Access to Diagnostic Monitoring Laboratory Services at Point of Care through Implementation of National Laboratory Strategic Planning—the PEPFAR experience

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International Laboratory Branch
Global AIDS Program
Centers for Disease Control and Prevention
Atlanta, GA USA
The Maputo Declaration on Strengthening of Laboratory Systems, January 2008

Call on national governments to support laboratory systems as a priority by developing a national laboratory policy within the national health development plan that will guide the implementation of a national strategic laboratory plan. Governments should establish a department of laboratory systems within the Ministry of Health.

Call on national governments with support of their donors and partners in resource-limited settings to develop national strategic laboratory plans that integrate laboratory support for the major diseases of public health importance including HIV, tuberculosis, and malaria.
Approaches to Building Sustainable, Quality Laboratory Capacity

- Must be country owned and lead
- Work groups should include in-country ministries (health, finance, education, transportation, etc.) national, international, public and private partners
- Develop laboratory policy and implement national strategic plans for laboratories using an integrated approach
- Continuous improvement of laboratory performance through certification and accreditation
National Laboratory Policy

Foundation for developing sustainable laboratory health systems

National Strategic Laboratory Plans
Implementing a Laboratory Strategic Plan

- Country engagement
- Coordinating & technical committees
- Strengths, weaknesses, opportunities, and threats (SWOT) analysis
- Strategic plan:
  - Develop
  - Strategic plan implement
  - Strategic plan progress review & evaluate
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<tr>
<th>Country Engaged in Discussion</th>
<th>Coordinating and technical committees formed</th>
<th>Strategic plan developed</th>
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Support for HIV/AIDS programs but also
Viral Hepatitis, Sexually Transmitted infections
Flu, Tuberculosis, Malaria

Laboratory Systems
- Quality Management System
- Training & Retention Systems
- Equipment Maintenance Systems
- Supply Chain Management System
- Laboratory Information Systems
- Sample Referral Systems
- Policies

Laboratory Services
- Serology
- Molecular Testing
- Hematology
- Chemistry
- CD4
- Culture
- Microscopy

Strengthening Laboratory Health Systems & Sustainability
Potential Structure of a National Laboratory Network System in Resource Limited Countries

Functions

- Policy, Planning, Training, Quality Systems
- Referral testing

Responsibilities

- Oversight of regional level laboratories
- Oversight of government and non-government laboratories at regional level
- Support for government and non-government laboratory testing at district level
- Support for government and non-government laboratory testing support at health centers

Nkengasong et al
WHO AFRO Laboratory Accreditation process: a step-wise approach toward quality improvement

Commitment to continuous improvement
Strengthening Laboratory Management Toward WHO-AFRO Accreditation

Recommended Program Map

- Strengthen laboratory management
- Achieve immediate laboratory improvement
- Accelerate the process toward accreditation by WHO-AFRO

Pre-requisites to entry:
1. Lab strategic plan and policy drafted
2. Lab director, with decision-making power, in place
3. QA manager in place
4. Participant committed to same job responsibilities throughout the 18-month program (preferred)

Baseline Assessment

Gap Analysis & Action Plan

Workshop #1: Improvement Projects (3 months)

Workshop #2: Site Visits

Workshop #3: Site Visits

End-of-Training Assessment

On-going support by partners and CDC in-country staff (on-site mentoring, monitoring of improvement projects)

Attendees: An 18-month program with a series of workshops for the same group of lab managers

Additional Training/Technical Assistance Based on Gap Analysis (offered at ACILT or in-country by partners)

- Quality Control
- How To Be A Successful QA Manager
- SOP Writing
- BioSafety
- Quality Management System

Optional Complementary Training

- Skill-based training (e.g., SMID)
- Online Virtual Leadership Development Program (e.g., MSH)

Accreditation

Getting ready for final inspection

Month 0
Month 1
Month 4
Month 7
Month 12
Month 18

Month 15

Month 18

World Health Organization Africa

CDC

American Society for Clinical Pathology

CLINTON FOUNDATION
Point of Care Diagnostics

HIV Rapid Test Kits
HIV RTKs

- ~25 million people were tested by HIV rapid testing in 2010
- 1000s of testing sites/many more thousand personnel performing the test
- Settings: VCT, PMTCT, PITC, Mobile, HBCT and Lab
- Most testing performed by non-laboratory personnel --counseling, prevention, or health care
HIV RTKs

• 50+ rapid tests
• HIV-1/2, HIV-1 and 2 separate
• Emerging new technologies (oral fluid RT, Ag/Ab combo)
• Specimen types: serum, whole blood, oral fluid
• No easy way to evaluate tests in-country in a consistent manner
• Standardized approach and guidance needed
Key publications - 2010

Scaling Up HIV Rapid Testing in Developing Countries

Comprehensive Approach for Implementing Quality Assurance

Bharat S. Parekh, PhD, Mireille B. Kalou, MD, MPH, George Alemnji, PhD, Chin-Yih Ou, PhD, Guy-Michel Gershy-Damet, PhD, and John N. Nkengasong, PhD

Dried tube specimens: A simple and cost-effective method for preparation of HIV proficiency testing panels and quality control materials for use in resource-limited settings

Bharat S. Parekh, Juliana Anyanwu, Hetal Patel, Marie Downer, Mireille Kalou, Catherine Gichimu, Bera Steven Keipkerich, Nelly Clement, Michael Omondi, Oren Mayer, Chin-Yih Ou, John N. Nkengasong
Multi-Step Approach for Assessing Quality of HIV RTKs

1. Use of USAID-CDC Validated RT kits
2. Selection of appropriate rapid tests and testing algorithms for in-country use
3. Hands-on training of key trainers and subsequent roll out of training with emphasis on QA
4. Certification of testing personnel and testing sites
5. Implementation of standardized logbook and DTS based PT program (QA)
6. Identification and training of local partners to scale up QA program
7. Collection and analysis of data and develop reports with NRL
8. Corrective actions including site visits and limited retesting where needed
9. Annual refresher training of the testing personnel conducted regionally
10. Implementation of new lot verification and post-market surveillance
HIV Rapid Tests to Support Prevention, Care, and Treatment

- Trained about 10,789 health care personnel: Counselors, midwives, nurses, lab technicians
- CDC/USAID established a program to evaluate rapid tests in a systematic way for procurement with PEPFAR funding
- Simple and easy methods to ensure the quality of Rapid testing:
  - Standardized logbook
  - Dried Tube Spot for Proficiency Testing
Logbook data

- Systematic collection of page total data
- Training of users and reviewers
- Review and monitor ongoing agreement between
  - test 1 and 2,
  - site results and re-testing results, if re-testing is done
- Identify sites or personnel with poor agreements
- Follow up with corrective actions (training, kit issues etc.)
Kenya National MOH Laboratory Policy & Strategic Plan
RT-QA Saturation Strategy
comprehensive approach in selected countries

KENYA

– Country with large number of sites (>5,000)
– Has initiated implementation of some concepts
  • DTS PT program (from 400 sites in 2009 to 3000 sites)
  • Standardized logbook
– Readiness of CDC-Kenya staff, NHRL and MoH
– Lobby for resources + COP
– Periodic review of each component of ten commandments
Identification and training of local partners to scale up QA program

- Scope of the program
- Kenya = ~5,500 sites, >10,000 personnel
- PT program = 3 rounds (Feb, June and Oct)
- 50,000-60,000 tubes/round
- Need for decentralization
- Reduce to 2 rounds/year?
Kenya – DTS Based PT Program

- Large amount of data (~3000 sites)
- Data analysis – a huge challenge in-country
- Need for a systematic approach for data entry and analysis
- Prioritize issues for PT program
- Improvised Excel spreadsheet with macros, tables and plots
- Access database?
HIV RTKs—what have we learned?

- Comprehensive approach that includes multiple tools is essential
- Focus on any one tool is not adequate
- Close monitoring can lead to improvement
- Dedicated resources for all QA activities + data management/analysis are needed
- Improvement of quality over time must be demonstrated, e.g.
  - Agreement between test 1 and 2 (logbook)
  - # of personnel/sites passing PT (DTS PT program)
  - # of certified personnel (policy + training)
  - # of certified sites (policy + training)
- QA is a ongoing activity, not a periodic event
## EQA program - Country updates

<table>
<thead>
<tr>
<th>Country</th>
<th>No of CT sites enrolled in 2009</th>
<th>2010 QA plan</th>
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<tbody>
<tr>
<td>Botswana</td>
<td>120 sites + 216 testers</td>
<td>Enroll 200 new sites</td>
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<tr>
<td>Cameroon</td>
<td>30</td>
<td>Enroll 135 district labs Implement logbook in district labs</td>
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<tr>
<td>Côte d’Ivoire</td>
<td>94</td>
<td>Scale up PT to 200 sites Implement logbook in 600 sites Decentralization of retesting</td>
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<td>Ethiopia</td>
<td>36</td>
<td>105</td>
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<td>Haiti</td>
<td>170</td>
<td>NA</td>
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<td>Kenya</td>
<td>2000</td>
<td>Scale up to 5000 sites Use of logbook at all CT sites</td>
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<tr>
<td>Lesotho</td>
<td>15 sites (3/10 districts) + 139 testers</td>
<td>Scale up PT to 5 districts</td>
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<tr>
<td>Uganda</td>
<td>1100 (200 AFENET sites)</td>
<td>Scale up PT + logbook implementation</td>
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<tr>
<td>Tanzania</td>
<td>564 (200 AFENET sites)</td>
<td>Scale up PT + logbook implementation</td>
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Future POC Diagnostics Implementation
Considerations for New POC Technology

Past Challenges with Implementation of Rapid HIV Diagnostics

- Personnel- Training, competency, turnover
- HIV RTKs-Poor quality, inconsistent lots
- Test algorithm—None in place or not followed
- Patient and specimen ID-No standards
- Reporting-Poor and inadequate patient logbooks and reports
- Quality of testing—Not done or not monitored
- Supply chain-Stock outs, expired reagents
POC CD4 Testing

Introduction to Pima

• Pima is a true point-of-care solution for CD4 testing

• The platform consists of the Pima Analyser and the Pima test cartridge

• Designed to equally suit the needs of the healthcare professional in the field and in the laboratory, the Pima Analyser provides an affordable, effective and valuable tool in the management of HIV patients.
Implementation of Quality POC CD4 Testing

• Selection of appropriate assay
• Ensure service and supply chain are available
• Training—all aspects of the test including specimen collection, analysis, reporting, troubleshooting, supply chain, and quality control
• Specimen Management—proper and consistent ID
• Quality Testing—QC material for testing available, analysis of QC Results, internal and external monitoring, error rates and corrective action
• Reporting
Additional POC Testing

• Hemoglobin assay
• Syphilis testing
• Malaria testing
• Lateral flow Cryptococcus Ag tests
• Chemistry analytes- glucose, etc
• New molecular tests for infectious diseases and viral loads
GeneXpert—New TB POC Technology

Rapid Molecular Detection of Tuberculosis and Rifampin Resistance

Catharina C. Boehme, M.D., Pamela Nabeta, M.D., Doris Hillemann, Ph.D., Mark P. Nicol, Ph.D., Shubhada Shenai, Ph.D., Fiorella Krapp, M.D., Jenny Allen, B.Tech., Rasim Tahiri, M.D., Robert Blakemore, B.S., Roxana Rustomjee, M.D., Ph.D., Ana Milovic, M.S., Martin Jones, Ph.D., Sean M. O’Brien, Ph.D., David H. Persing, M.D., Ph.D., Sabine Ruesch-Gerdes, M.D., Eduardo Gotuzzo, M.D., Camilla Rodrigues, M.D., David Alland, M.D., and Mark D. Perkins, M.D.
Continuing Considerations for Future POC Testing

- Worldwide there has been a trend for more POC diagnostics, in areas of infectious disease detection and blood analyte monitoring for patient care.
- It has been recognized that in order to ensure quality of these POC diagnostics, proper quality management and laboratory support is essential for accurate and useful results.
- There must be a continuous evaluation of the quality of these POC assays to provide valuable input for the appropriate use for patient care.
- Plans must promote standards, guidelines and policy for the quality management and monitoring of POC assays, as well for all other laboratory testing.
Conclusions

- Strategic laboratory plans are a cornerstone for strengthening laboratory systems
- Provide a process to coordinate efforts, build synergies, and develop sustainable laboratory systems
- Scale up of HIV rapid test kit use provides lessons learned and best practices for implementation of new POC technologies
Launch: March 14-16
Addis Ababa
Ethiopia

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA
OUR MISSION
TO ADVANCE PROFESSIONAL LABORATORY
MEDICINE PRACTICE, SCIENCE, SYSTEMS,
AND NETWORKS IN AFRICA NEEDED TO
SUPPORT PREVENTIVE MEDICINE, QUALITY
CARE OF PATIENTS AND DISEASE CONTROL
THROUGH PARTNERSHIP WITH GOVERNMENTS
AND RELEVANT ORGANIZATIONS.

ASLM Mission
ASLM will focus on 8 strategic areas:

- **Policy** – advancing development of laboratory policies in Africa
- **Advocacy, Communication, and Resource Mobilization** – advocating for resources to improve laboratories throughout Africa
- **Laboratory Accreditation and Quality Management Systems** – expanding WHO-AFRO “Laboratory Progress Towards Accreditation” program across Africa
- **Laboratory Workforce Development** – improving in-service laboratory science education by enhancing the quality of training and increasing access by laboratory professionals
- **Laboratory-clinical interface** – enhancing the interaction between laboratory professionals and clinicians through continuing medical education
- **Research Capacity and Publication** – Increasing technical capacity and developing platforms for dissemination and communication of laboratory science research
- **Technical Assistance** – improving access to high quality technical assistance consultants and materials
- **Laboratory Strategy and Networks** – Strengthening public health network capacity