Journal: Texila International Journal of Public Health
Publisher: Texila International Journal
ISSN: 2520-3134
Volume 13 Issue 4, 2025
DOI: 10.21522/TIJPH.2013.13.04.Art037

Quality at the Core: Strengthening Healthcare Delivery in Sub-Saharan Africa through Laboratory Quality Management Systems

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Abstract

Laboratory Quality Management Systems (LQMS) are pivotal in ensuring accurate, reliable, and timely diagnostic services, which are foundational to effective healthcare delivery. In Sub-Saharan Africa, the role of LQMS has become increasingly critical due to the region's diverse healthcare challenges and resource constraints. This review systematically examines the multifaceted impact of LQMS on healthcare systems within the region, drawing from a broad spectrum of scholarly literature and case studies. Key areas explored include enhancing diagnostic accuracy, improving operational efficiency, and facilitating timely clinical interventions. The review further investigates how LQMS fosters compliance with international quality standards such as ISO 15189 and ISO/IEC 17025, supports laboratory accreditation, and promotes trust among healthcare providers and patients. Additionally, the paper assesses the impact of LQMS on public health outcomes by examining its role in disease surveillance, outbreak response, and health system resilience. Challenges related to LQMS implementation, including infrastructural limitations, workforce capacity, and regulatory inconsistencies, are critically assessed. Moreover, the benefits and limitations of standardization in laboratory practices under LQMS frameworks are discussed, highlighting the importance of metrological traceability and global coordination. Through a structured thematic analysis, this review highlights the importance of strategic investment in quality management infrastructure, stakeholder training, and policy development to fully realize the potential of LQMS in enhancing healthcare delivery across Sub-Saharan Africa.

Keywords*: Healthcare Delivery, Laboratory Accreditation, Laboratory Quality Management System, Public Health Laboratories.*

Introduction

The integrity and effectiveness of modern healthcare systems are heavily reliant on the accuracy, reliability, and timeliness of laboratory test results. Laboratory Quality Management Systems (LQMS) serve as a strategic foundation for achieving these objectives by embedding systematic processes that govern the technical and managerial activities within laboratories. These systems are critical for ensuring diagnostic precision, guiding appropriate clinical interventions, and improving overall patient outcomes [1, 2].

A Quality Management System (QMS) provides a structured framework for planning, controlling, and continuously improving all laboratory operations that influence test outcomes and user satisfaction. Within this context, LQMS constitutes a specialized

Received: 01.08.2025 ***Accepted: 25.09.2025*** ***Published on: 24.12.2025***
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application of QMS tailored to the complex demands of clinical, research, regulatory, and public health laboratories. Through the enforcement of standardized protocols and quality assurance procedures, LQMS mitigates errors, reduces variability, and enhances reproducibility in laboratory outputs [1, 2].

Beyond accuracy and standardization, LQMS significantly contributes to operational efficiency. It enables laboratories to optimize resource utilization—including human resources, instrumentation, and consumables—thereby expediting turnaround times without compromising quality. Efficient laboratory workflows are crucial for time-sensitive clinical decision-making, especially in high-demand healthcare environments [2].

Furthermore, the implementation of LQMS is integral to achieving and maintaining compliance with internationally recognized standards such as ISO 9001:2015, ISO/IEC 17025:2017, ISO 15189:2022, and WHO prequalification. Accreditation under these frameworks serves as a formal acknowledgment of a laboratory's technical competence and quality assurance capabilities. This not only boosts institutional credibility but also fosters confidence among patients, clinicians, regulatory agencies, and funding bodies [2].

The broader implications of LQMS extend into the realms of health economics and public health. By reducing diagnostic errors and eliminating redundant testing, LQMS contributes to cost-effectiveness in healthcare service delivery. Reliable and consistent laboratory services strengthen clinical decision-making, improve health outcomes, and elevate public trust in healthcare systems. Moreover, LQMS supports national and global public health objectives by ensuring the integrity of laboratory data used for disease surveillance, outbreak management, regulatory decisions, and health policy formulation [2].

Considering these multifaceted benefits, the adoption of robust LQMS frameworks is indispensable for healthcare systems aiming to deliver high-quality, evidence-based, and patient-centered care. LQMS not only enhances individual laboratory performance but also serves as a critical pillar in the architecture of modern, resilient, and responsive healthcare delivery.

Research Objective

This systematic narrative review aimed to comprehensively evaluate the impact of Laboratory Quality Management Systems (LQMS) on laboratory performance and healthcare delivery in resource-limited settings of Africa. Specifically, it investigates how LQMS influences diagnostic accuracy, operational efficiency, cost-effectiveness, standardization of practices, compliance with international accreditation standards, customer satisfaction, and overall public health outcomes. The objective is to identify the key benefits, challenges, and enablers of LQMS implementation, thereby providing strategies for sustainable quality improvement in laboratory services.

Materials and Methods

This comprehensive review employed a systematic search with a narrative analysis to evaluate the roles and impact of LQMS in healthcare delivery, particularly within the context of Sub-Saharan Africa. The review was strategically guided by well-defined research questions, which enabled focused inquiry across multiple thematic domains.

Study Selection Criteria and Screening Process

To identify relevant literature, a systematic search was conducted across three major electronic databases, including PubMed, Scopus, and Web of Science. The study employed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, which were used to screen the articles [15].

Studies were selected based on predefined inclusion and exclusion criteria, which considered factors such as publication timeframe, language (English), study designs, and geographical relevance to Sub-Saharan Africa. The inclusion criteria encompassed peer-reviewed journal articles, publicly accessible reports, theses, conference proceedings, and academic projects published between January 2001 and May 2025.

Search Strategy

The search strategy utilized specific keywords and controlled vocabulary terms related to "laboratory quality management systems," "healthcare delivery," "laboratory accreditation," and "public health laboratories" together with Boolean operators (AND, OR, NOT) to enhance retrieval precision. The articles obtained from screening were imported into EndNote. Initially, duplicates were removed. Later, the search results underwent a two-tiered screening process: firstly, titles and abstracts were reviewed to eliminate articles not related to the study; secondly, full-text of the included articles was retrieved and assessed based on the eligibility criteria/research scope. The articles that met the eligibility criteria were included in the present review.

Data Extraction and Analysis

A narrative approach was used to synthesize the findings in addition to thematic analysis. Emerging patterns were categorized under six major thematic areas aligned with the research questions, facilitating a structured and coherent presentation of results. The present study used a rigorous methodological framework that ensured a transparent, reproducible, and in-depth exploration of existing literature on LQMS, enabling a well-grounded discussion of its significance in strengthening healthcare systems across diverse laboratory settings.

Results

An initial search retrieved approximately 5,000 Pub1000 records. After the removal of duplicates and non-relevant entries through title, abstract, and full-text screening, a total of 40 studies were included in the final synthesis. The PRISMA-ScR flow diagram details the identification, screening, and selection process from the initial search to the final inclusion of studies (Figure 1).

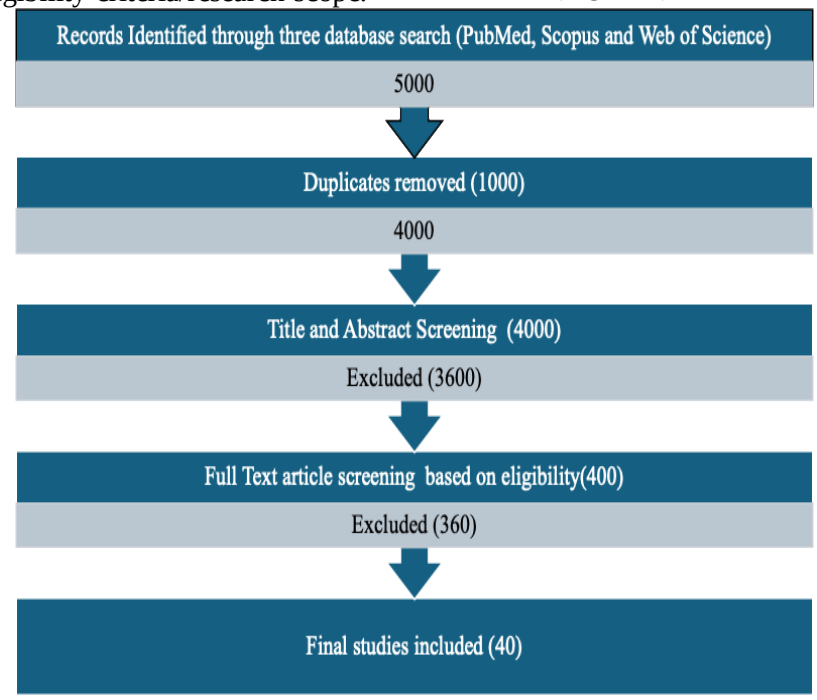

Figure 1. Systematic Review Study Selection Flowchart (PRISMA-ScR)

The Role of Laboratory Science, Global Health and LQMS in Medical and Public Health Laboratories

Babyar (2020) highlights the role of medical laboratory science in advancing global health, recognizing its contributions to healthcare delivery, disease surveillance, and scientific advancement. Despite increasing recognition of both clinical and biomedical laboratories, their effectiveness is hindered due to operational inefficiencies, workforce shortages, and fragmented regulatory environments [15]. The researcher advocated strategic reforms, including standardized credentialing, explicit regulatory frameworks, and improved public-private coordination to strengthen laboratory systems [15]. A globally integrated laboratory ecosystem characterized by a well-prepared workforce, harmonized standards, and collaborative research agendas—are essential for improving population health outcomes [15]. Central to this is the role of laboratory accreditation and compliance with quality standards. International accreditation systems and regional initiatives such as the WHO AFRO aim to build resilient and high-performing laboratory networks. While progress has been made, sustained investment, policy reforms, and international collaboration remain critical to overcome implementation challenges [9, 6, 11-15].

Medical and public health laboratories are cornerstones of healthcare delivery, particularly in disease diagnosis, monitoring, treatment, and response to outbreaks. A paucity of efficient laboratory services may result in misdiagnosis, irrational medication use, avoidable hospitalizations, and poorer patient outcomes[5]. Recognizing these critical challenges, especially in resource-constrained settings in African countries, the importance of LQMS has been emphasized since 2010. A quality laboratory system is defined by adherence to internationally accepted standards, ensuring test accuracy, reliability, and timeliness. [5]. Additionally, the ISO 15189 and ISO 17025 standards, as well as the World Health Organization (WHO) prequalification, serve as the benchmark for the competence of medical, general, and pharmaceutical laboratories, certifying labs capable of delivering high-quality test results. Accreditation and/or prequalification to this standard/guideline affirms a lab's technical proficiency and strengthens its role in clinical and regulatory decision-making and public health policy. [6].

Significance of Enhancing Accuracy and Reliability

For research, clinical diagnostics, testing, and manufacturing laboratories to operate effectively and efficiently, an LQMS is essential. The significance of having a strong and flexible LQMS is becoming increasingly clear considering changing technological environments and growing operational demands. These systems support a variety of activities, from clinical testing and research to regulatory compliance, by guaranteeing the timeliness, accuracy, reproducibility, and dependability of laboratory outputs [3, 4]. An effective LQMS helps avoid crucial mistakes that can jeopardize data integrity and institutional credibility by offering a systematic framework for identifying and reducing risks. Choosing an LQMS model that is appropriate for the functions of the laboratory is crucial, considering the variety of models that are available, ranging from regulatory frameworks to consensus standards. Sustainable development and scientific progress are fostered by efficient implementation that is based on fundamental quality principles [3, 4]. Overall, a thorough LQMS aligns laboratory performance with more public health objectives while improving operational efficiency and result accuracy as well as institutional reputation [3].

Implementation of LQMS in African Countries

Implementing an LQMS and achieving ISO 15189 accreditation in Africa has been hindered by inadequate infrastructure, limited technical capacity, and human resource shortages. However, these barriers were addressed through the introduction of phased initiatives by the World Health Organization (WHO) and National Ministries of Health, outlined below:

1. Strengthening Laboratory Management Towards Accreditation (SLMTA): Launched in 2009, this program trained laboratory managers and staff through workshops, mentorship, and practical improvement projects that gained global traction for its measurable impact on laboratory quality [6].
2. Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA): A checklist-based assessment tool by WHO-AFRO that rates laboratory progress from zero to five stars, guiding labs towards ISO 15189 accreditation. While not certifying technical competence, SLIPTA indicated a lab's dedication to quality improvement [6].
3. Additionally, to support these efforts, tools like the LQMS training toolkit and the Laboratory Quality Stepwise Implementation (LQSI) tool were developed. to support laboratories to independently implement QMS aligned with international best practices [6].
4. Further in 2012, the African Society for Laboratory Medicine (ASLM) was tasked with enrolling 2,500 laboratories in SLIPTA to support 250 public laboratories attaining international accreditation by 2020—targets aimed at bolstering the impact of public health programs, including HIV and tuberculosis [6].

Accreditation and Quality Indicators

Accreditation ensures that laboratories implement quality systems effectively, enhancing technical operations, service delivery, and market competitiveness. This process hinges on comprehensive LQMS implementation, guided by both management and technical requirements [4, 7]. Quality indicators play a key role in benchmarking laboratory performance and guiding continuous improvement. Adherence to these indicators supports accreditation efforts and prevents service degradation due to quality system lapses [7-9]. Mulleta et al. (2021), an Ethiopian study, revealed that only 20.2% of health center laboratories had significantly improved services, achieving over 55% of quality targets. Factors linked to better performance included the presence of standard operating procedures (SOPs), proper documentation, preventive maintenance, regular staff meetings, customer feedback reviews, quality plans, result verification procedures, specimen guidelines, and established quality indicators [4, 10]. The study highlighted the importance of a structured QMS in ensuring the accuracy, reliability, and timeliness of laboratory results.

Impact of Implementation of LQMS on Patient Outcomes and Public Health

The implementation of LQMS is instrumental in improving the quality, accuracy and timeliness of diagnostic services, thereby influencing the patient outcomes and public health disease management. A cross-sectional study conducted in 2017 across selected Ethiopian government hospitals assessed awareness of LQMS implementation among 184 laboratory professionals [9]. While awareness of LQMS was universal among respondents, only 79% were actively involved in its implementation. Among 18 LQMS components evaluated, five exhibited weak implementations: internal quality control for all tests, development and dissemination of quality manuals, adequacy of storage space, action planning based on internal audits, and monitoring of environmental conditions.

Internal quality control practices across all test types emerged as a significant challenge [9].

Beyond individual facility assessments, systemic barriers continue to hinder access challenges to diagnostic services across Africa. The African Society for Laboratory Medicine (ASLM) and the Africa Centres for Disease Control and Prevention (Africa CDC) persistent constraints on human resources, funding, and technical capacity severely limit laboratory performance. Furthermore, the lack of standardized systems for evaluating and registering new diagnostic tools delays the adoption of improved technologies, compounding the diagnostic gap [6].

The public health consequences of these systemic gaps are far-reaching. For example, despite well-established HIV programs, approximately 40% of HIV-positive individuals on antiretroviral therapy do not receive the recommended annual viral load monitoring. In 2016, 21% of infants born to HIV-positive mothers in West and Central Africa did not get access to early diagnostic testing within eight weeks of life—a critical window for effective intervention. Similarly, the tuberculosis (TB) burden remains high, with the WHO's 2016 Global TB report revealing that nearly 70% of TB cases were unreported in Africa. In half of African countries, fewer than 10% of patients had access to rifampicin resistance testing, and only 60% of countries offered second-line drug resistance testing [6].

Efforts to address shortcomings have included strategic declarations aimed at strengthening laboratory systems. The Freetown Declaration of 2015, built on the earlier Maputo Declaration, advocated the delivery of diagnostic services through integrated national laboratory networks. These networks were designed to provide comprehensive, equitable, and cost-effective diagnostic services. Despite disease-specific investments—particularly in HIV and TB—national laboratory systems remained under-resourced and fragmented. This dysfunction limits Africa's capacity to effectively implement the "prevent, detect, respond" framework that underpins public health security. The consequences were substantial: in 2015 alone, Africa experienced and estimated $2.4 trillion in productivity losses and 630 million years of healthy life lost due to disease burden [6].

Additionally, diagnostic access remains critically low for diseases without dedicated international programs. For instance, nearly 90% of individuals infected with hepatitis B or C remain undiagnosed, despite these viruses causing 60% of liver cancer cases. In Senegal (2015–2016) it was found that <30% of pregnant women at the primary care level received essential diagnostic tests for conditions critical to maternal and child health. Also, inadequate cervical cancer screening had led to delayed diagnosis, with nearly half of related deaths attributed to late detection. Notably, only 2 out of 55 African countries had the capacity to detect the SARS-CoV-2 virus when the first COVID-19 case emerged in Egypt in February 2020 [6].

Such diagnostic gaps significantly compromise timely disease detection, appropriate treatment, and broader healthcare quality, impeding progress toward Universal Health Coverage (UHC). To mitigate these gaps, the ASLM and Africa CDC report recommended adopting robust, affordable, context-appropriate diagnostic solutions for low-resource settings. Tools such as rapid diagnostic tests (RDTs), community-level or self-testing kits, and point-of-care molecular technologies (e.g., GeneXpert® and m-Pima®) have shown promises in enhancing diagnostic speed and accuracy. However, the full potential of these technologies is often underutilized due to fragmented implementation, weak systems integration, and critical infrastructure gaps, particularly in supply chain management, sustainable financing, and trained workforce availability [6].

Evolution of Accreditation and International Standards Compliance

The evolution of laboratory accreditation has shifted from a narrow focus on procedural compliance to a more comprehensive and globally integrated system of quality assurance. While early accreditation frameworks primarily ensured adherence to established protocols, the contemporary models emphasize sustained quality improvement, risk-based thinking, and cross-border credibility in an increasingly globalized and technologically advanced landscape [11].

Central to this evolution has been the widespread adoption of international standards such as ISO/IEC 17025, which defined broader requirements for the competence of testing and calibration laboratories. These standards have provided a formalized structure for implementing robust quality systems, promoting global trust in laboratory results. National and international accreditation bodies, supported by mutual recognition agreements, have further enhanced the credibility of laboratory results worldwide, streamlining trade and cross-border cooperation [11]. The role of international bodies—such as the International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF)- has been critical in this transformation. Through mutual recognition arrangements, these organizations have facilitated greater alignment among national accreditation, bodies, streamlining international trade, cross-border collaboration and research initiatives [11].

Technological innovations have further strengthened accreditation processes. Innovations in data management, traceability, and quality control have significantly improved efficiency and accuracy and transparency of laboratory operations. Consequently, accreditation is now firmly recognized as a cornerstone of quality assurance—bolstering confidence in laboratory testing across healthcare systems, regulatory agencies, and commercial sectors worldwide.

The WHO AFRO Model: Stepwise Accreditation in Resource-Limited Settings

In many low-and-middle-income countries, resource constraints, systemic complexity, and infrastructure limitations hinder full compliance with international laboratory standards. To address these challenges, the World Health Organization Regional Office for Africa (WHO AFRO) developed and implemented the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) tailored to facilitate gradual progress toward ISO 15189 compliance in resource-constrained settings [12]. SLIPTA employs a 0- to 5-star rating system to evaluate laboratory performance against a standardized checklist. Laboratories scoring below 55% receive no stars, while those who meet or exceed 95% are awarded the highest five-star rating. This scalable model allows laboratories to benchmark progress, receive targeted feedback, and implement continuous improvement strategies [12]. However, it is important to note that SLIPTA is not a substitute for ISO 15189accreditation but rather a transitional mechanism. It encourages high-performing laboratories to build capacity incrementally while pursuing full international compliance. The framework effectively addresses affordability, sustainability, and accessibility challenges, making it a practical solution for elevating laboratory quality and promoting harmonization with global standards [12].

Strengthening Laboratory Systems through Quality Control and Management

Effective quality management and control mechanisms are essential for ensuring the safety and reliability of medical products and healthcare services. In West Africa, national and regional quality control laboratories serve a central role in verifying the reliability of testing services and strengthening public health

infrastructure. However, sustained improvements in laboratory Quality Management Systems (QMS) require long-term, collaborative investments from all stakeholders, along with a focus on continuous learning and system-wide integration [13]. A qualitative study in Rwanda assessed LQMS implementation and sustainability across selected laboratories using semi-structured interviews and performance metrics [14]. The findings revealed significant improvements in key service indicators such as turnaround time, patient wait time, and result accuracy following LQMS adoption. Crucial success factors included supportive hospital management, consistent staff training, efficient procurement processes, and recognition of professional qualifications of laboratory professionals. However, persistent challenges—such as limited training opportunities, inadequate infrastructure, delays in reagent procurement, and difficulties in maintenance service contracting—posed threats to long-term sustainability [14]. To maximize impact, the authors recommended strengthening procurement systems, improving supply chain efficiency, and reviewing inventory management protocols. Strengthening these components is vital for sustaining LQMS implementation across the health sector [14].

Persistent Gaps in LQMS Implementation

Despite measurable progress in accreditation and quality system strengthening, several core LQMS components continue to exhibit limited implementation. A study evaluating 18 core LQMS components found that five were especially weak: performance of internal quality control for all tests, development and dissemination of comprehensive quality manuals, adequacy of storage space, formulation of action plans following internal audits, and monitoring of environmental conditions. Internal quality control was a widespread challenge [10]. Similarly, a review of 12 key quality indicators in another lab in sub-Saharan Africa revealed poor or very poor performance in areas critical to overall system reliability: document control (77.7%), record control (70.3%), development of manuals and policies (69.7%), process and procedure development (68.6%), and internal communication (65.1%). These findings highlight internal quality control, documentation practices, and storage infrastructure as priority areas requiring intervention [9].

From Framework to Function: Country Experiences in Enhancing Laboratory Efficiency and Resource Use

Execution of LQMS in Nigeria

The use of Quality Management Systems (QMS) in Nigerian medical laboratories is still nascent, with a restricted number of institutions attaining accreditation. The implementation of Quality Management Systems (QMS) has predominantly focused on Government National Regulatory Agencies and few other private facilities. These agencies oversee private regulated laboratories and public health laboratories addressing infectious diseases such as HIV/AIDS and tuberculosis, driven by initiatives from the World Health Organization's African Region (WHO AFRO), particularly the Strengthening Laboratory Management Toward Accreditation (SLMTA) and Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) programs. These approaches have markedly improved and maintained quality management in designated institutions.

Notwithstanding these advancements, certain obstacles endure. Laboratories persist in facing insufficient infrastructure, ongoing funding limitations, equipment deficiencies, climate-related obstacles, and restricted training chances. Moreover, a deficiency of driven individuals further hinders advancement. Despite major strengths, especially in laboratory safety and the application of ISO/IEC 17025 and ISO 15189

core quality standards, substantial deficiencies persist in document control, internal audits, and occurrence management [16]. The successful implementation of a Quality Management System (QMS) in Nigeria necessitates a systematic approach, reinforced by robust managerial support, compliance with national health standards, active engagement in External Quality Assurance (EQA) programs, and a transformative culture shift among laboratory personnel. Despite the growing awareness of QMS advantages, considerable efforts remain necessary to enhance comprehension, tackle implementation obstacles, and broaden QMS integration throughout public and private laboratories countrywide [16].

Regional Capacity Development via SRL Training for LQMS in Uganda

The Supranational Tuberculosis Reference Laboratory (SRL) in Uganda exemplifies regional capacity enhancement by delivering specialized Laboratory Quality Management System (LQMS) training to National Tuberculosis Reference Laboratories (NTRLs) across 21 countries since 2015. The training, carried out from 2017 to 2021, was assessed utilizing the Kirkpatrick model, which evaluates reactivity, learning, behavior, and outcomes [17]. The evaluation findings indicated significant success. Most participants achieved scores exceeding 80% on post-training evaluations, with 14 of the 18 laboratories exhibiting quantifiable enhancements in quality practices. Moreover, other laboratories obtained elevated SLIPTA ratings, and five NTRLs successfully secured ISO 15189:2012 accreditation by 2021, with one maintaining its position. Participant response robustly affirmed the program's pertinence and influence, highlighting its efficacy in improving laboratory quality systems and reinforcing best practices [17].

Regulatory Reformation and Operational Superiority in Tanzania

Tanzania's pharmaceutical regulatory framework exemplifies how operational efficiency can be markedly enhanced via a systematic and comprehensive quality management strategy. Essential facilitators of this change comprised a comprehensive legal and policy framework that defined roles and norms, inclusive stakeholder involvement promoting multi-sector collaboration, and continuous capacity-building programs to enhance institutional competency [18]. Moreover, proficient organizational leadership was crucial in directing reforms, promoting adaptation, and guaranteeing the continuity of implementation. The amalgamation of these factors revolutionized Tanzania's regulatory framework from early ineffectiveness to a position of prominence in the East African area. The success of this change underscores the significance of strategic leadership, partnerships, and resilience in the establishment of adaptive and sustainable regulatory frameworks [18].

Hybrid Mentorship for Laboratory Accreditation in Malawi

The COVID-19 epidemic significantly disrupted laboratory certification initiatives, especially for programs reliant on in-person support and supervision. In Malawi, the pursuit of ISO 15189 accreditation for HIV molecular laboratories necessitated a swift strategic adjustment. The answer entailed the implementation of a hybrid mentorship model that integrated virtual and in-person training and evaluation [19]. The initiative commenced with a cohort of five laboratories chosen based on performance criteria, implementing weekly virtual mentorship meetings alongside in-person audits as travel limitations were progressively eased. A further cohort of four laboratories was then incorporated into the identical hybrid architecture. The mentorship comprised the electronic submission of

progress reports, virtual capacity-building workshops, and ongoing remote interaction with technical specialists [19]. The results were notable: within three years, 90% of the collaborating laboratories attained ISO 15189 accreditation. The hybrid method was both cost-effective and displayed adaptability and resilience in addressing issues related to limited resources and public health emergencies. The efficacy of this methodology highlights the significance of continuous, adaptable mentorship approaches in improving laboratory standards and attaining certification under intricate circumstances [19].

Thus, operational efficiency and resource management are crucial for attaining sustainable laboratory quality. The early-stage QMS adoption in Nigeria, Uganda's cross-national LQMS training activities, Tanzania's legislative reforms, and Malawi's mentorship innovations during the pandemic illustrate the imperative for flexible, well-supported, and contextually relevant quality initiatives. Advancing infrastructure, enhancing staff capacity, and fortifying institutional leadership—while utilizing technology and fostering regional collaboration—will be essential for establishing robust and high-performing laboratory systems throughout Africa [19].

Customer Satisfaction

Customer satisfaction is a cornerstone of quality assurance in medical laboratory services and is embedded within internationally recognized Quality Management System (QMS) frameworks such as ISO 9001, ISO 15189, and ISO 17025. These standards recognize patients and their families, healthcare professionals, and institutional stakeholders as primary customers whose feedback is critical to service improvement. Monitoring customer satisfaction is not only a regulatory requirement but also a strategic tool for enhancing service delivery and fostering trust in healthcare systems [20].

Integrating Patient Feedback into QMS

To systematically incorporate customer insights, laboratories are encouraged to implement structured service satisfaction surveys. These surveys are typically designed and administered by quality officers or laboratory directors following ISO standards, ensuring consistency and reliability in feedback collection [19]. By targeting all client groups that interact with laboratory services, including patients, clinicians, and support staff, these surveys offer a holistic view of service performance. Administered at regular intervals, these surveys support real-time monitoring of performance and timely identification of service gaps, procedural errors, or inefficiencies that may compromise quality. The results are analyzed to inform corrective and preventive actions, forming a feedback loop that drives continuous quality improvement. [20].

Benefits of QMS-Aligned Satisfaction Monitoring

The integration of patient satisfaction monitoring within a QMS framework yields several tangible benefits. Improvements in service delivery have been linked to enhanced patient experiences, faster recovery times, and a greater likelihood of patients returning for future services. Furthermore, by demonstrating responsiveness to client concerns, laboratories build confidence among healthcare users, contributing to a more reliable and patient-centered health system [20].This proactive engagement with customer feedback also reinforces the principles of Total Quality Management (TQM), promoting a culture of accountability, transparency, and continuous service enhancement. This alignment ensures laboratories remain patient-centered, transparent, and quality driven in their operations [20].

Customer Satisfaction in the Broader Public Health and Research Context

Beyond individual laboratory operations, customer satisfaction and quality assurance are increasingly relevant within the broader context of regional health cooperation in Africa. While African regional organizations have long supported national health systems, their role in enhancing health research systems, critical for addressing complex health challenges, has gained prominence in recent years, particularly considering recent public health emergencies [21]. A review of 15 regional organizations involved in health research mapped their activities across four core pillars: governance, resource creation, research production and utilization, and financing. Interviews with 18 representatives revealed that organizations with mandates in health or higher education are actively engaged in agenda-setting, policy harmonization, and knowledge dissemination. Most notably, these entities play key roles in shaping governance and promoting the use of research findings in policy and practice [21]. However, significant gaps persist in infrastructure, research capacity, and financing. While some organizations focus on strengthening human resources, few support the creation of physical infrastructure or regional research networks. Moreover, limited coordination among regional actors and insufficient advocacy capacity have constrained the potential of these bodies to fully support national health research systems [21].

These findings underscore the need for strategic engagement with regional organizations to maximize their comparative advantages in supporting national health objectives. Strengthening their role in customer-focused research, fostering infrastructure development, and building capacity for advocacy and financing can create a more cohesive and responsive regional health ecosystem. By reinforcing both service quality at the laboratory level and systemic health research at the regional level, African nations can more effectively meet current and future health challenges. Ultimately, an integrated approach—linking QMS-based customer satisfaction strategies with regional collaboration in health research—can elevate the standard of care and reinforce the resilience of healthcare systems across the continent [20, 21].

The Role of QMS in Enhancing Customer Satisfaction in Public Health Laboratories

The implementation of an LQMS in public health laboratories enhances customer satisfaction by improving the quality, efficiency, consistency, and responsiveness of services. These laboratories play a pivotal role in surveillance, outbreak response, and health system resilience. QMS-driven practices—such as continuous quality improvement, standardized procedures, feedback mechanisms, and regular performance evaluations—enable public health laboratories to provide accurate, timely, and client-centered results [22, 23]. Public health settings where timely and reliable laboratory information can influence disease control strategies and health outcomes at a population level [22]. Through structured processes such as continuous quality improvement, standardized operating procedures, customer feedback mechanisms, and regular performance monitoring, a QMS helps public health laboratories deliver high-quality, client-centered services. Satisfied customers, ranging from clinicians to public health agencies, are more likely to trust and rely on laboratory results, which are essential for effective diagnosis, treatment, and public health interventions [23].

Standardization: Benefits, Barriers and Strategic Directions

Importance of Standardization in Laboratory Testing

Standardization in the laboratory ensures consistency, accuracy, and comparability of results across healthcare systems. This

consistency is particularly critical when test results are used in conjunction with clinical guidelines or fixed reference intervals to inform medical decisions. ISO 17511:2020 serves as the international roadmap for standardization for achieving the metrological traceability, linking calibrators, control materials, and patient samples to recognized reference measurement systems [24].

Despite a clear framework, the global implementation of standardized laboratory practices face several challenges, especially in low resource settings. These include the limited availability of commutable, matrix-based certified reference materials (CRMs) and competent National Metrology Institutes (NMIs), which are fundamental to reliable calibration hierarchies. CRMs ensure that laboratory results accurately reflect patient conditions across different devices and methods. However, only a fraction of the thousands of clinically significant measurands currently have appropriate CRMs available. Similarly, only a few countries in Sub-Saharan Africa have NMI with the capacity and capability for required metrological traceability. [24]. The main barriers hindering LQMS implementation against the key enabling factors that facilitate adoption and sustainability in resource-limited settings (Table 1).

Table 1. Challenges and Enablers of LQMS Adoption in Sub-Saharan Africa

Challenges	Enablers
Infrastructure limitations	International standards (ISO)
Workforce capacity gaps	Training and mentorship programs
Regulatory heterogeneity	Stepwise accreditation models
Limited funding	Stakeholder collaboration
Lack of standardization	Regional and global coordination

Prioritization and Resource Constraints

A major outcome of an international workshop held in December 2021 was the recommendation to prioritize standardization efforts for measurands with the highest clinical impact. Tests such as creatinine, HbA1c, and prothrombin time—frequently used in chronic disease management and anticoagulation monitoring—were highlighted for immediate action. These analytes often guide high-stakes clinical decisions, making their standardization particularly urgent [24]. Developing a commutable CRM is a complex and resource-intensive process. Commutability studies are required to confirm that CRMs behave similarly to patient samples across various analytical systems, an essential characteristic for reliable calibration. Effective collaboration among NMIs, CRM producers, and in vitro diagnostic medical device (IVD-MD) manufacturers is crucial. Early involvement of IVD-MD manufacturers in the CRM development process can mitigate the technical difficulties of retrofitting calibration systems after product release, streamlining the adoption of standardized reference materials [24].

Regulatory Heterogeneity and Global Disparities

Regulatory variability among countries represents another significant barrier to global harmonization. In-vitro Diagnostics and Medical Devices (IVD-MDs) often require separate regulatory approval processes in multiple jurisdictions, each with distinct evidentiary requirements, timelines, and review mechanisms. This fragmentation increases costs and delays for manufacturers aiming to recalibrate devices annually in line with ISO standards using traceable reference standards. Notably, many recalibrations involve

mathematical adjustment factors that do not change the functional performance of devices, suggesting that a risk-based, simplified regulatory approach could be more efficient [24]. International regulatory alignment, with shared expectations and harmonized submission pathways, would significantly reduce redundancy and promote the broader adoption of standardized calibration practices. Such cooperation among regulators, standardization bodies, and manufacturers is critical to accelerating global standardization and ultimately improving patient care [24].

Advancing Standardization Through Education

An equally important aspect of standardization is building internal capacity within laboratories through education and training. A study conducted in Malta explored this dimension by assessing the training needs of laboratory professionals across various sectors, including pharmaceutical quality control, diagnostics, research, and forensic science. The aim was to improve adherence to ISO 17025:2017, a globally recognized standard for testing and calibration laboratory competence [25]. Using a validated questionnaire, the study identified a high demand for education on ISO 17025:2017, quality control procedures, measurement uncertainty, ISO 9001:2015, and Good Laboratory and Manufacturing Practices. Based on these findings, a tailored two-day course was developed and delivered to 22 personnel from forensic laboratories. The curriculum, spanning 14 hours, focused on both the theoretical foundations and practical applications of quality management systems, particularly within the forensic context [25]. Participant feedback from the course was overwhelmingly positive, with attendees citing high satisfaction with the course content, instructional quality, and organization. These results confirm the effectiveness of specialized, standard-focused training in enhancing laboratory personnel's understanding and implementation of quality standards [25]. Summarily, achieving comprehensive global standardization in laboratory medicine requires a multifaceted approach. This includes the clinical prioritization of analytes, increased production and dissemination of commutable CRMs, and streamlined, harmonized regulatory frameworks. Equally vital is the empowerment of laboratory professionals through targeted education that addresses specific gaps in knowledge of quality management systems. International collaboration across scientific institutions, regulatory bodies, industry, and educational platforms is essential to overcome technical, logistical, and policy-related barriers. By doing so, the healthcare sector can realize the full benefits of standardized laboratory testing, improved diagnostic accuracy, enhanced patient safety, and more efficient and trustworthy clinical decision-making worldwide [24, 25].

Discussion

The manuscript compiles essential findings regarding the implementation and effects of LQMS in healthcare delivery, with a focus on African countries. Using international standards such as ISO 15189 and evidence from regional programs like SLMTA and SLIPTA, the section highlights how LQMS enhances diagnostic accuracy, strengthens public health systems, improves operational efficiency, and fosters stakeholder trust. Also, it critically examines challenges related to accreditation, standardization, and sustainability, offering insights into the strategic value of LQMS in global health contexts.

Enhancing Accuracy and Reliability

The implementation of a robust LQMS, particularly aligned with international standards such as ISO/IEC 17025 and ISO 15189, significantly enhances the accuracy and reliability of diagnostic services across all laboratory phases. The pre-analytical phase is

often the most error-prone, especially in LMICs contributing to most laboratory errors [26, 27]. LQMS adoption introduces standardized procedures, an integrated framework for risk assessment, internal quality control (IQC), and external quality assessment (EQA), competent personnel, effective internal audits, and continual quality improvement, ensuring laboratories produce valid, timely, and reproducible results [26, 28, 31].

Programmes such as the SLMTA and SLIPTA—developed by WHO AFRO and partners—have been instrumental in guiding laboratories in resource-limited settings towards progressive quality improvements and accreditation. Evidence from 47 countries reported that these programmes improved document control, equipment management, turnaround times, and staff competencies—factors essential for diagnostic accuracy and institutional trust [29, 30]. Adopting LQMS strengthens institutional reputation and accountability.

Impact on Patient Care and Public Health

Reliable and well-structured laboratory systems are fundamental to delivering accurate, timely, and actionable diagnoses, which in turn directly impact patient outcomes and the effectiveness of public health systems. An effective and fully implemented LQMS reduces diagnostic errors, mitigates risk management, and improves patient outcomes (i.e., morbidity and mortality) [31]. In many LMICs, including Africa, the limited access to quality-assured diagnostics led the healthcare providers to rely on syndromic or presumptive diagnosis, particularly in rural or resource-constrained settings with implications—misdiagnosis, delayed treatment, and antimicrobial resistance [31, 32].

Functional LQMS frameworks enhance outbreak preparedness, integrate with health information systems, and support disease surveillance [32, 33]. The COVID-19 pandemic illustrated how established quality systems enabled timely molecular testing and sustained diagnostic capacity [33]. To reduce existing diagnostic gaps, especially in sub-Saharan Africa, LQMS must be included in national initiatives and backed by leadership, training, and long-term funding [31, 32].

Accreditation and International Standards Compliance

Laboratory accreditation, particularly under ISO 15189, serves as a standard for quality and proficiency [12, 34]. Although financial limitations frequently impede advancement, programs such as SLMTA and SLIPTA provide incremental, contextually relevant routes to accreditation [29, 30]. Success narratives, exemplified by Rwanda's nationwide implementation of LQMS, illustrate how policy endorsement and institutional commitment can facilitate quantifiable enhancements [30, 35].

Accreditation enhances local credibility and promotes involvement in international collaborations and clinical studies [12, 35]. Ongoing evaluation guarantees persistent adherence and fosters professional responsibility and pride, strengthening the laboratory's position within the health system.

Operational Efficiency and Resource Management

LQMS improves operational efficiency by implementing standardized workflows, defining roles clearly, and organizing documentation systematically [35]. In resource-constrained environments, this results in improved inventory management, diminished reagent waste, and enhanced utilization of workers and equipment. Insights from Nigeria and Malawi demonstrate that mentorship centered on quality and hybrid training models can maintain performance enhancements even during emergencies like the COVID-19 pandemic [36, 37].

Regional initiatives and reference laboratories have facilitated resource sharing

and capacity enhancement across borders, minimizing redundancy and expediting advancements toward certification.

Enhancing Customer Satisfaction

Customer satisfaction serves as both a quality metric and a catalyst for service enhancement in medical laboratories. Feedback systems connected with QMS enable laboratories to get insights from patients and healthcare providers, facilitating service enhancements and bolstering confidence. Research indicates that laboratories employing ISO-based Quality Management System frameworks experience improved communication, decreased turnaround times, and increased trust in test outcomes [37].

In low-resource environments, feedback loops have mitigated service bottlenecks and cultivated a culture of responsiveness and openness, essential for continued stakeholder engagement.

Standardization: Opportunities and Challenges

Standardization guarantees the comparability and precision of test outcomes across laboratories. ISO 17511:2020 establishes the metrological traceability framework essential for worldwide harmonization [39]. Nonetheless, the restricted accessibility to commutable certified reference materials (CRMs) and the disjointed regulatory frameworks continue to pose substantial obstacles.

It is essential to enhance the efficiency of regulatory approval processes, especially with recalibration [3]. Moreover, quality management must extend beyond just accreditation checklists. Pillai et al. observe that no singular Quality Management System (QMS) encompasses all World Health Organization (WHO) Quality System Essentials (QSEs), underscoring the necessity for integrated, multi-standard methodologies that prioritize continuous enhancement.

Conclusion

An effectively executed LQMS improves diagnostic precision, operational efficacy, patient confidence, and public health results. Initiatives like SLMTA and SLIPTA have demonstrated efficacy in resource-limited settings. To maintain and expand these advancements, laboratories must incorporate QMS concepts with national health policies, prioritize worker training, and promote regional and international collaboration. LQMS is not merely a technological instrument; it is a strategic investment in robust, patient-centered healthcare systems.

Conflict of interest

No conflict of interest.

Ethical Approval

Not Applicable.

References

[1]. Valdivieso-Gómez, V., Aguilar-Quesada, R., 2018, Quality management systems for laboratories and external quality assurance programs, in Quality Control in Laboratory; *IntechOpen.*

[2]. Adekoya, A., Okezue M. A., Menon, K., 2025, Medical laboratories in healthcare delivery: A systematic review of their roles and impact. *Laboratories*, **2**(1): p. 8.

[3]. Pillai, S., Calvert, J., Fox, E., 2022, Practical considerations for laboratories: Implementing a holistic quality management system. *Frontiers in Bioengineering and Biotechnology*, **10**: p. 1040103.

[4]. Akase, S., Kpera, T., 2024, Ensuring Accuracy, Ensuring Life; a Crucial Role of Quality Management Systems in Medical Laboratories. *ScienceOpen Preprints.*

[5]. Tanko, R., et al., 2021, Assessment of Clinical laboratory using WHO AFRO-SLIPTA Quality Standards in a Referral Hospital laboratory in Ghana.

[6]. Odhiambo, C. O., et al., 2023, Examining 7 years of implementing quality management systems in medical laboratories in sub-Saharan Africa. *Tropical Medicine & International Health*, 28(2): p. 126-135.

[7]. Manickam, T. S., Ankanagari, S., 2015, Evaluation of quality management systems implementation in medical diagnostic laboratories benchmarked for accreditation. *Journal of Medical Laboratory and Diagnosis,* **6**(5): p. 27-35.

[8]. Bogusz, M. J., Hassan, H., 2011, Role of accreditation procedures in maintaining quality. Quality assurance in the pathology laboratory: forensic, technical, and ethical aspects. *Taylor & Francis Group, Boca Raton,* p. 139-204.

[9]. Girma, M., Deress,T., Adane, K., 2020, Laboratory Quality Management System and Quality Indicators Implementation Status as Perceived by Laboratory Professionals in Preparation for the Accreditation Process from Selected Government Hospitals of Ethiopia. *Clinical Laboratory*, 86(4).

[10]. Mulleta, D., et al., 2021, The impact of laboratory quality management system implementation on quality laboratory service delivery in health center laboratories of Oromia region, Ethiopia. *Pathology and Laboratory Medicine International*, p. 7-19.

[11]. Dwivedi, A. P. D., 2024, Laboratory Accreditation: Evolution and Development, in Handbook of Quality System, Accreditation and Conformity Assessment, *Springer.* p. 1-18.

[12]. Gershy-Damet, G. M., et al., 2010, The World Health Organization African region laboratory accreditation process: improving the quality of laboratory systems in the African region. *American journal of clinical pathology,* 134(3): p. 393-400.

[13]. Ifudu, N. C., et al., 2023, Continual Improvement in Laboratory Quality Management System of a Regulatory Laboratory in West Africa. *The Proceedings of the BIRS Community,* 1(1): p. 9.

[14]. Kayobotsi, C., 2016, Laboratory Quality Management Systems towards Accreditation in Rwanda: A case study of selected laboratories in Rwanda.

[15]. Babyar, J., 2020, Direct reliability: strategies to revolutionize healthcare. *Journal of Public Health,* 28: p. 89-95.

[16]. Nwaokorie, F. O., Ojo, E. A., 2021, Overview of the implementation of quality management system in Nigerian medical laboratories. *University of Lagos Journal of Basic Medical Sciences,* 6 (1 & 2).

[17]. Dorothy, N., et al., 2023, Evaluating the effectiveness of Uganda's Supranational TB Reference Laboratory quality management system training program. *Human Resources for Health,* 21(1): p. 89.

[18]. Fimbo, A. M., et al., 2024, Strengthening regulation for medical products in Tanzania: An assessment of regulatory capacity development, *1978–2020. PLOS Global Public Health,* **4**(10): p. e0003241.

[19]. Moyo, H., et al., 2024, Hybrid Mentorship of Medical Laboratories to Achieve ISO 15189: 2012 Accreditation in Malawi: The University of Maryland Malawi Experience. *Global Health: Science and Practice,* 12(6).

[20]. Etukudoh, N. S., Obeta, U. M., 2021, Patients'(clients) satisfaction with medical laboratory services contributes to health and quality improvement, in Healthcare Access, *IntechOpen.*

[21]. Jones, C. M., et al., 2022, The roles of regional organisations in strengthening health research systems in Africa: activities, gaps, and future perspectives. *International Journal of Health Policy and Management,* 11(11): p. 2672.

[22]. Jane Keathley, M. S., 2012, QMS: a model for laboratory services GP26-A4. *Laboratory Medicine,* 43(1): p. 26-28.

[23]. World Health, O., 2011, Laboratory quality management system: handbook, in Laboratory quality management system: handbook.

[24]. Miller, W. G., et al., 2023, Overcoming challenges regarding reference materials and regulations that influence global standardization of medical laboratory testing results. *Clinical Chemistry and Laboratory Medicine (CCLM),* 61(1): p. 48-54.

[25]. Rivera Jr, R. L., 2021, Training needs in quality systems: a course on standards: ISO 17025: 2017.

[26]. Plebani, M., A., Aita, Sciacovelli, L., 2021, Patient safety in laboratory medicine. *Textbook of patient safety and clinical risk management,* p. 325-338.

[27]. Datema, T. A. M., 2020, Strengthening health laboratories in low-and middle-income countries through implementation of a quality management system.

[28]. Mtotela, W., 2020, Strategies for Implementing the International Organization for Standardization 15189 for Medical Laboratories.

[29]. Yao, K., et al., 2016, The SLMTA programme: Transforming the laboratory landscape in developing countries. *African journal of laboratory medicine,* 5(2): p. 1-8.

[30]. Datema, T. A. M., et al., 2020, Review of the stepwise laboratory quality improvement process towards accreditation (SLIPTA) version 2: 2015. *African Journal of Laboratory Medicine,* 9(1): p. 1-7.

[31]. Petti, C. A., et al., 2006, Laboratory medicine in Africa: a barrier to effective health care. *Clinical Infectious Diseases,* 42(3): p. 377-382.

[32]. Fleming, K. A., et al., 2021, The Lancet Commission on diagnostics: transforming access to diagnostics. *The Lancet,* 398(10315): p. 1997-2050.

[33]. Ondoa, P., et al., 2020, Preparing national tiered laboratory systems and networks to advance diagnostics in Africa and meet the continent's health agenda: Insights into priority areas for improvement. *African Journal of Laboratory Medicine*, 9(2): p. 1103.

[34]. Johnson, P. R., 2024, Quality Assurance and Quality Management of the Medical Laboratory. *Manual of Molecular and Clinical Laboratory Immunology,* 1: p. 384-392.

[35]. Ogbuka, J. C., Ogbuene, E. B., 2024, A Review of Continuous Improvement of Environmental Quality Management Standards in sub-Saharan Africa: The Nigeria Medical Laboratories perspective. *Zhongguo Kuangye Daxue Xuebao*, 29(4): p. 318-328.

[36]. Adekola, T. A., 2023, Regional cooperation, intellectual property law and access to medicines: a holistic approach for least developed countries: *Taylor & Francis.*

[37]. AlHarshan, M. S. H., 2023, The Implementation of Quality Management Systems in Laboratory, Nursing, Radiology and Their Impact on Patient Care and Safety. *Saudi J Med Pharm Sci,* 9(12): p. 802-807.

[38]. Kigozi, E., 2022, A Phenomenological Study of Tutors' Insights on the Meaning of Quality of Education in Selected Primary Teacher Training Colleges (PTTCs) in Uganda. *Education Quarterly Reviews,* 5(4).

[39]. van den Besselaar, A. M. H. P., et al., 2024, Defining a metrologically traceable and sustainable calibration hierarchy of international normalized ratio for monitoring of vitamin K antagonist treatment in accordance with International Organization for Standardization (ISO) 17511: 2020 standard: communication from the International Federation of Clinical Chemistry and Laboratory Medicine–SSC/ISTH working group on prothrombin time/international normalized ratio standardization. *Journal of Thrombosis and Haemostasis,* 22(4): p. 1236-1248.

[40]. Owino, B. O., 2023, Implementation of TQM in Healthcare Laboratory Services: Shifting from Compliance Towards a Systems Quality Improvement Approach.