

Innovative Approach to Improving Adherence to Quality Standards at HIV Rapid Testing Sites in Cameroon using the Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) Checklist

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ABSTRACT

Within the past decade, HIV prevalence in Cameroon has dropped significantly from 11.8% in 2002 to 4.3% in 2015, but the quality of HIV rapid test results is still a challenge. Data from a 2012 HIV sentinel survey among pregnant women tested showed 18.8% received false negative results. Therefore, achieving HIV epidemic control by 2020 in accordance with the UNAIDS 90-90-90 targets critically depends on the accuracy of “the first 90”. The HIV Rapid Test Quality Improvement Initiative (RT-QII) is a catalytic effort, building upon in-country PEPFAR programs to address known gaps in the quality assurance cycle (QAC) of HIV rapid testing.

Between June 2014 and April 2016, 169 HIV RT sites were selected from four regions in Cameroon to pilot RTQII. Twenty-eight quality corps volunteers (Q-Corps) were trained and competent on HIV rapid testing and QAC. Additionally, at least one staff from all selected sites was trained using a standardized comprehensive HIV quality assurance package. Sites were audited quarterly by Q-Corps using the SPI-RT checklist having 08 sections or major quality elements, and corrective actions were provided during monthly field visits. Baseline and last assessment data were compared using the chi-square test for site levels and a paired t-test for mean scores of different checklist elements.

All 169 sites recorded significant ($P < 0.0001$) progress with 34% at level 0, 33% at level I, 33% at level II, compared to 0% at level 0, 7% at level I, 66% at level II, 28% at level III during baseline and last assessments respectively. The mean scores (73%) of quality elements were significantly ($P < 0.006$) higher at last assessment when compared to baseline (48%).

RT-QII led to significant quality improvement in the pilot sites and will serve as an efficient approach for optimizing the quality management systems of all facilities providing HIV testing services in Cameroon.

Background

HIV constitutes a significant health problem in Cameroon with a prevalence of 4.3% with adults aged 15-49 being the most affected [1]. The prevalence in Cameroon has dropped significantly from 11.8% in 2002 to 4.3% in 2015, but the quality of HIV test results is still a challenge. In-country efforts geared towards the control of the disease involves the adoption of the World Health Organization (WHO) ‘test and treat’ option [2] and the UNAIDS targets of 90-90-90 by 2020[3]. The former requires the immediate placement on antiretroviral therapy (ART), of any person tested positive while the latter depends on the accuracy of the ‘first 90’. To

this effect, a false-positive HIV diagnosis could result in an unnecessary initiation of life-long ART and the potential for stigma, discrimination. Hence ensuring quality of HIV rapid test results is vital in the control of the epidemic in Cameroon.

In order to scale up HIV rapid testing in Cameroon, HIV testing is performed in laboratory and non-laboratory settings with its implication being the performance of HIV rapid test by laboratory and non-laboratory staff. Quality issues have been reported between these tester groups with

How to cite this paper: Priscillia Mosoke | Juliana Ndasi | Laura Dimite | Charles Efueta | Bienvenu Etogo | Keisha Jackson | Peter Fonjungo | Souleymane Mboup | Judith Shang | Patrick Njukeng "Innovative Approach to Improving Adherence to Quality Standards at HIV Rapid Testing Sites in Cameroon using the Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) Checklist" Published in International Journal of Trend in Scientific Research and Development (ijtsrd), ISSN: 2456-6470, Volume-4 | Issue-4, June 2020, pp.730-735, URL: www.ijtsrd.com/papers/ijtsrd31221.pdf



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laboratory personnel producing more accurate results than their non-laboratory counterparts^{[4] (7)}. A false negative rate of 18.8 % reported in Cameroon during a 2012 sentinel surveillance survey^[5] emphasized the urgent need for the effective integration of quality systems in HIV testing points to improve quality assurance of HIV rapid testing and produce accurate and reliable test results.

Health Systems Strengthening (HSS) was emphasized in a \$63 billion comprehensive global health initiative (GHI) announced by President Barack Obama in May 2009 and was also an important focus of \$49 billion program of the US President's Emergency Plan for AIDS Relief (PEPFAR) and Global fund to fight AIDS, malaria and tuberculosis. This funding offered an opportunity to end the neglect of laboratory systems which are often neglected in resource-poor setting.⁶

In collaboration with the US Centers for Disease Control and Prevention (CDC) Cameroon and the Cameroon Ministry of Public Health (MoPH), Global Health Systems Solutions (GHSS) started implementing HIV rapid testing quality assurance in 2009 to improve the quality of HIV rapid test results with PEPFAR funds. By June 2016, nine hundred and thirty two (932) testing sites received training on quality assurance and nine hundred and twelve (912) sites enrolled in HIV Dried Tube Specimen (DTS) Proficiency Testing (PT)⁷. However, limited human and financial resources for regular site supportive supervision resulted in significant gaps which hindered the realization of program objectives. With a reported average national HIV PT success rate of 65%⁷ which required urgent amelioration, the above challenges limited effective continuous identification of quality gaps at testing sites and provision and implementation of corrective actions for continuous improvement.

As a measure to mitigate these challenges and successfully achieve the QA program goals, the HIV Rapid Testing Quality Improvement Initiative (RTQII) was introduced. The RTQII which builds on in-country US President's Emergency Plan for AIDS Relief (PEPFAR) program using innovative approach such as quality corps (Q corps) volunteers to improve the quality of HIV results was welcome to support the existing efforts in the country. The Q-Corps concept is modeled on the US Peace Corps program used to support and improve community projects in various departments including health, agriculture, and education.¹⁰

The Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) is an aspect of RTQII and is implemented through the use of a specific tool the SPI-RT Checklist.

The tool developed by WHO/CDC Atlanta and piloted in this study assesses quality elements to determine if testing sites provides 1) accurate and reliable results; 2) well managed and adhering to quality practices and; 3) identify areas for improvement. It provides guidance on QA practices for sites using HIV rapid tests to diagnose HIV infection^[8] and used for continuous quality improvement which progressively leads to adherence to quality standards at HIV rapid testing sites. The second version of the checklist⁽⁹⁾ used for this report has 8 sections with a total score of 70. The checklist scores are categorized into 5 levels with a score <40% corresponding to level 0, 40-59% corresponding to level 1, 60-79% corresponding to level 2, 80-89% corresponding to level 3, 90% and above level 4.

In this report we present the use of SPI-RT checklist through Quality –Corp Volunteers for continuous quality improvement in 169 RTQII pilot sites in four regions of Cameroon. This is for the period, June 2014 to April 2016.

Methodology

Study area and design

In this report, we present a pilot study which involved HIV Testing and Counseling (HTC) sites participating in RTQII. A total of 169 sites in four PEPFAR focused regions of Cameroon were enrolled in the South West Region (90), North West Region (36), Littoral Region (24) and Center Region (19). Sites were enrolled periodically following the progress of QA implementation in the different regions. Among the four regions, QA was implemented first in the South West region. Reason for the high number of study sites in this region compared to the other regions.

Criteria for site selection and distribution in the four PEPFAR focused regions included the following:

- Participation in the QA program with indicators such as enrollment in the DTS PT program and having at least one tester who has received training on QA using the standardized comprehensive HIV QA package.
- Provision of HTC services geared towards the prevention of mother-to-child transmission of HIV (PMTCT).

Enrollment of sites commenced in the South West Region (June 2014) and later extended to the Littoral and North West Regions (January 2015) and finally to the Center Region (October 2015). Progress and extent in QA implementation in the regions, influenced the commencement and number of sites in the regions. Sites were enrolled periodically as QA implementation progressed, from the South West region to the other regions with the centre region being the last.

Recruitment, training and deployment of Q-Corps volunteers

Two categories of Q-Corps volunteers were recruited; the Ministry of Health Volunteers (MCQs), constituting staff of the MoH health facilities and Community Volunteers (VCQs), constituting individuals working voluntarily or on part-time basis in private health facilities as well as unemployed university graduates in the community.

Location was a key element used for the recruitment of all Q-Corps as they were each expected to reside in one of the four PEPFAR focused regions and implement activities in their region of residence. In addition to location, selection of MCQs was also based on their commitment to the QA program and this was assessed by their performance in pre and post assessments during QA trainings and the adherence of their facilities to QA guidelines (availability of Standard Operating Procedures, use of job aids for testing, proper waste management and PT performance among others). The VCQs on the other hand had to apply for the position and were required to have at least a bachelor's degree in health or basic medical sciences.

Based on these criteria 28 Q-Corps (11 MCQs and 17 VCQs) were selected for training and subsequent deployment.

All selected Q-Corps were then effectively given a comprehensive hands-on training by 4 RTQII master trainers from GHSS and two trainers from CDC-Atlanta. Core elements of the training included the following:

- Training on the QA cycle with emphasis on site supportive supervision using the Q-Corps
- Practical hands-on HIV testing, DTS testing, logbook data entry and analysis
- The roles and responsibilities of Q-Corps
- Training on the use of baseline data gathering tool, Stepwise Quality Improvement of Point of Care Testing (SPI-POCT) followed by practical sessions.
- Training on electronic tool for data collection and analysis.
- Professional ethics

The Q-Corps volunteers upon deployment were responsible for field implementation of SPI-RT as well as collection and entry of field data. Field implementation of SPI-RT involves quarterly SPI-RT audit and data collection and monthly provision and follow-up of corrective actions to identified non-conformances. Q corps also provided on the spot training during monthly visits. Minimal allowances (lodging and feeding) were provided to them during field visits.

Results

National Performance of Study Sites

When baseline data was compared with last assessment, of the 169 sites evaluated at baseline and last assessment, all 169 sites recorded significant progress ($p < 0.0001$) with 34% at level “0”, 33% at level “I”, 33% at level “II” and 0% at level “0”, 7% at level “I”, 66% at level “II”, 28% at level “III” comparing baseline and last assessment respectively as seen in figure 1 below. There was no site at level “4” at last supervision

Data collection and analysis

The SPI-RT checklist version 2.0 was used for data collection. This checklist has eight major sections evaluating key quality elements specific to HIV rapid testing. The eight sections are:

- Personnel Training and Certification
- Physical Facility
- Safety
- Pre-Testing Phase
- Testing Phase
- Post-Testing Phase
- Document and Record
- External Quality Assessment

It also contains elements of the Quality Management System (QMS) and provides guidance on QA practices for sites using HIV rapid tests to diagnose HIV infection.

Baseline and last assessment data collected from all 169 pilot sites between June 2014 and April 2016 were entered into Microsoft Excel 2013 and analyzed. Site-level analysis was performed and mean scores of all eight sections on the checklist were obtained. Baseline and last assessment data were compared using the chi-square test for site levels and a paired t-test for mean scores of different checklist elements.

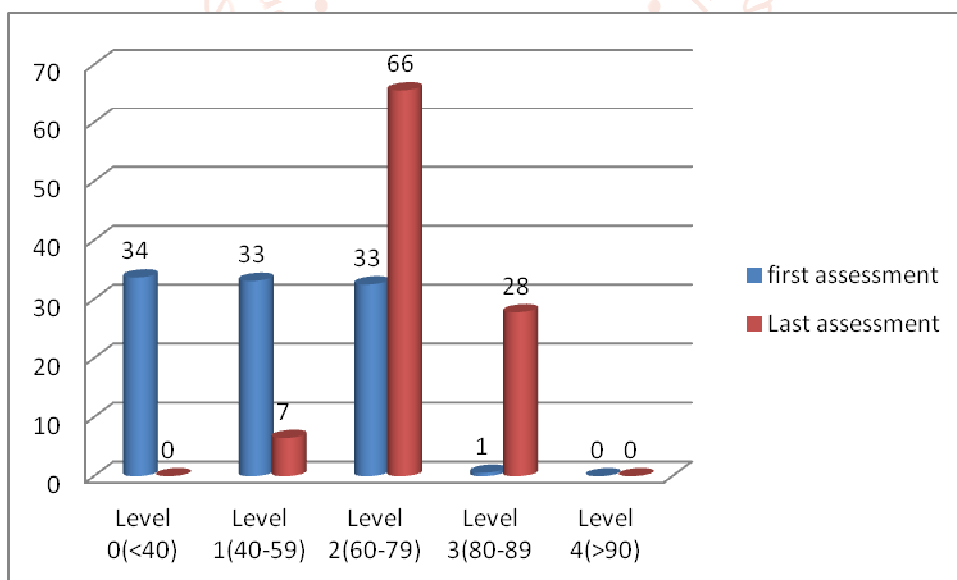


Figure 1: National Percentage of Pilot Sites at different level during first and last assessments

Comparing mean scores of eight elements of the checklist at baseline and last assessment revealed an increase in all elements at last assessment, with personnel training and certification having the least increase and lowest scores. The mean scores (73%) of elements were significantly ($P < 0.006$) higher at last assessment when compared to baseline (48%). This is an indication that the RTQII program has had a positive impact on all checklist items in all regions.

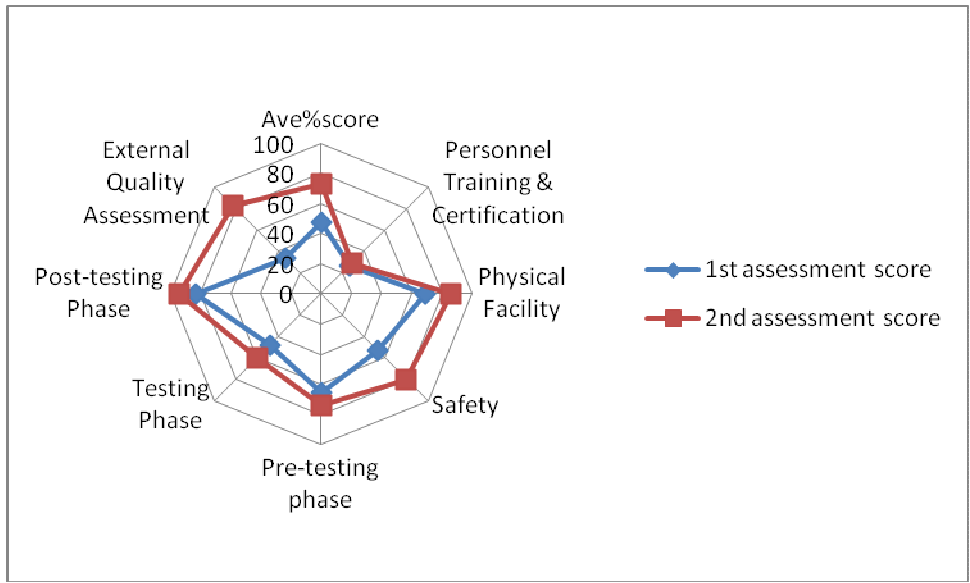


Figure 2: National Percentage of Mean Scores of Elements on the SPI-RT Checklist

Regional Performance of Study Sites

Comparing site levels of the four regions at baseline and last assessment, it was observed that Southwest region had the highest percentage (57%) of sites at level “0” at baseline and no site as the other three regions at level “0” at last assessment while Littoral region had the highest percentage (46%) of sites at level “3” at last assessment as seen in table 1 below.

Table1: Site levels for Regions at Baseline and Last Assessment

Site Level	Region							
	Centre Region		Littoral Region		North-West Region		South-West Region	
	Baseline (%)	Last assessment (%)	Baseline (%)	Last assessment (%)	Baseline (%)	Last assessment	Baseline (%)	Last assessment (%)
0	0	0	17	0	6	0	57	0
1	32	5	46	8	58	6	20	37
2	63	74	38	46	36	56	23	73
3	5	21	0	46	0	39	0	20
4	0	0	0	0	0	0	0	0

Comparing the average scores for the main elements at baseline and last assessment for the four regions revealed that the southwest region had the highest progress of 40% and 72% respectively while the centre region had the least progress of 65% and 74% respectively as seen in figure 3.

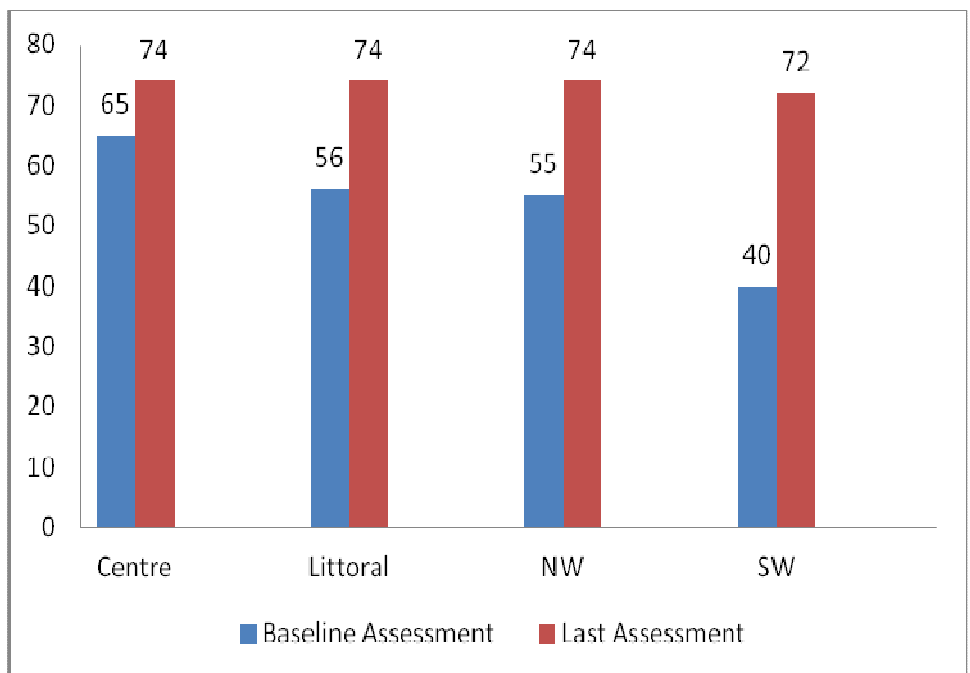


Figure 3: Mean Scores of Main Elements on the Checklist for Four Regions

Discussion

The present study is to our knowledge the first carried out in the country using the SPI-RT checklist for continuous quality improvement and adherence to quality standards at HIV rapid testing sites. However the Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA) checklist has been used in the country for continuous quality improvement in laboratories enrolled in the Strengthening Laboratory Management towards Accreditation (SLMTA) program (12). While the SLIPTA checklist has more items and implemented through on site mentors who are full time staff, the SPI-RT checklist is implemented through monthly site visit by quality corps volunteers. The use of volunteers other than full time staff results in a lower cost of implementation of the SPI-RT checklist compared to SLIPTA resulting in more sites covered using the SPI-RT.

The SPI-RT checklist is a tool used for continuous quality improvement at HIV rapid testing sites through periodic site audits during which non conformances are identified and corrective actions for identified non conformances are implemented.

The present study recorded significant progress ($p < 0.0001$) recorded nationally and regionally comparing baseline and last supervision of the site levels. There was also significant progress ($P < 0.006$) comparing mean scores of quality elements at baseline and last supervision.

Recent study carried out in Kenya¹⁰, Malawi¹⁰ and Tanzania¹⁰ recorded improved performance with the use of this checklist during periodic audits.

The significant progress recorded in this study at last supervision when compared to baseline correlated to regular site visits with on the site corrective actions and monthly follow up on corrective actions.

The South West region which has been longest in the program, recorded the highest progress at last supervision when compared to the progress recorded in other regions while the Centre region which has been the shortest in the program recorded the least progress at last supervision when compared to the progress recorded in other regions. This further supports the fact that regular site supportive visits with on the spot corrective actions and monthly follow up on elements on the SPI-RT checklist will lead to quality improvement and adherence to quality standards at HIV rapid testing sites.

Out of the 8 major elements of the checklist, personnel training and certification had the lowest scores comparing baseline and last assessment. The finding were obvious because there is no HIV rapid testing certification program in the country and also due to the fact not all HIV rapid testers at HIV testing sites in the country have received a comprehensive training using a standardized curriculum. Also no site could attain level '4' site due to the preceding issue.

Though the present study showed significant quality improvement more would have been done if there was a certification program in the country and all testers trained and be certified before performing HIV rapid test.

The high percentage of sites in the South-West region at level "0" at baseline compared to other regions is attributed to the high percentage (28%) of non laboratory study sites in the region compared to the other regions. Testing is performed by non laboratory staff such as nurses, midwives etc in these sites.

Conclusion

In conclusion the SPI-RT checklist approach to continuously improve on quality standards and promote adherence to quality practices through monthly site supportive supervision visits by Q corps is commendable.

We observe a significant quality improvement with many sites changing levels from 0,1 or 2 to 1,2 and 3. However, some would have progress to the highest level but for the fact that all testers in the testing sites are not trained and there is no certification program in the country.

If the country establishes a certification program and only trained and certified testers are allowed to test then many sites will move to level 4 and we recommend the rolling out of this program to other sites in Cameroon.

Acknowledgement:

We appreciate the support of the Ministry of Public Health Cameroon through the department of Pharmacy and Laboratory.

We are grateful to the quality corp volunteers for their commitment to this project.

Source of funding: This study has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention Cameroon and Cheikh Anta Dioup University Senegal.

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