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Preanalytical Errors, Analytical Errors, and Postanalytical Errors and the Financial Performance of Hospitals

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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Abstract

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by

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MBA, Ohio University, 2017

BS, Weber State University, 2015

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

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May 2025

Abstract

Hospital administrators and financial decision-makers face ongoing challenges in maintaining positive operating margins, which are critical for sustaining healthcare services and delivering high-quality patient care. Errors in clinical laboratory testing—preanalytical, analytical, and postanalytical—can lead to inefficiencies, increased costs, and reduced financial performance. Grounded in total quality management, the purpose of this quantitative correlation study was to examine the relationship between preanalytical errors, analytical errors, and postanalytical errors and hospital operating margin. The participants were clinical laboratory leaders who completed an anonymous survey using Survey Monkey as a data collection tool. The sample size for this study included 77 participants. The results of the multiple linear regression showed a statistically significant relationship, $F(3, 73) = 13.438$, $p < .001$, $R^2 = .356$. In the final model, one predictor was statistically significant, with the preanalytical error demonstrating a contribution ($t = 3.663$, $p = <.001$, $\beta = .379$). A key recommendation is for healthcare leaders to adopt TQM principles that minimizes errors in the preanalytical phase of testing and educating all stakeholders to implement better protocols aimed at error prevention. The implications for positive social change include the potential to improve hospital sustainability, which can lead to greater financial stability, reduced healthcare costs, and enhanced patient care, ultimately fostering better public health outcomes and stronger community well-being.

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Dedication

I dedicate this doctoral study to my mother, Michele Levy, whose unwavering support has been instrumental throughout this process. My entire family, including Raquel Levy and Jaiden Willis, has provided encouragement and demonstrated patience during this demanding journey. I also wish to honor the memory of my father, Raymond Levy, whose influence inspired my pursuit of a medical career and instilled in me the values that have guided me to this point.

I extend my heartfelt appreciation to my best friend, Mellaney Edwards, for her steadfast support and financial assistance, as well as for her unwavering faith in me. Finally, I would like to express my gratitude to Stephen Moore, who motivated me to return to school to pursue my doctoral degree.

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I extend my heartfelt gratitude to my committee chair, Dr. Irene Williams, for her invaluable guidance throughout this process, as well as to Dr. Charlie Shao. Their recommendations and support have significantly contributed to the enhancement of this body of work.

This achievement is a collective accomplishment that reflects the unwavering support of my family and my broader support network. I express my sincere appreciation for the inspiration and vitality that I have received from my Lord and Savior Jesus Christ, enabling me to persevere.

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Section 1: Foundation of the Study

Clinical laboratory errors can be a significant challenge for healthcare organizations and not just in terms of patient care and satisfaction. The financial impact of such errors can be severe and long-lasting. According to Lin and Fang (2021), in a report from the Institute of Medicine in 2000, as many as 98,000 patients died from medical errors. Inaccurate test results can lead to misdiagnosis and incorrect treatment plans, resulting in additional healthcare costs such as extra testing, procedures, hospital stays, and medication. The cost of fixing these errors can also be significant, mainly if the mistake results in litigation. This can harm the healthcare organization's financial performance.

Background of the Problem

The healthcare environment challenges the clinical laboratory to deliver improved patient care while decreasing costs and increasing efficiencies (Osborne, 2017). The usefulness of laboratory testing is extensively known; 70% of provider diagnoses are based on laboratory results, and the processes make up 5% of healthcare costs while the decisions made translate into the remaining 95% of the costs (Farsani et al, 2022; Hallworth, 2011). The estimated medical error cost annually is between $17.1 and $29 billion in the United States (Hammerling, 2012). Laboratory errors at each phase of testing play a role in the rising cost.

The preanalytical testing phase is critical in ensuring accurate laboratory test results. According to Simundic and Lippi (2012), the preanalytical testing phase is the most vulnerable and significant challenge in the laboratory testing process. This phase includes activities such as specimen collection, processing, and transport, which are often not standardized or harmonized globally. Errors in this phase can lead to inaccurate results, affecting patient care and treatment. Research by Zemlin (2018) indicated that up to 70% of errors occur during the preanalytical phase, with the potential for up to 73% of these errors being preventable.

The analytic phase, in contrast, involves the actual testing process and accounts for only 0.1% of errors (Sakyi et al., 2015). This phase is tightly regulated by the Clinical Laboratory Improvement Amendments (CLIA), and laboratory professionals are well-trained in quality control procedures to minimize errors. The postanalytical phase, which includes result reporting, has a higher error rate of about 4% (Sakyi et al., 2015). Timely and accurate result reporting is essential for patient care, particularly in critical care areas where delays can have serious consequences. Overall, a focus on improving processes at each phase of testing, especially the preanalytical phase, can help reduce errors and enhance the quality of laboratory testing.

Problem and Purpose

A lack of quality management systems in medical laboratories results in errors, costing the United States healthcare industry approximately 29 billion dollars annually (Zahar et al., 2016; Zineldin et al., 2014). The general business problem that prompted this research is erroneous results caused by errors made during the testing process can lead to decreased patient and provider satisfaction and increased costs in the healthcare industry. The specific business problem is healthcare managers have limited knowledge of the relationship between (a) preanalytical, (b) analytical, and (c) postanalytical errors in the clinical laboratory and the financial performance of a hospital organization in the United States.

The purpose of this quantitative correlational study was to examine the relationship between preanalytical, analytical, postanalytical errors and financial performance of hospitals in the Unites States. I used a survey to collect data to complete the study. The findings of this research have potential implications for positive social change that include the potential to provide healthcare leaders justification to implement processes that improve laboratory quality to reduce errors, which may positively impact patient outcomes and decrease healthcare costs.

Population and Sampling

The sampling population of my study consists of a survey of clinical laboratory leaders from hospital organizations in the United States. Preanalytical, analytical, and postanalytical errors and the healthcare organization’s profitability will be analyzed between 2020 and 2023. Each of the hospital laboratories selected must perform moderate or high complexity testing and hold a certificate of accreditation from the state survey agency or CLIA operating branch. This study was planned to include at least 77 hospital laboratories. G*Power assessment identified the minimum sample size using a 0.05 alpha error probability and 0.8 power.

Nature of the Study

The quantitative research method is appropriate for this study. Among the three research methods, quantitative, qualitative, and mixed methods, the quantitative research method is suitable for this study as the data are numerical and deductive reasoning was used to link the theory and research (see Zou et al., 2014). The qualitative research method allows researchers to gain insights into why people engage in certain behaviors (Rosenthal, 2016), which is the most common method of data collection used in healthcare research (Leung, 2015). Because I was exploring the relationship between data sets and not looking to identify new strategies, the qualitative method would have been inappropriate for this study. Mixed-methods research can be complex as they use both qualitative and quantitative methods to explore themes and evaluate empirical data (Almalki, 2016; Williams, 2021). The qualitative component was unnecessary to answer my research question, and therefore, a mixed-method approach was inappropriate for this study.

The correlational research design was chosen to use non-biased data that are not as restrictive as an experimental design which can show an association or dependence between the variables that often have high validity that can contribute to further research. Correlational research comprises an examination of the association and impact between two or more variables (Saunders et al., 2016). The relationship between preanalytical, analytical, and postanalytical errors and financial performance, which aligns with quantitative research, was examined in my study. The study includes results collected from a survey.

Research Question and Hypotheses

What is the relationship between (a) preanalytical, (b) analytical, and (c) postanalytical laboratory errors and (d) financial performance?

Null Hypothesis (H_0): There is no significant relationship between (a) preanalytical laboratory, (b) analytical, and (c) postanalytical laboratory errors and (d) financial performance.

Alternate Hypothesis (H_1): There is a significant relationship between (a) preanalytical laboratory, (b) analytical, and (c) postanalytical laboratory errors and (d) financial performance.

Theoretical Framework

Total quality management (TQM) originated in the manufacturing industry to measure the overall performance of a plant (Ansari, 2022). TQM was the conceptual framework in this study because it focuses on continuous improvement to improve customer satisfaction and reduce poor-quality costs. The research method explores learning more about the validity of the data rather than TQM, which focuses on monitoring quality through statistical control (Vogelsang, 1999). TQM not only supports organizational and company leaders in identifying existing problems but aids in reaching a solution and ensuring the solution is sustained. TQM is achievable through senior leaders' commitment, teamwork, and metrics to measure and identify any inconsistencies and expose the root cause of the problem (Ansari, 2022). TQM can help nonprofit leaders initiate quality management standards that will help them manage processes and increase productivity to create and improve competitive advantages (Delduarte, 2021; Savov et al., 2017).

Operational Definitions

Analytical error: Any defect occurring during the testing process, which may include equipment malfunction, sample mix-ups, interference, undetected failure in quality control, and procedure not followed (Hicks, 2021; Tasneem et al., 2024).

Laboratory error: Any defect occurs from ordering tests through reporting results and interpretation and response (Lillo et al., 2012).

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

Preanalytical error: Any defect that happens before testing includes specimen collection, processing, and transport (Tasneem et al., 2024).

Postanalytical error: Any defect that happens after testing includes reporting the laboratory results to the requesting clinician and releasing testing results timely and to the appropriate provider, critical result reporting, corrected results, accuracy, and interpretation of results (RodrÍguez et al., 2019; Tasneem et al., 2024).

Quality control: Actions are used to monitor the performance of testing processes, detect potential errors, and correct discrepancies prior to reporting results (Lee, 2012).

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

Quality management system: A structured framework of policies, processes, and procedures that ensures proper patient preparation, specimen collection, and accurate and reliable test results while adhering to all applicable regulatory requirements and industry standards (MacCormack, 2019; Venkatesh, 2022)

Assumptions

Data quality plays a vital role in the data outcomes presented within a study. The first assumption was that the participants were clinical laboratory professionals with adequate experience identifying and distinguishing preanalytical, analytical, and postanalytical errors. The second assumption was that the data collected are accurate as the survey participants were qualified and had the knowledge needed to complete the survey. A third assumption was that each participant represents a different hospital laboratory because the survey would be anonymous. Assumptions are facts considered valid but not verified; any associated risk should be treated as such.

Limitations

The primary challenge was recruiting clinical laboratory leaders to participate in the survey crucial for the study's completion. I intended to engage with other leaders via professional networking platforms. Because I would not have access to their documentation, there may have been differences in how each leader evaluates error rates at different testing stages. These would affect the consistency of interpreting quality and financial performance data. Record-keeping methods differ across organizations. Ensuring confidentiality of survey responses by keeping participation anonymous was essential.

Delimitations

In any research study, delimitations play a crucial role in defining the scope and boundaries of the research (Coker, 2022). These characteristics are a direct result of the limitations inherent in the study and are also influenced by the deliberate decisions made by the researcher during the planning phase. The participants of this study were only from hospital laboratories in the United States. Independent reference laboratories were excluded from the study.

Significance of the Study

This study is significant because of the cost related to laboratory errors and the impact on patient care; a study on the factors potentially affecting financial performance could have a significant business impact in the healthcare industry. Previous researchers have shown that financial performance is impacted by preanalytical errors; however, the full testing process should be evaluated (Ly, 2017). Healthcare issues are not only a business problem. Because the study was related to laboratory quality, there would likely be a positive social impact. The study focus was on increasing the understanding of healthcare leaders and the quality drivers impacting financial performance. Failure to provide accurate laboratory results affects a provider’s ability to diagnose and treat patients, which can be detrimental to patient care (Carlson et al., 2012). Such errors are costly due to additional resources needed to investigate and address the concern, which leads to follow-up testing (Ly, 2017).

Contribution to Business Practice

Identifying and mitigating preanalytical, analytical, and postanalytical errors is crucial in any business practice, especially in industries where accuracy is paramount. By ensuring that these errors are identified and addressed, businesses can maintain their reputation for accuracy and reliability. This is particularly important in industries such as healthcare, where incorrect test results could lead to misdiagnosis or improper treatment.

In the healthcare industry, errors in analysis could lead to costly lawsuits, regulatory penalties, and higher costs for patient care.

Additionally, by proactively identifying and mitigating these errors, businesses can improve efficiency and reduce costs associated with retesting, rework, or potential legal consequences. Implementing quality control measures and employee training programs can help to minimize the occurrence of these errors, ultimately leading to improved business performance and customer satisfaction.

Implications for Social Change

Identifying and mitigating preanalytical, analytical, and postanalytical errors in medical laboratory testing is pivotal for societal progress. These errors possess the potential to yield inaccurate test outcomes, which in turn may lead to erroneous diagnoses or treatment strategies. Improved education, training, and quality control protocols are imperative in addressing and diminishing laboratory errors, as they pave the path for better patient results and bolster the credibility of the healthcare system.

Upholding precise and dependable laboratory testing is critical on a social transformation front to elevate healthcare outcomes universally. Such efforts can furnish more efficient diagnoses, treatment plans, and overall patient management. Advocating for refined procedures and training to diminish errors in laboratory testing, allows healthcare to inch closer to a system that prioritizes patient safety and quality care for all individuals.

A Review of the Professional and Academic Literature

The purpose of this quantitative correlational study was to examine the relationship between preanalytical, analytical, and postanalytical errors and the financial performance of a healthcare organization. The hypothesis posits that the amalgamation of preanalytical, analytical, and postanalytical errors may impact the financial performance of a healthcare organization. The literature review encompasses data concerning the theoretical framework and variables.

During the process of conducting a thorough examination of existing literature, I used the flowing keywords in my searches: *quality, healthcare, clinical errors, clinical laboratory, finance, quality indicators, nonprofit, quantitative research, medical errors*, and *laboratory errors*. Only articles that were directly relevant to the study were assessed for the purpose of conducting a comprehensive literature review. The majority of literature utilized in the research is limited to a publication period of no more than 5 years, as this timeframe aligns with the stringent academic standards set forth by the DBA program at Walden University (see Table 1). I located a blend of research sources obtained from the databases of Walden University Library: Academic Search Complete, ProQuest Central, Business Source Complete, ABI/INFORM Global, ScienceDirect.

Table 1

Literature Review

	Total	Published within 5 years	% Peer reviewed
Peer reviewed (2020–2024)	35	31	88
Non-peer reviewed	5	3	

Application to the Applied Business Problem

The purpose of this quantitative correlation study was to explore the relationship between laboratory errors at each phase of testing and financial performance. According to Rodziewicz et al. (2024), recent studies reported adverse events that occur during medical care in the United States contribute to more than 400,000 hospitalizations annually while another estimated that more than 200,000 patient fatalities are preventable medical errors. In fact, medical errors are the third leading cause of death in the United States (Rodziewicz et al. 2024). Given the magnitude of this problem, all healthcare institutions should explore ways to address the causes of these mistakes. Previous research has shown that laboratory medicine has attempted to address errors in test results, but the problem persists. As part of these efforts, laboratories need to develop and implement effective processes to minimize errors because laboratory tests account for a significant portion of healthcare spending. Compared to other healthcare sectors, medical laboratories have been at the forefront of pursuing total quality. Laboratory errors occur at a rate of 0.012% to 0.6% and can cause temporary harm or even lead to death (Agarwal et al., 2012). Even without adverse outcomes, laboratories should take all mistakes seriously because clinicians rely on laboratory results for accurate diagnoses and treatment.

Implementing the TQM system could be key to minimizing laboratory errors. TQM emphasizes the control of processes through standardized procedures and protocols and encourages a continuous cycle of feedback and improvement (Alshrbaji et al., 2022). Clinical laboratory results influence 70% of clinical diagnoses and decisions, making them crucial for patient care (Hicks, 2021; Lam & Church, 2024). Errors in laboratory testing can jeopardize patient safety and increase costs for the healthcare system (Jafari et al., 2022). Efforts have been made to reduce errors in both the analytical and postanalytical phases, but errors in the preanalytical phase remain a challenge (Syeda et al., 2022). Developing a comprehensive TQM system could minimize errors by identifying their root causes and implementing effective solutions (Farisani et al., 2022). By targeting all phases of the laboratory process, TQM is a robust strategy for reducing the frequency and impact of errors.

Independent Variable A: Preanalytical Errors

As highlighted by Simundic and Lippi (2012), the preanalytical phase of testing poses the greatest vulnerability and challenge. The preanalytical phase encompasses activities such as specimen collection, processing, and transportation that precede the actual testing. The management of these activities needs more standardization and global harmonization, as noted by Simundic and Lippi (2012). A significant portion of specimen collections occur at the patient's bedside without supervision from laboratory personnel. Therefore, the clinical laboratory must establish criteria for specimen rejection to ensure samples meet the necessary testing criteria and minimize the likelihood of errors. Zemlin (2018) stated that this phase is responsible for up to 70% of reported errors, up to 73% of which are preventable.

The financial impact of preanalytical errors in North American hospitals is substantial. In North American hospitals, the average expense associated with preanalytical errors has been calculated to be $162 for critical inpatient cases, $357 for noncritical inpatient cases, and $337 for outpatient cases, which includes emergency department patients (Dundar & Bahadir, 2023). Delayed and imprecise laboratory findings lead to postponed or erroneous diagnoses and treatments, thus elevating hospital expenses (Tasneem et al., 2024). Most of the preanalytical process occurs outside the laboratory, as it necessitates the participation of nonlaboratory personnel. Current research has indicated that preanalytical errors are responsible for a significant portion, ranging from 60% to 93% of all rejections. These errors occur at frequencies between 0.2% and 8% (Cao et al., 2016; Mukhopadhyay et al., 2021). Identifying the source of error and root cause is necessary to address the process and train individuals engaged in the preanalytical phase, including physicians, nurses, interns, and transport personnel (Dundar & Bahadir, 2023). To effectively address preanalytical errors, understanding the sources is crucial.

Source of Errors

Addressing sources of errors in the preanalytical phase starts with order entry. The initial step of the preanalytical phase commences with the completion of forms and laboratory requisitions. The requisition forms necessitate specific information, including the clinician's details (name and contact number), patient details (name, date of birth, gender, and location), billing information, diagnosis, and medication list. These details are crucial for accurately interpreting the results and the specific tests requested.

Farisani et al. (2022) noted that more patient information can lead to clarity in result interpretation. In outpatient settings, clinicians often rely on manual processing and are known for their challenging handwriting. Data transcription and order entry mistakes commonly contribute to preanalytical errors (Lam & Church, 2024). This issue can also arise in the inpatient setting, particularly for microbiology and pathology testing that require manual requisition (Lam & Church, 2024). While the electronic medical record system reduces the likelihood of errors in test ordering, its implementation remains unavailable in developing countries (Zemlin, 2018). Automating manual processes standardizes workflows and leads to fewer errors and sample rejections.

Errors that occur during the collection process can lead to sample rejection. Insufficient or inaccurate samples sent to the laboratory often result in sample rejection. According to Zemlin (2018), hemolysis is the leading cause of rejection, accounting for up to 70% of cases. Other reasons include clotting of the specimen and insufficient volume. Modern automated instruments can detect hemolysis, lipemia, and icteric samples by setting thresholds within the middleware (Tasneem et al., 2024). If the level of interference exceeds this threshold, the sample is automatically rejected. Among these interferences, lipemia is the most common and can significantly affect the accuracy of laboratory results (Zemlin, 2018). Lipemic samples are usually caused by improper timing and process of blood sampling after a meal or the administration of synthetic lipid emulsions. Unlike other interferences, lipemia can be eliminated through centrifugation, allowing for accurate measurement. To maintain sample integrity and suitability for testing, clinical laboratories must establish effective criteria for specimen rejection (Tsai et al., 2019). Continuous quality improvements in sample collection and processing protocols are necessary for minimizing errors.

Issues related to incorrect specimen collection can significantly impact the accuracy of laboratory results. Rejection of blood samples drawn into incorrect tubes or containers is a relatively common issue in routine laboratory practice (Tasneem et al., 2024). Dundar and Bahadir (2023) found that clotted samples accounted for over one third of the errors before analysis. This phenomenon is caused by inadequate mixing of the blood with anticoagulant in the tube or by leaving the tubes in a horizontal position.

Coagulation is a significant preanalytical error that leads to inaccurate blood cell count and hemostasis test results, as the blood cells are trapped in the clot and coagulation factors are consumed during the coagulation process (Tasneem et al., 2024). Hemolysis, on the other hand, typically arises from excessively vigorous mixing of blood with the anticoagulants in the tube, forceful withdrawal and distribution of blood into collection tubes, and using butterfly needles for blood collection. These two preventable errors continue to occur at a high rate, especially in critical care areas (Tasneem et al., 2024). Therefore, implementing standardized and universally applicable policies regarding the management of nonconforming samples, along with the inclusion of relevant quality indicators, will pose a greater challenge to enhancing overall quality (Dundar & Bahadir, 2023). Given the significant challenges associated as preanalytical errors, the focus must shift to mitigating analytical errors that can further compromise test accuracy and patient care.

Independent Variable B: Analytical Errors

The analytical phase of laboratory testing is crucial and prone to several specific challenges. The phase occurs during the testing process, and testing personnel may encounter issues such as equipment malfunction, sample mix-ups, interference, undetected failure in quality control, and failure to follow procedures. Analytical errors, which account for approximately 7%–13% of all errors, are primarily attributed to instrument malfunction, quality control issues, reagent issues, calibration problems, human error, and interferences during testing (Syeda et al., 2022; van Moll et al., 2023). Diagnostic test systems are generally classified as moderately or highly complex testing and are subject to strict regulation under the CLIA, enacted in 1988. Clinical laboratories in the United States must obtain a CLIA certificate and undergo inspection every 2 years to ensure compliance with the law if they perform moderate or high-complexity testing (U.S. Government Publishing Office, 2021). Laboratorians are well-trained and knowledgeable about these rigorous regulations, contributing to the lower occurrence of errors in this phase.

Ensuring the accuracy and reliability of laboratory results requires stringent adherence to quality control protocols (Haynes & Fishwick, 2022). Laboratories must adhere to proper specimen collection, handling, storage, and testing requirements. Quality control encompasses a range of activities to verify and ensure the validity and reliability of the laboratory testing process. These activities include assessing and monitoring the laboratory's personnel, equipment, and methodology, comparing results with established standards and reference values, and implementing appropriate corrective actions in the event of deviations (Haynes & Fishwick, 2022). CLIA specifies the frequency of quality control testing based on the specific test and the discipline of the laboratory.

Analytical errors in the clinical laboratory can severely affect patient care and treatment outcomes (van Moll et al., 2023). These errors can impact a patient's diagnosis, treatment, and overall health, leading to unnecessary treatments, delays in treatment, or incorrect treatment options. Therefore, clinical laboratories must be aware of and address potential analytical errors to ensure the accuracy and reliability of their test results (Farisani et al., 2022; van Moll et al., 2023). By comprehensively addressing these issues, clinical laboratories can enhance patient outcomes and trust in laboratory testing.

Identifying and addressing potential sources of error is essential for maintaining the accuracy of laboratory results. Problems can arise from improper instrument calibration or insufficient calibration verification. Issues with the calibration of an assay can lead to inaccurate measurements and affect the accuracy of test results (Bishop, 2024). Laboratories should establish and follow strict calibration procedures to maintain the accuracy of their instruments. Human errors, such as sample mix-ups or incorrect pipetting, can also contribute to analytical errors (van Moll et al., 2023). Laboratories should implement quality control measures, such as double-checking samples and reagents, to minimize the risk of human errors.

Effective strategies are essential for minimizing analytical errors in clinical laboratories. Clinical laboratories should implement quality assurance and quality control measures to prevent analytical errors. Quality assurance involves establishing and maintaining processes to ensure the accuracy and reliability of test results, while quality control involves monitoring and verifying the performance of laboratory procedures and instruments (Bishop, 2024). Laboratories should regularly conduct internal quality control checks and participate in external proficiency testing programs to ensure the accuracy and reliability of their test results (Farisani et al., 2022). Laboratories can improve the reliability and dependability of diagnostic services by implementing effective quality assurance strategies.

Proper training and clear protocols are vital for errors in the laboratory and can minimize human error. Clear protocols include ongoing training on proper sample collection and handling techniques, instrument operation, and quality control procedures. Additionally, laboratories should establish clear guidelines for reporting and addressing errors to prevent the recurrence of analytical errors (van Moll et al., 2023). Furthermore, implementing stringent documentation and record-keeping processes can help ensure the traceability of test results and facilitate error investigation and resolution (Farisani et al., 2022). Prioritizing these measures in laboratories can significantly improve the overall accuracy of laboratory testing.

Standard Operating Procedures

Standard operating procedures (SOPs) play a vital role in maintaining the quality and consistency of clinical laboratory operations. Clinical laboratories are essential in providing accurate and reliable diagnostic results for patient care (Rayser, 2019). Clinical laboratories must have established SOPs to ensure quality and consistency in testing processes and laboratory operations. These guidelines are essential for outlining specific functions such as test methodology, laboratory safety, and data management and ensuring that all laboratory staff members adhere to the same standardized protocols (Rayser, 2019). One of the most critical areas covered by SOPs is specimen collection. Proper labeling of specimens, appropriate handling, transport, and storage procedures, as well as criteria for rejecting specimens, are all outlined in these guidelines. A good collection, transport, and storage process ensures that the integrity and quality of the specimens are maintained throughout the testing process (Cotta et al., 2022). Implementing and adhering to SOPs helps maintain the high standards required for delivering precise and reliable diagnostic results.

Testing procedures are another crucial aspect that SOPs cover (Rayser, 2019). Calibration and quality control procedures, protocols for various testing processes and assays, and proper operation, cleaning, maintenance, and troubleshooting of instruments are all outlined in these guidelines. Testing procedures ensure the testing processes' accuracy and reliability (Rayser, 2019). Data management is a key area covered by SOPs. Accurate entry of data, computerization of laboratory records, and thorough documentation and data reporting are all essential components of these guidelines. Complete and precise documentation ensures the integrity and confidentiality of patient information and test results (Rayser, 2019). This meticulous approach to documentation upholds the trustworthiness and credibility of laboratory results.

Personnel policies are also addressed in SOPs. The policies include orientation and training for personnel, staffing and scheduling guidelines, and ensuring personnel safety and health (Rayser, 2019). Performance evaluation and competency assessment are also outlined in these guidelines to ensure that all laboratory staff members are qualified and competent to perform their duties. Laboratory safety is paramount in clinical laboratories, and SOPs cover this area extensively. Handling chemical and biological hazards, proper use of personal protective equipment, emergency procedures, quality assurance, and risk assessment are all outlined in these guidelines to ensure the safety of laboratory staff and patients (Roghani et al., 2023). Ensuring comprehensive safety measures creates a secure working environment for all personnel and safeguards patient health.

A laboratory information management system is an essential component of clinical laboratory operations, and SOPs cover its implementation and use. Storage, retrieval, and analysis of data, implementation of barcoding and sample tracking, as well as historical trending and management reporting, are all covered in these guidelines to ensure the efficiency and accuracy of laboratory operations (Park, 2023). Proficiency testing is another crucial area covered by SOPs. Appropriate handling and communication during proficiency testing, use of certified testing materials and guidelines, and procedures for exceptions and corrective action in proficiency testing are all outlined in these guidelines to ensure the accuracy and reliability of testing processes (Park, 2023). Efficient data management and tracking significantly enhance operational workflows and data integrity.

Training and Competency

The expertise of clinical laboratory personnel is fundamental to the accuracy and reliability of diagnostic testing and patient care. Clinical laboratory personnel play a critical role in diagnostic and patient care as they perform various laboratory tests and procedures (Rayser, 2019). Their professional competence is essential for ensuring the accuracy and reliability of test results, which are crucial in guiding the diagnosis and treatment of patients (Cotta et al., 2022). To this end, laboratory personnel must undergo appropriate training and possess the necessary qualifications to carry out their duties effectively (Rayser, 2019). The competence and expertise of personnel underpins the high standards of diagnostic precision.

Regulatory standards such as the 1988 CLIA ensure that laboratory personnel meet specific qualifications. CLIA mandates that laboratory directors and CLIA certificate holders establish the qualifications for various roles within the laboratory, including general supervisors, technical supervisors, technical consultants, clinical consultants, and testing personnel (U.S. Government Publishing Office, 2021). These qualifications ensure that laboratory personnel have the knowledge, skills, and expertise required to perform their duties competently and safely (Cotta et al, 2022). Compliance with CLIA standards is essential for maintaining high quality laboratory operations and deliver excellent patient care.

Academic qualifications and ongoing education are vital for ensuring clinical laboratory personnel are equipped to perform their duties accurately and effectively. One of the critical requirements for clinical laboratory personnel is to possess relevant academic qualifications in chemical, physical, or biological science, medical laboratory science, or an equivalent field. Education is the foundational knowledge necessary for understanding laboratory testing procedures and interpreting test results accurately. Clinical laboratory personnel must participate in regular training programs and continuing education to stay abreast of advancements in laboratory medicine and enhance their skills (Cotta et al., 2022). Continuous investment in education ensures that laboratory staff can provide reliable and cutting-edge services to improve patient outcomes.

Certification and licensing play an essential role in validating the qualifications and ensuring the accountability of clinical laboratory personnel. In addition to education and training, clinical laboratory personnel are also required to obtain certification from reputable accreditation bodies such as the American Society for Clinical Pathology, the National Credentialing Agency for Laboratory Personnel, or the American Medical Technologists in some states. These certifications prove their competency and proficiency in their respective roles within the laboratory. Clinical laboratory personnel must also obtain a valid license from some states where they operate, ensuring their professional accountability and adherence to state regulations. Proper training and competency assure patients and healthcare providers that laboratory personnel are qualified and authorized to perform laboratory testing procedures (Cotta et al., 2022). Certification and licensing underscore the commitment of laboratory professionals to uphold the highest standards of practice.

Clinical laboratory personnel must have relevant work experience to demonstrate their practical skills and contribute effectively to patient care. According to CLIA, relevant work experience is also a crucial component of the qualifications for clinical laboratory personnel (U.S. Government Publishing Office, 2021). Education and experience allow laboratory personnel to demonstrate proficiency in performing laboratory testing procedures and handling various laboratory instruments and equipment. The qualifications and training required for clinical laboratory personnel are essential for ensuring the accuracy and reliability of laboratory test results. The competence of testing personnel ultimately has a direct impact on patient care and safety. By adhering to the regulations set forth by CLIA and obtaining the necessary education, certification, licensing, and experience, clinical laboratory personnel can demonstrate their professional competence and contribute to the delivery of high-quality laboratory services (Cotta et al., 2022). These stringent requirements highlight the critical role laboratory personnel play in the healthcare system.

Independent Variable C: Postanalytical Errors

The postanalytical phase encompasses various tasks, such as delivering laboratory results to the requesting clinician promptly and to the appropriate provider, highlighting critical results, rectifying inaccuracies, ensuring the accuracy of results, and interpreting results. Studies reveal that errors in this phase constitute approximately 19% of the total errors (Sakyi et al., 2015). As previously stated, accurate and timely reporting of results plays a vital role in diagnosing and treating patients. Any delays in reporting patient results can lead to delays in patient care, particularly in critical care settings where a delay can harm the patient. Reporting delays, reporting results to the wrong provider, incorrect result reporting, and misinterpreting patient results all fall within the testing phase. Zemlin (2018) emphasizes the importance of promptly communicating critical results to the clinician. Up to 10% of errors in this phase are estimated to be associated with reporting critical results.

According to Syeda et al. (2022), the occurrence of postanalytical errors accounted for 18.25% of all laboratory errors. While excessive turnaround time (8.6%)

and transcription errors (11.7%) were found to be major contributing factors in some literature, this study revealed that uninformed critical results were responsible for the majority of postanalytical errors. The reporting of critical values emerged as the most crucial aspect of the postanalytical phase. Over 6 months, a total of 1,800 critical value cases were identified, out of which 720 were not communicated to the relevant clinicians. Failure to notify critical values can endanger patients' lives if they are not promptly treated. A turnaround time exceeding the defined period was observed in 0.47% of reported specimens. Factors such as power breakdown, shortage of reagent-grade water, technical issues with the instrument, and unexpected workload were identified as potential causes for this delay in reporting results. Additionally, data transcription errors were observed in reporting 0.01% of specimens. The occurrence of mistakes in the overall testing procedure can differ between different institutions and fluctuate over time.

Postanalytical errors, or errors that occur after the testing process, can compromise the quality of laboratory results and ultimately affect patient care (Farisani et al., 2022). Understanding and addressing these errors is essential for ensuring the reliability of laboratory test results and improving patient outcomes. These errors can occur at various stages, including result reporting, interpretation, and communication with healthcare providers and patients. Some common postanalytical errors include transcription errors, misinterpretation of results, failure to report critical values, and inadequate communication of results (Syeda et al.,2022). Regular training and quality assurance measures are vital for minimizing these errors and enhancing laboratory services.

Transcription errors, or errors in recording and reporting results, are among the most frequently observed postanalytical errors in clinical laboratories. These errors can occur during the manual entry of results into the laboratory information system or through the mislabeling of specimens. Transcription errors can lead to incorrect interpretation of results, resulting in misdiagnosis or inappropriate patient treatment decisions. As such, measures to minimize transcription errors, such as implementing electronic result reporting and barcoding systems, are essential for reducing the risk of these errors (Park, 2023). Continuous evaluation and updating of these systems can further enhance effectiveness.

Misinterpretation of results is another significant postanalytical error that can affect the quality of laboratory test results. Laboratory professionals must be capable of accurately interpreting test results and determining their clinical significance. Misinterpreting results can lead to incorrect diagnosis, unnecessary further testing, or inappropriate treatment plans (van Moll et al., 2023). Regular training and continuing education for laboratory staff are vital for improving their ability to interpret test results accurately and effectively (Bishop, 2024). Strengthening collaboration between laboratory personnel and clinicians can also contribute to better interpretation and patient outcomes.

According to Sana et al. (2020), failure to report critical values is a potentially serious postanalytical error that can have severe consequences for patient care. Critical values, defined as results that indicate life-threatening or medically significant conditions, require immediate notification to the healthcare provider. Failure to report critical values promptly can lead to delayed or inadequate patient intervention, resulting in adverse outcomes for the patient (Sana et al., 2020). To mitigate this error, laboratories must establish clear protocols for identifying and reporting critical values and mechanisms for timely communication with healthcare providers.

Inadequate communication of results to healthcare providers and patients is another common postanalytical error that can compromise patient care (Chhatriwala et al., 2021). Effective communication of test results is essential for informing healthcare providers about the patient's condition and facilitating appropriate treatment decisions. Additionally, transparent and timely communication with patients is critical for ensuring their understanding of test results and facilitating informed decision-making regarding their healthcare. Laboratories should prioritize clear and effective communication strategies, such as electronic reporting systems and standardized result formats, to minimize the risk of this error (Syeda et al.,2022). Timely and efficient communication protocols laboratories can significantly improve patient safety.

Addressing postanalytical errors in the clinical laboratory requires a multifaceted approach encompassing training and education, process improvement, and regulatory oversight. Continuous education and training programs for laboratory professionals are critical for enhancing their skills and competencies in result interpretation and communication (Bishop, 2024; van Moll et al., 2023). Process improvement initiatives, such as implementing quality control measures and standardized protocols, can help reduce the risk of transcription errors and misinterpreting results. Regulatory standards and guidelines also play a crucial role in ensuring the quality of laboratory test results, with oversight agencies establishing requirements for result reporting, critical value notification, and communication with healthcare providers and patients (Chhatriwala et al., 2021). By adopting an integrated approach, laboratories can significantly minimize errors and improve overall patient care.

Postanalytical errors pose significant challenges to the reliability and accuracy of laboratory test results and can adversely affect patient care. By understanding the nature of these errors and implementing measures to address them, clinical laboratories can enhance the quality of their services and improve patient outcomes. Through continuous education, process improvement, and adherence to regulatory standards, clinical laboratories can minimize the risk of postanalytical errors and ensure the integrity of their test results (Tsai et al., 2019; van Moll et al., 2023). Consistent efforts in these areas are critical for maintaining high standards of laboratory practice and patient safety.

Dependent Variable: Financial Performance of Hospital Organizations

Clinical laboratories play a critical role in the financial health of hospitals, serving as a significant source of revenue while also contributing to substantial operational costs. The laboratory’s revenue-generating activities directly relate to the procedures and treatments requiring pre- and post-testing. The clinical laboratory is central to the hospital’s ability to bill for these diagnostic tests, making it an essential income stream. To receive reimbursement from federally funded programs such as Medicare and Medicaid and other insurance agencies, compliance with CLIA regulations is necessary. These regulations govern the quality standards for laboratory testing and require laboratories to obtain specific CLIA certificates based on the complexity of their testing

(U.S. Government Publishing Office, 2021). Enforcement of CLIA standards is critical, as sanctions can be imposed for noncompliance, including civil and criminal penalties, suspension or revocation of CLIA certificates, and substantial fines (*National Intelligence Report*, 2012). Consequently, maintaining stringent adherence to these regulations ensures the laboratory's operational continuity and financial viability within the healthcare system.

Hospitals' financial performance is heavily influenced by the operational costs of running a clinical laboratory, as the laboratory can significantly impact the hospital's financial performance. The costs associated with staffing, equipment, supplies, maintenance, and regulatory compliance can add up quickly. Ensuring efficient and accurate testing processes can also contribute to the hospital's financial health, as delays or errors in testing can lead to increased patient stays, readmissions, and potential legal costs (Cavenaugh, 1981). Therefore, diligent laboratory operations management is imperative for sustaining the hospital's economic health.

Hospital executives must consider the financial impact of the clinical laboratory on a hospital's profit and loss. While it serves as a significant source of revenue, it also comes with substantial operational costs and potential financial risks associated with non-compliance and errors. Effective management of the clinical laboratory's operations is crucial for the overall financial success of the hospital. Hospitals need to recognize the substantial impact of the clinical laboratory on their economic performance. The laboratory's role in revenue generation, compliance with regulations, and managing operational costs all influence the hospital's bottom line. Proactive management and oversight of the clinical laboratory are essential for maintaining the hospital's financial health and ensuring the continued provision of high-quality patient care.

Cost of Errors

Timely and precise laboratory results are crucial for optimal patient care and institutional efficiency. Delayed and inaccurate laboratory results can severely affect patients and healthcare institutions (Cavenaugh, 1981). When test results are delayed or inaccurate, it can lead to delayed or incorrect diagnosis and treatment, potentially worsening the patient's condition and prolonging their recovery process. Delayed results can also increase the risk of adverse events and complications, leading to extended hospital stays and increased healthcare costs. Achieving high standards in laboratory testing is essential for enhancing patient outcomes and reducing healthcare expenditures.

Financial repercussions from delayed and inaccurate laboratory results can be substantial for healthcare institutions. A study estimated the mean cost of preanalytical errors to be $162 for inpatient critical, $357 for inpatient noncritical, and $337 for outpatient including emergency department patients in North American hospitals (Dubar & Bahadir, 2023). These costs are associated with the additional resources required to address the consequences of delayed or inaccurate test results, such as repeated testing, prolonged hospital stays, and further treatments. Minimizing errors in laboratory processes is vital for patient safety and financial sustainability (Santos et al., 2021). Investing in error reduction strategies can yield significant cost savings and improve overall healthcare efficiency.

Preventing diagnostic errors is essential for mitigating legal and financial liabilities. Furthermore, delayed or incorrect diagnosis and treatment can lead to malpractice claims and litigation, further increasing the financial burden on healthcare institutions (Cavenaugh,1981). Therefore, healthcare providers must implement measures to minimize the occurrence of delayed and inaccurate laboratory results, such as implementing quality control processes and utilizing advanced technology to improve testing accuracy and turnaround times. By doing so, healthcare institutions can improve patient outcomes, reduce costs, and mitigate potential legal risks.

Ensuring accuracy in laboratory results begins with the preanalytical process. The preanalytical process in laboratory medicine is a critical step in ensuring the accuracy and reliability of test results (Lam & Church, 2024). However, it is also the stage where the most common errors occur. The most prevalent errors in the preanalytical process include sampling and preparation errors, hemolysis, lipemic blood samples, improper transport, and inadequate sample quality and quantity (Tasneem et al., 2024). Addressing these preanalytical issues is vital to maintaining the integrity of laboratory testing and keeping the cost of error low.

Common sampling and preparation issues can significantly affect laboratory results' reliability. Sampling and preparation errors can occur due to improper collection techniques, mislabeling of samples, or contamination (Lam & Church, 2024). Hemolysis, the breaking down of red blood cells, can occur during sample collection, handling, or transportation, leading to inaccurate test results. Lipemic blood samples, caused by the presence of excess lipids, can interfere with specific assays and lead to erroneous results.

Improper transport of samples, such as exposure to extreme temperatures or prolonged transit times, can also compromise the integrity of the sample. Lastly, adequate sample quality and quantity can help the ability to perform necessary tests or lead to inconclusive results (Tasneem et al., 2024). Common errors not addressed through training and adherence to protocols can lead to negative outcomes increasing costs.

The prevalence of preanalytical errors highlights the urgent need for effective mitigation strategies. Recent studies have revealed that preanalytical errors account for a significant proportion of total rejections, ranging from 60% to 93% (Dunbar & Bahadir, 2023). This high frequency of errors underscores the importance of implementing strategies to mitigate these issues and improve the overall quality of laboratory testing. By addressing and preventing these common errors, healthcare providers can enhance the accuracy and reliability of diagnostic and monitoring tests, ultimately improving patient care and outcomes keep the cost of care low (Lam & Church, 2024; Santos et al., 2021). A robust quality management system is key for consistent excellence in operations.

Quality Management System

A quality management system (QMS) is an essential component of any clinical laboratory's operations, as it sets the foundation for ensuring accurate and reliable test results, ultimately contributing to improved patient care and outcomes (Bishop, 2024; (Venkatesh, 2022). Implementing a QMS within a clinical laboratory is crucial for guaranteeing proper patient preparation, specimen collection, and precise test results while adhering to regulatory requirements and industry standards (Thakur et al., 2023). This structured framework encompasses policies, processes, and procedures that oversee all aspects of laboratory operations, including sample collection, handling, analysis, and reporting. The QMS serves as a comprehensive program that aims to engage individuals within the organization to gather data, report findings, and develop initiatives for process improvement (Venkatesh, 2022). QMS is a structured framework that encompasses polices, procedure, and. Processes to ensure adequate oversight of laboratory operations.

One of the critical elements of a QMS for a clinical laboratory is document control, which involves the systematic management of documents to ensure that the most current and relevant documents are available for use (Rayser, 2019). QMS includes procedures, work instructions, and forms, among others, and is essential for maintaining consistency and compliance within the laboratory. Instrument and equipment maintenance is another crucial aspect of a QMS, ensuring that all instruments and equipment are properly maintained, calibrated, and operated to produce accurate test results (Park, 2017). Quality control is also an integral component, involving the monitoring and validating of test results to ensure accuracy and reliability (Cotta et al., 2022). Proficiency testing, corrective and preventive actions, personnel training and competency, and risk management are vital elements of a QMS in a clinical laboratory (Bishop, 2024; Thakur et al., 2023). Collectively, these components work together to ensure high standards and continuous improvement within the clinical laboratory.

A well-designed QMS should be an ongoing mechanism for self-assessment, monitoring, and addressing identified compliance gaps (Beyanga et al., 2018). QMS involves the implementation of regular audits and reviews to identify areas for improvement and ensure compliance with regulatory requirements and industry standards. The QMS should also include mechanisms for addressing non-conformities and implementing corrective and preventive actions to mitigate potential risks to patient care and safety (Park, 2017). Personnel training and competency are critical in ensuring that laboratory staff are well-equipped to perform their duties and produce accurate and reliable test results (Bishop, 2024). Risk management is also essential within a QMS, as it involves identifying and mitigating potential risks to patient care and safety and ensuring that appropriate measures are in place to prevent errors and adverse events (Beyanga et al., 2018; Park, 2017). QMS mitigates risks through root cause analysis and audits which contributes to optimal patient care and safety.

The overarching goal of a QMS in a clinical laboratory is to ensure the accuracy, reliability, and consistent fulfillment of patients' and healthcare providers' needs (Park, 2017). By implementing a QMS, clinical laboratories can demonstrate their commitment to quality and excellence, enhancing their reputation and fostering trust with patients and healthcare providers. QMS can improve operational efficiency and cost-effectiveness by promoting a culture of continuous improvement and excellence within the laboratory (Bishop, 2024). A robust QMS can help clinical laboratories remain competitive in the rapidly evolving healthcare landscape by demonstrating their commitment to quality and patient safety (Tasneem et al., 2024). Continuous improvement fostered by a QMS improves overall laboratory performance and contributes to optimal patient care and safety.

Application of Theoretical Framework

Leading experts consider TQM a strategic tool for competing in today's competitive business market. TQM continuously improves products and processes to meet or exceed customer expectations (Ansari, M., 2022). This approach requires all stakeholders, including management, workforce, suppliers, and customers, to share responsibility for the quality of the product or service (Dahlgaard-Park, 2018; Tonjang & Thawesaengskulthai, 2024). By adopting TQM, leaders can effectively monitor process management, customer feedback, leadership commitment, strategic planning, supplier quality management, and employee engagement. The ultimate goal of TQM is to enhance the quality of products and services, improve performance, and achieve a larger market share (Asagbra & Harris, 2022; Delduarte, 2021). When implemented successfully, TQM not only fosters a culture of continuous improvement but also a propels the organization toward sustained competitive advantage and long-term success.

TQM has its roots in the work of quality leaders such as Edwards Deming, Joseph Duran, Armand Feigenbaum, and Kaoru Ishikawa. The evolution of TQM can be traced back to postWorld War II when the Japanese Union of Scientists and Engineers formed a committee to improve productivity and quality of life in Japan (Powell, 1995). American companies later adopted TQM to compete with Japanese companies in the 1980s. Initially applied in manufacturing, TQM gained popularity and spread to various service industries, including healthcare, banking, higher education, real estate, hotels, and tourism.

On a global scale, the healthcare industry has faced significant quality issues in recent decades. They pose a worldwide concern. According to a comprehensive examination, a study conducted in Australia revealed that 16.6% of all hospitalizations had avoidable negative consequences, leading to mortality in almost 5% of instances where iatrogenic harm occurred (Carver, 2023). Laboratory medicine, a subset of healthcare, has been at the forefront of quality improvement efforts but continues to face challenges in delivering high-quality services. Diagnostic professionals rely on laboratory results to diagnose and manage patients' conditions. Erroneous results can lead to emotional distress, adverse effects, and increased costs. To address these issues and reduce costs, many healthcare organizations have adopted TQM as a strategic approach to improving quality and increasing firm value. Each of the selected studies employed the TQM theoretical framework in varying manners. Enumah et al. (2022) argued that hospitals that can uphold highly dependable systems and allocate consistent resources towards continuous quality enhancement and improved performance tend to possess greater financial stability.

Quality management in the clinical laboratory is critical to healthcare delivery (Venkatesh, 2022). A QMS involves the application of principles, policies, and procedures to ensure that the testing performed is accurate, reliable, and consistent. QMS and TQM are two complementary approaches that can help clinical laboratories achieve and maintain high levels of quality in their testing processes (Bishop, 2024; Farisani et al., 2022). Integrating QMS and TQM can enhance patience care, reduce errors, and contribute to overall healthcare improvement.

A QMS is a set of organizational policies, procedures, and processes that ensure the quality of laboratory testing as it encompasses the entire testing process, from the collection of samples to the reporting of results. A well-designed QMS helps to prevent errors, identify and correct problems, and continuously improve the quality of testing services (Venkatesh, 2022). Additionally, a QMS provides a framework for meeting regulatory requirements and accreditation standards. Critical components of a QMS include quality control, quality assurance, and quality improvement. Quality control involves using internal and external quality control materials to monitor the accuracy and precision of testing (Cotta et al., 2022). Quality assurance focuses on preventing errors through standardized protocols, training, and ongoing monitoring and evaluation of testing processes (Day et al., 2023). Quality improvement involves identifying opportunities for improving testing quality and implementing measures to address these opportunities (Beyanga et al., 2018).

TQM is a management philosophy emphasizing continuous improvement of processes and systems to meet or exceed customer expectations. In the clinical laboratory, TQM is a proactive approach to quality management that involves all laboratory staff's participation in identifying and resolving quality issues. TQM also emphasizes the importance of customer focus, teamwork, and a commitment to excellence (Kareska, 2023). One of the key principles of TQM is the involvement of all laboratory staff in the quality management process (Venkatesh, 2022). Quality management includes laboratory technologists, technicians, pathologists, and other clinical personnel involved in the testing process. By involving all staff in the quality management process, laboratories can harness their workforce's collective knowledge and expertise to identify and address quality issues.

TQM also emphasizes the importance of data-driven decision making. By collecting and analyzing data on key performance indicators, such as test results, turnaround times, and customer satisfaction, clinical laboratories can identify opportunities for improvement and track the impact of quality improvement initiatives over time (Farisani et al., 2022). This data-driven approach to quality management helps to ensure that decisions are based on evidence rather than subjective opinions (Venkatesh, 2022; Kareska, 2023). Consequently, clinical laboratories can achieve more reliable and consistent outcomes in their operations.

Another important aspect of TQM in the clinical laboratory is the emphasis on continuous improvement. TQM encourages laboratories to regularly review and improve their testing processes, procedures, and systems for better quality outcomes. TQM includes using quality improvement tools and techniques, such as root cause analysis, process mapping, and the Plan-Do-Study-Act cycle, to identify and address quality issues. According to Kareska (2023), Clinical laboratories can ensure continuous improvement through the use of TQM by the following:

1. Implementing a QMS: This involves documenting and standardizing the laboratory's processes and procedures to ensure consistency and high-quality performance (Venkatesh, 2022). A QMS can help the laboratory identify and address areas for improvement, leading to better service and customer satisfaction.

2. Setting clear quality objectives and targets: The laboratory can continuously monitor its performance and make adjustments to improve customer satisfaction by establishing measurable quality objectives and targets.
3. Training and development of staff: Investing in the training and development of laboratory staff can lead to improved skills and knowledge, resulting in better performance, higher quality results, and, ultimately, greater customer satisfaction (Bishop, 2024).
4. Customer feedback and engagement: Actively seeking and responding to customer feedback can help the laboratory identify areas for improvement and make changes that align with customer needs and expectations.
5. Continuous improvement efforts: Using TQM principles, the laboratory can continuously strive to improve its processes, identify and eliminate sources of error, and drive overall quality improvement (Farisani et al., 2022).
6. Collaboration and communication: Open communication and collaboration with all stakeholders, including staff, suppliers, and customers, can help foster a culture of quality and continuous improvement.
7. Process standardization and innovation: By standardizing processes and continually seeking innovative ways to improve operations, the laboratory can enhance its capabilities and ensure consistency in the quality of results (Park, 2017).
8. Compliance with industry standards and regulations: Adhering to industry standards and regulatory requirements can help ensure the laboratory meets the

highest quality standards, leading to greater customer satisfaction and confidence in the laboratory's services (Park, 2017).

Quality management systems and total quality management are essential tools for ensuring the quality of testing services in the clinical laboratory. By implementing QMS while embracing the principles of TQM, clinical laboratories can achieve and maintain high levels of quality in their testing processes (Farisani et al., 2022). QMS ultimately improves patient care and safety by ensuring accurate and reliable test results are provided to healthcare providers and their patients (Park, 2017; Tsai et al., 2019). A holistic approach not only enhances efficiency but also fosters a culture of continuous improvement and excellence in laboratory practice.

Transition

Section 1was an introduction into the study and the impact of laboratory errors at each testing on the financial performance of a healthcare organization. Laboratory errors can result in increased operational costs, potential litigation costs, and a decrease in patient satisfaction and trust, all of which can have a significant impact on the financial performance of a healthcare organization. Healthcare organizations must implement robust quality assurance measures inclusive of TQM principles to minimize the occurrence of laboratory errors and mitigate their financial impact (Farisani et al., 2022). By prioritizing quality assurance and error prevention, healthcare organizations can safeguard their financial health while ensuring optimal patient outcomes and trust.

Section 2: The Project

In this quantitative study, an investigation was conducted to assess the correlation between the variables. Section 2 includes a detailed outline of the study's methodology, design, and research components. Additionally, within this section, the various assumptions of multiple regression are discussed along with strategies for addressing them. The section is concluded with an examination of the data's validity.

Purpose Statement

The purpose of this quantitative correlational study is to examine the relationship between preanalytical, analytical, postanalytical errors and financial performance. I will use a survey to complete the study. The implication for positive social change includes the potential to provide healthcare leaders justification to implement processes that improve laboratory quality to reduce errors which may positively impact patient outcomes and decrease healthcare costs.

Role of the Researcher

The primary responsibility of a quantitative researcher is to examine data findings using unbiased statistical methods (Saunders et al., 2015). Researchers must be mindful of any potential biases in the data collection process and ensure the accuracy and completeness of the data (Bossuyt & Van Kenhove, 2018; Burgess et al., 2019). Research bias can manifest in various ways (Beals et al., 2018; Burgess et al., 2019), with challenges arising from the subject matter, methodology, or participant involvement. In my professional capacity, I gather and evaluate data required for laboratory quality programs and monitor metrics to ensure effectiveness of the quality program.

As outlined by Ashour (2018), it is a researcher's duty to accurately record and analyze data to generate dependable results. Researchers are expected to comprehend the research protocol and adhere to the approved plan established by the institutional review board (IRB; Melbøe, 2018). I utilized a survey I created on Survey Monkey to collect the data needed for the research variables. I worked through the Independent Hospital Network, the American Society of Clinical Pathology, American Society of Clinical Laboratory Science, and medical laboratory scientist forums to recruit participants to complete the survey. Researchers may encounter the challenge of balancing integrity with data collection methods (Ashour, 2018; Burgess et al., 2019). According to LeCroix et al. (2017), researchers should maintain objectivity even if they have a relationship with the participants due to prior interactions.

The Belmont Report established principles of respect for individuals, beneficence, and justice to guide researchers in ensuring ethical treatment of study participants (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). Participants in this study are comprised of data from clinical hospital laboratories, with no direct contact with patients using a survey. The volunteers participating in the survey will remain anonymous adhering to the first principle of the Belmont Report by safeguarding patient confidentiality.

Participants

The study was comprised of a random sample of laboratory leaders. The criteria for completing the survey were if the participant confirmed being a clinical laboratory leader working in a hospital laboratory. If they answered no, the survey immediately ended, and data were not collected from that participant. The survey was posted on laboratory leader forums for individuals who are members of the American Society of Clinical Pathology, the Independent Hospital Network, American Society of Clinical Laboratory Science, and medical laboratory science forums on social media.

Research Method

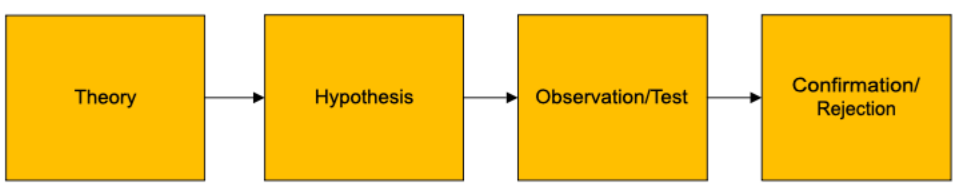
Quantitative research serves as a scientific method for aligning theoretical concepts with variables. This approach enables business leaders to forecast future business conditions, empowering them to adapt strategies accordingly. By leveraging the current economy and existing research, business leaders can capitalize on flexibility, fluidity, and systems thinking (Millar et al., 2018). The primary goal of quantitative research is to accumulate knowledge and gain a comprehensive understanding of a phenomenon, including its frequency, magnitude, and impact on the sample population. Proficiency in quantitative techniques equips researchers with the necessary tools to assess the effects accurately.

While there are distinct advantages to employing quantitative research methods, there are also drawbacks worth considering. Drawbacks include the limited scope of capturing a single moment in time, potentially diminishing the contextual depth or underlying significance of results to readers (Rahman, 2017). Quantitative research hinges on numerical measurements to explore social behaviors through statistical analysis (Pope et al., 2018). This method allows researchers to handle large sets of data and present findings in a more substantial sample size, reinforcing the credibility of the research outcomes. Furthermore, the availability of statistical software like SPSS streamlines the data analysis process.

After weighing the potential benefits of qualitative and mixed methods, I opted to pursue quantitative research due to its deductive nature, which involves examining data to validate a theory. This deductive approach aligns with positivism and the scientific method, emphasizing the statistical significance of findings (Pope et al., 2018). By starting with a logical pattern and testing it against observations, researchers can delve deeper into real-world phenomena or theories, scrutinizing and confirming them across diverse scenarios. Theory assumes a critical role in guiding the deductive process by providing a foundation for explanation, prediction, and comprehension. Through challenges and extensions to existing knowledge within specified assumptions, researchers can enhance their understanding of the subject matter (Abend, 2008). The deductive flowchart outlined in Figure 1 serves as a visual aid in illustrating the pivotal role of theory in deductive reasoning.

Figure 1

Deduction Flow



Source: www.research-methodology.net

Utilizing the TQM theoretical framework, I conducted a search for data to address the research inquiry: What is the correlation between preanalytical errors, analytical error, postanalytical error, and hospital financial performance? The null hypothesis (*H_0*) posited that there is no statistically significant relationship among preanalytical errors, analytical error, postanalytical error, and hospital financial performance, while the alternative hypothesis (*H_1*) asserted the presence of a statistically significant relationship between these variables. Qualitative and mixed methods present certain drawbacks, as the data obtained may be influenced by personal perceptions and opinions, leading to potential biases. Qualitative research, in particular, is vulnerable to personal bias, where individual feelings such as excitement or aversion toward specific participants may skew the results. Healthcare expenditure is more suitably analyzed using quantitative methods to mitigate biases, as numbers provide a more objective perspective. Mixed methods, incorporating both qualitative and quantitative approaches to data collection, would have failed to align with the study's objectives.

Research Design

For this study, I used an ex post facto correlational study design to examine the relationship between preanalytical errors, analytical errors, and postanalytical errors and hospital financial performance. Saunders et al. (2016) highlighted the value of correlational design in addressing particular business issues by utilizing descriptive statistics to quantify variables. Alternative study designs were considered less suitable for my objectives due to time constraints and the need to numerically depict the relationship between variables.

The concept of correlation indicates a connection between two variables, while causation suggests a direct or inverse causal relationship. Correlation quantifies the degree of association or co-occurrence between two variables within a range of -1 to +1. This measure is specifically applicable to linear relationships between variables (Green & Salkind, 2017). If the correlation coefficient is 0, a nonlinear relationship could still exist. Multivariate correlation examines the impact of more than two variables. A scatterplot visually represents the relationship between two or more variables to confirm whether they exhibit a linear relationship.

Ex post facto research presents both advantages and disadvantages. Simon and Goes (2013) concluded that ex post facto research is particularly well-suited for social studies in healthcare, as it does not require manipulation of human participants' characteristics. However, there is a challenge in interpreting the results based on the evidence gathered. I ensured that data collection was conducted uniformly across all hospitals and addressed any variances identified during this process. To overcome the challenges associated with ex post facto design, I leveraged my expertise and experience in healthcare and strived to enhance my understanding of the data set utilized in my study.

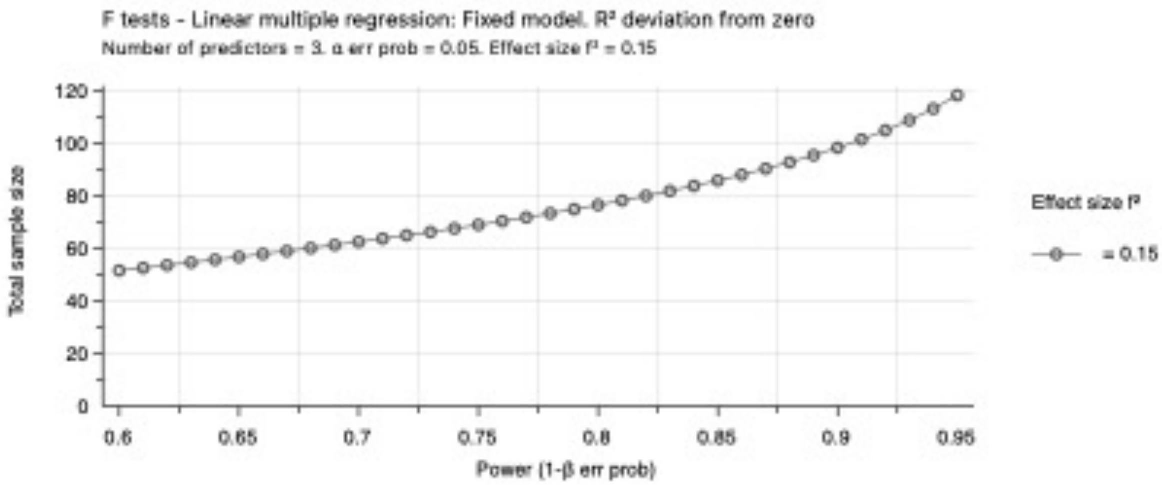
When examining data, descriptive statistics are utilized to depict data utilizing measures of central tendency and variability. The central position of the data is determined using the mode, median, and mean as outlined by Green and Salkind (2017). Measures of variability indicate the extent to which the variables differ using metrics such as range, quartiles, absolute deviation, variance, and standard deviation as specified by Green and Salkind (2017). Visual aids such as tables, charts, histograms, and graphs are employed to present the results visually, while statistical commentary are provided to analyze the findings. Furthermore, inferential statistics enabled the generalization of findings from a sample to the broader population.

Population and Sampling

Sampling inherently involves sampling error, necessitating users to make informed decisions when conducting inferential tests (Green & Salkind, 2017). To mitigate sampling error, I conducted a multivariate regression analysis and completed a power analysis to determine the minimum appropriate sample size. I used a convenience sampling strategy and selected participants from the target population based on their availability. Subsequently, I interpreted the inferential results and drew conclusions based on the data analyzed. In conducting the power analysis using G*Power version 3.1.9.6, I sought to include at least 77 hospital laboratories. G*Power assessment defined the minimum sample size using a 0.05 alpha error probability and 0.8 power. An a priori power analysis, assuming a medium effect size ($f^2 = .15$), $\alpha = .05$, and 3 predictor variables, identified that a minimum sample size of 77 participants was required to achieve a power of .80. Increasing the sample size to 118 would increase power to .99. Therefore, I sought between 77 and 118 participants for the study (Figure 2).

Figure 2

G Power as a Function of Sample Size*



Ethical Research

Researchers encounter ethical dilemmas at every phase of their research endeavors. This section addresses measures implemented to ensure the study adhered to ethical standards. The analysis involved survey data that did not include personal identification, human participants, or ethical concerns regarding data collection. An IRB approval from Walden University was required to protect beneficiaries in the use of survey data. Walden University's ethics approval number for this study is 10-25-24-1140963. Permission to conduct the research was requested, and once approved, the data were obtained and secured with complex passwords on external media. After completion of the project, the information will be securely destroyed after 5 years, in adherence to all IRB protocols to prevent ethical research standard violations and IRB regulations. All 77 participating hospitals were given the informed consent form.

Statistical and graphical analysis of the data were conducted using SPSS Version 28.0 for Mac, providing tools such as Pearson's correlation coefficient analysis, multiple regression, and descriptive statistics. This software is well-suited for analyzing large data sets that predict linear relationships between multiple independent and dependent variables. SPSS was utilized to examine the relationships between preanalytical errors, analytical errors, postanalytical errors, and hospital financial performance, leading to the acceptance or rejection of null hypotheses based on inferences drawn regarding the variable relationships (Green & Salkind, 2017).

Data Collection Instruments

In the research study, survey results data will be utilized from at least 77 hospitals The population is clinical laboratory leaders in the hospital setting in the United States. Under CLIA regulation CFR. 493.1250 Analytic Systems, each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 and 493.1283, unless Health and Humas Services (HHS) approved a procedure specified in the State Operations Manual (CMS Pub 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. Statistical and graphical analysis of the data will be conducted using SPSS Version 28.0 for Mac, as it offers tools such as Pearson's correlation coefficient analysis, multiple regression, and descriptive statistics (Green & Salkind, 2017). SPSS is well-suited for analyzing large data sets that aim to predict linear relationships between multiple independent and dependent variables. The software will be instrumental in exploring the connections between the error rate at each phase of testing and hospital performance. Ultimately, conclusions will be drawn based on inferences regarding the relationships between the variables, leading to the acceptance or rejection of a null hypothesis.

Data Collection Technique

The purpose of this correlational quantitative study is to determine accept or reject the null hypothesis and determine if there is a relationship between preanalytical, analytical, postanalytical errors, and the financial performance of a hospital organization. I used data collected for clinical laboratory leaders through a survey I created on Survey Monkey (see the appendix), as the participants can refer to the data currently being tracked in hospitals as required by regulatory agencies to increase validity of the study. The survey respondent maintains anonymity by refraining from disclosing their name at any point, thereby ensuring that I remain uninformed about the participant's identity. Consequently, no explicit consent signature was required. Instead, the informed consent form guided respondents to indicate their implied consent through the act of completing the survey. Hospital laboratory administrators, supervisors, managers, and directors were solicited to participate in the survey via social forums and professional societies for laboratories. Participation was voluntary, and participants remain anonymous. Each participant was provided the informed consent form requesting permission to use their anonymous laboratory quality and financial data. The survey requested the preanalytical error rate, analytical error rate, postanalytical error rate, and the operating margin for the hospital's income statement. There are approximately 6,120 hospitals in the United States in 2024, according to the American Hospital Association. Requesting the data through a survey is the best method for collection as each hospital laboratory has its own interpretation of CLIA and regulatory agencies and may choose diverse methods to track errors at each phase of testing.

Data Analysis

Various data analysis techniques are employed by researchers to investigate the correlation between variables, such as t-tests, ANOVA, and multiple regression. The t-test is utilized to assess a hypothesis involving either a single mean or the discrepancy between two means (Green & Salkind, 2017). In quantitative DBA Doctoral studies, the presence of at least two independent variables renders the use of a t-test inappropriate. ANOVA is applied when researchers are comparing group averages within and between groups or across different time points (Green & Salkind, 2017). Saunders et al. (2016) employed the ANOVA model to make predictions about continuous outcomes based on categorical predictor variables (Saunders et al. 2016). Both ANOVA and multiple linear regression are versatile, user-friendly, and powerful tools for evaluating the relationship between independent and dependent variables (Sirvrikaya et al., 2018). However, ANOVA is not suitable for my study as I have no intention of investigating differences in the variables.

Laboratory leaders calculate the error rates by taking the frequency of the errors in each phase (preanalytical, analytical, postanalytical) and dividing by the total number of errors. I have collected the data through an anonymous survey, I performed a multivariate linear regression analysis to examine the relationship between the three independent variables and one dependent variable. Financial performance was measured by the operating margin of the hospital provided by the survey participants. All variables are ratio and scale variables, see Table 2.

Table 2

Research Variables

Variables	Variable type	Scale of measurement	Measure
Preanalytical error rate	Independent variable	Ratio	Scale
Analytical error rate	Independent variable	Ratio	Scale
Postanalytical error rate	Independent variable	Ratio	Scale
Operating margin	Dependent variable	Ratio	Scale

Data collected from each hospital was reviewed for completeness and ensure errors rate are appropriately categorized. Preanalytical errors occur prior to testing during the collection, sample processing, and transport. Analytical errors occur during testing while the sample is being analyzed, and postanalytical errors occur after testing during the test resulting and physician interpretation of the patient result. Any missing or incomplete data were excluded from study.

Assumptions of Multiple Linear Regression

Various assumptions are linked to multiple regression analysis, including sample size, normality, linearity, homoscedasticity, independence of errors, and multicollinearity. Failure to meet these assumptions can significantly distort the results. To assess these assumptions, I utilized SPSS descriptive statistics. Following the guidelines outlined by Green & Salkind (2017), I will address any concerns related to these assumptions. The results of the tests conducted to evaluate these assumptions will be discussed in the subsequent paragraphs.

Normality

I thoroughly examined the variables to guarantee accurate representation of the data with the advised minimum of 20 data points for each variable. Through G*Power calculation, I confirmed the sample size aligns with the necessary standards required for my research. A robust sample size is sufficient to disregard the need for normality assumption even if it is satisfied.

Linearity

The presumption of linearity may underestimate the existing relationship (Green & Salkind, 2017). The linear connection implies that any deviation in independent variables leads to an exact change in the dependent variable. A method to evaluate linearity involves examining scatterplots between variables. Nonlinear patterns on the scatterplots indicate a violation of the assumption. In such cases, the cause of the violation was investigated, and the data point responsible were removed from the data set before proceeding further. If the researchers are unable to exclude data points due to a small sample size, they might need to consider abandoning the regression model (Green & Salkind, 2017). Given the ample sample size, I did not expect any difficulties with this assumption.

Homoscedasticity

Homoscedasticity refers to the presence of a constant and equal variable, often visualized by a cone or bowtie shape (Green & Salkind, 2017). Deviating from homoscedasticity can lead to bias, inaccuracies in standard errors, and incorrect conclusions. Assessment of homoscedasticity were conducted through examination of scatterplots and correlation analysis. In cases where heteroscedasticity was detected, a thorough review of each variable for normal distribution and removal of outliers was performed. If homoscedasticity is not achieved after data transformation attempts, weighted least squares regression were implemented. Highly skewed variables can be addressed through logarithmic transformation, while count variables can benefit from square root transformation (Green & Salkind, 2017). Significant deviation from the homoscedasticity assumption is necessary to pose a substantial issue.

Independence of Residuals

Independence of errors checks the assumption that there is no residual pattern, indicating that each variable is independent and there are no serial correlations present (Green & Salkind, 2017). Residual statistics was examined for possible outliers in SPSS by running the Casewise diagnostics test to identify any outliers outside of three standard deviations. In such instances, cases would be identified and reviewed for any potential outliers and removed. Subsequently, the data were re-analyzed to ensure that any violations were corrected. Additionally, the independence of residuals was assessed for the presence of normal probability (P-P). The normal probability plot of the regression standardized residuals should reveal the data points in an approximate straight line.

Multicollinearity

Multicollinearity refers to the dependence of independent variables on each other (Green & Salkind, 2017). To assess multicollinearity within the data, a correlation matrix was utilized in SPSS to identify any potential issues. A variance inflation factor exceeding ten signifies high variance inflation, indicating redundancy of a variable with other variables (Green & Salkind, 2017). If multicollinearity is detected, potential solutions include removing a predictive variable or utilizing ridge regression. If the VIF value in collinearity statistics is below ten, it suggests that multicollinearity is not a concern.

The assumptions of linear regression ensure the reliability and accuracy of variable data. Following descriptive statistics, efforts will be made to address assumptions by removing outliers and acquiring a substantial sample size. By examining the normal probability plot (P-P) and scatterplot of standardized residuals, outliers, normality, linearity, homoscedasticity, and independence of residuals will be assessed. A lack of significant deviations from assumptions, demonstrated by a reasonably straight line or lack of systematic patterns in the scatterplot of standardized residuals, would indicate adherence to normality assumptions (Green & Salkind, 2017). Bootstrapping can be utilized to mitigate potential data assumption implications and establish a 95% confidence interval based on bootstrapping samples.

Interpreting inferential results will involve an assessment of beta weights, confidence intervals, significance values, R^2, and F values. The significance of relationships and the nature of these relationships can be determined through p-values and coefficients in regression analysis (Greenland et al., 2016). Beta weights signify the contribution of an independent variable to the regression effect while holding other variables constant (Green & Salkind, 2017). Confidence intervals predict the range of values containing the true population value with 95% probability (Greenland et al., 2016). R^2 represents the variance in the dependent variable attributed to predictor variables, ranging from 0 to 1 (Green & Salkind, 2017). These inferential results will be further examined in detail in section three of the study.

Study Validity

Validity is recognized as an essential aspect of research representing the extent to which the findings can be applied, defined operationally, and transferred (Yin, 2018). The concepts of reliability and validity are both crucial in the development of successful research, each with distinct characteristics. The validation of a study plays a critical role as the results may either lead to further exploration or the discontinuation of the survey. In certain medical contexts, research may progress to clinical trials as a way to advance education (Araya et al., 2019). Due to the potential for disagreement among participants or between participants and researchers, validity often gives rise to moments of conflict and challenges to epistemic authority (Caretta & Pérez, 2019).

The concept of validity refers to the accuracy of a measure in assessing its intended purpose (Green & Salkind, 2017). Considering validity in relation to a specific research scenario, as it is not an inherent instrument attribute is imperative. The examination of both reliability and validity is essential, as they are interrelated elements that should be evaluated (Chaudhary et al., 2013). Research by Souza et al. (2017) highlights that instruments lacking reliability cannot be considered valid, while reliable instruments may still be deemed invalid. Therefore, a high level of reliability does not guarantee validity. To ensure a valid conclusion, it is necessary for independent variables to be the sole factors influencing the dependent variable, as various confounding variables could impact hospital profitability.

Transition and Summary

The purpose of this quantitative correlational study is to examine the relationship between preanalytical error, analytical error, postanalytical error, and hospital financial performance in the United States. The sample for this study was obtained using a survey inclusive of data provided by 77 hospitals. The descriptive analyses provided an overview of the study population and will include means, standard deviations, frequencies, range of scores, and percentages (Green & Salkind, 2017). The data analysis will enable a comparison of laboratory errors at each phase of testing to determine whether hospital profitability is impacted. The findings of the data analysis is detailed in section three.

Section 3: Application to Professional Practice and Implications for Change

Introduction

The purpose of this quantitative, correlational study was to examine the relationship between preanalytical errors, analytical errors, and postanalytical errors and hospital financial performance. The independent variables were (a) preanalytical errors, (b) analytical errors and (c) postanalytical errors. The dependent variable was hospital financial performance. The null hypothesis (H_0), indicating that there was no statistically significant relationship between preanalytical, analytical, and postanalytical errors and hospital financial performance, was rejected, prompting the acceptance of the alternative hypothesis (H_1) that there was a statistically significant relationship between preanalytical, analytical, and postanalytical errors and hospital financial performance. The survey data was aimed to review if a relationship exists between preanalytical, analytical, postanalytical errors, and hospital financial performance and the study findings confirmed rejection of the null hypothesis. Recognizing the existence of a relationship can significantly influence healthcare managers in their pursuit of more cost-effective care options. Reducing the escalation of healthcare expenditures may yield societal benefits and enhance access to healthcare services. The aim of this study was to examine an alternative perspective on healthcare costs for consideration within the healthcare community.

Presentation of the Findings

In subsequent subsections, I will provide pertinent descriptive statistics, followed by a comprehensive assessment of the assumptions underlying multiple regression analysis. Following these preliminary evaluations, I will present the outcomes of the inferential statistics, utilizing both graphical and numerical representations obtained from my survey data. Finally, I will reassess my research question and hypotheses, aligning them with my findings while incorporating a theoretically grounded explanation of these results. This section will conclude with a summary of the analysis concerning the performance of the statistical model in relation to my research objective.

Descriptive Statistics

The data set comprised various factors, including preanalytical, analytical, and postanalytical errors and hospital financial performance. Table 3 presents the descriptive statistics for the study variables, with a mean of 2.5584 and a standard deviation of 1.09417. A thorough visual inspection of the data was conducted to eliminate any incomplete or missing data elements, following the determination of the required sample size using G*Power (Figure 2). The analysis incorporated sample size information from 77 hospitals collected between October 2024 and January 2025. The objective of screening the data was to validate all assumptions associated with the multiple linear regression model, which included examining residual plots and normal probability plots.

Table 3

Descriptive Statistics

	M	SD	*n*
What is the operating margin from your income statement of your hospital?	2.5584	1.09417	77
What is your postanalytical error rate?	1.4935	.85260	77
What is your analytical error rate?	1.7013	1.11290	77
What is your preanalytical error rate?	2.4156	1.33131	77

Source: SPSS output, $N = 77$

Testing of Assumptions

I used several assumption tests to assist in validating the findings of the research study. These tests encompassed multicollinearity, normality, linearity, homoscedasticity, outliers, and independence of residuals. I carefully examined these tests and delineated the results in the subsequent paragraphs.

Multicollinearity is quantified using the variance inflation factor (VIF). A VIF value of ten or greater signifies the presence of multicollinearity (Mohammed, 2024). According to Garver and Williams (2024), the problem of high correlation among attributes, known as multicollinearity, leads to a number of known problems when running certain statistical models. Multicollinearity occurs when two or more attributes are highly correlated with one another. According to the coefficient output and collinearity statistics, the obtained VIF value indicates that multicollinearity is not a concern (see Table 4).

Table 4

Collinearity Statistics

		95.0% C.I. for B		Collinearity statistics	
Model		Lower	Upper	Tolerance	VIF
1	(Constant)	.792	1.726		
	What is your postanalytical error rate?	-.193	.474	.519	1.925
	What is your analytical error rate?	-.115	.318	.721	1.388
	What is your preanalytical error rate?	.173	.586	.556	1.799

Source: SPSS output, $N = 77$

Linearity was assessed through the examination of a residual scatterplot to determine whether the data points were randomly distributed around the mean value of zero. Figure 3 presents the scatterplot. Upon visual inspection, it was observed that the results exhibited an even distribution. Additionally, a Durbin-Watson test was conducted using SPSS to evaluate the possibility of homoscedasticity and ensuring normality (Bartels & Goodhew, 1981; Flores & Ocaña, 2022). As indicated in Table 5, the statistical value was between 1.5 and 2.5 indicating homoscedasticity was not violated. Bootstrapping was not needed because no assumptions were violated.

Figure 3

Scatterplot

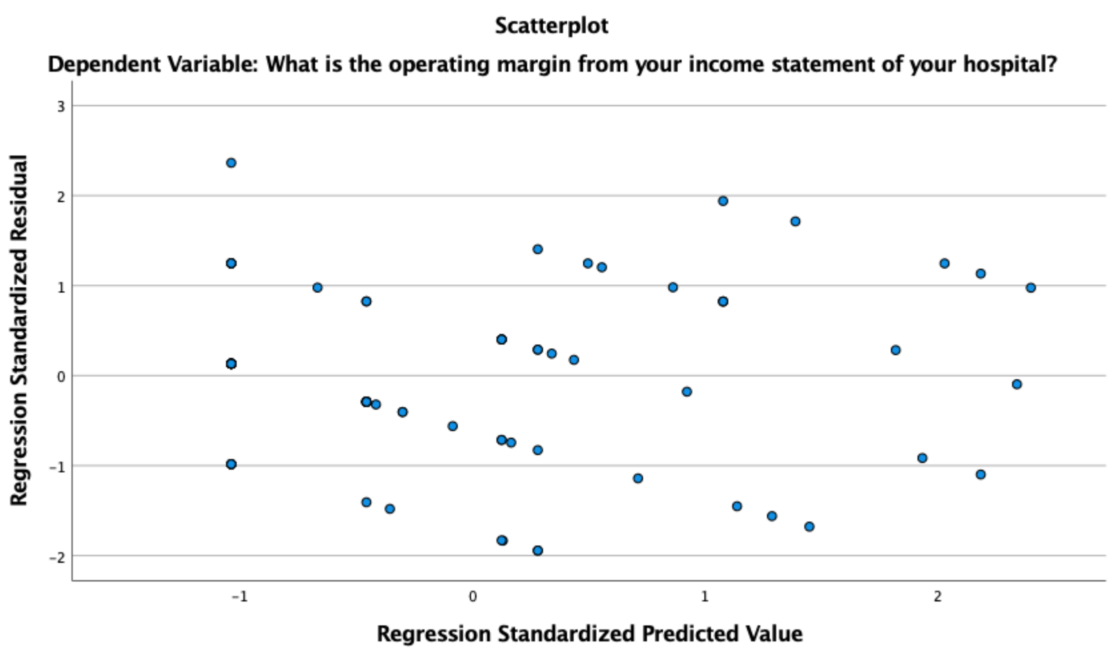


Table 5

Dubin-Watson Test Summary[b]

Model	R	R^2	Adjusted R^2	Std. error of the estimate	Durbin-Watson
1	.596[a]	.356	.329	.89609	2.017

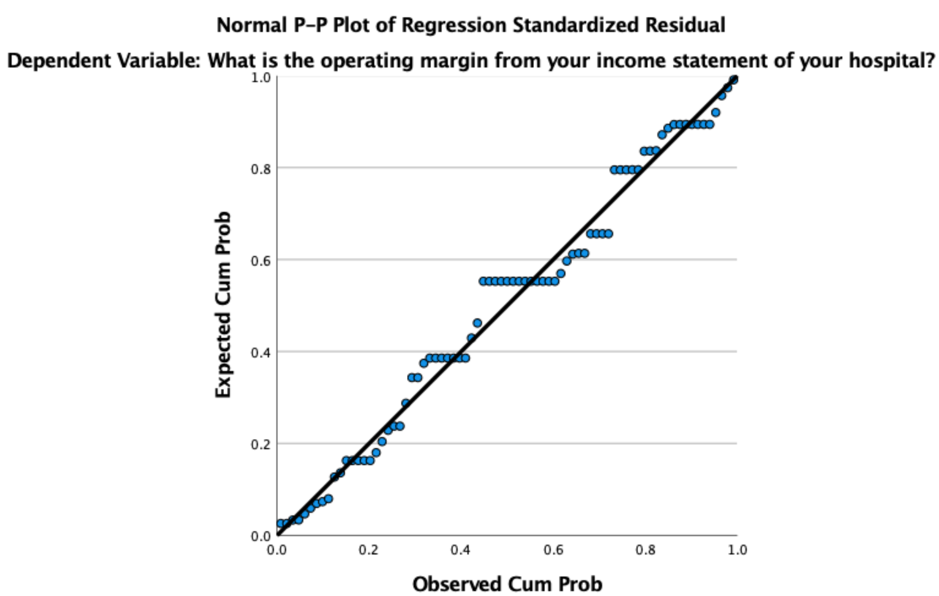
Note. a. Predictors: (Constant), preanalytical error rate, analytical error rate, postanalytical error rate; b. Dependent variable: Hospital operating margin

Source: SPSS output, $N = 77$

Outliers can negatively impact statistical conclusion for reliability and validity and leads to problems normality and homoscedasticity. I ran the casewise diagnostics in SPSS to identify any outliers outside of three standard deviations (Wiggins, 2000). No outliers were identified and no violations along with no violations noted for normality and homoscedasticity. The independence of residuals was assessed for the presence of normal probability (P-P). As depicted in Figure 4, the normal probability plot of the regression standardized residuals reveals that the data points approximate a straight line. No violations noted.

Figure 4

Normal P-P Plot



Inferential Statistics

A standard multiple regression analysis was performed with an alpha level of .05 (two-tailed), utilizing survey data to investigate the relationship between preanalytical, analytical, postanalytical errors, and hospital financial performance in hospitals within the United States. The dependent variable in this analysis was hospital operating margin, which represent the profitability associated with inpatient care and outpatient care in a hospital setting. The null hypothesis posited that there exists no statistically significant relationship between preanalytical, analytical, postanalytical errors, and hospital financial performance in hospitals. Conversely, the alternative hypothesis suggested a statistically significant relationship among these variables. The standardized coefficients (β) indicate the extent to which the profitability may increase or decrease. The multiple linear regression model significantly identified the growth of operating margin: $F(3, 73) = 13.438$, $p < .001$, $R^2 = .356$. The R^2 value of .356 suggests that approximately 35% of the variation in operating margin can be explained by the linear combination of the independent variables. In the final model, expressed as hospital operating margin = 1.259 + .379 (preanalytical error rate) + .102 (analytical error rate) + .141(postanalytical error rate), the preanalytical variable emerged as a statistically significant predictor, preanalytical ($t = 3.663$, $p < .001$, $\beta = .337$) (Green and Salkind, 2017). Table 6 provides a summary of the regression results. The findings from the multiple linear regression were statistically significant, confirming that preanalytical errors variables were significant in the model.

Table 6

Regression Analysis Summary for Independent Variable

Model		Unstandardized coefficients *B*	*SE*	Standardized coefficients β	t	Sig.
1	(Constant)	1.259	.234		5.375	<.001
	What is your postanalytical error rate?	.141	.167	.110	.841	.403
	What is your analytical error rate?	.102	.109	.103	.933	.354
	What is your preanalytical error rate?	.379	.104	.462	3.663	<.001

Note: *B* = unstandardized coefficient; *SE* = standard error; β = standardized coefficient; t = coefficient divided by standard deviation; Sig. = significance; *N* = 77. Dependent variable = Operating margin

Table 7 presents a summary of the correlations among the variables. Correlation analysis is utilized to ascertain the preliminary relationships between the variables (You & Banmongkol, 2024). I selected the quantitative correlation research design to examine the relationship between laboratory errors at each testing phase and hospital financial performance. A standard multiple linear regression, $\alpha = .05$ (two-tailed), was used to examine the relationships among independent and dependent variables. The independent variables were preanalytical error rate, analytical error rate, and the postanalytical error rate. The dependent variable was the hospital operating margin. The null hypothesis and alternative hypothesis were:

Null Hypothesis (H_0): There is no significant relationship between (a) preanalytical laboratory, (b) analytical, and (c) postanalytical laboratory errors, and (d) financial performance.

Alternate Hypothesis (H_1): There is a significant relationship between (a) preanalytical laboratory, (b) analytical, and (c) postanalytical laboratory errors, and (d) financial performance.

The study results showed that the null hypothesis was rejected because a statistically significant relationship with preanalytical errors exists. The alternative hypothesis was accepted. For overall regression model was significant, with one variable showing the need to further explore predictive modeling for the hospital financial performance.

Table 7

Pearson Correlation

		What is the operating margin from your income statement of your hospital?	What is your postanalytical error rate?	What is your analytical error rate?	What is your preanalytical error rate?
Pearson correlation	What is the operating margin from your income statement of your hospital?	1.000	.462	.366	.579
	What is your postanalytical error rate?	.462	1.000	.504	.652
	What is your analytical error rate?	.366	.504	1.000	.449
	What is your preanalytical error rate?	.579	.652	.449	1.000

Source: SPSS output, $N = 77$

Applications to Professional Practice

Incorporating strategies to identify and mitigate preanalytical errors is vital for optimizing business performance, particularly in sectors where precision is critical. In the context of business practice, especially in healthcare, addressing these errors is not only about ensuring operational efficiency but also about safeguarding financial health. Within the healthcare industry, preanalytical errors, such as incorrect patient preparation or sample mishandling, and analytical errors, such as inaccurate testing procedures, can lead to serious financial repercussions (Santos et al., 2021). Hospitals may face costly lawsuits due to misdiagnoses or improper treatments, which damage reputations and invite regulatory penalties. These financial burdens can escalate into higher operational costs and increased liability insurance premiums.

Erroneous conclusions can lead to unnecessary treatments, patient dissatisfaction, and potential loss of future business from damaged credibility. Actively identifying and correcting these errors can lead to substantial cost reductions and efficiency improvements. Minimizing retests, rework, and legal risks, businesses can focus financial resources more effectively, improving overall operational efficiency. Implementing stringent quality control measures, technology, and automation alongside thorough employee training programs can significantly decrease the likelihood of errors occurring (Mankar, 2024). These investments in accuracy and error prevention not only enhance financial stability but also elevate customer satisfaction, strengthening business reputation and fostering trust (Santos et al., 2021). Prioritizing the resolution of preanalytical errors, business practices can ensure robust financial performance while maintaining high standards of quality and service reliability.

Implications for Social Change

Preanalytical errors in medical laboratory testing significantly impact hospital financial performance and societal well-being. Addressing these errors is crucial for societal progress as they can result in inaccurate test outcomes, leading to misdiagnosis or inappropriate treatment strategies. In the preanalytical phase, the journey toward social change begins with a robust foundation in education and awareness. Enhancing educational programs and conducting comprehensive training for laboratory and healthcare staff, stakeholders aim to anticipate and prevent errors even before they occur. Emphasizing the importance of proper sample collection, handling, and documentation during training ensures a vast reduction in errors, leading to better healthcare outcomes.

Embracing technologies that automate and standardize testing processes furthers these improvements, paving the way for breakthroughs in patient care and minimizing erroneous results that can disrupt hospital operations. Accurate data analysis and timely feedback ensure errors are identified and rectified swiftly, minimizing their financial impact. Feedback also serves as a powerful tool for ongoing education and process improvement (Mankar et al., 2024). When preanalytical errors are systematically identified and minimized, the ripple effects resonate across the healthcare ecosystem. This engenders enhanced healthcare credibility, boosts patient trust, and supports fiscal stability in hospitals by avoiding costs related to retesting, misdiagnosis, and potential litigation.

By championing improved training and refined protocols to address laboratory errors, society collectively marches toward an inclusive healthcare system that prioritizes patient safety and quality care. These efforts contribute to more efficient diagnoses, optimized treatment plans, and effective patient management, demonstrating a universal commitment to healthcare excellence and reform (Farisani et al., 2022). Embracing systematic changes and TQM to mitigate laboratory errors envisions a healthcare future that values equity, quality, and safety for every individual, enhancing the overall social fabric.

Recommendations for Action

This quantitative correlational study aimed to assess the relationship between preanalytical, analytical, postanalytical error, and hospital financial performance. The findings indicated a significant correlation between the preanalytical errors and hospital operating margin, warranting further investigation. This research underscores the importance of considering hospital laboratory errors and hospital financial performance. Hospitals may allocate resource differently ensuring to invest in technology to mitigate errors especially in the preanalytical phase to mitigate quality risk and to keep costs low. Future research should focus on system analyses employing predictive modeling methodologies to see which types of errors under the preanalytical testing phase has a greater impact.

This study possesses certain limitations. First, it does not include hospital data outside the United States. Additionally, it does not encompass outpatient settings and services not connected to a hospital, which are crucial components of the comprehensive care delivery model. Second, the analysis is confined to hospital laboratories; therefore, independent laboratories were excluded, and more hospitals are choosing to partner with independent laboratories which has an impact on hospital financial performance and quality. Researchers may also consider exploring a study which includes secondary data to increase the validity of study. Last, the outcomes are restricted to multiple regression analysis; employing varied modeling approaches may enhance the statistical precision of the metrics with adjustments for reliability, an aspect constrained by the scope of this study.

Hospitals must consider adopting TQM initiatives aimed to reduce error rates in the preanalytical phase of the total testing process. As laboratory testing is integrated in each area of the hospital, every healthcare leader should be aware of the relationship between error preanalytical errors and hospital financial performance. Hospitals must provide training and invest in automation and technology available to mitigate error risk (Mankar et al., 2024). For sustainable implementation, healthcare executives must establish standardized protocols, have regular training and education sessions related to minimizing laboratory errors. Healthcare leaders must establish a system for providing feedback on discrepancies or errors to identify and address root cause (Santos et al., 2021). Interdisciplinary collaboration between laboratory staff and data analytics to identify and monitor trends is necessary ultimately leading to lower costs and higher quality of care in hospitals.

Recommendations for Further Research

Based on quantitative correlation study it confirms a relationship between preanalytical, analytical, postanalytical errors and hospital financial performance. The study was based on responses from an anonymous survey and the responses can be subjective as each hospital collects their quality data differently and interpretation may vary. I recommend repeating the study utilizing secondary data to ensure consistently of the data collected. Data collection will be a challenge as there is no public database that holds laboratory quality data. Also, additional quantitative analysis is warranted to identify causal links between preanalytical errors and financial outcomes.

In the future a researcher may perform qualitative research through interviews to gain insights into perceptions of error types and their financial implications. Another researcher can compare organizations with differing error rates and financial performance to identify successful strategies and areas of improvement. More research is also needed to investigate the role of technology and automation in reducing errors and improving both quality and cost-efficiency.

Reflections

Upon reflection, this experience has proven to be challenging but also exhilarating at the same time. The primary objective of this quantitative correlational study was to explore the relationship between laboratory errors at each phase of testing and hospital performed, aimed to confirm the relationship exist, educate laboratory managers and directors, and encourage more research around this topic. The rigorous study, perseverance, and effective time management skills were essential components of the

Walden University Doctor of Business Administration Program. The study incorporated data from an anonymous survey which took a lengthy amount of time to collect responses. Clinical laboratory leaders from various hospitals throughout the United States, they took the time the time to complete the survey, and I consider myself fortunate to have navigated this journey.

As the executive director of laboratory services, I take great pride in my academic achievements and the opportunity to enhance my understanding of the profession. I derive satisfaction from my contributions to the healthcare sector and the establishment of a foundation for future research endeavors. My doctoral study was motivated by the necessity to educate health leaders on the significance of clinical laboratory testing and its integral role within the hospital system. I remain committed to the education and advocacy of the clinical laboratory profession to ensure the delivery of quality patient care. Personally, I believe that the hallmark of effective leadership resides in the ability to create an environment that fosters the growth of others. I take pride in engaging in a journey that possesses the potential to facilitate the development and success of individuals.

Conclusion

In this quantitative correlational study, I investigated preanalytical, analytical, and postanalytical errors and their influence on hospital financial performance. The data for this research were obtained through an anonymous survey designed to assess error rates in each phase of laboratory testing, as well as operating margins, from clinical laboratory leaders across the United States. The primary research question was: What is the relationship between (a) preanalytical, (b) analytical, and (c) postanalytical laboratory errors, and (d) financial performance? The findings of this study indicated a significant relationship among one independent variable and the dependent variable. Applying the results of this research to professional practice, hospitals may implement error prevention strategies that not only enhance financial stability but also improve customer satisfaction, thereby bolstering their business reputation and fostering trust in the communities they serve. Furthermore, hospitals can facilitate social change by adopting TQM principles and instituting rigorous protocols that minimize errors and elevate the quality of care provided to every patient.

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Appendix: Laboratory Errors and Hospital Finance Survey

Laboratory Errors and Hospital Financial Performance

* 1. Are you a clinical laboratory leader working in hospital laboratory?

- ◯ Yes
- ◯ No

2. What region of the United States is your hospital laboratory located in?

- ◯ Northeast Region
- ◯ Southeast Region
- ◯ Midwest Region
- ◯ Southwest Region
- ◯ West Region

3. How many beds does your hospital have?

4. How often do errors result in additional operational cost?

- ◯ Not at all
- ◯ Slightly
- ◯ Moderately
- ◯ Significantly
- ◯ Drastically

* 5. What are examples of preanalytical errors you have encountered in your clinical laboratory?

- ☐ Patient Misidentification
- ☐ Improper Sample Collection
- ☐ Improper Handling and Transport
- ☐ Compromised specimens (hemolysis, lipemia, Clotted, QNS, etc.)
- ☐ Contamination
- ☐ Order entry errors

Other (please specify)

* 6. What is your pre-analytical error rate?

- 1%
- 2%
- 3%
- 5%
- 10%

Other (please specify)

7. What are examples of analytical errors you have encountered in your clinical laboratory?

- Instrument Errors
- Maintenance Neglect
- Reagent Problems (expired or contaminated)
- Quality Control (quality control alerts not addressed prior to patient testing)
- Deviation from established SOPs

Other (please specify)

* 8. What is your analytical error rate?

- 1%
- 2%
- 3%
- 5%
- 10%

Other (please specify)

9. What are examples of post-analytical errors you have encountered in the clinical laboratory?

- Manual Entry Errors
- Miscommunication with providers
- Result Misinterpretation
- Result Delivery Issues or Delayed Reporting
- Incomplete Reports
- Critical Result Reporting Delays

* 10. What is your post-analytical error rate?

- 1%
- 2%
- 3%
- 5%
- 10%

Other (please specify)

11. How would you rate your hospital's profitability?

- Highly profitable
- Moderately profitable
- Break-even
- Slightly Unprofitable
- Highly Unprofitable

* 12. What is the operating margin from your income statement of your hospital?

- 5%
- 2%
- 0%
- -2%
- -5%

Other (please specify)