Psychologist Dr. Helen Rothberg (2017) noted with her acronym, ADVICE, that a leader has to Act Decisively on their Visions but with the caveats of Integrity, Communication and Empathy for the members of their team.

Participative leadership is a positive motivator since there is two-way communication between the worker and the manager, while authoritarian leadership styles usually prove to be the worst and usually are used in the way of routine labor that is transactional in nature. Transformational leadership has shown to give the best results within nursing by fostering resultant overall improved patient outcomes and hence greater job satisfaction for all those involved (Lin, 2015). Employees are inspired to innovate and create change to help grow and shape the future success of an organization. Clinical laboratory upper management administrators within healthcare organizations should promote the use of transformational leadership training within their teams from the top down.

Money is unfortunately the first motivator that is considered by the employee with a manager, but Daniel Pink (2011) comments that an individual should have some sense of greater motivation connected to the tasks completed within the work place; he states that human motivation is largely intrinsic, and that the aspects of this motivation can be divided into autonomy, mastery, and purpose, arguing against old models of motivation driven by rewards and fear of punishment dominated by extrinsic factors such as money. Hence, demanding proficiency and accountability with metrics that have little meaning to the staff as one of our study participants Joanne noted, is detrimental to motivation; tech to work tasks ratios should be made periodically and studied more carefully ahead of assigning work to be done to a set group of individuals to complete within a specified turnaround time. The laboratory management should know how many employees and what skillsets of those employees are needed to complete a certain number of tasks, tests, or services.

Continuous learning in the clinical laboratory should be emphasized and not just performance goals. This educational process is needed for everyone in the team to keep pace with increased instrumentation and technological advances within science and medicine. Leaders presenting goals as timelines, while showing empathy and encouraging learning, helps the staff connect the goals to their purpose and fosters a sense of accomplishment of a job well done. Together with two-way communicative feedback, defined timelines will foster a better work atmosphere for both the leader and the employee.

Promoting an atmosphere within the clinical laboratory workplace to encourage continuous learning is a large factor within motivation of the employees. Certification with continuous maintenance programs requiring certificate holders to earn CMEs within a defined period as the ASCP (2019) does every three years since 2008, is a good way to validate knowledge needed to perform the various tasks required within the job. Certificate holders also elevate their self-esteem and foster a greater acceptance by colleagues especially if they are entry-level new workers as new MLS program graduates. Together with validation by certification of knowledge gained comes an increased sense of value of that person to themselves in the way of self-esteem and to a potential employer in the way of having the aligned skill sets matched to perform specific tasks within the clinical laboratory. Menger's (1976) subjective theory of value together with the concept of Rubin's (1927/1978) exchange theory of value within Marxian economics illustrate these facts: a potential job candidate viewed as a commodity has both subjective value and an objective exchange value or social marginal utility value and that item's value depends on the consumer. If an employer values such training and/or credentials of a potential entry-level laboratory candidate, she or he should be more inclined to hire that individual via the exchange theory of value.

Summary Highlights

Subtheme 1: Increasing retirement of older workers.

- Backfill retiring workers with entry-level quick-start trained Laboratory Assistants
- Fill deficient staffing areas as phlebotomy with second career retirees or transitioning workers from related scientific fields

Subtheme 2: Poor recruitment and marketing of MLS programs.

• Mobilize current and past MLS program students plus retired clinical laboratory workers as volunteer or paid recruiters of new students

Subtheme 3: Declining retention of employees – no clear career pathway, poor job. recognition, rewards and compensation.

 Better recognize and reward laboratorians if not with salary and bonuses via special recognition events and awards (i.e. COVID 19 pizza and food drives to feed the front line healthcare workers with increased media coverage and even mini-neighborhood parades)

Subtheme 4: Certification with CMPs and licensing.

- Mandate in-house CMPs as Human Resource policy requirements
- Encourage earning specialty certifications
- Offer incentives for earning CMEs
- Develop on-site study groups for those taking certification and licensing exams
- Lobby for universal requirements at the federal level for licensing of medical technologists

Theme 2: Limited Clinical Student Internships and MLS Training Programs

Another reason for the decline of the clinical laboratory professional is linked to the reduction in MLS training programs coupled with a continuing decrease in the number of required prerequisite hands-on clinical hospital internships within these programs. All of the study participants noted a reduction of hospital internship programs within their state within their tenures as educators or employers. This has resulted from various reasons with respect to increased instrumentation within the laboratory, a reduction of student trainers and the overall consequence of economic cost-cutting at the local, state and federal levels. Due to a greater amount of technological instrumentation in the laboratory, there is less physical space to train student interns. Participants noted that perhaps 20 or 30 years back five or six students could be taken into a laboratory and trained by the staff whereas now some labs will only allow one or two students at a time. Also, since the staff has been continuously reduced over the past 20 to 30 years while the workloads have increased, there is now less staff available to mentor new MLS program students. The staff is focused on proficiencies of turn-around times of many different tests which have increased in complexity over the years, validating instrumentation and communication of accurate results to other clinicians.

The ever-present specter of everyone in business, including healthcare, always trying to do more with less is part of the local, state and federal economic cycle. In order to survive, small hospitals join larger healthcare networks which downsize and outsource services within them, plus the advance to personalized medicine for all for better care is promoting the fee for treatment outcomes model by the CMS instead of the current fee for services model (CMS, 2019). As noted by some of our study participants, student MLS program clinical internships are viewed as an expense for which many hospitals do not see a return on their investment (ROI).

Implications

A declining number of required employment prerequisite student hospital affiliated internship sites leads to a declining number of student MLS training programs. This fact in turn results in a decrease in student MLS graduates which contributes to the overall increasing shortage of clinical laboratorians. Bashawri et al. (2006) conducted a study due to initial concerns over whether to reduce or eliminate the internship period perhaps in an effort to accelerate the students into the marketplace at a faster rate to fill needed shortages. The survey results agreed with this researcher that such an internship was essential to the training and that the importance and necessity of the length of that internship period should not be reduced or eliminated. Our study participants also agree that it is only logical that students that matriculate from longer timeframe MLS programs are exposed to a greater amount of knowledge that can be used in the clinical laboratory workplace. Within the past year of 2020, in the way of trying to educate during the COVID 19 lockdowns, the use of remote learning has increased especially for the didactic classroom portions of some MLS programs. However, as one participant in this researcher's study noted, remote teaching and learning proved difficult and that hands-on training is preferred especially in the clinical hospital internship training portion of their laboratory program. Even though some educators support decreasing the time of internship within an MLS program and supplementing the time with virtual simulation exercises, they are not equivalent to the in person hands-on ones in a clinical laboratory.

The decline in student internships has resulted from the many factors of economics, the number of hospitals willing to host students, the physical space in a laboratory to include the students, time constraints and attitudes of today's clinical laboratory employees. The study participants commented on all of these aspects. Increased instrumentation in the clinical

laboratory has been highlighted as one of the internal reasons why the laboratories cannot train several student interns at a time within an MLS program creating a need to recruit more clinical sites to host these students. Laboratory professionals are focused on proficiency of outcomes and therefore quality assurance (QA) and quality controls (QC) are in focus for all testing, especially those involving instrumentation. Accuracy, which is closeness to a true value and precision, repeatability, are both key requirements from instrumentation which needs to be validated by QC tests as Levy-Jennings charts and Westgard Rules (Turgeon, 2019). These validation procedures demand the absolute focus of the instrument operator. Trying to be an educator or mentor and answer a student intern's questions and demonstrating the correct way to conduct testing is not a prime focus within their job as noted by our study participants.

Of course this lack of mentorship comes under the umbrella of cost saving and economics which is the result of health organization networks acquiring and absorbing smaller community hospitals that were struggling on their own financially. Many hospital labs are not seen as a good return on investment (ROI) but as a cost within the larger network, so outsourcing of the individual labs to contractors occurs in an effort to increase the quality of patient care. Thus, consolidating the workforce, increasing automation and increasing work inputs to increase quality care, decreases the motivation of laboratorians in their workplaces and student candidates to enroll in MLS programs.

Recommendations

Physical laboratory training space, decreased attentiveness and motivation of staff to train both students and employees with economics, all play a part within declining internships and MLS training programs. In an effort to solve physical space problems academic institutions can work with their hospital internship sites to stagger their student internships within a class enrollment. In this way the student to trainer ratio is reduced for a greater learning atmosphere. Greater partnering of hospitals within large network healthcare organizations can achieve a better balance of internships for students. Large networks as the one in this study have many different size capacity hospitals within their networks for university and college MLS program educators to reach out to. The right hospital match to the right student class is key. Some labs may be more heavily using histology rather than blood processing while others may have more increased instrumentation for specimen accessioning. A federal student internship matching program should be created for MLS program students as there is for medical school resident matching programs. Making the right matches could lead to increased motivation by the student to stay longer on the job when hired and also be an asset to the employer to fill the correct needs at the time.

An effort has to be made to encourage fellow MLS program students together with other scientific discipline students of higher education to form support groups to recruit, market and foster awareness of the various laboratory professional career pathways and the MLS programs available. Retired laboratorians and current employees can also either volunteer or be paid a stipend to participate in marketing awareness programs at the middle, high school and college levels. Guidance counselors within the middle and high schools should be targeted since students begin to start thinking about future careers at those times. On the economic front ASCLS (2019) supports that MLS training programs should be included in Title VII and STEM curriculums, then STEM educational grant money can be applied for student enrollments. Also as participants in this study noted, students enrolled in MLS programs with affiliated hospital clinical laboratory internships are more likely to be hired within that organization after graduation. Here then there is a benefit to both the student gaining a job and the hospital lab gaining a trained employee

aligned with Menger's (1976) subjective value theory and the exchange theory of Rubin (1927/1978). In this researcher's opinion lobbying the federal, state and local governments for funding for MLS educational programs is needed but unfortunately the need seems to come to light only in times of disease crises as outbreaks of viruses like the flu and COVID-19.

Summary Highlights

Subtheme 1: Lack of physical space to train.

• Use staggered scheduling of students in internships so they are not all in the laboratory with instrumentation at the same time

Subtheme 2: Decreased staff resulting in less student mentors and trainers.

• Enlist part-time retired laboratory workers and other hospital intra-departmental clinicians to give their time as educators as either volunteers or paid per diem staffers

Subtheme 3: Consequences of economics – hospital consolidations and changing models of payment.

• Lobby local, state and federal government entities especially the U.S. Congress to aliquot greater funding to the education of critically needed clinical laboratory students and staff; the declining staffing numbers are especially noted during disease outbreak times (i.e. COVID 19 and flu virus surges)

Theme 3: Consequences of Increased Laboratory Instrumentation

There have been positives and negatives of increased technology and instrumentation within the clinical laboratory noted by our study participants. On the plus side technology has given us new tests that can help clinicians diagnose disease much faster so that treatments can begin earlier. Work outputs on a daily basis have increased dramatically with the advent of instrumentation, allowing many automated tests to be completed faster than manual ones of the past. However, on the downside, less workers are now required in the laboratory. In fact, even though laboratorians with a bachelor's degree, preferably in medical technology are required at the supervisory level, they are not required at the entry level to complete specific supervised tasks especially using automated instrumentation. The upper-level staffers are now focused more on validation quality assurance and quality controls of the instrumentation to make sure the automated patient tests are accurate and thus have little or no time to train new employees and graduates. One study participant noted that many a time she looks for a new employee with broad knowledge and experience with the ability to work independently within rapidly changing situations in her laboratory. Not all new posted clinical laboratory positions are geared for entry-level new graduates.

Implications

Both positives and negatives are part of laboratory automation in 2021 which is a complex mix of robotics, computers and liquid handlers integrated with scientific technological advances. The positive of high throughput outputs of the testing of patient samples and a quicker turnaround time for results for clinicians is noted along with increased safety margins resulting from less manual handling of samples and being able to use much lower amounts of patient samples to produce more accurate results. But on the negative side, it was already noted that some of these instruments take up a large amount of physical floor space leaving little space for laboratorians to work. Increased instrumentation in some labs can lead to greater downsizing of staff and a catch-22 situation: an attempt to improve quality patient healthcare by speed and accuracy then causes a limiting factor of not having enough staff to monitor the instrumentation. This was noted by our study participant Greg who commented that an instrument does not

replace a person. A cascading effect already mentioned with the increase in instrumentation is the fact that there is greater focus of the staff on instrument validation. In addition a downsized staff results in less trainers and mentors being present in the lab for new employees and students. Hence, the staff is gaining more knowledge with respects to instrumentation on the job as employees, but not as students in their MLS programs due to the decline of hands-on internships and only some discussion of the theoretical behind instrumentation in the didactic classroom.

Recommendations

For laboratorians to work with increased technology and instrumentation is to welcome it as a positive transformative change. Both educators and employees as leaders should express this fact to their teams of both entry-level new staff and veteran employees. Within MLS programs technology needs to be highlighted in line with the fast-paced growth in the various other educational STEM programs. In the opinion of this researcher, teaching the theory behind the instrumentation needs to continue but more hands-on work with instrumentation in the clinical laboratory needs to be incorporated into MLS program internships and not less time as some opponents might suggest.

Process improvement strategies as Six Sigma (Breyfogle, 2003) are needed to determine the right balance of the number of laboratory workers needed especially with the increased amount of automation, complexity of tests conducted, and volume and speed of tests needed within shortened turnaround times. As study participant Joanne noted, a realistic number of techs to work output ratio studies should be done for clinical laboratories on a regular basis. The current clinical laboratory management of promoting a faster larger input/output turnaround while requiring staff to sometimes proactively learn new technologies and instrumentation independently, leads to worker burnout, declining retention of staff and hence fuels the overall increasing shortage of laboratory professionals.

Continuous formal education programs in the workforce should be offered and encouraged not only to maintain certification CMEs within CMPs, but for the fact that more knowledge is needed to be learned as technology increases within the clinical laboratory and allied scientific fields of medicine and pathology. New entry-level MLS program graduates can be fast-track trained to advance on their career pathways in the workplace by taking on the responsibilities of the routine QA validations of laboratory instrumentation. This cross training would free up some time of the veteran laboratory professionals to foster and mentor student interns and entry-level employees about various automated and manual testing procedures. When the trainees become proficient on more specific testing procedures they then become greater assets to the entire laboratory team.

Summary Highlights

Subtheme 1: Increased work output with focus on proficiencies and test outcome metrics.

• Process improvement assessments to analyze the number of laboratory technicians to workflow output ratios are needed

Subtheme 2: More staff is now focused on instrumentation QA/QC validation rather than training new employees and graduates.

• Expansion of continuous education programs to be able to train more in-house lab staffers to be better mentors and trainers

Theme 4: Developmental Soft Skills Needed for Success and Career Advancement

Many varied soft skills were valued within our participant employers of clinical laboratories and promoted within MLS training programs by our educators. The many facets of communication on all levels, troubleshooting, problem solving especially with instrumentation, critical thinking, teamwork with intra-educational continuous learning and of paramount importance, the ability to easily be able to accept and adapt to changes no matter how quickly they occur were highlighted soft skills.

Our study participants themselves have taken various pathways to achieve their goals of being employers and educators within their careers. This illustrates that fact that there is not one unique program that a prospective student of laboratory science must take. There is the traditional four-year medical technologist academic program with affiliation with a university or college to earn a bachelor's degree in medical technology followed by proper certification, but there are other routes. A two-year university or community college program yielding a medical technician associate degree, online didactic classroom programs and shorter entry-level laboratory assistant programs are other ways for one to enter the workforce of the clinical laboratory. Enrolling in these shorter than four-year alternate pathway programs one can more easily and economically test the waters of being employed within the clinical laboratory before making a commitment to a longer-term career choice.

Implications

Soft skills and their development need to be continually stressed within MLS educational programs since they are important within the clinical laboratory workplace. All of the study participants agreed that communication, troubleshooting, problem solving, critical thinking, team work and the ability to easily to be able to accept and adapt to change are important soft skills.

But they also all noted that these skills, even though they are emphasized within mission statements of many educational MLS training programs, are not being developed until the handson clinical hospital internship for some and then later for other students after graduation when they are working as employees within a workplace environment.

A simple deficiency as poor communication skills can lead to missed deadlines, displeasure with colleagues, or conflict in the workplace. Study participants noted that telephone etiquette was very important; this is a skill that is not specifically taught but is initially experienced by most MLS students within their clinical internships. Several study participants noted that students and lab employees have to be able to talk about complex patient tests and results with physicians, nurses and other clinical care staff within the hospital. They also found that troubleshooting and problem solving are important soft skills for a staff employee to have since they are needed to quickly diagnose and solve problems with instrumentation; a laboratory professional who can accomplish these tasks can save the organization time and money since no instrument repair technician will need to be called to a site.

The ability to quickly adapt to change aligns with good teamwork within the laboratory since everything within the laboratory, especially the hospital laboratory as Dan noted, can change daily. The entire team has to be able to quickly adapt to stop one workflow and pick up another more highly demanded workflow. Everyone has to learn new life and death methods of testing as needed when new virus strains as COVID-19 need to be rapidly tested for waiting patients. Critical thinking and problem solving work together in these situations. Without teamwork and supervision of one's work mistakes made can be catastrophic. The third leading cause of all deaths behind cancer and heart disease in the United States result from medical errors (Makary et al. 2016). The hospital clinical laboratory tends to function on something

different each day as Dan noted, while a large corporate outsourced specimen processing clinical laboratory operates on a more repetitive routine workflow. Thus, two different types of work ethic mentalities of MLS student graduates may also be seen: one who prefers routine work versus one who wants to do something different each day with a willingness to adapt to changing conditions.

A student thinking of pursuing a career in the clinical laboratory must realize that there are various pathways to reach their end goal as many of our study participants noted in their own life career journeys. As Greg suggested, if a new MLS graduate or entry-level laboratory professional does not know or cannot see a vision ahead on the career path ladder, they can become lost and leave the profession. Without a clear career pathway, defined goals ahead and the motivation to achieve those goals from educators and employers, the individual's advancement plan after graduation flounders. Clear career ladders work in concert with greater awareness, marketing and recruitment of students for MLS programs as were previously discussed.

Recommendations

As discussed, there is not one career pathway which one should follow to an entry-level position within a clinical laboratory. This fact should be stressed at not only the pre-MLS program application stage by academic institutions and educators but also during the MLS student's training period in the classroom and clinical hospital internship and by management within the workplace after an MLS graduate is hired. As seen in this study's research, several of the participants took various educational pathways to make their moves up the laboratory professionals' career ladder. The various options of not only medical technician two-year associate degree and four year medical technologist bachelor degree programs are available, but

one can enroll in alternate certificate programs that may be shorter and more economically feasible for the prospective student. Another option would be for a student who majored in a non-clinical science area within a higher institute of learning to make a transition into the clinical laboratory without having to go through a two-year or four-year program. As noted by study participant, Patricia, a new prospective clinical laboratory employee who has some science background may be able to transition into the clinical laboratory environment by earning certifications via examination for specialty categories as microbiology or blood banking. Hence, a formal two- or four-year MLS program may not be necessary. All the study participants agreed that the Medical Laboratory Assistant (MLA) certification suited for entry-level laboratory assistants from the ASCP (2019) can give those students who fast-track a laboratory professional education within an alternate route MLS program a steppingstone to a fulfilling career within the clinical laboratory; the MLA certification validates their fast-track course knowledge to themselves and to their colleagues within the laboratory team, fostering a quicker acceptance by the veteran lab staffers new graduates resulting in greater collaboration within the team.

In order for one to be successful within the clinical laboratory and advance within the ranks of the team, one has to have and develop certain soft skills while also knowing the career pathway that is to be followed. On the part of the entry-level laboratory professional, communication, troubleshooting, problem solving, critical thinking, teamwork, and the ability to accept change are all necessary soft skills to have at least as a foundation as an MLS student and then further develop in the workplace. The employer's responsibility is to clearly present a defined career pathway for the individual lab worker to follow. Study participant Greg noted that he saw a difference in the laboratorian and the military structure of the police force, who he has periodically trained in laboratory science essentials. A police academy graduate leaves the

educational sector knowing what steps they need to take to advance up the ranks to further their career, while a laboratorian usually does not. Hospital and corporate specimen processing labs present different proficiency goals as benchmarks to employees but these usually serve to decrease intrinsic motivation (Yenice, 2019).

Positive approaches to better overall development of the soft skills mentioned are encouraging and developing more intra-educational events within the various other science major programs for the MLS students, including cross functional study groups, intra-clinical consultation groups within the workplace and participation in point-of-care (POCT) teams where laboratorians can present their work and at the same time learn about how other clinicians fit into the overall healthcare organization team to provide quality patient care. Laboratorians can shadow advanced medical technologist instrument operators and instrument service technicians as a way to develop greater trouble shooting and problem solving skills. As study participant Susan noted, MLS students are now allowed to report critical results to clinicians; staffers should work with student interns to develop critical thinking so that they can report these critical results accurately and so that they are correctly understood to clinicians.

There is a difference within the hospital clinical laboratory and a corporate specimen processing clinical laboratory with respect to a daily routine. The hospital routine as noted by Dan can be ever changing and that's what he likes about it, while in the corporate laboratory the work is more routine as performing "factory work." This is important when a student MLS graduate is presented with a job opportunity in the workplace with respect to their view and the employer's view. It's important to match the right person to the right job. Study participant Sally mentioned that she sometimes wants someone with clinical laboratory experience who can work independently within an entry-level clinical laboratory bench position; hence, not everyone should start out as entry-level workers, but she stated that everyone should start out doing handson laboratory bench testing work to acquire the necessary experience. Using the subjective value theory of Menger (1976) together with the exchange value theory of Rubin (1927/1978) one can see how their constructs hold true. Placing the wrong person in the wrong job could lead to only disillusionment after MLS program graduation since student expectations in the workplace are not met.

Academic institutions of higher learning need to stress the need for the laboratory professional and that the outlook for career options in the field are high as noted by the Bureau of Labor Statistics (BLS) (2019). The educators within the MLS programs need to coordinate with colleagues teaching other programs, especially within the sciences to bring greater awareness to the field and work together to develop alternate laboratory professional training programs. In this way a potential laboratory professional has a broader set of educational options to choose from rather than only the medical technician or medical technologist journey.

The development of quick-start shorter in time and less costly laboratory training programs for both the student and the institution providing them will serve to benefit the educational institution, the graduate and the prospective employer. The educational institution benefits by becoming known as an avenue for one to economically fast-track into an entry-level clinical laboratory position that can provide a start to an exciting career for the student and the employer benefits by being able to hire someone to backfill the vacating positions from retiring workers much quicker than waiting for two-year medical technician students and four-year medical technologist students to graduate. As per the latest ASCP vacancy survey, a top management concern is to be able to hire qualified knowledgeable replacements for their retirees (24.2%) within a three-to-six month period (Garcia et al., 2018). As our study participants

commented, alternative quick-start programs can also provide either a steppingstone to advanced learning and education within the workplace or a "test the waters" approach so that one who is not suited for the career can then move on to another career more quickly. Hence these programs then are a plus to both new graduates and the employer who hires them. Educators developing these types of new alternative training programs should follow a McTighe and Thomas (2003) Backward Design model in which one looks more at what specific hands-on skills and theoretical knowledge is required by the employer to complete tasks within the clinical laboratory as opposed to using only the ADDIE model of instructional design which generically structures the curriculum with respect to Analyze, Design, Develop, Implement and Evaluate as an overall conceptual framework (Branson, et al., 1975). In order to develop successful alternative programs as discussed, educators and employers must work together to create suitable curriculums.

Summary Highlights

Subtheme 1: Communication, troubleshooting, problem solving, critical thinking

- Increase intradepartmental events within the workplace especially using point-ofcare-testing (POCT) for interactions with patients and other clinicians and encourage staffers to promote and present more of their work as a way to market the profession and recruit new students
- Increase hands-on equipment and manual testing training; let staffers shadow instrumentation service technicians and representatives to gain more instrument operation knowledge

• Using communication, troubleshooting and teamwork link new students and staffers with advanced technicians and technologists so that they can do more critical result reporting

Subtheme 2: Teamwork with intra-educational events.

• Help to match the right job to the right person (i.e. the ever changing hospital laboratory daily needs versus the factory type repetitive work of a corporate processer)

Subtheme 3: Flexibility with an openness to accept and adapt to change.

• Stress that the field of clinical laboratory medicine is ever changing within the fast pace advances of technology and medicine as a positive point to encourage continuous learning with adaptation to transformative change along the way

Subtheme 4: Development of alternative programs and defined career pathways.

- Define various career pathways and encourage students to pursue specialty certifications within their careers
- Develop new quick start shorter in length programs to backfill needed laboratory positions faster which students can then use as stepping-stones for new career pathway trials

Conclusion

As noted by all of the participants within this study there is an awareness of the increasing shortages of clinical laboratory professionals over the last 20 to 30 years, but little has been done to solve the problem. The dilemma is a very complex one as seen by the many factors which contribute to these shortages: increasing retirements of older lab workers, poor recruitment and marketing of existing MLS programs which have declined due to economic cost

saving measures within academic institutions and hospital health organization networks. Stemming from these main reasons, declines in laboratory staff retention, lack of physical laboratory space to train students, an apathetic staff who prefer not to train students and employees matched with the need for a greater fostering of recognition, rewards and encouragement for continuous education have to be recognized and addressed by both educators and employers.

Recommendations for reform have been noted within the summary highlights sections. There is a need to onboard previous retirees, MLS program alumni and current students to promote and market MLS programs especially at the middle school and high school levels. Retirees could also be hired back as part-time workers within the labs to mentor student interns and train new employees. An intra-educational learning environment is needed among clinical laboratory professionals as a consultative staff working in concert with other clinicians to foster a better work atmosphere for these laboratorians with respect to respect, rewards and recognition not only by compensation to increase staff retention.

Academic institutions of higher learning have to reach out to healthcare organization networks and negotiate the required needed increase in prerequisite clinical internship student training sites within their local hospitals from the top down. Veteran lab staffers have to work with new entry level employees and student interns to prime the next generation of laboratorians to maintain a high quality of patient care in the community. Educators need to work with employers to craft MLS programs that are in line with what is needed in the workforce with respect to the proper skill sets and knowledge required for career success and longevity. Adams, J., Defleur, M. H., & Heald, G. R. (2007). The acceptability of credentials earned online for obtaining employment in the health care professions. *Communication Education*, 56(3), 292–307. https://www-tandfonline-com.une.idm.oclc.org/doi/citedby/10.1080/03634520701344959?scroll=top&needAccess

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Appendix A

Participation Request Email

From: Noll, George Sent To: Subject: Educational Research Project

Hi XXXXXX

I am emailing you to let you know that I am in the final stages of an educational project dissertation about how current MLS programs in general prepare students for work in today's clinical laboratory. This project involves me gaining individual perceptions from both educators and employers (lab supervisors and managers). This will be accomplished by me interviewing individuals by phone and recording their perceptions.

I would like you to participate in this study; it should only take about 30 minutes after which you will receive a verbatim transcript of your interview.

By looking at various themes from the data collected within these interviews I hope to gain insights into improving current laboratory training programs and or be able to create new ones.

Please let me know via email ASAP when you will be able to speak with me.

Value Perceptions of Basic Clinical Laboratory Assistant Training with Certification (Abstract):

The problem of practice looks at the perception of the value of traditional clinical medical laboratory workers' training with accreditation credentials. This study will examine the perception of the value of Medical Laboratory Science (MLS) program training and validation of that training with respect to entry-level clinical laboratory professionals. The demand for clinical laboratory professionals is increasing due to the number of retirees expected to peak by 2024, and is expected to yield a two to one job vacancy gap mainly in entry-level positions. There is a need to examine the perceived value of such traditional educational clinical laboratory programs from the viewpoints of the MLS educators and employers that can affect change efforts to better match these programs with what is required within the career path and respective employment field. Research questions asked are: how do MLS program educators describe their understanding of how traditional MLS programs of study prepare students for work in the clinical laboratory and how do clinical laboratory employers for work in their clinical laboratory? A qualitative Interpretative Phenomenological Analysis (IPA) design will be used with ten participants within our healthcare laboratory network.

Results may give courageous insight into improvement of current medical laboratory science educational programs and collaborative educational rehabilitation laboratory training courses and creative ideas for new similar courses for compassionate outcomes for physically challenged and neurodiverse students.

Thank you George Noll University of New England Doctoral Candidate gnoll@une.edu

Appendix B

CONSENT FOR PARTICIPATION IN RESEARCH

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

TITLE OF THE STUDY:

VALUE PERCEPTIONS OF BASIC CLINICAL LABORATORY ASSISTANT TRAINING WITH CERTIFICATION

Who is conducting this study?

Principal Investigator: George Noll

Sub-Investigators: xxxxxxx

Sponsor: NA

Concise Summary

The problem of practice looks at the perception of the value of traditional clinical medical laboratory workers' training with accreditation credentials. This six month study will examine the perception of the value of Medical Laboratory (MLS) program training and validation of that training with respect to entry-level clinical laboratory professionals. The demand for clinical laboratory professionals is increasing due to the number of retirees expected to peak by 2024, and is expected to yield a two to one job vacancy gap mainly in entry-level positions. There is a need to examine the perceived value of such traditional educational clinical laboratory programs from the viewpoints of the MLS educators and employers that can affect change efforts to better match these programs with what is required within the career path and respective employment field. Research questions asked are: how do MLS program educators describe their understanding of how traditional MLS programs of study prepare students for work in the clinical laboratory and how do clinical laboratory employers describe their understanding of how traditional MLS programs of study prepare students for work in the clinical laboratory and how do clinical laboratory employers describe their understanding of how traditional MLS programs of study prepare students for work in the clinical laboratory and how do clinical laboratory employers describe their understanding of how traditional MLS programs of study prepare their understanding of how traditional MLS programs of study prepare to programs of study prepares to programs of study prepares to programs of st

participants within the healthcare laboratory network at three of the healthcare organization's hospitals named xxx, xxx and xxx. There are no significant risks to the participants or potential benefits to them. However, results can be extrapolated to help improved current traditional and non-traditional MLS programs and to create new ones.

Why is this research being conducted and why have I been asked to take part?

You have been asked to take part in this study because you have been a graduate of a Medical Laboratory Science (MLS) program and are either an educator or a supervisor/manager (employer) within a clinical laboratory. This form gives you important information about the research study. It describes the purpose of this research study, and the risks and possible benefits of participating. If there is anything in this form you do not understand, please ask questions. Please take your time.

Taking part in this research study is voluntary. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

The purpose of this research study is to examine the value perceptions of both educators and employers within the clinical laboratory professional field by their lived experiences in an effort to collect their impressions of how the current MLS educational programs act as a prerequisite for executing various activities required of the entry-level clinical laboratory assistant. The study will also provide insight into what participants value about the instruction and how well their MLS pedagogy programs have prepared them for specific activities in the clinical laboratory workplace. There are specific deficiencies within the areas of specimen processing, reference laboratory send-outs, and the general core chemistry laboratories where there are not enough of these entry-level workers (Garcia et al., 2018).

Central research questions seek to record the lived experiences of a specific population that can affect change efforts on the educational preparedness of entering clinical laboratory workers.

- How do MLS program educators describe their understanding of how traditional MLS programs of study prepare their students for work in the clinical laboratory?
- How do clinical laboratory employers describe their understanding of how traditional MLS programs of study prepare potential employees for work in their clinical laboratory?

How many people will take part in this study?

Approximately 10 to15 people will take part in this study at xxxxx within the hospital clinical laboratories of the healthcare organization.

What is involved in this study?

Recruitment and consent will be conducted by phone and email solicitation which will include this healthcare organization's informed consent template to be completed and signed by any study candidates who agree to become participants. Purposive sampling will be used by the researcher. No surveys, focus groups or educational interventions will be conducted. Post consent, phone interviews will be conducted by the researcher as the data collection instrument as described in this protocol.

Qualitative data will be collected from research participants by the researcher as the instrument using a semi-structured open-ended question interview format of 30 to 60 minutes via phone. Audio recordings of the interviews will be made by an Apple IPhone7 and backed up on a digital audio tape recorder. The audio files will be then transcribed by a reputable company that has no interests in the health care system of the participants. This researcher will follow the tenets of Interpretive Phenomenological Analysis (IPA) by using inductive reasoning in the way of a bottom up analysis to isolate themes within the verbatim transcripts to record results and then provide a discussion of these results. This is not a quantitative study and hence there is no statistical analysis.

No medical devices or investigational new drugs or placebos will be used in this qualitative social sciences study.

There will be no randomization or blinding and participant selection is purposive. There will be no collection of any medical data information (esp. HIPAA and PHI) to be used for any research purposes.

How long will I be in this study?

Each subject's participation in the study will involve one 30 minute to 60 minute phone interview with the researcher as the data collection instrument. Each participant will receive at a later time via email a verbatim transcription of their own interview so that they can review it as way of a member checking procedure.

What are the risks involved in this study?

> This is a minimal risk study.

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.
You menu refuse to ensure on the state of the state of the state.

You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Are there benefits to taking part in the study?

> There is no potential for direct benefit to the participant.

There are no benefits for participating in this study other than the scientific knowledge gained. However, this research may help others in the future.

How will information about me be kept private?

All participants will be given a pseudonym or coded ID, known only to the researcher and the participant. Audio recordings will be prefaced with the pseudonym/coded ID. Verbatim transcripts will be transcribed by a reputable company with no known association with the healthcare system. Any reference to the healthcare system will be made in general terms and any proper names including the healthcare system will be given a pseudonym or coded ID. If there are any hard copy study documents such as printed consent forms, they will be kept in a locked safety deposit box while any digital files, including scanned documents will be kept on the internal hard drive of a password protected computer. No external drives will be used. The recorded audio with consent forms will be secured as such until the conclusion of the study when they will then later be presented for destruction when cleared by the healthcare and university institutions, followed by any audio devices and media transfer devices then being wiped of those files.

What information do researchers want to use?

As part of this research study, some general personal information about you may be collected. This may include general information about your educational and career background with associated experiences that you wish to share.

Who can see my information? Information may be shared with the following:

- The researcher and other authorized staff at the healthcare organization;
- People at the healthcare organization who oversee and evaluate research, including the Institutional Review Board and Compliance programs.
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the US Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP);
- Representatives of University of New England (i.e. graduate committee and IRB) whom this study is being completed for a dissertation.

Information that could identify you will not be shared with anyone outside of the research team unless you provide your written consent on this form, or it is required or allowed by law. The results of this study may be shown at meetings and published in journals (esp. within the University of New England digital library archives) to inform other educational and health professionals. No publication or presentation will include any information that could identify you.

How will my information be protected?

If there are any hard copy study documents such as printed consent forms, they will be kept in a

locked safety deposit box while any digital files, including scanned documents will be kept on the internal

hard drive of a password protected computer. No external drives will be used. The recorded audio with

consent forms will be secured as such until the conclusion of the study when they will then later be

presented for destruction when cleared by the healthcare and university institutions, followed by any

audio devices and media transfer devices then being wiped of those files. Study records will be retained

for a length of time as specified by the healthcare organization xxxxxx and the University of New England.

- > No Certificate of Confidentiality is required.
- We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Data collected in this study might be used for future research or distributed to another investigator for future research without your consent. If used for future purposes, the data will not include any information that could identify you, such as your name, medical record number or date of birth.

What are the costs?

There is no cost for any of the subjects to participate in this study.

Will I be paid to participate in the study?

No remuneration or gifts of any kind will be paid to any of the participants in this study.

What are my rights as a research participant?

Your decision to take part in this study is voluntary. If you decide not to participate or if you choose to withdraw after beginning the study, you can do so without penalty and you will not lose any benefits to which you are entitled. You are encouraged to ask questions before deciding whether you wish to participate and at any time during the course of the project. You will be told of any new findings that may change your decision to be in this study. If information becomes available that may influence your decision to take part in this study you may be asked to sign a revised consent form or consent form addendum.

You are not waiving any of your legal rights by signing this informed consent document. As part of the consent process, you will receive a signed copy of this informed consent document.

Can I leave the study before it is finished? Can I be removed from this study without my approval?

You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this researcher, healthcare organization or the university.

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. However, all data that have already been collected for study purposes will remain.

Who can I call if I have questions or problems?

You are encouraged to ask questions before deciding what you want to do. If you decide to take part, feel free to ask questions at any time during your participation.

For questions about this research project, please contact: PI Contact Information: George Noll Email: <u>George.Noll@xxxx.org</u> or <u>gnoll@une.edu</u> Phone: xxx-xxx-xxxx For questions regarding your rights as a research participant or any research-related concerns, you can call the healthcare organization Research Integrity Office at xxx-xxxx.

Participant/Authorized Representative Signature(s)

I have read this consent form or it has been read to me. All of the questions that I had were answered to my satisfaction. I have been told that I will receive a signed copy of this consent form for my records. By signing this consent form I have not waived any of the legal rights which I otherwise would have as a participant in a research study. Name of Subject (Please Print)

Signature of Subject (18 years or older)	Date
Name of Authorized Representative (if different than participant)	Relation to Participant:
	Parent Legal Guardian
Signature of Authorized Representative	Date

Institutional Signature(s)

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to be in the research study.

Person Obtaining Consent

Signature of Person Obtaining Consent

Date

Name of Impartial Witness (if applicable)

Signature	of	Impartial	Witness	(if
applicable)				

Date

Child Assent to Take Part in this Research Study

For children capable of providing assent: I have explained this study and the procedures involved to ______ in terms he/she could understand, and he/she freely assented to take part in this study.

Person Obtaining Assent

Signature of Person Obtaining Assent

Date

xxxx have been used to redact information that would jeopardize anonymity of the healthcare organization; University of New England IRB has the non-redacted copy.