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Assessment Of Laboratory Quality Management Systems In Primary Healthcare

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Abstract

Background: Good quality management systems (QMS) in clinical laboratories are a prerequisite for providing quality diagnostic services in primary healthcare settings, especially in resource-constrained settings.
Objective: The main aim of this study was to evaluate the status of implementation of quality management systems in laboratories located in primary healthcare centers.
Methods: This descriptive cross-sectional study was carried out between January and June 2025, covering 75 randomly selected laboratories located in primary healthcare centers. A validated checklist, which included 12 quality system essentials, was used for data collection, as recommended by ISO 15189:2012 and WHO SLIPTA (Stepwise Laboratory Quality Improvement Process Towards Accreditation). The checklist had a total of 258 points.
Results: The mean overall compliance score was found to be 38.7% (100.2 ± 32.4 points out of 258). The mean score for the sections varied considerably, ranging from a maximum of 62.4% in Documents and Records to a minimum of 24.8%, 29.3%, and 26.7% in Facilities and Safety, Equipment Management, and Occurrence/Incident Management, respectively. Using the SLIPTA rating system equivalence, it was found that out of the total 75 laboratories, 68 scored 0 stars (0-105 points), 6 scored 1 star (106-145 points), and only 1 scored 2 stars (146-185 points), while no laboratory scored 3 stars and above. Major gaps were found in the areas of equipment calibration, where only 18.7% were found to be fully compliant, internal quality control practices, where only 31.0% were found to be compliant, and corrective action documentation, where only 22.7% were found to be compliant.
Conclusion: Laboratory QMS implementation in primary healthcare centers continues to remain low, and most centers remain at the baseline level.

Keywords: Laboratory quality management system, Primary healthcare centers, ISO 15189, SLIPTA, Compliance assessment.

Introduction

Reliable laboratory services in primary healthcare settings are essential in ensuring the accuracy of diagnosis, effective decisions on treatment, and the quality of care in general. Diagnostic errors resulting from suboptimal laboratory services are known to compromise clinical outcomes considerably, especially in settings where there are challenges in maintaining consistent quality standards in the laboratory services. However, the integration of artificial intelligence in healthcare services has presented itself as a revolutionary solution to the quality challenges in clinical laboratories in innovative ways (Shiwlani et al., 2024).
Significantly, AI technologies have shown immense potential in revolutionizing different aspects of healthcare delivery, including patient care, diagnosis, and treatment planning, through enhanced data processing capabilities, predictive analysis, and decision support (Shiwlani et al., 2024). In particular,

AI-based cloud computing systems can be used in the real-time surveillance and early detection of abnormalities, which can be applied to the monitoring of laboratory performance indicators and quality deviations (Munagandla et al., 2024). In addition, AI-based applications in public health management have been proven effective in disease modeling, resource optimization, and management, which are principles that can be applied in error modeling, failure prediction, and quality control in laboratories (Chintala, 2022).

To facilitate transparent, reproducible, and high-quality reporting of health research, a set of structured evaluation tools is necessary to assess existing systems and facilitate improvements (Moher et al., 2010). In relation to QMS in laboratory settings, such evaluations are essential in providing critical baseline information regarding existing levels of compliance to international standards, thus identifying areas that could be addressed by AI-based interventions in the future, such as documentation, predictive maintenance, and intelligent incidents.

This study aims to evaluate the implementation of QMS in primary healthcare facilities through a standardized and checklist-based evaluation, similar to existing quality frameworks. This aims to identify existing levels of compliance and potential areas to improve, thus laying the groundwork for potential AI-based interventions in the future to facilitate quality improvements and progression towards accreditation.

Methods

Study Design

This study employed a cross-sectional descriptive design that incorporated quantitative aspects to ensure a comprehensive evaluation of the existing quality management systems in primary healthcare laboratories. The selection of a cross-sectional design was intentional, as it allows researchers to obtain a comprehensive view of quality management practices in a number of healthcare facilities simultaneously, which is essential in identifying existing compliance patterns, strengths, and deficiencies in quality management systems in a relatively shorter period, as opposed to longitudinal designs that are more resource-intensive. It is recognized as an optimal design choice in quality management systems, particularly in diagnostic services, to conduct quality audits, especially in situations that require rapid generation of knowledge to inform interventions and policy initiatives. In addition, the design employed a high level of objectivity and reproducibility through the integration of standardized scoring systems to enable direct comparisons to international standards. It also incorporated a comparative analysis of the findings through stratification according to critical aspects of laboratory practices, such as staffing levels and volumes of tests conducted, to identify potential influencing factors in quality management systems, as recommended in guidelines for reproducible and transparent research in health systems (Moher et al., 2010).

Study Setting and Target Population

The studies were carried out within the walls of the clinical laboratories of primary health care centers providing basic and essential diagnostic tests to the community and outpatients. These laboratories provide a standard set of tests, including hematologic tests, basic clinical chemistry, parasitologic tests, urinalyses, and limited microbiologic tests, which form the basis of early disease detection and control at the primary health care level.

The target population included all fully functional laboratories operating within primary healthcare centers that perform moderate complexity testing and provide basic laboratory support for preventive, curative, and surveillance activities. These laboratories were chosen based on their position as the initial interface of diagnosis, where quality issues have significant implications for clinical decision-making. Inclusion criteria for the laboratories included having been operational for at least one year, having an average daily test volume of over 50 specimens, and having expressed a willingness to participate fully in the assessment process. Exclusion criteria included highly specialized referral laboratories, those that are privately operated, or those that experienced operational issues such as significant infrastructural changes. These criteria ensured that the laboratories included in the assessment process were representative of those found within primary healthcare settings worldwide.

Sampling Technique and Sample Size Determination

To achieve this, the study employed a multi-stage stratified random sampling approach, which ensured the representativeness and minimization of bias in the sample. First, primary healthcare facilities, which can be described as administrative or operational clusters, were stratified on the basis of factors that have been shown to affect lab performance, such as the population, geographic accessibility, and annual diagnostic workload. A total sample frame was developed from reliable sources, which included all the facilities that met specific criteria from authoritative sources, such as health system registries. Subsequent random sampling was carried out by employing computer algorithms.

The final sample size of 75 laboratories was arrived at through a calculation that ensured statistical precision, employing a formula that estimates a proportion in a finite population, taking into consideration a 95% confidence level, an expected level of compliance of 40% based on similar regional estimates, and a margin of error of 5%. Adjustments to the sampling plan were made to allow for potential levels of non-response, over-sampling in strata that are under-represented to ensure that a range of operational contexts, including those with fewer resources, are represented. This sampling plan not only ensured internal validity but also assisted in ensuring external validity, thus generalizing to primary healthcare laboratory networks in resource-constrained environments (Carter, 2017).

Instrument Development and Validation

The main tool used for the assessments was a meticulous and precise checklist based on universally accepted guidelines and standards, mainly the ISO 15189:2022 standard on quality and competence in medical laboratories, with some addition and integration with the World Health Organization's Stepwise Laboratory Improvement Process Towards Accreditation checklist. This combination offered the extensive technical requirements of the ISO 15189 standard with the advantage of the stepwise scoring and progressive approach offered by the SLIPTA checklist, which is based on the translation of quality basics into a checklist with a scoring system suitable for progressive improvement in resource-constrained situations (World Health Organization, 2011). The checklist is well-structured and covers all the quality system fundamentals in twelve areas: organizational structure and personnel competence; document control and record management; client interaction and service delivery; facility infrastructure and biosafety; equipment calibration and maintenance; procurement and inventory control; process management; internal and external quality control; information systems security; occurrence management with corrective and preventive actions; internal auditing and management review; and continual improvement.

Scoring was structured on a graduated scale based on the level of compliance, with individual components allocated 0 for non-implementation to 2 for full compliance, resulting in a maximum cumulative score of 258. Percentage compliance was also calculated on a global and individual essential basis, with the SLIPTA star rating system being employed to facilitate interpretation and accreditation pathway planning. The tool development process also entailed various stages of validation, including content validation through iterative review by a panel of quality experts in laboratory quality, linguistic validation by forward and backward translation of the tool, and pilot testing of the tool in non-participating laboratories to enhance the clarity of the tool and scoring consistency. Inter-rater reliability was also comprehensively explored, revealing high coefficients to confirm the robustness of the tool for field application (Ciacovelli et al., 2023).

Data Collection Procedures

Data acquisition was done within a specified six-month interval through direct on-site evaluations by a specialized team of auditors who have advanced qualifications in medical laboratory science. For each facility, the data acquisition process was meticulously standardized. It started with an introductory session to elucidate the objectives of the study, encourage cooperation, and address any questions. It was followed by an examination of documents, such as policies, procedures, training records, quality control records, and calibration records. For the observational data acquisition, direct monitoring of the workflow was done, starting from the reception of specimens to the dissemination of test results. In addition, direct verification of infrastructure, safety provisions, and equipment functionality was done. Interviews of the staff of the medical laboratory and their supervisors were done to determine the competency levels of staff, quality policy, and any barriers to quality implementation. Evidence was acquired through electronic means using digital platforms to ensure accuracy, immediacy, and completeness. In addition, some proficiency testing of quality was done through the use of blinded

control materials for priority test procedures to objectively corroborate the reliability of test results. This process is consistent with the best practices for diagnostic quality assessment (Lubin et al., 2021).

Assessor Training and Standardization

To ensure consistency and reduce the risk of observer bias, all raters underwent an extensive training program prior to the study, which included theoretical training in quality standards, scoring exercises, and mock audits. Standardization training included consistent interpretation of items on the checklist, ethical handling of data, and respectful communication with facility staff. Inter-rater agreement was maintained through group debriefing sessions and joint assessments during initial fieldwork, with any scoring differences resolved through consensus to ensure high inter-rater reliability throughout the study period.

Data Management and Integrity Assurance

Data collected was processed with very stringent policies that emphasized data security and precision. Daily synchronization of data entries into encrypted and restricted access central repositories was performed, and local backup arrangements were made to prevent data loss. The master data set was created with inherent data validation checks to identify any anomalies, and a double entry verification approach was used on a large proportion of the data. Cleaning of data was performed with a systematic approach to outliers and inconsistencies. Anonymization of data with unique coding was used to protect facility confidentiality from the start.

Statistical Analysis Plan

Analysis was enabled through high-end software environments to accommodate descriptive and inferential statistics. Central tendency, variability measures, and confidence intervals defined compliance scores globally and by quality essential. Categorical classification identified performance levels, while non-parametric analyses and correlation studies investigated relationships with contextual factors. Multivariable modeling identified independent determinants of quality implementation, while diagnostics evaluated model integrity. Visual representations aided pattern recognition on compliance scores, which enabled nuanced interpretation of findings.

Quality Control Measures

This was achieved through the implementation of multiple layers of protection, which included instrument piloting, real-time validation, independent verification, and the review by an expert panel on the results of the interim analysis.

Ethical Considerations

The study received approval from all the relevant review boards, which ensured that administrative permission was granted at all levels. In addition, the study ensured that the participants were not penalized by emphasizing the importance of voluntary participation, ensuring the confidentiality of the study by anonymizing the data, and reporting the results in an aggregated manner. The study was conducted in an ethical manner by ensuring that it met all the requirements under the international guidelines on the ethical conduct of health systems research, which included the principles of respect, beneficence, and justice (Moher et al., 2010).

Results

The objective of this study was to evaluate the implementation of laboratory quality management systems in 75 primary healthcare laboratories through the use of a standardized checklist system based on established international frameworks and comprising a maximum of 258 points in 12 quality system essentials. On average, laboratories achieved a compliance score of 100.2 ± 32.4 points, which translates to only 38.7% of the total possible score. Such low levels of compliance indicate a wide gap in structured quality practices among laboratories, with results largely clustered at baseline levels.

Table 1: Distribution of Performance Levels Based on Star Ratings (n=75)

Performance Level	Score Range (Points)	Percentage Range	Number of Laboratories	Percentage (%)
0 Stars	0–137	<55%	68	90.7
1 Star	138–172	55–64%	6	8.0
2 Stars	173–207	65–74%	1	1.3
3 Stars	208–242	75–84%	0	0.0
4 Stars	243–257	85–94%	0	0.0
5 Stars	≥258	≥95%	0	0.0

Table 1 shows a summary of the performance distribution based on the graduated star rating system. An overwhelming majority of the labs (90.7%, n=68) were rated at 0 stars, indicating a lack of systematic quality management beyond mere functionality. Only six labs achieved 1 star, and just one lab achieved 2 stars. No lab achieved 3 or more stars. This distribution indicates that most labs are still at the preparatory stage in their quality management journey, with basic structural foundations absent or incomplete. The absence of labs at the higher end of the distribution indicates that moving to a more mature quality management approach is the exception and possibly facilitated by extraordinary local or external support. This is because moving to a more mature quality management approach is a stepwise process in which basic deficiencies need to be sequentially overcome before moving on to more advanced needs.

Figure 1. Distribution of Laboratories According to Performance Levels Based on Star Ratings (n = 75).

Figure 1 shows the proportional distribution of the laboratory performance level based on the star rating system through a waffle chart. Each unit in the chart represents one percent of the sample. From the chart, it is very clear that the distribution is highly unbalanced with a dominant percentage in the lowest performance level. To be precise, the laboratories that were rated zero stars make up 90.7% of the total sample. This shows that the vast majority of the laboratories failed to achieve the minimum performance and quality standards.

In addition, only a small percentage of the laboratories were rated higher. To be precise, 8.0% were rated one star, while only 1.3% were rated two stars. However, it is worth noting that none of the laboratories were rated three stars and above. This shows that the institutions are completely missing in the advanced performance level.

Table 2: Mean Compliance Scores Overall and by Quality System Essential (n=75)

Quality System Essential	Maximum Points	Mean Score ± SD	Percentage Compliance (%)	95% Confidence Interval
Overall Score	258	100.2 ± 32.4	38.7	36.9–40.5
Documents and Records	36	22.5 ± 6.8	62.4	59.8–65.0
Organization and Personnel	42	23.1 ± 8.2	55.1	52.3–57.9

Client Management and Customer Service	18	9.2 ± 3.5	51.1	48.5–53.7
Information Management	20	9.8 ± 4.1	49.0	46.3–51.7
Purchasing and Inventory	24	11.4 ± 5.3	47.5	44.7–50.3
Process Control	30	13.8 ± 6.1	46.0	43.4–48.6
Internal Quality Control and EQA	28	12.3 ± 5.7	43.9	41.3–46.5
Assessment (Audits and Review)	16	6.5 ± 3.2	40.6	38.2–43.0
Continual Improvement	12	4.7 ± 2.8	39.2	36.7–41.7
Occurrence/Incident Management	18	4.8 ± 3.1	26.7	24.3–29.1
Equipment Management	30	8.8 ± 4.9	29.3	27.1–31.5
Facilities and Safety	24	6.0 ± 3.9	24.8	22.7–26.9

Table 2 shows a detailed analysis of the mean compliance scores in the overall system and individual quality essential areas. It is worth noting that the highest scores were achieved in the Documents and Records area, at 62.4%, and in Organization and Personnel, at 55.1%. This implies that these are relatively easier to comply with, even under adverse circumstances. On the other hand, the lowest scores were in Facilities and Safety (24.8%), Equipment Management (29.3%), and Occurrence/Incident Management (26.7%). This shows a significant disparity in that aspects that require more management and paperwork are given more priority than those that require infrastructure and error management strategies. It is also worth noting that a significant number of standard deviations in most areas point to a high level of heterogeneity among individual facilities, in which a few areas are relatively better managed despite overall poor performance. In conclusion, the overall mean compliance of 38.7% indicates that there is a systemic problem in that critical operational components are underdeveloped in most facilities, compromising diagnostic reliability.

Figure 2. Radar Chart of Mean Compliance by Quality System Essential (n = 75)

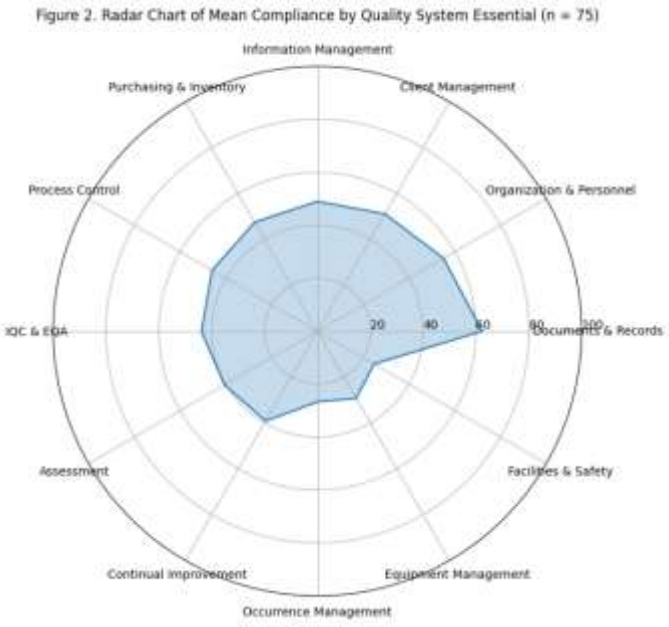

Figure 2 shows a radar chart representing the mean percentage of compliance with the quality system essentials. From the radar chart, it is clear that there is an imbalance in the implementation of quality system components. For instance, the highest extension of the radar chart is seen in Documents and Records, which means that there is higher compliance compared to other quality system components.

In addition, moderate compliance is seen in Organization and Personnel, Client Management, and Information Management. These are some of the quality system components that have some aspects of quality management. However, there is a significant contraction of the radar chart seen in Facilities and Safety, Occurrence/Incident Management, and Equipment Management. These quality system components have major gaps in quality management. Moreover, the minimal extension of the radar chart is seen in Assessment and Continual Improvement, which means that there is no quality management approach towards internal audit, assessment, and continual improvement.

Table 3: Compliance Status for Key Critical Items in Underperforming Essentials (n=75)

Critical Item	Quality System Essential	Fully Compliant (n)	Percentage Fully Compliant (%)	Partially Compliant (%)	Non-Compliant (%)
Equipment calibration and verification	Equipment Management	14	18.7	42.7	38.6
Preventive maintenance logs	Equipment Management	18	24.0	38.7	37.3
Temperature monitoring for reagents/storage	Facilities and Safety	16	21.3	36.0	42.7
Biosafety measures (PPE, waste management)	Facilities and Safety	19	25.3	40.0	34.7
Incident reporting system in place	Occurrence Management	17	22.7	34.7	42.6
Root cause analysis for incidents	Occurrence Management	15	20.0	30.7	49.3
Daily internal quality control practices	Internal QC and EQA	23	30.7	38.7	30.6
Participation in external quality assessment	Internal QC and EQA	28	37.3	32.0	30.7

Table 3 analyzes the level of compliance for the chosen high-priority items in the weakest quality essentials, supported by key analytical controls. The level of complete compliance with equipment calibration was reached in only 18.7% of laboratories, with close to 39% demonstrating complete lack of this practice, reflecting the challenges in planning and implementing the technical process. Items related to biosafety also demonstrated low levels of complete compliance (21-25%), reflecting the poor infrastructure available for safe storage and disposal. Management of occurrence items was particularly low, with root cause analysis completely implemented in only 20% of the facilities, reflecting the poor institutional learning processes available for addressing errors. Daily internal quality control was slightly better at 30.7% complete compliance but remained inconsistent. The high level of partial compliance demonstrated for these items suggests that many of the laboratories have started with primitive approaches; however, sustainability is compromised by the lack of complete follow-through or intermittent resource availability. These identified weaknesses are critical points for potential analytical errors and safety deviations, reflecting the need for priority corrective efforts.

Figure 3. Compliance Status of Critical Items in Underperforming Quality System Essentials (n = 75)

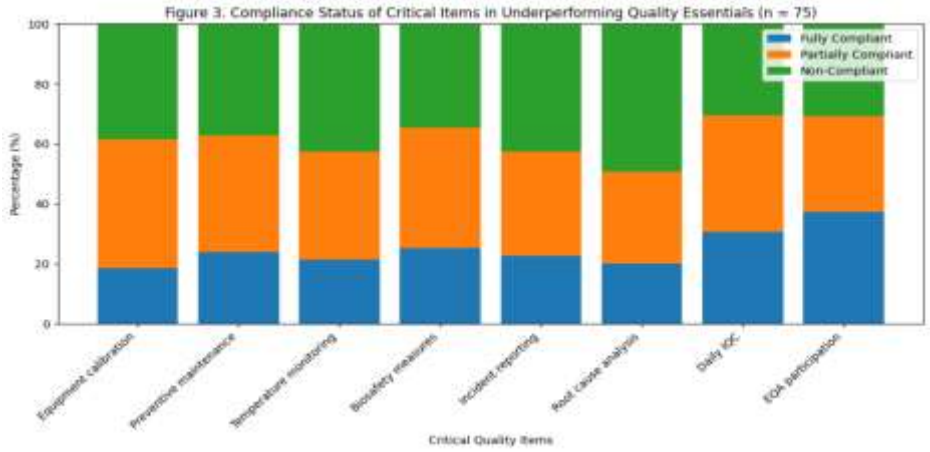

Figure 3 shows the compliance status of important items in a low-performing Quality System using a stacked bar chart. In all the items we looked at, the number of practices that fully meet the requirements is very low, not going higher than 37. 3% This shows there are significant gaps in how well they are being put into action. Important areas like checking equipment, regular maintenance, and keeping track of temperatures show many problems with following rules. This indicates that there are weaknesses in how things are monitored and recorded regularly. Notably, looking into the reasons behind incidents shows the highest level of non-compliance at 49. 3% This highlights a major problem with how we investigate issues and make corrections. In the same way, safety practices like biosafety measures and reporting incidents are not being followed properly. This highlights risks to the safety of workers and the reliability of the services. In comparison, taking part in internal quality control and external quality assessment shows a higher level of complete compliance than other areas. However, most of the time, there is still only partial compliance, which means that many quality assurance procedures are not fully followed. In general, the figure shows that there is a strong need for specific actions to improve quality, especially in managing operations, safety measures, and handling incidents in an organized way.

Table 4: Subgroup Comparison of Overall Compliance by Laboratory Operational Characteristics (n=75)

Characteristic	Category	Number of Laboratories	Mean Overall Score ± SD	Percentage Compliance (%)	p-value
Staff Number	<5 staff	32	85.4 ± 28.6	33.1	<0.001
	5–10 staff	28	108.7 ± 30.1	42.1	
	>10 staff	15	128.9 ± 34.2	50.0	
Average Daily Test Volume	<100 tests	40	89.3 ± 29.8	34.6	<0.001
	100–300 tests	25	110.5 ± 31.4	42.8	
	>300 tests	10	132.6 ± 35.7	51.4	
Years of Operation	<5 years	18	92.1 ± 30.5	35.7	0.012
	5–10 years	35	101.8 ± 32.0	39.4	
	>10 years	22	112.4 ± 33.8	43.6	

Table 4 displays variations in overall compliance according to key operational characteristics. Laboratories with larger staff sizes (>10 personnel) recorded significantly higher mean compliance (50.0%) than those with fewer than five staff (33.1%), with strong statistical difference ($p<0.001$). Higher daily test volumes likewise correlated with improved performance (51.4% for facilities handling >300 tests versus 34.6% for <100 tests), implying that greater throughput may stimulate enhanced

managerial oversight or attract additional resources. Facilities operational for more than 10 years outperformed newer ones (p=0.012), potentially benefiting from accumulated institutional knowledge and gradual enhancements. These findings indicate that scale, workload, and longevity serve as facilitating factors for quality system adoption, whereas smaller and lower-volume laboratories encounter amplified obstacles, necessitating differentiated support strategies to reduce performance inequities.

Figure 4. Subgroup Comparison of Overall Compliance by Laboratory Operational Characteristics (n = 75)

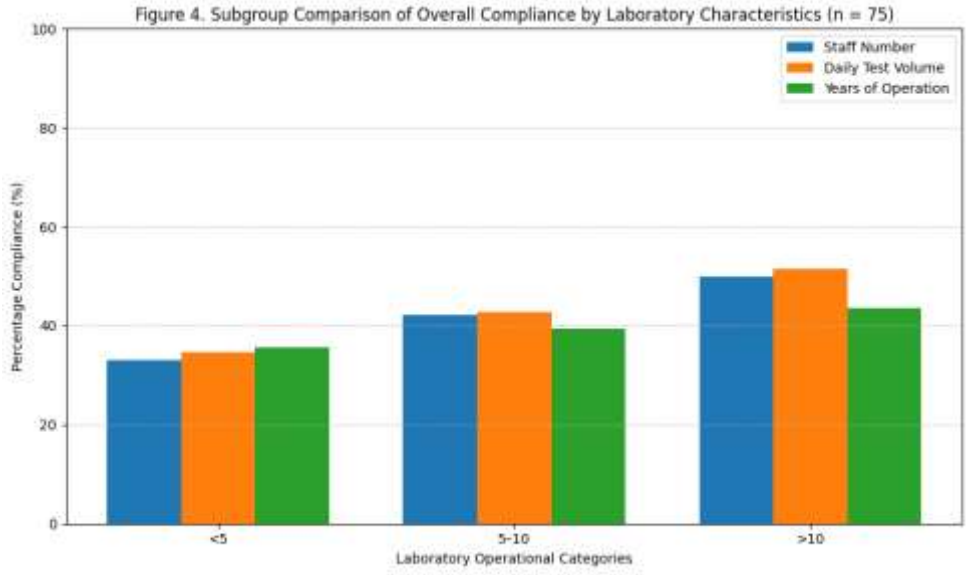

Figure 4 shows a comparison of how well different groups follow quality system rules based on important features of their lab operations. As the number of staff increases, laboratories follow rules better. Laboratories with more than ten staff had the best average compliance at 50. 0%, while those with fewer than five staff had a lower average at 33. 1% This difference was important ($p < 0.001$), showing that a stronger workforce helps improve the quality system. Likewise, laboratories that did more tests each day showed better levels of following the rules. Facilities that conduct more than 300 tests every day had the best compliance rate at 51. 4% In contrast, labs that do fewer than 100 tests had a much lower compliance rate of 34. 6% The difference between these two groups is significant ($p < 0.001$) This finding means that doing more tests might be linked to better organized work processes and stronger checks on quality. Laboratories that have been running for more than ten years had better compliance (43. 6%) than those that have been open for less than five years (35. 7%) Even though the difference was not as big as what we saw with staffing and test volume, it was still statistically significant ($p = 0.012$) In general, the information shows that the size of a lab, how much work it has, and how developed it is play an important role in following quality rules. This highlights the need for specific support programs to help smaller, less busy, and new labs improve.

Table 5: Correlations Between Individual Quality Essentials and Overall Compliance Score

Quality System Essential	Spearman's Correlation Coefficient (ρ)	p-value
Facilities and Safety	0.68	<0.001
Equipment Management	0.65	<0.001
Occurrence/Incident Management	0.62	<0.001
Internal Quality Control and EQA	0.59	<0.001
Documents and Records	0.55	<0.001
Organization and Personnel	0.52	<0.001

Table 5 presents correlation coefficients between selected quality essentials and the global compliance score. The strongest associations were with Facilities and Safety (ρ=0.68), Equipment Management (ρ=0.65), and Occurrence Management (ρ=0.62), all highly significant. This suggests that strengthening these operational and corrective domains yields substantial leverage on overall system performance, as they directly mitigate risks to accuracy and safety. Moderate correlations with administrative essentials indicate that while documentation and organization provide necessary foundations, tangible improvements in infrastructure and error management drive broader systemic gains. Such insights advocate for prioritized resource allocation to high-impact, low-performing areas to maximize efficiency of quality enhancement efforts.

Collectively, the results portray a landscape of persistently suboptimal quality management in primary healthcare laboratories, characterized by predominant baseline performance and pronounced weaknesses in infrastructure, equipment, safety, and incident handling. The identified variations and correlations offer actionable guidance for tailoring interventions, with emphasis on supporting smaller facilities and targeting foundational operational upgrades to foster sustainable progress toward reliable diagnostic services.

Discussion

The results of this study demonstrate a strikingly low level of quality management system (QMS) implementation across the evaluated primary healthcare laboratories, with an overall mean compliance score of 38.7% and 90.7% of facilities rated at 0 stars according to the stepwise accreditation framework. This predominant baseline performance indicates that most laboratories function with minimal structured quality processes, posing substantial risks to diagnostic accuracy, patient safety, and effective disease management. The overwhelming concentration at the lowest performance tier is consistent with numerous quality audits in resource-limited diagnostic settings, where primary-level facilities often exhibit foundational operations without comprehensive quality frameworks. Comparable evaluations of laboratory practices in public health facilities have similarly identified widespread deficiencies in key areas such as documentation, equipment maintenance, and safety protocols, frequently linked to resource constraints, limited training opportunities, and inconsistent supervisory support (Adam, 2019). The parallels observed here suggest that these shortcomings represent systemic challenges common to primary healthcare laboratory networks operating under similar operational pressures.

The variation across quality system essentials provides deeper insight into implementation priorities and barriers. Documents and Records achieved the highest compliance at 62.4%, closely followed by Organization and Personnel at 55.1%, whereas Facilities and Safety (24.8%), Equipment Management (29.3%), and Occurrence/Incident Management (26.7%) emerged as the most deficient areas. This consistent pattern—stronger administrative and documentation performance contrasted with weaker operational and infrastructural elements—is a frequent observation in laboratory quality assessments conducted in constrained environments. The relative success in documentation likely reflects its comparatively lower demand for financial or technical resources, relying primarily on policy formulation and routine record-keeping. On the other hand, the marked weaknesses in facilities and safety underscore enduring infrastructural limitations, including inconsistent utilities, inadequate workspace design, and insufficient provisions for personal protective equipment or waste disposal systems. These observations align with detailed biosafety risk evaluations that highlight analogous vulnerabilities, stressing how deficient physical environments and risk mitigation strategies increase exposure to avoidable hazards for laboratory personnel and surrounding communities (Sobhy and Elmahdy, 2019). Furthermore, comprehensive reviews of clinical laboratory biosafety have emphasized that such deficiencies, often amplified during public health emergencies, necessitate systematic enhancements to safeguard operations and prevent adverse events (Cornish et al., 2021).

The pronounced gaps in equipment management, evidenced by full compliance with calibration in only 18.7% of laboratories, constitute a major threat to analytical reliability. Incomplete preventive maintenance records and verification procedures similarly reflect difficulties in securing technical expertise, replacement components, or reliable service agreements. This scenario contributes substantially to instrument downtime and potential result inaccuracies, a challenge widely documented in settings with limited laboratory infrastructure (Nkengasong et al., 2018). Compounding these issues, the suboptimal occurrence and incident management—with functional reporting mechanisms in just

22.7% of facilities and root cause analysis in 20.0%—restricts systematic error identification and resolution. In the absence of effective incident handling, recurring deficiencies persist, hindering overall quality maturation. This limitation mirrors experiences from risk control applications in accredited laboratories, where formalized protocols for specific hazards, such as hazardous material storage, demand structured approaches that are frequently underdeveloped in primary-level settings (Mok et al., 2023).

Internal quality control and external quality assessment showed moderate but still inadequate compliance, with daily internal controls fully practiced in 30.7% of laboratories and external assessment participation in 37.3%. These levels suggest irregular monitoring of analytical performance, elevating the risk of undetected variations in test results. The prevalence of partial implementation indicates sporadic rather than embedded practices, often interrupted by supply inconsistencies or personnel changes. Subgroup analyses revealed meaningful differences, with facilities employing larger staff complements (>10 personnel) and processing higher daily test volumes (>300) attaining significantly superior overall scores (50.0% and 51.4%, respectively) compared to smaller or lower-volume operations. This relationship implies that greater operational scale may promote heightened attention to quality processes or facilitate resource mobilization. Laboratories with longer operational histories also demonstrated better performance, likely accumulating experiential knowledge and progressive refinements. These associations correspond to systematic analyses of documentation practices, which connect improved outcomes to elements like staff preparation, motivational factors, and guideline accessibility—features more consistently maintained in larger or more established facilities (Kassie et al., 2023).

The correlational findings further elucidate the interdependence of quality components, with Facilities and Safety, Equipment Management, and Occurrence/Incident Management exhibiting the strongest links to overall compliance (ρ = 0.68, 0.65, and 0.62, respectively). This indicates that targeted enhancements in these operational domains generate substantial system-wide benefits by directly addressing fundamental risks to precision and safety. Administrative essentials displayed moderate correlations, suggesting that while documentation and organizational structures form essential bases, tangible progress in infrastructure and corrective mechanisms drives comprehensive advancement. Collectively, these results carry significant implications for primary healthcare service delivery. Inadequate laboratory quality erodes confidence in diagnostic results, contributes to clinical errors, and impedes efficient resource utilization, particularly in populations dependent on public diagnostic services. In resource-constrained health systems, where laboratory testing informs the majority of clinical decisions, such deficiencies intensify disparities and obstruct broader health objectives (Nkengasong et al., 2018).

The current findings echo patterns from various quality audits in comparable primary healthcare contexts, where facilities routinely score below midpoint thresholds due to analogous barriers (Adam, 2019). Nonetheless, the relatively stronger documentation performance may signal positive influences from recent emphases on record-keeping as an accessible starting point for quality initiatives. The complete absence of higher-tier ratings contrasts with outcomes from structured support programs, where guided interventions have facilitated advancement toward accreditation. This difference underscores the transformative potential of coordinated external assistance. Methodological strengths of the study include the application of a validated comprehensive checklist encompassing all quality essentials, representative sampling, and multifaceted data collection integrating observation, document review, and interviews. These features bolster the credibility and applicability of conclusions to analogous primary diagnostic networks.

Certain limitations warrant consideration. The cross-sectional approach provides a temporal snapshot, limiting inferences about longitudinal trends or causal relationships. Potential response bias in staff interactions was minimized through observational triangulation, though not entirely eliminated. The exclusive focus on primary healthcare laboratories restricts extrapolation to advanced or specialized tiers. External factors, such as intermittent supply disruptions during the assessment period, may have transiently affected observed performance. Subsequent investigations should employ prospective designs to evaluate intervention efficacy and expand proficiency testing to broader analyte ranges for direct error quantification. In-depth qualitative inquiries into staff experiences would further illuminate implementation obstacles.

Practical recommendations arise directly from the identified priorities. Immediate actions should target facilities and safety improvements, encompassing stable utility provisions, controlled storage solutions, and thorough biosafety education to address proximate risks (Cornish et al., 2021; Sobhy and Elmahdy, 2019). Equipment management can be bolstered via centralized calibration networks, scheduled maintenance agreements, and digitized tracking systems. Occurrence management requires cultivation of blame-free reporting environments, standardized analytical tools, and routine review cycles. Existing documentation strengths should be capitalized upon to formulate detailed standard operating procedures that bridge administrative and operational domains, as robust procedures are pivotal for enduring quality (Freeman et al., 2021). Capacity-building initiatives customized for primary-level personnel, combined with progressive mentorship frameworks, could expedite advancement through initial performance tiers. At the policy level, dedicated quality funding streams and incorporation of laboratory metrics into oversight mechanisms are indispensable for durability (Nkengasong et al., 2018).

In conclusion, the suboptimal QMS implementation revealed in this study represents a pivotal opportunity for strengthening primary healthcare laboratory services. Although challenges are considerable, the documented instances of partial compliance and performance variations by facility characteristics provide clear pathways for intervention. By concentrating on high-leverage essentials and building upon administrative foundations, strategic efforts can substantially improve diagnostic quality, optimize patient care, and fortify health systems against current and future demands.

Conclusion

This study provides a comprehensive assessment of laboratory quality management systems in primary healthcare laboratories, revealing a persistently low level of implementation characterized by an overall mean compliance score of 38.7% and 90.7% of facilities operating at the baseline (0-star) level according to the SLIPTA framework. These findings highlight critical systemic deficiencies, particularly in facilities and safety, equipment management, and occurrence/incident management, which collectively undermine the reliability of diagnostic services essential for effective primary care delivery. While strengths in documentation and organizational elements offer a foundational platform for improvement, the pronounced gaps in operational and infrastructural components indicate that most laboratories lack the robust processes needed to ensure consistent accuracy, precision, and safety in test results.

The suboptimal performance documented here has far-reaching implications for patient outcomes and health system efficiency. In primary healthcare settings, where laboratories inform the majority of clinical decisions, deficiencies in quality management contribute to diagnostic errors, delayed interventions, and increased resource wastage. The identified associations—higher compliance in larger, higher-volume, and longer-established facilities—suggest that scale and experience facilitate quality adoption, while smaller facilities face amplified barriers. These patterns emphasize the need for equitable resource distribution and tailored support to reduce performance disparities across laboratory networks.

Ultimately, the results underscore an urgent call for targeted, multifaceted interventions to advance laboratory quality toward accreditation readiness. Prioritizing infrastructure upgrades, equipment maintenance programs, biosafety enhancements, and incident management systems will yield high-impact gains, building on existing administrative strengths through standardized procedures and ongoing training. Mentorship initiatives aligned with stepwise frameworks, combined with policy commitments to dedicated quality funding and performance monitoring, represent practical pathways to sustainable improvement. By addressing these gaps, primary healthcare laboratories can evolve into reliable pillars of diagnostic excellence, enhancing patient safety, clinical confidence, and overall health system resilience in resource-constrained environments.

Future efforts should focus on longitudinal evaluations to measure intervention impacts, expanded proficiency testing to quantify error rates, and integration of digital tools for real-time quality monitoring. Such advancements will not only elevate current performance but also position laboratories to meet emerging diagnostic demands and contribute meaningfully to universal health coverage goals.

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