

Overview: HIV Rapid Test Continuous Quality Improvement (RTCQI)

HIV Serology Diagnostics and Incidence Team
International Laboratory Branch, DGHT
CDC Atlanta

June 3, 2024

RTCQI Best Practice Workshop – Africa Region, Cape Town



Division of Global HIV & TB



Outline

- Context of RTCQI
- The concept of RTCQI
- Tools for RTCQI implementation
- Where we are & the way forward

In the era of "Test and Start"

HIV misdiagnosis = unnecessary lifelong antiretroviral treatment

OPEN ACCESS Freely available online PLOS ONE

False Positive HIV Diagnoses in Resource Limited Settings: Operational Lessons Learned for HIV Programmes

OPEN ACCESS Freely available online PLOS ONE

The Evaluation of a Rapid *In Situ* HIV Confirmation Test in a Programme with a High Failure Rate of the WHO HIV Two-Test Diagnostic Algorithm

EXPERT REVIEWS

Causes of false-positive HIV rapid diagnostic test results

Boeras et al. *Journal of the International AIDS Society* 2011, 14:18
<http://www.jiasociety.org/content/14/1/18>

RESEARCH Open Access

Indeterminate and discrepant rapid HIV test results in couples' HIV testing and counselling centres in Africa

Debrah I Boeras^{1,2,4}, Nicole Luisi³, Etienne Karita³, Shila McKinney^{3,6}, Tyrtonza Sharkey⁶, Michelle Keeling⁶,
Francis Ouma^{3,7,8}, George Wanyenze^{3,9}, Moses R Kamya³, Harriet Mayanja-Kizza³, Robin Fatch³, David R Bangsberg⁴, Thomas Coates⁵,
Steven Baveewo¹⁰, Moses R Kamya¹, Harriet Mayanja-Kizza¹, Robin Fatch¹, David R Bangsberg¹, Thomas Coates¹,
Judith A Hahn¹ and Rhoda K Wanyenze²

Baveewo et al. *BMC Research Notes* 2012, 5:154
<http://www.biomedcentral.com/1756-0500/5/154>

RESEARCH ARTICLE Open Access BMC Research Notes

Potential for false positive HIV test results with the serial rapid HIV testing algorithm

Steven Baveewo¹, Moses R Kamya¹, Harriet Mayanja-Kizza¹, Robin Fatch¹, David R Bangsberg¹, Thomas Coates¹,
Judith A Hahn¹ and Rhoda K Wanyenze²

The Gleaner Jamaica WI Established 1834

'Gov't pays big for wrong diagnosis'

\$9 Million HIV Error

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Published: Sunday | April 13, 2014



DAILY NATION NEWS BUSINESS COUNTRIES SPORTS BLOGS & OPINION LIFE & LOCAL

Police arrest second nurse in Esther Mwakazi HIV misdiagnosis saga


WEDNESDAY JANUARY 19 2017



Suggested Sites http://www.zero-hiv.org-w... Web Slice Gallery

Couple misdiagnosed with HIV to sue health centre, demands compensation

Oct. 17, 2016, 3:00 pm | By BRIAN OTIENO @yobramos4



zero-hiv.org-w... Web Slice Gallery

WOMAN WHO WAS MISDIAGNOSED WITH HIV TO GET FINAL RESULTS

Posted on Nov 21, 2016 7413 Views



Ms Elizabeth Zghe Mwakazi, who was misdiagnosed with HIV and put on ARVs with her toddler son, with Haki Africa programme officer Francis Annu at Kenyatta National Hospital after she underwent tests on Friday. PHOTO | DENNIS ONSONGO

By EUNICE KILONZO

A woman who was wrongly diagnosed with HIV in Kwale and put on ARVs for three months together with her one-year-old son will get her final status test results by the end of this month.

Rapid Expansion of HIV Rapid Diagnostic Tests

Large scale

- As of September 30, 2022, 64+ million individuals received HIV testing through PEPFAR
- 1% misdiagnosis rate = 640,000 people

Testing in Non-Traditional Settings

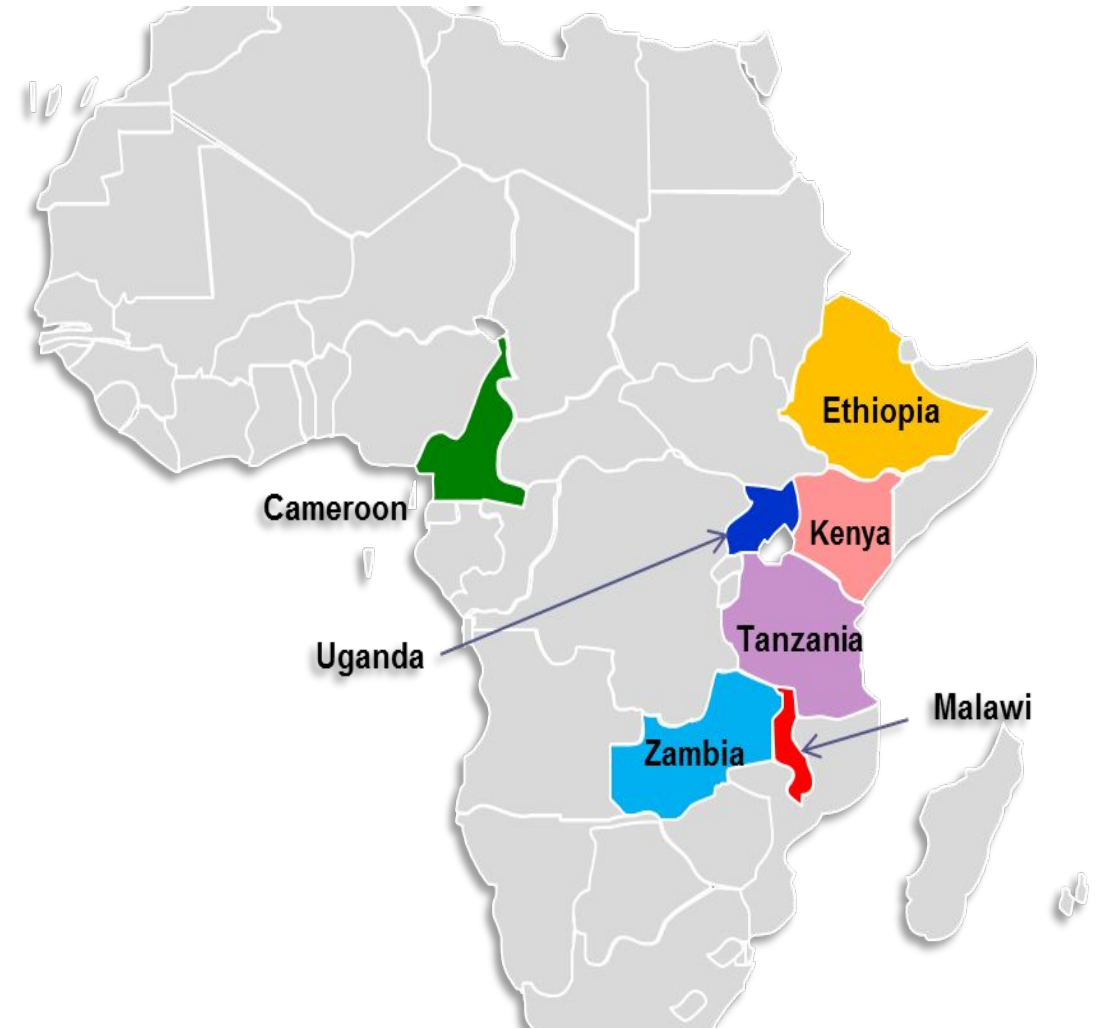


Realities of HIV Testing Under Program Conditions

- Poor training and training often done by peers
- Testing algorithm and procedures not followed
- Disorganized workspace
- Run-time not followed, no timers
- Safety concerns
- Poor finger-prick procedure
- PT program inconsistent
- Little or no supervision
- No corrective actions/feedback

Rapid Testing Continuous Quality Improvement (RT-CQI) Initiative

- Launched in 2014 as a proof of concept in 7 focus countries
 - Cameroon, Ethiopia, Kenya, Malawi, Tanzania, Uganda, and Zambia
- Driven by innovation to achieve better uptake, coverage, and impact
- Aim at reducing HIV testing errors to ensure the accuracy of HIV test result delivered to clients.



Five Components/Pillars of RTCQI

Policy Engagement

- Provide a framework for quality testing
- Develop and implement country-specific policy
- Engage stakeholders & advocate for resource allocation

Establishing a Certification Program

- Develop a competency-based training program and certify testers
- Monitor quality compliance and certify testing sites
- Analyze data for gap analysis and corrective actions

Increasing Proficiency Testing

- Increase coverage and participation in PT program (DTS)
- Analyze data for corrective actions

Five Components/Pillars of RTCQI

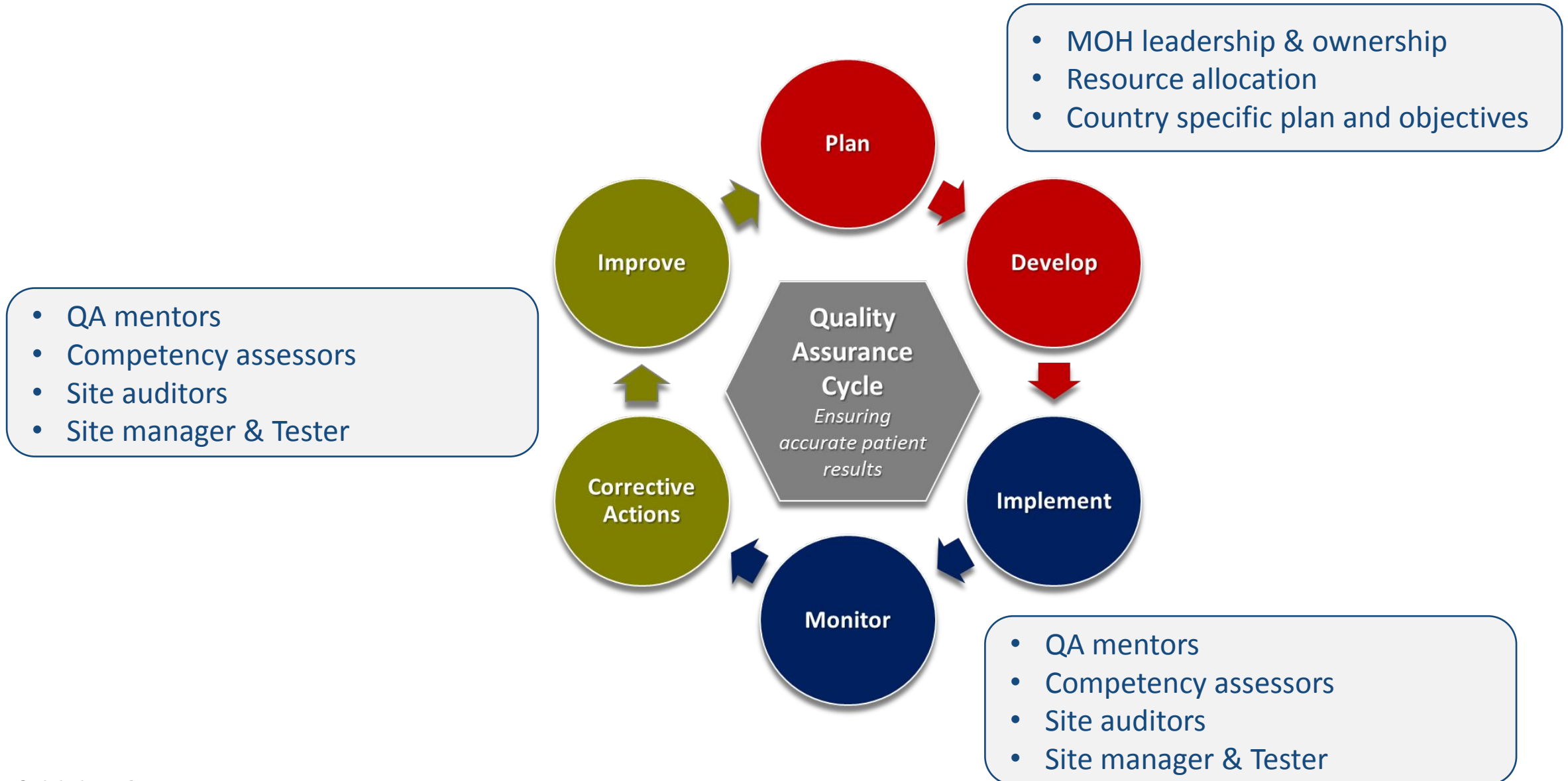
Scaling up Standardized HTS Register

- Increase uptake of standardized HIV testing register
- Analyze register data regularly for corrective actions

Lot testing & post market surveillance

- Strengthen national capacity to implement verification of new lot & post market surveillance

RTCQI Emphasize Quality Assurance Cycle



RTCQI (Initiative) Follows Seven Principals

1. Is intended to be catalytic

2. Establish baseline coverage of QA

3. Improve uptake, coverage & impact of QA

4. Develop country specific targets

5. Emphasize site visits, monitoring & recognition

6. Use Innovative Strategies

7. Emphasize Quality Assurance Cycle (QAC)

Innovative Tool – 1

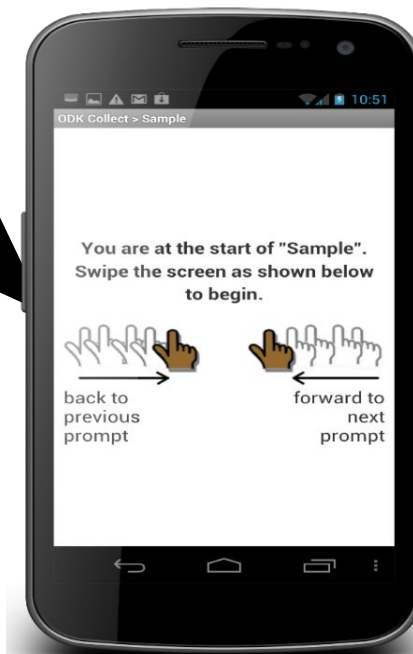
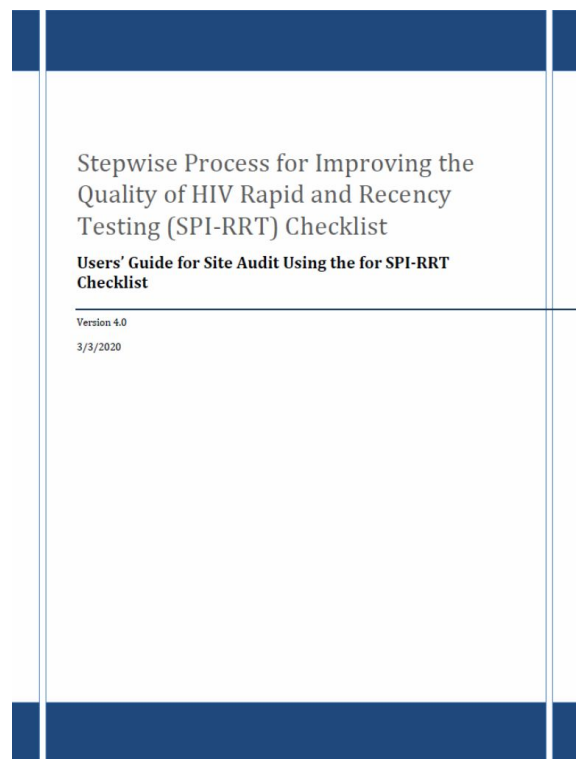
3 activity-based training packages for capacity building

- RTCQI overview – training of QA officers/Q-Corps/QA mentors
- SPI-RRT* training – training of auditor for site certification
- Tester certification training – training of competency assessor

*SPI-RRT, Stepwise Process for Improving the HIV Rapid and Recency Testing

Innovative Tool – 2

SPI-RRT checklist for site monitoring toward certification

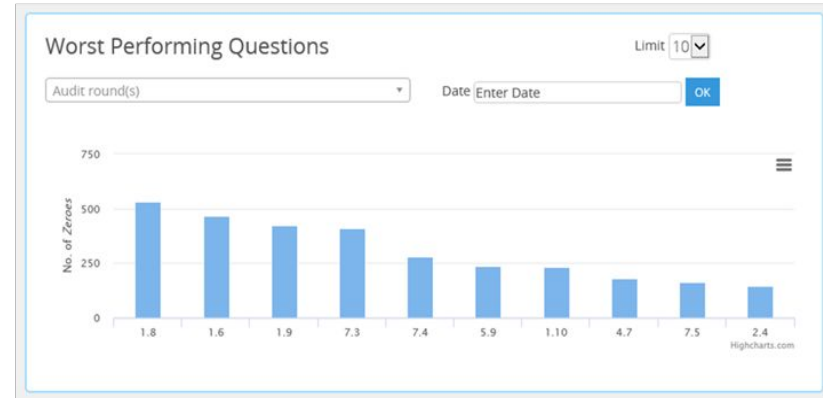
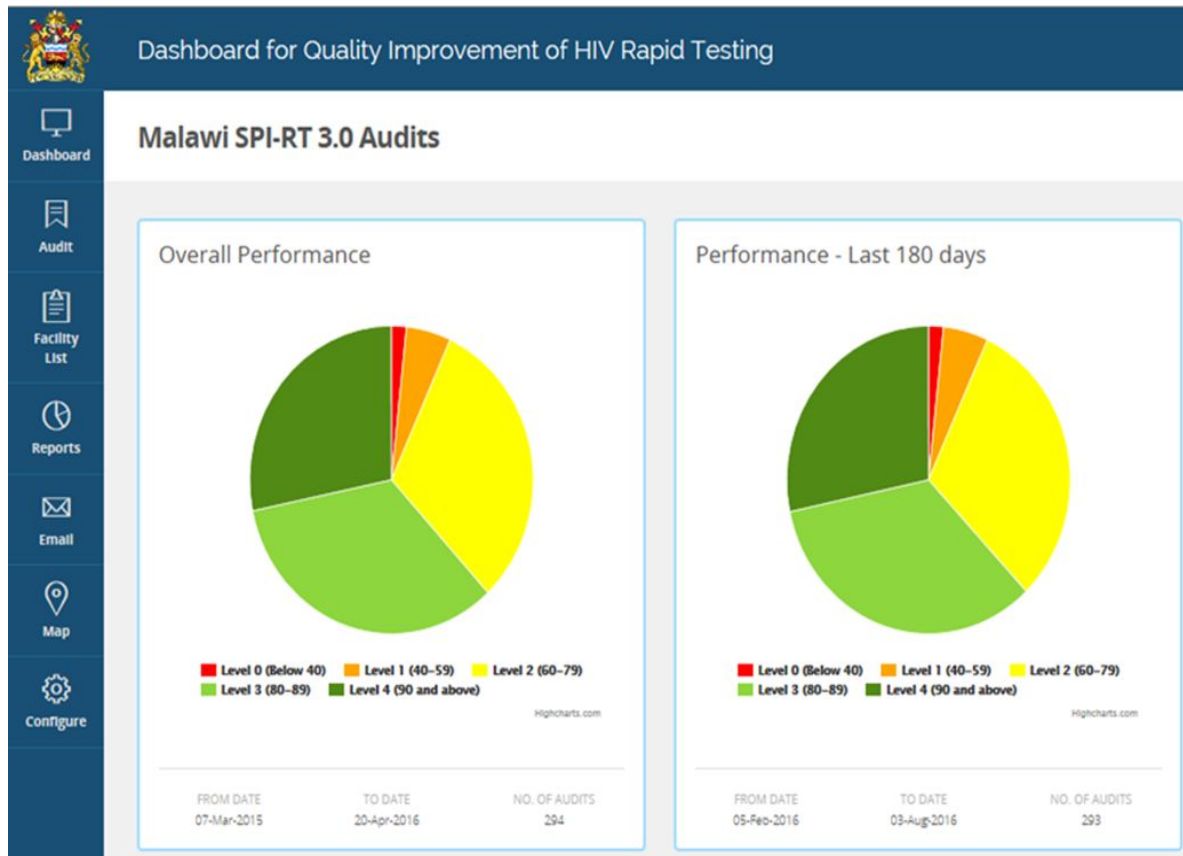


Level 4	<ul style="list-style-type: none"> >90% Eligible for national site certification
Level 3	<ul style="list-style-type: none"> 80% - 89% Close to national site certification
Level 2	<ul style="list-style-type: none"> 60% - 79% Partially ready for national site certification
Level 1	<ul style="list-style-type: none"> 40% - 59% needs improvement in specific areas
Level 0	<ul style="list-style-type: none"> <40% Need improvement in all areas and remediation

Audit Score Sheet		
Section	Section Name	Total Points
Section 1	Personnel Training and Certification	10
Section 2	Physical Facility	5
Section 3	Safety	11
Section 4	Pre-Testing Phase	13
Section 5	Testing Phase	9
Section 6	Post-Testing Phase	9
Section 7	External Quality Assessment	8
Section 8	HIV-1 Recent Infection Surveillance Using Rapid Test For Recent Infection	11
TOTAL SCORE		64/75

Innovative Tool – 3

SPI-RRT dashboard for site monitoring data visualization



Innovative Tools – 4 & 5

- Dried Tube Specimen (DTS) increased PT coverage and uptake
- ePT tool for data management and visualization

1 Using plastic pipette, add 7 drops of buffer to each tube

2 Tap the tubes to mix well

3 Leave tubes standing upright at room temperature overnight.

4 The next day, tap tubes, mix and test according to national algorithm

5 Record the results on the Results Submission form or ePT website

WELCOME TO [e-PT] PROGRAM!
Proficiency Testing enable laboratories to assess their performance in conducting test methods within their own laboratories when their data are compared against other laboratories that participate in the same program.

WHAT CAN WE DO FOR YOU THROUGH PT PROGRAM?

TRAINING

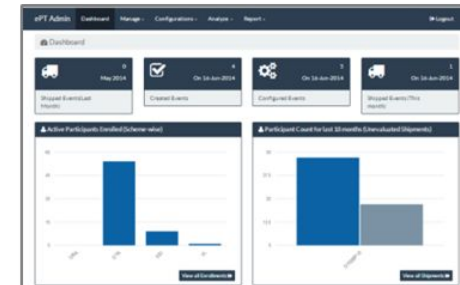
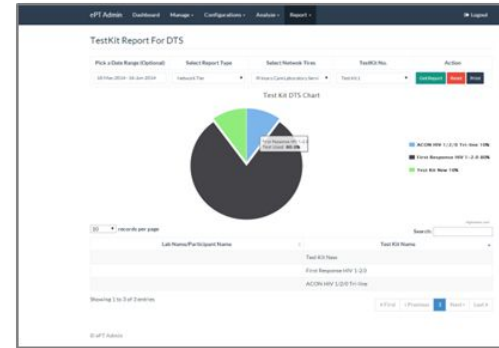
- Panel preparation
- e-pt database training: results entry and validation, reports viewing and reports download
- Corrective actions

TECHNICAL ASSISTANCE

- Panel preparation assistance
- Results entry and validation, reports viewing and reports download assistance (remote technical assistance and on-site technical assistance for using

PUBLICATIONS

- RTQI- Reporting Guidelines - Draft
- RTQI- Reporting Guidelines - Presentation
- RTQI- Reporting Tool - User Guide
- Baseline Assessment Tool - Draft
- Handbook for improving HIV testing and counselling
- Parekh, B. S., J. Anyanwu, et al. (2010). Dried tube specimens: a simple and cost-effective method for preparation of HIV proficiency testing panels and



Participant Response Report

Pick a Date Range (Optional) Select Scheme Type (Optional) Select Report Type Action

Participant Response Chart

Records per page: 10

Shipment Code	Shipment Type	PT Survey Code	PT Survey Date
GHVDT520Aug13	Dried Tube Specimen	GHVDT5 Round 1b	20-Aug-2014
GHVDT530Jul14	Dried Tube Specimen	GHVDT5 Round 2	30-Jul-2014
GHVDT520Aug14	Dried Tube Specimen	GHVDT5 Round 3	25-Aug-2014
DTS1014-SEP9	Dried Tube Specimen	SEP01	01-Sep-2014
DTS1014-SEP15	Dried Tube Specimen	SEP05	15-Sep-2014
DTS1014-3	Dried Tube Specimen	OCT01	07-Oct-2014
ROUND1-2014	Dried Tube Specimen	EVENT RD1-2014	22-Oct-2014
DTS1114-1	Dried Tube Specimen	DTSPTNOV10R1	10-Nov-2014

Innovative Tools – 6 & 7

Serial No.	Client or Specimen ID	Age (Yrs)	Sex	Date Tested	TEST1 Results	TEST2 Results	FINAL RESULTS	Operator Name / Initials	Sent for Further QA Testing	Date Sent	Final QA Results	Date Received	Comments
1	M F				R NR	R NR	P N						
2	M F				R NR	R NR	P N						
3	M F				R NR	R NR	P N						
4	M F				R NR	R NR	P N						
5	M F				R NR	R NR	P N						
6	M F				R NR	R NR	P N						
7	M F				R NR	R NR	P N			3/3/08	P N	10/3/08	Neg on 2 ELIS
8	M F				R NR	R NR	P N						
9	M F				R NR	R NR	P N						
10	M F				R NR	R NR	P N						
11	M F				R NR	R NR	P N						
12	M F				R NR	R NR	P N						
13	M F				R NR	R NR	P N						
14	M F				R NR	R NR	P N						
15	M F				R NR	R NR	P N						
16	M F				R NR	R NR	P N						
17	M F				R NR	R NR	P N						
18	M F				R NR	R NR	P N						
19	M F				R NR	R NR	P N						
20	M F				R NR	R NR	P N						

Data Analysis and QA Tool for HIV Logbook

QA Tool for HIV Rapid Testing Facility Name: Test Facility

Home Admin Management Data Entry Report

HIV Logbook

Function of a Standardized Logbook

- Captures client and testing information
- Same format at all testing sites
- Integrate testing QA elements in the logbook
- Easy to review
- Identifies issues with test kit performance, personnel, site and validity of testing algorithm.

Data Analysis

Data Analysis Criteria

- Overall agreement rate between two tests greater or equal to 90%
- Rate of invalids < 1%
- Monitor test performance of a site over time
- Monitor invalid results overtime
- Compare the performance of test operators
- Compare the test performance across sites
- Assess the testing algorithm

Resources

International Laboratory Branch Resources, Centers for Disease Control and Prevention

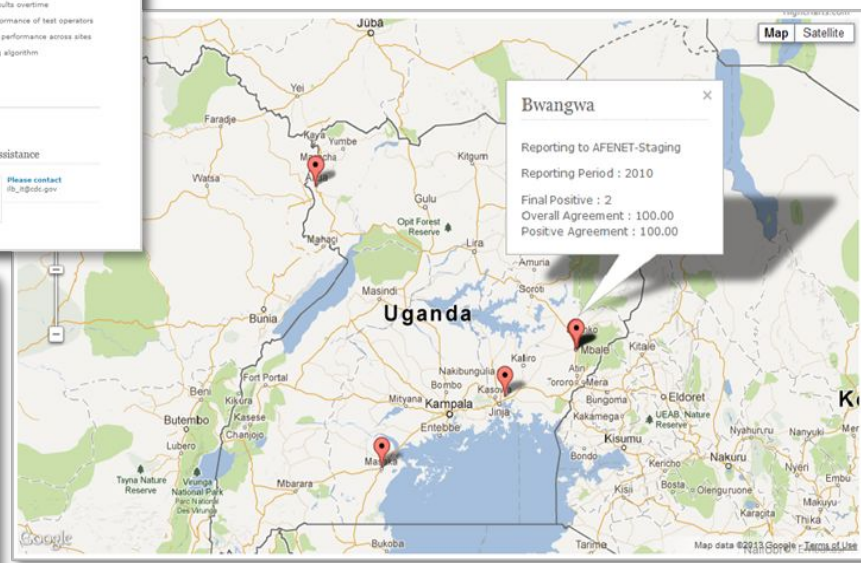
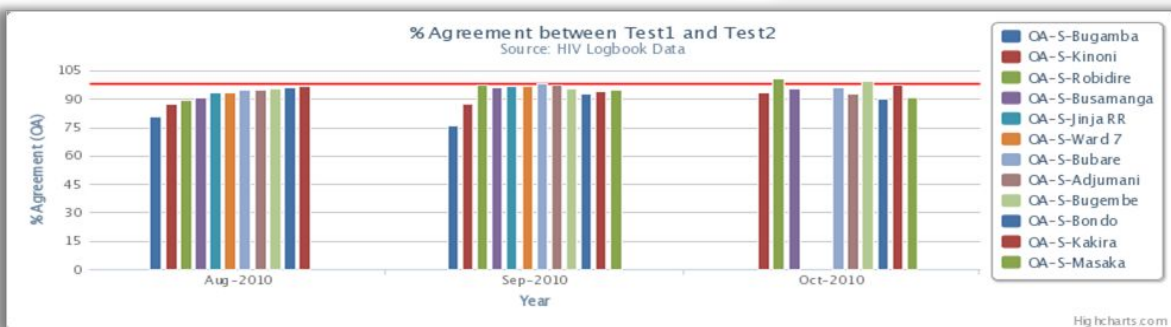
Handbook for improving HIV testing and counseling

Parakh, B. S., M. B. Kalou, et al. (2010). Scaling up HIV rapid testing in developing countries: international guidelines for implementation in health care. Am J Trop Med Hyg.

Technical Assistance

Please contact ib_b@cdc.gov

- Standardized HTS logbook
- eTool for logbook data visualization/use



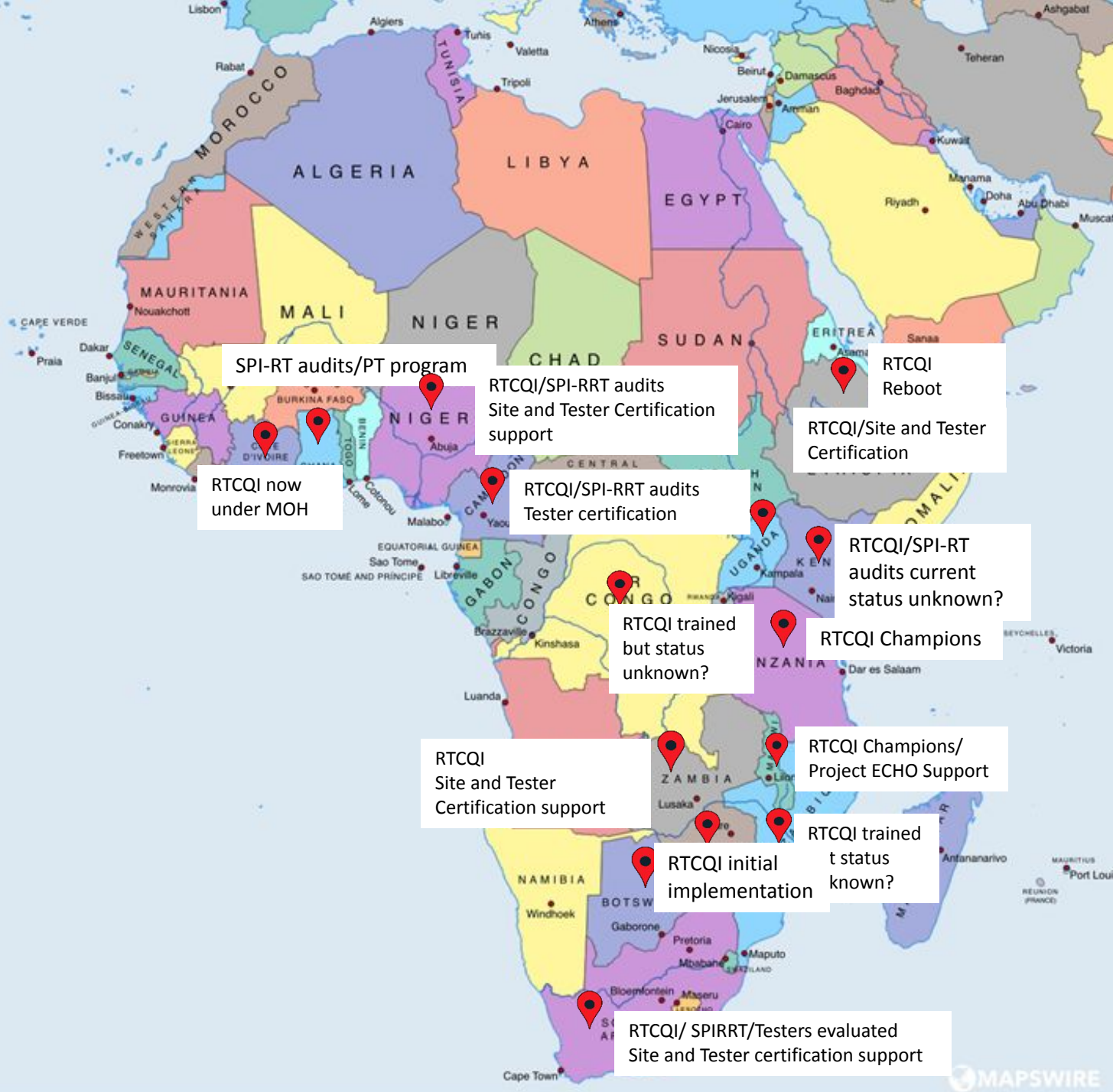
Implementation of Distance Learning Program

• Project ECHO

- Provides accessible and cost-efficient clinical mentorship and continuing professional education
- Fosters the development of peer networks and communities of practice that increase provider satisfaction
- Trains healthcare workers while they remain at their posts, reducing costs related to travel and minimize service disruption



RTCQI Countries



A Big Stride – From Initiative to Program

- Endorsement by MOH to incorporate RT-CQI in National HTS guidelines in **+10** countries



Prospects

- Continue to advocate for and provide technical support in implementation of RTCQI
- Provide technical support in country testing algorithm review
- Lay out and strengthen national guidelines for the implementation of RTCQI
- Support in-country capacity building
- Strengthen the use of data for continuous quality improvement
- Apply the concept/principals of RTCQI to other POC testing for impact
- Develop innovative, practical, and efficient ways for continuous quality improvement on rapid testing.

Contact us

- Contact your country Implementing Subject Matter Expert (ISME) from Serology Team/ILB
- Directly contact
 - Xiaojuan Tan, xit0@cdc.gov
 - Floris Wray-Gordon, kvf5@cdc.gov
 - Ernest Yufenyuy, yod0@cdc.gov

