INFLUENCE OF TOTAL QUALITY MANAGEMENT PRACTICES IMPLEMENTATION ON THE STRATEGIC COMPETITIVENESS OF SELECTED DIAGNOSTIC LABORATORIES IN NAKURU COUNTY

MICHAEL NYONGESA WALEKHWA

A Project Submitted to the Institute of Post Graduate Studies in Partial Fulfilment of the Requirements for the Award of Master of Business Administration (Strategic Management) Degree

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DECLARATION

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Signed:_________________________ Date:_________________________

Michael Nyongesa Walekhwa

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The project entitled, "**Influence of total Quality Management Practices Implementation on the Strategic Competitiveness of Selected Diagnostic Laboratories in Nakuru County ,**" written by **Michael Nyongesa Walekhwa,** is presented to the Institute of Postgraduate Studies of Kabarak University. We have reviewed the research project and recommend it be accepted in partial fulfillment of the requirement for the Award of Master of Business Administration (Strategic Management) .

Signed:_________________________ Date:_________________________

Prof. Simon Kipchumba

Department of Commerce

Kabarak University

Signed:_________________________ Date:_________________________

Dr. Nehemiah Kiplagat

Department of Commerce

Kabarak University

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DEDICATION

I dedicate this work to all quality management personnel across participating laboratories.

ABSTRACT

Diagnostic medical laboratories are integral to health systems globally, underpinning clinical decision-making and public health surveillance. In Kenya, however, increasing incidences of false-positive and false-negative results have raised concerns about laboratory effectiveness and quality assurance. Within Nakuru County, limited documentation exists on the adoption and strategic value of Total Quality Management (TQM) practices in enhancing competitiveness and sustainability. This study investigated the influence of TQM implementation on the strategic competitiveness of selected diagnostic laboratories in Nakuru County. The study was anchored in strategic quality frameworks, including the Six Sigma Theory, Juran's Trilogy of Quality Management, and Kaoru Ishikawa's Theory of Total Quality Control. A convergent parallel mixed-methods design was applied, using expert and homogeneous sampling to recruit 48 participants. Quantitative data were collected using standardized questionnaires, while qualitative insights were obtained through key informant interviews. Ethical clearance was obtained from Kabarak University Research Ethics Committee (KUREC), and NACOSTI issued a research license. The study found that 61.9% of participants were laboratory technologists or technicians, 47.6% had over a decade of experience, and 57.1% possessed bachelor's degrees. Private laboratories accounted for the most significant proportion (47.6%), with 61.9% holding KENAS accreditation. Resource availability was moderately constrained (57.1%). Strategic human resource variables such as job role and experience were statistically significant in influencing revenue diversification ($p = 0.021$) and the adoption of staff training and personalized service strategies ($p = 0.011$). Higher educational attainment was associated with stronger financial performance ($p = 0.007$), highlighting the role of human capital in strategic execution. TQM structures were formally documented in 90.5% of the laboratories, with 47.6% having defined performance metrics across all processes. Strong correlations were observed between the use of performance metrics and measurement frequency ($r = .726$) and between the use of performance metrics and process improvement initiatives ($r = .645$). Familiarity with the PDCA cycle significantly influenced both its practical application ($r = .917$) and participation in continuous improvement practices such as Kaizen ($r = .646$). Root-cause analysis, particularly the "5 Whys" method (52.4%), was reported by 42.9% of laboratories. Financial performance was rated as stable by 61.9% of respondents, and ISO 15189 compliance was seen as enhancing training and internal feedback systems. Notably, frequent data visualization and the use of performance analytics were associated with higher profit margins and improved service quality. In conclusion, the study demonstrates that effective TQM implementation serves as a critical strategic lever for enhancing operational efficiency, service quality, and competitive positioning in the diagnostic laboratory sector. Nonetheless, persistent challenges such as resource limitations and inconsistent adherence to standard operating procedures (SOPs) limit the full realization of strategic benefits. To sustain competitiveness, laboratory managers should prioritize strategic investments in resource mobilization, institutionalization of TQM practices, and capacity development.

Keywords: *Total Quality Management, Competitiveness, Diagnostic Laboratories, Nakuru County*

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LIST OF ABBREVIATIONS AND ACRONYMS

CQI	Continuous Quality Improvement
DDDM	Data-Driven Decision-Making
ISO	International Organization for Standardization
KENAS	Kenya Accreditation Service
LIMS	Laboratory Information Management System
LMICs	Low- and Middle-Income Countries
OpEx	Operating Expenditure
PDCA	Plan-Do-Check-Act
QMS	Quality Management System
QC	Quality Control
RCA	Root Cause Analysis
ROI	Return on Investment
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
SOP	Standard Operating Procedure
TAT	Turnaround Time
TQM	Total Quality Management
WHO-AFRO	World Health Organization -Regional Office for Africa

OPERATIONAL OPERATIONAL DEFINITION OF TERMS

Total Quality Management : A systematic, organization-wide approach focused on Continuous improvement, customer satisfaction, and process excellence in diagnostic laboratory operations.

Process Management: The structured documentation, standardization, monitoring, and control of laboratory procedures to ensure consistency, accuracy, and efficiency.

Continuous Improvement : An ongoing effort to enhance processes, services, and performance using structured methodologies such as PDCA, Kaizen, and Root Cause Analysis.

Data-Driven Decision-Making: The use of laboratory performance data, quality indicators, and analytics to guide operational and strategic decisions.

Strategic Competitiveness : A laboratory's ability to achieve superior performance, quality outcomes, customer satisfaction, and financial sustainability relative to other service providers.

Quality Management System: A formal framework of policies, SOPs, records, and monitoring systems used to ensure the reliability and quality of laboratory services.

Standard Operating Procedures: Official written instructions describing how specific laboratory tasks must be performed to ensure standardization and compliance.

Performance Metrics: Quantifiable indicators such as turnaround time, error rates, accuracy, and productivity used to assess laboratory performance.

Turnaround Time: The total time taken from specimen receipt to reporting of results, used as a key efficiency indicator.

Root Cause Analysis : A structured problem-solving method used to identify the underlying causes of laboratory errors or nonconformities.

PDCA Cycle : A four-step continuous improvement model, Plan, Do, Check, Act, used to test and refine improvements.

Kaizen : A continuous improvement philosophy emphasizing small, incremental changes to enhance efficiency and quality.

Process Standardization: Ensuring uniformity in laboratory procedures through consistent application of SOPs and documented processes.

Quality Control: Routine technical procedures or checks used to ensure the accuracy and reliability of laboratory test results.

Customer Satisfaction: The degree to which laboratory clients (clinicians, patients, institutions) perceive services as meeting or exceeding expectations.

Feedback Mechanisms: Systems such as surveys, complaints logs, or interviews used to collect stakeholder input on laboratory services.

Accreditation (ISO 15189) : Formal recognition, often by KENAS, that a laboratory meets international standards for competence and quality.

Financial Performance: The laboratory's ability to generate revenue, manage operational costs, and achieve sustainability.

Resource Availability: The adequacy of human, financial, infrastructural, and technological resources needed to support laboratory quality systems.

Documentation Review Frequency : How often QMS documents, SOPs, and processes are updated to reflect current practices or technologies.

Stakeholder Engagement : The involvement of internal and external stakeholders (staff, managers, clinicians, clients) in quality improvement processes.

Laboratory Competitiveness Index : A composite measure derived from quality ratings, customer satisfaction, and financial indicators reflecting the laboratory's overall competitiveness.

CHAPTER ONE

INTRODUCTION

1.1 Background of the Study

In today's highly competitive healthcare environment, diagnostic laboratories play a crucial role in providing timely, accurate diagnoses, which are fundamental to effective treatment and patient care. The increasing demand for high-quality healthcare services has placed immense pressure on these laboratories to improve operational efficiency, accuracy, and overall service delivery. One approach that has gained significant attention in achieving these goals is the implementation of Total Quality Management (TQM) practices (Hidayah et al., 2022). TQM is a comprehensive management approach that focuses on continuous improvement, customer satisfaction, and the involvement of all employees in the quality process (Ramadhanty, 2023). Leadership commitment is essential for setting the vision, goals, and direction of the laboratory, while employee involvement ensures that all staff members are engaged in the quality improvement process (Steinmann et al., 2018). Continuous improvement focuses on identifying and eliminating inefficiencies, while customer focus emphasizes meeting the needs and expectations of patients and healthcare providers. Data-driven decision-making involves using performance metrics and statistical tools to monitor and improve laboratory processes.

Globally, the healthcare industry has witnessed a surge in the adoption of TQM practices to improve service quality and maintain a competitive edge (Zehir & Zehir, 2023). According to a report by the World Health Organization (WHO), healthcare institutions that have successfully implemented TQM practices have reported significant improvements in service quality, patient satisfaction, and operational efficiency (Aburayya, 2020). For instance, in the United States, the adoption of TQM practices in healthcare facilities has been associated with a 20% reduction in patient complaints and a 15% increase in patient satisfaction scores (WHO, 2020). Similarly, in Europe, TQM practices have led to a 10% reduction in diagnostic errors and a 12% improvement in turnaround times for laboratory results (European Quality Management Association, 2019).

Across Africa, the adoption of Total Quality Management (TQM) practices in healthcare, particularly in diagnostic laboratories, has been varied but shows promising trends. In South Africa, for example, laboratories that implemented TQM practices reported a 22% reduction in diagnostic errors and a 15% improvement in patient turnaround times between 2018 and 2021, according to a study by the South African Medical Research Council (Maphumulo & Bhengu, 2019; Van Moll et al., 2023). In Nigeria, the adoption of TQM practices in major urban healthcare facilities led to a 30% increase in patient satisfaction scores and a 25% decrease in operational inefficiencies, as reported by the Nigerian Institute of Medical Research in 2020 (Egwunatum et al., 2021). Similarly, in Ghana, the introduction of TQM in public diagnostic laboratories was associated with a 20% reduction in patient complaints and a 10% increase in diagnostic result accuracy, as documented by the Ghana Health Service in 2019 (Kploanyi et al., 2023).

In Kenya, the implementation of Total Quality Management (TQM) practices in diagnostic laboratories has seen varied success across different counties. A survey conducted by the Ministry of Health in 2022 revealed that in Nairobi, 60% of public and private laboratories had adopted some form of TQM practices, leading to a reported 18% improvement in diagnostic accuracy and a 25% reduction in patient wait times (Ministry of Health, 2022). In contrast, counties like Kisumu and Mombasa have struggled to consistently implement TQM, with only 35% of laboratories in Kisumu and 40% in Mombasa reporting active TQM practices (Ombewa, 2018). These counties have faced significant challenges, including inadequate funding, limited access to continuous training for laboratory staff, and resistance to the cultural shift required for TQM implementation. The gaps in TQM adoption are further highlighted by disparities in patient satisfaction and diagnostic errors, with Kisumu recording a 30% higher rate of patient complaints related to laboratory services than Nairobi (Ayuo, 2016; Omore, 2022).

In Nakuru County, adoption of Total Quality Management (TQM) practices across diagnostic laboratories has been uneven, reflecting both progress and ongoing challenges. Key laboratories such as the Nakuru County Referral Hospital Laboratory, Mediheal Group of Hospitals Laboratory, Valley Hospital Laboratory, and Pathologists' Lancet Kenya have implemented varying degrees of TQM initiatives (Kutol, 2022). The Nakuru County Referral Hospital Laboratory, for instance, has integrated several TQM practices, resulting in a 22% reduction in diagnostic errors and a 15% improvement in patient turnaround time, according to a 2023 report by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) (Oyoo, 2015). On the other hand, smaller private and public laboratories in the county struggle to fully implement TQM due to limited resources, insufficient staff training, and challenges in maintaining consistent quality standards. Despite efforts, gaps remain, particularly in rural and semi-urban areas, where laboratories are less well equipped to adopt comprehensive TQM practices. The disparity in TQM implementation contributes to inconsistencies in diagnostic accuracy and service delivery within Nakuru County, highlighting the need for targeted interventions and support to ensure uniform quality standards across all diagnostic facilities.

Strategic competitiveness in diagnostic laboratories is a multifaceted concept that extends beyond mere service provision to encompass factors such as service quality, efficiency, innovation, cost management, and customer satisfaction (Kadira, 2022). Laboratories that achieve strategic competitiveness deliver accurate, timely diagnostic results and continuously adapt to the changing demands of the healthcare industry (Adekoya, 2025). This includes leveraging advanced technologies, optimizing workflows, and maintaining high-quality standards to remain competitive in a rapidly evolving market. Total Quality Management (TQM) practices are integral to achieving strategic competitiveness. It involves a holistic approach to quality improvement, where every aspect of the laboratory's operations is continuously evaluated and enhanced. Through TQM implementation, laboratories can streamline processes, reduce waste, and foster a culture of excellence that permeates the organization at all levels. This, in turn, leads to improved service quality, reduced turnaround times, and greater customer satisfaction.

For instance, strategic competitiveness encompasses the ability to meet or exceed customer expectations consistently (Khatab, 2021). Laboratories that implement TQM practices are more likely to deliver high-quality services that align with patient and clinician needs, thereby building trust and loyalty. Moreover, the continuous improvement focus inherent in TQM helps laboratories stay ahead of industry trends, adopt new technologies more effectively, and respond swiftly to regulatory changes. Studies have demonstrated the tangible benefits of TQM implementation in enhancing strategic competitiveness. A 2014 study by the Kenya Medical Research Institute (KEMRI) found that diagnostic laboratories that adopted TQM practices saw a 25% increase in customer satisfaction and a 20% reduction in operational costs compared to those that did not (Diamond, 2015). These laboratories were better positioned to compete in the market by offering superior services at lower cost, thereby attracting more clients and improving their financial performance. While TQM is a key driver of laboratories' strategic competitiveness, the extent of its implementation in Nakuru County remains largely unknown. Against this backdrop, this study sought to evaluate the influence of the implementation of TQM practices on the strategic competitiveness of selected diagnostic laboratories in Nakuru County.

1.2 Statement of the Problem

The diagnostic laboratory sector plays a critical role in the healthcare system, providing essential services that support accurate diagnosis, effective treatment, and overall patient care. However, the strategic competitiveness of these laboratories is increasingly under scrutiny as the demand for high-quality, cost-effective, and timely diagnostic services rises. Total Quality Management practices, which emphasize continuous improvement, customer focus, and process optimization, have been widely recognized as a potential solution to enhance the performance and competitiveness of diagnostic laboratories. Yet, the extent to which TQM practices have been implemented and their influence on the strategic competitiveness of diagnostic laboratories in Nakuru County remains inadequately understood.

Despite growing recognition of TQM's importance in healthcare, evidence suggests that many diagnostic laboratories in Nakuru County continue to struggle with operational inefficiencies, inconsistent service quality, and customer dissatisfaction (Kutol, 2022). For instance, data from the Nakuru County Health Department indicate that only 40% of diagnostic laboratories in the region have partially adopted formal quality management systems, with a significant number operating without any structured quality control mechanisms. This lack of standardization has led to disparities in service delivery, with some laboratories reporting higher error rates and longer turnaround times compared to those with established TQM practices. Furthermore, the competitive landscape in Nakuru County's diagnostic laboratory sector is becoming increasingly challenging. Laboratories face competition not only from within the country but also from neighboring countries and private entities that offer more advanced diagnostic technologies and superior customer service. This competition is exacerbated by the fact that many laboratories in Nakuru County are small to medium-sized enterprises that may lack the resources to invest in comprehensive TQM programs, further limiting their ability to compete effectively. A 2021 survey found that 30% of patients and healthcare providers in Nakuru County expressed dissatisfaction with the quality and timeliness of diagnostic services, citing delays in test results and perceived inaccuracies (Moses, 2021).

Moreover, the financial performance of these laboratories is directly impacted by their ability to attract and retain clients, which is closely linked to their strategic competitiveness. Without implementing TQM practices, laboratories are more likely to incur higher operational costs due to inefficiencies, resulting in reduced profitability and sustainability. The Kenya Medical Research Institute (KEMRI) has reported that laboratories with robust TQM practices experience up to 20% lower operational costs and a 15% increase in client retention compared to those without such practices (Shaikh, 2025). Given the critical role that diagnostic laboratories play in the healthcare system and the challenges they face in maintaining competitiveness, there is an urgent need to examine the influence of TQM practices on their strategic competitiveness. This study sought to evaluate the impact of TQM implementation on the strategic competitiveness of selected diagnostic laboratories in Nakuru County.

1.3 Objectives of the Study

1.3.1 General Objective of the Study

To establish the impact of the implementation of Total Quality Management practices on the strategic competitiveness of selected diagnostic laboratories in Nakuru County.

1.3.2 Specific Objectives of the Study

i. To assess the influence of the level of implementation of process management practices on the strategic competitiveness of selected diagnostic laboratories in Nakuru County.

ii. To evaluate the effect of continuous improvement practices on the strategic competitiveness of selected diagnostic laboratories in Nakuru County.

iii. To establish the influence of data-driven decision-making practices on the strategic competitiveness of selected diagnostic laboratories in Nakuru County.

1.4 Research Questions

i. How does the level of implementation of process management practices affect the strategic competitiveness of diagnostic laboratories in Nakuru County?

ii. What is the effect of continuous improvement practices on the strategic competitiveness of diagnostic laboratories in Nakuru County?

iii. How do data-driven decision-making practices influence the strategic competitiveness of diagnostic laboratories in Nakuru County?

1.5 Justification for the Study

The World Health Organization (WHO) has emphasized the importance of universal access to quality diagnostic services as a critical component of achieving universal health coverage (UHC), a key aspect of the United Nations Sustainable Development Goals (SDGs). Sustainable Development Goal 3 aims to ensure healthy lives and promote well-being for all ages, including achieving UHC, access to essential medicines and vaccines, and providing safe, effective, quality, and affordable access to these for everyone. To achieve these goals, the WHO recommends improving the quality of diagnostic services and implementing TQM practices in the healthcare sector. Similarly, the Kenya Vision

2030 initiative recognizes the critical role of diagnostic laboratories in improving healthcare services. The initiative aims to transform Kenya into a middle-income country with a high quality of life for its citizens by 2030. This vision includes improving healthcare services, particularly in underserved areas such as Nakuru County. Therefore, the proposed study on the influence of TQM practices on the strategic competitiveness of selected diagnostic laboratories in Nakuru County is justified by the need to improve the quality of diagnostic services and contribute to achieving UHC, SDGs, and the Kenya Vision 2030 initiative.

1.6 Significance of the Study

The findings of this study will be helpful to diagnostic laboratories in Nakuru County and other similar organizations in the healthcare sector. The study will help identify areas where TQM practices can be improved and strategies to overcome the challenges diagnostic laboratories face in implementing TQM. The study will also provide recommendations to strengthen TQM practices in diagnostic laboratories, thereby enhancing service quality and increasing competitiveness.

This study will also contribute to the existing body of literature on TQM practices and their impact on the strategic competitiveness of organizations in the healthcare sector. The findings of this study will serve as a reference for future research in this field and help improve understanding of the impact of TQM practices on the strategic competitiveness of healthcare organizations.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This section provides a comprehensive overview of the implementation of TQM practices in medical laboratories, examining theories such as Six Sigma, Juran's Trilogy, and Deming's Theory. The empirical assessment examines global, regional, and local studies on process management, continuous improvement, and data-driven decision-making within TQM. The conceptual framework analyzes the TQM elements that affect strategic competitiveness. Additionally, the summary of gaps identifies research opportunities for future advancements.

2.2 Theoretical Review

2.2.1 Juran's Trilogy of Quality Management

Juran's Trilogy of Quality Management is a framework developed by Joseph Juran, a pioneer in the field. The framework consists of three components: Quality Planning, Quality Control, and Quality Improvement (Dou, 2020). The Quality Planning component focuses on identifying customer needs and developing a plan to meet them. The Quality Control component involves implementing the plan and monitoring the process to ensure it is followed. Finally, the Quality Improvement component focuses on continuous improvement to enhance the quality of the products or services an organization provides. The Quality Planning component of Juran's Trilogy is critical to implementing TQM practices in diagnostic laboratories. Quality Planning involves identifying the needs and expectations of the laboratory's customers, which includes physicians and patients.

The laboratory must ensure its services meet customer needs by developing a plan outlining the processes and procedures required to achieve the desired quality level. This can be achieved by conducting customer satisfaction surveys, analyzing customer feedback, and benchmarking against other laboratories in the region or the country.

The Quality Control component of Juran’s Trilogy involves implementing the plan developed during Quality Planning. This component requires the laboratory to establish and monitor the processes and procedures in place to achieve the desired quality level. Quality Control involves using statistical tools and techniques to monitor the laboratory's performance and ensure it meets the quality standards established during Quality Planning. The Quality Improvement component of Juran’s Trilogy is a critical aspect of TQM implementation in diagnostic laboratories. Quality Improvement involves continuous monitoring of laboratory performance and implementing changes to improve the quality of services provided. The laboratory must establish a culture of constant improvement and involve its staff in the improvement process. This can be achieved by conducting regular training and education programs, establishing quality improvement teams, and implementing a system to capture and analyze data to identify areas for improvement.

Several studies have demonstrated the application of Juran’s Trilogy of Quality Management in the healthcare industry. For example, a study by Mohammad Gholipour et al. (2021) applied Juran’s Trilogy to evaluate the quality of radiology services in a hospital in Iran. The study found that implementing Juran’s Trilogy improved the quality of services provided by the radiology department. Similarly, a survey by Al-Ali (2021) applied Juran’s Trilogy to evaluate the quality of laboratory services in Jordan. The study found that implementing Juran’s Trilogy improved the quality of laboratory services and enhanced the laboratory’s competitiveness.

2.2.2 Deming's Theory of Total Quality Management

Deming's Theory of Total Quality Management is a framework developed by W. Edwards Deming, a pioneer in quality management (Aldwihi et al., 2020). The framework consists of 14 points intended to guide organizations in improving the quality of their products and services. The 14 points can be categorized into four key areas: understanding customer needs, continuous improvement, leadership, and statistical analysis. Understanding customer needs is critical to implementing TQM practices in diagnostic laboratories. Diagnostic laboratories must understand the needs of their customers, which include physicians and patients, to provide high-quality services. Deming's theory emphasizes the importance of understanding customer needs and meeting them.

This can be achieved by conducting customer satisfaction surveys, analyzing customer feedback, and benchmarking against other laboratories in the region or the country. The focus on continuous improvement is a critical aspect of Deming's theory. The theory emphasizes that organizations must continually strive to improve their products and services to remain competitive. This can be achieved by establishing a culture of continuous improvement, involving staff in the improvement process, and implementing a system to capture and analyze data to identify areas for improvement. Leadership is another key aspect of Deming's theory.

The theory emphasizes the importance of leadership in driving the implementation of TQM practices. Leaders must provide the necessary resources, establish clear goals, and foster a culture of continuous improvement. Leaders must also be involved in the improvement process and guide staff members. Statistical analysis is a critical component of Deming's theory. The theory emphasizes the importance of using statistical tools and techniques to analyze data and identify areas for improvement.

Diagnostic laboratories must use statistical analysis to monitor their performance and ensure they meet the quality standards established during the implementation of TQM practices.

Several studies have demonstrated the application of Deming's Theory of Total Quality Management in the healthcare industry. For example, a study by Zare et al. (2019) applied Deming's theory to evaluate the quality of laboratory services in a hospital in Iran. The study found that implementing Deming's theory improved the quality of laboratory services and enhanced the laboratory's competitiveness. Similarly, a survey by Al-Abdali (2021) applied Deming's theory to evaluate the quality of laboratory services in Jordan. The study found that implementing Deming's theory improved the quality of laboratory services and enhanced the laboratory's competitiveness.

2.2.3 The Six Sigma Theory

The Six Sigma theory, introduced by Bill Smith at Motorola in the 1980s, is a methodology that focuses on improving quality and reducing process variation to achieve enhanced performance and customer satisfaction (Schroeder et al., 2008). It originated in the manufacturing industry and has since been applied to various sectors, including healthcare. The theory aims to minimize defects and errors by using statistical analysis and data-driven decision-making.

In the context of Total Quality Management (TQM), Six Sigma, pioneered by Bill Smith, plays a significant role in enhancing the performance of medical laboratories (Elder, 2008). Medical laboratories are critical in providing accurate and reliable diagnostic information, which directly impacts patient care. By integrating Six Sigma principles into TQM frameworks, laboratories can streamline processes, reduce errors, and optimize resource utilization. One of the key aspects of Six Sigma is the DMAIC

(Define, Measure, Analyze, Improve, Control) methodology. In the Define phase, laboratory processes and goals are clearly defined and aligned with customer requirements and organizational objectives. The Measure phase involves collecting relevant data and metrics to assess the current state of the processes. This data-driven approach enables laboratories to identify areas of improvement and set performance benchmarks.

In the Analyze phase, statistical tools and techniques are employed to analyze the collected data and identify the root causes of variations and errors (Thakur et al., 2023). This analysis helps laboratories pinpoint specific process areas that require improvement. In the Improve phase, interventions and process modifications are implemented to eliminate defects and enhance the efficiency and effectiveness of laboratory operations. The Control phase, also known as the "Improve" phase in some variations of the methodology, ensures that the improvements achieved are sustained over time. Control mechanisms, such as process monitoring and performance measurement, are put in place to ensure ongoing adherence to the improved processes. By consistently monitoring performance and implementing corrective actions when necessary, laboratories can maintain the desired level of quality and performance.

By correlating Six Sigma theory, developed by Bill Smith, with the performance of medical laboratories, the implementation of Six Sigma principles can yield several significant benefits. Firstly, it can reduce errors and inaccuracies, thereby improving the accuracy and reliability of laboratory test results. This, in turn, enhances patient safety and outcomes by enabling healthcare providers to make informed decisions based on accurate diagnostic information. Secondly, Six Sigma emphasizes customer satisfaction. In the case of medical laboratories, customers include both healthcare providers and patients. By ensuring accurate and timely test results, laboratories can enhance customer satisfaction and build trust with healthcare providers and patients alike. Additionally, the data-driven nature of Six Sigma enables laboratories to identify process bottlenecks, optimize resource utilization, and improve turnaround times. This can lead to increased operational efficiency, cost reduction, and enhanced overall laboratory performance.

2.3 Empirical Review

2.3.1 Effect of Process Management on Strategic Competitiveness of Laboratories

Process management practices are fundamental to systematically identifying, designing, implementing, controlling, and continuously improving organizational processes. Esteemed scholars such as Leoneti et al. (2020), Hutchins et al. (2019), Juran and De Feo (2010), and other prominent researchers have unequivocally underscored the profound significance of process management in achieving operational excellence and delivering superior customer satisfaction. A rich body of scholarly work has corroborated the effectiveness of these practices, including studies by Johnson (2002), Smith and Ton (2013), and others. These studies have demonstrated the pivotal role of process mapping, rigorous analysis, strategic redesign, comprehensive performance measurement, and the application of widely recognized improvement methodologies such as Lean and Six Sigma. By embracing these robust practices, organizations can drive operational efficiency, minimize waste, enhance quality, and ultimately excel in meeting and surpassing customer expectations.

A plethora of studies has provided invaluable insights into process management practices. Notably, Chang (2016) highlighted the pivotal role of process mapping and analysis in identifying and scrutinizing key organizational processes to uncover areas for improvement. In addition, Chountalas and Lagodimos (2018) and Sujova and Marcinekova (2015) underscore the substantial benefits of process analysis, particularly in pinpointing bottlenecks, inefficiencies, and untapped opportunities for improvement.

Furthermore, research by Hsu et al. (2020) has highlighted the transformative impact of process redesign and the successful application of improvement methodologies, such as Lean and Six Sigma, to achieve heightened process efficiency and bolster overall quality. The work of Arya et al. (2018) further reinforces these findings by emphasizing the importance of strategic process redesign and the use of improvement methodologies to drive waste reduction and operational excellence. Additionally, Terziovski (2006) and Jun and Cai (2010) illuminate the positive relationship between process improvement initiatives and customer satisfaction, underscoring the far-reaching implications of effective process management. Furthermore, Micheli and Mura (2017) and Ukko and Saunila (2020) emphasize the significance of comprehensive process performance measurement, highlighting its role in monitoring, controlling, and optimizing key organizational processes.

Furthermore, process performance measurement is a pivotal and indispensable aspect of effective process management within the TQM framework. Extensive research by Hall (2011) and Arzu Akyuz & Erman Erkan (2010) illuminates the profound significance of process performance measurement not only for monitoring and controlling key organizational processes but also for establishing a direct link between process performance metrics and overall organizational outcomes. In addition to these seminal studies, a diverse range of scholarly work has consistently reinforced the criticality of process performance measurement. Research by Chan & Chan (2004) examines the impact of process performance indicators on organizational productivity and highlights the importance of aligning these metrics with strategic goals. The comprehensive study by Nasiri et al. (2020) examines the relationship between process performance measurement and financial performance, underscoring the potential to enhance profitability and competitive advantage through robust process measurement systems.

Furthermore, the work of Vukšić et al. (2013) delves into the use of advanced analytics and real-time monitoring to enable proactive process performance management and rapid decision-making. Collectively, these studies provide a compelling body of evidence that substantiates the crucial role of process performance measurement in driving organizational excellence and facilitating data-driven decision-making.

The collective findings of the reviewed studies unequivocally emphasize the utmost significance of process management practices within the realm of TQM. However, it is essential to note that variations exist across research methodologies, industries studied, and contextual factors, contributing to a rich and diverse landscape for understanding the implementation and impact of these practices across different organizational settings. In addition to the previously mentioned studies, an array of influential research supports these conclusions. For instance, Davenport (2014) examines the role of process management practices in the healthcare industry, highlighting the unique challenges and opportunities for quality improvement.

The study by Conforto et al. (2014) examines the application of process management practices in the manufacturing sector, elucidating their effects on operational efficiency and product quality. Moreover, Smart et al. (2009) examine the implications of process management practices in the service industry, emphasizing their impact on customer satisfaction and service delivery excellence. These studies, in conjunction with others, highlight the versatility and adaptability of process management practices across diverse sectors, underscoring their vital role in driving organizational performance and quality improvement. The synthesis of these varied studies further enhances our understanding of the complexities associated with implementing process management practices and elucidates the contextual factors that influence their effectiveness.

2.3.2 Effect of Continuous Improvement on the Strategic Competitiveness of Laboratories

Continuous improvement, known as Kaizen, is a systematic approach rooted in the TQM philosophy that emphasizes incremental, ongoing enhancements across all facets of an organization. Esteemed scholars in the field of TQM, including Shewhart and Deming (1986), Toda et al. (1985), and a multitude of other researchers (Mukhopadhyay, 2020; Nadeem et al., 2013; Rothlauf, 2014), have extensively emphasized the paramount importance of continuous improvement as a foundational element for achieving operational excellence and delivering high-quality products and services. Building upon this foundation, the conceptual framework of constant improvement encompasses a range of principles that serve as guiding pillars for organizations. Notably, these principles include unwavering customer focus, fostering a culture of employee empowerment, optimizing processes to eliminate inefficiencies, and embracing data-driven decision-making as the cornerstone of organizational progress.

Further reinforcing these core principles, a range of influential studies by authors such as Souza et al. (2022) and Eniola et al. (2019) examine the application of continuous improvement methodologies and their profound impact on organizational performance, product quality, customer satisfaction, and competitive advantage. Additionally, Powell's (1995) research explores the relationship between continuous improvement and organizational learning, elucidating how a culture of ongoing improvement can facilitate knowledge sharing and foster innovation.

Within the realm of Total Quality Management (TQM), numerous scholarly works have significantly contributed to our understanding of continuous improvement. These studies have rigorously examined its technical intricacies, comprehensiveness, and appeal, shedding light on its practical implementation and transformative impact. Notably, the research conducted by Uunona and Goosen (2023) delves deeply into the application of continuous improvement methodologies, specifically Lean and Six Sigma, across diverse industries. Their findings highlight the remarkable effectiveness of these methodologies in streamlining processes, minimizing waste, and ultimately improving overall organizational performance. Similarly, the work of Luo et al. (2023) examines the relationship between continuous improvement practices and organizational performance, emphasizing the pivotal roles of a supportive organizational culture and engaged employees in successfully implementing these practices. These studies provide compelling evidence of the positive outcomes achieved through the adoption of continuous improvement initiatives.

Moreover, the comprehensive review by Robinson and Ginder (2020) explores various continuous improvement approaches, including Total Productive Maintenance (TPM) and Quality Function Deployment (QFD), elucidating their unique benefits and challenges. Their research provides valuable insights into the diverse methodologies available for organizations seeking to embrace continuous improvement.

Furthermore, the study conducted by Fainshmidt et al. (2019) examines the impact of continuous improvement on manufacturing performance, emphasizing the crucial role of employee involvement, leadership support, and process standardization in driving successful implementation. Their findings contribute to a deeper understanding of the factors influencing the effectiveness of continuous improvement efforts. Additionally, the work of Clauss et al. (2021) explores the role of continuous improvement in enhancing product development processes, demonstrating its significance for faster time-to-market, lower costs, and higher customer satisfaction. This study highlights the broad applicability of continuous improvement principles beyond traditional manufacturing settings.

An abundance of scholarly research has explored the integration of technology into continuous improvement initiatives, unveiling its potential to amplify the comprehensiveness and effectiveness of these practices. Notably, the work of Elkefi et al. (2021) sheds light on the synergistic relationship between technology and continuous improvement, specifically examining the incorporation of Lean Six Sigma and statistical process control. Their findings demonstrate that leveraging technological advancements can further expand the scope and impact of continuous improvement efforts.

In addition to McDermott et al. (2022), other researchers have also investigated the role of technology in continuous improvement. For instance, Belhadi et al. (2020) examine the use of data analytics and artificial intelligence for continuous improvement, highlighting their transformative potential. Their research showcases how advanced analytics can enable proactive problem-solving, predictive analysis, and real-time monitoring, thereby revolutionizing the continuous improvement landscape.

Furthermore, Valakhanovich (2020) focuses on the integration of digital tools, such as process mining and simulation, into continuous improvement initiatives. Their study highlights the value of these technologies in providing insights into process inefficiencies, facilitating scenario analysis, and supporting decision-making for improvement actions. Additionally, Sturgeon (2021) explores the role of information systems and technology infrastructure in enabling continuous improvement efforts across complex supply chains. Their research emphasizes the importance of integrated information systems, collaborative platforms, and data-sharing capabilities in facilitating seamless communication and coordination among stakeholders.

2.3.3 Data-Driven Decision Making and Strategic Competitiveness of Laboratories

Data-driven decision-making is widely recognized as a pivotal component of contemporary business and organizational practices. Empirical literature has made significant contributions in exploring the numerous benefits, challenges, and best practices linked to data-driven decision making. A multitude of studies have investigated the profound impact of data-driven decision-making across diverse facets of organizational performance, strategy formulation, and operational efficiency, further reinforcing its importance in today's landscape (Ali and Johl, 2022; Karami et al., 2021; Nguyen et al., 2022).

For instance, a comprehensive study by Awan et al. (2021) examined the association between data-driven decision-making and firm performance across a wide range of industries. Their research revealed a strong positive correlation, indicating that organizations that effectively leverage data in decision-making consistently outperformed their competitors in terms of productivity and profitability. Furthermore, Palo and Padhi (2003) conducted an extensive analysis to assess the role of data-driven decision-making in enhancing decision quality. Their findings highlighted that organizations that prioritize data analysis and employ sophisticated analytical techniques tend to make more accurate, well-informed decisions, leading to improved outcomes and a more decisive competitive advantage.

Moreover, studies have examined specific sectors to elucidate the impact of data-driven decision-making across industries. In healthcare, Cresswell et al. (2020) examined the influence of data-driven decision-making on clinical outcomes and patient satisfaction. Their research underscored the transformative power of data-driven insights in healthcare decision-making, resulting in improved patient care, reduced costs, and enhanced overall healthcare delivery.

Likewise, within the financial sector, Chi et al. (2019) explored the role of data-driven decision-making in risk management and investment strategies. Their study showcased the profound impact of data analytics in detecting fraudulent activities, managing market risks, and optimizing investment portfolios, enabling organizations to make informed decisions and achieve superior financial performance. Furthermore, studies have also delved into the challenges and barriers encountered in implementing data-driven decision-making. Berntsson Svensson & Taghavianfar (2020) investigated the organizational, technical, and cultural obstacles that organizations face during the transition to a data-driven decision-making approach. Their research shed light on the significance of data literacy, organizational culture, and data governance in facilitating successful adoption and implementation.

2.4 Conceptual Framework

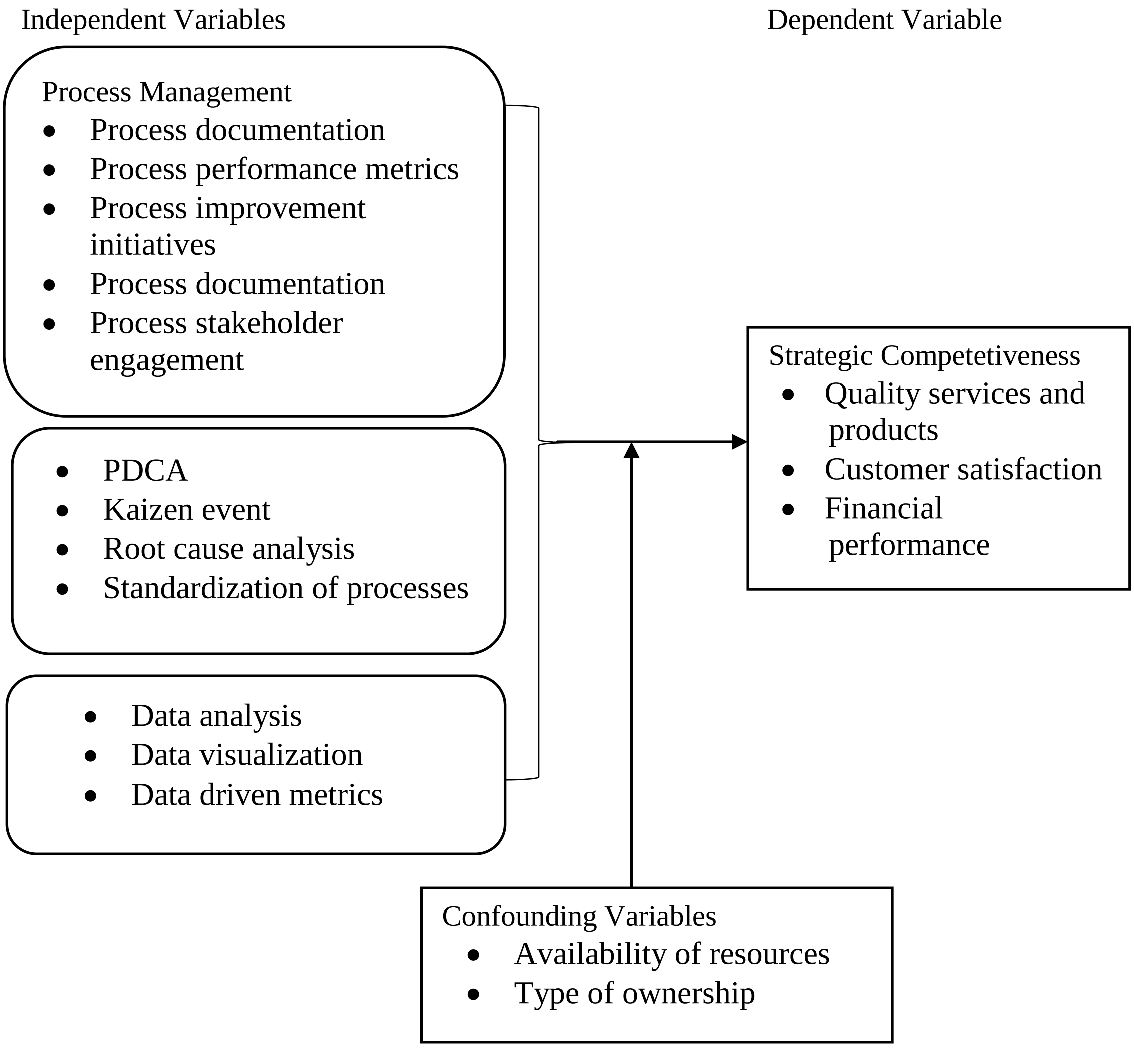
At the core of the framework lies the dependent variable: the medical laboratory's strategic competitiveness. This variable represents the laboratory's overall performance and competitive advantage in the healthcare industry. It encompasses factors such as market share, customer satisfaction, financial performance, and quality of services provided. The independent variables in the framework are process management, continuous improvement, and data-driven decision-making. Process management is the systematic approach to organizing and controlling laboratory processes to achieve operational efficiency and effectiveness. It involves establishing transparent processes, standard operating procedures, and performance metrics to ensure consistent and high-quality service delivery.

Continuous improvement focuses on the ongoing enhancement of laboratory processes, systems, and practices. It involves identifying areas for improvement, implementing changes, and monitoring the outcomes to drive incremental advancements. Continuous improvement fosters a culture of innovation, learning, and adaptation within the laboratory, enabling it to stay ahead of competitors and deliver superior services. Data-driven decision-making emphasizes the use of data and analytics to inform decision-making processes. It involves collecting, analyzing, and interpreting relevant data to gain insights, identify patterns, and make informed decisions. Data-driven decision-making enables laboratories to base their strategies and actions on objective evidence, leading to more effective resource allocation, process optimization, and performance improvement.

The framework also acknowledges the influence of confounding variables, specifically the type of laboratory (public or private) and resource availability. The type of laboratory may affect factors such as funding, infrastructure, and regulatory compliance, thereby influencing strategic competitiveness. Additionally, the availability of resources, such as skilled personnel, equipment, and technology, can affect the laboratory's ability to implement process management, continuous improvement, and data-driven decision making effectively. (See figure 1 below.)

Figure 1

Conceptual Framework



Source: Authour, 2025

2.5 Research Gaps

There are several gaps in the literature on the relationship between the implementation of Total Quality Management (TQM) practices and the strategic competitiveness of diagnostic laboratories, both in empirical and theoretical terms. Empirically, the majority of the studies on this topic have been conducted in developed countries, such as the United States and Europe, and have focused on large-scale healthcare organizations. Consequently, there is a lack of research on the application of TQM practices in smaller healthcare settings, such as diagnostic laboratories in low- and middle-income countries, and how this influences their strategic competitiveness. Furthermore, the existing studies have predominantly used quantitative methods, and the qualitative aspects of TQM practices have received limited attention. Therefore, there is a need for more qualitative research to explore the experiences and perceptions of laboratory managers and employees regarding the implementation of TQM practices and their influence on strategic competitiveness.

From a theoretical perspective, there is a gap in the literature regarding the mechanisms that underpin the relationship between TQM practices and strategic competitiveness in diagnostic laboratories. While previous research has established a positive relationship between TQM practices and organizational performance in healthcare settings, the precise mechanisms by which TQM practices contribute to strategic competitiveness remain unclear. Additionally, there is a need to explore the moderating role of contextual factors, such as ownership type, resource level, and regulatory environment, in shaping the relationship between TQM practices and strategic competitiveness. Finally, while TQM practices are widely recognized as a practical approach to improving organizational performance in healthcare settings, the theoretical frameworks that underpin these practices have received limited attention in the literature. Therefore, there is a need for more research to explore the theoretical foundations of TQM practices and their implications for improving the strategic competitiveness of diagnostic laboratories in Nakuru County.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Introduction

This chapter presents the study methodology that will be employed to investigate the implementation of Total Quality Management (TQM) practices and their influence on the strategic competitiveness of selected diagnostic laboratories in Nakuru County. The chapter presents the research design, the population of interest, data collection methods, sampling and recruitment techniques, ethical considerations, and the rationale for data management.

3.2 Research Design

This mixed-methods research employed a convergent parallel design, as described by Demir and Pismek (2018). Both quantitative and qualitative data were collected simultaneously but analyzed separately. Quantitative data were collected from subordinate and operational staff members, while qualitative data were collected from management and technical staff at the selected laboratories.

3.3 Location of the Study

This study was conducted in selected laboratories in Nakuru County, including Nakuru PGH, Naivasha Sub-County Hospital, Scan Lab, Nakuru West Sub-County Hospital, and Pathology Lancet Kenya. Nakuru County was strategically chosen as a primary healthcare hub in Kenya's Rift Valley region, with a significant number of diagnostic laboratories across both public and private sectors. The county's diverse population, mix of urban and rural areas, and the ongoing quality improvement efforts in its healthcare system provide a relevant and comprehensive setting for examining the implementation of TQM practices and their impact on the strategic competitiveness of diagnostic laboratories. (See table 1 below).

3.4 Population of the Study

The target population of this study comprised operational staff, quality officers, section heads, and managers of selected diagnostic laboratories in Nakuru County.

3.4.1 Inclusion Criteria

The following rationale guided the inclusion of subjects in the study. Participants were required to be individuals currently working in diagnostic laboratories registered with the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) to ensure professional legitimacy and standardization of practices across the study sites. Additionally, eligible participants must have served in the selected laboratory for at least 1 year immediately before the study, providing sufficient experience and familiarity with the laboratory's operational processes and management systems. Finally, only individuals who voluntarily agreed to participate and provided written informed consent were included in the study to uphold ethical standards and ensure respect for autonomy.

3.4.2 Exclusion Criteria

The exclusion criteria for the study comprised employees who declined to provide informed consent, as participation was strictly voluntary, and individuals who had worked in the selected diagnostic laboratories for less than one year immediately preceding the study, as they were considered to have insufficient exposure to the laboratory's operational and management systems.

3.5 Sampling Framework

3.5.1 Sampling Technique

Expert and homogeneous sampling techniques, which are forms of purposive sampling technique according to Etikan et al. (2016), were employed to recruit subjects. This method was suitable because it entails selecting respondents who meet the predetermined requirements. The inclusion and exclusion criteria as listed in items 3.41 and 3.4.2 above were strictly applied. Expert sampling was used to recruit subjects for the qualitative portion of the study, while homogeneous sampling was used to recruit subjects for the quantitative portion.

3.5.2 Sample Size Determination

Quantitative Data

Table 1

Sample Size Determination for Quantitative Data

	Total Number of Laboratory Personnel	Total of Personnel to be Included (n=x)
Nakuru Level 5 Hospital	20	12
Scan Lab	17	10
Naivasha Subcounty Hospital	15	9
Nakuru West Sub-County Hospital	13	5
Pathology Lancet Kenya - Nakuru	18	12
Total	83	48

Qualitative Data

Data saturation determined the sample size for the qualitative portion of the study, the point at which new information is no longer obtained from additional participants. A purposive sampling technique was employed to select key informants, including laboratory managers, quality managers, and employees involved in TQM implementation, from the sampled diagnostic laboratories. As such, a projected sample size of 10-30 participants, as reported by Guest et al., was applied. Saturation was monitored by reviewing transcripts and notes from the interviews to determine whether new information was still being obtained or whether themes and patterns were consistently emerging.

3.6 Instrumentation

The study used structured questionnaires to collect data from operational (technical and subordinate) employees and interview guides for members of management (quality officers and department heads). The questionnaire was divided into three sections: a subjects and laboratory demographics section, and a level of TQM implementation section, as per the specified objectives. The interview guide had a single section that covered the level of TQM implementation in terms of process management, continuous improvement, and data-driven decision-making. Appointments for consenting and data collection were requested through personal visits to the selected facilities, emails, and over registered phone numbers.

3.6.1 Validity

Instrument and process validity were established through expert review and piloting of the data collection tools. The questionnaire, designated as Appendix I, and the interview guide, designated as Appendix II, were subjected to expert evaluation by two study supervisors, one senior academic from the School of Business and Economics and a Quality Management Systems expert. Their recommendations and feedback were carefully reviewed and incorporated to enhance the clarity, relevance, and adequacy of the instruments before data collection commenced.

Subsequently, a pilot study was conducted among staff working in the diagnostic laboratories at Kenyatta University Teaching, Referral and Research Hospital (KUTRRH) and Mbagathi County Hospital (MCH). The purpose of this pre-test was to assess the effectiveness, reliability, and comprehensiveness of the data collection instruments and to determine their ability to elicit information relevant to the study objectives. Observed weaknesses or methodological challenges identified during the piloting phase were addressed and corrected before the main study began.

3.6.2 Reliability

This served to ensure the consistency, accuracy, and stability of the results to be obtained during the implementation of the proposed study. Inter-rater reliability, where multiple raters independently assess the same data to assess the degree of agreement, shall be employed. This was done through anonymous review of the questionnaire and interview guide by two independent experts. One is a strategic management expert, and the other is a quality management systems expert.

3.7 Data Collection Procedures

Data were collected after all requisite approvals were obtained. These include: permission from IPGS, ethics review, and approval from the Kabarak University Research Ethics Committee (KUREC), a research license from NACOSTI, and written permits from the selected diagnostic laboratories (where applicable, the County Government of Nakuru). Subjects who met the inclusion criteria were identified, duly briefed about the study, and properly consented by having them voluntarily sign the informed consent form. Thereafter, standardized questionnaires were administered to operational staff members, while interview guides were administered to members of management of the selected diagnostic laboratories. Questionnaires were administered through personal visits to the facilities and, where applicable, via Google Survey forms. On the other hand, the researcher scheduled appointments with selected members of management to conduct interviews in their offices or any other spaces where they felt comfortable.

3.8 Data Analysis

The collected data were analysed using SPSS version 25. Descriptive statistics such as mean, median, mode, and standard deviation were used to summarize the data and provide an overview of the level of TQM implementation in diagnostic laboratories in Nakuru County. This method helped determine the level of TQM implementation in these organizations. Correlation analysis was used to assess the relationship between the implementation of TQM practices and the strategic competitiveness of diagnostic laboratories in Nakuru County. This method helped determine the effect of TQM practices on the strategic competitiveness of these organizations. Multiple regression analysis was used to examine the relationship between the implementation of TQM practices and the strategic competitiveness of diagnostic laboratories in Nakuru County, while controlling for other factors that may influence competitiveness. This method helped assess the effect of TQM practices on the strategic competitiveness of these organizations. Qualitative data collected through in-depth interviews with key stakeholders in diagnostic laboratories in Nakuru County were analysed using content analysis. This method provided insights into the challenges these organizations face in implementing TQM practices and identified strategies to overcome them. Content, thematic, and discourse analysis were done to analyse qualitative data. (See table 2).

Table 2

Data Analysis Matrix

Objective	Variables	Analyses
To assess the level of implementation of process management practices in selected diagnostic laboratories in Nakuru County.	Process documentation Process performance metrics Process improvement ıitiatives Process documentation Process stakeholder engagement	Descriptive statistics Content, thematic, and discourse analysis Chi-square
To evaluate the performance of continuous improvement practices implemented in selected diagnostic laboratories in Nakuru County	• PDCA • Kaizen event • Root cause analysis • Standardization of processes	Descriptive statistics Correlation analysis Multiple regression
To establish the extent of utilization of data-driven decision-making practices in selected diagnostic laboratories in Nakuru County	• Data collection • Data analysis • Data visualization • Data-driven metrics	Descriptive statistics Content, thematic, and discourse analysis

3.9 Ethical Considerations

To ensure that this study's implementation adhered to all established research ethical principles, several measures were taken. Permission to conduct the study was first obtained from the Institute of Postgraduate Studies (IPGS), followed by ethical approval from the Kabarak University Research Ethics Committee (KUREC). In addition, a research license was secured from the National Commission for Science, Technology, and Innovation (NACOSTI), authorizing the study's execution in accordance with national research regulations.

All participants were carefully identified and provided with comprehensive information about the study objectives, procedures, and their rights, after which informed consent was obtained to ensure voluntary participation. To maintain confidentiality, all collected data were securely stored, and hard-copy materials were kept under lock and key in the researcher's private office. In contrast, electronic data were password-protected and accessible only to the principal investigator. Furthermore, all data were de-identified to safeguard participants' anonymity and confidentiality. The data will be retained for three years following the completion of the study, after which they will be permanently disposed of through shredding and digital deletion.

This study was conducted solely for academic and scientific purposes, aiming to generate empirical evidence on the relationship between the implementation of Total Quality Management (TQM) practices and strategic competitiveness among selected diagnostic laboratories in Nakuru County. Neither the researcher nor any participant had any secondary or conflicting interests in the study's outcomes.

CHAPTER FOUR

DATA ANALYSIS, PRESENTATION, AND DISCUSSION

4.1 Introduction

This chapter presents empirical findings aligned with the study's general and specific objectives on the impact of Total Quality Management (TQM) practices on the strategic competitiveness of diagnostic laboratories in Nakuru County. The presentation proceeds from descriptive profiles of participants and laboratories to objective-wise descriptive evidence, integrating direct quotations to illuminate operational realities. Consolidated inferential results (correlations and chi-square tests) are reported at the end of the chapter to show statistical associations between TQM constructs and competitiveness indicators.

4.2 Response Rate and Demographics

4.2.1 Response Rate

Table 3 presents the response rate for the study, summarizing the number of questionnaires distributed and returned, along with the corresponding percentage of responses.

Table 3

Response Rate

Distributed	Returned	Response Rate
48	38	79.2%

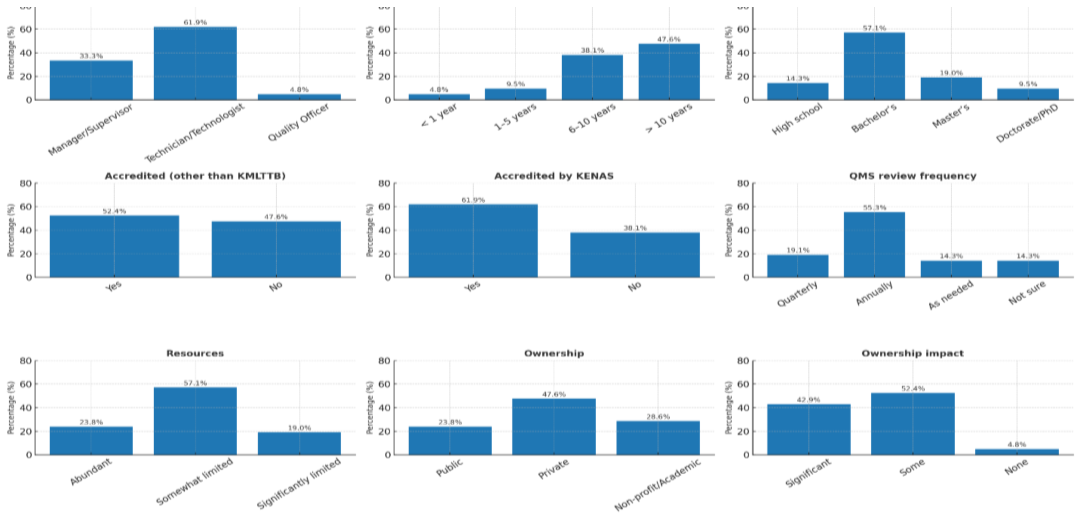
A total of 48 questionnaires were distributed to the targeted respondents, out of which 38 were completed and returned, yielding a response rate of 79.2%. This response rate indicates a high level of participation among the intended respondents. The response rate enhances the validity and generalizability of the findings by minimizing the potential for non-response bias, which could distort results when differences between respondents and non-respondents are present. It also suggests that the data collection procedures, including questionnaire design, communication, and follow-up, were adequate and appropriate for the target population. Several factors may have contributed to this outcome, including respondents' interest in the study topic, institutional support, and effective communication between researchers and participants. However, while the response rate is satisfactory, the non-returned 21% still represents a portion of the population whose views were not captured, which could marginally limit the completeness of the dataset.

4.2.2 Participant and Laboratory Characteristics

Figure 2 illustrates the demographic and institutional characteristics of the study participants and their respective laboratories. It presents the distribution across key variables, including job position, years of experience, education level, accreditation status, quality management system (QMS) review frequency, resource availability, ownership type, and perceived impact of ownership on operations.

Figure 3

Demographic Distribution of Participants and Laboratory Characteristics (N = 38)



The demographic profile of respondents reveals a workforce composition that is both technically grounded and managerially diverse. A majority (61.9%) of participants were technicians or technologists, reflecting the operational backbone of diagnostic laboratories, where day-to-day quality control and analytical accuracy are carried out. The presence of 33.3% managers or supervisors complements this, ensuring that responses capture both the technical and administrative perspectives necessary for a comprehensive assessment of TQM. This blend of roles enhances the study's validity by integrating insights from those implementing processes and those shaping strategic direction.

Workforce experience was notably extensive, with 85.7% of respondents possessing over six years of experience in laboratory practice. Such longevity implies strong tacit knowledge, procedural familiarity, and cultural embedding in laboratory operations. From a TQM perspective, experienced personnel are critical drivers of continuous improvement because they understand process variations, non-conformities, and the historical trajectory of quality interventions. Their long tenure also indicates organizational stability, which facilitates the development of a sustainable quality culture and institutional memory within laboratory systems.

Educational attainment was generally high; 76.1% of respondents held a bachelor’s degree or higher, underscoring a technically competent and academically prepared workforce. This academic grounding supports the adoption of structured quality management systems, data interpretation, and evidence-based decision-making. In the context of TQM, highly educated personnel are more likely to appreciate systematic approaches, engage in root cause analysis, and utilize performance indicators effectively. It also aligns with the increasing professionalization of laboratory science in Kenya, where regulatory bodies emphasize continuous professional development and certification as prerequisites for practice.

Regarding institutional quality systems, the findings reveal substantial accreditation penetration. 61.9% of laboratories were accredited by the Kenya Accreditation Service (KENAS), and 52.4% held additional quality credentials beyond those issued by the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB). This layered accreditation demonstrates the institution's commitment to internationally recognized quality frameworks, such as ISO 15189, and reflects adherence to competence, traceability, and continuous improvement. The coexistence of multiple accreditation layers also indicates benchmarking against both local and global standards, fostering credibility and trust in diagnostic outputs.

Despite the strong technical and quality orientation, resource limitations remain a critical challenge. Over half of the respondents (57.1%) reported somewhat limited resources, and a further 19.0% experienced significant constraints. These findings suggest that while personnel and quality frameworks are robust, financial and infrastructural inputs may lag. Inadequate resourcing can restrict equipment calibration, staff training, and the frequency of quality monitoring, core pillars of TQM effectiveness. The imbalance between accreditation achievements and operational constraints underscores the dual challenge of sustaining certification while coping with resource scarcity.

Ownership patterns also carry critical managerial implications. The majority of laboratories were privately owned (47.6%), reflecting Kenya’s mixed healthcare delivery system, in which private laboratories play a pivotal role in diagnostic services. Ownership structure emerged as a significant contextual determinant: 95.3% of respondents acknowledged that ownership influences decision-making. This perception highlights how organizational governance models shape strategic priorities, resource allocation, and the formulation of quality policies. In privately owned facilities, decisions may be more agile but resource-driven, whereas in public institutions, bureaucratic inertia persists despite policy support for quality systems. Thus, ownership context shapes the intensity, adaptability, and sustainability of TQM adoption.

4.3 Influence of the Level of Implementation of Process Management Practices on Strategic Competitiveness

4.3.1 Documentation and Accessibility of Core Processes

Table 4 below shows data from the sampled laboratories on process documentation, review frequency, and accessibility.

Table 4

Process Documentation, Review Frequency, and Accessibility

Variable	Category	n	%
Documented QMS	Yes	34	90.5
	No	4	9.5
Documented processes	Yes	38	100
	No	0	0
Review/update frequency	Quarterly	7	19.0
	Annually	20	52.4
	As needed	11	28.6
Access to documents	Central repository/intranet	12	32.3
	Shared drives/folders	9	23.8
	Printed copies	15	39.1
	Not easily accessible	2	4.8

The results demonstrate a near-universal level of process formalization within the participating laboratories, with 90.5% implementing QMS and 100% maintaining documented procedures. This near-total adoption signifies a mature quality culture where organizational processes are structured, standardized, and guided by well-defined protocols. Such formalization is foundational to TQM, as it ensures consistency, traceability, and continual improvement (Deming, 1986; Oakland, 2014). The existence of written procedures enhances reproducibility and accountability across core laboratory functions from specimen reception to result reporting, thereby minimizing procedural variability and error (Maruta & Wanyoike, 2019).

These findings closely align with earlier studies. For instance, Osei et al. (2020) reported that over 85% of accredited medical laboratories in Ghana had implemented formal QMS frameworks, emphasizing their role in achieving consistent diagnostic quality. Similarly, Mutonga et al. (2019) found that structured documentation was strongly associated with improved compliance during ISO 15189 audits among Kenyan laboratories. The present study's higher adoption rate may reflect progressive institutionalization of QMS practices, likely driven by increased regulatory oversight, staff training, and participation in international accreditation schemes (Mutonga et al., 2019; Osei et al., 2020).

The predominant annual review cycle (52.4%) indicates that most laboratories conduct systematic evaluations of their QMS documentation once a year. This schedule meets regulatory expectations and provides sufficient time for performance assessment and controlled updates. Comparable patterns have been reported by Abimiku et al. (2018), who found that most public health laboratories in Nigeria maintained annual review intervals to comply with national and international standards. However, from a dynamic perspective, yearly reviews, while stabilizing, may not fully reflect the pace of technological innovation and evolving diagnostic protocols. Studies by Maruta and Wanyoike (2019) noted that laboratories implementing quarterly or rolling reviews were more adaptable to new methods and achieved faster corrective action closure rates.

Consequently, while annual reviews promote procedural discipline, more frequent review cycles may enhance responsiveness and competitiveness, particularly in laboratories handling rapidly changing test technologies (Maruta & Wanyoike, 2019).

The diverse modes of process accessibility, including printed manuals (39.1%), intranet platforms (32.3%), and shared digital drives (23.8%), reflect a hybrid documentation model that bridges traditional and digital knowledge management. This approach supports both staff who prefer physical copies for quick reference and those who are comfortable with digital systems. The persistence of printed manuals mirrors findings by Kiguba et al. (2021), who observed that laboratories in resource-limited settings maintain hard copies to mitigate risks of power or network interruptions. Conversely, the adoption of intranet and shared-drive systems indicates growing digital transformation, consistent with global trends toward electronic document control systems (EDCS), as highlighted by WHO-AFRO SLIPTA (2022).

From a TQM standpoint, maintaining multiple access channels enhances inclusivity and ensures that quality information reaches all staff levels. However, it also introduces potential risks related to version control and document synchronization. As Okeke et al. (2020) note, hybrid systems often experience inconsistencies between printed and electronic documents, potentially leading to nonconformities during audits. Therefore, transitioning to a fully digitized QMS with controlled access, automated review reminders, and audit trails would further strengthen process integrity, efficiency, and compliance.

4.3.2 Performance Measurement and Communication Practices

Table 4.4 presents findings on the extent to which laboratories establish, monitor, and communicate performance metrics as part of their quality management and continuous improvement processes.

Table 5

Establishment, Monitoring, and Communication of Performance Metrics

Variable	Category	n	%
Metrics established	All processes	18	47.6
	Some processes	16	42.9
	None	4	9.5
Monitoring cadence	Monthly	9	23.9
	Quarterly	13	33.3
	Annually	13	33.3
	Irregular/None	4	9.5
Communication frequency	Regular	16	42.9
	Occasional	16	42.9
	Not communicated	6	14.2

The results indicate that 47.6% of laboratories maintain performance metrics across all processes, while 42.9% apply them selectively. This distribution demonstrates a commendable level of measurement culture maturity, with nearly 9 in 10 facilities having institutionalized at least some degree of performance tracking. Such integration of metrics into laboratory operations aligns with global quality management trends emphasizing data-driven decision-making and continuous improvement. Comparable studies in Kenyan and regional laboratory systems (e.g., Rotich et al., 2019; Antignac et al., 2018) similarly found gradual progress toward full performance integration, with most laboratories transitioning from isolated quality indicators to comprehensive, system-wide measurement frameworks. The near balance between full and partial metric adoption observed here suggests that while measurement awareness is strong, complete standardization across all departments remains a growth area (Gatimu et al., 2020; Maphumulo & Bhengu, 2019).

Regarding monitoring frequency, the findings show a predominance of quarterly and annual reviews (66.6%), with about 25% conducting monthly assessments. This pattern suggests a pragmatic balance between oversight and operational feasibility. Laboratories appear to align their review cycles with available resources and workload demands. Quarterly monitoring is consistent with ISO 15189 recommendations for periodic management review and internal audit cycles, ensuring both accountability and manageable administrative load. However, laboratories performing monthly reviews likely demonstrate higher maturity and responsiveness, especially in dynamic testing environments where process performance can fluctuate rapidly (Maruta & Wanyoike, 2019; Oakland, 2014). Similar patterns were reported in other Kenyan health facility studies, where quarterly evaluations dominated but monthly reviews were more prevalent in high-volume or externally accredited settings (Gatimu et al., 2020).

Communication of performance outcomes appears relatively robust: 85.8% of laboratories reported regularly or occasionally disseminating results to stakeholders. This high rate of reporting reflects a positive feedback culture, an essential component of TQM (Oakland, 2014). Effective communication ensures that findings are not only collected but also translated into actionable improvements. The presence of established communication channels also signifies that laboratories recognize the value of transparency and participatory engagement in quality enhancement (Leoneti et al., 2020; Liguori & Kisslinger, 2021). When compared with previous studies in healthcare organizations, this level of communication is consistent with institutions where leadership support and stakeholder feedback mechanisms are well developed (Gatimu et al., 2020).

4.3.3 Improvement Pathways and Stakeholder Engagement

Table 6 outlines the mechanisms through which laboratories identify improvement opportunities, apply structured methodologies to implement changes, and engage stakeholders throughout the quality enhancement cycle.

Table 6

Improvement Identification, Methodologies, and Stakeholder Interfaces

Variable	Category	n	%
Pursuit of improvements	Regularly	20	52.4
	Occasionally	16	42.9
	Not actively	2	4.8
How identified	Employee suggestions	4	9.5
	Customer feedback	11	28.6
	Process audits/evaluations	21	57.1
	Other	2	4.8
Methodology in place	Defined & followed	25	66.7
	Inconsistent	11	28.2
	None	2	4.8
Primary stakeholders	Employees	14	38.1
	Customers	7	19.0
	Management	16	42.9
Addressing needs	Surveys/feedback	18	47.6
	Meetings/consultations	13	33.4
	Formal channels	7	19.0
Communication quality	Regular	22	57.1
	Inconsistent	16	42.9

The results indicate that improvement was an active and institutionalized agenda across most laboratories, with 95.3% reporting regular or occasional improvement activities. This reflects a strong culture of continuous quality improvement, consistent with TQM principles, in which organizations strive for ongoing process refinement rather than episodic correction. The prominence of audit-driven improvement (57.1%) underscores the pivotal role of internal and external quality audits in identifying systemic weaknesses and driving compliance-oriented change. This finding aligns with prior research in Kenyan and regional laboratory systems (e.g., Rotich et al., 2019; Antignac et al., 2018), which also found that audit outcomes remain the most common catalyst for structured improvement initiatives.

Customer feedback emerged as the second primary source of improvement ideas, confirming that service users, whether clinicians or institutional partners, are increasingly recognized as key stakeholders in shaping laboratory performance (Gatimu et al., 2020; Maphumulo & Bhengu, 2019). However, the selective involvement of customers noted here corresponds with the business-to-business (B2B) nature of medical laboratory operations, where feedback loops tend to flow through regulated channels rather than open consumer interfaces. Similar observations were reported by Gatimu et al. (2020) and Miller et al. (2019), who found that compliance protocols and referral systems mediated laboratory-client relationships, limiting direct customer participation in quality decisions.

The adoption of defined improvement methodologies by 66.7% of respondents indicates a notable reduction in ad-hoc approaches. Methodological frameworks such as root cause analysis, Plan-Do-Check-Act (PDCA), and corrective and preventive action (CAPA) systems enhance the rigor, traceability, and reproducibility of improvement interventions. These findings echo those of Bhat et al. (2021), who demonstrated that formalized improvement cycles correlate with higher process efficiency and audit performance in accredited facilities. The remaining one-third who still operate without structured methodologies may face challenges in documenting lessons learned or sustaining gains from corrective actions.

Stakeholder engagement patterns reveal that management and employees form the primary interfaces for improvement initiatives, reflecting a predominantly internal feedback culture. This hierarchical and participatory blend aligns with ISO 15189:2022's emphasis on management review and staff involvement in nonconformity analysis. The relatively lower customer participation reflects the structured, compliance-driven environment of diagnostic laboratories, where improvements are often initiated internally and externally validated. Communication quality between laboratories and stakeholders was mixed, with 57.1% of facilities reporting regular communication and 42.9% describing it as inconsistent. Regular communication facilitates transparency and shared ownership of quality goals, which are essential to effective stakeholder engagement and service delivery (Leoneti et al., 2020). In contrast, inconsistent communication may weaken stakeholder confidence and hinder collaborative quality improvement efforts, especially in resource-limited settings where trust and clarity are key drivers of institutional partnerships (Luo et al., 2023; Liguori & Kisslinger, 2021).

When compared with international studies, such as those by O'Donnell et al. (2014) and Temple & Steyn (2011), the results suggest that Kenyan laboratories are approaching global norms in embedding structured improvement systems. However, a relative gap persists in leveraging cross-functional, customer-driven innovation, which is increasingly emphasized in advanced TQM frameworks.

4.3.4 Operational Challenges in Process Management

"We have processes in place, but sometimes they're not strictly followed due to high workload and limited personnel." "SOPs exist, but consistent enforcement is hard; infrastructure gaps matter." "Some guidelines are outdated relative to new equipment; updates lag." The qualitative feedback highlights persistent implementation and sustainability challenges within laboratory process management systems despite formalized procedures and an established QMS. Respondents acknowledged the existence of structured processes and Standard Operating Procedures (SOPs), yet emphasized inconsistent adherence due to workload pressures and limited personnel. This underscores a well-documented phenomenon in quality management where compliance often fluctuates under operational strain. Similar findings have been reported by Rotich et al. (2019) and Gatimu et al. (2020), who noted that staff shortages and increased testing demand compromise process fidelity and reduce opportunities for supervision and internal audit follow-up.

The mention that "SOPs exist, but consistent enforcement is hard; infrastructure gaps matter" reflects the interdependence between human capacity and resource adequacy. Even the most robust procedural frameworks depend on enabling infrastructure such as adequate workspace, functional equipment, and supportive digital systems to facilitate compliance. This observation resonates with studies by Antignac et al. (2018), which show that infrastructural and logistical deficiencies are significant barriers to sustaining quality systems in resource-limited laboratories. Thus, process lapses are not merely behavioral but often systemic, driven by contextual constraints beyond individual control.

The third insight, *"Some guidelines are outdated relative to new equipment; updates lag,"* reveals a temporal misalignment between process documentation and technological evolution. In dynamic diagnostic environments, rapid equipment upgrades can outpace revisions to the corresponding SOPs, leading to procedural gaps. Comparable studies (e.g., Bhat et al., 2021) report similar challenges in maintaining document control when laboratories adopt new testing platforms faster than their quality documentation cycles allow. Such delays hinder standardization, introduce variation, and pose compliance risks during accreditation audits.

4.4 Effect of Continuous Improvement (CI) Practices on Strategic Competitiveness

4.4.1 PDCA Familiarity and Implementation

Table 7 summarizes respondents' familiarity with and application of the Plan-Do-Check-Act (PDCA) cycle within laboratory quality management systems.

Table 7

PDCA Familiarity and Use

Variable	Category	n	%
PDCA familiarity	Very familiar	13	33.3
	Somewhat familiar	9	23.8
	Not familiar	16	42.9
PDCA implementation	Extensive	8	19.0
	Some extent	14	38.1
	Not implemented	16	42.9

The results indicate uneven familiarity with the Plan-Do-Check-Act (PDCA) cycle, a fundamental continuous improvement framework in TQM. Only 33.3% of respondents reported being *very familiar* with PDCA, while 42.9% had *no familiarity at all*. This disparity points to an unequal diffusion of quality-improvement knowledge across the participating laboratories. The familiarity appears to be concentrated among managerial and quality assurance personnel, with limited penetration to technical and operational staff. Such a pattern reflects a top-down orientation of quality systems where structured improvement tools are not yet fully embedded into routine laboratory practice at all staff levels.

This uneven distribution mirrors findings from Rotich et al. (2019), who observed that while laboratory managers in Kenya demonstrated conceptual awareness of PDCA and related continuous improvement models, front-line technologists often viewed these tools as administrative rather than operational. Similarly, Bhat et al. (2021) reported comparable trends across low- and middle-income countries (LMICs), where limited training, weak mentorship structures, and inadequate institutional emphasis on participatory quality improvement hampered the utilization of the PDCA cycle.

Implementation patterns in the present study closely paralleled familiarity levels. A combined 57.1% of respondents reported *some or extensive PDCA implementation, whereas 42.9% repor*ted *no implementation*. This close correspondence underscores the strong link between knowledge and practice. Laboratories with trained or quality-oriented staff are more likely to integrate PDCA principles into daily operations. This aligns with Maruta (2018), who emphasized that the successful institutionalization of PDCA in African medical laboratories depends on both conceptual awareness and organizational support mechanisms, such as periodic quality improvement workshops and staff involvement in audit-based feedback cycles.

The findings, therefore, highlight a critical capacity gap in operationalizing continuous improvement. While the presence of QMS frameworks suggests structural maturity, the limited diffusion of PDCA practices implies that constant improvement is not yet deeply institutionalized across all staff levels. Strengthening training programs, promoting cross-level mentorship, and embedding PDCA principles into routine laboratory performance review meetings could bridge this gap (Maruta & Wanyoike, 2019; World Health Organization Regional Office for Africa [WHO-AFRO], 2022).

In line with previous literature (Maruta & Wanyoike, 2019; WHO-AFRO, 2022), expanding familiarity and application of PDCA beyond managerial staff can foster a culture of shared responsibility, where every staff member actively contributes to identifying inefficiencies, testing corrective measures, and sustaining quality gains. This shift from compliance-driven to learning-driven quality management represents the next phase of laboratory quality evolution in resource-limited contexts.

4.4.2 Kaizen Participation and Perceived Effectiveness

Table 8 presents findings on respondents' participation in and perceptions of Kaizen, a continuous-improvement philosophy emphasizing small, incremental changes to enhance efficiency and quality.

Table 8

Kaizen Participation and Perceptions

Variable	Category	n	%
Kaizen participation	Multiple times	7	18.5
	Once	9	23.7
	Never	22	57.8
Perceived effectiveness	Highly effective	5	13.2
	Moderately effective	4	10.6
	Not effective	28	76.2

The results indicate limited engagement with Kaizen activities: 57.8% of respondents reported never participating in such initiatives. This finding points to a weak institutionalization of a continuous improvement culture within the studied laboratories. Although Kaizen, meaning "change for the better," is widely recognized as a core component of Total Quality Management (TQM), its operational adoption in this context appears minimal (Imai, 1986). The high proportion of respondents (76.2%) perceiving Kaizen as *not effective* further underscores a lack of tangible outcomes or visible value associated with its implementation

This pattern suggests that Kaizen, while conceptually acknowledged, remains poorly embedded in day-to-day laboratory operations efforts (Rotich et al., 2019). The gap between awareness and actual application may be attributed less to flaws in the Kaizen philosophy itself and more to contextual and structural barriers such as inadequate staff engagement, absence of systematic follow-up, and reliance on event-based improvement sessions rather than ongoing, incremental improvement cycles (Bhat et al., 2021). Similar observations were made by Rotich et al. (2019) in Kenyan laboratory settings, where Kaizen initiatives failed to achieve sustainability due to limited managerial support and weak alignment with QMS activities. Likewise, Bhat et al. (2021) found that in many healthcare and industrial organizations across LMICs, Kaizen implementation faltered when introduced as an isolated project rather than as part of a broader organizational culture of learning and feedback.

The perceived ineffectiveness of Kaizen (76.2%) in this study may therefore reflect implementation design weaknesses rather than methodological inadequacy. Laboratories that conduct sporadic Kaizen events without integrating them into existing QMS cycles or without recognizing staff contributions are unlikely to experience measurable performance gains. As Maruta (2018) and Okeke et al. (2020) emphasize, Kaizen thrives in environments where management commitment, regular feedback loops, and visible reinforcement of improvement outcomes are institutionalized.

Additionally, insufficient training and communication may have contributed to the low perceived value of Kaizen. When staff do not understand the methodology's intent or fail to see how their input leads to organizational improvement, engagement naturally declines (Gatimu et al., 2020). The absence of linkage between Kaizen outcomes and broader institutional goals, such as accreditation readiness or service quality, further weakens its motivational power (Maruta & Wanyoike, 2019).

Comparatively, studies in more mature quality environments, such as those reported by Osei et al. (2020) in Ghanaian laboratories, demonstrate that sustained Kaizen success depends on embedding improvement cycles into QMS review processes, establishing cross-functional improvement teams, and celebrating incremental achievements to maintain momentum. Thus, the findings from this study highlight a critical opportunity to re-engineer Kaizen implementation from an occasional activity to a systematic, participatory, and feedback-driven process.

4.4.3 Root Cause Analysis and Process Standardization

Table 9 presents data on the extent to which laboratories apply and standardize Root Cause Analysis (RCA) within their corrective and preventive action processes. RCA is a critical element of Quality Management Systems (QMS), enabling organizations to identify underlying causes of nonconformities and implement sustainable corrective measures (Ishikawa, 1986).

Table 9

Root Cause Analysis (RCA) Practices and Standardization

Variable	Category	n	%
RCA frequency	Consistently	16	42.9
	Occasionally	20	52.4
	Not conducted	2	4.8
RCA tools (multi-select)	5 Whys	20	52.4
	Fishbone	18	47.6
	Fault tree	11	28.6
	Pareto	7	19.0
Process standardization	Extensive	16	42.9
	Some extent	22	57.1
	Not standardized	0	0

The results indicate that Root Cause Analysis (RCA) has become a mainstream quality management practice, with 95.3% of laboratories applying it at least occasionally. This high rate of adoption underscores a strong institutional awareness of structured problem-solving and continuous improvement principles within diagnostic laboratory operations (Singh & Prakash, 2020). The widespread use of established analytical tools such as the

5 Whys and Fishbone (Ishikawa) diagrams aligns with Lean and Total Quality Management (TQM) methodologies, reflecting a mature shift from reactive troubleshooting toward systematic investigation of nonconformities (Antignac et al., 2018).

The universal standardization of RCA, whether extensive or partial, further strengthens procedural consistency and enables reproducible results. Standardization ensures that corrective and preventive actions are not only well documented but also comparable across departments, thereby promoting organizational learning and continuous capability development. This alignment with international best practices mirrors findings from Antignac et al. (2018) and Bhat et al. (2021), who noted that accredited laboratories in Kenya and other sub-Saharan African countries increasingly integrate RCA into their Quality Management Systems (QMS) as a key tool for audit readiness, risk mitigation, and sustained compliance.

Comparable international studies show similar trends. For instance, Singh and Prakash (2020) in India and Miller et al. (2019) in the United States reported that institutions implementing Lean or ISO 15189 frameworks routinely adopt RCA to reduce recurrence of quality incidents and strengthen preventive culture. However, they also emphasized that RCA's effectiveness depends on the depth of analysis and management support rather than on its mere procedural existence (Miller et al., 2019).

In this study, the near-universal uptake and standardization of RCA suggest a high level of quality system maturity among participating laboratories. Nevertheless, the challenge remains to ensure that RCA outcomes lead to actionable change, continuous feedback, and measurable performance gains. Sustained training and leadership commitment will be critical to transforming RCA from a compliance tool into a strategic driver of innovation and operational excellence (Maruta, 2018).

4.4.4 Continuous Improvement (CI) Capacity Constraints

"We believe in CI, but budget and training limit execution." "We encourage ideas; implementation lags due to funding/time." "Many suggestions remain on hold; intent is strong, capacity is thin." The qualitative insights reveal a strong commitment to the philosophy of Continuous Improvement (CI) among laboratory personnel, yet a clear gap exists between intent and execution capacity. Respondents consistently expressed belief in CI principles and the importance of ongoing process refinement, but emphasized that budgetary limitations, inadequate training, and time constraints hinder consistent implementation. Statements such as *"We believe in CI, but budget and training limit execution"* underscore the resource dependency of improvement initiatives, in which the success of CI programs is often contingent on management's investment in both financial and human capital (Maruta, 2018; Kholif et al., 2018).

The feedback *"We encourage ideas; implementation lags due to funding/time"* and *"Many suggestions remain on hold; intent is strong, capacity is thin"* further illustrate the implementation gap between idea generation and actual process transformation. This pattern aligns with findings from Rotich et al. (2019) and Gatimu et al. (2020), who reported that Kenyan laboratories often demonstrate enthusiasm for TQM and CI frameworks but face systemic barriers related to resource allocation, workload, and limited technical coaching. Similar international observations have been made in studies by Miller et al. (2019) in the U.S. and Singh & Prakash (2020) in India, where CI initiatives faltered when organizational support, protected time, or financial resources were insufficient.

Collectively, these narratives reflect an environment where the cultural foundation for improvement is present, but the structural and resource enablers remain underdeveloped.

The gap between aspiration and execution limits the translation of innovative ideas into tangible outcomes, reducing CI's potential impact on quality and efficiency.

4.5 The Influence of Data-Driven Decision-Making (DDDM) Practices on Strategic Competitiveness

4.5.1 Data Collection Protocols and Methods

Table 10 presents findings on the data collection methods and the extent of Standard Operating Procedure (SOP) coverage guiding these processes within participating laboratories.

Table 10

Data Collection Methods and SOP Coverage

Variable	Category	n	%
Collection method	Manual	11	28.6
	Automated	7	19.0
	Hybrid	20	52.4
SOPs for data collection	All processes	18	47.6
	Some processes	20	52.4

The findings show that data capture is predominantly hybrid (52.4%), reflecting a transitional phase where laboratories are balancing legacy paper-based workflows with emerging digital systems. This hybrid model suggests pragmatic adaptation to infrastructural realities, leveraging the reliability and familiarity of manual records while progressively integrating Laboratory Information Management Systems (LIMS) and other electronic data tools (Crews et al., 2019; Mutonga et al., 2019). Similar trends have been reported in studies across Kenyan and regional healthcare systems (e.g., Rotich et al., 2019; Gatimu et al., 2020), where complete digitization remains constrained by costs, connectivity gaps, and limited technical support. Internationally, comparable transitional patterns have been observed in LMIC laboratory settings (Miller et al., 2019; Osei et al., 2020), where hybrid documentation is seen as a stepping stone toward complete digital transformation.

Standard Operating Procedure (SOP) coverage was universal, with all laboratories reporting either full or partial implementation of SOPs for data collection. This indicates strong procedural discipline and alignment with ISO 15189 quality management requirements (International Organization for Standardization [ISO], 2012), which emphasize the pre-analytical phase as a significant determinant of diagnostic quality. Universal SOP coverage ensures a minimum level of procedural consistency, reducing variability in collection, labeling, and handling practices. However, the coexistence of paper and electronic data flows poses risks of duplication or transcription errors if not well synchronized (Singh & Prakash, 2020).

4.5.2 Analytical Techniques and Personnel Assignments

Table 11 presents findings on the analytical methods applied within participating laboratories and the responsibility structures governing their implementation and oversight.

Table 11

Data Analytical Methods and Responsibility Structures

Variable	Category	n	%
Methods (multi-select)	Descriptive	25	66.7
	Inferential	11	28.6
	Regression	11	28.6
	Machine learning	7	19.0
Responsibility	Dedicated team	7	19.0
	Assigned individuals	13	33.3
	Various staff	14	38.1
	Not a priority	2	4.8

The findings reveal that descriptive statistics remain the predominant analytical approach across the participating laboratories, emphasizing a continued focus on summary reporting and routine performance tracking rather than advanced analytical modeling. This reliance on descriptive methods suggests that most laboratories are oriented toward compliance-based reporting, summarizing counts, averages, and trends rather than engaging in predictive or causal analysis that could inform strategic quality improvement. Such a pattern aligns with previous studies in Kenya and sub-Saharan Africa (Rotich et al., 2019; Gatimu et al., 2020), which found that while data collection is often robust, the analytical depth of laboratory reports remains limited to routine descriptive summaries.

Nevertheless, the emergence of inferential and regression analyses (28.6%) represents a positive transition toward evidence-based decision-making. These methods allow laboratories to explore relationships between process indicators, such as turnaround time, reagent use, and error rates, and key quality outcomes, providing more actionable insights. This growing analytical maturity mirrors observations by Maruta (2018) and

Singh & Prakash (2020), who emphasized that laboratories adopting inferential analysis frameworks are better positioned to identify process inefficiencies, evaluate interventions, and inform continuous improvement cycles within QMS.

A particularly notable finding is the adoption of machine learning (ML) approaches in 19.0% of laboratories, marking an early yet encouraging step toward data-driven innovation (Rahman et al., 2021; Kinyua et al., 2022). ML techniques, such as pattern recognition and predictive modeling, hold substantial promise in improving diagnostic accuracy, anticipating equipment failures, and optimizing workflow scheduling. According to Miller et al. (2019) and Rahman et al. (2021), predictive analytics in laboratory medicine has led to significant gains in clinical efficiency and error reduction in high-income contexts. The presence of ML initiatives within the study population, albeit limited, indicates growing awareness of the transformative potential of digital analytics in healthcare. However, realizing the full benefits of ML requires robust data infrastructure, skilled personnel, and governance frameworks to ensure data quality, privacy, and ethical use.

Regarding organizational responsibility, the results show that data analysis duties are primarily handled by general staff (38.1%) or individual officers (33.3%), while only 20% of laboratories reported having dedicated analytical teams. This structure suggests that analytics is not yet fully institutionalized as a specialized function but instead distributed as an additional responsibility among existing personnel. Similar findings were reported by Rotich et al. (2019) and Gatimu et al. (2020), who observed that most Kenyan laboratories conduct data analysis within general QMS or monitoring and evaluation units, lacking formal data science departments. In contrast, laboratories in high-income countries, such as those described by Singh & Prakash (2020), typically operate dedicated data analytics divisions equipped with biostatisticians, informaticians, and data engineers to support real-time quality monitoring and decision-making.

This structural gap reflects the broader challenge of developing analytical capacity within healthcare systems in LMICs (Mutonga et al., 2019; Manya & Rankin, 2022). Without dedicated analytical units and trained personnel, laboratories may struggle to transition from descriptive reporting to predictive and prescriptive analytics. The limited institutionalization also restricts the translation of data into strategic knowledge for continuous improvement, innovation, and policy influence.

4.5.3 Data Visualization Practices and Tools

Table 12 presents findings on the frequency and tools used for data visualization within participating laboratories.

Table 12

Data Visualization Frequency and Tooling

Variable	Category	n	%
Frequency	Regular (all relevant data)	18	47.6
	Occasional (projects/reports)	20	52.4
Tools (multi-select)	Excel	33	85.7
	Tableau	5	14.3
	Python/R	5	14.3
	Power BI	2	4.8

The findings indicate that data visualization is a routine practice across all laboratories (100%), demonstrating strong recognition of its importance in monitoring performance and supporting decision-making. The universal use of visualization, whether regular or occasional, suggests that laboratories have embedded graphical reporting into their QMS processes, aligning with ISO 15189's emphasis on evidence-based review and communication of performance data (ISO, 2012; Wangkahat et al., 2012).

However, the choice of tools reveals both strengths and developmental opportunities. Microsoft Excel dominates (85.7%) as the primary visualization platform, reflecting accessibility, familiarity, and cost-effectiveness. While Excel provides sufficient functionality for descriptive reporting and static charts, its scalability for advanced analytics, automation, and interactive dashboards remains limited (Crews et al., 2019). A smaller proportion of laboratories have adopted specialized tools such as Tableau and programming environments such as Python/R/R, indicating the emergence of data science competencies among select institutions (Gatimu et al., 2020). Additionally, the appearance of Power BI marks a shift toward a more dynamic and integrated data visualization ecosystem.

Similar patterns have been observed in Kenyan and regional laboratory settings (Rotich et al., 2019; Gatimu et al., 2020), where Excel-based visualization remains the norm due to budgetary and skill constraints. Internationally, laboratories in high-income countries increasingly leverage advanced visualization platforms and automated dashboards for real-time monitoring (Miller et al., 2019; Singh & Prakash, 2020), a practice yet to be widely replicated in resource-constrained contexts.

4.5.4 Use of Data-Driven Metrics in Operational Control

Table 13 presents findings on the types of performance metrics employed by participating laboratories to monitor quality, efficiency, and service outcomes.

Table 13

Performance Metrics Employed

Metric (multi-select)	n	%
Turnaround time (TAT)	29	76.2
Accuracy rate	16	42.9
Productivity measures	11	28.6
Error rates	11	28.6
Degree of DDDM use	Extensive	9
	Some extent	29

The results show that Turnaround Time (TAT) serves as the anchor performance metric for most laboratories (76.2%), reflecting its centrality in measuring service efficiency and customer satisfaction. This focus is consistent with both local and international studies (e.g., Rotich et al., 2019; Miller et al., 2019; Singh & Prakash, 2020), which identify TAT as the most universally applied indicator of laboratory performance due to its direct impact on clinical decision-making and patient outcomes. The prominence of TAT underscores laboratories' emphasis on operational speed and process flow optimization, core attributes of practical Quality Management Systems (QMS).

Accuracy metrics, tracked by approximately 40% of laboratories, represent the second layer of performance assessment, focusing on analytical validity and error minimization. While the presence of productivity and broader error indicators in one-third of laboratories indicates growing attention to efficiency and quality variance (Antignac et al., 2018), the uneven adoption pattern suggests that performance measurement remains partially fragmented across different process domains. Comparable findings in Kenyan and regional contexts (Gatimu et al., 2020; Antignac et al., 2018) highlight that while accreditation has improved awareness of performance monitoring, the integration of comprehensive metric suites covering quality, cost, safety, and innovation remains limited.

The observation that 76.2% of laboratories use metrics to some extent, with about one-quarter applying them extensively, signals a maturing performance culture transitioning from compliance-driven reporting toward systematic management use. However, the full institutionalization of metrics that link data to decision-making and continuous improvement is still evolving. Internationally, laboratories in more advanced QMS environments employ multi-dimensional dashboards encompassing quality, operational, financial, and customer metrics, enabling real-time oversight and predictive analytics (Singh & Prakash, 2020; Maruta & Wanyoike, 2019).

4.5.5 Decision Practices and Constraints

"We collect data, but decisions are often needs-driven; tooling and skills are limited."

"Strategic choices are time-pressured, limiting full analysis."

"Data are there, but reliability/tools/skills are gaps; judgment fills the void." The qualitative evidence reveals a data-aware but capacity-constrained decision environment, where laboratories recognize the importance of data-driven management but face systemic barriers to its full realization. Respondents repeatedly cited tooling, data reliability, and analytical skill gaps as key constraints, leading to reliance on judgment or immediate operational needs rather than structured data analysis. Statements such as *"We collect data, but decisions are often needs-driven; tooling and skills are limited"* highlight the disconnect between data availability and its practical use—an issue widely reported in quality management literature from low- and middle-income contexts (Rotich et al., 2019; Gatimu et al., 2020).

The comment *“Strategic choices are time-pressured, limiting full analysis”* illustrates how time constraints and reactive decision cultures hinder deliberate, evidence-based planning. This reflects organizational realities where short-term operational pressures frequently overshadow systematic performance review (Mutonga et al., 2019; Miller et al., 2019). Similar trends have been observed internationally; studies by Miller et al. (2019) in the U.S. and Singh & Prakash (2020) in India note that even in mature quality environments, managerial time scarcity remains a significant obstacle to embedding analytics in strategic processes.

The statement *“Data is there, but reliability/tools/skills are gaps; judgment fills the void”* underscores the triad of challenges: data quality, analytical infrastructure, and technical expertise that limit effective data utilization. When decision-makers lack confidence in data accuracy or lack the tools to interpret it, intuition often substitutes for analysis (Singh & Prakash, 2020; Rahman et al., 2021). While experiential judgment is valuable, overreliance can reduce transparency, accountability, and long-term performance learning.

4.6 Strategic Competitiveness of Selected Diagnostic Laboratories

4.6.1 Service and Product Quality

Table 14 presents findings on respondents’ overall perceptions of laboratory quality performance, summarizing self-assessed ratings of service excellence, reliability, and compliance with established QMS standards.

Table 14

Overall Quality Ratings

Category	n	%
Excellent	13	33.3
Good	22	57.1
Average	3	9.6
Below average	0	0

The findings indicate that perceived quality was overwhelmingly positive, with 90.4% of respondents rating their laboratory performance as “Good” or “Excellent.” This high self-assessment suggests a strong internal confidence in the effectiveness of the existing QMS and overall service delivery standards. Such perceptions are consistent with institutions that have achieved accreditation or implemented structured quality frameworks, where staff awareness of standardized procedures and compliance expectations fosters a sense of organizational pride and assurance in service quality (Maruta, 2018; Rotich et al., 2019).

However, high perceived quality should be interpreted with caution. Similar studies in Kenya and other sub-Saharan contexts (e.g., Rotich et al., 2019; Gatimu et al., 2020) have found that self-reported quality ratings often exceed externally validated performance outcomes, reflecting optimism bias or limited benchmarking against objective indicators. Internationally, comparable trends have been noted in healthcare organizations (Miller et al., 2019), where internal perceptions of excellence sometimes mask underlying process inefficiencies or resource gaps.

Nonetheless, the results point to a strong baseline of quality consciousness among laboratory personnel, a vital precursor to continuous improvement. Positive perceptions can foster motivation, collective ownership, and a proactive approach to quality maintenance. The next step for laboratories is to complement these subjective assessments with objective, data-driven quality evaluations, integrating external audits, customer feedback, and performance metrics (Clauss et al., 2021; Singh & Prakash, 2020).

4.6.2 Customer Feedback Channels and Satisfaction Levels

Table 15 presents findings on feedback and satisfaction indicators, capturing how laboratories collect, analyze, and respond to input from clients, staff, and other stakeholders.

Table 15

Feedback and Satisfaction Indicators

Variable	Category	n	%
Feedback channels (multi-select)	Satisfaction surveys	31	81.0
	Complaint resolution	24	61.9
	Focus groups/interviews	11	28.6
	Online reviews/ratings	11	28.6
Satisfaction measurement	NPS	2	4.8
	Surveys	24	61.9
	Repeat rate	5	14.3
	Complaint resolution rate	7	19.0
Satisfaction level	Very satisfied	2	4.8
	Satisfied	33	85.7
	Neutral	4	9.5

The findings indicate that surveys (81.0%) and complaint management processes (61.9%) are the principal feedback mechanisms employed by laboratories, underscoring an institutional commitment to gathering stakeholder input through structured and reactive channels. Surveys enable broad, periodic assessments of satisfaction and service quality, while complaint mechanisms provide continuous, event-driven opportunities for improvement. This combination reflects a balanced feedback approach consistent with ISO 15189 and TQM principles, where customer perception is integral to service refinement (ISO, 2012; Wangkahat et al., 2012).

Stakeholder satisfaction was generally positive, with 90.5% of respondents reporting delighted, satisfied, or neutral experiences, and only a small minority (9.5%) expressing neutrality or dissatisfaction. This pattern suggests that laboratories have achieved a baseline of acceptable service performance and responsiveness, fostering user confidence in laboratory processes and outputs. Similar trends have been reported in Kenyan and regional studies (Rotich et al., 2019; Gatimu et al., 2020), where structured feedback mechanisms and accreditation have contributed to improved service reputation and trust.

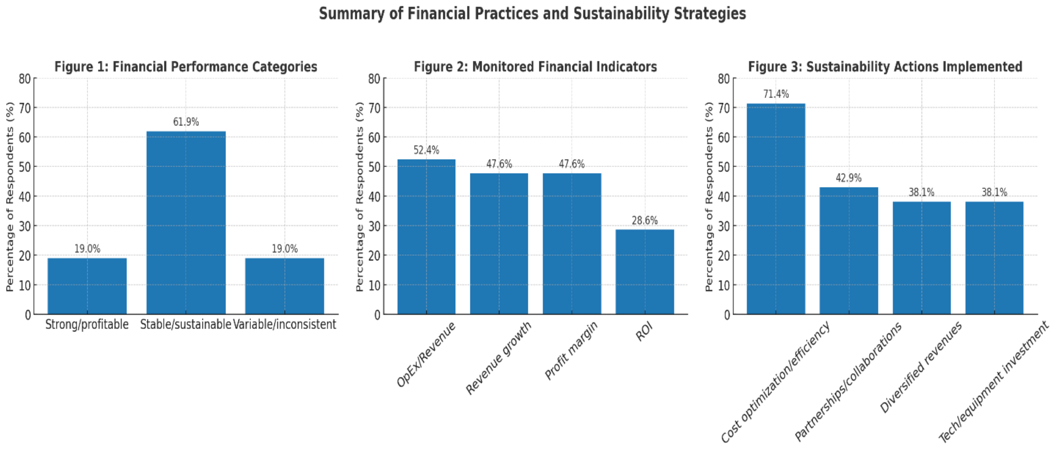
The limited use of Net Promoter Score (NPS) tools (4.8%) highlights a preference for direct survey instruments over standardized benchmarking indices (Miller et al., 2019). While traditional surveys effectively capture contextual feedback, the absence of comparative metrics like NPS may constrain benchmarking against peer institutions and tracking of long-term satisfaction trends. Internationally, laboratories and healthcare organizations increasingly integrate NPS and digital sentiment analysis to complement conventional surveys (Miller et al., 2019), enhancing cross-institutional comparability and predictive insights into client loyalty.

4.6.3 Financial Performance and Sustainability Practices

Figure 4 presents the distribution of financial performance ratings, key economic indicators monitored, and sustainability actions implemented across the participating laboratories.

Figure 4

Financial Ratings, Monitored Indicators, and Sustainability Actions



The findings indicate that most laboratories reported stable financial positions (61.9%), with 19.0% achieving strong profitability, reflecting relative resilience within the diagnostic services sector. This economic stability suggests effective cost management and consistent service demand, particularly in a healthcare environment increasingly emphasizing quality and accreditation. Similar observations have been made in Kenyan private health facilities, where accredited laboratories tend to be more financially stable due to greater client confidence and institutional partnerships (Rotich et al., 2019; Gatimu et al., 2020).

Performance monitoring practices are primarily focused on operational expenditure (OpEx) and revenue tracking, along with growth and profit margin indicators, suggesting a pragmatic financial management orientation. These metrics allow laboratories to maintain short-term fiscal balance while ensuring service continuity. However, only 28.6% tracked Return on Investment (ROI), indicating limited use of long-term profitability and efficiency measures. This mirrors trends seen in regional studies, where laboratory financial monitoring remains focused on operational viability rather than strategic reinvestment or capital productivity (Antignac et al., 2018).

Regarding sustainability strategies, cost optimization (71.4%) emerged as the most common approach, reflecting a defensive posture centered on efficiency rather than growth. Partnerships (42.9%), particularly with suppliers or healthcare networks, provide collaborative avenues for resource sharing and stability. Nonetheless, the relatively modest presence of diversification and technology investment (just under 40%) suggests cautious innovation adoption, possibly due to constrained budgets or risk aversion. Internationally, financially robust laboratories increasingly pursue digital transformation, diversified service portfolios, and R&D collaborations to sustain competitiveness (Miller et al., 2019; Singh & Prakash, 2020).

4.7 Association between TQM Practices and Strategic Competitiveness

4.7.1 Integration Lens and Cross-Objective Synthesis

This objective integrates the process-management (Section 4.3), CI (Section 4.4), and DDDM (Section 4.5) profiles with competitiveness outcomes (Section 4.6). The consolidated inferential results (Section 4.8) quantify these linkages, showing how measurement discipline, PDCA/RCA usage, documentation cadence, and stakeholder practices statistically align with quality, customer, and financial outcomes (Maruta, 2018; Singh & Prakash, 2020).

4.7.2 Practitioners' Perspectives on TQM

“Root-cause analyses help fix issues properly; quality improves when we do them consistently.”

“Standardized procedures reduce variability but must be updated to match new technologies.”

“Dashboards would help; current analysis is manual, slowing response.” The qualitative responses provide valuable insight into the laboratories’ collective understanding of quality management practices, highlighting three interrelated themes: problem-solving culture, process standardization, and data-driven decision-making.

The first statement, “Root-cause analyses help fix issues properly; quality improves when we do them consistently,” emphasizes the perceived importance of root-cause analysis (RCA) as a foundational tool for continuous quality improvement (CQI). Respondents recognize that identifying and addressing underlying causes, rather than symptoms, leads to sustainable corrective actions and measurable improvements in laboratory performance. This finding aligns with studies by Maruta (2018) and Rotich et al. (2019), which highlight RCA as a critical mechanism for reducing recurring nonconformities and fostering a proactive quality culture. The emphasis on *consistency* suggests that while RCA is conceptually understood, its practical application may still vary across departments, reflecting the need for structured follow-up systems, documentation, and management oversight to ensure continuity and institutional learning.

The second statement, *“Standardized procedures reduce variability but must be updated to match new technologies,”* illustrates an understanding of standardization as both a strength and a potential constraint. Standard operating procedures (SOPs) are essential for ensuring reproducibility, compliance, and reliability in diagnostic processes (Oakland, 2014). However, respondents acknowledge that outdated or rigid procedures can limit innovation and adaptation to emerging diagnostic technologies. This reflects a mature appreciation of dynamic standardization, where processes must evolve to incorporate new methods, equipment, and regulatory requirements. Similar observations have been reported by Gatimu et al. (2020) and Bhat et al. (2021), who found that laboratories in resource-limited settings often struggle to update procedures promptly due to limited technical expertise or slow document control systems. Thus, balancing procedural consistency with technological responsiveness is vital for maintaining both quality assurance and scientific relevance.

The third statement, *"Dashboards would help; current analysis is manual, slowing response,"* highlights the need for digital transformation and real-time data analytics in laboratory management. Manual data analysis is time-consuming, prone to human error, and limits the ability to respond swiftly to performance trends or operational anomalies. Respondents' call for dashboards suggests a desire for visual, automated, and integrated monitoring systems, which can improve situational awareness and support evidence-based decision-making. This observation resonates with the findings of Singh and Prakash (2020), who reported that laboratories adopting digital dashboards experienced faster corrective action turnaround and enhanced communication between management and technical teams.

Collectively, these statements reflect a progressive understanding of quality management principles among laboratory staff, particularly in linking continuous improvement, adaptability, and technology-driven analytics. However, the responses also underscore existing capacity and infrastructural gaps, including inconsistent RCA practice, delayed SOP updates, and the absence of digital quality tools, which constrain the full realization of TQM principles (Mutonga et al., 2019).

4.8 Inferential Statistics

4.8.1 Participant Demographics Versus Financial Performance

Table 16 presents the results of chi-square (χ^2) tests examining the associations between respondents' demographic characteristics and their laboratories' financial management practices.

Table 16

Demographics Versus × Financial Practices (χ^2 Tests)

Variables	χ^2 (df)	p	φc
Job position × Revenue diversification	7.766 (2)	.021	.608
Experience × Staff training/competency	9.011 (2)	.011	.671
Experience × Personalized services	11.078 (3)	.011	.726
Experience (6–10 or >10) × Customer surveys	10.624 (3)	.014	.711
Education × Financial performance rating	17.635 (6)	.007	.916
Education × OpEx/Revenue monitoring	7.879 (3)	.049	.628

Key: r = Pearson correlation coefficient; χ^2 = chi-square statistic; df = degrees of freedom; φc = Cramér's V.

The chi-square analysis revealed several statistically significant associations between respondents' demographic characteristics and key operational or performance variables, indicating that professional attributes influence how laboratories manage quality and financial practices.

A significant relationship between job position and revenue diversification ($\chi^2 = 7.766$, $p = .021$, φc = .608) suggests that managerial or supervisory staff are more likely to engage in or advocate for diversified revenue streams compared to technical personnel. This aligns with the strategic nature of leadership roles, in which financial sustainability and business model innovation are part of managerial accountability (Miller et al., 2019).

The relationship between experience and staff training or competency development ($\chi^2 = 9.011$, $p = .011$, φc = .671) highlights that more experienced personnel tend to prioritize or influence training initiatives. This could reflect a deeper appreciation for continuous professional development, consistent with Total Quality Management (TQM) principles emphasizing learning as a driver of sustained quality (Oakland, 2014). Similarly, experience was positively associated with personalized services (χ^2 = 11.078, p = .011, φc = .726), suggesting that seasoned professionals are more responsive to client-specific needs, likely drawing on accumulated tacit knowledge to tailor laboratory interactions and outputs.

The significant association between experience (6–10 or >10 years) and customer surveys (χ^2 = 10.624, p = .014, φc = .711) reinforces the role of experience in shaping customer engagement and feedback mechanisms. Experienced staff are likely to be more aware of the link between client satisfaction and service sustainability, thereby ensuring consistent use of feedback instruments.

Educational attainment also showed strong correlations with financial and operational monitoring. The link between education and economic performance rating (χ^2 = 17.635, p = .007, φc = .916) implies that higher academic qualifications enhance financial literacy, enabling more accurate performance evaluation. Similarly, education and OpEx/Revenue monitoring (χ^2 = 7.879, p = .049, φc = .628) were significantly associated, indicating that educated staff are better positioned to track and interpret key financial ratios, thereby supporting informed resource allocation.

Across all associations, effect sizes (φc = .608–.916) denote moderate to strong relationships, affirming that individual competencies and institutional roles substantially influence quality, customer focus, and financial performance practices. Comparable studies (Rotich et al., 2019; Miller et al., 2019; Singh & Prakash, 2020) have similarly shown that professional experience and education levels are critical enablers of quality system maturity and organizational adaptability.

4.8.2 Process Metrics and Effectiveness

Table 17 presents the key process metrics and their perceived effectiveness across participating laboratories. The table summarizes how laboratories monitor, evaluate, and utilize process indicators to assess operational efficiency and quality performance.

Table 17

Process Metrics and Effectiveness

Variables	r	p
Metrics availability × Monitoring frequency	.726	< .01
Metrics availability × Communication frequency	.715	< .01
Metrics availability × Pursuit of improvements	.645	< .01
Metrics availability × Stakeholder communication mechanisms	.505	< .05
Monitoring frequency × Pursuit of improvements	.509	< .05
Monitoring frequency × Communication frequency	.629	< .01
Pursuit of improvements × Structured methodology	.678	< .01

The correlation results presented in Table 17 demonstrate strong, statistically significant associations among several key process management and effectiveness variables, underscoring the central role of metric availability and monitoring frequency in driving quality improvement in laboratory operations.

The powerful positive correlation between metric availability and monitoring frequency ($r = .726$, $p < .01$) indicates that laboratories with well-defined process metrics tend to engage in more frequent, systematic monitoring. This relationship suggests that the mere existence of measurable indicators creates an operational culture of accountability, where performance tracking becomes a regular managerial practice. Similar findings have been reported by Maruta (2018) and Rotich et al. (2019), who found that the institutionalization of performance metrics fosters more consistent oversight and timely detection of process deviations in laboratory settings.

A comparably strong relationship between metrics availability and communication frequency ($r = .715$, $p < .01$) reflects the link between data generation and internal communication. Laboratories that routinely collect and analyze performance data are more likely to share this information across teams, promoting transparency and collaborative problem-solving. This finding aligns with Oakland’s (2014) Total Quality Management (TQM) framework, which emphasizes that effective feedback and communication are integral to sustaining a culture of continuous improvement.

The association between the availability of metrics and the pursuit of improvements ($r = .645$, $p < .01$) further demonstrates that laboratories with established metrics systems are more proactive in initiating corrective and preventive actions. The presence of measurable indicators appears to motivate evidence-based interventions rather than reactive responses. This supports Bhat et al. (2021), who reported that data-informed laboratories demonstrate greater agility in implementing improvement initiatives than those without structured measurement systems.

The moderate but significant correlation between metrics availability and stakeholder communication mechanisms ($r = .505$, $p < .05$) highlights the external dimension of quality communication. Laboratories that maintain robust internal metrics also tend to engage more effectively with stakeholders, such as clinicians, regulatory bodies, and clients, through regular reporting and feedback loops. This finding suggests that data-driven communication strengthens trust and collaboration, consistent with observations by Osei et al. (2020) on laboratory–stakeholder engagement as a pillar of quality assurance.

Further, the positive correlation between monitoring frequency and pursuit of improvements ($r = .509$, $p < .05$) underscores the reinforcing relationship between continuous measurement and continuous improvement. Frequent monitoring provides timely insights that facilitate prompt corrective actions and drive iterative enhancements in laboratory processes. Similarly, the relationship between monitoring frequency and communication frequency ($r = .629$, $p < .01$) suggests that as laboratories monitor performance more regularly, they also intensify communication across teams, ensuring that process insights are effectively translated into operational adjustments.

Finally, the strong positive correlation between pursuit of improvements and structured methodology ($r = .678$, $p < .01$) indicates that laboratories pursuing quality enhancements are more likely to adopt formal improvement tools such as PDCA, Kaizen, or RCA. This reflects a transition from informal corrective actions to systematic, data-driven continuous improvement, aligning with best practices recommended by WHO-AFRO (2022) in the SLIPTA framework. However, while the statistical relationships are robust, the findings also imply potential capacity gaps among laboratories lacking well-defined metrics or structured methodologies. Strengthening data infrastructure, staff training in analytical tools, and leadership commitment to communication-based performance review systems would further enhance process effectiveness and sustain continuous improvement across the sector.

4.8.3 Relationships between Continuous Improvement Practices Variables

Table 18 summarizes the relationships between key variables associated with continuous improvement practices among participating laboratories. The correlation and chi-square results highlight the degree of association between familiarity with improvement tools, their implementation, and perceived effectiveness.

Table 18

Continuous Improvement Practices (Correlations & χ^2)

Relationship	Statistic	Value	p	Effect
PDCA familiarity × PDCA implementation	r	.917	< .01	—
PDCA familiarity × Kaizen participation	r	.646	< .01	—
PDCA implementation × Kaizen participation	r	.655	< .01	—
Kaizen participation × Perceived effectiveness	r	.460	< .05	—
RCA performed × Overall quality	r	.691	< .01	—
Fishbone × Staff training/competency	r	.587	< .01	—
5 Whys × Satisfaction surveys	r	.508	< .05	—
Standardization × Financial performance rating	r	.624	.003	—
PDCA familiarity × ISO adherence	χ^2 (2)	7.616	.022	φc=.617
PDCA implementation × Perceived quality	χ^2 (4)	10.063	.039	φc=.489
PDCA implementation × Revenue-growth monitoring	χ^2 (2)	6.278	.043	φc=.560
Kaizen participation × Online reviews/ratings	χ^2 (2)	6.300	.043	φc=.548
Kaizen participation × Revenue-growth monitoring	χ^2 (2)	8.333	.016	φc=.645
RCA performed × Overall quality	χ^2 (4)	17.364	.002	φc=.643
RCA performed × ISO compliance	χ^2 (2)	6.296	.043	φc=.561
RCA performed × Timely responses	χ^2 (2)	6.850	.033	φc=.571
RCA performed × Financial performance rating	χ^2 (2)	10.843	.028	φc=.719
Fishbone × High-quality strategies	χ^2 (1)	3.958	.047	φc=.456
Fishbone × Staff training/competency	χ^2 (1)	6.537	.011	φc=.458

Table 18 presents both correlation and chi-square statistics assessing the relationships between various continuous improvement tools and laboratory performance indicators. The results highlight strong, statistically significant associations between familiarity, application, and perceived outcomes of structured quality improvement methodologies, including PDCA, Kaizen, RCA, Fishbone, and the 5 Whys.

The correlations reveal notably strong associations. PDCA familiarity and PDCA implementation are almost perfectly correlated ($r = .917$, $p < .01$), indicating that laboratories whose staff are more knowledgeable about the PDCA cycle are also the most likely to apply it in practice. Similarly, PDCA familiarity and Kaizen participation ($r = .646$, $p < .01$) and PDCA implementation and Kaizen participation ($r = .655$, $p < .01$) show that awareness of structured improvement tools fosters broader engagement with complementary methodologies. The link between Kaizen participation and perceived effectiveness ($r = .460$, $p < .05$) further suggests that direct involvement in improvement activities positively influences staff perceptions of their impact on quality outcomes.

A strong correlation between RCA performance and overall quality ($r = .691$, $p < .01$) underscores that laboratories conducting root cause analyses more consistently report higher perceived quality levels. Likewise, the positive associations between Fishbone analysis and staff training ($r = .587$, $p < .01$) and between 5 Whys and satisfaction surveys ($r = .508$, $p < .05$) suggest that systematic analytical tools are being linked with capacity building and client feedback mechanisms—key elements of a learning-oriented quality culture. Significantly, process standardization also correlated positively with financial performance ($r = .624$, $p = .003$), indicating that disciplined procedural control contributes to operational efficiency and profitability.

The chi-square (χ^2) results complement these findings by confirming significant relationships between continuous improvement practices and institutional outcomes. For example, PDCA familiarity and ISO adherence ($\chi^2 = 7.616$, $p = .022$, $\varphi c = .617$) demonstrate that laboratories familiar with PDCA principles are more compliant with ISO 15189 standards. Similarly, PDCA implementation and perceived quality ($\chi^2 = 10.063$, $p = .039$, $\varphi c = .489$) and PDCA implementation and revenue-growth monitoring

(χ^2 = 6.278, p = .043, φc = .560) show that applying PDCA not only enhances perceived service quality but also drives financial performance monitoring.

Further associations strengthen this interpretation: Kaizen participation is significantly related to online reviews/ratings (χ^2 = 6.300, p = .043, φc = .548) and revenue-growth monitoring (χ^2 = 8.333, p = .016, φc = .645), implying that continuous improvement fosters both external client satisfaction and internal performance measurement. Likewise, RCA performance exhibits strong relationships with multiple organizational dimensions, including overall quality (χ^2 = 17.364, p = .002, φc = .643), ISO compliance (χ^2 = 6.296, p = .043, φc = .561), timely responses (χ^2 = 6.850, p = .033, φc = .571), and financial performance rating (χ^2 = 10.843, p = .028, φc = .719) collectively underscoring RCA's critical role in driving both compliance and operational excellence. Additionally, Fishbone analysis was significantly associated with high-quality strategies (χ^2 = 3.958, p = .047, φc = .456) and staff training/competency (χ^2 = 6.537, p = .011, φc = .458), confirming its relevance as a diagnostic and educational tool within laboratory quality systems.

The collective results provide compelling evidence that continuous improvement tools are both conceptually and operationally interlinked and that their systematic use yields measurable benefits across technical, financial, and organizational domains. The strong correlations among PDCA, Kaizen, and RCA highlight a maturing culture of structured problem-solving, in which laboratories that embrace one improvement framework are likely to adopt others as complementary strategies. This mirrors the findings of Maruta (2018) and Bhat et al. (2021), who reported that the integrated application of TQM methodologies reinforces learning cycles, enhances corrective actions, and promotes sustainable quality outcomes.

The significant relationship between RCA and quality or financial performance is particularly notable. It reinforces the notion that laboratories that apply RCA effectively are more likely to prevent the recurrence of errors, optimize processes, and strengthen compliance, resulting in both improved service delivery and economic efficiency. These findings align with Rotich et al. (2019), who observed that consistent use of RCA in Kenyan laboratories led to reductions in nonconformities and improved audit outcomes.

Similarly, the associations involving Fishbone and 5 Whys tools reflect the value of root-cause analysis frameworks not only for problem-solving but also for organizational learning. Laboratories integrating these techniques into training and feedback systems are cultivating a data-driven, participatory culture of improvement, consistent with the WHO-AFRO SLIPTA (2022) model for progressive laboratory quality enhancement.

Moreover, the observed relationships between PDCA and ISO adherence underscore that continuous improvement frameworks are foundational to quality management compliance. ISO 15189 accreditation emphasizes evidence-based corrective actions, process standardization, and performance review, all principles inherently embedded in PDCA methodology (ISO, 2012; Oakland, 2014). Laboratories demonstrating familiarity with and implementation of PDCA therefore exhibit higher compliance maturity and a more strategic approach to quality assurance.

The relationship between standardization and financial performance reinforces the well-established TQM principle that process consistency drives efficiency and profitability. Laboratories that standardize workflows reduce error rates, enhance resource utilization, and improve customer satisfaction, translating to better financial outcomes, echoing findings by Osei et al. (2020) in Ghanaian laboratory networks.

4.8.4 Process Documentation & Stakeholder Interfaces

Table 19 presents the relationships between process documentation practices and stakeholder interface mechanisms among participating laboratories. The correlation and chi-square results illustrate how documentation quality, accessibility, and review frequency relate to stakeholder communication, feedback systems, and client satisfaction.

Table 19

Process Documentation & Stakeholder Interfaces (Correlations & χ^2)

Relationship	Statistic	Value	p	Effect
Update frequency × Satisfaction surveys (use)	r	–.465	.034	—
Overall quality × CQI initiatives	r	–.494	.027	—
ISO adherence × Staff training/competency	r	.471	.036	—
Staff training × Online reviews	r	.480	.032	—
Complaints process × Online reviews	r	.496	.022	—
Documented QMS × Focus groups/interviews	χ^2 (1)	5.526	.019	φc=.513
Documented QMS × Survey/NPS/repeat mix	χ^2 (3)	13.263	.004	φc=.795
Documented QMS × ROI monitoring	χ^2 (1)	5.185	.023	φc=.509
QMS review frequency × Feedback-based improvements	χ^2 (3)	8.179	.042	φc=.624
Process review frequency × Partnerships	χ^2 (2)	6.523	.038	φc=.557

Table 19 presents correlations and chi-square associations examining how process documentation practices, QMS review frequency, and stakeholder engagement mechanisms interact to influence laboratory quality and operational effectiveness. The findings highlight both positive and negative relationships, reflecting the complex interplay between documentation rigor, staff capacity, and stakeholder feedback systems in driving continuous quality improvement.

Two negative but statistically significant correlations are observed. The first, between update frequency and use of satisfaction surveys ($r = -.465$, $p = .034$), suggests that laboratories that review or update their documents more frequently tend to use satisfaction surveys less often. This inverse relationship may imply that rapid internal updates sometimes occur independently of systematic stakeholder feedback mechanisms. Similarly, the negative correlation between overall quality and CQI initiatives ($r = -.494$, $p = .027$) indicates that laboratories reporting higher perceived quality may conduct fewer formal CQI activities, potentially reflecting complacency once baseline quality objectives are met, or an overreliance on routine processes rather than structured improvement cycles.

The remaining correlations are positive and statistically significant, emphasizing complementary relationships between documentation, competency, and feedback mechanisms. A strong positive correlation between ISO adherence and staff training/competency ($r = .471$, $p = .036$) confirms that laboratories maintaining ISO 15189-aligned systems are more likely to invest in continuous staff training, reinforcing the centrality of human capacity in quality compliance. Likewise, staff training and online reviews ($r = .480$, $p = .032$) and complaints process and online reviews ($r = .496$, $p = .022$) demonstrate that better-trained staff and structured complaints management processes contribute to enhanced client engagement and satisfaction, often reflected in positive online feedback.

The chi-square results further reinforce these associations. The relationship between documented QMS and focus groups/interviews ($\chi^2 = 5.526$, $p = .019$, $\varphi c = .513$) suggests that laboratories with formal QMS documentation are more likely to use qualitative stakeholder engagement methods. This approach enables them to gain deeper insights into service delivery and user experience—key aspects of participatory quality management. Additionally, documented QMS and survey/NPS/repeat-client mix (χ^2 = 13.263, p = .004, φc = .795) indicate a strong relationship between documentation maturity and the systematic use of structured feedback tools such as Net Promoter Scores (NPS), repeat-client monitoring, and satisfaction surveys. This aligns with Oakland's (2014) TQM principle that well-documented systems enhance feedback-based learning and customer-centered performance evaluation.

Furthermore, the relationship between documented QMS and ROI monitoring (χ^2 = 5.185, p = .023, φc = .509) indicates that laboratories with robust documentation frameworks are more likely to integrate financial performance tracking into their quality systems, reflecting an evolution toward data-driven quality management in which operational and fiscal indicators are jointly evaluated. Similarly, QMS review frequency and feedback-based improvements (χ^2 = 8.179, p = .042, φc = .624) suggest that laboratories conducting regular QMS reviews are more likely to translate feedback into tangible corrective or preventive actions, an essential marker of system responsiveness and continual learning. Finally, the significant relationship between process review frequency and partnerships (χ^2 = 6.523, p = .038, φc = .557) underscores that laboratories engaging in frequent internal process evaluations are also more likely to sustain partnerships and collaborations, possibly because such reviews enhance credibility and foster external trust.

The results collectively reveal that process documentation quality and review practices are central enablers of stakeholder engagement and quality performance. The strong associations between documented QMS, stakeholder feedback mechanisms, and ROI monitoring suggest that laboratories with structured documentation systems not only maintain compliance but also use their documentation frameworks as strategic management tools for performance measurement and stakeholder communication. This finding aligns with Maruta (2018) and Rotich et al. (2019), who reported that documented processes underpin both operational consistency and external accountability within African laboratories implementing ISO 15189 standards.

The positive correlation between ISO adherence and staff competency affirms the interdependence between human capacity and compliance maturity. As observed in Osei et al. (2020), laboratories that invest in regular staff training demonstrate stronger audit outcomes and maintain a culture of continual learning. Likewise, the relationships among staff training, complaint handling, and online reviews reflect a maturing understanding of client-centered quality assurance, in which well-trained staff and responsive complaint systems directly influence customer satisfaction and institutional reputation.

Conversely, the negative associations warrant critical reflection. The inverse relationship between document update frequency and satisfaction survey use may indicate fragmentation between internal and external quality loops, suggesting that frequent procedural updates are not always informed by client feedback. This disconnect could weaken the alignment between service improvement and stakeholder expectations. Similarly, the negative link between perceived quality and CQI initiatives may point to a stagnation effect, where laboratories perceiving themselves as high-performing reduce formal improvement efforts, a risk also highlighted by Bhat et al. (2021) in studies of laboratory complacency following accreditation.

The significant chi-square effects (φc values ranging from .509 to .795) underscore moderate to strong relationships, confirming that documentation maturity enhances both process and stakeholder-related outcomes. Laboratories that review their QMS more regularly not only achieve better compliance but also demonstrate adaptive learning behavior, transforming feedback into concrete quality improvements and fostering productive partnerships.

4.8.5 Performance Metrics & Strategic Outcomes

Table 20 presents the relationships between key performance metrics and strategic outcomes across the participating laboratories. The correlation and chi-square analyses examine how systematic monitoring of performance indicators such as efficiency, client satisfaction, and financial growth relates to broader organizational results, including quality improvement, innovation, and institutional competitiveness.

Table 20

Performance Metrics & Strategic Outcomes (Correlations & χ^2)

Relationship	Statistic	Value	p	Effect
Metrics availability × Monitoring frequency	r	.726	< .01	—
Metrics availability × Communication frequency	r	.715	< .01	—
Monitoring frequency × Communication frequency	r	.629	.003	—
Metrics established × ISO adherence	χ^2 (2)	11.435	.003	φc=.756
Metrics established × CQI engagement	χ^2 (2)	8.889	.012	φc=.667
Metrics established × Staff training	χ^2 (2)	6.325	.042	φc=.562
Metrics established × Prompt responses	χ^2 (2)	6.588	.037	φc=.560
Monitoring frequency × CQI implementation	χ^2 (3)	11.667	.009	φc=.764
Monitoring frequency × Revenue diversification	χ^2 (3)	9.854	.020	φc=.685
Communication frequency × ISO adherence	χ^2 (2)	6.585	.037	φc=.589
Communication frequency × OpEx/Revenue	χ^2 (2)	6.465	.039	φc=.583

Table 20 presents the correlations and chi-square results examining the relationships between performance metrics, monitoring and communication frequency, and strategic outcomes such as ISO adherence, CQI, staff training, and financial diversification. The results reveal strong, statistically significant positive associations, demonstrating that the presence of well-defined performance metrics and structured communication systems strongly influences laboratory quality and institutional outcomes (Singh & Prakash, 2020).

The correlation results show that the availability of performance metrics is closely linked to both monitoring and communication practices. A robust positive correlation between metrics availability and monitoring frequency ($r = .726$, $p < .01$) indicates that laboratories with clearly established indicators conduct more frequent reviews, reflecting a culture of systematic measurement and accountability. Similarly, the significant relationship between metrics availability and communication frequency ($r = .715$, $p < .01$) highlights that laboratories with measurable indicators communicate performance information more regularly across teams. This implies that data visibility promotes transparency, team alignment, and collaborative decision-making. The relationship between monitoring frequency and communication frequency ($r = .629$, $p = .003$) further supports this interpretation, suggesting that frequent performance monitoring encourages consistent internal communication and coordination, a critical factor in sustaining data-driven quality systems.

The chi-square results strengthen these findings by linking the establishment of metrics with broader organizational benefits. Laboratories that had formally established performance indicators demonstrated stronger ISO adherence ($\chi^2 = 11.435$, $p = .003$, $\varphi c = .756$) and higher levels of engagement in continuous quality improvement activities ($\chi^2 = 8.889$, $p = .012$, $\varphi c = .667$). These strong effect sizes ($\varphi c > .6$) indicate that laboratories using well-structured metrics are more likely to comply with international standards and maintain active improvement programs, supporting the argument that measurement serves as the foundation of quality assurance (Oakland, 2014). The association between metrics and staff training ($\chi^2 = 6.325$, $p = .042$, $\varphi c = .562$) further suggests that laboratories that systematically track performance are better equipped to identify skills gaps and implement targeted training programs. Similarly, the relationship between metrics and prompt responses ($\chi^2 = 6.588$, $p = .037$, $\varphi c = .560$) indicates enhanced operational responsiveness, suggesting that laboratories with measurable indicators can detect and address issues more quickly, thereby improving turnaround times and service reliability.

Monitoring frequency also showed significant links to key strategic outcomes. The relationship between monitoring frequency and CQI implementation ($\chi^2 = 11.667$, $p = .009$, $\varphi c = .764$) highlights that frequent monitoring fosters a culture of continual assessment and improvement, ensuring that laboratories adapt to emerging quality challenges in real time. Furthermore, the relationship between monitoring frequency and revenue diversification ($\chi^2 = 9.854$, $p = .020$, $\varphi c = .685$) underscores the strategic value of data analytics, as laboratories that track performance consistently are better able to identify financial opportunities and develop alternative income streams to support sustainability. Communication frequency, likewise, was strongly associated with ISO adherence ($\chi^2 = 6.585$, $p = .037$, $\varphi c = .589$) and OpEx/Revenue monitoring ($\chi^2 = 6.465$, $p = .039$, $\varphi c = .583$), suggesting that regular reporting and discussion of performance metrics enhance both compliance and cost efficiency.

4.8.6 Improvement Initiatives & Financial Indicators

Table 21 presents the relationships between quality improvement initiatives and financial performance indicators across participating laboratories. The correlation and chi-square analyses examine how adopting structured improvement practices, such as PDCA cycles, Kaizen activities, and Root Cause Analysis, relates to key financial outcomes, including profitability, revenue growth, cost efficiency, and return on investment (ROI).

Table 21

Improvement Initiatives & Financial Indicators (Correlations & χ^2)

Relationship	Statistic	Value	p	Effect
Active pursuit × Structured methodology	r	.678	.001	—
Identification method × OpEx/Revenue	r	–.507	.027	—
Identification method × Partnerships	r	–.674	.001	—
Financial performance rating × Profit margin	r	–.474	.035	—
OpEx/Revenue × Partnerships	r	.533	.015	—
ROI × Tech/equipment investment	r	.802	< .001	—
Cost optimization × Tech/equipment investment	r	.471	.036	—
Active pursuit × ISO adherence	χ^2 (2)	7.917	.019	φc=.629
Active pursuit × Staff training	χ^2 (2)	6.276	.043	φc=.560
Identification methods × Partnerships	χ^2 (2)	9.899	.007	φc=.704

The correlation results show several noteworthy patterns. A strong positive correlation was observed between active pursuit of improvement and use of structured methodologies (r = .678, p = .001), indicating that laboratories actively engaged in improvement efforts tend to adopt systematic frameworks such as PDCA cycles, Root Cause Analysis, or Kaizen. This relationship suggests that sustained improvement is unlikely without structured methodological support, reinforcing the notion that institutionalizing improvement processes is key to achieving consistent quality outcomes.

Conversely, negative correlations were observed between identification methods and OpEx/Revenue (r = –.507, p = .027) and between identification methods and partnerships (r = –.674, p = .001). These inverse relationships imply that laboratories that rely on informal or reactive methods to identify improvement opportunities tend to exhibit lower cost efficiency and fewer strategic partnerships. This finding suggests that ad hoc or unstructured approaches to problem identification may divert resources or limit opportunities for collaborative growth.

A moderate negative correlation between financial performance rating and profit margin ($r = -.474$, $p = .035$) was also noted, indicating that laboratories reporting higher perceived financial stability do not necessarily maintain proportionately higher profit margins. This may suggest that financially stable laboratories operate with narrow but consistent margins, reflecting a focus on sustainability rather than high profitability, an observation consistent with public or not-for-profit laboratory models.

Positive relationships were observed between OpEx/Revenue and partnerships ($r = .533$, $p = .015$), indicating that laboratories actively tracking operational expenditure relative to revenue are also more engaged in collaborative ventures. This reflects a data-driven management approach in which cost-performance monitoring enables better alignment with partners and donors. Similarly, strong positive correlations were found between ROI and technological or equipment investment ($r = .802$, $p < .001$) and between cost optimization and technological investment ($r = .471$, $p = .036$). These findings emphasize that laboratories that strategically invest in modern equipment and digital technologies achieve higher returns on investment and greater cost efficiency. These results align with global evidence that technology-driven automation and equipment upgrades yield significant gains in laboratory throughput and cost reductions.

The chi-square results further reinforce these patterns. A significant association between active pursuit of improvement and ISO adherence ($\chi^2 = 7.917$, $p = .019$, $\varphi c = .629$) indicates that laboratories engaged in continuous improvement are more likely to comply with ISO 15189 quality standards. Similarly, active pursuit of improvement and staff training ($\chi^2 = 6.276$, $p = .043$, $\varphi c = .560$) shows that laboratories investing in improvement activities also prioritize capacity building, underscoring the synergy between quality culture and staff development. Finally, identification methods and partnerships ($\chi^2 = 9.899$, $p = .007$, $\varphi c = .704$) demonstrate a strong relationship between how improvement opportunities are recognized and the ability to sustain strategic collaborations. Laboratories that use structured identification mechanisms, such as risk assessments, audits, and performance dashboards, are more likely to maintain effective partnerships than those that rely on informal or reactive processes.

The results collectively demonstrate that structured and proactive improvement efforts are key drivers of financial and operational performance. Laboratories that pursue continuous improvement using formal methodologies tend to achieve better compliance, stronger financial outcomes, and more productive partnerships. The strong correlation between active pursuit of improvement and structured methodology ($r = .678$) reflects a culture of systematic problem-solving that aligns with Total Quality Management (TQM) principles, where data-driven decision-making and standardized processes foster sustained improvement. This finding supports the assertions of Maruta (2018) and Bhat et al. (2021), who observed that African laboratories that integrated PDCA and Kaizen frameworks into their QMSs achieved superior audit performance and greater staff engagement.

The negative relationships between unstructured identification methods and financial/partnership indicators highlight a persistent challenge in many laboratories' reactive management. Facilities that identify problems informally or only after nonconformities occur are less likely to optimize costs or attract strategic collaborators. This mirrors the findings of Rotich et al. (2019), who reported that laboratories in Kenya without formal risk identification tools exhibited higher operational inefficiencies and weaker stakeholder confidence. These results emphasize the need for laboratories to institutionalize systematic problem-identification tools such as root cause analysis logs, internal audits, and risk registers.

The strong positive relationship between ROI and investment in technology ($r = .802$) and the association with cost optimization ($r = .471$) underscore the financial return of modernization. Laboratories that allocate resources to advanced analytical equipment, laboratory information management systems (LIMS), and digital automation experience measurable efficiency gains. This aligns with Singh and Prakash (2020) and Osei et al. (2020), who note that technology investment is among the most reliable predictors of operational sustainability in medical laboratories, particularly in competitive or resource-constrained environments.

The chi-square associations provide additional evidence of a link between improvement culture, compliance, and human capital development. Laboratories that consistently pursue improvement not only perform better in ISO compliance but also invest more in staff training, reinforcing the cyclical relationship between human resource development and quality performance. As Oakland (2014) and WHO-AFRO (2022) assert, quality improvement initiatives thrive when leadership commits to continuous staff development and integrates training outcomes into QMS processes.

Finally, the relationship between identification methods and partnerships highlights the strategic dimension of improvement culture. Laboratories that employ structured, data-driven approaches to identify areas for improvement are better positioned to attract and retain partners, including donors, accrediting bodies, and collaborating research institutions. This is because such laboratories project transparency, reliability, and accountability qualities that underpin trust in collaborative engagements.

4.8.7 Stakeholder Involvement & Strategic Indicators

Table 22 presents the correlations and chi-square analyses examining stakeholder involvement and key strategic performance indicators among participating laboratories. The study explores how the degree of stakeholder engagement through feedback systems, partnerships, and participatory decision-making relates to organizational outcomes, including quality performance, innovation, client satisfaction, and financial stability.

Table 22

Stakeholder Involvement & Strategic Indicators (Correlations & χ^2)

Relationship	Statistic	Value	p	Effect
Stakeholder involvement × Personalized services	r	–.480	.028	—
Stakeholder involvement × QC procedures/monitoring	χ^2 (2)	9.675	.008	φc=.696
Stakeholder involvement × Personalized services	χ^2 (2)	6.467	.039	φc=.555
Stakeholder involvement × ROI monitoring	χ^2 (2)	7.897	.019	φc=.628
Methods to understand needs × Staff training	χ^2 (2)	6.154	.046	φc=.555
Regular/effective communication × Standards adherence	χ^2 (2)	6.806	.009	φc=.583

Table 22 presents the relationships between stakeholder involvement and key strategic performance indicators, highlighting how external engagement and communication practices influence laboratory quality, operational efficiency, and continuous improvement outcomes. The results reveal a mix of significant positive and negative relationships, reflecting both the potential and the complexity of stakeholder participation in driving organizational performance within laboratory settings.

The correlation between stakeholder involvement and personalized services ($r = –.480$, $p = .028$) indicates a statistically significant negative association. This suggests that laboratories with higher levels of stakeholder engagement may offer fewer personalized services, possibly because such facilities prioritize standardized, protocol-driven operations to ensure compliance and consistency across clients. In contrast, laboratories with less structured stakeholder engagement may rely more heavily on individualized client relationships to build trust and satisfaction. This pattern aligns with findings from Maruta (2018) and Bhat et al. (2021), which note that as laboratories evolve toward formalized quality systems, personalized interactions often give way to standardized processes that ensure uniformity and equity in service delivery. However, this does not necessarily imply reduced quality; instead, it points to a balance between personalization and procedural rigor.

The chi-square results reinforce the significance of stakeholder engagement in fostering quality assurance and strategic alignment. A strong relationship between stakeholder involvement and quality control (QC) procedures or monitoring ($\chi^2 = 9.675$, $p = .008$, $\varphi c = .696$) demonstrates that laboratories involving stakeholders such as clients, clinicians, and regulatory agencies are more likely to maintain robust quality control systems. This relationship underscores how feedback from external users and partners strengthens internal monitoring mechanisms, thereby improving precision, compliance, and accountability. These findings are consistent with those of Rotich et al. (2019), who found that stakeholder-driven audits and feedback significantly enhanced QC adherence and reduced nonconformities in Kenyan laboratories.

Similarly, the significant association between stakeholder involvement and personalized services ($\chi^2 = 6.467$, $p = .039$, $\varphi c = .555$) complements the earlier correlation result, confirming that while stakeholder participation influences service design, it often encourages structured, standardized approaches rather than individualized ones. This reflects a strategic shift from reactive, client-specific responses toward proactive, system-wide quality management, a hallmark of mature quality systems.

The relationship between stakeholder involvement and ROI monitoring ($\chi^2 = 7.897$, $p = .019$, $\varphi c = .628$) suggests that laboratories that actively engage stakeholders are also more likely to track and evaluate their return on investment. This link indicates a recognition that stakeholder confidence and satisfaction are closely tied to financial sustainability and accountability. Laboratories that maintain transparent stakeholder relationships tend to adopt more rigorous financial monitoring systems, ensuring that resources are used efficiently to deliver value to both clients and institutional partners. These findings align with the broader TQM principle that stakeholder satisfaction and organizational profitability are mutually reinforcing outcomes when quality systems are well-integrated (Oakland, 2014).

The significant relationship between methods to understand stakeholder needs and staff training ($\chi^2 = 6.154$, $p = .046$, $\varphi c = .555$) highlights the role of internal capacity development in effective engagement. Laboratories that invest in understanding client and stakeholder expectations are also more likely to train their staff to respond appropriately. This suggests that the ability to interpret and act on stakeholder input depends on staff competence and professional development. Osei et al. (2020) similarly reported that laboratories with structured feedback analysis mechanisms often combine them with targeted staff training to align service delivery with client expectations and quality objectives.

Lastly, the relationship between regular and effective communication and standards adherence ($\chi^2 = 6.806$, $p = .009$, $\varphi c = .583$) indicates that consistent internal and external communication enhances compliance with operational and regulatory standards. Effective communication ensures that staff understand their roles, clients remain informed, and regulators receive timely documentation, ultimately fostering a culture of openness and shared responsibility for quality. As noted by WHO-AFRO (2022), transparent communication channels are a defining characteristic of laboratories that successfully sustain ISO 15189 accreditation.

4.8.8 Collection, Analysis, Visualization, and Metrics

Table 23 presents the relationships between data collection methods, analytical techniques, visualization practices, and performance metrics across participating laboratories. The correlation and chi-square analyses examine how different data management and analysis approaches, ranging from traditional tools such as Excel to advanced platforms like Power BI, Tableau, and Python/R /R, affect laboratory quality, operational efficiency, and financial performance.

Table 23

Collection, Analysis, Visualization, and Metrics (Correlations & χ^2)

Relationship	Statistic	Value	p	Effect
Collection method × Online reviews/ratings	r	.434	.049	—
Collection SOPs × Overall quality	r	.409	.065	—
Regression analysis × Dedicated analysts	r	–.512	< .05	—
Machine learning × Visualization frequency	r	–.553	< .05	—
Visualization frequency × Profit margin	r	.503	.024	—
Excel vs Tableau (combined indicator)	r	–.611	.003	—
Power BI × Tech/equipment investment	r	.471	.036	—
Financial performance rating × Profit margin	r	–.474	.035	—
Collection method × Revenue-growth monitoring	χ^2 (2)	6.667	.036	φc=.577
Collection method × Revenue diversification	χ^2 (2)	6.255	.044	φc=.546
Collection SOPs × Overall quality	χ^2 (2)	6.539	.038	φc=.558
Collection SOPs × Revenue diversification	χ^2 (1)	6.390	.011	φc=.552
Excel use × Complaint-resolution feedback	χ^2 (1)	5.688	.017	φc=.520
Power BI × Customer satisfaction rating	χ^2 (2)	9.975	.007	φc=.689
Python/R × Overall service/product quality	χ^2 (2)	14.000	.001	φc=.816
Degree of DDDM × Overall quality	r	.515	.017	—
Degree of DDDM × Standards adherence	r	–.471	.036	—
Degree of DDDM × Satisfaction surveys	r	–.389	.081	—
Extensive DDDM × Overall quality	χ^2 (2)	6.497	.039	φc=.556
TAT metric × QC strategies	χ^2 (1)	6.967	.008	φc=.606

Table 23 presents the relationships between data-driven decision-making (DDDM) practices, analytical tools, and key organizational outcomes in laboratories, illustrating how data collection, analysis, visualization, and reporting methods influence quality performance, financial indicators, and customer engagement. The results reveal a complex mix of positive and negative relationships, reflecting both the transformative potential and the emerging challenges of analytics adoption in laboratory quality systems.

The positive correlation between collection method and online reviews/ratings ($r = .434$, $p = .049$) indicates that laboratories that use structured, systematic data collection methods tend to receive higher client satisfaction ratings and more favorable online feedback. This relationship highlights the importance of reliable data-collection systems, such as automated forms or standardized feedback tools, for capturing service performance and driving evidence-based service enhancement. Similarly, the relationship between collection standard operating procedures (SOPs) and overall quality ($r = .409$, $p = .065$) is slightly above conventional significance levels, suggesting that formal documentation and adherence to collection procedures contribute to consistent service delivery and quality outcomes. These findings align with those of Rotich et al. (2019), who reported that laboratories with well-defined data and specimen-handling protocols achieved superior audit and customer satisfaction scores due to reduced operational variability.

Conversely, several negative correlations highlight emerging inefficiencies and transitional challenges in laboratory analytics. The negative relationship between regression analysis and the presence of dedicated analysts ($r = –.512$, $p < .05$) suggests that laboratories performing regression analysis tend to rely on multi-tasking personnel rather than specialized data analysts. This likely reflects resource constraints or limited analytical capacity, where statistical modeling is integrated into broader staff roles rather than handled by trained data scientists. Similarly, the negative correlation between machine learning and visualization frequency ($r = -.553$, $p < .05$) implies that laboratories experimenting with machine learning models may be using them in isolated pilot projects rather than integrated, continuously visualized systems. This trend is consistent with early-stage adoption patterns described by Miller et al. (2019) and Singh & Prakash (2020), in which machine learning remains underutilized in routine operational dashboards in low- and middle-income countries.

On the other hand, the positive relationship between visualization frequency and profit margin ($r = .503$, $p = .024$) indicates that laboratories regularly visualizing their performance data using dashboards or graphical summaries achieve stronger financial outcomes. Data visualization enhances situational awareness, supports timely decision-making, and enables management to identify inefficiencies affecting profitability. However, the strong negative relationship between Excel and Tableau use ($r = -.611$, $p = .003$) reveals a technological divide: laboratories that rely on basic tools like Excel tend to lag in advanced analytics. In contrast, those using modern platforms such as Tableau demonstrate more effective data visualization and integration.

This technological differentiation underscores the sector's evolving digital maturity. Complementing this, the positive correlation between Power BI use and technology investment ($r = .471$, $p = .036$) suggests that laboratories embracing Power BI dashboards also invest more in digital and equipment modernization, further reinforcing the link between technological capacity and analytical performance. The chi-square results deepen these insights. Significant associations were observed between collection method and financial performance dimensions, including revenue-growth monitoring ($\chi^2 = 6.667$, $p = .036$, $\varphi c = .577$) and revenue diversification ($\chi^2 = 6.255$, $p = .044$, $\varphi c =$

.546), implying that laboratories employing systematic data collection methods are better equipped to track and optimize financial indicators. Similarly, collection SOPs were significantly related to overall quality (χ^2 = 6.539, p = .038, φc = .558) and revenue diversification (χ^2 = 6.390, p = .011, φc = .552), indicating that procedural rigor in data management translates directly into improved service quality and diversified revenue streams.

The associations between analytical tools and performance outcomes were particularly striking. Excel use was associated with complaint-resolution feedback (χ^2 = 5.688, p = .017, φc = .520), suggesting that while basic tools remain prevalent, they primarily support administrative tracking rather than predictive or strategic analytics. In contrast, Power BI use was strongly associated with customer satisfaction rating (χ^2 = 9.975, p = .007, φc = .689), highlighting that advanced visualization tools enhance the ability to monitor and act upon client feedback in real time. The most robust association was observed between Python/R /R/R use and overall service or product quality (χ^2 = 14.000, p = .001, φc = .816), reflecting the power of advanced analytics for improving diagnostic accuracy, error prediction, and process optimization, key pillars of quality in modern laboratory management.

Further, the positive correlation between the degree of DDDM and overall quality (r = .515, p = .017) indicates that laboratories that integrate data-driven approaches more extensively report higher perceived quality. However, the negative correlations with standards adherence (r = –.471, p = .036) and satisfaction surveys (r = –.389, p = .081) suggest that early adopters of DDDM may be prioritizing analytical sophistication over procedural conformity or traditional client feedback mechanisms. This observation is consistent with the transitional digitalization phases described by Osei et al. (2020), in which data analytics initiatives initially outpace regulatory frameworks. Nonetheless, the significant association between extensive DDDM and overall quality ($\chi^2 = 6.497$, $p = .039$, $\varphi c = .556$) confirms that the net effect of analytics integration remains positive and transformative.

Finally, the association between turnaround time (TAT) metrics and quality control strategies ($\chi^2 = 6.967$, $p = .008$, $\varphi c = .606$) highlights how time-based performance indicators are increasingly being used as proxies for quality management effectiveness. Laboratories monitoring TAT more systematically are also more likely to employ robust QC systems, ensuring efficiency without compromising accuracy, an observation echoed in Maruta (2018) and WHO-AFRO (2022).

The results collectively depict laboratories at different stages of the digital transformation journey. While many institutions have adopted structured data collection and visualization practices that correlate positively with quality and financial performance, others remain constrained by reliance on basic tools and limited analytical specialization. The strong correlations between modern analytics platforms (Tableau, Power BI, Python/R) and performance outcomes underscore the importance of investing in digital infrastructure and analytical training to leverage data for strategic decision-making fully.

At the same time, the mixed findings regarding DDDM and standards adherence reveal a potential gap between innovation and compliance where laboratories advancing in analytics must ensure alignment with ISO 15189 and national quality standards to maintain credibility and accreditation readiness. Therefore, balanced digital integration, coupling technological advancement with robust procedural control, will be critical to achieving both operational agility and long-term quality sustainability.

CHAPTER FIVE

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

5.1 Summary of Findings

The study sought to determine the impact of implementing Total Quality Management (TQM) practices on the strategic competitiveness of selected diagnostic laboratories in Nakuru County. Specifically, it examined three key dimensions of TQM process management, continuous improvement, and data-driven decision-making (DDDM) and their combined influence on laboratory quality, compliance, financial performance, and institutional sustainability.

5.1.1 Process Management Practices

The study established a high level of process formalization among laboratories, with 90.5% implementing QMS and 100% maintaining documented procedures. Standardized processes enhanced operational efficiency, accountability, and compliance with ISO 15189 requirements. Process documentation was available in both print and digital formats, reflecting a hybrid management environment.

Regular review of QMS documentation, mainly on an annual basis, supported procedural discipline and compliance, but limited agility in responding to technological or regulatory changes. Strong associations were found between documentation maturity and ISO adherence ($\chi^2 = 11.435$, $p = .003$), CQI engagement ($\chi^2 = 8.889$, $p = .012$), and financial performance ($r = .624$, $p = .003$), confirming that robust process management contributes directly to competitiveness.

5.1.2 Continuous Improvement Practices

Continuous improvement practices such as PDCA, Kaizen, and RCA showed a strong influence on quality and compliance outcomes. A robust correlation was observed between PDCA familiarity and implementation ($r = .917$, $p < .01$) and between RCA performance and overall quality ($\chi^2 = 17.364$, $p = .002$, $\varphi c = .643$).

However, participation in Kaizen activities was limited, with 57.8% of respondents reporting no participation, indicating partial institutionalization. The findings revealed that laboratories with structured methodologies achieved superior outcomes in ISO compliance, financial performance, and staff competence. The results also highlighted the importance of training and leadership commitment in ensuring the effectiveness of continuous improvement.

5.1.3 Data-Driven Decision-Making (DDDM) Practices

The study revealed a progressive but uneven adoption of DDDM approaches. Strong positive correlations were observed between metric availability and monitoring frequency ($r = .726$, $p < .01$) and between visualization frequency and profit margin ($r = .503$, $p = .024$). Laboratories employing advanced analytics platforms such as Power BI, Tableau, and Python/R /R/R demonstrated higher operational efficiency, ROI, and client satisfaction.

However, a negative correlation between DDDM and adherence to standards ($r = –.471$, $p = .036$) suggested that early adopters of analytics sometimes deprioritized procedural compliance. Furthermore, laboratories relying solely on basic tools like Excel were found to have limited analytical capacity and slower responsiveness to quality insights.

Overall, the study found that data-driven decision-making significantly enhances operational agility and strategic competitiveness but requires adequate technical capacity, training, and alignment with QMS frameworks.

5.2 Conclusions

5.2.1 General Conclusion

The study concludes that implementing TQM practices significantly enhances the strategic competitiveness of diagnostic laboratories in Nakuru County. Laboratories that embed TQM principles through structured processes, continuous improvement mechanisms, and data-driven decision-making demonstrate superior performance in quality, financial outcomes, compliance, and client satisfaction.

TQM, when integrated as a strategic management approach rather than a compliance requirement, fosters innovation, accountability, and sustainability, positioning laboratories for long-term success within a competitive healthcare landscape.

5.2.2 Specific Conclusions

i. Effective process management improves operational stability, service reliability, and compliance, thereby strengthening institutional competitiveness. However, laboratories must evolve toward more adaptive and technology-supported systems to maintain continuous relevance.

ii. Structured and participatory continuous improvement enhances service quality and strategic competitiveness. Sustained leadership support and inclusive staff engagement are essential to institutionalize an improvement culture across all laboratory levels.

iii. Data-driven decision-making is a strategic enabler of competitiveness. Its effectiveness depends on integrating analytical insights into QMS cycles, maintaining regulatory alignment, and enhancing staff competency in data interpretation and visualization.

5.3 Recommendations

i. Diagnostic laboratories should fully embed TQM principles, process management, continuous improvement, and data-driven decision-making into their strategic and operational structures. Leadership should champion quality as a strategic driver of competitiveness, ensuring that quality goals are aligned with financial performance, innovation, and accreditation objectives.

ii. Laboratories should strengthen their process management by implementing dynamic review cycles (quarterly or semi-annual) and migrating to digital QMS platforms that enable real-time updates, version control, and accessibility. This will improve responsiveness to evolving diagnostic technologies, regulatory standards, and client needs.

iii. Continuous improvement tools such as PDCA, RCA, and Kaizen should be institutionalized across all departments, not limited to management levels. Regular staff training, mentorship, and incentive-based recognition systems should be introduced to promote ownership of quality improvement initiatives and sustain a learning culture.

iv. Laboratories should invest in modern analytics tools (Power BI, Tableau, Python/R /R) and integrate them with Laboratory Information Management Systems (LIMS) to support evidence-based decision-making. Capacity building in data analytics and visualization should be prioritized, ensuring that data-driven insights are systematically incorporated into QMS reviews, financial planning, and customer satisfaction improvement strategies.

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APPENDICES

Appendix I: Study Questionnaire

Dear Participant,

I appreciate your willingness to participate in our study on the impact of implementing Total Quality Management (TQM) practices on the strategic competitiveness of selected diagnostic laboratories in Nakuru County.

The purpose of this study is to examine how TQM practices impact the competitiveness of diagnostic laboratories. By understanding the specific TQM practices that contribute most to strategic competitiveness, we can identify implementation challenges.

Your participation is voluntary, and your responses will remain confidential. Please provide honest and thoughtful answers to the questionnaire, which will take approximately [estimated time] to complete.

If you have any questions or concerns, please feel free to contact the principal investigator, **[Dr. Michael N. Walekhwa, at [walekhwam@gmail.com or 0705-290520].**

Thank you for your valuable contribution to this research.

No	Question	Options	
Section A: Subject And Laboratory Demographics			
1.	What is your current job position in the laboratory?	Laboratory Manager/Supervisor	
		Support Staff	
		Technician/Technologist	
		Quality Officer	
2.	How many years of experience do you have working in the laboratory?	Less than 1 year	
		1-5 years	
		6-10 years	
		More than 10 years	
3.	What is your highest level of education?	High school diploma or equivalent	
		Bachelor's degree	
		Master's degree	
		Doctorate/Ph.D. degree	

4.	Is your laboratory accredited by any recognized accreditation body other than KMLTTB?	Yes	
		No	
5.	Is your laboratory accredited by KENAS?	Yes	
		No	
6.	Does your laboratory have a documented quality management system (QMS) in place?	No	
		Yes	
7.	How frequently is your laboratory's quality management system reviewed and updated?	Quarterly	
		Annually	
		As needed	
		Not sure	
Section B: Process Management			
1.	Do you have documented processes in your laboratory?	Yes	
		No	
2.	How frequently are the processes reviewed and updated?	Quarterly	
		Annually	
		As needed	
		Not sure	
3.	Are the documented processes easily accessible to all relevant stakeholders?	Yes, through a centralized repository or intranet	
		Yes, through shared drives or folders	
		Yes, through printed copies	
		No, not easily accessible	
4.	Are there established performance metrics to measure process effectiveness and efficiency?	Yes, for all processes	
		Yes, for some processes	
		No, there are no established performance metrics.	
5.	How often are process performance metrics measured and monitored?	Monthly	
		Quarterly	
		Annually	
		Irregularly/Not at all	
6.	Are the process performance metrics communicated to relevant stakeholders?	Yes, regularly	
		Yes, occasionally	
		No, not communicated	
7.	Does your organization actively	Yes, regularly	

	pursue process improvement initiatives?	Yes, occasionally	
		No, not actively	
8.	How are process improvement initiatives identified?	Through employee suggestions	
		Through customer feedback	
		Through process audits or evaluations	
		Other (please specify):……………	
9.	Is there a structured approach or methodology for implementing process improvements?	Yes, clearly defined and followed.	
		Yes, but inconsistently applied.	
		No, there is no structured approach.	
10.	Who are the primary stakeholders involved in the process?	Employees	
		Customers	
		Management	
		Suppliers	
		Regulatory bodies	
		Other (please specify):	
11.	How are the needs and expectations of process stakeholders identified and addressed?	Regular surveys or feedback collection	
		Meetings or consultations	
		Formalized feedback channels	
		Other (please specify):	
12.	Are there mechanisms in place to ensure effective communication with process stakeholders?	Yes, regular communication channels exist.	
		Yes, but communication is not consistent.	
		No, there are no specific mechanisms in place.	
Section C: Continuous Improvement			
1.	Are you familiar with the PDCA cycle as a continuous improvement framework?	Yes, very familiar	
		Yes, somewhat familiar	
		No, not familiar	
2.	Has your laboratory implemented the PDCA cycle for process improvement?	Yes, extensively	
		Yes, to some extent	
		No, not implemented	
3.	Have you participated in a Kaizen event within your laboratory?	Yes, multiple times	
		Yes, once	
		No, never participated.	

4.	How effective do you believe Kaizen events are in improving laboratory processes?	Highly effective	
		Moderately effective	
		Not effective	
5.	Does your laboratory conduct root cause analysis to identify the underlying causes of process issues or errors?	Yes, consistently	
		Yes, occasionally	
		No, not conducted	
6.	Which tools or techniques does your laboratory utilize for root cause analysis? (Select all that apply)	Fishbone diagram	
		5 Whys	
		Fault tree analysis	
		Pareto analysis	
		Other (please specify):	
7.	Are processes within your laboratory standardized through documented procedures?	Yes, extensively	
		Yes, to some extent	
		No, processes are not standardized.	
Section D: Data-Driven Decision-Making			
1.	How is data collected in your laboratory?	Manual data entry	
		Automated data capture	
		A combination of manual and automated methods	
		Not sure	
2.	Are there established protocols or standard operating procedures (SOPs) for data collection?	Yes, for all data collection processes	
		Yes, for some data collection processes	
		No, there are no established protocols.	
3.	Which data analysis methods or techniques are commonly used in your laboratory? (Select all that apply)	Descriptive statistics	
		Inferential statistics	
		Regression analysis	
		Machine learning algorithms	
		Other (please specify):	
4.	Are there dedicated personnel responsible for data analysis in your laboratory?	Yes, we have a dedicated data analysis team.	
		Yes, there are individuals responsible for data analysis tasks.	
		No, data analysis tasks are performed by various staff	

		members.	
		No, data analysis is not a priority in our laboratory.	
5.	How often is data visualized in your laboratory for more straightforward interpretation and understanding?	Regularly, for all relevant data	
		Occasionally, for specific projects or reports	
		Rarely is data visualization not commonly used.	
6.	Which data visualization tools or software are used in your laboratory? (Select all that apply)	Microsoft Excel	
		Tableau	
		Power BI	
		Python/R programming	
		Other (please specify):	
7.	Are data-driven metrics utilized to measure performance or quality in your laboratory?	Yes, extensively	
		Yes, to some extent	
		No, data-driven metrics are not used.	
8.	Which data-driven metrics are commonly used to assess laboratory performance? (Select all that apply)	Turnaround time	
		Accuracy rate	
		Productivity measures	
		Error rates	
		Other (please specify):	
Section D: Other Factors			
1.	Does your laboratory have sufficient resources (e.g., funding, equipment, supplies) to support the objectives of the study?	Yes, resources are abundant.	
		Yes, resources are somewhat limited.	
		No, resources are significantly limited.	
2.	How would you rate the availability of resources in your laboratory?	High availability	
		Moderate availability	
		Low availability	
3.	What is the ownership type of your laboratory?	Public/government-owned	
		Private/independent	
		Non-profit/academic institution	
		Other (please specify):	
4.	How does the ownership type impact the operations and decision-making processes in your laboratory?	Ownership has a significant impact.	
		Ownership has some influence.	
		Ownership does not have a	

		noticeable impact.	
Section E: Strategic Competitiveness			
1.	How would you rate the overall quality of services and products offered by your laboratory?	Excellent	
		Good	
		Average	
		Below average	
2.	What measures or strategies are implemented to ensure the delivery of high-quality services and products? (Select all that apply)	Adherence to international quality standards (e.g., ISO 15189)	
		Continuous quality improvement initiatives	
		Regular staff training and competency assessments	
		Quality control procedures and monitoring	
		Other (please specify):	
3.	How do you gather feedback from customers to assess the quality of services and products? (Select all that apply)	Customer satisfaction surveys	
		Complaint resolution processes	
		Focus groups or interviews with customers	
		Online reviews and ratings	
		Other (please specify):	
4.	How do you measure customer satisfaction in your laboratory?	Net Promoter Score (NPS) or similar rating system	
		Customer satisfaction surveys	
		Repeat customer rates	
		Complaint resolution rates	
		Other (please specify):	
5.	How would you rate customer satisfaction in your laboratory?	Very satisfied	
		Satisfied	
		Neutral	
		Dissatisfied	
		Very dissatisfied	

6.	What initiatives or actions are taken to improve customer satisfaction? (Select all that apply)	Timely response to customer inquiries and requests	
		Personalized services and attention to individual needs	
		Process improvements based on customer feedback	
		Enhanced communication channels with customers	
		Other (please specify):	
7.	How would you rate your laboratory's financial performance?	Strong and profitable	
		Stable and sustainable	
		Variable or inconsistent	
		Poor or struggling	
8.	Which financial metrics or indicators are regularly monitored to assess the economic performance of your laboratory? (Select all that apply)	Revenue growth rate	
		Profit margin	
		Return on investment (ROI)	
		Operating expenses as a percentage of revenue	
		Other (please specify):	
9.	How does your laboratory ensure financial sustainability and growth? (Select all that apply)	Cost optimization and efficiency measures	
		Diversification of revenue streams	
		Strategic partnerships or collaborations	
		Investment in advanced technologies or equipment	
		Other (please specify):	

Thank You So Much For Participating In This Study

Appendix II: Interview Guide

(Each Response Selected Should Be Explained)

Objective 1: To assess the level of implementation of process management practices in selected diagnostic laboratories in Nakuru County.

[1] How would you rate the level of implementation of process management practices in your laboratory?

a) Highly effective and fully implemented

b) Moderately effective with room for improvement

c) Limited implementation or not effectively implemented

[2] Which process management methodologies or frameworks are utilized in your laboratory? (Select all that apply)

a) Six Sigma

b) Lean management

c) Total Quality Management (TQM)

d) Business Process Reengineering (BPR)

e) Other (please specify): ____________

[3] How often are process performance metrics monitored and evaluated in your laboratory?

a) Continuously and in real-time

b) Regularly at predefined intervals

c) Occasionally or on an ad-hoc basis

d) Rarely or not at all

Objective 2: To evaluate the performance of continuous improvement practices implemented in selected diagnostic laboratories in Nakuru County.

[1] How frequently are continuous improvement practices implemented in your laboratory?

a) Continuously and proactively

b) Regularly as part of improvement initiatives

c) Occasionally, or when specific issues arise

d) Rarely or not systematically

[2] Can you provide examples of specific continuous improvement initiatives implemented in your laboratory? (Select all that apply)

a) Kaizen events

b) Root cause analysis (RCA)

c) PDCA (Plan-Do-Check-Act) cycles

d) Standardization of processes

e) Other (please specify): ____________

[3] How are the outcomes or results of continuous improvement efforts measured or evaluated in your laboratory?

a) Key performance indicators (KPIs)

b) Customer satisfaction surveys

c) Process cycle time reduction

d) Error or defect rates

e) Other (please specify): ____________

Objective 3: To establish the extent of utilization of data-driven decision-making practices in selected diagnostic laboratories in Nakuru County.

[1] How would you describe the current extent of utilization of data-driven decision-making practices in your laboratory?

a) Fully integrated into all decision-making processes

b) Partially utilized, with some room for improvement

c) Limited utilization

[2] What types of data are collected and analyzed to inform decision-making processes in your laboratory? (Select all that apply)

a) Patient demographic data

b) Test results and quality control data

c) Operational performance metrics

d) Financial data and cost analysis

e) Other (please specify): ____________

[3] How are data-driven metrics used to monitor and evaluate the performance of your laboratory?

a) Real-time dashboards and visualizations

b) Trend analysis and benchmarking

c) Statistical analysis and data modeling

d) Decision support systems or software

e) Other (please specify): ____________

[4] Quality Services and Products:

a) How would you rate the overall quality of services and products provided by your laboratory?

i) Excellent

ii) Good

iii) Fair

b) In your opinion, what factors contribute to the high quality of services and products in your laboratory?

i) Skilled and trained staff

ii) State-of-the-art equipment

iii) Robust quality control processes

[5] Customer Satisfaction:

a) How satisfied are your laboratory's customers with the services and products they receive?

i) Very satisfied ii) Somewhat satisfied

iii) Not satisfied

b) What measures does your laboratory have in place to assess and improve customer satisfaction?

i) Regular customer feedback surveys

ii) Complaint management system

iii) Continuous training of staff on customer service

[6] Financial Performance:

a) How would you assess the financial performance of your laboratory?

i) Strong and profitable

ii) Steady and stable

iii) Weak and struggling

b) What strategies does your laboratory employ to enhance its financial performance?

i) Cost reduction initiatives

ii) Diversification of services

iii) Strategic partnerships and collaborations

Appendix III: Informed Consent Form

STUDY TITLE: INFLUENCE OF TOTAL QUALITY MANAGEMENT PRACTICES IMPLEMENTATION ON THE STRATEGIC COMPETITIVENESS OF SELECTED DIAGNOSTIC LABORATORIES IN NAKURU COUNTY

PI: Dr. Michael N. Walekhwa Affiliated Institution: Kabarak University

Co-investigator(s) Affiliated Institution(s)

Dr. Nehemiah Kiplagat: Kabarak University

Prof. Simon Kipchumba: Kabarak University

Introduction

You are invited to participate in this research study being undertaken by the above-listed investigators. This form will help you gather information about the survey so you can decide whether to participate voluntarily. You are encouraged to ask any questions regarding the research process, as well as any benefits or risks that you may accrue by participating. After you have been adequately informed about the study, you will be requested to either agree or decline to participate. Upon deciding to participate in the survey, you will be further asked to affirm that by appending your signature/thumbprint on this form. Accepting or declining to participate in this study does not in any way waive the following rights, which you're entitled to:

a. Voluntary participation in the study:
b. Withdrawing from the study at any time without the obligation of having to explain and;
c. Access to services that you're entitled to

A copy of this form will be provided to you for your own records

Should I continue YES/NO ____________

This study has been reviewed and approved by Kabarak University Research Ethics Committee (KUREC)

What is the Purpose of the Study?

The main reason(s) for conducting this study are to answer the following questions:

i. To assess the level of implementation of process management practices in selected diagnostic laboratories in Nakuru County.
ii. To evaluate the performance of continuous improvement practices implemented in selected diagnostic laboratories in Nakuru County.
iii. To establish the extent of utilization of data-driven decision-making practices in selected diagnostic laboratories in Nakuru County.

(To answer these research questions, you are requested to answer question(s) voluntarily and/or accept some procedures performed on you.)

Who can Take Part in the Study?

The inclusion criteria for subject selection in this study require that participants meet the following conditions: they should be employed in diagnostic laboratories registered with the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB); have a minimum work experience of at least one year in the selected laboratory immediately preceding the study; and voluntarily agree to participate and sign the informed consent form. These criteria ensure that the study includes individuals who work in laboratories that meet regulatory standards, possess sufficient knowledge and experience, and are willing to contribute to the research while safeguarding their rights as participants. The sample size shall be 48 subjects.

In Case You Agree to Participate in the Study, What Will Happen?

This is what is going to happen once you have agreed to participate in the study:

- It will take about 15 minutes to fill out the questionnaire.
- Second, a qualified and well-trained interviewer will ask you questions in a private place

where you will feel comfortable. In case there is any question you feel uncomfortable responding to, you will not be coerced into responding. The questions will be on the following areas: (list the areas below)

- Lastly, you are requested to provide your contact details (phone number or another reliable contact method). This will help reach you in case new information regarding the study emerges. Other reason(s) for requesting your contact details are)

- The contact details you will provide shall remain confidential to the lead researcher (PI).

What Potential Risks Are Associated with Participation in this Study?

i. Confidentiality and Privacy

Risk: Potential disclosure or breach of participants' personal information.

Mitigation: Anonymization of data, secure storage, restricted access, and clear consent protocols.

ii. Psychological and Emotional

Risk: Emotional stress or discomfort during sensitive discussions.

Mitigation: Clear explanation of study purpose, voluntary participation, supportive environment, and withdrawal option.

iii. Information Bias or Misinterpretation

Risk: Inaccurate or biased information leading to misinterpretation.

Mitigation: Rigorous data collection methods, standardized protocols, cross-validation, and triangulation.

In case you aren't comfortable answering any of the questions during the interview because of feeling embarrassed or uncomfortable, it will be within your rights to decline. Otherwise, every measure has been taken to ensure the interview is conducted in a private area with minimal to no interference, so you feel comfortable.

If at all you suffer any injury, illness, or complication(s) by participating in this study, kindly contact us immediately using the contact details provided at the bottom of this form. The study clinician will attend to you, and if further assessment or treatment is needed, you will be referred accordingly.

What Benefits are you going to accrue by participating in the Study

What Will it Cost You to Participate in the Study?

i. Contribution to Knowledge: Participants contribute to advancing scientific knowledge in the field of diagnostic laboratories, benefiting the broader scientific community.

ii. Professional Development: Engaging in the study allows participants to reflect on their own practices, leading to personal and professional growth.

iii. Improved Practices and Quality of Care: Findings from the study may inform recommendations and best practices, leading to enhanced processes and better patient care.

Will Any Expenditure that You Incur by Participating in the Study be Refunded? Or will you be paid for participating in the Study?

There will be no cost associated with participating in this study.

In Case I have any Further Questions/Concerns in the Future, Whom Should I contact?

If you need further clarification or have questions about your continued participation in the study, feel free to contact the PI at {*0705-290520*}. In case of concerns regarding your rights and/or obligations as a research participant, do not hesitate to contact the secretary, KUREC on {*KUREC: kurec@kabarak.ac.ke*}

What Alternative Options Are Available to Me?

The decision to participate is entirely voluntary. You will be free to withdraw from the study at any point during the survey without providing any explanation.

How Will the Findings of this Study Be Communicated or Shared?

The study findings will be communicated through scientific publications, conference presentations, and, potentially, policy briefs or reports.

Statement of Consent

I have comprehensively read the consent form, and/the information has been comprehensively read to me by the researcher. I have understood what the study is about, and all the questions and concerns I had have been addressed in a clear and concise manner. The study benefits and foreseeable risks have been explained to me. I totally understand that my decision to participate in this study is voluntary, and I have the right to withdraw at any point during the study.

I freely consent to participate in this study.

Signing this form does not in any way imply that I have given up the rights I am entitled to as a participant.

I agree to participate in this research. YES____________________________NO_________

I agree to provide my contact details for follow-up. YES________________NO_________

Participant's Name ____

Participant's Signature/Thumbprint______________________Date ____________________

Appendix IV: List of Diagnostic Laboratories in Nakuru County

1	Pathologists Lancet Kenya
2	PathCare Kenya Ltd
3	Metropolis Star Lab
4	ScanLab Center CDN
5	Vivax Medical Clinic and Laboratories
6	Jalaram Diagnostics Center Nakuru
7	Nakuru Specialist Hospital
8	Nakuru Level 6 Hospital
9	Bliss Medical Center, Nakuru
10	Menengai Medical Clinic Laboratory
11	AAR Healthcare Nakuru
12	Bridgids Medical Services
13	Valley Hospital
14	Quality Modern Hospital
15	Algadir Medical Center
16	Mediheal Hospital Clinic
17	The Karen Hospital, Nakuru
18	Fountain Medical Center

Appendix V: KUREC Clearance Letter

KABARAK UNIVERSITY RESEARCH ETHICS COMMITTEE

Private Bag - 20157
KABARAK, KENYA
Email: kurec@kabarak.ac.ke

Tel: 254-51-343234/5
Fax: 254-051-343529
www.kabarak.ac.ke

OUR REF: KABU01/KUREC/001/01/12/23

Date: 5th December, 2023

Michael Walekhwa,
REG No. GMB/NE/3220/09/19
Kabarak University

Dear Michael,

RE: INFLUENCE OF TOTAL QUALITY MANAGEMENT PRACTICES ON THE STRATEGIC COMPETITIVENESS OF SELECTED DIAGNOSTIC LABORATORIES IN NAKURU COUNTY

This is to inform you that ***KUREC*** has reviewed and approved your above research proposal. Your application approval number is ***KUREC-011223.*** The approval period is ***5/12/2023 – 5/12/ 2024.***

This approval is subject to compliance with the following requirements:

i. All researchers shall obtain an introduction letter to NACOSTI from the relevant head of institutions (Institute of postgraduate, School dean or Directorate of research)
ii. The researcher shall further obtain a RESEARCH PERMIT from NACOSTI before commencement of data collection & submit a copy of the permit to **KUREC.**
iii. Only approved documents including (informed consents, study instruments, MTA Material Transfer Agreement) will be used
iv. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***KUREC***:
v. Death and life-threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***KUREC*** within 72 hours of notification;
vi. Any changes, anticipated or otherwise that may increase the risk(s) or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to ***KUREC*** within 72 hours;
vii. Clearance for export of biological specimens must be obtained from relevant institutions and submit a copy of the permit to KUREC;
viii. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal and;
ix. Submission of an executive summary report within 90 days upon completion of the study to ***KUREC***

Sincerely,

KABARAK UNIVERSITY
INSTITUTIONAL RESEARCH ETHICS COMMITTEE
APPROVED
P.O. PRIVATE BAG - 20157, KABARAK

Prof. Jackson Kitetu PhD.
KUREC-Chairman

Cc Vice Chancellor
DVC-Academic & Research
Registrar-Academic & Research
Director-Research Innovation & Outreach
Institute of Post Graduate Studies

As members of Kabarak University family, we purpose at all times and in all places, to set apart in one's heart, Jesus as Lord (1 Peter 3:15)
Kabarak University is ISO 9001:2015 Certified

Appendix VI: NACOSTI Research Permit

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **800872**

Date of Issue: **09/January/2024**

RESEARCH LICENSE

This is to Certify that Dr.. Michael Nyongesa Walekhwa of Kabarak University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Nakuru on the topic: INFLUENCE OF TOTAL QUALITY MANAGEMENT PRACTICES ON THE STRATEGIC COMPETITIVENESS OF SELECTED DIAGNOSTIC LABORATORIES IN NAKURU COUNTY for the period ending : 09/January/2025.

License No: **NACOSTI/P/24/32390**

800872

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions

Appendix VII: Evidence of Conference Participation

KABARAK UNIVERSITY

Certificate of Participation

Awarded to

Michael Walekhwa

for successfully participating in the 13th Annual Kabarak University International Research Conference held from 23rd – 24th June 2023 and presented a paper entitled ***"Influence of Total Quality Management Practices Implementation on the Strategic Competitiveness of Selected Diagnostic Laboratories in Nakuru County: A Scoping Review."***

Conference Theme

Bridging the Gaps in Global Health

Dr. Pamela Kimeto
Dean, School of Medicine and Health Sciences

Dr. Moses Thiga
Director - Research, Innovation and Outreach

Kabarak University Moral Code

As members of Kabarak University family, we purpose at all times and in all places, to set apart in one's heart, Jesus as Lord.

(1 Peter 3:15)

Kabarak University is ISO 9001:2015 Certified

Appendix VIII: List of Publication

Kabarak Journal of Research & Innovation Volume 16 Number 1 (2026)
ISSN 2305-784X (print) ISSN 2410-8383 (online)
https://journals.kabarak.ac.ke/index.php/kjri/

PROCESS MANAGEMENT PRACTICES AND THEIR INFLUENCE ON THE STRATEGIC COMPETITIVENESS OF DIAGNOSTIC LABORATORIES IN NAKURU COUNTY, KENYA

Authors:
Michael Walekhwa[1] [https://orcid.org/0000-0003-1337-1284]
Simon Kipchumba[1] [https://orcid.org/0000-0002-5006-6388]
Nehemiah Kiplagat[1] [https://orcid.org/0009-0002-5199-3770]

Affiliations:
[1] School of Business and Economics, Kabarak University, Private Bag, Nakuru, Kenya.

Corresponding Author:
Michael Walekhwa – E-mail: mwalekhwa@kabarak.ac.ke

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ABSTRACT

Effective process management is central to and plays a critical role in enhancing the operational efficiency and strategic competitiveness of diagnostic laboratories. Despite its importance, empirical evidence on how process documentation, monitoring, and standardization shape competitiveness in lowand middle-income settings remains limited. This study examined the influence of process management practices on the strategic competitiveness of diagnostic laboratories in Nakuru County, Kenya.A cross-sectional analytical study was conducted among 38 respondents drawn from public and private diagnostic laboratories. Data were collected using structured questionnaires and supplemented with qualitative insights from open-ended responses. Descriptive statistics, chi-square tests, and Pearson correlations were used to analyze quantitative data. Key process management variables included QMS documentation, process review frequency, performance metrics, communication practices, improvement pathways, and stakeholder interfaces. Strategic competitiveness was assessed through perceived quality, customer satisfaction, and financial indicators. Adoption of process management practices was high, with 90.5% of laboratories implementing documented QMS and all maintaining written procedures. Metrics availability showed strong correlations with monitoring frequency ($r = .726$, $p < .01$), communication frequency ($r = .715$, $p < .01$), and pursuit of improvements ($r = .645$, $p < .01$). Documented QMS significantly predicted the use of structured stakeholder feedback systems ($\chi^2 = 13.263$, $p = .004$, $\varphi c = .795$) and ROI monitoring ($\chi^2 = 5.185$, $p = .023$, $\varphi c = .509$). Qualitative responses highlighted challenges such as outdated SOPs, workload pressure, and limited infrastructure. Nonetheless, standardized processes, regular reviews, and clear communication were reported to enhance reliability, compliance, and stakeholder confidence. Overall, 90.4% of laboratories rated their quality performance as "Good" or "Excellent.Strong process management practices including documentation, regular monitoring, structured improvement, and stakeholder engagement significantly enhance strategic competitiveness.