Increasing Accountability for the Reliability of Rapid HIV Test Results:
Observations from Seven Facilities in Rungwe District Council, Tanzania
TECHNICAL REPORT

Increasing Accountability for the Reliability of Rapid HIV Test Results: Observations from Seven Facilities in Rungwe District Council, Tanzania

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DISCLAIMER

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For more information on the work of the USAID ASSIST Project, please visit www.usaidassist.org or write assist-info@urc-chs.com.

Recommended citation

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### Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ASSIST</td>
<td>USAID Applying Science to Strengthen and Improve Systems Project</td>
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<tr>
<td>CDC</td>
<td>U.S. Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CHMT</td>
<td>Council Health Management Team</td>
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<tr>
<td>CTC</td>
<td>Care and Treatment Centre</td>
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<tr>
<td>EQA</td>
<td>External quality assurance</td>
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<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<tr>
<td>HLI</td>
<td>Health Links Initiatives</td>
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<tr>
<td>HTC</td>
<td>HIV treatment and care</td>
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<td>HTS</td>
<td>HIV testing services</td>
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<td>IP</td>
<td>Implementing partner</td>
</tr>
<tr>
<td>IQC</td>
<td>Internal quality controls</td>
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<tr>
<td>MOHCDGEC</td>
<td>Ministry of Health, Community Development, Gender, Elderly and Children</td>
</tr>
<tr>
<td>PEPFAR</td>
<td>U.S. President's Emergency Plan for AIDS Relief</td>
</tr>
<tr>
<td>PMTCT</td>
<td>Prevention of mother-to-child transmission</td>
</tr>
<tr>
<td>POC</td>
<td>Point of care</td>
</tr>
<tr>
<td>QI</td>
<td>Quality improvement</td>
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<tr>
<td>RHMT</td>
<td>Regional Health Management Team</td>
</tr>
<tr>
<td>RTQII</td>
<td>HIV rapid testing quality improvement initiative</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard operating procedures</td>
</tr>
<tr>
<td>SPI-RT</td>
<td>Stepwise Process for Improving the Quality of HIV Rapid Testing</td>
</tr>
<tr>
<td>URC</td>
<td>University Research Co., LLC</td>
</tr>
<tr>
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<td>United States Agency for International Department</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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Executive Summary

Introduction

In 2015, the USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project in collaboration with the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGEC) and implementing partners (IPs) was tasked to support activities to improve the quality of HIV rapid testing at point-of-care testing sites (i.e., testing points) in 27 U.S. President's Emergency Plan for AIDS Relief (PEPFAR) scale-up saturation districts of the Tanzania mainland under the regional HIV rapid testing quality improvement initiative (RTQII) supported by PEPFAR.

In 2015, ASSIST supported the Regional Health Management Team (RHMT) of Dodoma Region and the Dodoma Municipal Council to conduct HIV testing services quality assessments and coach health workers in 16 facilities on HIV testing services (HTS) quality improvement (QI). In July-September 2016, ASSIST supported the MOHCDGEC to carry out a baseline quality audit in 485 rapid testing points in 204 health facilities in 22 of the PEPFAR scale-up saturation districts and subsequently was asked to support improvement activities for rapid HIV testing in three regions: Mbeya and Rungwe district councils in Mbeya Region, Arusha Region, and Nyamagana Municipal Council in Mwanza Region.

This technical report describes the HIV rapid testing QI support that ASSIST provided in Rungwe District Council, where the project supported the Rungwe Council Health Management Team (CHMT) and IPs to instigate improvement efforts in 22 rapid HIV testing points at seven health facilities. The rapid testing points, which are outside the traditional laboratory-based testing process, included point-of-care rapid HIV testing at prevention of mother-to-child transmission (PMTCT), voluntary counseling and testing, tuberculosis/HIV, and sexually transmitted diseases clinics.

Interventions

ASSIST conducted a one-day meeting with the RHMT and Rungwe CHMT to share and discuss the RTQII baseline assessment findings. The district health management team members selected HIV rapid testing focal persons to oversee the quality of HIV rapid testing services at both the council and facility levels. They developed a work plan for the council focal person and weekly supervision checklists for the facility focal person to be used as a guide during supportive supervision visits and to monitor the implementation of HIV rapid testing QI.

In November 2016, ASSIST conducted the first QI learning session for HIV rapid testing focal persons and facility QI teams to equip them with knowledge and skills on problem analysis, including systems and process analysis; how to use fishbone analysis to identify the root causes of performance gaps identified in the HIV rapid testing quality domains; the use of tree diagrams to outline changes for improvement; and how to apply plan-do-study-act cycles to test and implement changes to close the safety performance gaps.

The HIV rapid testing focal person mapped and reviewed the implementation process of HIV rapid testing in testing points and coordinated the aforementioned activities to improve the quality of HIV rapid testing and ensure reliability and accuracy of the results given to clients. The focal person provided standard operating procedures (SOPs) and job aides for safety practices and HIV rapid testing procedures to all testing points; re-allocated the trained HTS providers to specific testing points; re-oriented all providers on the use of SOPs and job aides during testing practice; requested and ensured availability of disinfectants and waste bins to all testing points; and conducted on-site supervision on safety precautions like proper waste segregation spills containment, sharps and biohazards waste disposal, and proper use of personnel protective equipment throughout the testing process as well as compliance with HIV rapid testing standards. The focal person also conducted QI monthly meetings to review the implementation progress.

The facility focal person, in collaboration with the council focal person, conducted monthly in-house training and mentorship for HTS providers on how to perform HIV testing procedures, especially on required volume for blood sample and time required for result interpretation. They prepared both HIV positive and negative samples for each testing point in the facility weekly and ensured HTS providers
performed internal quality controls under supervision immediately after receiving new kits. They conducted weekly onsite review and coaching on updating the standardized HIV rapid testing registers (National HIV treatment and care registers, national logbooks, HMIS book No 6, and monthly summary reports), focused on the completeness and accuracy of data. The facility focal person liaised with council and regional laboratory technologists for enrollment of all testing points not enrolled in external quality assurance (EQA) and managed to enroll 75% of testing points into the EQA program. To facilitate participation in the EQA program, the focal person used text messages to inform the testing points whenever the EQA panels arrived from the national reference lab and other updates on HIV rapid testing.

Results

Through this effort, compliance with HIV rapid testing standards in the 22 testing sites in seven facilities in Rungwe District improved from 40% in August 2016 to 83% in April 2017. Compliance to safety standards improved from 39% in August 2016 to 82% in April 2017. Post-testing and documentation improved from 55% in August 2016 to 86% in April 2017. Compliance with EQA protocols increased from 23% in August 2016 to 63% in April 2017.

Conclusions and Recommendations

QI is an evidence-based approach that can be used by front-line workers to improve the quality of HIV rapid testing by using locally available resources. Improving the quality of HIV rapid testing requires commitment from all levels, including HIV testing service providers, QI teams, and management from the facility, council, and regional levels. The identification and selection of an HIV rapid testing focal person with role and responsibility to oversee and coordinate quality of HIV rapid testing in all testing points increased accountability for the reliability of the HIV rapid testing. Work plans and checklists were used as guides to monitor and evaluate the HIV rapid testing process on a weekly and monthly basis. Provision of SOPs and job aides, orientation of providers on importance of compliance to HIV rapid testing standards, and onsite supervision were among the tactics that led to improvement.

Through a blend of quality assessment, QI problem solving, assignment of HTS focal persons, and commitment of leadership to QI activities not only increased accountability for the reliability of HIV rapid test results, but also improved morale and commitment of HIV rapid test providers and empowered them to take responsibility for improving the quality of services they provide.
I. Introduction

Tanzania is committed to achieving the UNAIDS/U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) 90-90-90 targets while scaling up the Test and Treat Strategy for those clients found to be HIV-positive. This approach requires a continuous and systematic approach to ensure good quality, accuracy, and reliability of rapid HIV diagnostics for HIV testing services. Overtime, HIV rapid testing has transcended the traditional laboratory-based sites to point-of-care sites including Care and Treatment Center (CTC), prevention of mother-to-child transmission of HIV (PMTCT), voluntary counseling and testing (VCT), tuberculosis/HIV (TB-HIV) and sexually transmitted infection (STI) clinics, etc. Given the diversity of test sites (e.g., community testing for voluntary medical male circumcision clients and mobile testing) the demand calls for non-laboratory staff, such as nurses, and clinicians to perform HIV rapid testing. Whereas expansion of HIV rapid testing beyond the laboratory has increased access and uptake of testing, opportunities for misdiagnosis through operator errors, poor specimen quality, and improper handling have also increased.

Point-of-care HIV rapid testing has the potential to increase access to patient diagnosis and treatment if properly deployed. With the large increase in the use of HIV-related point of care testing, there is the need for new ways to monitor and strengthen testing sites to ensure quality results.

In 2013, PEPFAR introduced an HIV rapid testing quality improvement initiative (RTQII) in seven countries, including Tanzania. The goal of RTQII to scale up coverage of HIV rapid testing quality improvement (QI) and assurance activities and improve the quality and safety of rapid testing services. In 2014, Tanzania piloted RTQII in four high HIV burden regions (Mbeya, Iringa, Njombe, and Shinyanga) at 208 testing points in eight districts, including seven facilities per region (one regional referral hospital, two district hospitals, two health centers, and two dispensaries). The RTQII baseline audit was conducted in December 2014 by Health Links Initiatives (HLI), a Tanzanian non-governmental organization in December 2014 using the Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) checklist developed with PEPFAR support through the U.S. Centers for Disease Control and Prevention (CDC). The audit revealed that 40% of the assessed testing points were at level 0 (scoring 0%-39%), 58% at level 1 (40%-59%), and only 2% at level 2 (60%-79%). Level 2 is considered the minimum level required to be considered for national site certification. Most of the testing points needed improvement in all quality standards. Moreover, the deficiencies noted were across all testing modalities with a focus on CTC sites where testing is always performed.

Continuous quality improvement (CQI) with onsite supportive supervision and implementation of corrective actions has shown to be effective in improving gaps identified in HIV testing services. Based on the lessons learned from RTQII pilot sites in Tanzania, the USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project was tasked by USAID to provide technical assistance on the QI approach to Regional and Council Management Teams, laboratory technicians, and non-laboratory HIV testers in point-of-care testing in 22 high-volume scale-up saturation districts.

In July-September 2016, ASSIST supported the MOHCDGEC to carry out a baseline quality audit in 485 rapid testing points in 204 health facilities in 22 of the PEPFAR scale-up saturation districts. Following on the HIV rapid testing quality audit, ASSIST was asked to support improvement activities for rapid HIV testing in three regions: Mbeya and Rungwe district councils in Mbeya Region, Arusha Region, and Nyamagana Municipal Council in Mwanza Region.

Rungwe District Council is located in the southern highlands of Tanzania. It is one of the 22 councils implementing the RTQII to ensure accuracy and reliability of test results among clients attending HIV testing services in the district by increasing uptake of standardized HIV logbooks, increasing coverage of the proficiency testing program, and monitoring compliance with quality standards at testing points. The district was chosen by the Tanzanian Ministry of Health, Community Development, Gender, Elderly, and Children (MOHCDGEC) to participate in RTQII because it is among those PEPFAR-supported districts with over 100 clients tested for HIV per month at all levels of health facilities (hospitals, health centers, and dispensaries).
This technical report describes the HIV rapid testing QI support that ASSIST provided in Rungwe District Council, where the project supported the Rungwe CHMT and IPs to instigate improvement efforts in 22 rapid HIV testing points at seven health facilities.

II. Baseline Quality Audit

In partnership with MOHCDGEC RTQII quality auditors, ASSIST supported a rapid assessment of compliance with World Health Organization (WHO) rapid HIV testing quality elements in 485 rapid HIV testing points in 204 health facilities located in 22 PEPFAR scale-up saturation districts across 14 regions of Tanzania. The RTQII audit process scores sites along seven standards for rapid testing: personnel training and certification, physical facility, safety, pre-testing phase, testing phase, post-testing phase, and external quality assurance (EQA) through proficiency testing (PT). Across the seven quality standards, none of the facilities performed at an expected level, although sites generally scored at an acceptable level for physical facility and pre-testing. As shown in Figure 1, the performance gaps were much wider with personnel training and certification (81%), EQA (70%), testing phase (61%) and safety (50%).

Figure 1: Performance gap for each quality element, 485 testing points, 204 health facilities, 22 PEPFAR high volume scale-up saturation districts, July-September 2016

Specific performance challenges identified in the baseline audit included:

1. **Personnel Training and Certification** had an average score of 19%. The audit found no periodic certification and recertification among testers; inadequate competency assessment in HIV rapid testing prior to client testing and no refresher training within two years; and insufficient capacity of testers on safety and waste management procedures and practices.

2. **Physical Facility** had an average score of 75%. Gaps identified included limited space with multiple tasks conducted at the same place; insufficient lighting; and inadequate lockable cupboards for keeping registers and test kits after use.

3. **Safety** had an average score of 50%. The audit found testing sites with no infection prevention guidelines; missing standard operating procedures (SOPs) and job aides on safety management in all testing points; inadequate supply of personal protective equipment and disinfectants in all testing points; inadequate handwashing facilities in most testing points; and improper handling of sharps, infectious, and noninfectious waste.
4. **Pre-testing** phase had an average score of 67%. Findings included inadequate copies of national HIV testing guidelines, SOPs, and job aides for HIV testing algorithm at testing points; no stock management process in most testing points; and inadequate supply of test kits (e.g., UniGold).

5. **Testing** phase had an average score of 39%. Testers were not adhering to HIV rapid testing procedures; most sites lacked a timer; and there were inadequate practices in performing quality controls as per HTS guidelines.

6. **Post-testing** phase had an average score of 52%. There was inconsistent use of logbook/HTC register in most of testing points; improper documentation in the HTC register/logbooks; and no summation at the end of each page.

7. **EQA** (including proficiency testing and supportive supervision) had an average score of 30%. There was low enrollment of testing points into the EQA/PT program; inadequate implementation of corrective actions for improving performance; lack of regular supervisory visits; improper documentation; no retraining during supervision; and inadequate review of EQA/PT reports and results by in charges.

A. **Baseline Audit Findings in Rungwe District Council**

Seven facilities in Rungwe District Council containing 22 testing points were included in the baseline audit. The audit in Rungwe was carried out in August 2016 by a team of trained auditors from MOHCDGEC and ASSIST together with the Mbeya Regional HTS Coordinator and the Rungwe District Laboratory Technologist. The team used different assessment methods, including direct observation of the site operations, review of site records and documents, interviews (open-ended questions), and following clients' specimens through the testing procedure, to determine performance gaps. They used the SPI-RT tool to assess the seven rapid testing standards areas.

The audit in the seven Rungwe facilities found the main gaps in four of the seven standards domains: safety, testing, post-testing, and EQA.

1. **Safety**

National Guidelines for Infection Prevention and Control require all HIV testing providers to adhere to safety precautions as HIV rapid testing exposes testers to both infectious and non-infectious waste and proper handling of these wastes is critical to ensure safety of testers and clients. The standard for safety precaution requires all point-of-care testing sites to have SOPs and job aides for safety precaution (including waste management and disposal, spill management, and addressing accidental injuries); personal protective equipment (gloves, boots, and aprons); availability of disinfectants and clean running water; and proper use of personal protective equipment and proper handling of sharp waste by HIV testing providers. During the assessment there was poor compliance to biohazard safety among HIV testing providers: Only eight (36%) out of 22 testing points in the seven facilities complied with procedures for biohazards safety; 14 (64%) testing points had no SOPs and job aides for biohazard safety, including instructions for gloves, handwashing, sharps and biohazards waste disposal, spills containment and disinfection. They also lacked appropriate disinfectant for cleaning the work area and had inadequate handwashing facilities.

2. **Testing phase**

HIV rapid testing practice should follow the approved National HIV Testing Algorithm and Procedures to ensure reliable and accurate results. The criteria indicate providers should use two types of HIV rapid test: SD Bioline and UniGold. When the first HIV test is non-reactive, the result is direct HIV-negative. When the first HIV test is reactive, providers must use the second test for confirmation of the positive result. Providers must perform quality controls for each new batch of test kits before procedure and follow testing procedures techniques (adequate use of blood drawing collecting tools, proper use of timer, and interpreting HIV rapid testing results). During the baseline assessment there was unsatisfactory compliance to testing procedure standards.

Only nine (40%) out of 22 testing points complied with testing procedure standards. The assessment found that 60% of point-of-care testers were not adequately following HIV testing procedures; testing
points had no SOPs or job aides on HIV testing procedures; testing points were not using positive and negative quality control specimen routinely according to HTS guidelines; there was no timer or time monitor leading to testers reporting results outside the recommended time range of 10-20 seconds; lack of quality control testing on new batches of test kits; and there was no evidence of routine review of the quality control record.

3. Post-testing phase and documentation

Complete and correct documentation of the HIV testing process is critical to ensure the accuracy and reliability of HIV test results. National HTS standards require all testing points to use standardized registers and logbooks with all key elements. To ensure confidentiality, sites must have proper records of invalid results and proper record keeping. During the assessment there was inadequate compliance to documentation standards. Only 55% of testing points complied with documentation standards including proper use of the available HIV registers and securing of logbooks, while 45% of testing points had no standardized registers and logbooks. Furthermore, for those testing points using logbooks, they did not capture all quality elements (e.g., name of test kits and lot number), and results were not accurately recorded, with many reporting the result of the first test without confirmation. The majority of the logbooks lacked summation at the end of each page, and some sites reported only using one type of HIV test kit.

4. External quality assurance

The availability of HIV rapid tests with high performance characteristics does not guarantee accurate test results. Errors can occur at each step of the testing process, and measures must be in place to assure the quality of HIV testing. To ensure accurate and reliable HIV test results, all testers should be assessed for competency and performance. The EQA process helps to identify gaps in conducting quality HIV testing in compliance with national HTS standards. To achieve quality HIV rapid testing, all testing points should be enrolled in the national EQA/PT program and receive panels from the national reference laboratory. HIV testing providers should perform corrective action for unsatisfactory results and ensure regular supportive supervision and timely feedback. In the assessment there was unsatisfactory compliance to EQA standards. Only six (27%) out of 22 testing points assessed were enrolled in the EQA program and complied with the standard. The majority of testing sites (74%) testing points were not enrolled in the EQA program; moreover, the mechanism to enroll them was not understood, and there was no strategy for implementing corrective action in case of unsatisfactory results. None of the 22 testing points had any documentation of periodic supportive supervision conducted by district, regional, or national levels on quality assurance procedures.

III. Improving HIV Rapid Testing Quality

Following the baseline audit, ASSIST, in collaboration with MOHCDGEC and IPs, supported the Rungwe CHMT and the seven health facilities to improve the quality of HIV services at all points of care.

A. Methodology

In November 2016, ASSIST in collaboration with the Robert Wood Johnson Foundation, the IP in Rungwe District, conducted a one-day meeting with the Mbeya RHMT and Rungwe CHMT to review and discuss the RTQII baseline assessment findings. During the meeting, the RHMT and CHMT members analyzed the problem to determine the cause for poor performance of HIV rapid testing in the testing sites. They learned that the absence of a focal person and a work plan, plus inadequate supervision and monitoring of HIV rapid testing process, were causing poor performance. The health management team members then identified and selected HIV rapid testing district and facility focal persons. The district laboratory technologist was assigned as focal person to oversee the activities at the council level and each site’s laboratory technician was assigned as the focal person for the facility. The roles and responsibilities of a focal person are in Appendix I. They developed work plans to be used as a guide for their supportive supervision (monthly at the district level, weekly for the facility).

Increasing Accountability for the Reliability of Rapid HIV Test Results
ASSIST, with representatives from MOHCDGEC and the Rungwe CHMT, conducted the first QI learning session in November 2016 for facility QI teams comprised of facility focal persons and other personnel. The objectives of the learning session were to discuss and share RTQII baseline findings and performance gaps; to equip facility QI teams and HIV rapid testing focal persons with knowledge and skills on problem analysis, including system and process analysis; to train teams on how to use fishbone analysis to identify the root causes of performance gaps; to train teams to use the tree diagram to outline changes for improvement; and to train teams to apply plan-do-study-act cycles to test and implement changes to close the safety performance gaps.

The CHMT and QI teams proposed the following improvement changes to close the gaps:

- Each point of care testing site assigned the focal person to oversee the HIV testing points’ quality issues, assuming daily responsibility and accountability for quality issues.
- Provide SOPs and job aides for safety practices to all testing points.
- Re-allocate the trained HTS providers to specific testing points.
- Re-orient all providers on the importance and use of SOPs and job aids during testing practices.
- Request and ensure availability of disinfectants and waste bins to all testing points.
- Conduct on-site supervision on safety precautions like rationale for proper waste segregation.
- Use labeled buckets for waste segregation and ensure proper use of personal protective equipment throughout testing process.

IV. Results

The HIV rapid testing focal persons mapped and reviewed the implementation process of HIV rapid testing and coordinated the implementation of a series of activities which simultaneously improved the quality of HIV rapid testing, ensuring reliability and accuracy of results.

A. Increasing compliance to HIV rapid testing safety standards

Focal persons listed and distributed SOPs and job aides for biohazard safety standards including orientation of health care workers on handwashing techniques, glove use, spill containment, sharps and biohazards waste disposal, and importance of disinfection before and after testing procedure and decontamination process. The focal person re-oriented HTS providers on biohazard safety precautions during clinical meetings followed by onsite coaching on compliance to safety measures. Through this effort, the compliance to HIV rapid safety standards improved from 39% in August 2016 to 82% in April 2017 (Figure 2).
Figure 2: Baseline and follow-up performance of the HIV rapid testing quality domain “safety”, 22 testing sites, 7 facilities (August 2016 and April 2017)

<table>
<thead>
<tr>
<th>Domain: Safety Phase</th>
<th>BEFORE Q1 August 2016</th>
<th>AFTER Q1 April 2017</th>
</tr>
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<tbody>
<tr>
<td>Emptying of waste containers as per SOP and/or job aides</td>
<td>84%</td>
<td>39%</td>
</tr>
<tr>
<td>Proper handling of sharps and wastes</td>
<td>92%</td>
<td>40%</td>
</tr>
<tr>
<td>Availability of disinfectant for cleaning working area</td>
<td>87%</td>
<td>21%</td>
</tr>
<tr>
<td>Availability of clean water and soap for hand washing</td>
<td>87%</td>
<td>45%</td>
</tr>
<tr>
<td>Proper use of PPE by all testers during testing</td>
<td>92%</td>
<td>61%</td>
</tr>
<tr>
<td>Consistent use of PPE by all testers</td>
<td>89%</td>
<td>59%</td>
</tr>
<tr>
<td>Personal protective equipment (PPE) for testers available</td>
<td>74%</td>
<td>64%</td>
</tr>
<tr>
<td>SOPs/job aids to address accidental injuries in place</td>
<td>47%</td>
<td>26%</td>
</tr>
<tr>
<td>SOPs/job aids to manage body fluids in place</td>
<td>71%</td>
<td>66%</td>
</tr>
<tr>
<td>SOPs/job aids for waste management in place</td>
<td>75%</td>
<td>10%</td>
</tr>
<tr>
<td>SOPs/job aids for safety in place</td>
<td>71%</td>
<td>10%</td>
</tr>
</tbody>
</table>

B. Increasing Compliance to HIV Rapid Testing Standards

The HIV rapid testing focal person supported HIV testing providers to review the proposed improvement changes for the testing phase by listing all trained testers and re-allocating them according to testing point needs and ensuring that each point of care testing site had at least one trained HIV testing provider. The focal person also listed all testing points without SOPs and job aides for the testing procedure and ensured that SOPs and job aides were made available and displayed and that all testers were orientated on how to use them. In collaboration with laboratory technicians under supervision of the district laboratory technologist, the focal persons conducted monthly in-house training and mentorship to HTS providers on HIV testing procedures, with emphasis on required volume for blood sample collection and time required for result interpretation. The focal person assigned the laboratory technician to prepare both HIV positive and negative samples for each testing point in the facility weekly and ensure HTS providers performed internal quality controls immediately after receiving new kits under supervision. Through this effort, the compliance to HIV rapid testing standards improved from 40% in August 2016 to 83% in April 2017 (Figure 3).
C. Increasing compliance to post-testing and documentation standards

The HIV rapid testing focal persons supported HIV testing providers to review the progress made on implementation of proposed tested changes for improving documentation by providing weekly onsite coaching and mentoring on reviewing and updating the source documents which National HIV HTC registers, National Logbooks, HMIS book No 6, and monthly summary reports. During onsite supportive supervision, focal persons focused on the completeness and accuracy of data. In ensuring compliance to proper documentation, they assigned the HIV testing providers to review completeness and accuracy of data daily before the end of duty. Focal persons developed local checklists (Appendix II) capturing all elements in a standardized logbook and HTC registers to be used as guide in each testing point for monitoring documentation of standardized registers. They also developed SOPs for documentation of HIV standardized registers and logbook to encourage daily use and displayed them at each testing point and oriented all HIV rapid testing providers on importance of adherence. This was followed by discussions of challenges in clinical and QI meetings. These efforts led to improvement in documentation from 55% to 86% (Figure 4).

D. Increasing compliance to EQA standards

The focal person reviewed all testing points enrolled in EQA, those not enrolled, and those with unsatisfactory results. To increase enrollment and compliance to EQA standards, the focal person worked with district and regional laboratory technologists to enroll all testing points in the EQA program and collaborated with the district lab technologist to conduct training to HIV rapid testing providers and facility in charges on how to perform EQA and corrective actions as needed. They managed to enroll 75% of testing points into the EQA program. In ensuring that there is compliance to EQA, the focal person used text messages to inform the testing points whenever the EQA panels arrived from the National Reference Laboratory and other updates on HIV rapid testing. Compliance to EQA improved from 23% to 63% (Figure 5).
Figure 4: Baseline and follow-up performance of the quality domain “post-testing phase and documentation”, 22 testing sites, 7 facilities (August 2016 and April 2017)

V. Discussion and Conclusion

QI is an evidence-based approach that can be used by front-line workers to improve the quality of HIV rapid testing by using locally available resources without additional funds. Improving the quality of HIV
Increasing Accountability for the Reliability of Rapid HIV Test Results

Rapid testing requires commitment from all levels including HIV testing providers, QI teams, and management from facility, council, and regional levels. It also requires the presence of a specific person to oversee and coordinate the process, such as the focal person. In increasing accountability for the reliability of HIV rapid testing, the Rungwe District management introduced improvement changes to achieve the quality of HIV rapid testing. The teams found that the changes all facilitated improvement, but the most important change was identifying and utilizing a focal person to oversee compliance to standards.

The monthly evaluation of the performance of point of care testing and commitment of focal persons to ensure the availability and display of SOPs and job aids on HIV rapid testing procedures and safety precautions were among the tactics which led to improvement. Involvement of HIV testing providers in self-evaluation using the locally developed checklist (see box and Appendix II) motivated providers as they measured their performance by identifying challenges and changes for improvement while continuing with the process.

The provision of guidelines and supplies without a focal person to mentor and coach HIV testing providers on how to use them and provide follow-up does not yield required results. This was made evident by comparing performance in Rungwe District, which made use of HIV rapid testing focal persons, and Mbeya District Council, with no HIV rapid testing focal person (Figure 6).

Figure 6: Performance of HIV rapid testing quality elements in sites with focal person in Rungwe District Council (left) compared to sites with no focal person in Mbeya District Council (right) (August 2016 and April 2017)

A. Lessons Learned

Blending quality assurance, QI problem solving processes, use of a focal person, and engaging leadership in QI activities not only increases accountability for the reliability of the HIV rapid testing results, but also improves morale and commitment of HIV rapid testing providers and empowers them to take responsibility for improving the quality of services they provide.

Through the QI methods and the use of focal persons, the HIV rapid testing providers are now able to improve quality of HIV rapid testing through daily review of their performance and identify areas for improvement.

Example of checklist contents

- Does staff follow safety precautions when performing HIV rapid testing?
- Is internal quality control done to all new batch of HIV rapid test kits before procedure, according to the SOP and national guideline?
- Are appropriate corrective actions taken when internal quality control and EQA do not produce expected results?
- Are HIV-positive clients with HIV reactive result by test one confirmed by test two?
- Are SOPs and job aids for safety and waste management available and are HIV testing providers adhering to them?
Annex

Annex I: Roles and Responsibilities of HIV Rapid Testing Focal Person

1. Prepare and share a list of testers who have been trained on HIV rapid testing and ensure each testing points have trained testers.

2. Request and distribute HIV rapid testing kits in all testing points.

3. Identify all testing points without SOPs/job aides on national HIV algorithm and provide national HIV algorithm to all testing points.

4. Identify testing points without standardized registers and logbooks and provide standardized registers and logbook to all testing points.

5. Conduct onsite supportive supervision to HIV testers on adherence to HIV testing procedures, EQA program safety precautions, and proper documentation of standardized registers and logbook.

6. Identify all testing points without SOPs/job aides on how to manage spills of blood and other body fluids, waste management, safety practices and Post Exposure Prophylaxis and ensure availability of SOPs/job aides on how to manage spills of blood and other body fluids to all testing points, how to dispose infectious and non-infectious waste and Post Exposure Prophylaxis.

7. Prepare and distribute known positive and negative quality control specimen and monitoring adherence to the use of positive and negative quality specimen according to the guideline.

8. Supervise weekly self-assessment at each testing point.

Annex II: Onsite Monitoring Checklist
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<thead>
<tr>
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<tbody>
<tr>
<td><strong>RUNGWE DISTRICT COUNCIL</strong></td>
<td><strong>Weekly RTQI Monitoring Checklist</strong></td>
<td></td>
</tr>
<tr>
<td>Facility Name……………………</td>
<td>Testing point…………………… Date ……………………………………</td>
<td></td>
</tr>
<tr>
<td><strong>YES</strong></td>
<td><strong>NO</strong></td>
<td><strong>COMMENT</strong></td>
</tr>
<tr>
<td>1</td>
<td>Are SOPs and job aides for HIV rapid testing procedure available and HIV testing providers adhering to them?</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Are HIV rapid testing results interpreted and recorded according to the SOP and national algorithm?</td>
<td></td>
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<tr>
<td>3</td>
<td>Are HIV rapid test kits and reagents stored properly?</td>
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<tr>
<td>4</td>
<td>Does staff follow safety precautions when performing HIV rapid testing?</td>
<td></td>
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<tr>
<td>5</td>
<td>Is internal quality control done to all new batches of HIV rapid test kits before procedure, according to the SOP and national guideline?</td>
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<tr>
<td>6</td>
<td>Are appropriate corrective actions taken when internal quality controls and EQA results do not produce expected results?</td>
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<tr>
<td>7</td>
<td>Are HIV positive clients with HIV reactive result by test 1 confirmed by test 2?</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Are SOPs and job aides for safety and waste management, available and HIV testing providers adhered to it?</td>
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Reviewed by …………………………………

Signature…………………………. Date…………………………

Increasing Accountability for the Reliability of Rapid HIV Test Results