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PEPFAR's Vision on HIV Rapid Testing Continuous Quality Improvements (HIV-RTCQI)

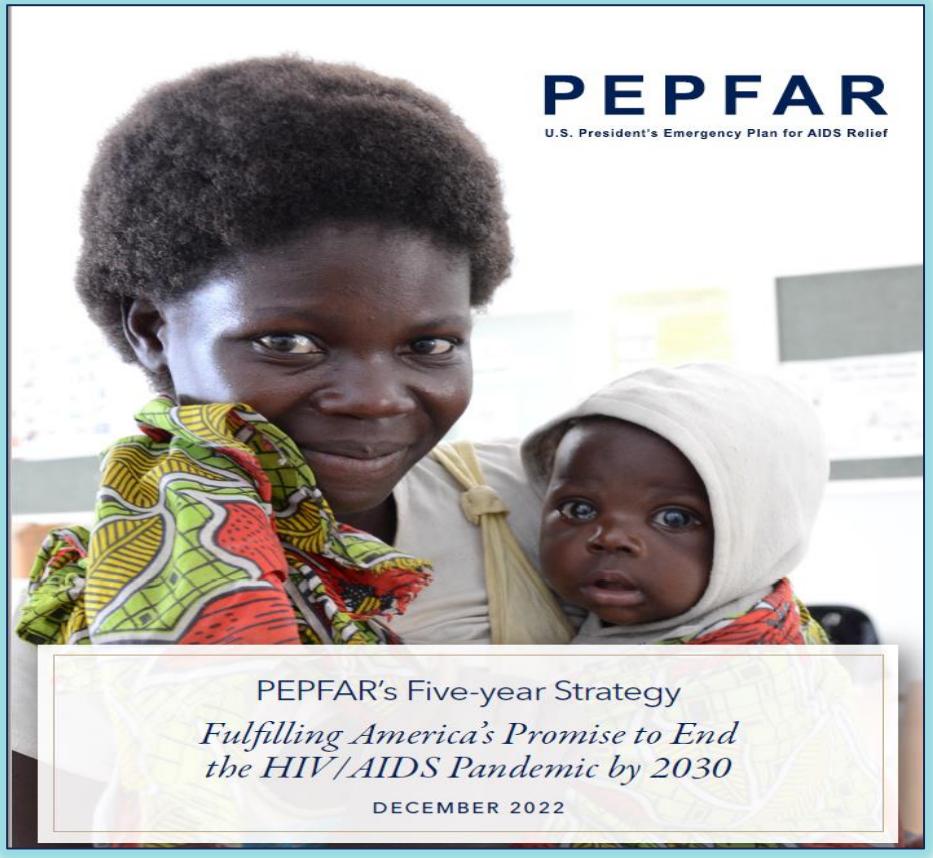
George Alemnji, PhD, MPH
Senior Technical Advisor and Team Lead, Laboratory and Surveillance ,
Bureau of Global Health Security and Diplomacy (GHSD) Washington DC

RTCQI Workshop, June 3rd 7th , Cape Town, South Africa

Introduction

- According to the U.S. CDC, 70% of medical decisions depend on laboratory test results.
- A 1% test error is huge in the context of total tests performed. For example, consider a PEPFAR program which tests up to 80 million people a year. A 1% error rate is 800K and a 0.1% error rate is 80K.
- Diagnostic errors have ethical, clinical and policy implications.
- Timely delivery of accurate test results has important clinical, programmatic, and public health implications.
- There is need for more innovations to support laboratory quality and timely data.
- There is increasing evidence of countries not incorporating quality components in their algorithm.

PEPFAR's Five-year Strategy | Strategic Pillars and Enablers



Enablers

ENABLER 1: COMMUNITY LEADERSHIP

Strengthening and building the capacity of community leadership to support task sharing and identify and address critical barriers RTCQI

ENABLER 2: INNOVATION

Need for more innovations in RTCQI process

ENABLER 3: DATA

High quality and integrated laboratory information management systems support data-driven decisions in laboratory policy development and program implementation

Quality and Timely Data

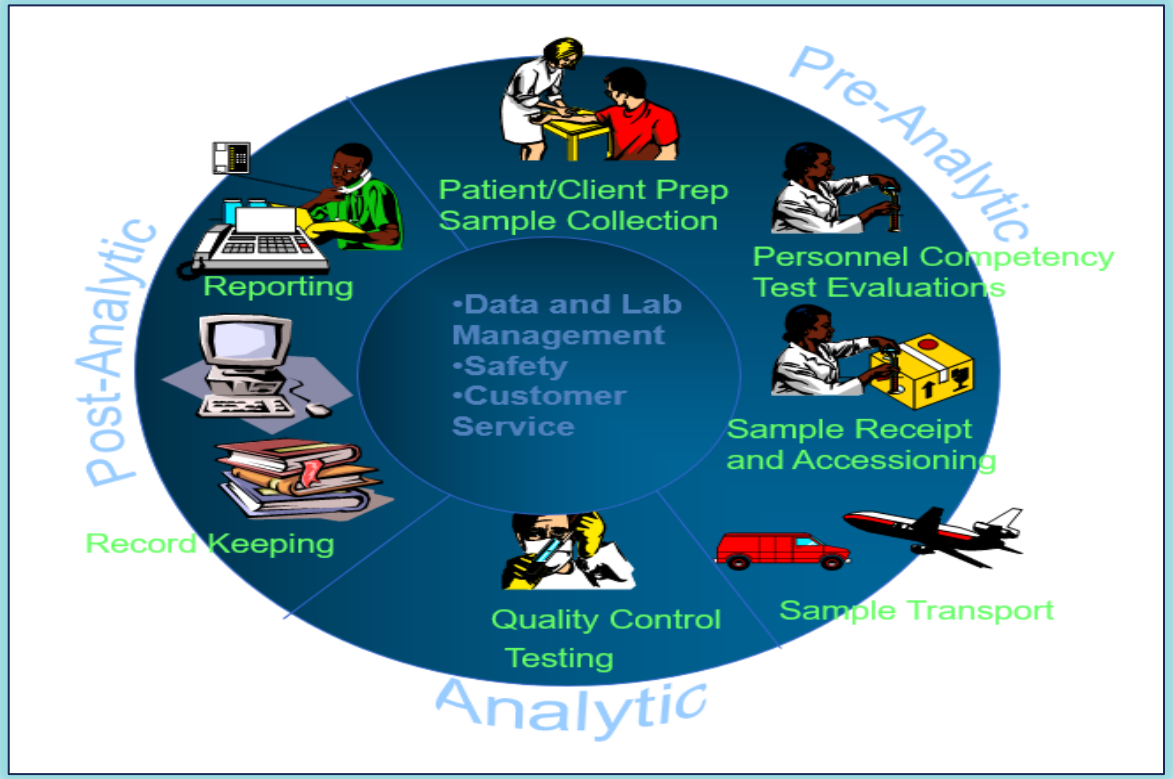
Quality Data

Data quality is the measure of how well suited a data set is to serve its specific purpose. Measures of data quality are based on data quality characteristics such as accuracy, completeness, consistency, validity, uniqueness, and timeliness.

Timely Data

Timeliness refers to expected time of availability and accessibility of data in making business decisions.

Lab Data Errors Occur in Pre-analytical, Analytical, or Post-analytical Phases



https://iris.who.int/bitstream/handle/10665/44665/9789241548274_eng.pdf?sequence=1

Assessment of Types and Frequency of Errors in Diagnostic Laboratories Among Selected Hospitals in East Wollega Zone, Oromia, Ethiopia

- Overall, 1124 (58.5%)
- Pre-analytical phase 807 (71.8%)
- Analytical phase 85 (7.6%)
- Post-analytical phase 232 (20.6%)

https://www.dovepress.com/assessment-of-types-and-frequ232 ency-of-errors-in-diagnostic-laboratories-peer-reviewed-fulltext-article-PLMI#:~:text=Laboratory%20error%20is%20defined%20as,interpreting%20and%20reacting%20to%20them%E2%80%9D.&text=An%20error%20in%20the%20clinical,impossible%20to%20perform%20error%2Dfree.

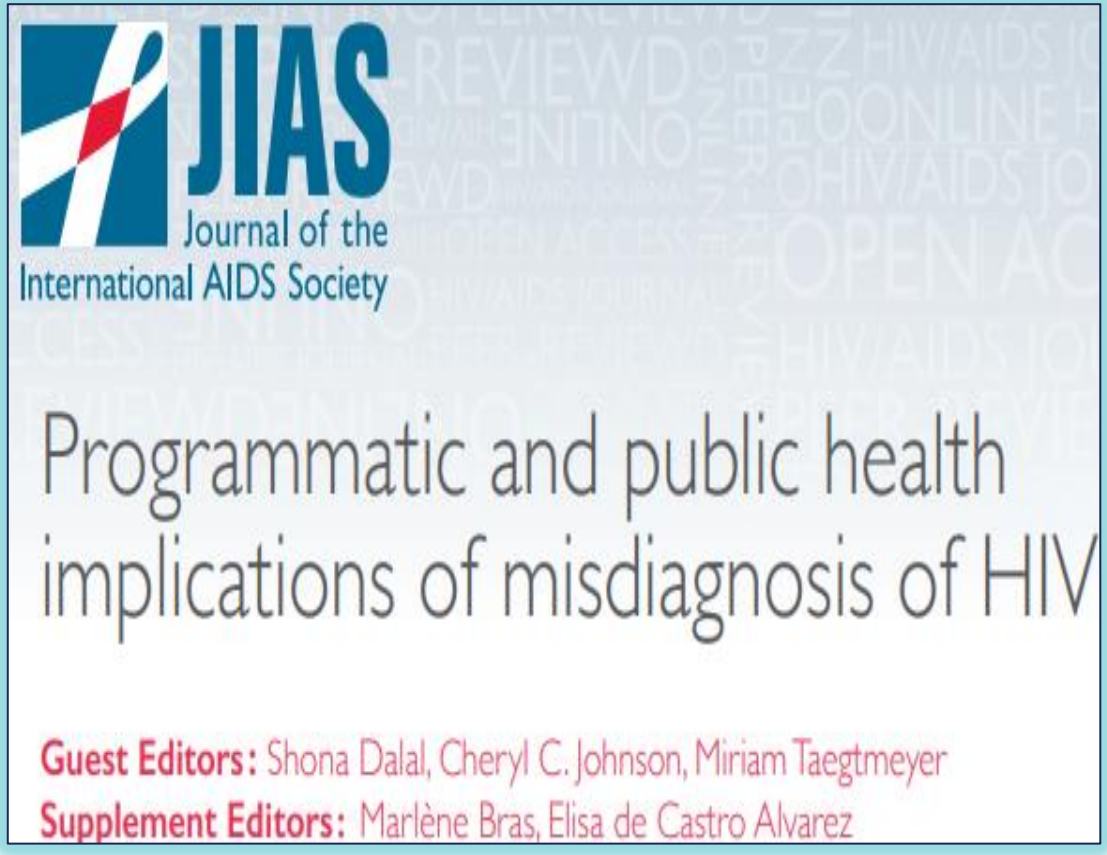
The Laboratory is Blamed for Every Error

[Laboratory errors – why the laboratory is not (always) to blame]

More than half of the so called ‘’laboratory errors’’ have already happened before the analysis starts in the laboratory and many mistakes are made after the analysis itself. Pre- and post-analytical errors cause 60 to 90% of all unexpected or erroneous values; only 10 to 15% are caused by analytical problems.

https://pubmed.ncbi.nlm.nih.gov/25630293/

Programmatic and Public Health Impact of Misdiagnosis



- Worsening the condition,
- Confusion,
- Being prescribed the wrong medication,
- Not being prescribed medication,
- Lost time seeing other healthcare providers,
- Overall impact on the national surveillance system
- Impact on programmatic and policy decision making

https://www.hst.org.za/publications/NonHST%20Publications/Programmatic%20and%20public%20health.pdf

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The Magnitude of HIV Misdiagnosis in Africa

73K people may be misclassified as HIV-positive in 11 African countries

The findings originated from a survey of more than 220,000 patients self-reporting as HIV-positive in Cameroon, eSwatini, Ethiopia, Ivory Coast, Lesotho, Malawi, Namibia, Tanzania, Uganda, Zambia and Zimbabwe.

https://www.healio.com/news/infectious-disease/20190506/73k-people-may-be-misclassified-as-hivpositive-in-11-african-countries

HIV misdiagnosis in sub-Saharan Africa: performance of diagnostic algorithms at six testing sites

The performance of algorithms at several sites failed to meet expectations and thresholds set by the World Health Organization, with unacceptably high rates of false results.

https://www.researchgate.net/publication/318034391_HIV_misdiagnosis_in_subSaharan_Africa_performance_of_diagnostic_algorithms_at_six_testing_sites

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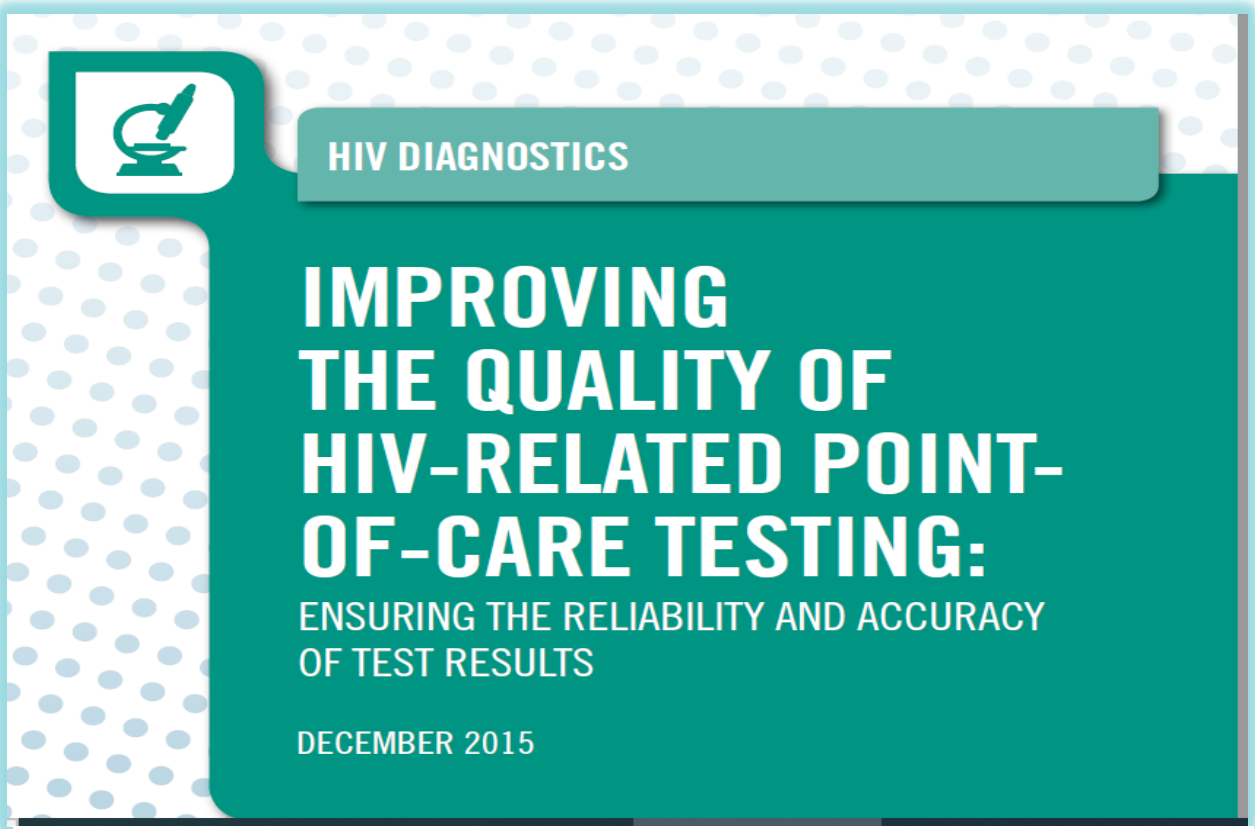
How do we Minimize Diagnostic Errors?

PEPFAR Rapid HIV Testing Continuous Quality Improvement (RT-CQI)

Purpose

In February 2014, a consensus meeting of major stakeholders and partners was held at the United States Centers for Disease Control and Prevention in Atlanta that clearly identified the need for new recommendations for improving the quality of HIV-related point-of-care testing. The purpose of this handbook is to address the weaknesses in current point-of-care testing quality assurance programmes, identify key activities that will help in developing and implementing sustainable high-quality HIV rapid diagnostic tests and HIV-related point-of-care testing within laboratory and non-laboratory settings. This handbook seeks:



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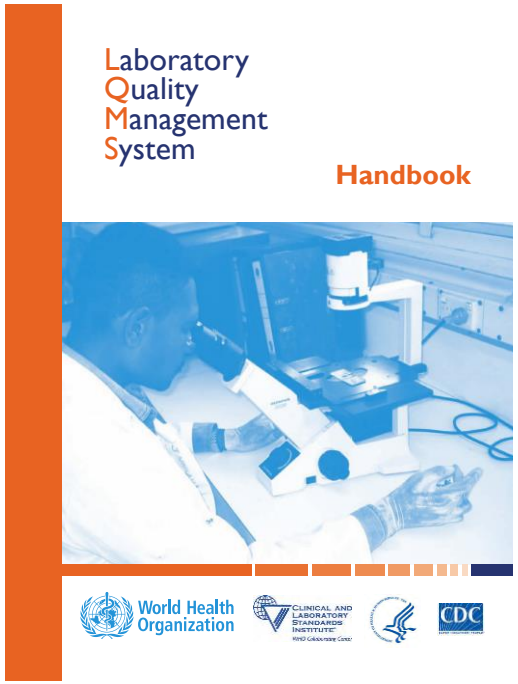
World Health Organization

CDC Centers for Disease Control and Prevention

WHO Guides

2011 | 2015 | 2015 & 2019 | 2022

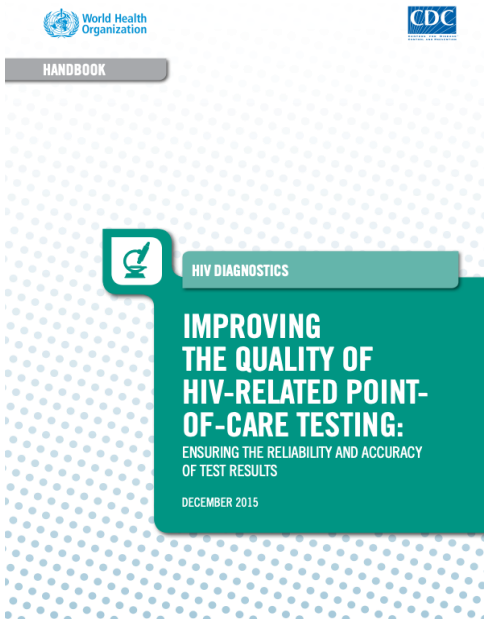
CDC, WHO Lyon; Laboratory quality management system: handbook



https://www.who.int/publications/i/item/9789241548274

LQMS Training Toolkit and LQSI tool

WHO improving the quality of HIV-related point-of-care testing: ensuring the reliability and accuracy of test results



https://iris.who.int/bitstream/handle/10665/199799/9789241508179_eng.pdf

RTCQI and SPI-RT and SPI-POCT

WHO Consolidated guidelines on **HIV testing services** quality chapter

https://iris.who.int/handle/10665/336323

ISO 15189: 2022

https://www.iso.org/standard/76677.html

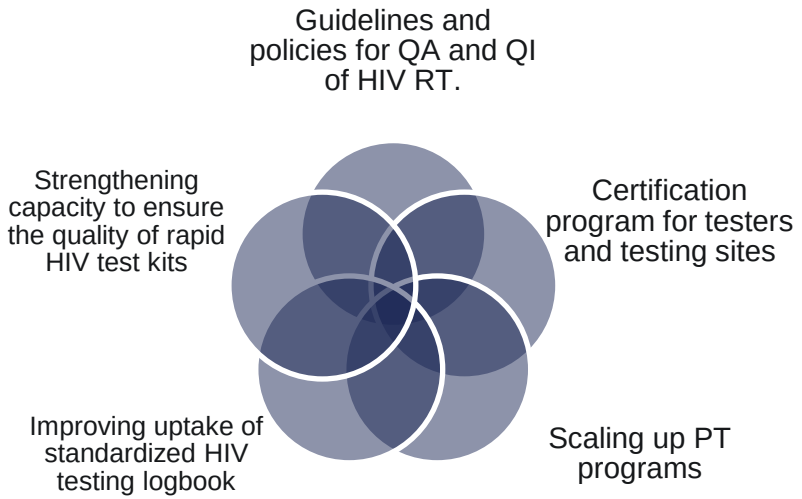
SLMTA and SLIPTA check list

World Health Organization

Programs, Tools, and training for POCT

HIV Rapid Test-Continuous Quality Improvement (RT-CQI) program and SPI-RT checklist

- To ensure trained non-laboratory personnel conduct HIV rapid testing at decentralized sites.
- Solution: CDC and WHO developed a multi-pronged approach for quality assurance and certification of testing staff. (**RT-CQI**) based on WHO guidelines on **improving the quality of HIV-related point-of-care testing (2015)** that uses **SPI-RT**
- Key Components :



- This program is implemented in most PEPFAR-supported countries to support accurate and reliable rapid HIV testing

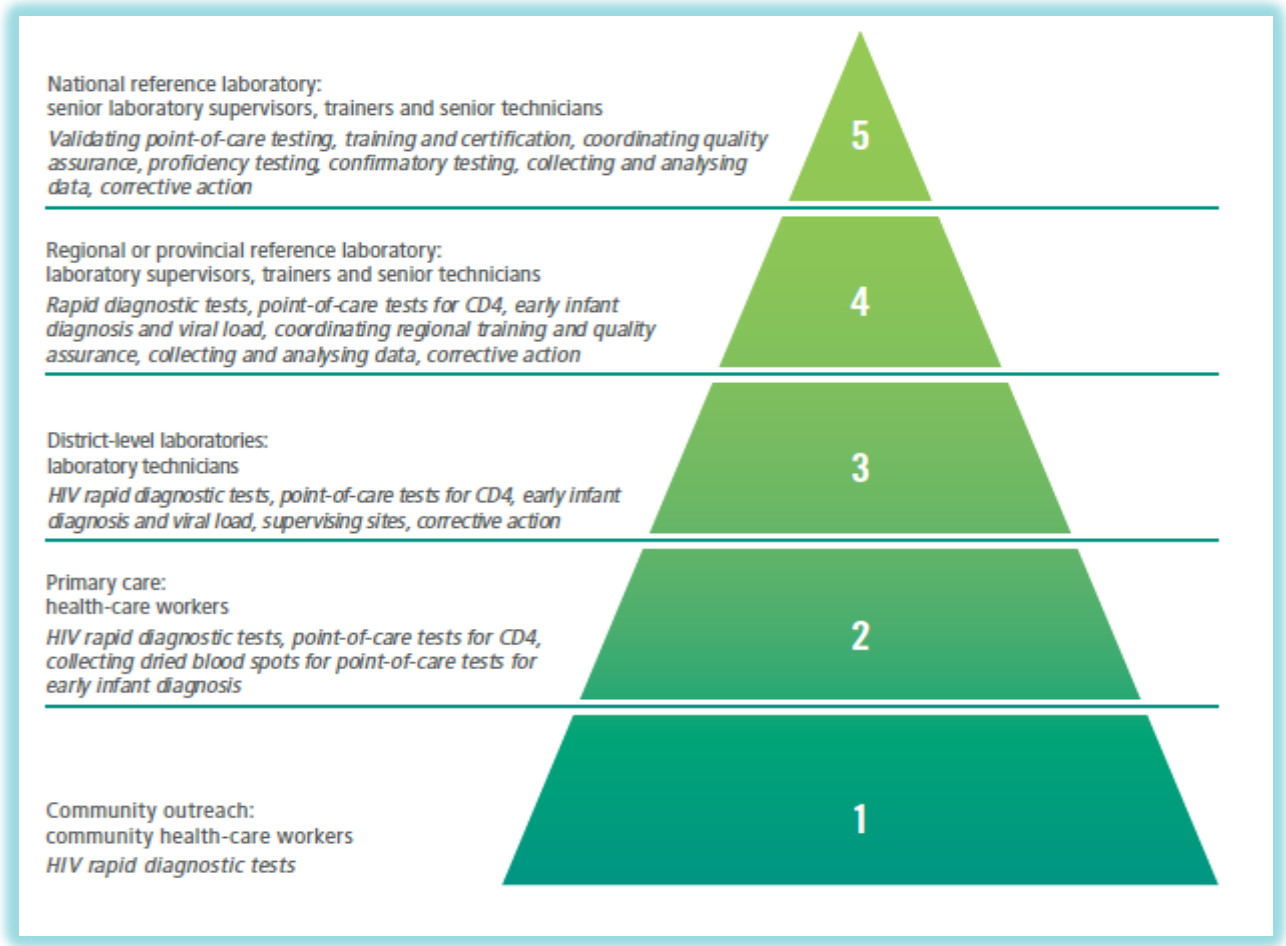
Challenges of using resources in countries without external support

non-PEPFAR-supported countries or countries not having support from a third party, can not easily implement QA

World Health Organization

Need for Quality Testing at All Levels of Tiered Health Systems

Point-of-care testing within the tiered health system



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HIV Testing Strategies | Quality of Testing is More Critical than Just Testing Strategy

PEPFAR Addendum to Fiscal Year 2024 Technical Considerations

National HIV testing strategies: WHO has recently released an information note, "Preventing HIV misdiagnosis," reminding countries of the importance of implementing a national testing strategy that requires 3 consecutive reactive test results to increase the positive predictive value prior to establishing an HIV seropositive diagnosis. PEPFAR is available to provide technical assistance to ministries of health that choose to adopt a 3-test strategy, though this does not imply that PEPFAR is able to fund associated resources (e.g., commodities, trainings, etc.).

Key Enablers of Successful HIV Quality Testing

1. Ensure strong CQI processes, including the incorporation of HIV RT-CQI, for all countries, regardless of the testing algorithm being used.

2. Encourage all countries implementing either algorithm to conduct retesting for verification before commencing ART. Retesting for verification will significantly improve the PPV even with the 2-test algorithm.

3. Encourage strong post market surveillance for all testing approaches.

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Quality Improvement and Accreditation | Key to Minimizing Diagnostic Errors

Laboratory Accreditation is most Efficient Approach to Sustainability

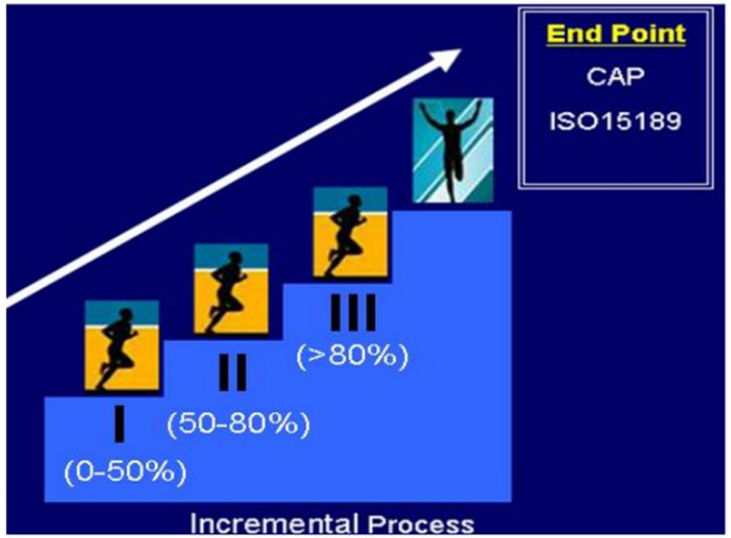
Strengthening Laboratory Management Toward Accreditation (SLMTA)

Implement Practical and sustainable Quality Management Systems

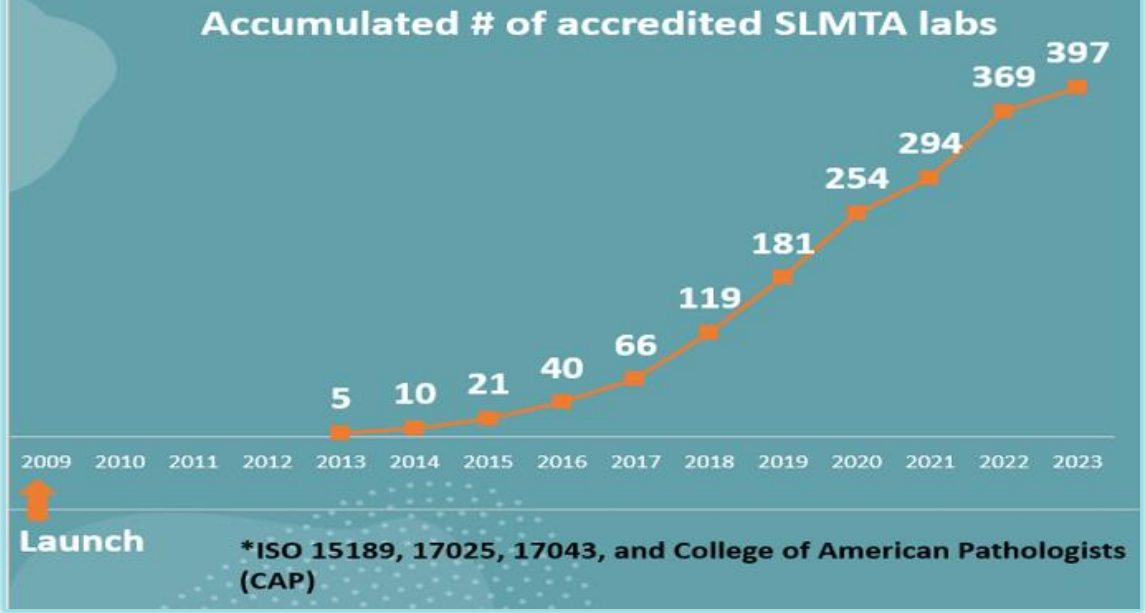
WHO AFRO Laboratory Accreditation –

Commitment to continuous improvement

- WHO AFRO *
- WHO AFRO **
- WHO AFRO ***
- WHO AFRO ****
- WHO AFRO *****



397 SLMTA laboratories in 26 countries have attained accreditation to international standards*



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How do we Ensure Availability of Timely Data?

Improved Turn-Around TIME (TAT)

Faster Test Results Mean Better Outcomes For HIV Patients

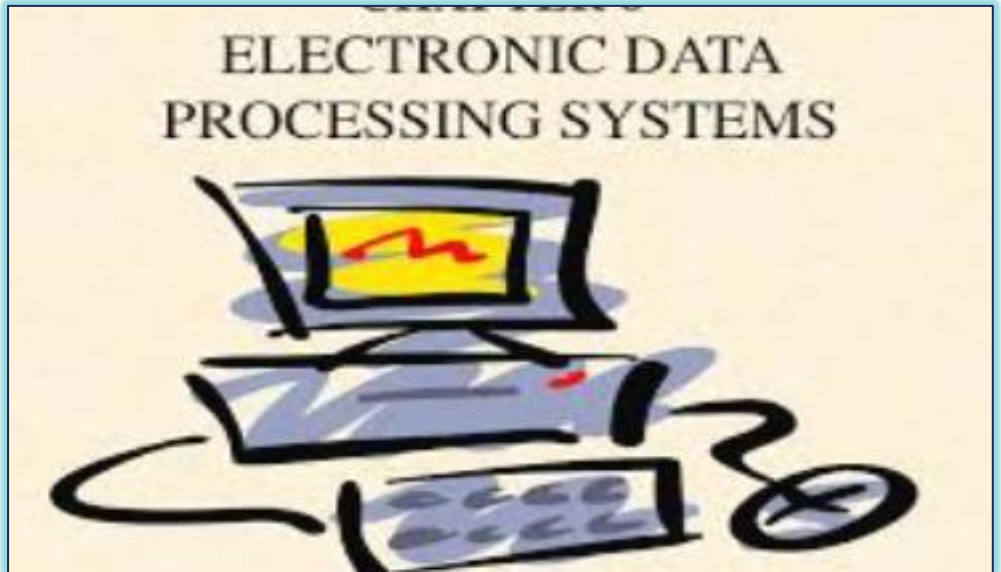
Faster Turnaround Improves Care

Decentralizing Testing Infrastructure

Transition from paper based to Electronic Data Systems to Improve TAT and Minimize Error

Paper Based System

Electronic Based System



Cameroon's Data Reporting Systems Pre & Post PEPFAR

Pre-PEPFAR Era

PEPFAR intervention (2011)

Current state

Paper based Tools

- Paper based data collection & Reporting tools
- Unharmonized National Reporting tools
- Existence of Option B+ sites

Electronic Systems

- Electronic tools: DHIS2, DAMA, EMR
- Harmonized National Reporting tools
- All Option B+ sites transitioned to Care and Treatment sites
- *Paper based tools remain primary data source for electronic tools

Digital Health Strategic Plan

- Digital Health strategic plan operational
- Interoperability layer being developed
- National HISs strengthened to eliminate parallel reporting in the long run

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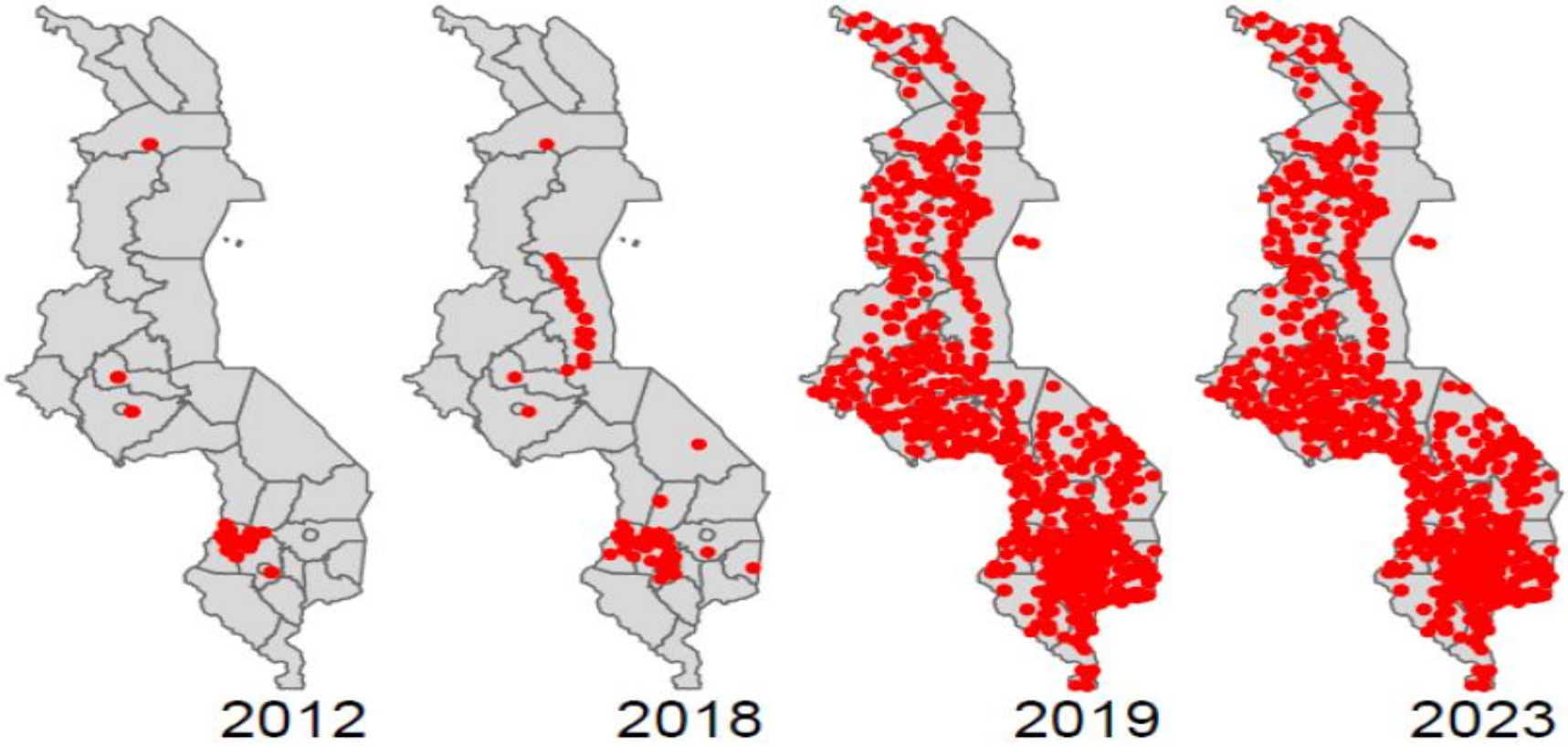
Electronic Medical Record (EMR) Coverage in Malawi, 2012-2023



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Note: this is specific to the HIV-ART EMR

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Data/Publications Supporting HIV-RTCQI Activities

Yenealem *et al. BMC Infectious Diseases* (2023) 23:315
https://doi.org/10.1186/s12879-023-08285-x

BMC Infectious Diseases

RESEARCH Open Access

HIV rapid test performance among health facilities enrolled in HIV rapid test quality improvement initiative (RTQII) in Ethiopia

Results: The overall acceptable performance (100% PT score with the correct algorithm followed) was found to be 62% while 12% scored 80% and 11% scored between 20 and 60%. The rest 15% were not considered as acceptable due to failure to adhere to the National HIV Testing Algorithm. Testing sites that participated in External Quality Assessment/Proficiency Testing schemes have shown better performance than those that did not participate with 70% and 56% performance respectively (p=0.057).

RESEARCH ARTICLE

Investigating the quality of HIV rapid testing practices in public antenatal health care facilities, South Africa

Duduzile F. Nsibande[1,2]*, Selamawit A. Woldesenbet[3,4], Adrian Puren[3], Peter Barron[4], Vincent I. Maduna[5], Carl Lombard[6,7], Mireille Cheyip[8], Mary Mogashoa[8], Yogan Pillay[9], Vuyolwethu Magasana[1,2], Trisha Ramraj[1,2], Tendesayi Kufa[3,4], Gurpreet Kindra[8], Ameena Goga[1,2,10], Witness Chirinda[1]

Facilities in districts implementing the HIV Rapid Test Quality Improvement Initiatives and supported by the President's Emergency Plan for AIDS Relief (PEPFAR) had significant higher median overall scores (65.6% IQR: 53.9-74.2%) (P-value from rank sum test:<0.001) compared with non-PEPFAR-supported facilities (56.6% IQR:47.7-66.0%). We found sub-optimal implementation of HIV rapid testing practices. We recommend the expansion of the PEPFAR-funded Rapid Testing Continuous Quality Improvement (RTCQI) support to all Antennal care testing sites.

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RESEARCH ARTICLE

An overview of the quality assurance programme for HIV rapid testing in South Africa: Outcome of a 2-year phased implementation of quality assurance program

Selamawit Alemu Woldesenbet[1,2]*, Mireille Kalou[3], Dumisani Mhlongo[4], Tendesayi Kufa[1,2], Makhosazana Makhanya[5], Adeboye Adelekan[5], Karidia Diallo[5], Mahlatse Maleka[6], Beverley Singh[1], Bharat Parekh[3], Amanda Mohlala[7], Peter T. Manyike[7], Tim J. Tucker[7,8], Adrian J. Puren[1,9]

Conclusion: Facilities performance on the domains that are critical for accuracy of diagnosis (i.e. pre-testing, testing and post-testing) remained largely unchanged. This study provided several recommendations to improve QA implementation in South Africa, including the need to improve routine use of internal control for corrective action

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RESEARCH ARTICLE

Cost implications of HIV retesting for verification in Africa

Arielle Lasry*, Mireille B. Kalou, Paul R. Young, Jacqueline Rurangirwa, Bharat Parekh, Stephanie Behel

Division of Global HIV & TB, Center for Global Health, Centers for Disease Control and Prevention, Atlanta, Georgia, United States of America

Conclusion: Results show that to reduce HIV misdiagnosis, countries in Africa should implement the WHO's recommendation of retesting for verification prior to ART initiation, as part of a comprehensive quality assurance program for HIV testing services.

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Lessons from PEPFAR for Global Health Security

"To best prepare for the health security threats of tomorrow, we must fight the pandemics we are facing today"

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Thank you