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Stratified Evaluation of Quality Management Practices in HIV Rapid Testing Laboratories: Evidence from the South Region of Cameroon

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Abstract

Ensuring high-quality HIV rapid testing is critical to accurate diagnosis and effective treatment, especially in resource-limited settings like Cameroon. This study conducted a stratified evaluation of quality management systems (QMS) in HIV rapid testing laboratories across the South Region of Cameroon using the WHO Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RRT) tool. The objective was to assess adherence to quality standards across facility types and support levels, and to identify critical gaps in implementation. A total of 99 laboratories were audited between 2022 and 2024, stratified by ownership (government, private, faith-based, and community-based organizations) and PEPFAR support. Results showed that PEPFAR-supported laboratories had significantly higher mean SPI-RRT scores (59) compared to non-supported sites (14), $p < 0.001$. Community-based organizations demonstrated the highest compliance (28 ± 21), followed by faith-based (25 ± 23), private (25 ± 17), and government-owned facilities (14 ± 21). Notably, only 12% of laboratories reached SPI-RRT Level 3 or 4, indicating limited readiness for certification. The lowest-scoring elements included quality control, document management, and corrective actions, highlighting systemic weaknesses in QMS implementation. District-level disparities were also evident, with Sangmelima and Kribi outperforming other districts in readiness scores. These findings provide essential insights into quality assurance challenges in decentralized HIV testing programs and underscore the need for targeted interventions, including technical mentorship, continuous quality improvement, and enhanced supervision to improve diagnostic reliability.

Keywords: *Cameroon, HIV Testing, Laboratory Audit, Quality Management, SPI-RRT.*

Introduction

Viability and reliability of HIV testing are the cornerstone of successful disease monitoring, patient treatment, and prevention measures. For resource-poor settings such as Cameroon, HIV rapid testing continues to be the central diagnostic tool at peripheral levels of care, particularly for rural settings and underserved areas [1]. Although scalable, comments have continued to surround the quality of rapid testing services due to variations in adherence to standard protocols, inadequate personnel training, improper documentation procedures, and inefficient quality control systems [2, 3]. To overcome these challenges, the World Health Organization (WHO) created the Stepwise Process for Improving the Quality of HIV

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Rapid Testing (SPI-RRT), a standardized approach to assessing the quality of testing sites along seven Core Essential Elements: training, infrastructure, safety, pre-testing, testing, post-testing measures, and monitoring of quality [4, 5]. The instrument has been implemented within several national settings to evaluate laboratory preparedness for certification and to stimulate Continuous Quality Improvement (CQI) efforts. Yet empirical evidence of SPI-RRT scale-up within Cameroon's decentralized testing contexts remains scarce [6].

Although there has been a national drive to scale up HIV rapid testing, decentralized laboratories' quality assurance systems within Cameroon remain fragmented, with little comprehension of performance differences by ownership type, by region, or by level of donor coverage. Such a gap compromises diagnostic accuracy as well as the integrity of HIV-related health interventions.

Existing Solutions and Their Limitations

Some facilities introduced solutions, such as in-service training, external quality evaluations (EQA), and technical mentorship, with donor support (e.g., PEPFAR). The solutions, however, were not introduced with equal intensity, and evidence to demonstrate their effectiveness remains sporadic or anecdotal [7, 8]. Moreover, prior evaluations have hardly segmented performance information by ownership or facility level.

Best Solution Found

The SPI-RRT instrument provides a defined, tested approach to benchmarking quality and identifying targeted gaps. Once implemented across stratified categories, ownership, donor funding, and facility location, it can unveil essential information bearing on systemic and facility-level roadblocks to quality assurance. Accomplishments so Far: The SPI-RRT instrument has, globally, been applied to enhance laboratory performance in nations including Kenya, Nigeria, and South Africa [9] [10]. The instrument has been applied at pilot scale in Cameroon to guide CQI activities and benchmark performance. The current study expands this by applying the instrument at full scale across the entire South Region [11, 12].

The general objective of this evaluation was to assess the functionality of HIV rapid testing laboratories within Cameroon’s South Region, using the SPI-RRT tool, with a specific interest in stratifying quality management practices by facility type and support status.

Novelty of the Work

This study is the first to conduct a stratified assessment of SPI-RRT scores across 99 testing laboratories in Cameroon’s South Region, comparing PEPFAR-supported and non-supported facilities, and evaluating readiness across ownership types and geographic locations. It provides empirical evidence to support targeted quality improvement strategies and contribute to national HIV diagnostic policy development.

Conceptual Framework for Stratified Evaluation of HIV Testing Quality in Cameroon

Figure 1 below illustrates the conceptual framework for the stratified evaluation of the quality of HIV rapid testing across Cameroon's South Region. The framework intersects key inputs (facility level, funding source, and district characteristics), processes (SPI-RRT audits assessing seven Core Essential Elements and quality management actions), and outputs (readiness for certification levels on a scale of 0 to 4 stars). The structure illustrates how the facilities are stratified by ownership, donors, and geographic zone to identify performance gaps and inform tailored interventions.

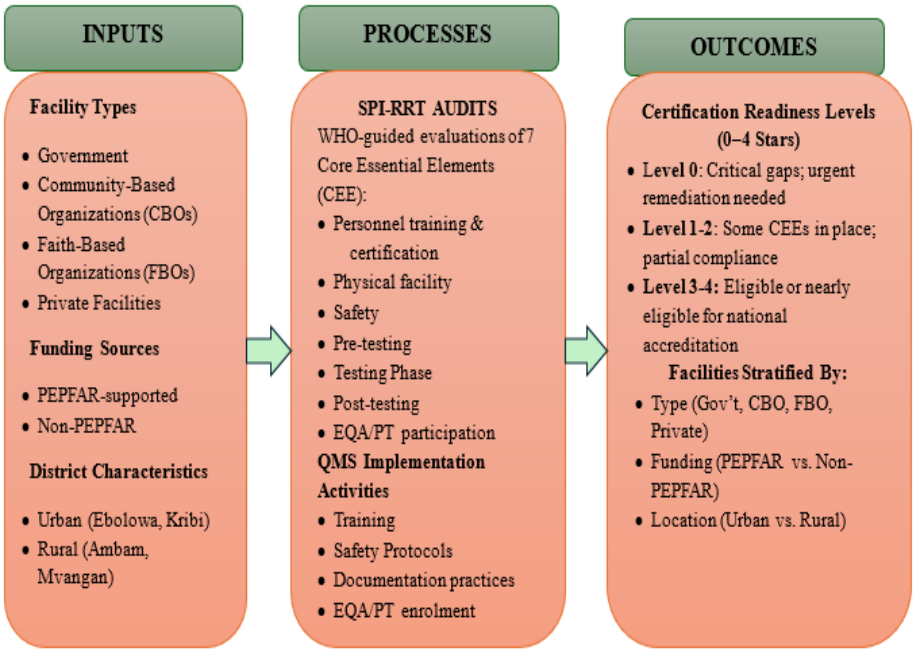

Figure 1. Conceptual Framework for Stratified Evaluation of HIV Testing Quality in Cameroon

Materials and Methods

Description of the Site

Research was undertaken in the South Region of Cameroon, one of the nation's ten administrative regions, located in the southernmost region, adjacent to the Atlantic Ocean to the west, to the south by Gabon, and to the southwest by Equatorial Guinea. The regional distribution is mixed, with major cities including Ebolowa, Kribi, and Sangmelima, and several rural health districts, including Ambam, Mvangan, and Djoum. The region's economy relies on agriculture, fishing, logging, and cross-border trade. The network of healthcare ranges from regional hospitals to district hospitals, with integration for some to the level of clinics, private clinics, faith-based clinics, together with community-based organization (CBO) clinics. The capacity of laboratories varies significantly, with some having the advantage of external funding, for instance, PEPFAR, whereas other has little external funding.

Description of the Experiments Done

A total of 99 HIV rapid testing laboratories were included in the study. These facilities represent a complete census of all laboratories that met the national eligibility criteria for HIV rapid testing within the South Region of Cameroon during the study period (January 2022–March 2024). No sampling procedure was applied because the objective was to obtain a full regional picture of laboratory quality performance across all ownership types and support levels. The inclusion of all eligible facilities strengthens the representativeness and reliability of the findings. The WHO Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RRT) checklist was used to evaluate laboratory quality management practices. The SPI-RRT tool assesses seven CEE: (1) personnel training and certification, (2) physical facility, (3) safety, (4) pre-testing phase, (5) testing phase, (6) post-testing phase, and (7) participation in EQA or proficiency testing (PT). Each element was scored, and total scores were mapped to quality levels ranging from Level 0 (critical gaps) to Level 4 (eligible for national accreditation). Data collection also included laboratory audits, personnel competency assessments, and observation of adherence to standard operating procedures (SOPs).

Description of the Laboratory Methods

Facility evaluations were conducted by trained assessors certified in the use of the SPI-RRT tool in accordance with WHO guidelines. Before commencing data collection, assessors underwent a joint calibration session to harmonize scoring practices and reduce variability. During field deployment, inter-rater reliability checks were performed through paired assessments of selected facilities, cross-review of scoring sheets, and supervisory verification of discrepancies. These quality control measures ensured consistent interpretation and scoring of tool items across assessors. For personnel competency, a structured skill assessment was conducted for the HIV rapid test, covering the pre-analytical (sampling collection and preparation), analytical (test performance, timing, and result interpretation), and post-analytical (documentation and reporting) phases. Adherence to the national HIV testing algorithm, where applicable, was confirmed. Laboratory safety included inspection of the biosafety measures, PPE usage, and waste disposal practices. The documentation review included SOPs, IQC records, EQA/PT participation certificates, and correction action logs.

Description of Statistical Methods Used

Quantitative data were entered and analyzed using IBM SPSS Statistics Version 27. The analysis consisted of descriptive and inferential statistical procedures aligned with the structure of the results. Descriptive statistics (means, standard deviations, frequencies, and percentages) were used to summarize SPI-RRT performance across the seven CEE and to characterize facilities by district, ownership type, PEPFAR support status, and HIV testing tier. These descriptive summaries provided the basis for identifying general performance trends and variability within and between facility groups.

To compare mean SPI-RRT scores between PEPFAR-supported and non-PEPFAR facilities, an independent-samples t-test was conducted. This analysis was used to determine whether the observed differences in overall performance and core element scores between the two groups were statistically significant. Results presented in the findings section reflect the calculated mean differences and significance values ($p < 0.05$).

Differences in performance across ownership categories (government, private, faith-based, and community-based organizations) were assessed using a one-way Analysis of Variance (ANOVA). This test examined whether mean SPI-RRT scores varied significantly across the four ownership groups for each core essential element and for the overall score. Where the ANOVA indicated significant group differences, the interpretation of results was supported by examining the distribution of means and standard deviations across categories.

Post-hoc Analyses

For ANOVA models that demonstrated statistically significant differences across facility ownership categories, post-hoc pairwise comparisons were conducted using the Tukey Honestly Significant Difference (Tukey HSD) test. This procedure allowed identification of specific group-to-group differences while adjusting for multiple comparisons. Tukey HSD was selected because it maintains appropriate control of Type I error rates and is suitable for comparing groups with unequal sample sizes. The post-hoc results provided additional clarification on which facility categories differed significantly in their SPI-RRT scores following the omnibus ANOVA results. Confidence intervals (95% CI) for mean differences were also generated to support the interpretation of effect sizes.

Associations between facility characteristics and accreditation readiness levels (Level 0–Level 4) were analyzed using chi-square tests.

This allowed assessment of whether readiness levels were dependent on district, ownership type, or donor support status. Significant relationships were interpreted based on chi-square values and p-values reported in the results.

To estimate the precision of selected performance indicators, 95% confidence intervals (CI) were calculated and presented in the results summary. Confidence intervals were used particularly when describing mean overall SPI-RRT scores and district-level variations in readiness. All statistical tests were conducted at a significance level of $p < 0.05$. The analytical procedures applied were consistent with the study objectives and the structure of the results, enabling clear interpretation of differences in quality performance across facility categories, geographic areas, and donor support levels.

Results

Description of the General Characteristics of Testing Facilities

It is important to note that Round 1 and Round 2 assessments were not conducted for the same facility categories. Only PEPFAR-supported sites were evaluated in both Round 1 (2022) and Round 2 (2024) in order to monitor longitudinal changes resulting from structured mentorship and technical assistance. Non-PEPFAR facilities were evaluated only in Round 2, as they were included later when the assessment expanded to cover all eligible laboratories in the region. Therefore, comparisons between rounds reflect performance changes only among PEPFAR-supported sites, while comparisons between PEPFAR and non-PEPFAR facilities rely solely on Round 2 data. This clarification is essential to avoid misinterpretation when viewing the tables and performance trends.

Table 1 below captures the overall characteristics of the HIV testing sites in two rounds of assessments: Round one (Oct to Dec 2022) and Round Two (Jul to Sep 2024). The important variables examined include Health District, HIV Testing Capacity (Tier), Site Type, and Affiliation. Under Health District Coverage, the overall number of tested sites reviewed rose significantly in the two rounds, from 29 in Round One to 99 in Round Two. The greatest contribution to the capacity for tests in both rounds was the Ebolowa District, from 24.1% 7 in Round one to 19.2% in 19 Round two. Other districts, such as Ambam, Djoum, Kribi, and Kye-Ossi, made smaller contributions but stayed consistent in the two rounds. Sites were grouped according to their client capacity for tests. Tier 1 (>2000 clients), which was constant in both rounds, in the form of 1 site in both rounds. Most of the sites were Tier 3 (500-1000 clients), which increased from 51.7% in Round One to 35.4% in Round Two. A major change was observed in Tier 4 (<500 clients), rising to 58.6% in Round two from 27.6% in Round one, indicating an increase in sites with smaller test capacities. In Round One, all 29 (100%) sites were PEPFAR-supported facilities. By Round two, 29(29.3%) out of the 99 sites were PEPFAR-supported facilities, and the other 70(70.7%) were non-PEPFAR-supported facilities. Most of the sites were government-affiliated in both rounds (72.4% in Round One and 69.7% in Round Two). It was observed that the representation of the faith-based and private organisations changed slightly, as the Faith-Based sites increased to 11.1% from 10.3%, and the Private affiliations increased to 17.2% from 10.3% across the two rounds. This depicts the increase in HIV testing capacity in the South Region of Cameroon, as well as the growth in capacity at lower-capacity sites (Tier 4) and the diversification of site affiliations toward more non-PEPFAR-funded and private entities. The analysis identifies major trends in the scale-up of HIV testing services, particularly in rural or lower-capacity areas.

Table 1. Description of the General Characteristics of Testing Facilities

Description of the general characteristics of the testing facilities		
Variables	**Round one Assessment (October to December 2022)**	**Round Two Assessment (July to September 2024)**
Health District	1(3.4%)	8(8.1%)
Ambam	2(6.9%)	4(4%)
Djoum	6(20.7%)	20(20.2%)
Ebolowa	7(24.1%)	19(19.2%)
Kribi	2(6.9%)	4(4%)
Kye-Ossi	1(3.4%)	4(4%)
Lolodorf	3(10.3%)	9(9.1%)
Meyomessala	1(3.4%)	8(8.1%)
Mvangan	1(3.4%)	2(2%)
Niete	0(0%)	4(4%)
Olamze	1(3.4%)	12(12.1%)
Sangmelima	3(10.3%)	5(5.1%)
Zoetele	2(6.9%)	99(100%)
Total	29(100%)	8(8.1%)
HIV Case Management Capacity (Tier)		
Tier 1 (Above 2000 Clients)	1(3.4%)	1(1%)
Tier 2 (1000 To 2000 Clients)	5(17.2%)	5(5.1%)
Tier 3 (500 To 1000 Clients)	15(51.7%)	35(35.4%)
Tier 4 (Below 500 Clients)	8(27.6%)	58(58.6%)
Total	29(100%)	99(100%)
Site Type		
PEPFAR	29(100%)	29(29.3%)
Non-PEPFAR	0(0%)	70(70.7%)
Total	29(100%)	99(100%)
Affiliation		
Community-Based Organization	2(6.9%)	2(2%)
Faith-Based Organization	3(10.3%)	11(11.1%)
Government	21(72.4%)	69(69.7%)
Private	3(10.3%)	17(17.2%)
Total	29(100%)	99(100%)

Evaluation of Facility Performance Across Several Domains in PEPFAR and NON-PEPFAR Facilities of the South Region, Cameroon

Table 2 above illustrates the performance evaluation of the 7 CEE in the PEPFAR and NON-PEPFAR facilities to which assessments were conducted in two rounds for PEPFAR (N=29) and a single round for NON-PEPFAR facilities (N=70). The findings indicate significant performance differences, whereby PEPFAR facilities have consistently improved and performed far better than NON-PEPFAR facilities.

1. **Personnel Training and Certification:** PEPFAR-supported facilities enhanced their score from a baseline of a mean of 5 (SD=2) in Round 1 to a mean of 7 (SD=2) in Round 2, while NON-PEPFAR-supported facilities achieved only a mean score of 0.
2. **Safety:** PEPFAR-supported facilities showed high scores (Mean = 10; SD = 2 in Round 1 and SD = 0 in Round 2), while NON-PEPFAR-supported facilities scored a mean of 4 (SD=0).
3. **Testing Stage:** PEPFAR-supported facilities enhanced from a mean of 7 (SD=2) in Round 1 to 9 (SD=1) in Round 2, while NON-PEPFAR-supported facilities reported a mean of 1 (SD=0).
4. **Total Scores:** PEPFAR facilities improved overall performance, increasing from a mean of 49 (SD=12) in Round 1 to 59 (SD=4) in Round 2. Non-PEPFAR facilities lagged, with a mean score of 14 (SD = 6).

The results demonstrate that PEPFAR-supported facilities have prospered through structured interventions, scoring higher in all areas of pre-testing, testing, and external quality assessments. However, non-PEPFAR-supported facilities exhibited considerable gaps in staff training, testing processes, and safety protocols; the need to close these performance gaps was underscored.

Table 2. Evaluation of Facility Performance Across Several Domains in PEPFAR and NON-PEPFAR Facilities

Core Essential Element (CEE)	**Round 1 Assessment PEPFAR (N=29) Mean (Std Deviation)**	**Round 2 Assessment PEPFAR (N=29) Mean (Std Deviation)**	**Round 2 Assessment NON-PEPFAR (N=70) Mean (Std Deviation)**
Personnel Training and Certification	5(2)	7(2)	0(1)
Physical Facility	5(1)	5(0)	5(0)
Safety	10(2)	10(0)	4(0)
Pre-Testing Phase	11(3)	13(1)	3(1)
Testing Phase	7(2)	9(1)	1(0)
Post-Testing Phase - Documents and Records	7(2)	9(1)	1(0)
External Quality Assessment (Proficiency Testing/EQA and Site Supervision)	5(3)	8(1)	3(4)
Overall Score	**49(12)**	**59(4)**	**14(6)**

Core Essential Elements (CEE) Across Different Affiliations or Organization Types

Table 3 below illustrates the audit of CEE within various organizations, Community-Based Organizations (CBOs), Faith-Based Organizations (FBOs), Government (Gov't),

and Private, revealing considerable performance differences:

1. CBOs posted the highest scores in all the areas for which data are provided: Personnel Training (Mean = 7, SD = 1), Safety (Mean = 10, SD = 0), and Overall Score (Mean = 50, SD = 3). Their low standard deviations reveal uniform performance across facilities.
2. FBOs, Government & Private organizations underperformed as compared to CBOs in Personnel Training (Mean = 2, SD = 3), Post-Testing Phase (Mean = 2-3, SD = 4), and External Quality Assessment (Mean = 1-2, SD = 3-4).
3. Scores for non-CBO organizations have very high variability (SD = 17–23), indicating inconsistent standard compliance.

The substantial variability observed in Table 3 warrants clarification. Community-Based Organizations (CBOs) exhibited extremely low standard deviations (SD = 0–1) because the sample size for this group was very small (only two sites), and both facilities demonstrated uniformly strong adherence across all SPI-RRT indicators. This naturally produced minimal variability. In contrast, the Faith-Based, Government, and Private facility categories consisted of larger and more heterogeneous groups. These groups included facilities with both very low and moderate levels of quality system implementation, resulting in markedly high standard deviations (e.g., SD up to 23). This pattern reflects true performance disparities within these categories rather than measurement error, and it underscores systemic inconsistencies in quality management practices across non-CBO facilities. These Round Two results, both PEPFAR and non-PEPFAR-supported facilities, highlight CBOs as a model for best practice and indicate the need for focused interventions in FBOs, government, and Private organizations to enhance training, testing, and quality assessment strategies.

Table 3. Core Essential Elements (CEE) Across Different Affiliations or Organization Types

Core Essential Element (CEE)	**CBO**		**FBO**		**Gov't**		**Private**	
	Mean (Std.Dev.)	**Std. Error**	**Mean (Std.Dev.)**	**Std. Error**	**Mean (Std.Dev.)**	**Std. Error**	**Mean (Std.Dev.)**	**Std. Error**
Personnel Training and Certification	7(1)	1.000	2(3)	0.982	2(3)	0.350	1(3)	0.675
Physical Facility	5(0)	0.000	5(0)	0.091	5(1)	0.350	5(1)	0.177
Safety	10(0)	0.000	5(4)	0.844	6(3)	0.328	6(2)	0.582
Pre-Testing Phase	13(0)	0.000	6(4)	1.319	6(4)	1.319	6(1)	0.863
Testing Phase	9(1)	0.500	3(4)	1.083	4(3)	0.417	4(3)	0.834
Post-Testing Phase - Documents and Records	9(0)	1.000	2(4)	1.245	3(4)	0.486	2(4)	0.869
EQA (Proficiency Testing/ and Site Supervision)	6(1)	1.000	2(4)	1.090	2(3)	0.416	1(3)	0.762
Overall Score	**50(3)**	**3.500**	**25(23)**	**6.654**	**28(21)**	**3.666**	**25(17)**	**4.764**

The variability observed in Table 3 above requires clarification for proper interpretation. Community-Based Organizations (CBOs) recorded very low standard deviations (SD = 0–1) because the group consisted of only two facilities, and both demonstrated consistently

strong and uniform performance across all SPI-RRT elements. This naturally produced minimal variability.

In contrast, government, faith-based, and private facilities each had larger sample sizes and markedly heterogeneous performance levels, which resulted in very high standard deviations (e.g., SD up to 23). These groups included facilities with weak quality systems alongside others with moderate or strong implementation, leading to wide score dispersion. This variability highlights systemic inconsistency in quality management implementation among non-CBO facilities and supports the interpretation that CBOs represent more uniform and structured models of HIV testing service delivery.

Performance of Health Districts by Level

The performance analysis of Health Districts presented in Figure 2, which identifies important district-to-district variability in the achievement of quality standards:

Struggling Districts (Level 0)

Most facilities in the districts of Ambam, Ebolowa, Kribi, Sangmelima, Meyomessala, and Mvangan remain at Level 0 due to critical performance gaps. These Districts need urgent attention to solve the core service delivery and quality management problems.

Moderate Performance (Levels 1 and 2)

Districts such as Ebolowa, Kribi, and Zoetele have a combination of structures in Levels 1 and 2, which demonstrates incremental improvement but still require specialized support to achieve higher levels of compliance.

High-Performance Districts (Levels 3 and 4)

Districts including Ebolowa, Kribi, and Sangmelima have made encouraging strides. A few of the sites reach Level 3 and some reach Level 4 to qualify for national certification. These top-performing sites represent potential replication sites for best practice in lower-performing areas (Figure 3).

The results highlight the requirement for a differentiated quality improvement approach:

1. Struggling districts need in-depth capacity building and focused mentoring to overcome system weaknesses.
2. Moderate-performing districts require ongoing technical assistance and continual monitoring to facilitate advancement towards certification.
3. High-performing facilities must be utilized as centers for learning to facilitate cross-district knowledge sharing.

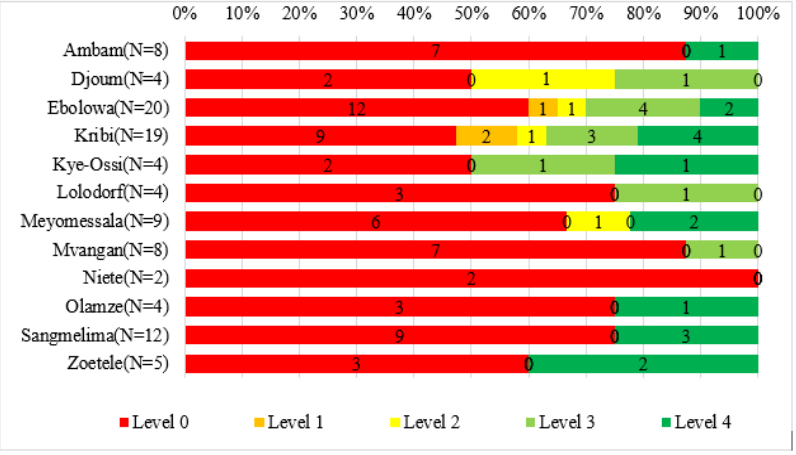

Figure 2. Performance of Health Districts by Level

SPI-RRT Scoring Ranges and Level Definitions	
Levels	*Description of results*
Level 0 (0–39%)	Needs improvement in all areas and immediate remediation
Level 1 (40–59%)	Needs improvement in specific areas
Level 2 (60–79%)	Partially eligible
Level 3 (80–89%)	Close to national site certification
Level 4 (90–100%)	Eligible for national site certification

Figure 3. SPI-RRT Scoring and Level Definitions

Discussion

The disparities observed across facility types reflect deeper structural and operational gaps that are strongly linked to specific Core Essential Elements (CEE) of the SPI-RRT tool. The widest performance gaps were observed in Personnel Training and Certification, Testing Phase, Post-Testing Documentation, and External Quality Assessment (EQA), all of which require sustained mentorship, SOP availability, regular supervisory visits, and documented corrective actions [13]. Government and private facilities showed substantial variability in these indicators, largely due to inconsistent staff competencies, infrequent retraining, and limited participation in EQA programs. Conversely, CBO facilities demonstrated uniformly high performance across these elements, particularly in safety, testing accuracy, and documentation completeness, underscoring the high degree of standardization in their operational procedures [2, 14].

Potential Confounders Influencing Performance Differences

Several potential confounders likely influenced the observed disparities (Table 1). Facility size and testing volume differ significantly across facility categories; higher-volume government sites may experience workflow pressure, increasing the risk of procedural deviations [15]. Staffing profiles also vary, with government and private facilities relying on mixed cadres, some without formal laboratory training, while CBOs often employ fewer but more consistently trained staff. Supervisory frequency is another key confounder; PEPFAR-supported sites, which include many CBOs, benefit from regular technical assistance visits, while non-supported facilities receive infrequent oversight. These factors collectively contribute to the heterogeneous performance seen in non-CBO sites and underscore the need for targeted, system-wide capacity building.

Critical Interpretation of Why CBOs Performed Exceptionally Well

The unexpectedly strong performance of CBO sites can be explained by several contextual factors. First, the sample size for CBO facilities was very small, which naturally reduced variability and contributed to the near-zero standard deviations observed in Table 3 [16]. Second, CBOs tend to have tightly focused service delivery models with smaller testing volumes, allowing closer adherence to procedures and easier implementation of quality measures. Third, most CBOs receive targeted donor-driven mentorship and frequent supervisory support, especially in HIV community testing programs, which strengthens performance in training, documentation, and testing accuracy [17]. These characteristics create an environment in which quality practices are applied more consistently than in larger, more heterogeneous government and private facilities.

Performance Disparities by Donor Support

The stark contrast between PEPFAR-supported facilities and those not supported by PEPFAR (Table 2) underscores the transformative impact of structured, external support. PEPFAR-funded facilities showed significant improvement across all CEEs, a trend consistent with findings from Kenya and South Africa, where sustained mentorship and EQA participation enhanced laboratory quality [10, 18, 19]. A critical interpretation of the SPI-RRT scores reveals that the widest performance gaps were not in static elements like Physical Facility (which scored similarly), but in dynamic, process-oriented elements. The most substantial disparities were observed in:

Personnel Training and Certification (Mean: 7 vs. 0): This indicates a near-total lack of formal training and competency assessment in non-PEPFAR-supported facilities, directly impacting test accuracy and interpretation.

Testing Phase (Mean: 9 vs. 1) and Post-Testing Phase (Mean: 9 vs. 1): These gaps point to critical failures in adhering to standard operating procedures, proper documentation, and accurate result reporting in non-supported facilities.

External Quality Assessment (Mean: 8 vs. 3): The lower score for non-PEPFAR-supported facilities reflects a lack of participation in proficiency testing and external oversight, meaning errors likely go undetected and uncorrected.

These specific gaps in training, process adherence, and quality control are the primary drivers of the low accreditation readiness and pose the greatest risk to diagnostic reliability.

Organizational Affiliation and Core Essential Elements

The stratification by organizational type (Table 3) yielded a surprising finding: Community-Based Organizations (CBOs) achieved the highest mean SPI-RRT score. However, this result requires cautious interpretation. The exceptional performance and minimal variability (SD = 0–1) within the CBO group are likely influenced by its tiny sample size (only two sites). It is plausible that these two CBOs were "model sites" or pilot projects receiving intensive, focused support, which is not representative of CBOs at a larger scale. This potential selection bias limits the generalizability of their performance as a category.

Beyond the CBO anomaly, the high standard deviations observed in Faith-Based, Government, and Private facilities (SD up to 23) are highly informative. They do not merely indicate measurement error but reveal profound systemic inconsistency within these sectors. This suggests that quality management is not institutionalized but is instead dependent on variable factors such as individual facility leadership, the presence of a dedicated quality officer, or sporadic supervisory visits. The finding that government facilities, which form the backbone of the public health system, had the lowest mean score (14 ± 21) is particularly concerning and highlights systemic under-investment in public-sector quality assurance [20].

Geographic Inequities in Performance

The district-level analysis further illustrates the consequences of uneven resource distribution. Higher-performing districts like Sangmelima and Kribi are urban centers that typically benefit from better infrastructure, more trained personnel, and greater access to supervisory visits and supply chains. In contrast, rural districts like Mvangan and Djoum are often marginalized, reinforcing the well-documented urban-rural divide in laboratory services in Cameroon and similar contexts [2]. This geographic stratification necessitates a differentiated quality improvement approach rather than a one-size-fits-all strategy [2].

Confronting Confounders: Staff Cadre, Supervision, and Facility Size

The interpretation of these results must account for potential confounders not fully captured by the SPI-RRT tool. A key confounder is staff cadre and turnover. PEPFAR-supported sites may benefit from additional, often more specialized, staff or lower turnover rates due to better incentives, directly impacting training scores and procedural adherence. Furthermore, the frequency and quality of supervision are intrinsically linked to donor support. PEPFAR's structured mentorship model creates a continuous feedback loop for quality improvement, whereas non-supported facilities may experience only infrequent, punitive inspections from overstretched district health teams. Finally, while our data includes testing tier (a proxy for size and client volume), the analysis could be strengthened by explicitly discussing how facility size and patient load interact with quality systems. Smaller, rural Tier 4 facilities likely face compounded challenges of isolation, inadequate resources, and less-skilled staff, making consistent QMS implementation particularly difficult.

Implications for Quality Management Strategy Implementation

Overall, the findings suggest the existence of quality management strategies, but with uneven application throughout the South Region. Donor-funded facilities, urban locations, and some organizational types exhibit preparedness for accreditation, whereas government-owned, non-funded, and rural facilities fall behind, specifically for CEEs like quality control, corrective measures, and continuous quality improvement [21]. Correction of these gaps will need government-driven investments in training, infrastructure, and institutionalized EQA/PT participation, with intentional mentorship aimed at duplicating the performance improvements observed among PEPFAR-funded facilities [22].

Comparison with Other Studies

The overall low percentage (12%) of facilities reaching Level 3 or 4 readiness aligns with other SPI-RRT implementations in sub-Saharan Africa, where achieving accreditation readiness without sustained external support remains challenging [23]. Our stratified analysis, however, adds crucial nuance by pinpointing that this challenge is most acute for government-owned, non-funded, and rural facilities.

Study Limitations

This study has several limitations that should be considered when interpreting the findings. First, although assessors were trained and underwent calibration exercises before data collection, the possibility of assessor bias cannot be eliminated. Differences in the interpretation of certain SPI-RRT indicators or subjective scoring judgments may have influenced the results, particularly in borderline cases where documentation or practices were inconsistently applied.

Second, the maturity of laboratories across facility types varied substantially. Some facilities, particularly government and private sites, were at very early stages of establishing quality management systems, while others, such as PEPFAR-supported and certain CBO facilities, had been exposed to repeated mentorship cycles and had more advanced quality structures. These differences in system maturity likely affected performance outcomes independently of operational capacity and may have contributed to the large standard deviations observed within certain facility groups.

Third, the study relied exclusively on quantitative SPI-RRT assessment data, without triangulating with qualitative insights from laboratory personnel. Interviews or focus group discussions could have provided additional context on staffing challenges, workflow barriers, supervisory gaps, and perceptions of quality improvement processes. The absence of such qualitative data limits the depth of

interpretation, particularly regarding the underlying drivers of poor performance in non-supported laboratories.

Despite these limitations, the study provides a comprehensive, region-wide assessment of HIV rapid testing quality and highlights critical areas requiring targeted improvement [24, 25].

Conclusion

This stratified analysis of quality management practices among HIV rapid testing laboratories in the South Region of Cameroon has identified considerable variations in performance and implementation, driven mainly by donor support, organizational mission, and geographic setting. Whereas PEPFAR-funded, urban, and community- or faith-based facilities exhibited greater adherence to the WHO SPI-RRT Core Essential Elements and stronger accreditation readiness, numerous government- and rural-based facilities are hampered by inadequate infrastructure, insufficient staff training, poor documentation systems, and a lack of continuous quality improvement activities.

These findings underscore the pressing need for a balanced approach that sustains the gains achieved in donor-supported sites while extending quality improvement interventions to underperforming facilities. Strengthening government ownership of quality management systems, expanding technical mentorship, ensuring regular EQA/PT participation, and addressing urban–rural inequities are essential to building a resilient and equitable HIV diagnostic network.

Through filling these gaps and entrenching strong laboratory quality management systems, Cameroon can take steps towards its national and international HIV targets, ensuring all persons, no matter where they reside or facility level, gain accurate, reliable, and timely HIV diagnosis.

Contribution to Knowledge

This work contributes several valuable additions to understanding and developing quality assurance for HIV rapid testing laboratories in resource-scarce environments:

1. Empirical Evidence from a Stratified Assessment: It is the first comprehensive, stratified examination on the quality assurance procedures of HIV rapid tests in the South Region of Cameroon, and finds inequalities by ownership, donor support status, and location.
2. Identification of Core Performance Gaps: The study identifies certain weaknesses in Core Essential Elements, most notably in personnel training, quality control, documentation, and continuous quality improvement, that constrain accreditation readiness in most facilities.
3. Documentation of Donor Impact: Through the quantitative measurement of performance contrasts between PEPFAR-assisted and non-assisted sites, the analysis highlights the transformative impact of continued technical and financial support on the quality results of laboratories.
4. Urban-Rural and Institutional Inequities: The results indicate substantive geographic and organizational differences in the application of quality management, providing nuanced evidence to support focused interventions that target system inequities in HIV diagnostic services.
5. Programmatic and Policy Direction: The findings provide actionable recommendations for program managers, implementing partners, and policymakers to create specialized mentorship, training, and infrastructure support approaches that can expedite accreditation readiness and enhance diagnostic accuracy across all facility levels.

Through the integration of a WHO-recommended quality evaluation framework (SPI-RRT) and stratified performance analysis, this work develops the methodological and

contextual knowledge needed to improve laboratory systems in Cameroon and other contexts, thereby supporting the ultimate objective of reaching the UNAIDS 95-95-95 targets.

Data Availability

The datasets generated and analyzed during the current study are not publicly available due to confidentiality agreements with the participating health facilities and the Cameroonian Ministry of Public Health. However, anonymized data are available from the corresponding author upon reasonable request and with permission from the South Regional Delegation of Public Health.

Conflict of Interest

The author declares that there is no conflict of interest related to this study. Although some of the laboratories assessed in this research receive technical or logistical support from programs such as PEPFAR, the data presented and the analysis conducted are entirely independent and do not reflect the views, performance evaluations, or reporting standards of PEPFAR or its affiliated partners.

These results are drawn exclusively from the field data provided by the researcher through standard tools (i.e., SPI-RRT checklist and competency assessment questionnaire), and no programmatic or financial influence from any external sponsor, including PEPFAR, has influenced the methodology, findings, interpretation, or recommendations from this study.

Author Contributions

- **Abanda Emmanuel Chafah:** Conceptualization, Methodology, Investigation, Data Curation, Formal Analysis, Writing-Original Draft, Writing-Review & Editing.
- **Dr. Nshom Emmanuel Mboh:** Validation, Writing-Review & Editing, Project Administration.
- **Dr. Bodzewan Emmanuel Fonyuy:** Supervision, Writing-Review & Editing.
- **Dr. Awandem Ernest Forku:** Project Administration, Writing Review & Editing.
- All authors have read and approved the final version of the manuscript.

Ethical Approval

This study was approved by the South Regional Delegation of Public Health, Cameroon (Ref: No: 947/AR/MIN-SANTE/SG/DRSPS/BEP). Informed consent was obtained from all participants involved in the interviews and focus group discussions. All data were anonymized to ensure confidentiality.

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