Advances in National Laboratory Strategic Planning in Africa Improves Quality of Services: A PEPFAR Major Success Story

John Nkengasong, PhD

Associate Director of Laboratory Science
Division of Global HIV/AIDS, Center for Global Health
Center for Disease Control and Prevention

APHL Annual Meeting
June 1, 2014
A Decade of Commitment to Strengthening Laboratory Medicine in PEPFAR-Supported Countries
Outline

• Introduction
• Role of Laboratory Strategic Plan
• Laboratory Systems
• Need to strengthen Institutions
PEPFAR 10 Year Goals:

- Treatment for at least 6 million people
- Prevention of 12 million new infections
- Care for 12 million, including 5 million orphans and vulnerable children
- Training of at least 140,000 new health care workers in HIV/AIDS
HIV Testing Offered In PEPFAR-Supported Countries Between 2004-2013

Millions

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Value</td>
<td>1.9</td>
<td>3.7</td>
<td>7.2</td>
<td>12.7</td>
<td>21.6</td>
<td>28.5</td>
<td>32.8</td>
<td>40.5</td>
<td>49.0</td>
<td>57.7</td>
</tr>
</tbody>
</table>
Number Of HIV-Infected Adults And Children Receiving Antiretroviral Therapy

<table>
<thead>
<tr>
<th>Year</th>
<th>Millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>0.07</td>
</tr>
<tr>
<td>2005</td>
<td>0.25</td>
</tr>
<tr>
<td>2006</td>
<td>0.5</td>
</tr>
<tr>
<td>2007</td>
<td>1.1</td>
</tr>
<tr>
<td>2008</td>
<td>1.7</td>
</tr>
<tr>
<td>2009</td>
<td>2.5</td>
</tr>
<tr>
<td>2010</td>
<td>3.2</td>
</tr>
<tr>
<td>2011</td>
<td>3.9</td>
</tr>
<tr>
<td>2012</td>
<td>5.1</td>
</tr>
<tr>
<td>2013</td>
<td>6.7</td>
</tr>
</tbody>
</table>
The Case For Strengthening Laboratory Systems

Laboratory Systems and Services Are Critical in Global Health

Time to End the Neglect?

John N. Nkengasong, PhD,1 Peter Nasboga, MD, MPH,2 Okey Nwananyenwu, PhD,2 Guy-Michel Gershy-Damet, PhD,4 Giorgio Roscigno, MD,5 Marc Bulterys, MD, MPH, Barry Schoub, MD,7 Kevin M. DeCock, MD, MPH,8 and Deborah Birx, MD8

Key Words: National laboratory systems; Laboratory strengthening; Global health; Public health; Infectious diseases

DOI: 10.1200/JOP.2020.012860

A Shifting Paradigm in Strengthening Laboratory Health Systems for Global Health

Acting Now, Acting Collectively, but Acting Differently

John N. Nkengasong, PhD
State Of Laboratories Infrastructure In 2004
Need To Renovate Laboratories To Support The Treatment And Prevention Programs
The Renovated Laboratory
The Inauguration
State Of Reference Laboratories In 2014

Chennai, India

Dar es Salaam, Tanzania

Addis Ababa, Ethiopia
“Although challenges remain, the improvement of laboratories under PEPFAR support and guidance has been a signature achievement of the program ----During the committee’s country visits, this was a theme emphasized with near universality”
Vision and Mission Statement

To support countries to strengthen sustainable, integrated laboratory systems to provide diagnostics services for effective implementation of prevention, surveillance and treatment programs across disease (HIV, TB, Malaria, OI’s, etc.)
PEPFAR Laboratory Framework For Multiple Diseases

Laboratory Systems
- Quality Management
- Workforce Development
- Biosafety & EQP Maintenance
- Supply Chain Management
- Laboratory Information
- Sample Referral
- Facilities/Policies

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

Stronger & Sustainable Health System
1

Services
Number Of PEPFAR-Supported Laboratories In Selected Countries As Of September 2008 (N= 1,917)
Dried Blood Spot-based PCR Testing Has Helped Scale-up Early Infant Diagnosis

Scaling up DBS-PCR testing in developing countries
2 Systems
The Maputo Declaration on Strengthening of Laboratory Systems

**Recognize** that in order to improve and sustain access to laboratory services, there must be an integration of laboratory support for tuberculosis, malaria and HIV disease programs. The aim of this effort should be to sustain any improvements made to a laboratory as part of the greater health system from a public health perspective.

**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 donors and implementing partners to ensure that in supporting laboratory strengthening that proper consideration is given to fostering national ownership.

**Call** on academic institutions and research funders to accelerate efforts to develop new diagnostic tools applicable to resourced-limited settings.

**Call** on donors and development partners to commit to work collaboratively with each other and with coordination from the national governments to support strengthening of laboratory systems in order to create one unified, integrated national laboratory network. These laboratory strengthening efforts should seek to build public private partnerships.

Done in Maputo, Mozambique on 24 January 2008
<table>
<thead>
<tr>
<th>Country</th>
<th>Engaged in Discussion</th>
<th>Coordinating &amp; Technical Committees Formed</th>
<th>Strategic Plan Developed</th>
<th>Strategic Plan Implemented</th>
<th>Strategic Plan Progress Reviewed &amp; Evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barbados</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Botswana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cambodia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cameroon</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cote d'Ivoire</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethiopia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ghana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guyana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haiti</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kenya</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesotho</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesotho</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malawi</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mozambique</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Namibia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Namibia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nigeria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nigeria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rwanda</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rwanda</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swaziland</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swaziland</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Africa</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Africa</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tanzania</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tanzania</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uganda</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uganda</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vietnam</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Kigali, Rwanda – 2009

1. Roadmap to accreditation and framework to measure progress
2. Training program to improve laboratory quality management
WHO-AFRO Stepwise Laboratory Quality Improvement Process Towards Accreditation

Benchmarks a laboratory’s progress towards accreditation using a 0-to-5 star scale

Audit checklist based on ISO 15189 standard

≥ 95%

85-94%

75-84%

65-74%

55-64%

0 Stars

1 Star

2 Stars

3 Stars

4 Stars

5 Stars

Strengthening Laboratory Management Toward Accreditation

Training program to improve laboratory quality management

Workshops, Mentorship, Improvement Projects, Audits (12-18 months)

Workshop #1

Workshop #2

Workshop #3

Behavioral Changes & Laboratory Improvement

Baseline Audit

Site Visits

Site Visits

Site Visits

Exit Audit
Global Reach Of The SLMTA Program

<table>
<thead>
<tr>
<th>Region</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Countries</td>
<td>39</td>
</tr>
<tr>
<td>Laboratories</td>
<td>501</td>
</tr>
<tr>
<td>Trainers</td>
<td>433</td>
</tr>
<tr>
<td>People trained</td>
<td>1644</td>
</tr>
</tbody>
</table>

- Latin America and the Caribbean (N=14)
- Africa (N=23)
- South East Asia (N=2)
SLMTA Results

96 Million Tests Conducted Annually in 501 SLMTA Laboratories

Before SLMTA
16% of tests done in laboratories with at least 1 star

After SLMTA
67% of tests done in laboratories with at least 1 star
Evidence of Laboratory Improvement

Laboratory Floor Plan Redesign

Signage

Personnel Files

Documents & Records
Recognition!

Kenya receiving ISO15189 - 2013
Accredited Laboratories in Sub-Saharan Africa

Only 34 laboratories accredited outside of SA (2 public labs)

37 of 49 countries have NO accredited laboratories

Source: Schroeder LF et al, American Journal of Clinical Pathology (in press)
• National Health Laboratory Quality Assurance and Training Centre
• Muhimbili National Hospital, awaiting application
• Mbeya Referral Hospital
• KCMC Referral Lab, awaiting application
• Mnazi mmoja Lab, assessed by SADCAS

Bugando lab
Mbeya Referral Hospital
Map of Botswana Showing Accreditation Status of MOH Laboratories

| 4 | State Reference Laboratories Accredited |
| 1 | District Hospital Laboratory Accredited |
| 5 | MOH district /referral Laboratories under Accreditation Cycle |
Map of India Showing Accreditation Status of State Reference Laboratories

Legend:

- Red (●): 5 State Reference Laboratories Accredited
- Blue (○): 10 State Reference Laboratories under Accreditation Cycle

- GMC, Surat
- LTMG Sion, Mumbai
- BJMC, Ahmedabad
- BYL, Mumbai
- KEM, Mumbai
- MPSMC Jamnagar, Baroda
- JJ Hospital, Mumbai
- GMC, Baroda
- BJMC, Pune
- GMC, Hyderabad
- GHTM, Chennai
- PGIMER, Chandigarh
- HIMS, Dehradun
- LHMC, New Delhi
- NHA, Kohima
Vietnam ISO15189 Accredited Labs with CDC Support (PEPFAR Funding)

- Preventive Medicine Center-HCMC, Microbiology Lab, Ho Chi Minh
- Phan Ngoc Thach Hospital, Microbiology Lab, Ho Chi Minh
- Pasteur Institute (HCMC), HIV Lab, Ho Chi Minh
- Pasteur Institute (HCMC), HIV DR Lab, Ho Chi Minh
- National Institute of Hygiene and Epidemiology, HIV Lab, Hanoi
- Bach Mai Hospital, Microbiology Lab, Hanoi
- National Lung Hospital Microbiology Laboratory (Nat’l TB Reference Lab), Hanoi
- National Institute of Hygiene and Epidemiology, HIV DR Lab, Hanoi
- Hue Central Hospital, Microbiology Lab, Hue
PEPFAR Laboratory Framework For Multiple Diseases

Laboratory Services

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

Laboratory Systems
- Quality Management
- Workforce Development
- Biosafety & EQP Maintenance
- Supply Chain Management
- Laboratory Information

Sample Referral
Facilities/Policies
Strengthening Sample Transport Networks - Uganda

- Initial pilot of 19 hubs reached 625 health facilities.
- Scaled up to 60 hubs serving 1700 health facilities launched.
Specimen Referral and Transport: Solutions

- Boda boda to aid sample and result delivery
- Integrated sample referral
- Rif resistant TB samples
- Post office
- NTRL LPA/culture
- Toll free line
Sample Transport Costs For DBS Decreased By 62% After Setting Up The Sample Referral System

Before NSRTN | After NSRTN
---|---
Masaka (68 parcels) | $2,312 | $792
Jinja (72 parcels) | $2,448 | $824
Gulu (50 parcels) | $1,700 | $812
Overall average (190 parcels) | $6,460 | $2,428

62%
PEPFAR Laboratory Framework For Multiple Diseases

Laboratory Services

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

Laboratory Systems
- Quality Management
- Workforce Development
- Biosafety & EQP
- Maintenance
- Supply Chain Management
- Laboratory Information
- Sample Referral
- Facilities/Policies
TB, HIV, Malaria - Integrated laboratories, Zaria, Nigeria
TB and HIV Labs in Chennai, India
PEPFAR Laboratory Framework For Multiple Diseases

Laboratory Systems
- Quality Management
- Workforce Development
- Biosafety & EQP Maintenance
- Supply Chain Management
- Laboratory Information
- Sample Referral
- Facilities/Policies

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

To provide integrated hand-on training courses to expand laboratory capacity in Africa for diagnosis and monitoring of major infectious diseases including HIV, TB and Malaria

• 1,136 Trainees
• 39 Countries
Human Resource Development for Laboratory

Source: IOM Report 2013
Institutions & Public Private Partnerships
Launch of the African Society for Laboratory Medicine

ASLM 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.
Ministers of Health at Launch of ASLM
African Society for Laboratory Medicine

ASLM Regional Ambassador Program

Dennis Agbonlahor (Nigeria)
William Ampofo (Ghana)
El-Hadj Belabbes (Algeria)
Adil Ismail (Sudan)
Mohamed Ally Mohamed (Tanzania)
Jean Sakande (Burkina Faso)
Daniel Sess (Cote d'Ivoire)

ASLM Collaborating Centers

Ethiopian Health and Nutrition Research Institute (Ethiopia)
Kenya Medical Research Institute (Kenya)
Institute of Human Virology (Nigeria)
West African Network Against AIDS, TB and Malaria (Senegal)
National Health Laboratory Service (South Africa)
National Health Laboratory Quality Assurance and Training Centre (Tanzania)

134 certified auditors
The Power of Partnership - Public Private Partnerships are Critical for Laboratory Strengthening Efforts

$18 Million PEPFAR partnership with BD

Support for Countries

Activities will be implemented through three primary means:

- Country-specific laboratory strengthening programs that offer PEPFAR and...
Conclusions And Key Lessons Learned

1. Leadership and Commitment from Agency
2. Strategic Partnerships and Relationships
The Beginning of Famine?

At Front Lines, AIDS War Is Falling Apart
By DONALD G. McNEIL Jr.
Published: May 9, 2010

As the Need Grows, the Money for AIDS Runs Far Short
By DONALD G. McNEIL Jr.
Published: May 9, 2010
Is the glass half full or half empty?
Thank You
## Acknowledgements

<table>
<thead>
<tr>
<th>CDC</th>
<th>Implementing Partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tom Hearn</td>
<td>ASM</td>
</tr>
<tr>
<td>Austin Demby</td>
<td>ASLM</td>
</tr>
<tr>
<td>Sherry Orloff</td>
<td>USAID</td>
</tr>
<tr>
<td>Debbi Birx</td>
<td>UNAIDS</td>
</tr>
<tr>
<td>Tom Shinnick</td>
<td>CLSI</td>
</tr>
<tr>
<td>Ron Ballard</td>
<td>APHL</td>
</tr>
<tr>
<td>Bob Martin</td>
<td>AFENET</td>
</tr>
<tr>
<td>John Ridderhof</td>
<td>ASCP</td>
</tr>
<tr>
<td>Mark Rayfield</td>
<td>BD</td>
</tr>
<tr>
<td>MOH colleagues</td>
<td>FIND</td>
</tr>
<tr>
<td></td>
<td>CHAI</td>
</tr>
<tr>
<td></td>
<td>WHO</td>
</tr>
</tbody>
</table>