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Medical Laboratory Managers Success with Preanalytical Errors

Huong Q. Ly
Walden University

Walden University

College of Management and Technology

This is to certify that the doctoral study by

Huong Ly

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Review Committee
Dr. Lynn Szostek, Committee Chairperson, Doctor of Business Administration Faculty

Dr. Karin Mae, Committee Member, Doctor of Business Administration Faculty

Dr. Judith Blando, University Reviewer, Doctor of Business Administration Faculty

Chief Academic Officer
Eric Riedel, Ph.D.

Walden University
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Abstract

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Huong Ly

MBA, Ellis University, 2010

BS, State University of New York at Plattsburgh, 1997

Doctoral Study Submitted in Partial Fulfillment

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Abstract

Clinicians rely heavily on accurate laboratory results to diagnose and treat their patients. Laboratory errors can occur in any area of total testing phases, but more than half of the errors occur in the preanalytical phase. Framed by the total quality management theory, the purpose of this multiple case study was to explore medical laboratory managers' strategies to reduce preanalytical errors. A purposive sample of 2 organizations with laboratories in southern California participated in semistructured face-to-face interviews. Company A had 2 participants and 3 participants participated in the study from Company B. Each participant had at least 5 years of laboratory experience, with a minimum of 2 years of management experience in preanalytical testing, and had completed one project to minimize laboratory errors. Thematic analysis exposed 5 main themes: quality improvement, recognition, reward, and empowerment, education and training, communication, and patient satisfaction. The participants highlighted the need for organizations to concentrate on quality management to achieve patient satisfaction. To achieve quality services, medical laboratory managers noted the importance of employee engagement, education and training, and communication as successful strategies to mitigate preanalytical errors. The recommendation for action is for laboratory leaders to review and apply effective strategies exposed by the data in this study to reduce preanalytical errors in their medical laboratory. Positive implications of this study include reduction of preanalytical errors, increased operational cost, and improved patient experience.

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Dedication

I would like to dedicate this study to the ones I hold close to my heart. First and foremost, I like to dedicate this study to my late mother, whom I am sure is smiling from above as I reached this milestone. Second, I would like to thank my father for instilling the value of education in me. Third, I would like to thank my sisters for being my backbones and support system throughout this journey. Last and most important, I would like to thank the three men in my life. To my sons, Ryan and Nick, the completion of this study proves that your mother can reach for the stars and the impossible is achievable. To the love of my life, I would like to thank you for your continuous support and relentless encouragement. Without you, the completion of this journey might have not been possible.

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This long and arduous journey would be impossible to achieve without the support of my Chair and committee. First, I thank Dr. Lynn Szostek for accepting my invitation to be my Chair. Her invaluable insights, patience, and continued support made this journey a bittersweet experience. I also thank Dr. Karen Mae for serving as second committee member. Finally, I thank Dr. Judith Blando for serving as university reviewer. Dr. Blando encouraged me to return to Walden University to finish the doctoral study. This trio of scholarly women made it possible to achieve this terminal degree.

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Section 1: Foundation of the Study

The Institute of Medicine reported that 1.5 million preventable medical errors were responsible for anywhere from 44,000 to 98,000 deaths annually in the United States (Kalra, Kalra, & Baniak, 2013). The cost of medical errors is 45 cents for every dollar spent. Laboratory medicine plays a pivotal role in the diagnostic process and in monitoring the effects of therapy (Carlson, Amirahmadi, & Hernandez, 2012). Clinicians use laboratory results to diagnose diseases and conditions, to make decisions about hospital admission and discharge, and to determine the appropriate course of treatment for patients. Accurate and timely laboratory results are important because a low incidence of laboratory error has important public health and patient safety implications. An inaccurate or incorrect test result may lead to additional cost and time consuming follow-up testing (Snydman et al., 2012). Understanding the processes leading to erroneous laboratory results in the preanalytical phase of testing should increase the quality of care for patients and decrease preventable waste of valuable health care resources.

Background of the Problem

Deaths associated with medical errors outpace the number of deaths occurring from motor vehicle accident, breast cancer, or HIV/AIDS (Kalra et al., 2013). The estimated cost of medical error is between $17.1 and $29 billion (Hammerling, 2012). Researchers showed the defect rate in health care in the U.S. to be between 31% and 69% (Hawkins, 2012). This research explored errors occurring in clinical medical laboratory,

a sector of health care delivery. Compared to other healthcare sectors, medical laboratories were a forerunner in the pursuit of quality (Lippi et al., 2013b).

Clinical medical laboratories performed approximately 6.8 billion tests and generated $52 billion in revenue in 2007 (Carlson et al., 2012). This amount represents only 2.3% of health care spending in the United States, but clinical medical laboratories play a pivotal role in diagnosis and patient management. Clinicians based their diagnosis decision on laboratory results 60-70% of the time (Abdollahi, Saffar, & Saffar, 2014). Laboratories need to take mistakes seriously because clinicians depend on their results to properly diagnose and treat patients (Plebani, 2014).

Clinical laboratory testing is comprised of three testing phases: preanalytical, analytical, and post analytical (Hammerling, 2012; Hawkins, 2012). These phases are also known as total testing phases (TTP), and dividing TTP into three different phases allows medical laboratory managers to hone in on and address errors in each phase. Examination of the successes of medical laboratory managers in reducing errors in the preanalytical phase is the goal of this study. Seventy-five percent of TTP errors occur in the preanalytical phase, and 26% can cause detrimental effects on patient care (Green, 2013). Given the magnitude of this issue, there was a need for this study.

Problem Statement

Reports indicated that up to 75% of laboratory errors occurred in preanalytical phase of testing (Naz, Mumtaz, & Sadaruddin, 2012). The cost to investigate and correct an error is nearly 25% of laboratory total expenses (Carlson et al., 2012). The general business problem is that erroneous laboratory results lead to monetary loss and negative

patient experience. The specific business problem is that some medical laboratory managers lack strategies to mitigate errors in the preanalytical phase.

Purpose Statement

The purpose of this qualitative case study was to explore in depth how medical laboratory managers reduce laboratory errors in the preanalytical phase. Participants for this case study were medical laboratory managers in at least two medical laboratories in southern California who reduced laboratory errors in the preanalytical phase. The information yielded from the semistructured interviews provided management and health care personnel with an avenue to reduce laboratory errors. Preventing the patient from experiencing detrimental physical or emotional effects caused by laboratory errors will contribute to a positive patient experience. This should elicit interest from leaders in health care sectors as well as patients. Eliminating laboratory errors will improve patient safety, reduce operational costs, and increase revenue.

Nature of the Study

The quality and quantity of data collection depends on the research method chosen. Research methodologies included quantitative, qualitative and mixed-methods. Quantitative research assumes that situations are measurable and observable through a systematic process (Petty, Thomson, & Stew, 2012a). Quantitative data are numerical, using statistical analysis while qualitative data consists of interview transcripts, observations, drawings, or films that were not quantifiable.

Quantitative research is not apposite for this study because the data collection is not numerical, nor does it use deductive reasoning to link theory and research (Zou,

Sunindijo, & Dainty, 2014). My intent was not to test a hypothesis, but to understand the perspectives of medical laboratory managers regarding their success in reducing errors.

A mixed methods approach combines both qualitative and quantitative methodologies to strengthen the breadth and depth of the subject under study (Wisdom, Cavaleri, Onwuegbuzie, & Green, 2012). Mixed methods was not appropriate for this study because the researcher was not interested in converging different methods to explain a single phenomenon (Wisdom et al., 2012).

The qualitative research method was appropriate for this study because I sought to understand the phenomena through the perspectives of the participants while identifying the experience of physical and social realities (Erlingsson, & Brysiewicz, 2013). This type of research produces a rich and complex description of people's perceptions under certain contextually specific situations. One difference between qualitative and quantitative research is the type of data collected (Van Griensven, Moore, & Hall, 2014).

The qualitative research design depends on which perspective the researcher aims to study. Three most commonly used qualitative research designs are case study, phenomenology, and ethnography. Phenomenological design aims to understand the lived experience of participants (Erlingsson & Brysiewicz, 2013), which was not the intent of this study. Ethnography is a study of people in their everyday setting by examining the shared patterns of behavior, beliefs, and languages within a cultural group (Petty, Thomson, & Stew, 2012b). I had no intent to live alongside medical laboratory managers to observe and interview the participants to develop an understanding of the cultural

influences of the phenomenon under study. Case study researchers adopt this design with the purpose of addressing an existing problem experienced by their professional practice (Harland, 2014). A qualitative case study design was the most suitable design for this study, as it allowed me to explore how medical laboratory managers reduce laboratory errors in the preanalytical phase.

Research Question

The central research question guiding this study was: How do medical laboratory managers reduce laboratory errors in the preanalytical phase?

Interview Questions

The interview questions were designed to capture the respondents' practical experience in reducing preanalytical errors. The following interview questions were intended to answer the main research questions as well as the supporting research questions.

1. How do you identify the areas that are the focus of preanalytical errors?
2. How do you diagnose the root cause of the problem? Do you use observations and documentation to help diagnose the root cause?
3. How do you implement interventions that could potentially yield favorable outcomes to minimize errors?
4. How do you reinforce the identified inventions to ensure effectiveness?
5. How important is quality in your organization?
6. What is your strategy to engage employees in developing a culture of quality?

7. How do you involve and empower all laboratory and other ancillary personnel in cooperative efforts to achieve quality improvements in the preanalytical phase?
8. How can quality improve operational costs, patient care experience, and competitive advantage?
9. How do you implement continuous improvement of employee's capabilities and work processes through training and education to reduce preanalytical errors?
10. What other preanalytical error reduction strategy you would like to share to help medical laboratory managers address this issue?

Conceptual Framework

Total Quality Management (TQM) theory framed this qualitative study. The framework of TQM concentrated on organizational survival (Zehir, Ertosun, Zehir, & Müceldilli, 2012). Total quality management assisted in generating a better understanding of medical laboratory managers' experiences with preanalytical errors and reveal their successes of minimizing these errors.

The origin of TQM is traceable to 1949 when the Union of Japanese Scientists and Engineers (JUSE) formed a committee composed of scholars, engineers, and government officials to address improving productivity and the quality of life in postwar Japan (Powell, 1995). Total quality management framework consists of aspects from Joseph Juran's concept of the quality trilogy, Philip Crosby's absolutes of quality management, Armand Feigenbaum's three steps of quality, and W. Deming's 14 points (Talib & Rahman, 2012). The combination of these important aspects created a framework that promoted adding value to the product or service by setting and meeting

goals with zero defects. Total quality management is accomplishable through top management commitment, teamwork, and methods to measure process variations to expose the root cause(s) of the problem.

Medical laboratory managers can use TQM to address laboratory errors through trial and learning cycle. TQM could also help medical laboratory managers identify the causes of preanalytical errors, diagnose the root cause of the problem, and implement interventions that could potentially yield favorable outcomes. When implementing TQM initiatives, the involvement of all stakeholders is important (Munechika, Sano, Jin, & Kajihara, 2014) in the quest to strive for zero defects in patient care while meeting or exceeding patient satisfaction (Nicolay et al., 2012).

Definition of Terms

Diagnostic error. A missed, wrong, or delayed diagnosis detected by some subsequent definitive test or finding (Plebani, 2013).

Laboratory error. Defined as any defect occurring at any part of the total testing phases (Lillo et al., 2012).

Medical error. The failure of a planned action to complete as intended, or the use of a wrong plan to achieve an aim (Hawkins, 2012).

Quality control. The statistical tool laboratories use to monitor performance of testing processes, detect potential errors, and correct discrepancies prior to reporting of results (Lee, 2012).

Quality indicator. Defined as the objective measure that allows the users to assess critical aspects of the testing processes (Plebani et al., 2014c).

Assumptions, Limitations, and Delimitations

Assumptions

Assumptions made in this study were oversimplified ideas with a lack of practitioner relevance (Böhme, Childerhouse, Deakins, & Towill, 2012). The first assumption was that the participants are medical laboratory managers with adequate experience in reduction of preanalytical errors. The second assumption was that the experience acquired by these professionals will provide insightful information to this study. A third assumption was that the invited participants will provide candid responses to the semistructured interview questions. Honest replies were essential to preserve data integrity and ensure the reliability and validity of this study. The final assumption was that the participants will share strategies they used to minimize laboratory errors.

Limitations

Limitations are potential weaknesses in a research study (Kratochwill et al., 2013). Identified limitations included geographical location, targeted population, and trustworthiness of responses provided by the participants. The chosen geographical location did not represent a comprehensive picture of the strategies used by medical laboratory managers on a national and international laboratory industry. Restricting the study to the state of California limits the generalizability of the findings resulting in selection bias. An expanded sample population would provide the study with increased validity and fewer data anomalies. Another limitation was the target population of the study. The preanalytical phase of testing involved clinicians, couriers, phlebotomists, laboratory assistants, and clinical laboratory scientists. However, this research limited

semistructured interviews to medical laboratory managers with abilities to minimize preanalytical errors. This limitation did not provide an inclusive view of all professionals involved in the preanalytical phase and eliminated a true random sampling of participants. The integrity of the results is also a limitation to the study. Although the assurance of confidentiality in the survey exists, the possibility of collecting untrustworthy answers might occur.

Delimitations

Delimitations are the boundaries of the research study (Włodarczyk, 2014). The scope of this qualitative study was to focus on the successes of medical laboratory managers in minimizing preanalytical errors. Delimitations in this study included the population and location. First, this study included medical laboratory managers with laboratory experience and excludes all other laboratory personnel. Second, the participant pool was inclusive to the state of California, which does not include participants from other states or countries. Because of the identified delimitations, the findings of this study did not assume the generalization of the successes of medical laboratory managers with minimizing laboratory errors.

Significance of the Study

The number of estimated deaths associated with medical errors, 98,000, remains largely unchanged since the release of the Institute of Medicine (IOM) report in 1999 (Ristić, Vasiljević, Rancić, & Ristić, 2014). The severity of this issue should promote all health care entities to develop measures to minimize or prevent such occurrences. The goal of this qualitative study was to address clinical laboratory errors. Errors caused by

laboratories affect the healthcare system because up to 70% of clinical decisions depend on laboratory results. Failure to provide accurate laboratory results affects the clinician's ability to diagnose and treat patients, resulting in adverse or detrimental events. Increased operational costs could also result from these errors (Carlson et al., 2012). Such errors are costly because of the additional resources required to investigate the issues with unnecessary follow up tests. Academic literature revealed a gap in the research pertaining to the strategies for reducing preanalytical errors, which prompted the need for this study. With this research, I revealed strategies that medical laboratory managers deployed to reduce errors in the preanalytical phase, and brought needed attention to the importance of accurately reporting laboratory results so clinicians could provide proper diagnoses and treatments.

The definition of a positive social change is an intentional process of creating results for improving human and social conditions (Sharma & Good, 2013). This study identified opportunities for laboratory managers to reduce errors; improve patient safety and decrease operational costs. Over and above reducing the cost of medical errors, saving lives is the focal point for health care delivery. Saving even one life will make a positive social impact on both the patient and health care providers.

A Review of the Professional and Academic Literature

The primary source used to investigate preanalytical errors was a narrative literature search. Using the existing data in the literature allowed the researcher to include peer-reviewed journal articles that explained the outcomes from various researches. A literature review allowed the researcher to extract evidence-based knowledge about the

effects of preanalytical factors on laboratory results. This enabled the researcher to summarize, explain, and interpret evidence pertaining to the preanalytical errors.

I obtained peer-reviewed journal articles from online portals, including Google Scholar, Labmedicine.com, ASCP.org, and Walden University Library, along with databases such as EBSCOhost, ProQuest, ABI/INFORM Global, ScienceDirect, and ProQuest Dissertation and Theses. A review of the reference sections of pertinent peer-reviewed journals also revealed additional information used in the literature review section. This literature review included 99 articles with more than 85% peer-reviewed journals published since 2012. These articles represented the most recent research of biomedical preanalytical errors. Key words used to search for pertinent peer-reviewed articles included: laboratory errors, diagnostic errors, quality assurance, total error, medical errors, pre-analytical variables, total quality management, medical quality management, quality management systems, and total quality management.

Application to the Applied Business Problem

The objective of this qualitative study with a case study design was to examine the success of medical laboratory managers in reducing errors in the preanalytical phase. Adverse events affect at least 1.3 million patients annually in the United States while receiving medical care (Hannawa, 2014). This number surpasses the combined number of injuries and deaths caused by motor and air crashes, suicides, falls, poisonings, and drowning. Deaths resulting from medical errors are the eighth leading cause of death in the United States. Given the magnitude of this issue, every institution in the health care industry should explore ways to remedy the causes of these mistakes. Published studies

illustrated that laboratory medicine attempted to address erroneous results, but despite efforts at continuous improvement, the problem continues. As part of this effort, laboratories need to develop and implement effective processes to minimize the occurrence of errors because laboratory tests represent between 2.3% and 4% of health care spending (Carlson et al., 2012; Warren, 2013). Compared to other healthcare sectors, medical laboratories have been a forerunner in the pursuit of total quality (Lippi et al., 2013b). The frequency of laboratory errors is between 0.012 to 0.6% (Agarwal et al., 2012). Approximately 25% of laboratory errors affect patient care with 8% causing temporary harm and 0.01% leading to death (Snydman et al., 2012). Even without the adverse outcomes, laboratories need to take all laboratory mistakes seriously because clinicians depend on laboratory results to properly diagnose and treat patients **(**Plebani, 2014**).**

Clinical laboratory medicine plays an integral role in patient care because medical laboratory results influence 70% of clinical diagnoses (Atay et al., 2014). Clinical decisions based on laboratory results include screening, early diagnosis, prognosis, appropriate treatment and monitoring (Plebani et al., 2014a). Errors made by the laboratory affect patient safety as well as costs to the healthcare system (Plebani, Chiozza, & Sciacovelli, 2013a). More important than the additional millions of dollars in wasted costs, these errors can cause adverse and potentially deadly effects for patients (Favaloro, Funk, & Lippi, 2012). The laboratory industry attempted to mitigate these errors by applying technological advances (Lippi, Plebani, & Favaloro, 2014). Laboratories replaced manual processes with fully automated science to improve result

accuracy and speed (Naz et al., 2012). This initative illustrated that the laboratory industry was working toward achieving reliable results, but achieving quality would require collaborative efforts from all healthcare entities. Laboratory testing is comprised of three phases: preanalytical, analytical, and postanalytical (Hawkins, 2012). These phases are also known as total testing phases.

TTP is a complex system that relies on procedures, equipment, technology and human skills to provide clinicians with accurate and precise results for timely diagnosis and treatment decision(s) (Agarwal et al., 2012). George D. Lundberg described TTP as a brain-to-brain loop concept (Hawkins, 2012). The brain to-brain loop provides a working paradigm to illustrate the physician to laboratory and the physician to patient relationship (Plebani, 2012a). The brain-to-brain loop concept also provides laboratory personnel with a systematic approach to identifying and classifying laboratory errors (Hawkins, 2012). TTP consists of a nine step testing sequence including ordering, collection, identification, transportation, separation (or preparation), analysis, reporting, interpretation, and action specified by the brain-to-brain loop concept (Plebani, 2012a). Breaking the total testing process into three distinct phases enables quality improvement initiatives to target each phase individually (Hammerling, 2012). TTP begins with the preanalytical step, where clinicians order the right test at the right time and the collection of sample(s) is performed on the right patient (Tate, Johnson, Barth, & Panteghini, 2014). The analytical phase includes sample analysis and reporting of the right results to the clinician. TTP concludes in the postanalytical phase with the clinician's interpretation of

the results and a decision on the course of treatment based on test results (Hawkins, 2012).

Errors can occur in any phase of testing (Abdollahi et al., 2014). Errors occur at a rate of 65.09% in the preanalytical phase, 11.68% in the analytical phase, and 23.2 % in the postanalytical phase (Abdollahi et al., 2014). Errors in the analytical phase have dramatically decreased in the past decade (Plebani et al., 2014b). The development and implementation of quality indicators and quality specifications for effective management of analytical procedures contributed to the decreased rate (Hammerling, 2012; Plebani et al., 2014a). The standardization of analytical techniques, reagents, and instrumentation showed improvements in the analytical phase (Plebani et al., 2013a). Postanalytical errors also decreased dramatically with the implementation of interfacing analyzers and laboratory information systems (Plebani et al., 2013b). Information technologies also allowed quicker validation of results and notification of critical values. However, preanalytical errors remained a challenge for all laboratories, as up to 70% of testing errors occurred in this phase of testing (Abdollahi et al., 2014; Dolci & Panteghini, 2014). Findings indicated that errors occurring during this phase of testing accounted for 46.0% to 68.2% of all errors in TTP (Hammerling, 2012; Hawkins, 2012). Other data indicated that 75% to 87% of preanalytical errors occurred in the preanalytical phase (Green, 2013; Kemp, Bird, & Barth, 2012).

Many of the errors occurring in the pre-analytical phase are beyond the control of the laboratory because many of the processes in this phase are manual, which are more prone to human errors (Lippi et al., 2012). Preanalytical errors continued to flourish even

though improvement initiatives, including automation and quality control, aimed to minimize these errors (Guimarães, Wolfart, Brisolara & Dan, 2012; Simundic, Cornes, Grankvist, Lippi, & Nybo, 2014). This phenomenon continued to exist because laboratories did not have supervision of many of the processes occurring beyond the laboratory walls (Simundic et al., 2014).

Substandard or inaccurate laboratory results from preanalytical errors prompted the need for this research. Attempts to reduce error should commence with a review of sources of these errors because errors in this earlier phase will cascade into the analytical and postanalytical phases. Preanalytical variables defined by the International Organization for Standardization (ISO) 15189:2012 include the clinician's assessment of a patient's condition, ordering of tests, patient identification at time of sample collection, collection of specimen, transportation of specimen, and specimen receipt at the laboratory (Plebani, Sciacovelli, Aita, Padoan, & Chiozza, 2014c).

The cost of preanalytical error is between 0.23% and 1.2% of total hospital operating costs (Green, 2013). This comes to approximately $1,199,122 annually in a hospital with 650 beds. Preanalytical errors are a significant burden to hospital operating costs because of repeat collection and retesting require additional resources (Green, 2013). Hospital and laboratory administrators should prevent or minimize the occurrences of these errors to alleviate the financial constraints at their facilities and decrease healthcare spending. Researchers studied preanalytical errors on a global scale in an attempt to reduce these errors. Various researchers explored the high rate of errors in this phase and suggested different solutions to minimize this problem (Gómez-Salgado

et al., 2015). Several researchers concentrated on sample processes (Karcher & Lehman, 2014; Plebani, 2014; Yılmaz, Kıral, Boğdaycıoğlu, & Uysal, 2013) while others focused on the effects of these preanalytical errors on patient safety (Green, 2013; Naz et al., 2012; Waheed et al., 2013). The exploration of diverse aspects of preanalytical errors was evident in the literature, but a study to explore the perspective of medical laboratory managers who successfully reduced laboratory errors in the preanalytical phase was not. This study aims to explore the perspective of medical laboratory managers to close the existing gap.

A well developed, implemented, and monitored quality management system (QMS) could aid clinical laboratories in producing accurate and reliable laboratory test results (Funk, Lippi, & Favaloro, 2012). Included in this QMS are quality standards meant to address sample processing, transportation, and storage of specimens. QMS should also include defined procedures, training, and competencies. Staff must adhere to these standards because any deviations could lead to undesirable outcomes in patient care. The most effective strategy to minimize laboratory errors was to develop a comprehensive Total Quality Management system (Hammerling, 2012). TQM could provide laboratory managers with tools to dissect preanalytical processes to analyze the root cause of errors. The revelation of the root cause of errors could lead to the development and implementation of solutions to mitigate this issue.

Application to Conceptual Framework

Leading practitioners view TQM as a strategic tool to compete in the current competitive business market. TQM concentrates on continuous improvement of products

or processes to meet or exceed customer expectations (Talib & Rahman, 2012). This framework demands that all stakeholders are responsible for the quality of the product they produced or used (Nicolay et al., 2012). Stakeholders include management, workforce, suppliers, and customers. Leaders can adopt TQM to monitor process management, customer feedback, leadership commitment, strategic planning, supplier quality management, and employee engagement. TQM, as a quality management practice, aims to improve quality of products and services, performance, and attain higher market share (Lee, 2012).

Quality leaders including Edwards Deming, Joseph Duran, Armand Feigenbaum, and Kaoru Ishikawa provided the foundation for TQM. The evolution of TQM traced back to post World War II when JUSE formed a committee to improve productivity and quality of life in Japan (Powell, 1995). American companies adopted TQM as a strategic tool to compete with Japanese companies in the 1980's. Initially, the implementation of TQM was in the manufacturing sectors, but as TQM gained popularity, the service industries including healthcare industry, banking sector, higher education institutions, real estate, and hotels and tourism sectors adopted TQM as a strategic move to appease customers while achieving quality metrics (Talib, 2013).

The health care industry has experienced quality issues on a global scale in the last few decades (Serteser, Coskun, Inal, & Unsal, 2012). The IOM report released by the United States in 1999 indicated that the quality of health care delivery is poor with as many as 98,000 preventable deaths occurring each year (Green, 2013). Laboratory medicine (a subset of health care delivery) is the forerunner of quality improvement in

health care, but continues to struggle with quality issues affecting their services (Hammerling, 2012). Diagnosticians rely on laboratory results to diagnose, evaluate, and management patients' conditions (Snydman et al., 2012). Erroneous results could cause emotional or adverse distress as well as increased cost. To improve quality, and alleviate costs, many health care organizations implemented TQM as a methodological strategy to achieve quality and increase firm value through process improvement (Lee, 2012). TQM has sustainable competitive advantage if implemented correctly (Talib, 2013).

TQM is relevant to this study because of its potential to improve laboratory performance. The highest standard of quality in the preanalytical phase of testing is achievable in laboratory medicine through the development and implementation of a TQM system (Hammerling, 2012). TQM is applicable to this study through standards defined by laboratory accreditation bodies such as the International Organization Standard 15189 (Talib, 2013). ISO 15189 is an internationally recognized standard that outlines specific requirements for medical laboratories to demonstrate their competence in delivering reliable laboratory services (Serteser et al., 2012).

Commitment is pledged to meet or exceed customer satisfaction by achieving defined quality and services. Customer orientation is the central focus of TQM by meeting or exceeding customer satisfaction. Doctors, nurses, and all ancillary entities are laboratory customers involved with the care of the patient. TQM requires that organizations know what customers need and how to achieve customer satisfaction. This aspect of TQM requires the organization to produce a quality product or service.

ISO 15189 required that organizations meet this condition through four

requirements: organization and management, review of contract, external services and supplies, and resolution of complaints (Allen, 2013). Organization and management require the laboratory to outline the needs and expectations of customers, as well as the role and responsibilities of each staff member. Review of contract requires laboratories to review the agreement of defined needs and expectations of customers periodically. External services and supplies requires the definition of procedures for handling inventory and storage to ensure that adequate supplies are available to meet the demand of the customers. Resolution of complaints defines the need to document, investigate, and provide corrective action to meet customer satisfaction. The support of senior management is essential for the success of TQM implementation. To encourage participation, top management should empower employees to suggest process improvement ideas and involve staff in the development and implementation of these processes. Without this element, the chance of implementing TQM successfully will decrease.

Involvement is including all team members from top to bottom to achieve a common goal (Talib, 2013). ISO 15189 requirements that address involvement include quality management systems, advisory services, and management review. QMS includes a laboratory's quality policy and quality objectives, as well as all other policies, processes, and procedures involved with laboratory operations. QMS dictates management involvement in communicating laboratory quality policy and quality objectives to all staff. Advisory services ensure that each staff member has mechanisms to provide input regarding services offered by the laboratory. Management review

requires regular assessment by all stakeholders to ensure the continual suitability and effectiveness of the QMS. This assessment should include discussion of the status of corrective and preventive actions, internal and external audit reports, feedback from customers, quality indicators, and any necessary changes needed to improve the QMS. Continuous improvement is the process of exploring for defects and correcting them (Talib, 2013). ISO 15189 requirements of identifications and control of conformities, corrective action, preventive action, quality and technical records, internal audits, and technical requirements meet TQM aspect of continuous improvement.

Continuous improvement outlined by ISO 15189 specified that laboratories must review their procedures regularly to identify potential sources of nonconformities and opportunities for improvement (Allen 2013). The expectation is for laboratories to expose root cause, develop, and implement corrective and preventive actions to address these conformities upon identification. When nonconformance occurred, root cause analysis was essential to expose possible errors and identify weaknesses in the system that allowed these failures to occur (Reid & Smyth-Renshaw, 2012). Laboratories should also implement preventive and corrective actions to avoid issues from occurring or recurring. Applying the TQM approach to detect preanalytical error requires the involvement of all employees in the mapping of all processes, development and implementation of all processes, and to define metrics for each process (Olofsson, Banker, & Sjoblom, 2013).

Laboratories need to perform internal audits at set intervals to ensure that all processes conform to QMS requirements. Quality and technical records need to be

available upon request and recorded according to regulations. Implementation of technical requirements, including personnel, preanalytical, analytical, and postanalytical procedures, is essential to ensure quality. Personnel procedures must outline adequate staffing as well as hiring, training, competency assessment, performance evaluations, and continuing education. Preanalytical, analytical, and postanalytical procedures should include all processes from test ordering to the release of results. These procedures must define each step involved and be available to staff. The procedures should be complete and written in a standard style so all employees can understand and follow them. Customer satisfaction is only achievable through continuous improvement and commitment from all stakeholders.

The components presented above are an integration of findings from a literature review of TQM as a quality improvement theory. Different aspects of TQM provide a conceptual framework for understanding and studying quality improvement in laboratory medicine. Components of TQM offer laboratory leaders a methodological approach to quality improvements. Laboratories should develop and implement an effective TQM system to reduce process variations, eliminate waste, minimize errors, and improve cost of quality. This framework can help laboratories gather data, analyze data, and diagnose the source of errors. TQM is applicable to this study because it promotes a quality culture by involving all employees in the detection, prevention, and management of errors. Most importantly, if implemented effectively, TQM has the potential to improve patients' experiences with laboratory testing. To summarize, TQM has the potential to ensure improvement of clinical operation and financial performance while increasing job

satisfaction among employees.

Relevancy of the Literature

The purpose of this case study is to explore medical laboratory managers' abilities to minimize laboratory errors. A thorough review of existing literature revealed three general categories pertaining to preanalytical errors: causes and types of errors, the effect of quality assessments, and the application of technological advancements and harmonization to minimize errors. This review of the literature presents findings from each area of focus, along with a discussion of their significance. This literature review groups the journals into three categories according to content, as noted above.

Preanalytical variables. Statland and Winkel introduced the term preanalytical factors in 1977 to describe variables that influenced laboratory results before the testing of the sample (Guder, 2014). This term evolved to preexamination procedures and then to preanalytical phase. Preanalytical phase is a complex and dynamic process and involves many health care professionals from different disciplines (Gómez-Salgado et al., 2014; Lippi et al., 2013b). The preanalytical phase includes sample collection, sample handling, and sample transportation (Yılmaz et al., 2013). Activities in this phase include, but are not limited to test request, patient and specimen identification, blood collection, centrifugation, sorting and deliverance of specimens to the laboratory (Naz et al., 2012). Errors in this phase are often random and undetectable by normal quality control methods. This phase is more vulnerable to errors because some activities occur outside the laboratory.

Laboratories need to examine the different causes of preanalytical errors because any trivial error could potentially harm the patient. Detectable preanalytical errors can require additional resources to recollect the specimen, add processing time, and delay of result reporting (Green, 2013). There have been situations where the error adversely affected patient diagnosis or treatment because the error remained unidentified until after the physician received the report. One report indicated that human mistakes contributed to the majority of preventable preanalytical errors (Rana, 2012). Another report suggested that system failure is the reason for errors and not just human fallibility (Kalra et al., 2013). Targeting individuals as problems is not an effective solution. To prevent mistakes, health care professionals need to examine the layers of complexity to expose factors causing laboratory errors. The human role in the collection of samples makes complete elimination of these errors an unrealistic goal. Implementation of preventive measures to minimize these errors in sample collection, sample collection techniques, collection of samples into proper containers, and proper storage and transportation is achievable through collaborative efforts.

A majority of preanalytical errors take place before the sample arrived at the laboratory (Green, 2013). Key preanalytical errors identified by various researchers are misidentification, incorrect samples, clotted samples, inadequate samples, hemolysis, inappropriate temperature, and time during specimen transportation. One study showed that 1% of preanalytical errors occurred in all samples, with the misidentification of samples noted as the main culprit (Upreti, Upreti, Bansal, Jeelani, & Bharat, 2013). Another study demonstrated that hemolysis is the major cause of preanalytical errors

resulting in specimen rejection (Giménez-Marín, Rivas-Ruiz, Pérez-Hidalgo, & Molina-Mendoza, 2014). Yet, another study showed that clotted samples are the leading contributor to preanalytical errors (Bhat, Tiwari, Chavan, & Kelka, 2012). Preanalytical errors occur more frequently in inpatients than outpatients (Plebani, 2014). Reasons attributed to this trend are (1) insufficient standard operating procedure for test request, sample, collection, handling, and transportation; and (2) inpatients are harder to draw because of age and disease issues.

Body of evidences in the literature revealed that many researchers aimed to uncover causes of preanalytical errors and corrective action suggestions for these issues, but there were a scant number of studies performed seeking the perspective of health care professionals. Two studies aimed to understand the perspective of professionals involved with the preanalytical process, and their hands on experience in this area, which might identify the types and causes of mistakes (Gómez-Salgado et al., 2014; Gómez-Salgado et al., 2015). The first study revealed three areas that could produce preanalytical variables: inadequate training, increased workload, and deficient work organization (Gómez-Salgado et al., 2014). Results from the second study indicated that workload increase is the main reason for variability in the preanalytical phase while commenting that organizational capability and teamwork could overcome these issues (Gómez-Salgado et al., 2015).

Test request. Heath care spending outpaced the growth rate of the United States gross domestic product (Warren, 2013). Evidence revealed that physicians directly influenced these costs. Test requests are under the control of the attending physicians

upon the completion of patient examination (Aarsand & Sandberg, 2014). Depending on the outcome of the examination, the physician diagnoses the condition and orders the proper analyses to complement the diagnosis. Studies indicated that clinicians are over ordering tests to diagnose a condition (Naz et al., 2012). There is a lack of correlation between the number of tests ordered per patient and clinical outcomes. Factors contributing to overuse of diagnostic tests include physicians' practice of defensive medicine, patient expectations, lack of understanding of the limitations of tests ordered, reordering tests because of an inability to retrieve previous results, and economic incentives (Feldman et al., 2013). Test requests vary depending on clinicians or the prevalence of disease in the area (Aarsand & Sandberg, 2014). Probable causes of inconsistent test requests include insufficient knowledge, inadequate training, and inability of the laboratory to perform the test. The misuse of laboratory services is under scrutiny worldwide because this practice affects the total healthcare cost and the increased risk of medical error and injury. Excessive test ordering lead to diagnostic errors (Epner, Gans, & Graber, 2013). For example, if a physician orders an inappropriate test and the analysis yields a false positive result, the clinician could inappropriately treat a patient based on this result. The clinician might order additional tests, or unnecessary procedures, that harm the patient. Other sources of errors caused by ordering physicians include incomplete or incorrect information on the test request form and underutilization of appropriate tests (Epner et al., 2013; Naz et al., 2012). Incomplete or incorrect information on the test request form can lead to delay of results and the possibility of misidentification of patients. Underutilization of appropriate tests

can lead to a missed or delayed diagnosis. These affect the quality of care that patients receive. The estimation of the inappropriate use of laboratory tests varies from 5% to 95%, depending on the tests ordered.

Data suggested the inconsistency of test ordering is due in part to the complexity of laboratory tests and inadequate training at the medical schools (Plebani, 2012a). The expansion of test menus makes ordering appropriate tests more difficult. Experts performed studies assessing strategies that could improve costs and efficiency. One study asked clinicians to substitute a request for an individual test with a clinical question or diagnostic suspicion (Laposata & Dighe, 2007). Based on the clinical question, the clinicians ordered a preliminary panel of tests with the intent to diagnose the disease conclusively. If a diagnosis is inconclusive, the clinicians could order further tests through diagnostic algorithms and reflex testing. The conclusion was that this strategy could reduce cost while providing accurate and faster diagnosis for the patients.

Another strategy involved the laboratory setting standards according to clinical conditions through predetermined test profiles or problems (Aarsand & Sandberg, 2014). When a patient presents a clinical manifestation of a myocardial infarction, and the system automatically orders a specific panel of tests to diagnose this condition, is an example of predetermined test profiling. An example of a problem-based test profile is when a sample yields a positive result and the order for subsequent tests automatically occurs. The laboratory can set up parameters to prevent repetitive testing. Failures to order tests and completing test request forms appropriately can lead to diagnostic errors. Collective efforts by laboratory and clinical staff to address this issue might reduce these

errors. The expertise that each group brings to the issue will improve patient safety by properly diagnosing the patient's condition through appropriate tests ordered.

Specimen collection. Proper specimen collection is the first step to ensure the quality of laboratory test results. Blood sample collection and handling are two important preanalytical activities in the TTP (Lippi et al., 2012). Addressing preanalytical variables in specimen collection, such as qualifications of blood collector, proper technique, and training and adherence to guidelines could increase the reliability of the test results. One issue that might arise during sample collection includes the lack of experience by collectors in handling the pressures of a busy clinic or multiple collection requirements (Lippi et al., 2013b). Another issue is the application of improper technique when extracting blood from patients (i.e., difficult blood draws or those derived from central lines) that could lead to partially clotted or hemolyzed samples. Inadequate training and adherence to policies were also sources of error in blood collection.

Phlebotomy. Blood collection, or phlebotomy, is the most common medical procedure performed on patients, and it involves complex procedures that require the operator to possess knowledge and manual skills. Phlebotomy is a manual procedure for which many experts cannot foresee the automation capability of this process (Waheed, Ansari, & Zaheer, 2013). Proper sample collection plays a pivotal role in avoiding preanalytical errors because errors have a tendency to occur in any situation where the processes are manual (Lima Oliveira et al., 2012).

Phlebotomists traditionally are the main operators for blood collection. However, other healthcare professionals also perform this duty (Favaloro et al., 2012). Inconsistent

training for healthcare professionals poses a problem with the quality of the blood drawn. Correct blood collection techniques and the skills of the trained operator ensure the collection of an optimal sample (Lippi at al., 2012).

Comparison studies assessing the occurrence of preanalytical errors between outpatient and inpatient units illustrated that preanalytical errors were more common in the inpatient units (Davidson, 2014; Upreti et al., 2013). The primary reason for this is that nurses and paramedical staff collect blood in inpatient units while phlebotomists collect blood in the outpatient units. The cause of the frequent occurrence of preanalytical errors in these inpatient units is the inconsistent training provided to the nurses and paramedical staff. Many of these professionals are not aware of the proper technique for collecting blood. Phlebotomists' main duties are to collect blood, and these individuals have certifications and training provided through educational policies (Lippi et al., 2012). Through proper techniques, phlebotomists are more productive in drawing blood safely and successfully. Phlebotomists must perform their duties in a skillful, safe, and reliable manner to create an atmosphere of trust and confidence. Important characteristics that phlebotomists should have include a proper manner, and the ability to communicate and interact with patients effectively (Waheed et al., 2013). Increased preanalytical errors occur when blood collection does not involve a phlebotomist at a primary health care center and in hospital wards (Simundic et al., 2013).

Preanalytical errors such as hemolysis and Ethylenediaminetetraacetic Acid (EDTA) contamination were lower when phlebotomists performed blood collection (Davidson, 2014). A study conducted at two hospitals in Scotland discovered that

hemolysis and EDTA contamination occurrences were higher in inpatient than in outpatients (Davidson, 2014). Another study compared misidentification, inappropriate collection vials, clotted samples, inadequate samples, diluted samples, and hemolyzed samples between inpatient and outpatient units. That study found that 1.34 % of preanalytical errors occurred in the inpatient units while only 0.69% occurred in the outpatient units. Common errors were misidentification or mislabeling of vials. Inadequate training provided to the nurses and other health care professional was the main reason this phenomenon existed (Davidson, 2014). As a result, proper phlebotomy practice has the potential to prevent and minimize preanalytical errors. Controlling phlebotomy is difficult, but if this area goes unrecognized, the quality of a sample test will be poor.

Improper techniques. Phlebotomy is the process where laboratory professionals perform venipuncture, capillary, or arterial puncture on patients (Waheed et al., 2013). Venipuncture is the collection of blood from the venous system. Capillary puncture is the collection of blood through the capillary from patients who are hard to draw, to minimize injury. Arterial puncture is the collection of blood from the arteries. Neglecting the importance of proper techniques used in blood collection could lead to the compromise of test results affecting patient safety.

Improper techniques, such as site preparation, prolonged application of tourniquet, inadequate collection, and wrong order of blood draws, are errors that could lead to falsified results (Waheed et al., 2013). Prolonged application of the tourniquet and excessive clenching of the fist affects the concentration of several analytes by

creating venous stasis, and changes the local pH balance (Lima-Oliveira et al., 2012). Venous stasis and excessive rubbing could introduce microorganisms to the sample, and simulate vascular dysfunction by introducing endothelial cells in the samples. Proper techniques ensure the quality of collected specimens, and include appropriate mixing of blood tubes and collection of sample in proper container (Lippi et al., 2012). Appropriate mixing of blood tubes creates a homogeneous solution of blood and additive. Using the appropriate container for specific tests minimizes erroneous results.

A study that evaluated the performance of 30 phlebotomists identified the main sources of error during blood collection (Lima-Oliveira et al., 2012). Techniques observed were tourniquet time, request for fist clenching, skin cleaning, order of tubes draw, and mixing of blood after collection. Twenty-eight of the phlebotomists observed removed the tourniquet within the 60 seconds recommended by the Clinical and Laboratory Standards Institute (CLSI). The study found that 83% of venipuncture procedures used excessive clenching of the fist and 85% applied significant rubbing at the venipuncture site. Many of these phlebotomists did not see the importance of appropriate collection order of blood, and 80% did not follow the recommended sequence. Many phlebotomists considered this practice as unnecessary and did not understand that adequate mixing of blood in tubes with anticoagulants or additives will ensure that those ingredients are working.

Applying proper technique during blood collection can help prevent hemolysis and may minimize interferences that can lead to erroneous results (Prajapati, Prajapati, & Vora, 2014). Hemolysis is the most common preanalytical interference and the main

reason for sample rejection in laboratories (Simundic &Lippi, 2012). The majority of hemolyzed venous blood specimens were the result of poor collection and handling of samples (Bölenius et al., 2013). Causative factors of hemolysis included injury caused by needles and application of the needle to the skin before the evaporation of alcohol from the skin. Applying proper phlebotomy techniques could minimize hemolysis (Lippi et al., 2013b).

Insufficient sample volume is problematic when the operator does not fill the tubes with the correct amount. Poor quality and inadequate volume of insufficient specimen contribute to over 60% of preanalytical errors (Rana, 2012). Erroneous results associated with insufficient sample volume can result in elevated analytes because of incorrect additives and blood ratios (Green, 2013). For example, if the collector only collects 3 mL of blood in a 5 mL heparin tube, the high heparin concentration might be erroneously elevated and could interfere with some analytes. Insufficient volume requires a redraw of specimen if the amount submitted cannot complete all tests ordered. This delays the receipt of test results and prolongs the patient's stay in the hospital, which results in added operational costs to the hospital. Possible causes of insufficient volume include the lack of knowledge by the phlebotomist and difficult sampling (Naz et al., 2012).

The order of blood draw is another technique that phlebotomists must follow to avoid errors. Collection of multiple tubes of blood is a common practice at many health care facilities. Each collection tube contains a specific additive that is suitable for particular types of tests (Lippi et al., 2012). The color of the rubber stopper on the tube

differentiates the addictive in the tube. To prevent additive carryover, CLSI guidelines recommended the order of the draw as: follow blood culture bottle or tube, coagulation tubes, nonadditive tube, clot activators, sodium heparin, lithium heparin, ethylenediaminetetraacetic acid, acid citrate dextrose, and oxalate or fluoride tubes. Collection of blood tubes out of order often produces inaccurate results, even with the most advanced laboratory instrument (Waheed et al., 2013). The modification of this sequence has the potential to introduce contamination into primary collection tubes through carrying over additives (Lima-Oliveira et al., 2012). Blood collection must follow specific orders to prevent cross contamination that could affect the analytical results. The order of blood draw affects the quality of sample and has the potential to cause erroneous results because of contamination from the previous blood collection tube (Rana, 2012). Transferring blood from one tube to another should not occur because this poses safety and technical issues. Proper blood collection tubes could prevent various preanalytical errors leading the adverse effect of laboratory errors on patient safety (Lippi et al., 2013b).

Wrong order of draw affects the results of tests and the following study illustrated this effect (Lima-Oliveira et al., 2013b). The study set out to prove that the incorrect order of blood draw could cause erroneous hyperkalemia and hypocalcemia. That case study collected specimens from a 45 year old male patient without any clinical complaints. The tube draw order was clot activator and gel separator (serum vacuum tube), K3EDTA, and lithium heparin. Potassium results were 4.8 mmol/mL and 8.5 mmol/mL for the serum vacuum tube and lithium heparin, respectively. Sodium results

were 2.36 mmol/mL for the serum vacuum tube and 1.48 mmol/L for the lithium heparin. Subsequent extraction of blood, excluding the K3EDTA tube, produced results of 4.7 and 4.5 mmol/mL for potassium and 2.37 and 2.38 mmol/L for the sodium. This proved that when K3EDTA drawn before lithium heparin affects the results of potassium and calcium in the blood, causing hyperkalemia and hypocalcemia. The spurious results required additional tests to rule out chronic kidney disease. This delay caused additional anxiety to the patient and increased costs to the health care system.

Training and education. The occurrence of preanalytical errors is more prevalent because this phase of testing involves professionals from different disciplines (Romero, Cobos, Gómez, & Muñoz, 2012). Improving blood specimen quality is the goal of reducing error in the preanalytical phase (Green, 2013). Insufficient training for improper puncture of veins or arteries can produce serious patient harm (Simundic et al., 2013). Blood collection is an important aspect of laboratory testing, but the existence of international guidelines on phlebotomy is scant (Lima-Oliveira et al., 2012). One set of guidelines is from the CLSI and another is from the World Health Organization. Phlebotomy processes vary tremendously across countries because of poor enforcement by the accrediting bodies (Simundic et al., 2013). Lack of training and adherence to guidelines are cited by multiple sources as the cause of blood collection errors.

Several studies indicated that adherence to predefined phlebotomy guidelines is poor (Green, 2013; Lima-Oliveira et al., 2012; Simundic et al., 2013). Reasons for low compliance to practical procedures are lack of theoretical knowledge, unfamiliarity with content of guidelines, poor attitudes toward the guidelines, and work overload (Green,

2013). Guidelines provided by CLSI and WHO are cumbersome and are not suitable for daily practice (Lima-Oliveira et al., 2012). Amending staff behavior toward established guidelines is proven difficult task (Bölenius et al., 2013). Lack of adherence to the guidelines occurs because of the complexity of the procedure, skepticism by the employees, and implementation of guidelines. The guidelines with the most success are easy to understand and applicable to the practice. Other impediments include lack of support from upper management, insufficient staff, and the roll out strategy of the implementation. Standardizing blood collection could be most beneficial for improving the quality of blood specimens (Green 2013). Mishandling or the lack of compliance to blood collection procedures is a serious issue that needs the collective involvement of international organizations, national societies, and professionals to resolve (Waheed et al., 2013). The international laboratory community needs to modify and adopt guidelines that would be appropriate for the phlebotomists to follow.

Upreti et al. (2013) noted that education and training and established quality procedures might decrease preanalytical errors. Better training in blood collection and standardization of professional phlebotomists will reduce the danger of misinterpretation of results and decrease laboratory operational costs (Davidson, 2014). Proper training, with emphasis on the sources of errors, should improve the quality of preanalytical errors (Lima-Oliveira et al., 2012). The most favorable outcome is for robust training and performance monitoring of phlebotomists through continuing education (Simundic & Lippi, 2012). Education and training of staff could ensure that specimen collection and handling do not create errors (Waheed et al., 2013). Equally important is for trained

phlebotomists to follow their laboratory's standard operating procedures and policies to avoid errors.

Surprise findings in two studies signified that interventional education increased the number of preanalytical errors (Bölenius et al., 2013; Romero et al., 2012). The findings contradict the beliefs of many scholars that training and education is a mechanism to reduce blood collection errors. To prove the benefits of updated training, the first study collected data from 29 primary care offices and hypothesized that updated training could reduce preanalytical error from the primary care office (Romero et al., 2012). Aggregation of data includes pre and post implementation of educational sessions. Preanalytical errors increased after implementation of education intervention, to the dismay of the authors. Most notable was the increased number of hemolyzed samples. The researchers cited that hemolysis could also occur in specimen handling and transportation. A similar study evaluated whether a correlation existed between educational intervention and hemolyzed samples (Bölenius et al., 2013). Results showed that a slight observation of increased hemolyzed specimens after the education intervention. The cause of this phenomenon was unknown, but the authors noted that hemolyzed specimens increased in the rural hospitals and decreased in urban hospitals. A possible explanation for this outcome is that urban hospitals adhered to guidelines; whereas, compliance at the rural hospital was scant. The complexity of blood collection procedure and various health care professional involvements in this process created errors. Researchers from various continents searched for solutions through various approaches (Romero et al., 2012). The recurring themes from these strategies were

training and adherence to guidelines. To mitigate blood collection errors, the international community must develop and foster the adoption of standardized guideline. Conclusions from these two studies noted that compliance to guidelines is more effective than training.

Specimen handling. Improper specimen handling can lead to rejections of samples. Sample rejection may occur if the samples are unsuitable for laboratory testing (Karcher & Lehman, 2014). Reasons for rejections included mislabeling, inadequate labeling, defects in the quality and quantity of samples received, and centrifugation. Significant consequences for patients and clinical management may result because of specimen rejection. The result of rejected samples was the recollection of blood and exposure of patients to discomfort because of repeated phlebotomy. The cascading effect was the delay of results and clinical diagnoses or treatments.

Misidentification. Misidentification can occur with the specimen or patient (Salinas et al., 2013). Incorrectly labeled or unlabeled specimen tubes were specimen misidentification errors that could occur during phlebotomy. Patient misidentification was notorious as a recurring error in the TTP (Aarsand & Sandberg, 2014). Two reasons leading to errors resulting in patient misidentification were performance of phlebotomy on the wrong patient and registering incorrect demographic information into the laboratory information system (LIS). Misidentification errors during sample collection could potentially delay diagnosis, cost additional resources to redraw and retest, and result in inappropriate medical treatment (Green, 2013). Patient misidentification is inexcusable and preventable, and eradication of this issue is fundamental to safety

improvement (Rana, 20120; Salinas et al., 2013). Proper patient identification in sampling collection is important because errors could have mild to life threatening consequences (Naz et al., 2012). Mismatching patient identity could lead to an acute hemolytic reaction in a blood transfusion, resulting in fatality. The safest approach to correct a misidentified sample is to recollect and retest the patient while performing an investigation of the event (Favaloro et al., 2012).

Overemphasizing the importance of proper identification is essential in curbing this issue (Favaloro et al., 2012). The Joint Commission (TJC) reiterated the importance of proper identification and supported this effort for the last decade (Lippi et al., 2012). To avoid misidentification in an outpatient setting, patients need to provide identification and to identify themselves. TJC endorsed the use of two patient identifiers, and to only label tubes when the phlebotomist is present during collection of blood samples and other specimens for clinical testing (Lippi et al., 2012). Avoidance of labeling after collection is necessary because this process is vulnerable to errors.

Hospitals implemented bar coding, radiofrequency, and wristbands to promote positive patient identification (Favaloro et al., 2012; Lippi et al., 2012; Naz et al., 2012). Other positive identifiers include printing labels for tubes, matching patient identification with the patient's full name, date of birth or medical record number, and identification of collection date and time (Naz et al., 2012). A working group under the ISO Technical Committee 212 is preparing a guidance document on quality practice for the collection and submission of primary samples for medical laboratory examination (Aarsand &

Sandberg, 2014). Ensuring compliance with standardized, correct patient identification procedure is important (Naz et al., 2012).

Unacceptable specimen qualities. The highest quality of blood received in the laboratory will yield the most reliable results. Studies, practitioners, and researchers stressed that hemolyzed samples, clotted samples could lead to erroneous results through the introduction of interference and activation of factors and platelets. Hemolyzed and clotted samples were the main causes of sample rejection.

A major factor affecting preanalytical errors producing unreliable laboratory test results is hemolysis (Dolci & Panteghini, 2014). Hemolysis in samples was the most prevalent among all preanalytical problems (Lippi, Avanzini, & Cervellin, 2013a). Hemolysis is the cause of approximately 70% of unsuitable specimens arriving to the laboratory (Green, 2013). Rejected samples caused by hemolysis outpaced other causes (insufficient, incorrect, and clotted samples) by five times (Heyer et al., 2012). Incorrect sampling procedures, mishandling of samples, or sample transportation was responsible for over 95% of hemolyzed samples (Naz et al., 2012). Hemolysis is the destruction of red blood cells that releases the hemoglobin and intracellular contents from the cells to surrounding plasma. A pink or red tint of the plasma or serum is indicative of hemolysis (Dolci & Panteghini, 2014). The color in the sample increases the spectrometric absorbance and can lead to high background absorbance reading that can yield inaccurate result. Through a variety of biological and analytical mechanisms, hemolysis can also produce interferences resulting in erroneous laboratory results. A slight amount of hemolysis can falsely elevate certain analytes, including but not limited to, lactate

dehydrogenase, creatinine kinase, potassium, aspartate amniotransferase, and alanine aminotransferase (Green, 2013). The false elevation of these levels may not provide the clinician with an accurate picture of the patient's condition for proper diagnosis.

Hemolysis might result from a problematic collection or the result of poor handling of blood post collection (Favaloro et al., 2012). Hemolyzed samples are a concern for coagulation tests because the breakdown of erythrocytes during blood collection could inhibit or activate both primary and secondary hemostasis in vitro (Plebani, 2012a). A problematic collection is forcing of blood through a large-bore needle causing red blood cells to lyse (Favaloro et al., 2012). Poor handling of blood post collection is vigorous mixing of sample causing red cells to rupture. Accurate mixing of blood after collection is necessary for the anticoagulant or clot activator to work effectively (Lima-Oliveira et al., 2013a). Avoidance of vigorous shaking of tubes after collection, traumatic venipuncture, and collection of insufficient volume to prevent hemolysis in samples is key (Rana, 2012). Although there was existing guideline to aid phlebotomists through this process, the lack of uniformity encouraged each phlebotomist to perform the steps differently. Researchers postulated that vigorous mixing resulted in hemolytic samples that led to sample rejection or erroneous results. A study evaluating the strength (gentle versus vigorous) of mixing and its effect on laboratory results showed that vigorous or gentle mixing did not produce variability with laboratory results (Lima-Oliveira et al., 2013a). To conclude, the authors explained that the findings of this study did not meet the paradigm that suggested incorrect mixing of blood promoted laboratory variability.

The existing problem with hemolyzed samples from the emergency department (ED) is delayed treatment because of recollection of samples (Heyer et al., 2012). Recollection of samples also subjected the patient to additional discomfort and added to the health care cost. Hospital ED has a hemolysis rate of up to 30%, which was highest among all hospital departments (Heyer et al., 2012; Lippi et al., 2013a). The causes for this elevated rate were lack of standard practices for blood collection in ED, inadequate training and competency, and insufficient oversight from the laboratory. Systematic review revealed improvement of certain techniques could reduce the hemolysis rate in ED (Heyer et al., 2012). Technique that prevented hemolytic activities were use a straight needle for phlebotomy, avoiding collecting blood from an intravenous (IV) line, using low vacuum tubes, and using less than or equal to 21 gauge syringes. Samples collected through the IV often produced hemolysis in sample (Lippi et al., 2013a). Venipuncture was the technique of choice for phlebotomy, but for patients in the ED, the use of phlebotomy through IV was unavoidable. A prospective study evaluated S-Monovette® serum tubes using manual aspiration as a tool to reduce erythrocyte injury in blood drawn from IV catheters (Lippi et al., 2013a). Results proved that manual aspiration using S-Monovette® serum tubes minimized stress on the IV line and reduce the likelihood of hemolysis when compared to standard vacuum tubes.

Current recommendations from the CLSI suggested using end-point measurement to reject hemolyzed specimens caused by possible clotting factor activation or interference (Favaloro et al., 2012; Plebani, 2012a). A systematic approach to identify hemolysis in samples was highly supported by clinical laboratory professionals because

of the high prevalence of unreliable results affecting clinical decisions. The standard practice to detect hemolyzed specimens was visual assessment, but this technique proved to be unreliable (Dolci & Panteghini, 2014). This technique proved to be ineffective in detecting slightly hemolyzed samples, was difficult to standardize, and had poor reproducibility. Automated assessment of the hemolysis index (HI) was a possible solution to detect the presence of cell-free hemoglobin in the sample.

Clotted samples were another cause of rejected samples in the preanalytical phase. Standard practice requires the visual inspection of the collection tubes for the presence of clots prior to centrifugation (Funk et al., 2012). Another method used to detect clot was to inspect the sample in a backlit setting. Improper mixing of blood after collection was the main reason for clotted samples (Upreti et al., 2013). Inadequate quality control during preparation of EDTA vials was another reason for clotted blood. While clots were easily detectable, microclots were difficult to detect and led to erroneous results. Microclots interfered with results by activating factors and platelets (Funk et al., 2012). Rejection of samples must occur if there is a suspicion of clots.

Well-documented studies revealed clotted samples as the main reason for specimen rejection. These studies evaluated rejection criteria, including specimens without barcodes, incorrect test requests, unsuitable container or tube, inappropriate specimen, insufficient volume, incorrect timing of sample, incorrect storage, inappropriate transport conditions, lipemic specimen, hemolytic specimen, and clotted specimen (Lay, Pinar, & Akbiyik, 2014). One study revealed that the specimen rejection rate was 2.7%, and clotted specimen had the highest rejection rate of 55.8% (Lay et al.,

2014). Another study performed at a university hospital in Porto Allegre concurred that clotted samples were the leading cause of specimen rejection (43.8%) (Guimarães et al., 2012). A third study identified clotted samples as the most common reason for rejection at 51.2% (Bhat et al., 2012).

Centrifugation. The majority of analytical specimens required for laboratory tests are plasma or serum (Yilmaz et al., 2012). Centrifugation is a specimen handling process to remove plasma or serum from blood components such as red blood cells, white blood cells, and platelets (Koenders, van Hurne, Glasmacher-Van Zijl, van der Linde, & Westerhuis, 2012). The application of centrifugal force separates the liquids of different densities (Yilmaz et al., 2012). The designs of centrifuges are with or without temperature control and different types of rotors. The steps involved with centrifugation include queuing, loading, balancing, centrifuging, deceleration to a stop, and uploading of the centrifuge. Centrifugation variables such as time, speed, and temperature can affect certain analytical outcomes.

Centrifugation can take as long as 20 minutes, and with the added pressures from clinicians for quicker turnaround time, laboratories explored avenues to reduce the duration of this process (Koenders et al., 2012). A comparison of 50 plasma and 50 serum samples centrifuged at 5 and 10 minutes at a centrifugal force of 1885 x g indicated that reducing the centrifugation time to 5 minutes did not affect laboratory results using serum. However, reducing the centrifugation duration to 5 minutes of plasma affected lipemic samples. The turbidity caused by lipemia interferes with certain laboratory tests (Simundic & Lippi, 2012). Tests affected by lipemia included, but were

not limited to phosphorus, creatinine kinase, total protein, alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, and latent iron-binding capacity. A separate experiment showed that lipemia decreased by 50% when centrifuged for 10 minutes (Koenders et al., 2012). Ultracentrifugation and micro-centrifugation procedures could remove lipemia from the sample (Simundic & Lippi, 2012). The conclusion was that scaling the centrifugation time to 5 minutes would not affect most analytical results and improved turnaround time (Koenders et al., 2012). The caveat of this conclusion was that laboratories should implement precautionary measures to monitor lipemic samples.

The lack of standardization of centrifugation speed on platelet activity prompted the need to investigate the effect of centrifugation speed on platelet activity (Merolla, Nardi, & Berger, 2012). Venous blood tubes from 10 healthy patients were centrifuged at 150, 200, 300, and 500 x g for 10 minutes. Results demonstrated that centrifugation speed decreased platelet count, mean platelet volume (MPV), and platelet aggregation at higher centrifugal speed. Decreased platelet count and MPV were the effect of higher numbers of platelets (small or large) removed from plasma caused by increased relative centrifugal force (RCF). Consequently, the removal of large platelets from the plasma caused decreased platelet aggregation. Standardization of centrifugation parameters for assessing platelet activities prevented ambiguous results (Merolla et al., 2012).

A precursor that promoted a study to appraise the effect of centrifuge temperature on enzymes and thyroid panel results was a problem with the electrolyte testing in their central biochemistry laboratory (Yilmaz et al., 2012). Technical staff reported gel contamination in serum separator tube. Initial investigation revealed that centrifuges

without temperature control might create heat, leading to the deterioration of the gel. The National Committee for Clinical Laboratory Standards (NCCLS) guidelines advised using temperature control for temperature sensitive analytes because centrifuges could create internal heat. A comparison of 42 patients (84 blood samples) in temperature controlled centrifuges and centrifuges without temperature control revealed the effect of centrifugation temperature on certain analytes. Results indicated that ALT and thyroid stimulating hormones values were significantly lower when spun in centrifuges without temperature control. However, free triiodothyronine and free thyroxine levels were higher in temperature controlled centrifuges. The authors warned that laboratories should be aware of possible internal heat production effects on analytical results.

Awareness of centrifugation variables is essential for producing high quality laboratory results. Variables such as centrifugation speed, time, and temperature could affect certain analytical results. Standardization of these variables would ensure laboratories are using the correct centrifuge parameters to decrease erroneous results.

Sample transportation. Sample transportation is a major contributor to delays of clinical laboratory results to inpatients and outpatients (Zaninotto et al., 2012b). Specimen transportation activities include duration of transportation, proper storage (time and temperature) of sample, packaging criteria and sample position during transport, identification of acceptability or rejection criteria of the samples and physical injury (Lippi & Simundic, 2012; Zaninotto et al., 2012a). Monitoring of these activities alleviated the reporting of inaccurate results resulting in detrimental effect on patient care (Funk et al., 2012). Proper transportation of blood specimens after collection ensured the

quality of sample (Rana, 2012). Some specimens required immediate transportation to the laboratory for testing while others required centrifugation and separation within 2 hours. The recommended position of sample transportation was in an upright position (Funk et al., 2012).

Increased pressure to reduce health care costs forced many organizations to centralize and consolidate laboratory activities (Plebani, 2012a). The economical and clinical advantages of consolidation and centralization of laboratory activities is still unclear (Da Rin & Lippi, 2014). Consolidation resulted in major changes to workflow and activities (Zaninotto et al., 2012a). Logistics of sample transportation is one area heavily affected by change in the health care landscape. With the centralization and consolidation of laboratory activities, the transportation of large numbers of specimens from satellite collection sites to core laboratories is more prone to errors. This change carries inherent risks for specimen integrity. The assurance of appropriate sample transportation procedure is important to preserve the integrity of the sample to produce high quality results.

Findings from the last few years exposed the effects of high speed pneumatic tube systems (PTS) (Plebani, 2012a). The adoption of PTS in medical facilities was meant to speed delivery of samples. The force exerted by PTS could cause physical trauma (i.e. hemolysis) to samples to some extent and change the concentration of some analytes as a result. PTS affected the results of certain analytes while others remained unchanged (Funk et al., 2012). A comparison between manual versus PTS sample deliveries signified that PTS added a significant bias to lactate dehydrogenase and magnesium test

results, while PTS did not affect other analytes (Sylte, Wentzel-Larsen, & Bolann, 2013). PTS may cause the cells to lyse and leak through the cell membrane resulting in interferences with the test results. The recommendation was for hand delivery of tests affected by rapid acceleration and deceleration forces in PTS.

Inappropriate temperature exposure during transportation, and delayed delivery of samples were two known variables that played a significant role in the quality of biological samples (Zaninotto et al., 2012a). Improper maintenance of samples at inappropriate temperature might accelerate degradation (Funk et al., 2012). For example, extreme exposure to inappropriate temperature could occur if staff leaves whole blood in laboratory collection boxes in the freezer or stored in a vehicle's trunk without proper insulation, and thus, produce inaccurate results. Many practitioners agreed to these facts, but the number of studies addressing the effects of these variables is nominal. This literature review found two studies exploring a remedy to address inappropriate temperature and prolonged transportation times (Zaninotto et al. (2012a; 2012b). The authors implemented an integrated transportation system, and studied the effectiveness of this system over a period of five years in one study (Zaninotto et al. (2012a). This system was comprised of secondary and tertiary containers, a temperature and time recording device, and a system allowing managers to determine the suitability of the samples based on a visual analysis. The integrated system allowed for monitoring the temperature of biological samples and transportation time throughout transportation, from the collection center to the core laboratory. A second comparative study analyzed the effectiveness of the implementation of the integrated system at reducing biases of six analytes (Zaninotto

et al., 2012b). Collection of data occurred before implementation (2007) and after implementation (2011) of the novel system. The study disclosed that improvement of the quality of samples resulted for thee of the six analytes after the implementation of the integrated system. Both studies took place at the University Hospital of Padova in Italy, and concluded that the implementation and monitoring of integrated transportation systems effectively optimized the transportation condition, prevented possible interferences, and improved preanalytical quality.

Sample transportation condition depends on the test ordered, distance, and time required between collection and analysis (Funk et al., 2012). Guidelines from the CLSI recommended the centrifugation of blood samples to remove blood cells from plasma or serum prior to transportation (Da Rin & Lippi, 2014). This process might prevent the deterioration of several analytes that could occur during transportation. There was evidence that prolonged contact of serum or plasma with blood cells can produce erroneous results with several analytes. The underlying assumption is that the integrity of centrifuged gel tube samples is intact if transported correctly. Determined to prove this assumption, two researchers performed a comparative study assessing the effect of transportation between centrifuged serum gel tube and lithium heparin gel tube (Da Rin & Lippi, 2014). There was consensus that centrifuged specimens were safe during shipment, but this study illustrated that ineffective transportation could compromise the integrity of the lithium-heparin gel tubes. Evidence from data collected from 30 random outpatient clinics indicated that serum gel tubes were a better choice for medium term transportation while lithium heparin gel tubes had the tendency to produce greater biases

in certain analytes post transportation. The recommendation was to centrifuge and aliquot samples prior to transportation to avoid significant physical trauma (Funk et al., 2012).

Failure to recognize the importance of specimen transportation can lead to unreliable test results affecting patient care. Implementation of an integrated transportation system could mitigate errors during specimen transportation and this method was relatively inexpensive (Lippi & Simundic, 2012). Another strategy to obviate errors during specimen transportation was to use serum gel tubes (Da Rin & Lippi, 2014). Another suggestion was to implement accurate standard operating procedures (SOPs) to standardize the processes in specimen transportation to reduce errors (Lippi & Simundic, 2012). Laboratories must implement, review, or revise their SOPs to ensure that their facilities are adhering to the proper guidelines to reduce preanalytical variables.

Quality Management

The beginning of the 21st century marked concerted efforts to improve patient care quality. It became a priority, and the focus, in all health care sectors (Allen, 2013). The 1999 publication of the U.S. Institute of Medicine report *To Err is Human: Building a Safer Health System* (Ram & Boermeester, 2013) prompted this movement. This report cited as many as 98,000 deaths each year from preventable medical errors. In 2002, Sir Liam Donaldson, the Chair of the World Health Organization's World Alliance for Patient Safety emphasized the importance of improving patient safety within laboratory medicine (Agarwal et al., 2012). Producing high quality laboratory results was a priority.

Quality in the laboratory is achievable through accreditation and quality management systems (Hammerling, 2012).

QMS is a tool used to control laboratory processes in a systemic and transparent way (Agarwal et al., 2012). Included in QMS are all activities involved with the operation (i.e. instruments, facilities, and people). QMS is also valuable to identify and implement strategies to ensure consistent high quality products (Munechika et al., 2014). Leaders adopted QMS to drive and sustain continual improvement through regular training and education of laboratory staff, introduction of automated technology, and internal audits at the work site (Bhat et al., 2012). This system encourages a quality oriented organizational structure and a positive work environment that benefits patients. Growing evidence affirmed that QMS has the ability to improve clinical operations as well as improve financial performance and increase employee satisfaction (Olofsson et al., 2013). QMS should have a quality assurance (QA) program and quality indicators (QIs) to monitor and ensure quality in a systematic way.

Quality assurance. QA is the systematic monitoring and evaluation of safe practices and it benchmarks practices from one laboratory against another to ensure that the operation is meeting the standards of quality (Plebani et al., 2014b). Accomplishment of laboratory QA is through accreditation, internal quality controls (IQC), and external quality assessment (EQA) (Berwouts et al., 2012). Accreditation ensures that laboratories have a system of standard procedures to perform theirs processes correctly to obtain quality results (Barth, 2012). The purpose of IQC is to monitor consistency over time and to minimize variation, determine expected distribution of values, calculate mean

and standard deviation, define limits for expected and unexpected results, and identify unexpected values (Lee, 2012). EQA provides a platform to assess laboratory performance by objectively comparing results from different laboratories (Berwouts et al., 2012).

Accreditation. The laboratory industry improved quality through efforts such as laboratory automation, laboratory consolidation, and accreditation of laboratories (Christian, 2011). As part of these efforts, accreditation played an important role in quality management. Accreditation was defined as the oversight of safe practices from accrediting organizations, comprised of professional groups, to ensure quality when delivering service (Hawkins, 2012). Accreditation is designed to monitor whether laboratories have standard procedures to perform their processes correctly to produce quality results (Barth, 2012). Organizations involved with measuring quality in laboratory services are the Clinical Laboratory Improvement Amendment (CLIA), the College of American Pathologist (CAP), The Joint Commission, and the International Organization for Standardization. These organizations work closely with one another to ensure quality in the laboratories.

The Centers of Medicare and Medicaid Services (CMS) is a governing organization regulating testing quality as required by CLIA (Hammerling, 2012). CLIA provides comprehensive standards for all laboratories to follow to assure quality standards in laboratory testing. The Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) emerged because of the media's attention to quality problems in medical laboratories (Christian, 2011). Prior to the enactment of CLIA 88, there was a lack of

regulation in laboratory services. Standards for qualifications of technical personnel, supervisors, and laboratory directors did not exist. Problems associated with unregulated laboratories include lower accuracy and unreliability of test results.

CLIA 88 provides a foundation for clinical diagnostic laboratory operations because all laboratories, regardless of whether they receive payment from Medicare or Medicaid programs, must have a current and valid CLIA certificate to test human specimens. CLIA 88 is the primary source of regulations addressing laboratory quality and quality assurance. The objective for establishing CLIA 88 was to ensure reliable and accurate laboratory testing with a concentration on quality controls, proficiency testing, credentials of laboratory testing personnel, requirements for result reporting, and appropriate documentation of standard operating procedures (Weiss, 2012).

CLIA 88 defined clinical laboratories as any facility analyzing human materials for providing information to clinicians for diagnosis, prevention, or treatment of any condition or assessing the health of human beings (Weiss, 2012). CLIA 88 specifies that all laboratories performing the same tests must follow the same standards or guidelines. CLIA 88 allows only qualified personnel to perform or supervise testing. CLIA 88 further subdivides personnel qualifications according to the complexity of testing. The program also defines requirements for laboratory directors and analytical staff according to laboratory category. CLIA 88 also mandates required periodic inspections by accreditation bodies (Howerton et al., 2010). CAP primarily leads the Laboratory Accreditation Program, but other accreditation bodies, including TJC and state health departments, also perform laboratory inspections (Weiss, 2012). CLIA 88 also requires

clinical laboratories to enroll and participate in External Quality Assessment (EQA) programs approved by the CMS.

CAP Laboratory Accreditation Program is an international accreditation program with the goal of improving quality in laboratory services through education, standard setting, and ensuring the compliance of regulatory requirements (Hawkins, 2012). Over 6,000 laboratories worldwide obtained accreditation from CAP. CAP's checklist questions are clear with their intent, and compliance to the checklist questions is a requirement to attain or maintain accreditation with CAP (Serteser et al., 2012). CAP also requires laboratories to produce evidence of compliance. CAP checklists are a specific discipline, and customized to each laboratory. The Laboratory General Checklist aims to monitor the preanalytical and postanalytical phases, as well as CAP laboratory safety goals.

CAP Laboratory General Checklist items are numbered. GEN.20348 monitors the preanalytical phase processes of accuracy of transmission of test orders, specimen transport and preparation, requisition accuracy, quality of phlebotomy services, and specimen acceptability. GEN.20364 deals with postanalytical activities such as accuracy of result transmission, turnaround time, and interpretation of results. Item GEN.20316 targets the preanalytical phase by requiring laboratories to have policies and procedures for patient or specimen identification, test order accuracy, specimen acceptability, sample labeling, and blood culture contamination.

Critical values are test results that could post a potential life-threatening situation if the laboratory does not report the value to the nurse or physician upon discovery.

GEN.20365 dictates that laboratories address CAP Laboratory Patient Safety Goals. CAP conducts onsite inspections every two years to ensure compliance to the checklists. Inspectors are practicing laboratory professionals using the checklists as a guideline. Review of the CAP checklists occurs on a continuous basis.

CAP also developed two programs, Q-PROBES and Q-TRACKS, to identify and monitor laboratory errors (McCay, Lemer, & Wu, 2009). Q-PROBES assesses all phases of laboratory testing while Q-TRACKS monitors process, outcome, health status, and patients' perception of quality. To help laboratories assess their competency, CAP is a provider of an EQA program. EQA directly compares methods and specific results of participating facilities using statistical analysis.

The Joint Commission International (JCI) is the international branch of TJC (Serteser et al., 2012). Since 1994, this branch has worked with health care organizations in over 80 countries to achieve patient safety. To obtain and maintain accreditation from JCI, health care organizations must implement the JCI International Patient Safety Goals (IPSGs) (Hawkins, 2012). JCI developed six IPSGs to promote improvement in patient safety. The first two IPSGs specifically targeted the preanalytical and postanalytical phases of TTP. The first, IPSG 1, requires organizations to define a process to identify patients accurately. This goal alleviates misidentification errors that could result in inappropriate diagnosis or treatment. One in 18 misidentification errors resulted in adverse patient experience (Hawkins, 2012). JCI requires the verification of two forms of identification when collecting or dispensing blood for clinical use. IPSGs expect laboratories to develop a process to communicate effectively between caregivers. This

goal applies to the preanalytical and postanalytical phase where communication is important to quality improvement. Preanalytical and postanalytical phases involve different care providers, including but not limited to, doctor, nurses, and laboratory personnel. Communication between these caregivers is essential to improve patient safety. In particular, this goal mandates defined policies and procedures for verbal and telephone requests and the read back of critical test results. Policies and procedures for verbal and telephone requests and read back of critical test results must include entering the order into a computer, reading back the order, and confirmation of what was written down and read back. These IPSGs force health care organizations to define processes to improve quality in laboratory practices. In addition to these IPSGs, onsite inspections take place on a three year cycle to ensure that laboratories can produce evidence of compliance.

ISO 15189 is an international accreditation organization that specifies quality and competence requirements for medical laboratories (Serteser et al., 2012). ISO 15189 has standards that address preanalytical, analytical, and postanalytical processes. To meet the standards, laboratories must have complete procedures for all processes for TTP, and these procedures should be available to staff performing the tasks (Allen, 2013). ISO 15189 requires laboratories to implement preanalytical procedures for ordering tests, patient identification, collection of primary sample, transportation of samples, and storage of samples. The requirements for the analytical phase include validation of all procedures prior to implementation by comparing the results with already validated procedures and training staff to perform the test and to trouble-shoot. Review of

procedures must occur periodically. Postanalytical requirements are procedures for reviewing and releasing results, proper storage of samples for repeat testing, and patient report. ISO 15189 requires laboratories to adopt continual improvement by systematically reviewing laboratory procedures for sources of nonconformity and opportunities for improvement. To summarize, implementation of ISO 15189 has the potential to contribute to patient safety by providing a foundation for quality with their defined standards targeting laboratory practices.

Quality controls. Quality controls (QC) are operational techniques and activities used to fulfill requirements for quality assurance (Lee, 2012). The intent of QC in the laboratory is to monitor the performance of test procedures to ensure accurate results and to alert when potential failure might occur (Ceriotti, Brugnoni, & Mattioli, 2015; Njoroge & Nichols, 2014). Measurement of QC is a means to detect systematic errors and to prevent laboratories from releasing erroneous results. QC includes all activities performed to assure continuous monitoring of the performance of the analytical system and to alert when an analytical process fails to meet the predefined analytical goals (Ceriotti et al., 2015). ISO 15189 requires laboratories to developed QC procedures designed to ensure precision and accuracy of test procedure.

When developing QC procedures, CLSI C243-A3 outlined several required steps (Ceriotti et al., 2015). The steps involved are (1) define the quality specification for the test, (2) select the appropriate control material, (3) determine the performance characteristics of the measurement procedure, (4) identify which QC material to use, (5) predict the possibility that the QC material will be out of specification performance, (6)

specify expected goals of QC performance, and (7) select QC material with performance that meets or exceeds the QC performance goals. The steps described above provide a guide for laboratories to follow when developing and implementing QC procedure.

Liquid QC material is a common way to monitor the performance of an analytical system (Njoroge & Nichols, 2014). Liquid QC is effective in detecting errors caused by incorrect technique by the operator or incorrect reagent preparation affecting QC and patient results. Laboratories test QC material in the same manner as patient samples. Standard operating procedure should outline the frequency, QC performance, control rules, and acceptable ranges. SOP should also describe acceptance and rejection criteria for QC results. The frequency of performing QC should conform to regulations set by the accreditation agencies. When QC result is out of range, and deemed as unacceptable, the laboratory cannot analyze or release patient test results. Operators are to monitor the QC data for shifts and trends to detect potential issues with the instrument or reagents.

One limitation of liquid QC includes the inability of the material to detect random and unpredictable errors such as hemolysis or lipemia (Njoroge & Nichols, 2014). Another limitation is the inability of liquid QC to detect preanalytical errors such as specimen mislabeling or postanalytical errors such as incorrect result entry. To mitigate the risks posed by liquid QC, various test systems employed alternative QC strategies in addition to liquid QC. New laboratory instruments incorporated bubble, clot, and hemolysis electronic check into the test system to address these possible errors. Some point of care systems incorporated internal quality control into the test devices to ensure test results were accurate.

Previous studies indicated that regulatory bodies, laboratory professionals, and the diagnostic industry focused on improving errors in the analytical phase of testing (Plebani, 2013). Errors in this phase of testing significantly decreased because of strict controls using QC materials. In the 1950s, the introduction of QC for the analytical phase aimed to ensure quality. Laboratory workers dedicated themselves fully to improve quality in this phase (Majkić-Singh & Šumarac, 2012). With analytical errors in check, laboratories need to shift the paradigm and implement QC for the preanalytical phase of testing. Although practitioners call attention to QC in the preanalytical phase, the literature review exposed an apparent gap because QC programs targeting the preanalytical phase are nonexistent.

External quality assessment. Accreditation bodies require medical laboratories to participate in an EQA program (James et al., 2014). EQA programs are useful to assess quality assurance in medical laboratories (Berwouts et al., 2012). Laboratories must participant in EQA schemes to maintain accreditation. The majority of laboratory professionals worldwide consider EQA and Proficiency Testing (PT) to be the same (James et al., 2014). Objectives for EQA and PT are different, though laboratory experts use these terms interchangeably. EQA focus on self-assessment and continuous improvement of quality for the benefits of the patients. PT, on the other hand, is a program where participating laboratories receive and analyze results with those of their peer group. For the purpose of this literature review, the term EQA represents both terminologies.

EQA serves as a tool for medical laboratories to confirm when tests are performing correctly, to alert when potential issues with the test arise, and to confirm when a test is performing well (Jones, 2015). EQA programs assess accuracy, precision, bias, analytical specificity, interferences, units, reference intervals, calculation, and interpretation of an assay. EQA and PT serve to provide reliable information to allow laboratories to assess and monitor the quality status of internal procedures and processes, the suitability of diagnostic systems, the accountability and competence of the staff, and uncertainty in laboratories results. The correct use of EQA could result in improvement of laboratory performance. EQA allows laboratories (1) to analyze appropriately and investigate root causes producing unacceptable results, (2) to detect trends of laboratory bias that might not be apparent from a result, and (3) to determine whether the problems could affect clinical decision-making. Participating laboratories, professional organizations, health-care providers, and health funding bodies view EQA data to judge the competence of laboratories. Manufacturers also use this data to monitor the analytical performance of their tests, post market release. The availability of proficiency testing results allows the public to assess the performance of a particular laboratory (Christian, 2011).

EQA programs should select samples appropriately to reassure laboratories that their test has the potential to achieve the highest standard of quality (James et al., 2014). Samples should mimic actual patient samples. Samples included in EQA should represent an appropriate range of values that could affect clinical decision. Participating laboratories should incorporate EQA samples into the normal flow of patient samples.

EQA requires laboratories to treat specimens as routine samples, and specifies that the government has the authority to perform onsite inspection to ensure equal treatment of all samples.

Multiple benefits of EQA programs include improving patient safety, minimizing test bias and imprecision, identifying interference substances across multiple methods, identifying laboratories with subpar performance, and satisfying requirements for accreditation and regulatory bodies. The effectiveness of EQA programs depends on two factors: the design of EQA schemes, and the procedures laboratories used to evaluate samples. Studies demonstrated laboratories participating in EQA showed improved laboratory performance. Laboratories can use the results provided by the programs to investigate the root causes of defects and implement effective measures to eliminate errors.

The steps involved with EQA programs are (1) the EQA provider prepares and distributes the samples to participating laboratories, (2) laboratories analyze the samples and submit the results to the EQA provider, and (3) the EQA collates the results and sends out reports to the participating laboratories (Jones, 2015). Then a designated laboratorian, with appropriate competency to review the results, takes appropriate actions to resolve incorrect responses (James et al., 2014). For example, laboratories need to investigative and correct action plans if the laboratory exceeds the total allowable error (Njoroge & Nichols, 2014). This signifies a possible drift of the test system when compared to their peers. To maintain CLIA certification, laboratories must successfully pass EQA for specific analytes with a score of at least 80% (Howerton et al., 2010). If a

laboratory fails to achieve satisfactory performance for any analytes on two consecutive challenges, CLIA can sanction the laboratory.

Existing EQA programs target the analytical phase, and programs addressing the preanalytical phase are scant (Kristensen, Aakre, Kristoffersen, & Sandberg, 2014). The challenge for accreditation bodies to develop EQA programs targeting the preanalytical phase is that many processes occur beyond laboratory walls. The preanalytical phase involves various locations, as well as health care professionals, and the laboratory does not have direct control of these. EQAs focusing on the preanalytical phase are in the development stage. Three types of preanalytical EQAs in development include Type I, Type II, and Type III. Type I involves the circulation of questionnaires asking laboratories to explain the proper procedures for handling certain aspects of preanalytical processes. Type II circulates samples containing a matrix (i.e. hemolysis, lipemic, or icteric) with the potential to interfere with results. Type III reports errors or adverse events. Actual reporting of analytical errors will provide laboratories with a platform to gauge the challenges faced by their peer group (Lippi et al., 2015). The three types of EQA have different focuses, but a combination of the three is probably necessary to detect and monitor the broad spectrum of preanalytical errors.

Another aspect to include in the EQA scheme is to provide a feedback report for all types for comparison of laboratory results to all participants. Included in the feedback report is an overview of existing guidelines or recommendations, as well as strategies to minimize errors. Challenges to developing EQA programs for the preanalytical phase exist; EQA organizations must make efforts to develop these programs because this phase

is more prone to errors than the other phases of TTP.

Accreditation, QC, and EQA are important programs for assessing quality assurance in medical laboratories. The CLIA, CAP, TJI, and ISO 15189 have the capabilities to guide clinical laboratories with quality assurance. Accreditation ensures that laboratories are performing all their processes correctly (Barth, 2012). QC and EQA programs allow laboratories to measure, monitor, and improve their analytical performance in a systematic way through a period to time (Plebani, Sciacovelli, Marinova, Marcuccitt, & Chiozza, 2013b). These programs provide medical laboratories with a means to benchmark their performance based on objective data.

Quality indicators. Much of the research into quality measurement focused on the use of quality indicators. Setting high quality standards in laboratory medicine is essential because clinicians used results generated by laboratories in diagnosing and treating patients (Hammerling, 2012). Developing and implementing reliable QIs can facilitate the achievement of quality of laboratory services (Plebani et al., 2013a). All laboratories should establish QIs to monitor their processes and assess possible errors (Majkić-Singh & Šumarac (2012). QIs are primary tools allowing users to measure and monitor quality improvement by comparing it against defined criterion (Plebani et al., 2013b). When implementing QIs, users can choose from two types of QIs (Barth, 2012). The first type monitors progress and improvements as well as possessing a system to investigate and correct errors when they occurred. These indicators include operational metrics and comparing results with peer groups. The second type of QI monitors turnaround time, test costs, and complaints. These indicators aim to evaluate

performance management and accountability. Collection of QI data should be sufficient to identify, correct, and continuously monitor defects and implement corrective or preventive actions (Plebani et al., 2013a). QIs are only effective with useful outcomes if there is clarity when delivering objectives and goals (Barth, 2012). QIs should be part of the quality improvement strategy. The design of QIs should include metrics that meet the requirements for the needs for improvement and performance management, and be measurable.

QIs allow laboratory managers to quantify the quality of their services (Plebani, Sciacovelli, Aita, Padoan, & Chiozza, 2014c). Current QIs concentrate on the analytical processes to monitor performance and efficiency of the operational processes (Barth, 2012). An apparent gap in laboratory quality management is the lack of concentration on the preanalytical phase, though there is insurmountable evidence that the majority of errors occurred in this phase (Lima-Oliveira et al., 2012). Correction of preanalytical errors requires laboratories to identify QIs in the preanalytical phase. The lack of standardization of phlebotomy is an important aspect where applying proper technique will ensure high quality results. An awareness of the importance of preanalytical phase will prompt expansion of national and international quality assurance programs to address quality issues in this phase (Guder, 2014). There is a need to develop an international standard of QI that will cover the entire spectrum of TTP (Plebani et al., 2013a). Traditionally, QIs in preanalytical errors include sampling errors that were composed of rejected samples, patient wristband misidentification, timing errors in sampling and preparation, inappropriate sample transport, and inadequate sample (Atay et

al., 2014). However, QIs expanded to include appropriate test request and complete request forms (Plebani et al., 2014c).

Accrediting bodies shifted their focus to measure quality indicators. In the U.S., the Division of Laboratory Systems in the Center of Disease Control (CDC) drives the initiative to improve quality in laboratory medicine (Barth, 2012). Their goal is to examine clinical quality and develop best practice guidelines. There was a pilot program testing a new method to promote quality improvement in laboratory medicine. This group identified 14 QIs in laboratory medicine to prevent errors. These included test order appropriateness, wristband identification errors, patient satisfaction with phlebotomy, specimen quality, proficiency performance, cervical cytology-histology mismatch, availability of inpatient results, corrected laboratory reports, critical value reporting, turnaround time, clinician satisfaction, and follow up of abnormal cervical cytology. The CDC encourages continuous collaboration between laboratory professionals to identify good practices. ISO 15189 also recognizes the importance of QIs to evaluate, monitor, and improve procedures and processes in the preanalytical phase (Plebani, 2014). QI could also identify errors and non-conformities occurring in all steps involved with preanalytical phase. In 2008, The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) introduced a working group known as Laboratory Errors and Patient Safety (WG-LEPS) with the sole purpose of identifying and evaluating applicable QIs in all phases of testing (Plebani et al., 2013b). According to WG-LEPS, the QI developer should consider four criteria. The first criterion requires QI to be relevant and applicable to all clinical laboratories on an international level. The

second requires it to focus on important medical laboratory quality issues based on scientific evidence. The third notes that QI should be measurable, with available data and defined acceptable thresholds. The fourth requires QI to serve as a measure of laboratory improvement. WG-LEPS developed the model of quality indicators (MQI) as a tool to promote investigation into errors in laboratory medicine, to collect data available on this issue, and to recommend strategies and procedures to improve patient safety (Plebani et al., 2013a). MQI consists of 56 quality indicators, of which 34 are for the preanalytical phase, seven for the analytical phase, and 15 for the postanalytical phase (Lippi et al., 2013b). The purpose of MQI is to provide a standardized structure for laboratories worldwide to report and collect comparable data. MQI also allows laboratories to analyze quality issues that could have potential effects on patient care.

In summary, QIs are fundamental tools that could provide sound evidence of quality in all procedures and processes in TTP (Plebani, 2012a). Quality indicators are useful to identify, address, and monitor performance measures in the testing process. A study indicated that there was a reduction of preanalytical and postanalytical errors after the completion of training on quality indicators (Agarwal et al., 2012). Errors dramatically dropped for errors in the pre-analytical phase and showed almost 100% improvements in the post-analytical phase after training. By identifying and monitoring problems, the clinical laboratory can develop improved processes to enhance patient safety. Quality indicators are effective tools in assessing and maintaining quality control in a systematic and transparent way. However, the success of implementing and monitoring QIs depends on the active involvement of all personnel performing the

preanalytical processes. Implementation and monitoring will require extra resources initially, but the reward will be the reduction of risk in errors, waste, and operation repetition (Plebani et al, 2014b).

Various organizations developed QIs to monitor continuous improvement activities aimed at alleviating errors in TTP. However, a disconnection between organizations resulted in different meanings of QIs with different goals. In particular, QIs in the preanalytical and postanalytical phases need further efforts from these organizations to achieve consensus in developing, implementation, analyzing, and monitoring of QIs. With different organizations launching their own version of QIs, laboratory professionals need to standardize current initiatives and terminologies, and develop QIs to address errors occurring in all processes of TTP (Plebani et al., 2013). The implementation of QIs is an essential component to monitoring continuous quality improvement programs (Plebani et al., 2014b). Quality indicators are useful for highlighting critical processes, analyzing root causes of nonconformity, reducing risk for errors, and improving laboratory performances.

Summary. Quality management of the preanalytical phase is achievable through consistent and continuous application of an evidence-based approach (Plebani et al., 2015). Evidence based approaches require laboratories to closely monitor their processes, implement a system to detect errors, and perform root cause analysis when the same error occurs frequently. QA and QI are two avenues that can aid medical laboratories in monitoring quality in their organizations. QA activities such as accreditation, QC, and EQA can provide laboratories with platforms to assess their

performance against the accreditations' defined standards and benchmark their performance with peer groups. QI can provide medical laboratories with fundamental tools to quantify their quality. As discussed above, apparent gaps exist pertaining to the quality management activities for the preanalytical and postanalytical phases. The medical laboratory industry needs to shift the focus of quality from the analytical phase to TTP. Total quality is achievable if quality management activities encompass all phases of TTP.

Possible Preventive Measures

Errors in health care that resulted in premature patient deaths are unacceptable, especially with cases where the medical error was preventable (Simundic et al., 2015). Laboratory errors can lead to diagnostic errors and reports indicated that laboratory contributed to approximately 40% of diagnostic errors. This literature review exposed two themes of possible preventive measures to mitigate preanalytical errors: harmonization and technological advancement. The harmonization of laboratory results occurs when results are comparable, regardless of the method used to measure the analytes (Miller, Tate, Barth, & Graham, 2014). Technological advancement is the use of technology to eliminate or minimize manually intensive processes.

Harmonization. The majority of laboratory errors occur in the preanalytical phase. The high prevalence in the preanalytical phase is the result of processes occurring outside of the laboratory, the involvement of numerous professions, inconsistent procedures, and low compliance with procedures. The fragmented practices of the preanalytical phase are in need of standardization and harmonization to mollify errors in

this phase. The laboratory industry has developed and implemented standardization and harmonization initiatives for the analytical phase (Aarsand & Sandberg, 2014). It's time to shift the paradigm to standardize and harmonize preanalytical phase processes. International and national organizations recognized that harmonization initiatives are essential to improving processes in the preanalytical phase. Any initiative will take the collective efforts of all stakeholders involved.

International efforts. International efforts to harmonize preanalytical phase activities are limited, and there is opportunity for improvement in the medical laboratory profession in this phase (Miller et al., 2014). Organizations that can potentially influence harmonization on an international level are European Federation for Clinical Chemistry and Laboratory Medicine (EFLM), the American Association of Clinical Chemistry (AACC), IFCC, and Consortium for Harmonization of Clinical Laboratory Results (ICHCLR). Efforts implemented by these organizations, and regulatory accreditation bodies such as ISO can help with harmonization by developing standards to guide the laboratories (Miller et al., 2014). ISO 15189 requires that laboratories develop, implement, and monitor QIs for all phases of TTP.

The EFLM has special interest to address harmonization in all processes of TTP (Simundic et al., 2015). Their goal is to contribute to the improvement of the quality delivered by laboratories. In efforts to achieve harmonization in the preanalytical phase, the EFLM and its Working Group for Preanalytical Phase (WG-PRE) decided to be the catalysts on several international projects (Lippi et al., 2015). Issues addressed by WG-PRE include test request, test selection, appropriate training, sample handling, and

application of QIs. EFLM believes that harmonization of the preanalytical phase will reduce the potential risk of errors and improve patient safety. EFLM is also soliciting the collaboration of laboratory professionals, health care practitioners, manufacturers, and accreditation bodies on the journey toward harmonization. The goal of EFLM is to encourage these groups to define a universal, acceptable, and applicable standards, and global implementation. EFLM will facilitate dialog between all interested parties. Interested parties have the opportunity to participate with the establishment of standardized procedures for preanalytical processes and help accreditation bodies to update existing recommendations. In contrast to the AACC's harmonization projects for the analytical phase, EFLM is raising awareness for the need of harmonization in the preanalytical and postanalytical phases of testing. EFLM established a new Working Group for Harmonization of TTP (WF-H) to achieve this goal. To achieve this goal, WF-H has to identify the critical areas that need harmonization. WF-H needs to be the coordinator and facilitator for initiatives on a national and international laboratory community. They also have to be the bridge between other working groups within EFLM and ISO organizations.

Another organization with a longstanding commitment in this area is the IFCC (Miller et al., 2014). The IFCC developed MQI to provide a standardized structure to report errors in the laboratory and to promote investigation when errors occurred (Plebani et al., 2013). Ongoing projects from IFCC WG-LEPS will provide external databases for comparison between laboratories and peer organizations (Plebani et al., 2014a). The realization of laboratory goals and improvements in performance are reachable with these

data. Current harmonization activities reached three agreements pertaining to QI values (Plebani et al., 2014c). First, QIs are an essential tool for quality improvement. Second, there is a need to comply with the current defined QIs. Third, there is consensus that IFCC MQI is the initiator in the laboratory industry to standardize QIs. The current MQI allows laboratories to select the most appropriate indicators applicable to their practices. The future goal of WG-LEG is to promote a set of approved QIs and to collect data from international laboratories to share the occurrence, root cause of laboratory errors, and appropriate corrective actions, as well as monitoring the effectiveness of improvement activities.

The formation of ICHCLR in 2013 was in response to the lack of coordination and prioritization of harmonization activities to meet the needs of laboratory medicine globally (Miller et al., 2014). ICHCLR was to provide a systematic approach to prioritize critical areas in need of harmonization based on clinical significance and technical feasibility, to act as liaison on global harmonization activities to avoid duplicate efforts, and to develop standardize procedures. The ICHCLR website serves as a platform for interested parties to obtain information on harmonization activities conducted by organizations worldwide. Any interested party may become an active participant in harmonization projects.

Preanalytical harmonization projects. The implementation of standardized analytical techniques and reagents, advancement in instrumentation, and information technologies resulted in a ten-fold reduction of analytical errors (Plebani et al., 2014c). The lack of attention to the preanalytical phase allowed errors to flourish in this phase.

The reason was that some procedures were not within the control of the laboratory. Focus needs to change to be patient-centered; where both clinicians and laboratorians work to develop safeguards to prevent errors. There is a need to develop fundamental procedures and processes to guide clinicians and laboratorians to perform processes correctly. Primary preanalytical phase processes in need of harmonization include appropriateness of the test requests, correct patient identification, sample handling, and QIs.

Test requests. Test requests are an area that has potential for harmonization (Aarsand & Sandberg, 2014). The lack of standardization in tests to order for prevalent diseases resulted in mismanagement of tests to diagnose patients. From this lack of standardization, clinicians were unclear on test availability and the composition of test profiles for different clinical conditions (Tate et al., 2014). Mismanagement of tests affects finance, with increased costs for reagents, consumables, and human resources for unnecessary consultations, treatments, and investigations (Plebani & Panteghini, 2014). Laboratory leaders in various organizations on the national and international arenas are addressing ways to harmonize test profiles for specific disease. Laboratories can also influence the test request order by providing physicians with test order forms with predefined tests that can optimize the use of laboratory resources from both a medical and economic viewpoint (Aarsand & Sandberg, 2014). One strategy is to develop predetermined test profiles for doctors according to the specific clinical situation. For example, if the patient has signs and symptoms of a myocardial infarction, the physician can order a test profile to diagnose this condition without wasting time and money on

inappropriate tests. Another strategy is for laboratories to develop a system according to problem-based requesting with algorithms for reflexive and reflective testing. For example, if CBC results indicate that the patient might have thalassemia, the system would order additional tests according to the predefined algorithms. Algorithms could also prevent the order of repetitive testing. Another strategy is to standardize the nomenclature for test procedures because of the growing adoption of computer systems to order tests (Miller et al., 2014). Common terminologies would minimize the confusion of which test to order, and provide a menu that would be the same, regardless of health care organization. This would enable physicians to be consistent, and efficient, when seeing patients at different institutions.

Several organizations released initiatives to harmonize laboratory test selection. EFLM Working Group on Guidelines is working on a systematic way to harmonize test selection according to the clinical presentation (Tate et al., 2014). The initiative launched by the United Kingdom Quality and Outcomes Framework (QOF) set certain minimum standards for testing activities with financial incentives (Lippi et al., 2015). This initiative helped avoid under-testing, but there was a lack of initiatives to address over-testing. Efforts by the Catalonian Health Services developed a project to assess the management of laboratory demands (Lippi et al., 2015). The variability of laboratory use is wide and there is a need to standardize this demand. Strategies used to enhance use are education and web site ordering for tests. As part of the core curricula, medical and nursing universities are teaching the fundamental use of laboratory resources. The adoption of software to order tests helps facilitate access to information and training,

communication of test cost, test request according to patient clinical presentation, and reduces or eliminates duplicate testing.

Test identification and sample handling. The most prevalent number of errors occurring in TTP are patient identification and sample handling (Aarsand & Sandberg, 2014). IFCC suggested the percent of patient identification errors should be less than 0.4%. Procedures for proper patient identification can achieve harmonization through guidelines and standards. ISO Technical Committee 212 is developing a document addressing the quality practice in collection and submission of samples for laboratory testing.

Harmonization of specimen collection and transportation could reduce variability of results (Miller et al., 2014). Collection of samples in proper containers with the correct specified amount reduces the risk of producing erroneous results. Proper specimen transportation conditions preserve the integrity and stability of the samples. Existing recommendations for specimen collection and transportation are inadequate, or incomplete, making it difficult for laboratories to relay the guidelines to care providers. The lack of standardization of specimen collection and transportation procedures contributes to varied and erroneous results. Harmonization of specimen handling is achievable through EQA organizations (Aarsand & Sandberg, 2014). Specimen handling includes sample material, preparation, sample collection, sample stability, and transportation of sample transportation.

EQA organizers can distribute samples to assess the laboratory's ability to handle samples. The ELFM-WG is addressing the standardization of sample collection

procedures to minimize uncertainty during the preanalytical phase (Tate et al., 2014). The success of harmonization activities is possible through monitoring. EQA is one method that monitors harmonization activities. EQA has the ability to detect any systematic drift in assay performance by comparing patient results with the peer groups (Tate et al., 2014). To monitor harmonization efforts and effects, EQA organizations are a natural choice in most settings, either by expanding existing schemes to assess other relevant phases of the TTP or by setting up new scheme (Aarsand & Sandberg, 2014).

Quality indicators. IFCC-WG is leading efforts to identify QIs for the global program of continual improvement (Tate et al., 2014). Quality indicators provide laboratorians with tools to measure the quality of selected activities by comparing against the benchmarked criteria (Plebani et al., 2014a). ISO 15189 mandates accredited laboratories to develop QIs to monitor and evaluate the performances of all aspects of TTP. ISO 15189 also stressed the need to assess QIs periodically for continued appropriateness. Although laboratories complied with this requirement, the different methods used to identify and manage QIs make it impossible to compare the results. Harmonization of QIs allows laboratories to compare themselves against their peers to ensure the deliverance of quality care. Accredited laboratories need to provide evidence of implementation of QIs because QIs are the tools used to assure risk management and promote patient safety (Plebani et al., 2014b). Although risk management assessment is a requirement of ISO 15189, laboratories need to select appropriate QIs to implement from the beginning, and to monitor the effectiveness of these QIs over time.

Harmonization of QIs needs to commence with the clear definition of QIs and to

minimize the variety of existent QIs (Plebani et al., 2014b). Criteria for developing QIs should be patient centered to promote quality and patient safety, consistent with definitions of laboratory errors, consistent with accreditation organizations requirements, applicable for promoting corrective or preventive actions, and address errors in all phases of TTP. Once identified, to manage the defined QIs other issues to consider are the standardization of systems for comparability between different laboratories and collaboration between operators, within and outside of the laboratory. The consensus among experts in the field is that harmonization of QI is achievable. Active involvement between the physicians, phlebotomists, and nurses will improve the appropriateness of test requests as well as the quality of samples (Plebani et al., 2014c). Validation of QIs requires international consensus of criteria and management methods. Accreditation providers will play a role in assuring laboratories are interpreting and applying ISO 15189 QIs requirements correctly. To encourage laboratorians to use QIs to measure quality, accreditation and international laboratory professionals should provide clear definition of QIs, and reward staff if applied correctly during survey visits.

Monitoring QIs performance in TTP will allow measurement and improvement of quality of services (Plebani et al., 2014a). MQIs developed by the IFCC are a starting point in promoting harmonization (Lippi et al., 2015); further efforts are needed to reach a consensus on the roadmap for harmonization. Harmonization requires the collaboration and active cooperation between health care providers from inside and outside of the laboratory. As ongoing progress with harmonization continues to evolve, laboratory leaders should advocate for the benefits of QIs as a tool to improve laboratory services

and patient safety. Raising awareness of the importance of QIs as a quality improvement tool is necessary to enhance laboratory services and patient safety.

Summary. Evidence shows that in the last four decades, there have been ongoing efforts to harmonize laboratory processes and there is a continuous movement toward this (Plebani & Panteghini, 2014). Relevant projects launched by various organizations demonstrated that these projects play a pivotal role in the quality of laboratory medicine (Tate et al., 2014). Harmonization might be a primary contributor to high quality in laboratory testing (Aarsand & Sandberg, 2014). To date, the majority of the focus has been on the processes within the laboratory because these processes are easier to control. Harmonization goals should be applicable to all laboratory disciplines, from test request to communication of result, and require equal consideration (Tate et al., 2014; Aarsand & Sandberg, 2014). Harmonization of operation procedures also has the potential to reduce errors and improve patient safety (Tate et al., 2014).

The likelihood of successful harmonization will depend on the cooperation of laboratories, organizations, and stakeholders from the laboratory and clinical fields (Aarsand & Sandberg, 2014). A system to identify and monitor errors must be in place prior to the development of harmonization initiatives. Another aspect to consider is how to standardize reporting laboratory errors and the implementation of corrective actions for these errors. Harmonization of these activities should improve quality in laboratory medicine. The success of harmonization will require collective efforts from national and international stakeholders (Tate et al., 2014). Development of harmonization initiatives will require close interaction between stakeholders in the clinical laboratory community,

diagnostic industry, clinicians, professional societies, IT providers, consumer advocate, and government industry. Achieving harmonization is a journey that will require well defined, and evidence based, procedures, transparent operations, effective communication, collaboration with all stakeholders, and cooperation from all participants (Plebani & Panteghini, 2014). To achieve this goal, there is a need for the involvement of organizations such as EFLM to facilitate the dialog between the different groups, with the intent to reach consensus in preanalytical standards (Simundic et al., 2015). Invited stakeholders participated in the establishment of universal standards for the preanalytical phase. The collective efforts should include accreditation bodies for their participation to incorporate the agreed upon standards into their required guidelines.

Acceptance of the initiatives will depend on effective communication and marketing strategies (Tate et al., 2014). Communication and marketing strategies should explain the relevant changes and educate clinicians on the initiatives. Better communication and collaboration between laboratorians and clinicians are essential for the success of harmonization initiatives (Plebani & Panteghini, 2014). The rift between these professions affects patient safety, and harmonization is a possible solution to bridge the professions through standardized terminologies and procedures for TTP.

The speed to achieve harmonization will be faster for some processes, where standardization and harmonization are already in progress (Aarsand & Sandberg, 2014). Any harmonization initiative addressing quality in laboratory medicine will require resources and funding. Experts also noted that harmonization is easier to achieve in certain parts of the world. Harmonization of the TTP will be a challenge for the

international laboratory community in the years to come (Aarsand & Sandberg, 2014). For the benefit of patients, laboratory medicine must deliver optimal care without potential harm. Substantial efforts are underway to advance the science and the technical processes to achieve harmonization (Miller et al., 2014). Monitoring the adoption of harmonization is also necessary to determine if it is effective (Tate et al., 2014). There is a need to support and organize these efforts on a global scale to deliver cost effective and clinically optimized laboratory medicine services.

Technological advancement. Technological advancements provide laboratories with tools to produce high quality results while improving efficiency (Lippi, et al., 2014). Automation involves the use of machines, control systems, and information technologies to improve productivity (Lippi et al., 2014). Modern technological advancements in laboratory medicine make it possible for laboratories to meet the demand of increasing test requests, while providing quality performance and timely test results (Plebani et al., 2014b). The drivers for automation include opportunity to simplify, reduce, or eliminate repetitive, complex, and harmful processes that require human intervention. An advantage of automation is its ability to produce results with a high degree of precision and accuracy. Many clinical laboratories adopted automation to reduce variability with sample identification, sorting, centrifugation, decapping, aliquoting, recapping and other specimen processing processes. Advantages of automation are prevention and reduction of human errors, process streamlining, consistent operating procedures, improved productivity and throughput, improved turnaround time, improved patient and operator safety, traceability of sample and data, and decreased operational costs while achieving

full compliance with regulatory certification or accreditation procedures. Automation experiments addressing preanalytical processes include computerized systems to address test ordering and misidentification, laboratory automation systems (LAS) to address specimen handling and transportation, and barcoding to identify misidentification.

Computerized systems. Computerized systems have capabilities to help laboratories achieve error reduction in the preanalytical phase as well as decrease operational cost. Implementation of computerized order entry can reduce preanalytical errors (Hammerling, 2012). Clinicians can order tests directly through the computerized order entry system, rather than by assigning a second person to transcribe orders; creating the potential for errors. Laboratory information systems have the capability to perform delta checks on patient results (Njoroge & Nichols, 2014). Delta checks are a preventive measure used by laboratories to detect significant differences between the current and previous test results for the same patient. Delta checks will flag and hold the questionable result for operator review before release. This process is useful in detecting preanalytical errors including mislabeled samples or incorrect patient identification.

Patient specimen and laboratory testing identification errors are the two leading causes of laboratory errors (Snyder et al., 2012). Patient identification errors are preventable and have the potential to cause patient harm. Eradicating patients' misidentification would improve patient safety (Salinas et al., 2013). International organizations recognized that errors with patient identity could produce serious harms to patients if not prevented. Errors contributing to misidentifications are mislabeling tubes or the misidentification of a patient. One root cause of error in patient identification is

incorrect demographic data entry. The authors conducted a study to explore the frequencies and consequences of incorrect demographic data in LIS. Clients had the option to order the test via an electronic ordering system or manually. For one year, two administrative assistants compared demographic data in the LIS to the one on the paper request form to detect potential identification errors. Errors occurred less frequently with electronic orders (Salinas et al., 2013). Placing test requisition into an electronic system could help minimize errors with patient identity.

Automation, databases, and computers improved productivity by eliminating tedious tasks, with substantial process improvement also creating a positive effect on patient safety (Lippi et al., 2014). Unfortunately, technological advancements cannot eliminate all errors occurring in laboratory medicine. One area that implementation of technological advancement is not possible is in phlebotomy. Phlebotomy is a manual process (Lillo et al., 2014). However, establishment of certain strategies to minimize phlebotomy errors is possible. Lillo et al.'s study indicated an improvement in missing samples after the introduction of a new process in the LIS (2014). The new program allowed the LIS to have the capability of printing custom labels, which correlated with each test request and corresponding tube. Results indicated that a customized label system has the ability to avoid missing samples by printing labels according to test requests. This technological advancement minimizes the potential of oversight from the phlebotomists. The study also revealed that patient satisfaction, with respect to phlebotomy, improved after the implementation of the custom label system. Another strategy is robotic working stations to provide a set of labeled blood tubes on a single tray

per patient to prevent misidentification (Hammerling, 2012). Automated phlebotomy could minimize error in tray preparation.

Laboratory automated systems. In response to pressures to reduce operational costs, improve quality, and to meet the demand of increased workloads, many medical laboratories are migrating toward automating many of their processes (Sedille-Mostafaie, Engler, Lutz, & Korte, 2013*)*. In the early 1990s, the laboratory industry realized that total laboratory automation (TLA) was the optimal solution to handling high throughput of samples, labor shortages, and decreased operational costs (Sedille-Mostafaie, Engler, Lutz, & Korte, 2013). Although TLA had the potential to accomplish the benefits mentioned, many small laboratories were unable to implement TLA because of lack of space and cost. As a result, manufacturers developed modular, task-oriented automation. As part of TLA, automated specimen processors and transportation systems were available, and proved to be effective at several large clinical laboratories. Modular preanalytical processors were also available to handle stockyards, conveyor belt transporters, centrifuges, decappers, barcode readers, aliquoters, and sorters.

The implementation of automation is common in several areas of diagnostic testing, especially in clinical chemistry and immunochemistry (Lippi et al., 2014). However, more complex testing such as hemostasis still requires the technical and clinical expertise of laboratory personnel to interpret the results. A study compared manual centrifugation and automated centrifugation to assess their influence on hemostasis specimen processing (Sedille-Mostafaie et al*.,* 2013). Optimal centrifugation is essential to produce platelet deficient plasma specimens because the removal of platelet

is necessary before the performance of coagulation tests. Centrifugation is time consuming, and results in impeding the continuous process flow for hemostasis testing. Manual processes of centrifugation include balancing of tubes, loading them into the centrifuge, and removal of tubes after completion of centrifugation step. Manual centrifugation of samples was at 1500 g for five and twenty minutes while automated centrifuge was set at 3000 g for seven minutes. A comparison of platelet counts between the manual and automated centrifuges revealed that the automated centrifuges produced acceptable platelet poor preparation, while the manually centrifuges produced too high (centrifuge for five minutes) or too low (centrifuge for twenty minutes) of platelet concentration. The authors noted that turnaround (TAT) did not improve with the implementation of the automated centrifuge. Although automated centrifuges did not affect TAT, a reduction of manual processes could lead to a reduction of errors. The recommendation was to implement automated centrifuges for hemostasis testing for laboratories that have high throughput to improve the quality and reliability of results (Sedille-Mostafaie et al., 2013).

Singapore General Hospital (SGH) implemented LAS to decrease cost, reduce waste, improve turnaround time, minimize manual processes, and simplify staff training (Lam & Jacob, 2012). There were several expectations from the implementation of the LAS. The expectation was for the LAS to automate sample processing. The expected throughput of the LAS was to process more than five million tests annually. Capabilities of the LAS included sample receipt, sorting, sample prioritizing, centrifugation, decapping and recapping samples, aliquoting, loading and unloading of samples, and

transfer of samples to storage. Data collection compared turnaround time, laboratory errors, and staff satisfaction before and after implementation of LAS. SGH implemented LAS in 2007. Data compared between June 2007 and April 2008 yielded several outcomes. Data comparison showed that turnaround time decreased by 30% for stat samples and 13.4% for routine samples post LAS implementation. In a surprise finding, there was an increase of laboratory errors post implementation of LAS. A contributing factor for these errors was the inexperience of staff with the LAS. Collected survey data for staff satisfaction took place for over a week in March 2008. Staff frustrations included barcode labeling, inadequate centrifuges to handle workload, and increased processing time. There was documentation of LAS advantages such as improvements in turnaround time, laboratory errors, and staff morale, but SGH did not experience these benefits post LAS implementation. Results indicated that as the staff gained more experience with the LAS, the advantages of the new system would become apparent.

Data shows a pattern of most preanalytical errors occurring because of mistaken or mishandled procedures during collecting and handling of blood samples (Lippi & Plebani, 2012). As a result, poor quality samples are unsuitable for laboratory testing. Leading the pack of poor quality is hemolysis. Hemolysis causes erroneous results and recollection to provide the clinicians with reliable results. This causes a delay with reporting results to the clinicians as well as increased operational costs. Visual inspection of hemolysis is also unreliable (Hammerling, 2012). Advancement of laboratory technology provided new and reliable means to eliminate these variables. One solution was to install liquid level sensors in the instruments to detect low volume and microclots

or bubbles. Another solution was to implement barcode or radiofrequency identification technology to allow bidirectional interfacing between the instruments and LIS. Barcodes are a preventive action to minimize identification and transcriptional errors. Management of unsuitable samples, especially with hemolysis, remains a major issue even with these breakthroughs. Traditionally, the degree of hemolysis is the visual comparison of the color in the tube against standardized color-coded scales. The hemolysis index has the ability to help phlebotomist, nurses, and laboratory technologists by eliminating visual inspection before analyzing the specimens (Lippi & Plebani, 2012). This technique resulted from the ambiguous interpretation of hemolysis in a sample. With newer models of diagnostic instruments, manufacturers installed a serum indices system that includes the HI. Hemolysis index has the ability to measure the cell-free hemoglobin in a sample and report if the sample is suitable for testing. Advantages of HI include eliminating the arbitrary judgment of visual inspection, transmission of HI to LIS, and assessment of sample suitability. Limitations of HI include unclear effects on turnaround time, only assessing sample quality without diagnostic benefits, and not having the capability to adjust test results.

Barcode identification. The wrong blood transfused to the wrong patient is the most frequent cause of morbidity in transfusion medicine (Heddle et al., 2012). This error can result in a hemolytic transfusion reaction and is the second leading cause of transfusion related death in the United States between 2005 and 2009 (Nuttall et al., 2013). Wrong transfusion poses a higher risk to the patient than contracting human immunodeficiency (HIV) or hepatitis C virus (HCV) (Murphy et al., 2012). Transfusion

errors are preventable if healthcare professionals perform the five stages correctly. The five stages involved with transfusion medicine are wrist banding the patient, sample collection, laboratory testing, issuing of blood products, and time of the transfusion. Laboratories are responsible for sample collection (preanalytical), laboratory testing (analytical), and issuing of blood products (postanalytical). Sample collection errors occur when the phlebotomist collects blood from the wrong patient or labels the tube incorrectly. A root cause analysis revealed that 58% of transfusion errors resulted from sample collection from the wrong patient and 36% resulted from patient misidentification (Adibi, Khalesi, Ravaghi, Jafari, & Jeddian, 2012). These two types of errors can cause ABO incompatibility and may result in hemolytic reaction or even death.

Barcode identification has the potential to mitigate transfusion errors (Nuttle et al., 2013). This system involves handheld computers to check if patient details on the wristband barcode match those on the barcode and on the blood bag. A study compared pre and post implementation of a barcode based blood identification system at Mayo Clinic, and revealed six transfusion errors with misidentification pre implementation compared to one misidentification post implementation (Nuttle et al., 2013). The one incident occurred when scanning of the blood product and patient wristband took place after starting the transfused unit. A positive identification system such as barcoding could reduce patient sample and identification errors (Snyder et al., 2012). Errors in transfusion medicine are avoidable thanks to the evolution of modern technologies such as the barcode identification system. However, there is a need for systems to monitor hemolytic episodes worldwide (Adibi et al., 2012; Nuttle et al., 2013). These systems

collect information on adverse or near miss events in transfusion therapy. Data collected exposed an increase of near miss transfusion errors after the implementation of the barcode system (Nuttle et al., 2013). Prior to pre implementation, there was one reported near miss transfusion errors; whereas, 34 near miss transfusion errors occurred after implementation.

Summary. Modern technological advancements in laboratory medicine make it possible for laboratories to meet the demand of increasing test requests while providing quality performance and timely test results. Laboratory automation has the ability to help most clinical laboratories profit from integrated preanalytical processes by limiting specimen handling, preventing mislabeling, and relieving laboratory staff from repetitive activities such as transporting specimens and loading analyzers (Lippi & Plebani, 2012). Researches discussed above demonstrated that automation of preanalytical processes is effective and achievable.

Transition

Section 1 was an introduction to the different elements of the chosen research topic of preanalytical errors. Areas explored included background of the problem, problem statement, purpose statement, nature of the study, research questions, the conceptual framework, assumptions, limitations, delimitations, and significance of the study. This section also included an extensive discussion of the review of the literature, which exposed three themes: causes of preanalytical errors, quality management, and possible preventive

Discussion for Section 2 will include the justification and rationale of the scope of the project, the researcher's role, the chosen method, research design, and strategies for accessing participants. Section 2will also discuss data collection, organization, and address issues concerning reliability and validity.

Section 3 will provide an overview of the study, findings from the research, the applicability of these results to mitigate errors in laboratory medicine, the implications for social change, recommendations for action and further study, reflections, and study conclusions.

Section 2: The Project

The goal of this qualitative case study was to explore the strategies used by medical laboratory managers to minimize preanalytical laboratory errors. Exploring these strategies may produced findings to prevent these errors. This research contributed to the objective of reducing medical errors responsible for thousands of deaths, costing billions of dollars annually.

This section discussed the purpose of this study, the researcher's role in collecting study data, study population, and the use of purposive sampling used to access study participants. Discussion of the qualitative research method and case study design, data collection strategy, analysis of data, and reliability and validity of the instruments used were also discussed in this section.

Purpose Statement

The purpose of this qualitative case study was to explore in depth how medical laboratory managers reduced laboratory errors in the preanalytical phase. Participants for this case study were medical laboratory managers in at least two medical laboratories in southern California who reduced laboratory errors in the preanalytical phase. The information yielded from the semi-structured interviews provided management and health care personnel with an avenue to reduce laboratory errors. Preventing the patient from experiencing detrimental physical or emotional effects caused by laboratory errors contributed to a positive patient experience. This elicited interest from leaders in health care sectors as well as patients. Eliminating laboratory errors will improve patient safety, reduce operational costs, and increase revenue.

Role of the Researcher

Defining the researcher's role was important to provide credibility for the research topic (Unluer, 2012). The researcher's role was to collect, organize, analyze, and interpret data a study produces (Mikėnė, Valavičienė, & Gaižauskaitė, 2013). I was the primary data collection instrument for this quality case study. Experience, training, or approach of the researcher played a pivotal role on the validity of collected information (Mikėnė et al., 2013). Data collection for this study included semi-structured, open-ended interview questions. Open-ended questions encouraged the participants to provide detailed responses based on their views, opinions, feelings, knowledge, and experiences (Mikėnė et al., 2013). Following data collection, I transcribed, disseminated, analyzed, and synthesized the data until meaning emerged. Reporting of results was based on evidence provided by the participants without the researcher's bias or viewpoints.

Credibility of the research topic depended on the experience and qualification of the researcher (Unluer, 2012). As a clinical laboratory scientist for two decades, I was acquainted with the issue of laboratory errors. Having been a manager of a clinical laboratory for more than five years, I dealt with this issue, and at times, experienced frustration at the occurrence of the events. My experience as a quality assurance manager enabled me to examine laboratory errors through a different lens. Given these professional experiences, I conducted this qualitative case study from different viewpoints. Participants consisted of medical managers from at least two organizations. The rationale for selecting this group of participants was because of their proven ability to implement processes demonstrating a reduction of preanalytical errors. The

advantages of choosing within my professional group were my ability to understand the phenomenon under study, and validate the answers given by participants because of my knowledge of the field. Being familiar with the topic was a potential drawback because familiarity might lead to bias and to unconsciously making the wrong assumptions.

The art of a qualitative research was to expose the human part of a story (Jacob & Furgerson, 2012). Interviews were the primary tools to extract the experience from the participants. Acquiring the proper interview skills enhanced the interviewer's ability to gain insights to the participants' experience of the subject under study. Having an interview protocol that elicited participants' perspectives on their successes with minimizing preanalytical errors was crucial to the interview. An interview protocol consisted of a list of interview questions as well as a procedural guide, which included scripts to direct the researcher through the interview process (Jacob & Furgerson, 2012). The interview protocol consisted of 10 semi-structured interview questions based on the literature review. Using the literature review as a guide to develop the interview questions allowed the researcher to concentrate on questions that produced meaningful data. This also validated the researcher's understanding of other scholars' findings of the subject.

Prior to collecting data, I obtained the required permissions from the Walden University Institutional Review Board (IRB). This process ensured that the researcher followed the protocol for ethical research outlined by the Belmont Report. The United States Department of Health, Education, and Welfare developed the Belmont Report in 1979 to protect participants in research studies (Greaney et al., 2012). This document

ensured that participants understood the nature of the experiment, their rights as participants, and their roles in the experiment. Once the IRB approved my application, I followed the Belmont Report protocol. This included informing participants of the consent process, protection afforded to research subjects, and respecting their rights.

Participants

I considered the data source to find evidence to support their explanations as part of the study design (Sangster-Gormley, 2013). The data source was the interviews conducted with medical laboratory managers in their real-life context with the primary goal of exploring their successes with preanalytical errors. I selected at least two health care organizations with laboratories in southern California. Within these health care organizations, the selection of potential participants was narrowed to medical laboratory managers with a minimum of two years of preanalytical experience with success of minimizing preanalytical errors. Recruiting participants without preexisting relationships with the researcher enhanced the authenticity of the data collected, as recommended by Isaac (2014). Purposive sampling aimed to recruit a specific group of participants who share similar characteristics in relation to the social phenomenon under study (Petty et al., 2012b). The participants' experiences provided perspectives to the central research question, "How do medical laboratory managers reduce laboratory errors in the preanalytical phase?"

To gain access to potential participants, I used my professional contacts or LinkedIn to identify the participant pool. I sent a recruitment letter to organizations with a laboratory in southern California. The recruitment letter (see Appendix A) included a

formal introduction with my name and credentials, an overview of the study, participant criterion, and contact information if they chose to participate. To encourage participation, the letter included assurance of confidentiality and a notice that the results and consent form would remain in my possession for 5 years. Upon completion of the recruitment process, I contacted the interested participants via telephone or email to provide additional information pertaining to the study. Additional information included the purpose of the study, their role as a participant, and risks and benefits to participate. Once the potential participant agreed to divulge their experience, I sent a consent form (see Appendix B) informing participants of the opportunity to take part in a scholarly study that could provide laboratory management with information to reduce preanalytical errors. Included in the consent form was the option to refuse participation at any point during the study without penalty, and disclosure of the lack of incentive for participating in the study. If the participant decided to withdraw, an email or verbal refusal would stop the data gathering process. The intent of these correspondences was to establish a trusting working relationship with the potential participants to elicit honest responses.

Research Method and Design

Research Method

The research question is the driving force behind research methods (Petty et al., 2012a). Quantitative, qualitative, and mixed methods are the main research methods used by researchers. Quantitative researchers used deductive reasoning to confirm or reject the hypothesis (Van Griensven et al., 2014). Qualitative research aims to explore the phenomenon occurring in its natural setting (Mikėnė et al., 2013). Three fundamental

characteristics that define qualitative research, as identified by Morse (as cited in Prion & Adamson, 2014), follow. First, the participants provided the truth and meaning of the research. Second, this type of research enabledthe researcher to develop a holistic view of the phenomenon under study based on the participants' perceptions of values, beliefs, and experiences. Third, the method of data collection was inductive and interactive. In other words, a researcher could change the inquiry process as a better understanding of the phenomena emerged (Prion &Adamson, 2014). The type of collected data defined the research method (Van Griensven et al., 2014). Data analysis consisted of the use of statistical tools to analyze the numerical data in quantitative research (Parylo, 2012; Prion & Adamson, 2014). This method condensed large amounts of data into interpretable results to test or verify the hypothesis. Data analysis in qualitative research can be time consuming and tedious. This process involved the synthesis of large amounts of written data such as interview transcripts, observations of non-verbal communication, drawings, or film (Van Griensven et al., 2014). Data collection and analysis can occur simultaneously and interpretation of results could change as new information emerges. Mixed methods research allows the researcher to conduct a hybrid of qualitative and quantitative research (Van Griensven et al., 2014). Investigators choose mixed methods approach to explore a more complete and deeper understanding of the subject under study by triangulating numerical and textual data. The goal of any chosen method is to provide results with convincing evidence to answer the research question.

Many researchers used mixed methods to strengthen their findings. Researchers employ mixed methods when data collected from a qualitative or quantitative approach

did not produce enough information to explain the research question (Wisdom et al., 2012). Mixed methods research was not appropriate for this study because semi-structured interviews were sufficient to produce a breadth and depth of understanding to the ability of medical laboratory managers at minimizing preanalytical errors.

Qualitative research is more applicable to answer the research question, "How do medical laboratory managers reduce laboratory errors in the preanalytical phase?" for several reasons. First, this study sought to understand the phenomena of laboratory errors with the views and experiences of medical laboratory managers in their natural settings (Isaacs, 2014). Second, qualitative research provided a close-up view with a deeper and richer understanding of the research topic (Cronin, 2014). Third, the inquiry into the research question was to use inductive reasoning to uncover shared experience by the participants, and not deductive reasoning to test theories or hypotheses (Harrison, 2013). Last, qualitative research was superior when attempting to explain or describe the perceptions of a population using a representative sample (Parylo, 2012). I sought to understand patterns, similarities, and differences between the participants' perspectives through the semi-structured interviews.

Factors indicating the use of quantitative methods included a deductive approach wherein a theory or hypothesis confirms the purpose statement, study variables, and research questions (Crede & Borrego, 2014). Several reasons indicated that quantitative research was not appropriate for this study. One reason is that the design of this study sought the individual perspective of each participant as opposed to controlling variables and context (Erlingsson & Brysiewicz, 2013). Another reason was the lack of

collaboration between the researcher and the participants. Involvement between participants and researcher in quantitative research is minimal to nonexistent because data collection is mainly through surveys or experiments (Parylo, 2012). Data collection in qualitative research involved the researcher interacting with the participants to extract their experiences with the subject under study. This study did not involve a large number of participants to project the studying findings onto a larger population, as recommended by Petty et al. (2012a). Quantitative researchers used statistical procedures to analyze the collected data (Parylo, 2012). The use of statistical procedure would not provide rich and vivid descriptions of the collected data. Achieving rich and vivid descriptions in qualitative research required careful coding, analysis, and interpretation of the semi-structured interviews.

The nature of the research problem under investigation, the qualitative method was a better choice to investigate medical laboratory managers' strategies to minimize preanalytical errors. Employing the qualitative research method was a means of finalizing results and exploring answers to the research question. A qualitative research method was appropriate for this study because it uncovered the perceptions of participants and provided detailed information about the complex phenomena. I strove to reach high standards of truth and credibility, and to achieve completeness in the data by exploring real-life contexts in which learning took place.

Research Design

Qualitative research uses textual data to recount the participant lived experience with the research topic (Erlingsson & Brysiewicz 2012). Sampling strategies, data

collection techniques, and data analysis are similar among the qualitative designs (Prion & Adamson, 2014). The differentiation is in the expression of the data and in which perspective the researcher aims to convey. Qualitative designs commonly used by researchers are phenomenology, ethnography, and case study (Petty et al., 2012b).

The origin of phenomenology design was from Germany at the start of 20th century (Petty et al., 2012b). Psychology and philosophy are two areas that are frequently used in this design to conduct research. This design sought to understand the unique lived experiences of individuals with the emphasis on pure description of the phenomenon (Erlingsson & Brysiewicz, 2012). A lengthy interview to explore the individual's perceptions, perspectives, and understanding of the phenomenon is another characteristic of this design (Zou et al., 2014). I contemplated adopting phenomenology design, but it did not align with this study. The primary focus of this study is to understand medical laboratory managers' multiple perspectives with reduction of preanalytical errors in their natural setting, and not individual experience with the phenomenon.

Ethnography design studies participants in their everyday setting with the intent of capturing their common behaviors from ordinary activities (Erlingsson & Brysiewicz 2012). This design often requires the researcher to participate in the cultural activities to describe the group's culture (Zou et al., 2014). In some instances, the researcher resides within the participants to develop an understanding of the shared patterns of behavior, beliefs, and language of the cultural group (Petty et al., 2012b). The tools to collect data for this design are observation and interview. Ethnography was not feasible for this study

because I was not going be an active participant in this study and did not have any intent to live in the natural settings (i.e. hospitals, reference laboratory) to understand medical laboratory manager's success with curbing preanalytical errors.

Case study research (CSR) is a qualitative design that focuses on a specific situation with the aim to investigate every angle of the situation (Cronin, 2014). This design involves a systematic inquiry and analysis of one or multiple cases to describe the phenomenon of interest. CSR is a powerful method for participants to recount their real-life experience of the situation and perhaps identify casual links of the experience as noted by Yin (as cited in Cronin, 2014). CSR has three advantages (Sangster-Gormley, 2013). First, CSR allows researchers to explore and explain complex phenomena in their natural setting. Second, this design enables researchers to expose the participants' perceptions of how they contribute and influence the phenomenon. Third, CSR enables researchers to understand variations in the setting. A well written CSR allows the readers to analyze the findings and determine its applicability to their experience with the phenomenon (Taylor, 2013).

Saturation is the point where data collection cannot produce any new or relevant information (Dworkin, 2012). In qualitative research, data saturation is hard to achieve because new information is continuously emerging (O'Reilly & Parker, 2012). Data saturation depends on the richness and depth of collected data to support the research question (Harland, 2014). There is no actual formula to determine data saturation in qualitative research. However, the intent of this study was to collect data until new or relevant information ceases to exist or until the collected data was sufficient to support

the research question.

I employed a multiple case study design to create an accurate and complete description of medical laboratory managers' experience with successful strategies to minimize preanalytical errors. The phenomenon of preanalytical errors occurs in real-life laboratory practices every day. Exploring the causative factors of laboratory errors is difficult because laboratory testing involves many layers of health care professionals. CSR is applicable to this research topic for three reasons. One, CSR will permit the exploration of participants' real-life experiences in their place of employment. Two, CSR will provide a platform for the researcher to understand the participants' contribution and influence in the reduction of preanalytical errors. Last, CSR exposes the multiple layers of health care processes that contribute to preanalytical errors. The principle reason for choosing a multiple case study is to compare data and their applicability to multiple settings (De Massis & Kotlar, 2014).

Population and Sampling

Sampling strategy depends on the nature of the study and availability of participants (O'Reilly & Parker, 2012). Probability and nonprobability are two sampling strategies used by researchers (Acharya, Prakash, Saxena, & Nigam, 2013). The definition of a probability strategy is a random process that provides equal opportunities for individuals to participate in the study. A nonprobability strategy is purposeful, and not random; where the recruitment of participants depends on inclusion criteria. Qualitative research usually adopts the nonprobability sampling strategy (Isaacs, 2014). This multiple case study used the nonprobability purposive sampling strategy to recruit

participants with the characteristics or shared experience to the phenomenon under study. The participants for this study were medical laboratory managers from two health care organizations. The qualified criterion were a minimum of 5 of laboratory experience, at least two years of management experience with preanalytical processes, completion of at least one project to minimize preanalytical errors, and worked for an organization in southern California. Medical laboratory managers were the forefront of their teams and had a significant role in any process improvement initiatives. The participants provided insights to the complexity of health care delivery and played a significant role with collaborative efforts to reduce preanalytical errors across health care disciplines. Selecting the purposive sampling strategy helped the researcher to focus on a defined group of participants to gather the richness of participants' perceptions of the phenomenon (O'Reilly & Parker, 2012).

The debate of sampling size of qualitative study is ongoing. Sample size depends on the research question, and a defined formula to determine the sampling size in qualitative research does not exist (Isaacs, 2014). A sample size of 12-26 participants might be appropriate in one study, while other studies start out with a smaller sample size and recruit more participants to achieve data saturation (Isaacs, 2014). The required number of participants depends on the amount of information necessary to achieve depth and breadth of the research question. Sampling for this multiple case study involved medical laboratory managers from two health care settings. The final selection reflected the medical laboratory managers' success with preanalytical errors and willingness to participate in the study. This multiple case study allowed me to analyze data from an

individual setting while comparing the results across different settings (Massis & Kotlar, 2014).

Ethical Research

Ethical considerations for any research method are the same. In any type of research involving human subjects, scrutinizing ethical considerations is necessary to ensure the protection of the subjects (Hoe & Hoare, 2012). In the United States, the Institutional Review Board plays a pivotal role in protecting human subjects by reviewing certain ethical issues in research studies (Lidz et al., 2012) and uses the Belmont Report as a reference when reviewing research involving human subjects (Kim, 2012). Exploitation of participants is not permissible, and safeguarding respect for each individual is essential according to the Belmont Report (Greaney et al., 2012). This report posited that participants must have autonomy, or the ability to make meaningful choices without limitations. Sufficient protection should be available for those who are unable to act autonomously. Qualitative research poses minimal risk in medical research, but is not risk free (Gibson, Benson, & Brand, 2012). Implementation of proper measures, such as assurance of anonymity and confidentiality, were necessary to protect all participants in this research.

I followed procedure to seek approval from the IRB prior to the recruitment and data collection processes. The IRB approved the application to conduct research and assigned 08-16-16-0293397 to this study. Upon approval from the IRB, I sent an invitation to organizations with laboratories requesting their participation in this scholarly study. Each organization received a letter or email outlining the purpose of the study, the

inclusion criteria, and contact information (see Appendix A). The invitation included an assurance of anonymity and a guarantee of confidentiality. Incentives with monetary value or exchange of favors were not permissible in this study. Prior to the face-to-face interviews, the participants signed a consent form (see Appendix B). The consent form outlined the option to refuse participation at any point of the study without reprisal. The participants could withdraw by email or by verbally expressing their intent to discontinue their participation at any time. Participation was strictly voluntary, and I will destroy all data collected prior to a participant withdrawing from the study.

Assurance of confidentiality has the potential to encourage organizations or individuals to participate in this study. To reduce the risks of breeching confidentiality, I assigned codes for all participants (Damianakis & Woodford, 2012). Coding removed identifying information to protect anonymity and minimize the possibility of recognition within the health care industry. I coded the participants as P1, P2, P3, and so on. Data did not reveal the identity of the organization or participant. To protect the confidentiality of participants, I will place the collected data and consent forms in a personal safe deposit box, where it will remain for a minimum of 5 years. Upon the expiration of the stated timeframe, I will shred the documents or permanently erase the files through a software program.

Data Collection Instruments

Semi-structured face-to-face interviews in conjunction with nonparticipant observations were the primary data collection instruments for this qualitative case study. Qualitative researchers aim to collect human experience through interviews,

observations, documents, and audiovisual materials (Jacob & Furgerson 2012). Structured, semi-structured, and unstructured interviews are the three main modes of interview instruments (Doody & Noonan, 2013). A structured interview requires the researcher to ask each participant the same set of questions in the same order and the expected answers are relatively short (Rowley, 2012). The advantage of this technique is that the yielded data are easier to code, compare, and analyze. Unstructured interviews often start out with open-ended questions, and the subsequent questions will evolve depending on responses from participants (Doody & Noonan, 2013). This technique is useful when the researcher has little knowledge about the topic or the intent is to collect background data. Semi-structured interviews are a hybrid between structured and unstructured interviews. The researcher begins with a set of predetermined questions, but can develop spontaneous questions to seek clarifications. The responses provided by participants will determine the direction of the questions (Stuckey, 2013). Face-to-face interviews produce richer breadth and depth (Englander, 2012). Semi-structured interviews and observations allow the collection of rich data, which are appropriate to understand medical laboratory managers' abilities to diminish preanalytical errors in their natural setting.

Possessing the proper interview skills and protocols enhances the researcher's ability to extract the participants' experience to the phenomena (Jacob & Furgerson, 2012). Before administering the questions to the participants, I refined my interviewing skills by practicing on a few colleagues. Improving my interviewing skills enabled me to encourage the participants to elaborate on their perspectives, as well as the details of their

experience. I also developed an interview protocol, which included list of interview questions and a scripted dialogue (see Appendix C). The interview protocol provided me with a tool to conduct the interviews more effectively. The scripted dialogue included a procedural guide to prompt me on what to say at the beginning and end of the interview. I provided the participant with an overview and purpose of the study, discussed the consent form, and answered any questions or concerns the participants had about the study at the beginning of the interview. The script included my contact information and a request to perform member checking at the end of the interview.

To affirm that the study was credible, I employed member checking. Member checking is a quality control process used in qualitative research to ensure that the collected data is accurate, credible, and valid (Harper & Cole, 2012). The participants had the opportunity to review their transcripts, which were verbatim audio recording of the interviews. I sent the transcribed interviews to each participant to verify the information. This process offered the participants an opportunity to dispute or approve the interview's summary of their views, feelings, and experiences. Correction of identified discrepancies took place prior to data organization and analysis. Member checking had the potential to convince the audience that the results are reliable, valid, and credible.

Data Collection Technique

Interviews, observations, drawings or film are among a few data collection techniques used in qualitative research (Van Griensven et al., 2014). I collected data through interviews and observations. Interviews are the technique used extensively to

collect data in qualitative research (Rowley, 2012). An interview is a means for the researcher to understand the thought process of participants (Stuckey, 2013). The advantages of interviews include the ability to gain insights from the participants, allowing participants to tell their own story, enabling the researcher to observe as well as listen, permitting the participants to explain reasons and give details for their interpretation of the issue, and allowing researchers to develop complex questions to explain the phenomenon under study (Doody & Noonan, 2013). The disadvantages of interviews are the perception of intrusiveness to the participant; they are time consuming and costly, could provoke strong feelings, and the interview process is susceptible to bias.

Two types of observations are available to the researcher: formal and informal (Petty et al., 2012b). Formal observation requires the researcher to request and schedule an observation session to evaluate a predetermined area. Informal observation involves the spontaneous request to observe random areas. The researcher can also be a participant or a nonparticipant observer. Participant observation requires the researcher to actively participate and take part in the observed situation. In nonparticipant observation, the researcher is only an observer and does not play a role in the situation. In this study, data was captured during interviews via field notes, audio and video recording made on an iPhone. An advantage of observation is that it permits a researcher firsthand experience to a given situation. The disadvantages of observation are that the presence of the researcher might alter the participants' behavior and this technique is time consuming. I adopted the formal nonparticipant observation method using field notes.

The systematic protocol for these semi-structured interviews involved planning

and conducting the face-to-face interviews. Planning was important to collecting effective data. Researchers recommended commencing this process with a set of predetermined open-ended questions that elicited detailed accounts of the participants' experience with the research topic (Doody & Noonan, 2013). Ten predetermined open-ended questions were formulated from the literature reviews and focused on the ability of medical laboratory managers to minimize preanalytical errors. These questions were in sequential order, but the flexibility of the semi-structured interview allowed the researcher to ask the questions out of sequence. Conducting the face-to-face semi-structured interviews for this multi case study took place at the participants' places of employment (Sangster-Gormley, 2013). Trust and rapport provided a platform for the participants to answer the questions more honestly. The interviews began with a casual conversation geared toward creating a comfortable and relaxing environment for the interview. The face-to-face semi-structured interview included asking all participants 10 open-ended questions. However, during or after the inquiry of the 10 questions, the participants could ask questions for clarification, or ask additional questions to provide clarity. Each interview took approximately 30 to 45 minutes. Following the formal interview process, nonparticipant observations of the organizations' preanalytical processes took place for duration of 30 to 60 minutes. The observations allowed me to gain insight into the workflow of preanalytical processes and their contribution to mitigating errors. I noted all observations and wrote a description of the observed situation. Transcription of the interviews was verbatim. Participants received a copy of the transcript and observation notes to review, dispute, and approve. Member checking

provided the assurance that the collected information was accurate.

Data Organization Technique

Qualitative research generates large amounts of data (Ward, Furber, Tierney, & Swallow, 2013), some collected data might be beyond the scope of the study (Ishak & Bakar, 2012). Case study requires that preparation of the collected information take place prior to data analysis (De Massis & Kotlar, 2014). Preparation involves data reduction, data display, data categorization, and data contextualization. Data reduction condenses and simplifies the collected data for ease of analysis and allows the researcher to focus on the evidence that could answer the research question (De Massis & Kotlar, 2014). One tool used by researchers to organize and arrange the data for ease of retrieval is data display. Dissecting and grouping of information into different categories for comparisons is data categorization. Data contextualization is comprised of assembling the data and identifying links and connections (De Massis & Kotlar, 2014). Preparation of data for this multiple case study involved all of the steps listed above. Data reduction removed all data that was beyond the scope of this study. Displayed data included data coding, which allowed me to mark and note information that have had similar themes. I used data categorization and contextualization to disassemble and assemble the information to search for relationships in the collected data.

Use of a database to organize the data can improve the reliability of the study (Baxter & Jacks, 2008). Microsoft Excel was the database employed to organize the collected data. This software has the ability to manage and organize data, is easy to use, and is cost effective (Watkins, 2012). I created a workbook containing spreadsheets

using Microsoft Excel to categorize all information pertaining to this study. This workbook included a list of potential participants, the receipt of their willingness to participate, the signed and dated consent form, and the schedule and location for the semi-structured interviews. The workbook also stored the verbatim transcription of the audio recordings. Prior to transcribing the data, as suggested by Rowley (2012), I listened to the recordings and took notes on the significant points that emerged from the interviews. Transcription of all semi-structured interviews and observation notes occurred within seven days to preserve the integrity of recorded data. The laptop used to house the data was password protected and encrypted to assure the security of the data. I also used Dropbox to retain data as a backup for unpredicted circumstances, which might erase the data from the laptop.

Removal of participant identity by coding assured anonymity and confidentiality of the study participants (Marais, 2012). Participant codes such as P1, P2, and P3 were the assignment for each participant. The designated coding, where P represents the participant and the numerical number represents the number of interviewees, removed any discriminating identity and protected the confidentiality of the participants as recommended by Lam and O'Higgins (2012). The data management plan provides that I will keep all hard copies such as audio recordings, observations notes, and consent forms in my personal safe deposit box. The Microsoft Excel workbook will remain in its electronic form on my laptop and Dropbox account for a minimum of 5 years. Upon the expiration of the required timeframe, all hard copies will be destroyed through a shredder or through a software program that erases files permanently.

Data Analysis

A systematic approach is necessary in qualitative data analysis (De Massis & Kotlar, 2014). Equally important is to outline the data analysis process to provide clear and a detailed explanation of the data analysis method to strengthen the study. The researcher must provide vivid descriptions of how the collected data emerged into valid findings from the study. Data will require the aid of a qualitative data analysis software (QDAS) program to produce themes. The three most popular QDASs on the market are Atlas.ti, MAXQDA, and NVivo (Humble, 2012). All three programs have capabilities to build theories and allow the import of textual, video, and audio data into the programs. These programs enable the researcher to engage in open coding and have the ability to diagram theoretical models. The program chosen for data analysis in this study was NVivo. The three programs are very similar and the rationale for choosing NVivo was cost. I have the program in my possession and NVivo has the capabilities that I need to complete the data analysis process.

I transported the transcribed interviews and observation notes into NVivo to initiate the data analysis process. This software helps researchers to systematically code and organizes their data (De Massis & Kotlar, 2014). NVivo can also facilitate data analysis by identifying themes, providing insights, and reveal relationships between the different concepts. This step was to sort the collected data into codes and themes. Information analysis could expose patterns and relationships between the cases to explain the research question.

NVivo is the best program to aid data analysis; however, the criticism with the program is bias (Sotiriadou et al., 2014). This program requires the researcher to develop a list of codes and rules as an attachment to the data. To alleviate the risk of bias, I will triangulate the data. Triangulation is the use of more than one approach to explain the research results (Wilson, 2014). This strategy can increase the confidence and validity of the findings (Yin, 2013) by providing richer and fuller data (Wilson, 2014). The four types of triangulation used in case studies are data triangulation, analyst triangulation, theory perspective triangulation, and methods triangulation. Data triangulation involves the collection of different data sources. The collection of data can be from different times, different locations, and different focal groups. Investigator triangulation involves more than one investigator in the data collection and analysis processes. Theory triangulation is comparing different theories with the goal to develop knowledge. Method triangulation uses multiple methods to explain the phenomena (Wilson, 2014). The data triangulation I used to explain the research question included data from the semi-structured interviews and nonparticipant observation notes.

Further data analysis, using within case and cross case analyses, will remove any lingering questions of bias. The first step is to perform a within case analysis to understand the conditions of the individual cases (Yin, 2013). This analysis could reveal factors contributing to the successes of the medical laboratory managers' successes with preanalytical errors. Next, conducting a cross case analysis could compare the differences and similarities between the cases. Cross case analysis could assist with an understanding of how each organization changed their internal processes to reduce

preanalytical errors. The objective of data analysis in CSR is to analyze all combined data sources and evaluate their applicability across different settings (Sangster-Gormley, 2013).

The research question, interview questions, and conceptual framework guided the data analysis process. Concentrating on these elements to conduct data analysis will prevent the researcher from analyzing data beyond the scope of the study (Sangster-Gormley, 2013). Selection of key characteristics of preanalytical errors to include in the interview protocol relied largely on the literature review. I compared the collected data to the research question, "How do medical laboratory managers reduce laboratory errors in the preanalytical phase?" and its connection to the conceptual framework of total quality management. The primary theme for this study was to expose medical laboratory managers' ability to reduce preanalytical errors. I searched for the participants' adoption and application of the framework to their internal processes in their quest to mitigate these errors.

Reliability and Validity

Qualitative researchers accept the variations of people's perceptions to the phenomena under study and that replicating the results is hard to achieve (Petty et al., 2012b). The tenets for rigor or trustworthiness in qualitative studies are credibility, transferability, dependability, and confirmability (Prion &Adamson, 2014). Credibility refers to the authenticity of the collected data (Houghton et al., 2013). Transferability is the ability to apply the study to another similar situation. Dependability is a strategy to assess the stability and consistency of data inquiry (Boesch, Schwainger, Weber, &

Scholz, 2013). Confirmability is the accuracy of the findings in relation to the enquiry process and not based on the researcher's biases (Petty et al., 2012b). Dependability defends the reliability of the qualitative study while credibility, confirmability, and transferability justify the validity of the study.

Strategies that this CSR employed were member checking, audit trail, triangulation, prolonged engagement, prolonged observation, and peer debriefing to prove credibility, transferability, dependability, and confirmability. Qualitative researchers use member checking to strengthen the accuracy, credibility, and validity of the study (Harper & Cole, 2012). Member checking provides the participants an opportunity to review their transcribed interviews and data analysis for the assurance that the recorded data are accurate and properly presented (Houghton et al., 2013). Triangulation is collecting and comparing data from multiple sources to gain meaningful views of the phenomenon (Cope, 2014). Audit trail includes detailed accounts of researchers' decisions and assumptions of the collected information. Prolonged engagement builds trusting working relationships with the participants to harvest rich and detailed responses. Prolonged observations of the participants' emotions and their responses during data collection would provide the depth of the study. Peer debriefing is a strategy that engages a colleague with similar experience to help code the collected data and validate the interpretations (Houghton et al., 2013).

Reliability

Reliability is the ability for the instrument to reproduce the same or similar outcome repeatedly (Boesch et al., 2013). The selected instrument for this CSR is the

semi-structured interview protocol containing predefined questions. A predefined set of interview questions provides a reliable instrument for data collection. The goal of these interview questions was to allow the participants to reflect on their experience in similar manner and provide consistent responses attesting to their successes with curbing preanalytical errors.

Dependability in qualitative research is synonymous to reliability in quantitative research (Houghton et al., 2013). Dependability is a strategy that qualitative researchers use to assess the stability and consistency of data inquiry (Boesch et al., 2013). Qualitative researchers use audit trail to defend the dependability of their study. Audit trail is a systematic approach qualitative researchers use to demonstrate that the data inquiry procedure is stable and consistent (Houghton et al., 2013). Audit trail could also provide traceability of changes made throughout the data inquiry process. Accepting that data inquiry processes in this CSR are fluid and difficult to replicate (Petty et al., 2012b), I will use an audit trail to defend all decisions made pertaining to participant recruitment and selection, interview protocol, data collection, and data analysis.

Validity

The outcome of a concept that the researcher determines to measure is known as validity (De Massis & Kotlar, 2014). Achieving validity for this CSR was completed through credibility, transferability, and confirmability. Verification of validity provides the reader the confidence that findings in this CSR are authentic and without biased views.

Establishing credibility for this CSR included using strategies such as prolonged

engagement, prolonged observation, peer debriefing, triangulation, member checking, and data saturation. Prolonged engagement requires the researcher to spend sufficient time with the participants to build trusting working relationships (Cope, 2014). To establish trust, I provided my credentials and ensured participants that all divulged information would remain confidential. This strategy promoted honest responses from the respondents without fear of exposure. Prolonged observations of the participants' demeanors during the interview and the organization processes allowed the researcher the opportunity to understand the phenomena under study per Houghton et al. (2013). I spent sufficient time at each organization to understand their successes with reducing preanalytical errors. Peer debriefing involved enlisting a colleague with similar background to provide insights to my interpretation of the data as recommended by Petty et al. (2012b). This strategy validated that my interpretations were correct and without bias. Data triangulation and member checking can provide credibility by validating that the analyzed data were accurate. Data triangulation from the semi-structured interviews and onsite observations proved similar findings regardless of data collection techniques. For member checking, I asked the participants to review the transcribed interviews and analyzed data to reflect on his or her experience with reducing preanalytical errors. To solidify credibility, I continued to collect data until attainment of data saturation. Data collection surpassed the goal of at least two organizations unless there was a lack of new emerging data (Houghton et al., 2013). Data saturation indicated a thorough performance with data collection and analysis.

Qualitative researchers do not aim to generalize their findings, but to allow the readers to determine the transferability of the data to other settings or contexts (Petty et al., 2012b). Transferability relies solely on the researcher's ability to provide rich and thick descriptions of the phenomenon under study (Erlingsson & Brysiewicz 2012). Delivering detailed information allowed the reader to gain proper understanding and determine if the study was applicable to their setting. Inclusion of appropriate quotations could boost transferability as suggested by Graneheim and Lundman (as cited in Houghton et al., 2013). To achieve transferability in this CSR, I provided dense descriptions of the context, participants, research method, and raw data, and presented the data with transparency.

Transition and Summary

Section 2 outlined the execution plan for this CSR. The section started with the purpose of the study and delved into the role of the researcher. Included in this section were the recruitment and inclusion criteria of the participants as well as the protections provided to the participants. A rationale for selecting CSR as research method and design was also included here. Other areas discussed in this section were data collection, data organization, and data analysis. The section ends with a discussion of reliability and validity strategies of this qualitative research. Section 3 will present the findings of the study as well as applications to professional practice, implications for social change, recommendation for action and further study, and study conclusions.

Section 3: Application to Professional Practice and Implications for Change

Introduction

The third and final section of the research study is the application of the findings to professional practice and the implications for change. The purpose of this qualitative multiple case study was to explore in-depth how medical laboratory managers reduce laboratory errors in the preanalytical phase. Participants for this case study were five medical laboratory managers from two medical laboratories in southern California who successfully reduced laboratory errors in the preanalytical phase. These medical laboratory managers have at least five years of laboratory experience; two of those years spent managing the preanalytical area and successfully completing one project to minimize preanalytical errors. These individuals are leaders within the laboratory industry with knowledge of minimizing preanalytical errors. A qualitative thematic analysis was the approach performed to analyze the interviews for this multiple case study. NVivo 11 by QSR was also employed to systematically code the responses of the managers in the interviews and form the themes addressing the research question of the study. The central research question that guided the study was: How do medical laboratory managers reduce laboratory errors in the preanalytical phase? This section also includes the following: Presentation of Findings, Applications to Professional Practice, Implications for Social Change, Recommendations for Action, Recommendation for Further Research, Reflections, and Conclusion.

Presentation of the Findings

I will present the outcome of the interviews through qualitative thematic analysis.

Seven hospitals with medical laboratories received the invitation to participate and two agreed to partake in this study. The two organizations received and signed the letter of consent prior to the interview process. Company A had two participants while three participants participated in the study from Company B. I scheduled the interviews at the participants' place of employment and conducted semistructured interviews to gain an in-depth understanding of strategies the medical laboratory managers used to minimize preanalytical errors. Each participant answered the 10 open-ended interview questions, and the purpose was to collect the respondents' practical experience in reducing preanalytical errors and to answer the main research question: How do medical laboratory managers reduce laboratory errors in the preanalytical phase? Participants spent no more than an hour reviewing and answering the interview questions. I spent an additional hour at each facility observing their preanalytical processes and captured the data through observational notes. Assignment of P1, P2, P3, P4, and P5 as aliases provided participants with identity protection. Transcription of the interviews took place within seven days after the interview. The participants received the verbatim transcripts to verify the accuracy of the information. This member checking process also allowed the participant an opportunity to refute or add additional information. Data analysis involved entering the transcribed data into NVivo 11 qualitative data analysis software. This software coded the data and exposed themes from the participants' responses. Five themes emerged within and cross case analyses: quality improvement, recognition, reward, and empowerment, education and training, communication, and patient satisfaction.

Case One: Company A

The first case was Company A where P1 and P2 provided interviews. In Company A, both managers emphasized the company's main priority of providing high quality of care and service. Table 1 contains the breakdown of themes for Company A.

Table 1

Breakdown of Themes for Company A

Thematic Label	Themes and Sub-Themes	Number of Occurrences
TL 1. Identifying the cause of the laboratory errors in the preanalytical phase	Monitoring and measuring of quality indicators	1
	Diagnosing the root cause of the problem	1
	• Reviewing each case using documentation, observation, and interviews	
	Processing of specimens	1
	• Ensuring the integrity using a specimen form	
TL2. Identifying and implementing the solutions and interventions in reducing laboratory errors in the preanalytical phase	Strengthening the skills and organizational involvement of staff members	
	• Training staff members accordingly	2
	• Praising and motivating of staff members	2
	• Assessing the work of staff members	2
	• Practicing of open communication	2
	Revising the Standard Operating Procedure or SOP as needed	2

	Monitoring problems through meetings on a regular basis	2
	Engaging members of the management in ensuring quality of service in their practice and culture	1
	Systematically encoding of data	1
TL3. Identifying the effects of reducing laboratory errors in the preanalytical phase	Avoiding loss in revenue from errors	
	• Improving customers' impressions of the laboratory	2
	• Not needing to repeat laboratory tests due to errors	2
	• Providing customers with better and quality care	1

Case Two: Company B

The second case of the study is Company B, where three managers, P3, P4, P5, participated. Again, all managers expressed the need to provide quality service. Table 2 contains the breakdown of themes for Company B.

Table 2

Breakdown of Themes for Company B

Thematic Label	**Themes and Sub-Themes**	**Number of Occurrences**
TL 1. Identifying the cause of the laboratory errors in the preanalytical phase	Re-assessing the policies and performance of staff members	
	• Examining the productivity and service of employees	2

	• Examining the policies of the company	1
	Diagnosing the root cause of the problem	
	• Reviewing the feedback of staff	1
	• Performing a root cause analysis	1
	Processing of specimens	1
	• Using specimens and documentation to look for the pattern of error	
TL2. Identifying and implementing the solutions and interventions in reducing laboratory errors in the preanalytical phase	Strengthening the skills and organizational involvement of staff members	
	• Practicing of open communication	2
	• Educating staff members about the policies and regulations	2
	• Monitoring and assessing the work of staff members	2
	• Training of staff members in correcting the errors	2
	• Recognizing and rewarding staff members	2
	Engaging members of the management in ensuring quality of service in their practice and culture	3
	Implementing a test of change	2
	Implementing a corrective action plan	1
	Monitoring of problems through meetings on a regular basis	1

	Practicing constant documentation	1
TL3. Identifying the effects of reducing laboratory errors in the preanalytical phase	Avoiding the loss in revenue from the errors	
	• Providing customers with better and quality care	2
	• Improving customers' impressions of the laboratory	2
	• Not needing to repeat laboratory tests due to errors	2
	Practicing preventive measures benefitting their customers	1

Theme 1: Quality improvement. Quality affects the individual's decision to choose a health care provider (Santos, Gravelle, & Propper, 2016). Patients are more likely to choose practices with highly published quality. The participants in this study also expressed this sentiment. In the within and cross analyses, all participants agreed that quality is their primary concern when delivering laboratory services. Quality is the cornerstone of medical laboratory services because it can reduce laboratory errors, improve patient experience, and decrease operational costs. These errors can increase operational costs because investigation and rework requires additional resources (Carlson et al., 2012).

In Company A, P1 and P2 emphasized that their company's main priority is to provide quality of care and service. Participants in Company B explained that quality is the focal point of their service because poor quality equates negative patient experience. P5 explained that improving quality could prevent rework, and P4 reiterated that

improving quality could decrease operational cost with a reduction of errors. P1 and P2 also expressed concern over the loss of revenue because of laboratory errors. P1 indicated, "The lab can't bill for the canceled tests means losing revenue. The lab also spends time in investigating the errors, which causes cost. The physicians not obtaining the lab reports on time causes them to seek for another lab." P2 concluded that by reducing errors, they are saving the resources and identified that rework affects the company negatively. By improving their process and system, errors are reduced leading to decreased operational cost. P4 shared that a reduction of preanalytical errors should have a domino effect to the company. By providing quality of care, the company could benefit from decreased operational cost, improved patient experience, and thus, gain competitive advantage by offering cheaper prices for their service with better customer experience. P5 asserted that Company B is constantly working to improve quality. She acknowledged that there are many options of healthcare available to consumers and providing quality affordable healthcare is a strategy the company uses to increase and retain their market share.

The two cases use similar quality improvement tools to assess, measure, and prevent errors from occurring or recurring. Tools used to focus on quality are QIs, root cause analysis, and preventive measures. QIs are primary tools allowing users to measure and monitor quality improvement by comparing it against defined criterion (Plebani et al., 2013b). Root cause analysis could expose possible errors and identify weaknesses in the system that allowed these failures to occur (Reid & Smyth-Renshaw, 2012).

Quality indicators (QIs). Researchers proved that the development and implementation of quality indicators and quality specifications for effective management of procedures contributed to a decreased rate of errors (Plebani et al., 2014a). Another group of researchers proved that a reduction of preanalytical errors resulted after the completion of training on QIs (Agarwal et al., 2012). Companies should implement QIs to monitor and assess their processes for possible errors (Majkić-Singh & Šumarac, 2012). P1 indicated that the company uses quality indicators to monitor laboratory errors. He asserted that the indicators allow them to focus and fix the areas that need improvement. P1 stated, "We have about 10 different QA indicators that we monitor on a monthly basis. When any one area is above our threshold or unusually high, we focus on that particular area." P2 also explained that the company monitors and discusses quality metrics with the QA department on a consistent basis. P5 explained that their company also tracks quality assurance parameters and addresses any anomaly. By identifying and monitoring the errors, laboratories can implement appropriate process improvement to enhance patient experience. Evidence based approaches require laboratories to closely monitor their processes, implement a system to detect errors, and perform root cause analysis when the same error occurs frequently (Plebani et al., 2015).

Root cause analysis. Root cause analysis is a systematic approach to exposing the causes of the errors (Reid & Smyth-Renshaw, 2012). P3 asserted that when an error surfaces, she reviews the workflow to determine the cause of the problem. Reviewing the workflow might expose the problem as personal or systematic. P3 said, "Like I said, is it the system or personnel issue? Then I reviewed the broad picture to see what is the

general outcome and then from broad picture to the minute detail and everything has to be documented and who knows what we will get from that documentation." P5 stated that before she can diagnose the problem, she needs to "understand the workflow, work process, I would need to understand everybody's piece." P4 added that conducting a root cause analysis is effective and gave the five why's as an example of examining and diagnosing the problem. She stated, "So, you do a root cause analysis and we would also do, for example, the 5 Whys."

P1 explained that they examine each case carefully to determine the root cause of the error or the issue. He furthered stated that the main methods used were examining documentations, interviewing the staff, and observing them as they complete their tasks. He stated, "We diagnose the root cause of the problem by back-tracking each case, reviewing documentation, interviewing staff, and observing while they perform the task." Another practice to perform root cause analysis at company A is to document issues or problems on the Specimen Integrity Form. P2 said that when processing samples, the processor uses the Specimen Integrity Form to search for issues or problems within the system. Using the Specimen Integrity Form can help the organization diagnose the problem by identifying the type and location of errors. P2 insisted, "As we are processing the specimens coming from the clients or the patient service center, we are able find out any problems with the specimens at that time."

Preventive measures. Patients can benefit when companies practice preventive measures. P3 believed that by practicing the preventive measures, their company increases the safety and quality of service provided to their customers. She stated, "A

good quality process maintains stability as in forecasting future errors and prevents them from happening. Therefore, Company B, we are big in preventing, preventive maintenance. I see quality as a preventive maintenance. We prevent bigger errors from occurring. Therefore, the outcomes are beneficial to our customers, which is valuing their health."

Identifying patterns of error is another preventive measure that both companies use. Company B spent much time and effort to determine the patterns and faults within their system. P4 stated, "Usually, in the laboratory, we do collect specimen processing errors and then from the data collected, look for common errors, patterns, or anything we could find." P2 explained that they use a spreadsheet to record the errors. The QA committee discusses and identifies all problem areas. By categorizing these errors, the company can identify which type of errors occurred more frequently, and then implement preventive and corrective actions to mitigate these errors. Another practice used by the managers at Company A was to monitor the problems through their regular meetings. P1 shared that they constantly and regularly monitor the issues in their area to ensure that they are performing and providing service effectively to their patients or clients. He stated, "We continue to monitor the problem area on a monthly basis to ensure its effectiveness." P2 added that they monitor their policies and SOPs through their regular meetings. The meetings are a mechanism to ensure correction of the issues and enforce training. P1 stated that one of the preventive measures implemented was revising their SOP. He stated, "We revise our SOP and train our staff accordingly." Company B also said that the most significant processes of identifying the cause of laboratory errors is

through the reassessment of the policies. P3 explained that they reassess their policies once issues arise. They test to see whether their policies are in line with their practices. If there are misalignments, they modify their policies and regulations.

Theme 2: Employee reward, recognition, and engagement. A direct correlation can be seen between accomplishing organizational tasks with employee reward, recognition, and engagement (Manzoor, 2012). P5 explained that motivation and energizing staff is really hard. Methods used to overcome these obstacles are through employee reward, recognition, and engagement programs. The literature review did not reveal these two strategies as ways to improve quality.

Employee reward and recognition. Organizations that adopt recognition by displaying appreciation and allowing their employees to participate in the decision making process experienced an increase in job satisfaction, thus stimulating the employees to work towards a common goal (Manzoor, 2012). P1 highlighted that they give great importance to their personnel by increasing their involvement and motivation to perform well for the company through commendations and small tokens as rewards for positive service: "We praise personnel on areas that they do well in and give them small tokens in doing so." P2 confirmed that they have incentive and recognition programs to increase the motivation of the staff members in performing beyond their assigned tasks and responsibilities. She stated, "We do have an employee incentive and recognition program that we have just implemented to employees that have improved and have gone above and beyond their job description." P4 explained that they value their staff members and one way to show this appreciation is through rewards and recognition

programs. Employees receive rewards and recognition when the department achieves quality goals.

Employee engagement. The definition of employee engagement is the involvement and commitment of employees towards the organization and its values (Anitha, 2014). Engaged employees are more responsible towards business goals, promote teamwork, and go above and beyond to perform their job. Organizations that embrace employee engagement gained competitive advantage. P1 explained that engaging staff ensures the practice of quality service and performance at all times. P1 said that the organization involves all team members in the pursuit of quality service. He stated, "It starts from the top – from the owners of the laboratory to the middle management and trickling down by engaging quality into our daily practice and culture." P3 emphasized that she constantly engages employees in the company's quest to provide their customers with a quality and safe healthcare service. P4 furthered that they combine efforts with the rest of the staff to ensure that the whole company and its system has one goal, which is to provide the best care for their customers. P5 emphasized the company's value for teamwork and collaboration. She believes that through teamwork, they are better equipped with the ability to provide the best service to their customers. P5 acknowledged that employee engagement is a difficult task. In order to implement a strategy successfully, medical laboratory mangers need to engage their staff. This is because they are the frontline workers who have a comprehensive understanding of each process. When engaging staff in root cause analysis or process improvement, it is important to remember each idea or opinion is equally important. Working

collaboratively with the staff will produce better outcomes than dictating to them what to do. P3 noted the importance of involving staff members in the root cause analysis. She shared that the examination should start with the collection of feedback from staff members to better identify the causes of the problems experienced. P5 alluded to the importance of teamwork within the company. She emphasized that her staff's involvement is crucial in order to make them feel empowered and important parts of the company and ensure the effectiveness of the process change. P3 shared that it is also important for them to gather feedback from their staff based on their firsthand experiences in order to promote and provide better quality of service to their customers. P3 stated that as a manager, she ensures that all employees are engaged within the system changes of the laboratory and organization. She explained that the buy-in and involvement of the members are significant to correcting the errors and issues present in their laboratory. P1 discussed that they also observe and review the work of staff members for feedback and constant improvement of their work. He stated, "Do more direct observation and review their work." P2 explained that the involvement of staff members in the development of a QA system to correct the issues is needed by saying, "Again, we focus on the training. We have communication throughout the laboratory. Also, we do get the employees involved in the QA management system so they can see where we are lacking and which department."

Theme 3: Training and education. The third major theme discovered was the strengthening of skills and organizational involvement of the staff members. Organizations rely on their workforce to be successful because workforce is the biggest

asset to any organization. An organizations' ability to thrive and survive depends on the efficient performance of employees (Tahir, Yousafzai, Jan, & Hashim, 2014). To optimize the performance of employees, organizations should implement training and education programs. These programs can contribute to the overall goal of the organization and benefit the organization as well as the individual. With the acquired knowledge and skills, trained employees are more efficient and can perform their job competently. Continuous training and education of employees could improve their job performance (Amin, Rashid Saeed, & Lodhi, 2013). These programs provide opportunities for employees to learn current and future skills. Organizations that invest in training and development enjoy increased productivity and a high return on investment.

Although two studies disputed that training and education can improve preanalytical errors (Bölenius et al., 2013; Romero et al., 2012), participants in this study repeatedly stated that they adopted training and education as ways to improve quality. Both cases indicated that training was crucial to reducing and preventing errors. P1 added that they train their staff to reduce the probability of laboratory errors and equip them with the knowledge and ability to manage the issues accordingly. He stated, "We revise our SOP and train our staff accordingly. By continuously enforcing quality, providing education, and assessing staff's competency. Also by assessing staff's capabilities; assigning tasks that they excel in." P2 echoed P1's response that their system involves a strict training for their employees by requiring them to attend various training programs. The trainings involved specimen processing, detecting problems and

issues accordingly. P2 described other training programs that they implement and require their personnel to complete; exposing their staff members to a more extensive training by rotating and assigning them in different departments aided in reducing the future preanalytical errors. P3 found it important to educate the staff in terms of their policies and regulations. By doing so, staff members are aware and knowledgeable of the goals, as well as the changes being implemented in their system. P5 explained that they always make sure to involve their staff members and give them the opportunity to learn both independently and with the guidance of the company. Their education of staff members involves the policies as well as training in their skills required by their job descriptions. P3 explained that they have a great understanding that their staff members have different methods of learning. P5 echoed that they have formal and informal staff trainings. P5 said that the education of staff members involves communication and training in improving their skills to achieve the company's overall goals. P5 reiterated that when a staff makes an error, she wants to teach by training and education. She believes that most mistakes are due to system and not intentional. P5 explains that these methods can help them understand the root cause of the problem and that they will stride to improve their performance. She stated, "You know, whatever it is, I feel like we should just, you know, make sure we study exactly what it is that they are doing, talk them through it, let them understand where we are coming from. So, I feel like through that it's more of a personal approach and I'm not just calling and say hey, you did this error, figure it out yourself, how you won't repeat this error in the future. So, that's a big thing, we would like to approach it from a teaching standpoint."

Theme 4: Communication. Communication is key for ancillary healthcare teams to improve medical error health care deliverance (Brock et al., 2013). Effective communication has the potential to improve quality and safety. Specifically, internal communication has potential to build a culture of transparency between management and employees (Mishra, Boynton, & Mishra, 2014). The literature review did not find communication as a strategy to mitigate errors, but cross analysis repeatedly exposed the use of this strategy. P1 explained that to ensure the involvement and commitment of staff members, management listens to the needs of their staff members or personnel. The communication system in place involves personnel on a constant basis with process improvement. P1 reemphasized the problem areas and the interventions during their monthly meetings. P5 mentioned that communication is ongoing in order to ensure that all staff are hearing the same message and are on the same page. Communication is done in the form of rounding, huddles, department meetings, and groups that work on process improvement projects. P4 explained that they would discuss and review quality findings pertinent to laboratory operations. She said that they develop the action plans to address the presence of preanalytical errors through their constant and regular meetings. In their meetings, they set their goals and ensure that these are conveyed to the rest of the staff members. P2 said, "We do review the errors with them that they are making… We have meetings, and reviews are done annually so employees can see how they are improving or what they need to improve on." P3 said, "[It] is very important that we listen to our frontline."

Theme 5: Patient satisfaction. The definition of patient satisfaction is the agreement between patient expectation of care and the received care (Al-Abri & Al-Balushi, 2014). A patient satisfaction survey is a tool used to assess the quality of health care delivery. P2 explained that patient satisfaction is of utmost importance for the medical laboratory to retain their patients. When a patient walks into a patient service center to have their blood drawn, the phlebotomist's job is to focus on that particular person and provide the best service. This practice was observed at Company A and Company B. Both companies practiced customer service by greeting the patients on arrival. When the patient was called, the phlebotomists introduced themselves and asked the patient for identification. Each phlebotomist concentrated on their patient until the completion of phlebotomy.

Laboratory errors could lead to dissatisfied patients. P4 indicated that patient satisfaction could increase by minimizing errors. P1 posited that errors can cause patients' dissatisfaction and decrease confidence in the medical laboratory. If errors are not minimized, medical laboratories will lose patients, and physicians will seek other competitors that could provide better care experience. Any negative experience will decrease a return visit from the patient. P5 indicated that they do not want their customers dissatisfied with their service; through reduction of errors, customers' experiences should improve as well. P1 discussed how the reduction of laboratory errors could lead to customer satisfaction and avoid a negative review and impression of their laboratory. He stated, "Errors cause unnecessary cancelation of tests, which causes patients having to come back for a redraw. That leaves patients with a bad impression or

confidence of the lab." P2 added that the reduction of error leads to customers being satisfied and happy with the services as well as their overall perception of the company. P1 explained that the reduction of errors also implies that customers are provided with a better service and quality care. He stated, "By eliminating errors, it will improve operational costs, give patients and physicians a better care experience, and advantage over other labs." P5 echoed that they also reassess the errors based on the customer service. She explained that customer service is one of the main targets and priorities of their company and any rework will increase the operational cost. Medical laboratory managers in Company A and B noted that quality care could improve customers' impression of the laboratory.

Findings related to TQM theory. The development of TQM occurred post World War II in an effort to improve productivity and the quality of life in Japan (Powell, 1995). This philosophy aims to improve quality in all aspects within a company and requires the collaborative efforts of the entire organization (Gimenez-Espin, Jiménez-Jiménez & Martínez-Costa, 2013). Components of TQM provide medical laboratory managers with a systematic approach to quality improvements. Implementing TQM allows laboratories to reduce process variations, eliminate waste, minimize errors, and improve operational costs. TQM is an important mechanism to promote effective operation while attaining competitive advantage. Influential aspects that contribute to the success of TQM are leadership, organizational skills and culture, management commitment, and empowerment (Powell, 1995).

TQM is applicable to this study through accreditation agencies such as ISO 15189. This accreditation agency, and others, defined a set of standards that medical laboratories must adhere to in order to obtain or retain their accreditation. ISO 15189 is an internationally recognized agency specifically regulating medical laboratories in demonstrating their ability to provide quality laboratory services (Serteser et al., 2012). Quality management is the element that is outlined by TQM and it correlates with the standards of ISO 15189. The medical laboratory managers in this study also demonstrated the importance of quality management.

The central focus of TQM is meeting or exceeding customer satisfaction and it requires that the organization produce quality service. International Organization for Standardization 15189 outlined the importance of meeting this requirement. It requires organizations to have processes in place to monitor the quality service. Organizations need to monitor quality service through client complaints and defects. Regular meetings must occur to address client complaints and defects and to determine the root cause of the problem in order to develop appropriate corrective and preventive actions to meet customer satisfaction.

Company A and Company B assess their quality through department meetings, huddles, and with the QA departments on a consistent basis. This assessment includes the review of client complaints, quality indicators, and any necessary changes needed to improve quality. Part of the assessment is to discuss the root cause of the error and allow them to develop preventive and correction actions. Company A and B use root cause analysis (RCA) to diagnose errors. RCA is a methodological approach to investigate the

cause of the problem (Reid & Smyth-Renshaw, 2012). This approach looks beyond human error to identify system issues that could contribute to errors. Based on the outcome of RCA, medical laboratories can implement precautionary action to prevent the errors from recurring. Participants from Company A explained that they use a form to track their samples. If an error occurs, they refer to the form and analyze for the root cause of the error. They analyze each case individually to determine the root cause. The main methods in use are examining documentations, interviewing the staff, and observing them as they complete their tasks. Company B mentioned that when an error occurs, they review the workflow to determine the error. Reviewing the workflow might expose the cause of error as systematic or personal. Company B uses the 5 Whys to expose the root cause of error. Both companies developed preventive actions based on the root cause of the error. Implementation of precautionary actions helps both companies prevent errors from recurring. Preventive actions have the ability to reduce rework, minimize waste, and increase operating margin. Both companies involve their staff in the in the implementation of preventive and corrective actions because they are the frontline staff and are more knowledgeable with the preanalytical processes.

International Organization for Standardization 15189 specified that laboratories must review their procedures regularly to identify sources of nonconformities and opportunity for improvement (Allen, 2013). The studied cases emphasized that they assessed their standard operating procedures (SOPs) on a continuous basis to ensure that practice matched the written procedures. The SOPs should define all steps involved in the preanalytical phase and these procedures should be available to all staff. Another

requirement is the training of all staff to these procedures. These practices are effective in creating quality standards in terms of the processes followed by the staff members, creation of well-defined procedures, training, and improving skills and competencies of staff members.

Another element that TQM and ISO 15189 require organizations to meet is the engagement and empowerment of all stakeholders in the development and implementation of process improvement. The two studied cases agreed that patient satisfaction is the focus of their businesses. To achieve patient satisfaction, TQM requires organizations to produce quality service. Successful implementation of TQM requires the involvement of all stakeholders. Empowering employees in the development and implementation of TQM encourages employees to express their ideas and allowed them to implement process improvements. Both companies emphasized the need to involve all stakeholders when implementing TQM initiatives. Engaging employees in the root cause analysis and implementation of preventive actions produces better outcomes. The employees are frontline workers and are more knowledgeable of the preanalytical processes. Engaging staff to assess and implement ideas to improve quality results in them feeling appreciated and rewarded. As a result, a happier and productive workforce will ensue. Without this element, implementing TQM will be less successful.

Results obtained from this study correlate with the conceptual framework of TQM. Patient satisfaction is the echoing theme among all participants in both cases under study. Company A and B use this framework to gather data, analyze data, and

diagnose the source of errors. In addition, both organizations engaged their workforce in diagnosing the errors and in implementation of preventive and or corrective actions. The current study examined the strategies used by medical laboratory managers to minimize preanalytical errors. Strategies used to minimize preanalytical errors aligned with quality management. Total Quality Management provides the framework for the studied organizations to concentrate and promote a quality culture. Providing quality service will lead to improved patient satisfaction, and organizations can gain and retain their market share of customers. Participants in Company A and Company B explained that patients or providers have many choices when receiving health care services. If they are not happy with the service they received, they will take their business elsewhere. Providing quality service will help medical laboratories gain competitive advantages over their competitors. A comprehensive TQM is the most effective strategy to lessen laboratory errors (Hammerling, 2012). By incorporating TQM aspects into the practices shared by the managers in the study, organization will benefit from the foreseen effects of reduced operational costs, improved financial performance, increased patient care experience, and increase job satisfaction with the staff.

Applications to Professional Practice

The purpose of this qualitative multiple case study was to identify strategies used by medical laboratory managers to mitigate preanalytical errors. Patient safety is an ongoing challenge in health care delivery (Cornes et al., 2016b). As an integral part of health care, medical laboratories contribute to this challenge. Accurate laboratory results are imperative in the diagnostic and efficiency of treatment of patients (Gupta, Yadav,

Mishra, & Sharma, 2015). Laboratory testing is divided into three phases: preanalytical, analytical, and post analytical (Cornes et al., 2016a). Errors can occur in any phase of testing, but the most prevalent is in the preanalytical phase with error rates up to 70%. Preanalytical errors include, but are not limited to, the following processes: test order, test request, sample collection and transport, and sampling. Preanalytical errors contribute to overall diagnostic and therapeutic errors (Cornes et al., 2016b). Although laboratories have to go through rigorous quality assessments by accreditation bodies, errors in the preanalytical phase continue to exist. Efforts made by organizations such as the European Federation of Clinical Chemistry and Laboratory Medicine Working Group for Preanalytical Phase (EFLM WGPRE) tried to mitigate these errors. As a part of contributing efforts, this study aimed to identify and expose strategies used by medical laboratory managers to reduced preanalytical errors.

The findings from this multiple case study could contribute to the health care industry in terms of reducing the laboratory errors in the preanalytical phase given that the current study readily offers effective and evidenced practices by medical laboratory managers. Overall, healthcare companies and their consumers should both benefit from the practices and methods presented in the current study. The applications of the findings take patients' lives into consideration by looking more in-depth into the recommended practices of the managers who participated in this study.

Laboratory errors affect patient safety (Plebani et al., 2013a), cost millions of dollars, and could cause detrimental effects for their patients (Favalaro et al., 2012). The current study concurs with findings from the researchers mentioned above. Healthcare

companies should gain insights from the practices that worked for Companies A and B in streamlining their management of laboratory processes and policies. This should allow healthcare companies to experience even more positive social outcomes in terms of their business and financial goals. For consumers, they will receive an improved quality of care from their health companies. The literature indicates that deaths resulting from medicinal faults are the eighth foremost cause of death in the United States. By following the meaningful and effective methods and practices shared by all five managers of the two companies analyzed, these numbers should decrease over time.

Implications for Social Change

From the findings of the study, healthcare companies are still very much committed to serving their consumers with the best quality of service and care that they can. The attitude portrayed by the managers should create a positive impression for healthcare companies that are often perceived as focusing merely on their business and financial concerns; while neglecting the human aspect of the practice. The study should serve as evidence that managers and their companies value their consumers and patients. The mindset displayed by these managers should also inspire and motivate other big and small healthcare companies to follow in these two companies' footsteps to start restructuring their companies with the goal of balancing the financial and human aspects of the business.

Another social change noted was the focus on constant improvement by the external and internal members of the healthcare companies. The companies in this study targeted the growth of their staff members and employees to reduce the preanalytical

laboratory errors. By learning and being more skillful in their tasks, staff members gained more experience and knowledge personally and professionally. Strengthening the capabilities of staff members should then improve the proper care provided to patients. The outcomes of this study add to the body of research for minimizing preanalytical errors. Thus, individuals from both inside and outside these healthcare companies should experience positive changes.

Recommendations for Action

All health care providers should view preanalytical errors as a serious problem because laboratory results influence approximately 70% of clinical decisions (Abdollahi et al., 2014). Results from this study provide medical laboratory leaders with strategies to mitigate the occurrence of preanalytical errors. Successful strategies used by the participants included employee engagement, reward and recognition program, and training and education.

Healthcare companies can consider the examination of the root causes of the problems first through careful documentation and observation of the problems. Also, healthcare companies can focus on the assessment of their employees and staff members to determine if the problems or issues are coming from them. Healthcare companies and their managers can consider focusing on the knowledge and skill improvement of their staff. By doing so, their staff members gain the tools and equipment to perform their tasks and responsibilities in the laboratory. The increased education of the staff should address laboratory errors experienced by the companies in the preanalytical phase.

Lastly, healthcare companies can implement employee recognition and engagement programs to reduce laboratory errors in the preanalytical phase.

Medical laboratory leaders can review and apply effective strategies to assist with the reduction of preanalytical errors in their medical laboratory. Any successful implementation of strategies to decrease errors in the preanalytical phase will result in better delivery of patient care. Leaders in health care delivery will view the reduction of these errors as a competitive advantage. By reducing these errors, patient satisfaction and retention will increase while operational cost will decrease.

Findings from this study add to the existing knowledge of preanalytical errors. My intent is to disseminate this information through various forums. I will provide a summary of the findings to all participants and ask them to share the information with their peers and colleagues. Another way to publicize the successes of the participants is through the publication of this study in ProQuest/UMI dissertation database. Interested audience can retrieve this information through this database. Also, I will seek for opportunities to broadcast this information through medical laboratory conferences, seminars, and academia settings.

Recommendations for Further Research

In this multiple case study, I exposed strategies used by medical laboratory managers to reduce preanalytical errors. The findings from two medical laboratories added to the limited research found in the existing literature pertaining to this topic. For future research, scholars can consider three recommendations to improve their research studies. First, researchers can consider employing a mixed-method study. The mixed-

method study would support the qualitative findings through the inclusion of the statistics on the laboratory errors in the preanalytical phase that occurred in the respective companies over the years. By triangulating the findings from the interviews and the data from the records, the researchers could provide evidence on whether the methods and practices they implement are effective or ineffective.

Second, researchers could consider increasing the number of participants in the interviews and expanding the geographical location to discover more themes as well as providing more meaningful insights from more participants. The population size of five medical laboratory managers at two health care organizations in southern California does not represent an all-inclusive view of strategies used to minimize preanalytical errors. Future study should consider a larger group of health care providers to determine the effectiveness of the strategies used by the participants. Expanding the geographical location might reveal different results from health care organizations that operate under different culture and environment conditions. Evaluating strategies used by medical laboratory managers beyond the defined geographical location may increase the ability of laboratory industry and other ancillary entities to minimize these errors. Limiting the defined geographical location also restricts the generalizability of the findings.

Last, the researchers could consider increasing the generalizability of the study by recruiting other preanalytical staff members. The targeted population of medical laboratory managers does not represent the involvement of all health care professionals in the preanalytical phase of testing. Understanding other health care professionals' perceptions, including clinicians, couriers, phlebotomists, laboratory assistants, and

clinical laboratory scientists, may expose strategies used by these individuals to minimize preanalytical errors. Therefore, a wider sample population that includes participants from other geographical locations and involvement of other health care professionals has the potential to increase validity, decrease selection bias, and fewer data anomalies.

Reflections

As I reflect on my journey with the DBA Doctoral Study process, I realized that this experience helped me grow as a student and professional aiming for lifelong learning. With the encouragement of Walden faculty, I was able to choose a topic that met the criteria of the DBA Doctoral Study. This encouragement enabled me to work through the many frustrations that arose along the way and to remain engaged until the completion of the DBA Doctoral Study.

Prior to considering this topic, I read many journal articles on the topic of laboratory errors. Narrowing the topic to preanalytical errors enabled me to focus sharply on the most problematic area of total laboratory testing. Further refining of the topic to strategies used by laboratory managers to mitigate laboratory errors provided a laser emphasis of possible solutions to the problem.

My interest in this phenomenon stemmed from my profession. Serving as medical laboratory manager and quality assurance manager, I often found it frustrating and disheartened to experience the effects of laboratory errors; misdiagnoses, delay of treatment, and increased operational costs. Choosing to concentrate on strategies used by medical laboratory managers to curb preanalytical errors allowed me to conduct the study without biases. I was able to collect and analyze data without biases because I do not

have any experience in the preanalytical phase of testing. Therefore, I was able to conduct the study without any preconceived knowledge of the responses to the interview questions.

The focus of this study was to explore strategies used by medical laboratory managers to successfully curb preanalytical errors. Although each participant revealed different perceptions, there were several strategies shared among the participants in their efforts to reduce these errors. The strategies exposed in this study enabled me to gain a deeper comprehension of laboratory medical managers' abilities to minimize preanalytical errors. Laboratory leaders can use the findings in this study to help them analyze and implement strategies to decrease preanalytical errors.

Conclusion

This research presented the processes of the two companies who have succeeded in reducing their laboratory errors in the preanalytical phase. Through the study, practices and methods were established which should aid other companies and medical practitioners in addressing their problems of the same type. The findings were important to identifying the root causes through careful and proper documentation of specimens and other resources. The main emphasis of the managers revolved around the need for staff members and personnel to be involved at all times; giving them value by constantly training and educating them to be equipped with the skills of determining and managing the errors strategically. Finally, the managers and their companies highlighted the importance of reducing laboratory errors to providing their consumers with the best service and quality care that they deserve. These findings indicate that with enough

effort and commitment from healthcare companies, their management, and staff members, more and more patients' lives can be saved. As companies try to improve their preanalytical practices and processes, patients also feel the values on the lives placed by these companies. In the end, and with proper application of the suggested methods, it is hoped that concrete and actual changes in patients' lives will be achieved.

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Appendix A: Recruitment Letter

Subject: Invitation to Participate in a Doctorate Study

Date: [Insert Date]

Dear Sir/Madam:

My name is Huong Ly and I am a student at Walden University, pursuing a Doctor of Business Administration degree (DBA). My credentials include over ten years as a clinical laboratory scientist performing assay analysis. In addition, I also have over five years of management experience, of which three are in quality assurance. I am conducting a case study in southern California exploring the success of medical laboratory managers with minimizing laboratory errors. The title of my study is "Exploring Medical Laboratory Managers Success with Preanalytical Errors." I would like to explore ways to help other laboratories reduce errors in this phase of testing. It is a fact that many laboratories encounter this relevant issue. Numerous researchers and practitioners cited up to 75% of errors occur in the preanalytical phase of testing. I would like to interview medical laboratory managers who meet the following criteria:

- Organization must be located in southern California.
- Laboratory manager must have a minimum of five years of laboratory experience.
- Laboratory manager must have at least two years of management experience with preanalytical process.
- Laboratory manager must have completed at least one project to minimize laboratory errors.

I will be the data collector and the data collection method is through face-to-face interview and observation of your preanalytical process. Rest assured that all divulged information will be anonymous and I will not share your data with other health care organizations. Note that there is a lack of incentive if you decide to partake in this study. If you meet the criteria and would like to participate in this study, my contact information is (714) 595-1389 or huong.ly@waldenu.edu. Thank you for your consideration.

Sincerely,

Huong Ly
DBA Student
Walden University

Appendix B: Consent Form

This is a research project being conducted by Huong Ly at Walden University. You are being asked to participate in a research study exploring your success with preanalytical errors. I am asking you to partake in this study because you are a medical laboratory manager with successes at curbing error in this phase of testing. Please read this form carefully before agreeing to take part in the study.

Voluntary: Your participation in this research study is voluntary. You have the option to not participate or withdraw without reprisal at any point of the study. You can withdraw either through an email or verbal request. You can email me at huong.ly@waldenu.edu

What the study is about: The purpose of this qualitative case study is to explore in depth how medical laboratory managers reduce laboratory errors in the preanalytical phase. Participants for this case study are medical laboratory managers who reduced laboratory errors in the preanalytical phase.

What we will ask you to do: If you agree to be in this study, you will complete a face-to-face interview at the organization where you work. Each interview will take about 60 minutes to complete. The interview questions revolve around your knowledge and success with the preanalytical errors. I will also need to spend about 30 minutes observing your preanalytical processes. In addition, I will need to spend an additional 30 minutes with you to review the collected data to validate the findings.

Risks and benefits: There is the risk that you will find some of the questions about your job conditions to be sensitive. There are no benefits to you. Laboratory work is very demanding and keeping errors to a minimum is critical. I hope to learn more about ways to minimize preanalytical errors that affect patient safety and health.

Compensation: There is no compensation for taking part in this study.

Confidentiality: I will not collect identifying information such as your name, email address, or IP address. In any type of report I make public, I will not include any information that will make it possible to identify you or your organization. All data is stored in a password protected electronic format. This consent form and study data will be in the researcher's possession for five years locked in a personal safe deposit box, then destroyed upon the expiration of the timeframe. The results of this study will be used for scholarly purposes only and may be shared with Walden University representatives or other health care facilities.

Contact information: If you want to talk privately about your rights as a participant, you can call Dr. Leilani Endicott. She is the Walden University representative who can discuss this with you. Her phone number is 612-312-1210. This research has been reviewed according to Institutional Review Board (IRB) procedures for research involving human subjects. The Walden IRB approval number for this study is XXXXXXXXX.

Statement of Consent: I have read the above information and acknowledge that by signing this consent form, I decided to partake in this study. I agree to terms outlined above.

_____	_____
Printed Name of Participant	Date of consent
_____	_____
Participant's Signature	Researcher's Signature

Appendix C: Data Collection Instrument – Interview Guide

The interview questions are:

1. How do you identify the areas that are the focus of preanalytical errors?
2. How do you diagnose the root cause of the problem? Do you use observations and documentation to help diagnose the root cause?
3. How do you implement interventions that could potentially yield favorable outcomes to minimize errors?
4. How do you reinforce the identified inventions to ensure effectiveness?
5. Does your organization consider quality as a top priority?
6. What is your strategy to engage employees in developing a quality culture?
7. How do you involve and empower all laboratory and other ancillary personnel in cooperative efforts to achieve quality improvements in the preanalytical phase?
8. How can quality improve operational costs, patient care experience, and competitive advantage?
9. How do you implement continuous improvement of employee's capabilities and work processes through training and education to reduce preanalytical errors?
10. Is there any other preanalytical error reduction strategy you would like to share to help medical laboratory managers address this issue?

Appendix D: Observation Protocol

Date: _____

Time: _____

Place: _____

Descriptive notes	**Reflective notes**
Phlebotomy (patient identification, phlebotomy procedure, specimen labeling)	
Specimen tracking	
Specimen transportation	
Specimen rejection	