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Quality Management System (QMS) Performance of Medical Laboratories in Secondary and Tertiary Healthcare Facilities in Nigeria: Results of a Multi-Facility Assessment Using the WHO SLIPTA Framework

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Abstract

Background

Quality management systems are critical for accurate, reliable, and safe medical laboratory processes. Compliance with ISO 15189:2022 demonstrates laboratory competence, supports continual improvement, and provides a pathway for national and international accreditation. Inadequate infrastructure, limited human resource capacity, and inconsistent adherence to quality standards limit QMS implementation in many Nigerian laboratories. This study aims to assess the status of QMS implementation in selected secondary and tertiary medical laboratories in Nigeria, identify performance gaps, and highlight areas for intervention.

Methods

A cross-sectional study was conducted in 60 public medical laboratories, including 10 Global Fund-supported laboratories in Lagos. Using the WHO Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) version 3 checklist, 58 certified QMS auditors conducted assessments across 36 states and the Federal Capital Territory. Data were collected using Kobo Collect and analyzed with SPSS, QGIS, Microsoft Excel, and descriptive statistics.

Results

Generally, QMS implementation was low. Forty-Seven (78.3%) laboratories achieved 0-star status; 3 (5.0%), 2 (3.3%), 5 (8.3%), and 3 (5.0%) achieved one, two, three, and four stars, respectively. Performance was strongest in Supplier and Inventory Management (56.1%) and Information Management (52.3%). The weakest domains were Assessment (19.4%), Continuous Improvement (22.0%), and Organization and Leadership (26.1%), highlighting major deficiencies in leadership, internal audits, and quality improvement systems.

Conclusion

Significant system-wide gaps remain in QMS implementation across secondary and tertiary medical laboratories in Nigeria. Strengthening leadership, workforce capacity, structured mentorship, integration of laboratory services, institutional commitment, and coordinated national quality initiatives is essential to improve laboratory quality, reliability, and patient safety while advancing laboratories toward ISO 15189:2022 compliance and accreditation

INTRODUCTION

Accurate, timely, and reliable medical laboratory services are the backbone of effective clinical care, disease surveillance, and a resilient health system. Laboratory results steer clinical decisions, confirm infections, guide treatment choices, and shape outbreak response. When clinical laboratory data cannot be trusted, patient safety, treatment adherence, and population health all pay the price [1, 2, 3].

A functioning quality management system (QMS) makes laboratory results fit for purpose. It provides the organizational framework and technical routines needed to keep results accurate, reproducible, and fit for clinical use. A standard codified internationally in ISO 15189:2022 for medical laboratories has been used to advocate and drive the implementation of quality clinical laboratory processes [4]. Gaining full ISO 15189 accreditation is difficult for many laboratories in low- and middle-income settings. The WHO Regional Office for Africa and its partners developed a more gradual route: the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist, now in its third version and aligned with ISO 15189:2022. This is often paired with a training programme called Strengthening Laboratory Management Toward Accreditation (SLMTA) [5]. SLIPTA scores a laboratory across 12 Quality System Essentials and assigns a star rating from zero to five. At the same time, SLMTA details hands-on training, mentorship, and improvement processes needed to close observed gaps following the audit [5]. Uptake of QMS across clinical laboratories has gradually been on the increase. As of 2024, 674 laboratories across 28 African countries had achieved SLIPTA certification, and auditor training has since expanded further, including new rounds aligned with the ISO 15189:2022 revision [6].

Nigeria's experience with this framework remains distinctly uneven. National reviews of QMS practice in Nigerian medical laboratories keep finding that formal quality systems are the exception rather than the rule outside a handful of disease-specific or donor-supported programmes, with infrastructural shortfalls, a shortage of trained laboratory scientists, and patchy accreditation uptake cited as recurring constraints [1, 7]. A twelve-month, government-led initiative across ten public secondary laboratories in Lagos State offers a more encouraging data point. Through this initiative, a state ministry of health drives quality improvement itself, rather than relying on a disease-specific donor programme. Using this approach, laboratories can climb the SLIPTA fairly quickly, even though most start at zero stars, but need sustained audits, mentorship, and funding to achieve the required quality level [8].

Nationally, QMS oversight sits with the Medical Laboratory Science Council of Nigeria (MLSCN), which has made QMS implementation a condition for laboratory registration and has itself joined international accreditation bodies; even so, only a small number of laboratories nationwide have been awarded full ISO 15189:2022 accreditation certificates, although perceived gaps still exist within the country [9].

Looking beyond Nigeria, a consistent pattern emerges across SLIPTA- and ISO-oriented laboratory strengthening efforts in Africa. Gaps such as internal audit, corrective action, and continual improvement are often prevalent even among well-resourced laboratories [9, 10].

In a four-country Southern African TB systems-strengthening project, staff and managers rated management support, infrastructure, and workload as bigger barriers to sustaining a QMS than technical

knowledge gaps [10]. A structured comparison of the SLIPTA checklist against Joint Commission International standards found the same trend. The requirements SLIPTA covers are mostly clustered around quality planning, quality control, and quality improvement [11]. In Ghana, a military hospital laboratory that had already achieved ISO 16189 accreditation still flagged documentation, laboratory safety, and management support as its biggest hurdles [12], while a nationwide star-rating exercise in Tanzania found similarly wide variation in laboratory readiness across primary healthcare facilities [13]. Together, these studies suggest that the managerial and behavioural side of a QMS- sustained leadership engagement, root-cause analysis, and documented follow-up- is harder to institutionalize than more procedural domains like inventory or supply-chain management, which paperwork and stock records can largely satisfy on their own.

The Secondary and Tertiary healthcare facilities in Nigeria do not play identical roles in the diagnostic network. Secondary (general) hospitals mostly carry the routine testing load that anchors primary-care referral. At the same time, tertiary centres add specialized testing, complex case management, and training of the next generation of medical laboratory scientists. A weak QMS carries different risks at each level, including, but not limited to, delayed diagnosis and referral at the secondary tier, compromised specialist care and training quality at the tertiary tier. Yet evidence comparing QMS maturity across both facility types nationally, using a standardized tool such as SLIPTA, remains thin.

Recent Nigerian QMS evaluations have tended to focus on a handful of facilities within one state or one donor programme rather than a genuinely national sample and representation [7, 8]. This is the gap the present study sets out to close. This study aimed to conduct a national QMS evaluation of selected secondary and tertiary healthcare facilities across the nation, measure the baseline QMS performance of selected secondary and tertiary laboratories across all 12 SLIPTA domains, identify the strengths and gaps that recur across those domains, including any differences by geopolitical zone; and build an evidence-based baseline that can guide where national interventions, mentorship, and resources are needed.

METHOD

Study design

This baseline evaluation followed a descriptive, cross-sectional audit design. It formed part of a nationwide QMS-strengthening intervention led by the Federal Ministry of Health and Social Welfare (FMoH&SW) through its Medical Laboratory Services Division (MLSD), funded under the Global Fund's Resilient and Sustainable Systems for Health (RSSH) grant and implemented jointly with the National Agency for the Control of AIDS (NACA).

Study setting and sample

Sixty-six (66) secondary and tertiary public medical laboratories were enrolled across all 36 states of Nigeria and the Federal Capital Territory (FCT), including 10 Global Fund-supported laboratories in Lagos State. Sixty of these returned complete, analysable Kobo Collect submissions and form the analytic sample for the domain-specific and star-rating results reported below; the remaining six records were excluded because of incomplete data capture.

Audit instrument

QMS performance was assessed with the WHO AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) version 3 checklist [5], which evaluates 12 Quality System Essentials: Documents and Records, Organization and Leadership, Personnel Management, Customer Focus, Equipment Management, Assessment, Supplier and Inventory Management, Process Management, Information Management, Nonconforming Events, Continual Improvement, and Facilities and Safety, aligned with ISO 15189:2022 requirements [4]. Each laboratory received an overall percentage score and a corresponding star rating from zero to five.

Auditors

Fifty-eight (58) certified QMS auditors, trained and certified on the SLIPTA methodology, were deployed in teams across all 36 states and the FCT to carry out the on-site audits.

Data collection

Audit data were captured electronically at the point of assessment using the Kobo Collect mobile data-collection platform. A response rate of 80% and higher was set to be sufficient to make a generalizable conclusion.

Data management and analysis

Data were cleaned and analysed in SPSS and Microsoft Excel, while QGIS was used to map performance by geopolitical zone. Descriptive statistics, means, standard deviations, frequencies, and percentages were used to summarize overall and domain-specific performance, regional variation, and how laboratories were distributed across star-rating categories.

RESULT

Of the 66 laboratories audited, 60 (90.9%) returned complete audit records. Table 1 summarizes overall performance across the 12 SLIPTA Quality System Essentials.

Table 1
Mean Domain-Specific Compliance (%) across 12 SLIPTA Quality System Essentials (n = 60 laboratories).

SLIPTA Quality System Essential	Mean score (%)	SD
1. Documents and Records	44.38	29.05
2. Organization and Leadership	26.09	27.65
3. Personnel Management	47.66	27.27
4. Customer Focus	36.89	33.43
5. Equipment Management	34.65	19.83
6. Assessment	19.44	29.53
7. Supplier and Inventory Management	56.10	24.82
8. Process Management	38.80	24.72
9. Information Management	52.30	22.62
10. Nonconforming Events	30.64	31.39
11. Continual Improvement	21.98	31.12
12. Facilities and Safety	45.54	24.03

Supplier and Inventory Management (56.1%) and Information Management (52.3%) came out as the two strongest domains. Assessment (19.4%), Continual Improvement (22.0%), and Organization and Leadership (26.1%) were the weakest, each falling well short of the 55% threshold needed for a single SLIPTA star.

Performance of evaluated clinical laboratories also varied considerably by geopolitical zone (GPZ), ranging from a mean of 53.3% in the South-West down to 15.5% in the South-South, as shown in Table 2

Table 2
Mean Overall Audit Performance (%) Across Geopolitical Zone.

Geopolitical zone	Mean score (%)
South-West	53.31
North-Central	40.47
North-East	37.62
North-West	35.65
South-East	31.69
South-South	15.48

Table 3 sets out the star ratings, based on the total SLIPTA score. Most laboratories (78.3%) scored 0 stars (< 55% compliance); only three (5.0%) reached the 4-star band (85–94% compliance), and none reached 5 stars.

Table 3
Distribution of Clinical Laboratories Across SLIPTA Star-Rating Bands.

Star rating	Compliance range	No. of laboratories	% of laboratories (n = 60)
0 star	< 55%	47	78.3
1 star	55–64%	3	5.0
2 stars	65–74%	2	3.3
3 stars	75–84%	5	8.3
4 stars	85–94%	3	5.0
5 stars	≥ 95%	0	0.0

All three clinical laboratories that achieved 4-star ratings were domiciled in Lagos State. These are Mainland Hospital, General Hospital Laboratory Lagos, and Lagos Island Maternity Hospital. The five 3-star laboratories were more spread out, across Lagos, Sokoto, Kaduna, and Anambra States, while the three 1-star laboratories were in the FCT, Oyo, and Yobe States. In other words, higher-performing laboratories clustered in a small number of states with a longer history of donor- or Global Fund-supported quality programming, rather than being spread evenly across the country.

DISCUSSION

This nationwide baseline suggests that formal QMS implementation across Nigeria's secondary and tertiary public laboratories remains low. More than three-quarters of evaluated laboratories (78.3%) had not yet reached the 55% compliance threshold needed for a single SLIPTA star rating. This finding aligns with previous studies conducted in Nigeria. Clinical laboratories enrolled in a comparable government-led initiative in Lagos State likewise started overwhelmingly at a zero-star baseline before structured mentorship and corrective-action support were introduced [8]. In the same vein, a broader assessment of Nigerian laboratories found that formal uptake of QMS practice and accreditation remains confined only to a small number of well-supported facilities [7]. A comparable star-rating exercise across primary healthcare facilities in Tanzania likewise found wide variation in readiness, reinforcing that an early-stage, unevenly distributed starting point is common across the region rather than being unique to clinical laboratories in Nigeria [13].

Domain-specific performance.

Assessment, Continual Improvement, and Organization and Leadership were evident as the weakest domains among assessed laboratories, each scoring below 27%. This finding is consistent with other

available evidence suggesting that challenges to sustainable implementation of QMS across healthcare facilities are mainly managerial and not technical. This result echoes a wider body of recent evidence on where SLIPTA- and ISO-oriented quality efforts tend to stall. A study in Southern Africa found that staff and managers rated management support, infrastructure, and workload as bigger obstacles to sustaining a QMS than technical knowledge gaps [10], while a structured mapping of the SLIPTA checklist against Joint Commission International standards found that the requirements least completely covered by SLIPTA cluster were quality planning, quality control, and quality improvement [10]. Even a Ghanaian military hospital laboratory that had already achieved ISO 15189 accreditation reported that documentation, laboratory safety, and management support made the accreditation journey the hardest [12]. Read together, these findings point to a fairly durable pattern: internal audit, corrective action, and continual improvement rely on sustained managerial routines, root-cause analysis, documented follow-up, and leadership review, which are harder to embed than a largely procedural domain like inventory or supplier management, where documentation and stock records go a long way on their own. The comparatively strong showing of Supplier and Inventory Management (56.1%) and Information Management (52.3%) in this baseline closely fits that pattern.

Regional variation.

Performance across regions ranged from 53.3% in the South-West down to 15.5% in the South-South. It is probably not a coincidence that all three 4-star facilities were located in Lagos State: Lagos hosts a large share of Global Fund-supported laboratories and was also the site of a separate, government-led QMS strengthening initiative that achieved rapid gains in facility star ratings over a comparable period [8]. That programme supported clinical laboratories achieved a better-quality rating than non-programme-supported laboratories, highlighted again the challenges associated with the fragmented implementation of QMS. A report published on national policy on Medical Laboratory Services and systems integration has highlighted the dangers of fragmented and soiled operation and advocated the adoption of the framework for services and systems integration across different ecosystems of healthcare [14]

A recent narrative synthesis of Nigerian laboratory service delivery similarly highlighted uneven distribution of workforce and infrastructure across the country, with laboratory-scientist-to-population ratios in some areas reported to be as low as one to 5,000 [1]. These findings suggest that concentrating donor and government-led quality investment in a particular region of the country, rather than embracing the national spread of resources, may explain much of the regional gap identified in this study. The weaker-performing zones-the South-South and South-East should be prioritized for targeted quality improvement interventions and support.

Comparison with national accreditation status.

Only three of the 60 laboratories audited (5.0%) reached the 4-star band, and none reached 5 stars, the level at which laboratories are typically encouraged to apply for full ISO 15189 accreditation. This finding is consistent with recent documented evidence that only a modest number of secondary and tertiary

clinical laboratories nationally have obtained the ISO 15189:2022 accreditation certificates despite the Medical Laboratory Science Council of Nigeria's statutory mandate to make QMS implementation compulsory for all registered clinical laboratories [9]. These findings provide empirical evidence for sustained implementation of laboratory strengthening efforts across the country, and domains such as leadership engagement, internal audit, and continual quality improvement should be prioritized since these domains consistently separate 0-star clinical laboratories from those with higher-rated scores both here and in the wider recent literature [10, 11].

Implications for intervention design.

The findings show that the weakest performing domains are: Assessment, Continuous Quality Improvement, and Organization and Leadership. These domains reflect managerial and behavioural rather than infrastructure. Future QMS interventions should focus on strengthening leadership, quality culture, and laboratory governance, in addition to building the technical capacity of the laboratory workforce. The SLMTA model of hands-on training, on-site mentorship, and structured improvement projects is likely to offer more return on investment than equipment or infrastructure provision alone [5]. The continued expansion of SLIPTA auditor training and ISO 15189:2022 orientation across the region [6] will most likely offer a ready-made channel through which result-oriented mentorship-led support could be extended to other low-performing clinical laboratories scattered across various zones. The strategy deployed in Lagos State is also instructive. It highlights that government ownership, dedicated resource mobilization, and continuous mentorship moved laboratories up the star scale within twelve months, offering a plausible, home-grown model to replicate in the lower-performing zones identified in this assessment [8].

LIMITATIONS.

This study was a one-time, cross-sectional baseline QMS assessment conducted across selected facilities. It does not provide information on changes in laboratory performance over time or the impact of the intervention. Six of the 66 participating laboratories (9.1%) had incomplete Kobo Collect data and were excluded from the domain-specific and star-rating analyses. Their exclusion may have introduced analytical bias if these laboratories differed systematically from those included in the analysis. Although all 58 auditors were certified in the WHO SLIPTA assessment methodology, inter-rater reliability among audit teams was not formally evaluated. This report presents only aggregate findings at the domain and geopolitical zone levels, but did not provide a detailed analysis of the specific checklist items contributing to low performance in individual laboratories.

CONCLUSION

This study shows that significant system-wide gaps remain in QMS implementation across secondary and tertiary medical laboratories in Nigeria. Strengthening the quality management system remains a critical priority for improving the quality, reliability, usability, and safety of medical laboratory services in Nigeria. For sustainable progress to be achieved, the right investments should be made through

coordinated national leadership, workforce capacity, structured mentorship, and stronger institutional commitment to quality improvement. Furthermore, adequate emphasis should be placed on strengthening leadership engagement, integrating internal audit and continual improvement practices into routine laboratory operations, and fostering a culture of quality at all levels of the health system, which could yield the needed result. Finally, upscaling government buy-in towards ISO 15189 accreditation and building resilient medical laboratory systems that will support quality healthcare and public health programmes.

Declarations

Ethical Approval and Consent to Participate

This study was not submitted to the National Health Research Ethics Committee (NHREC) of the Federal Ministry of Health and Social Welfare (FMoHSW) for ethical clearance as it was not deemed necessary. The study was carried out as a programmatic quality audit under the statutory oversight mandate of the FMoH&SW/MLSD. All participating states' health ministries and the management gave their informed consent to participate in the study. Audit data were aggregated and anonymized at the facility level before analysis and reporting. The study adhered strictly to the ethical principles of the Declaration of Helsinki.

Conflict of Interest

Nil

Consent to Participate

Not applicable

Consent to Publish

Not applicable

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Author Contribution

EE: Investigation, study design, data collection, literature search, interpretation of results, manuscript drafting, literature review, conceptual support, manuscript revision, interpretation of results, manuscript editing, and conceptual support GM: Conceptual support, study design, data collection, literature review, manuscript editing, interpretation of results, and manuscript revisionAL: Investigation, study design, data collection, literature search, interpretation of results, literature review, conceptual support, interpretation of results, and conceptual support BS: Study design, literature review, conceptual support, interpretation of results, and manuscript editingNO: Study design, literature review, conceptual support, interpretation of results, and manuscript editingEO: Manuscript drafting. literature review, manuscript revision, interpretation of results, data analysis, manuscript editingAO: Manuscript drafting, correspondence. literature review, conceptual support, manuscript revision, interpretation of results, manuscript editingAll authors have read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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Data Availability

The data generated for this study are available from the first author

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