Global Health Emergencies: Role of Laboratory Medicine

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Outline

- PEPFAR as a Global Health Emergency
- Gaps in Diagnostics
- Access to Diagnostics
- Impact of Diagnostics and Role of Clinicians
- Need for key Partnerships

Where we were before PEPFAR…

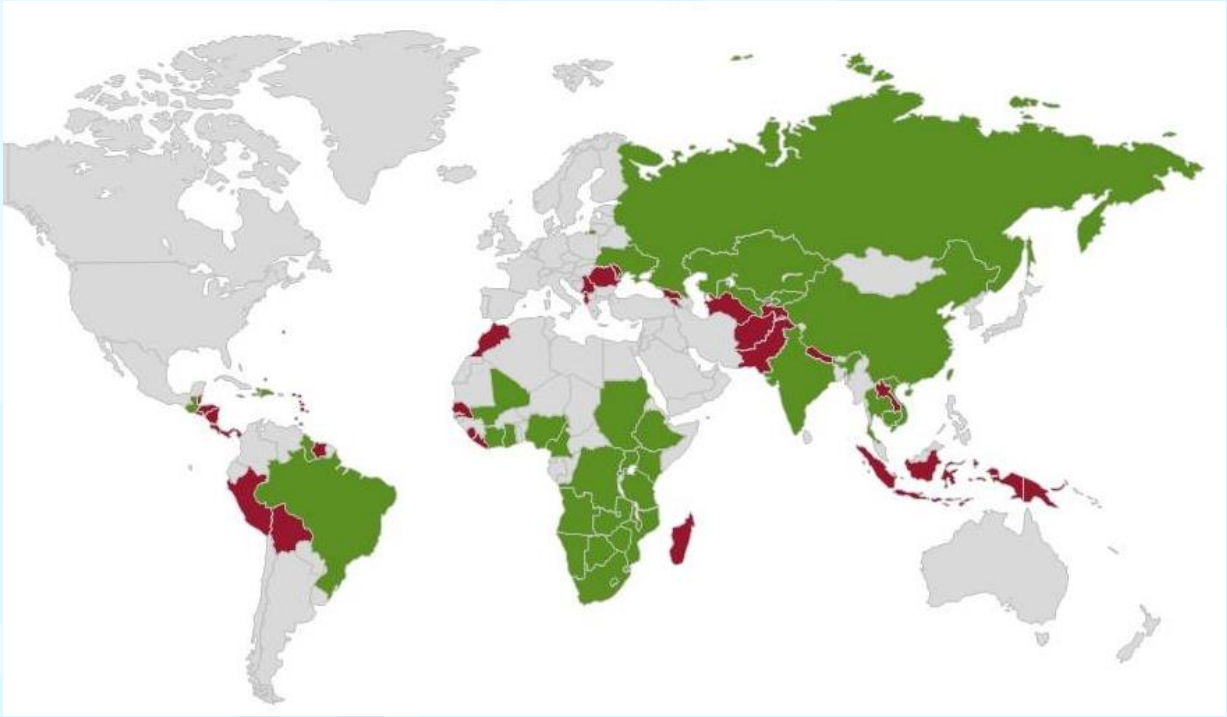
1991 – 2001:
Peak
of the
Pandemic

- **2001**: Nearly 10,000 new HIV infections daily
- **2002**: 50,000 on treatment in sub-Saharan Africa
- Health systems overwhelmed by the epidemic
- Life expectancy declines of over 20 years in some countries
- Loss of working age population – reversing decades of development progress
- Stigma and discrimination were pervasive

CDC PEPFAR-Supported Countries

Initial 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



Countries with HIV/AIDS program offices (N=41)

Additional countries receiving HIV/AIDS support (N=37)

Celebrating PEPFAR's Remarkable Success

Since its launch in 2003,

PEPFAR has saved millions of lives*

- **7.7 M people** on **life-saving ART**
- More than **one million babies** born HIV-free *(>240,000 infant infections averted in 2014)*
- **6.5 M men** received VMMC services
- **17 M people** received care and support, including **5 M orphans and vulnerable children**
- **21 M people** in priority and key populations reached with prevention interventions

The U.S. government has committed **more than $52 billion** to bilateral HIV/AIDS programs, the Global Fund, and bilateral TB programs since 2004.

Under the Obama Administration,

unprecedented progress

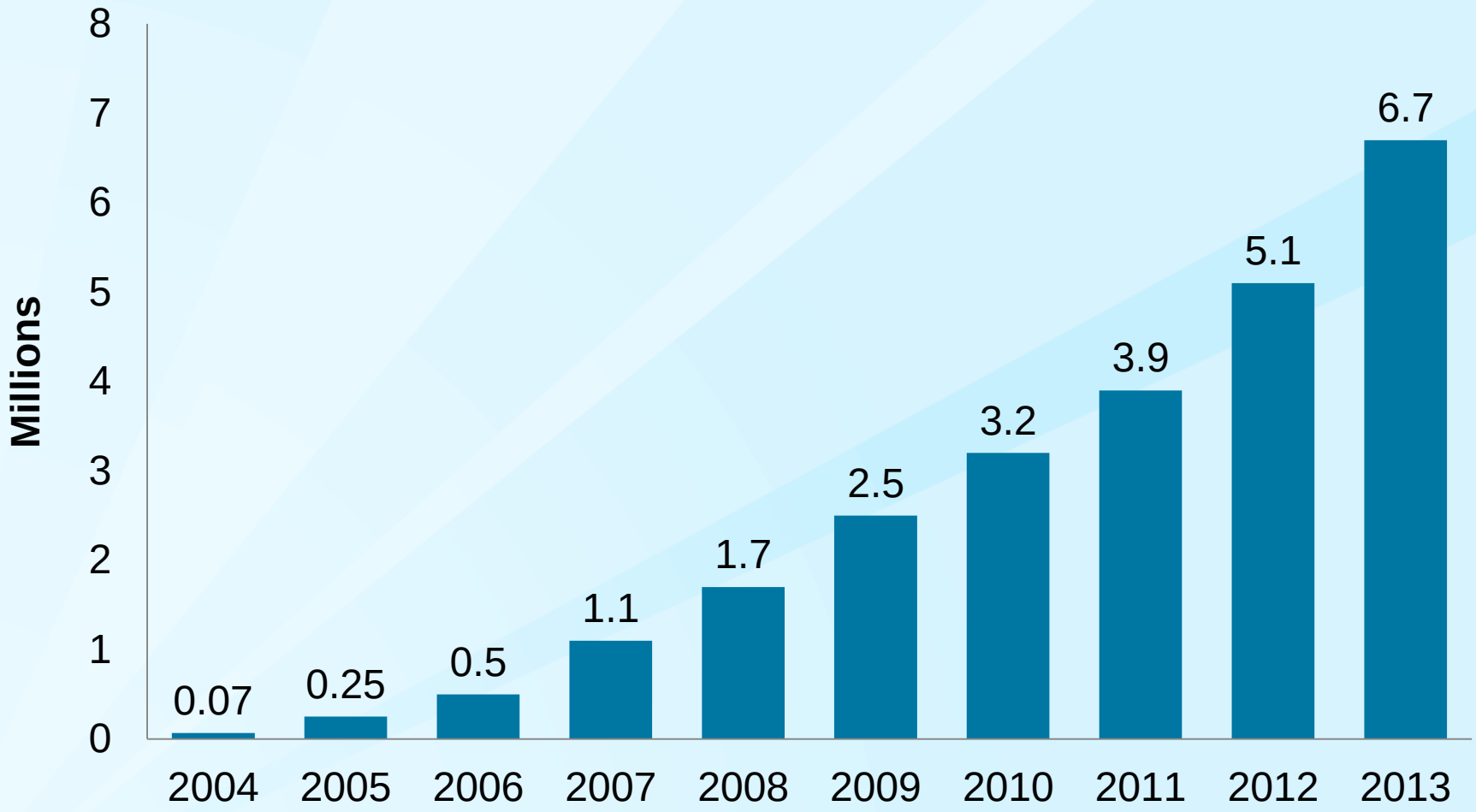
has been made, building on the strong foundation laid under the Bush Administration.

How much more can we achieve

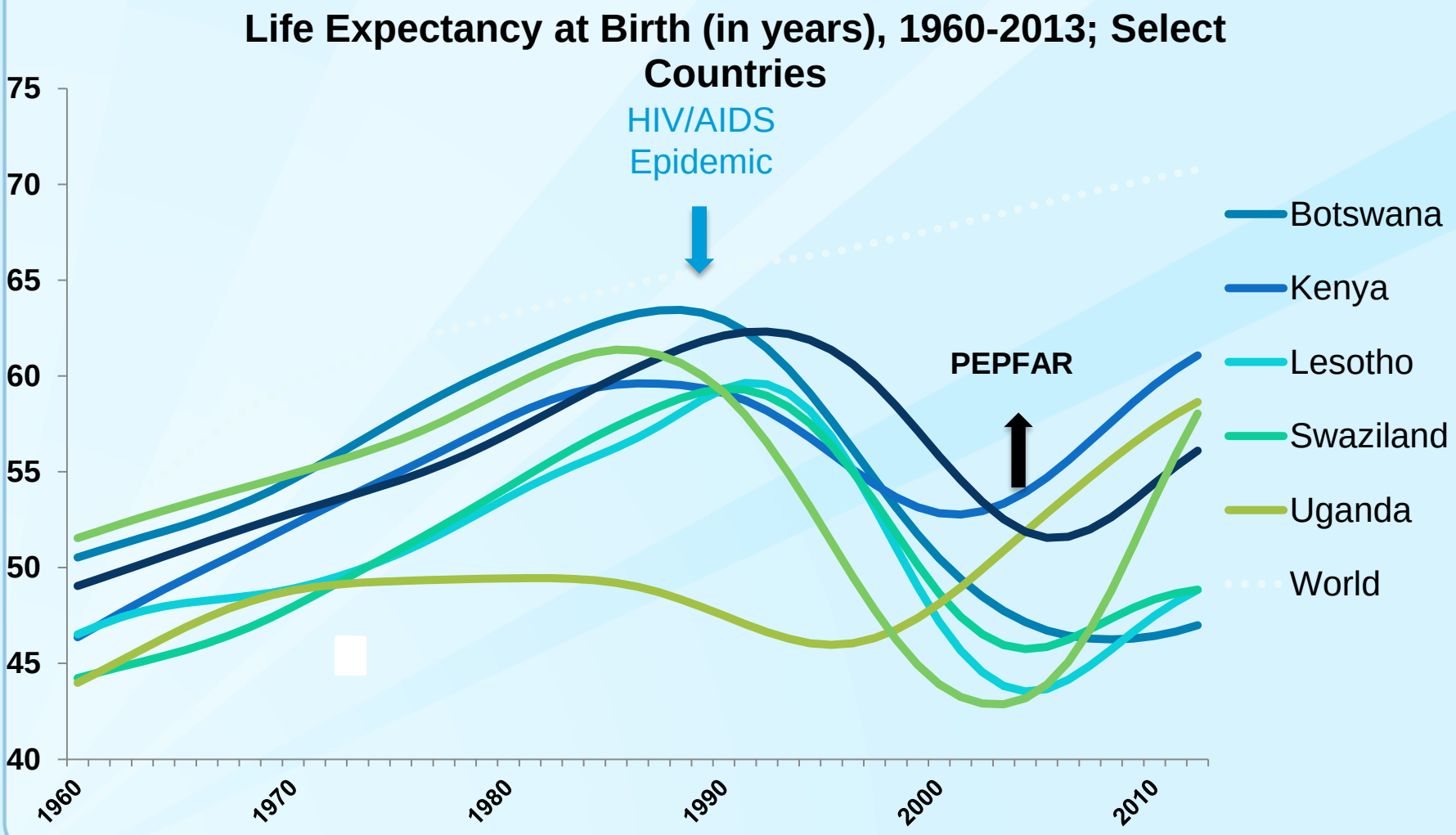
together?

Is it possible to control the pandemic while ensuring no one is left behind?

Number Of HIV-Infected Adults And Children Receiving Antiretroviral Therapy



Dramatic Impact of PEPFAR on Life Expectancy In Countries Significantly Impacted by HIV/AIDS



Source: World Bank, 2014

PEPFAR's Evolution

From Emergency Response to Sustainable Impact for an AIDS-free Generation

2003 – 2007: PEPFAR I

- Emergency response
- Delivering prevention, care, & treatment services
- Building & strengthening health systems to deliver HIV services

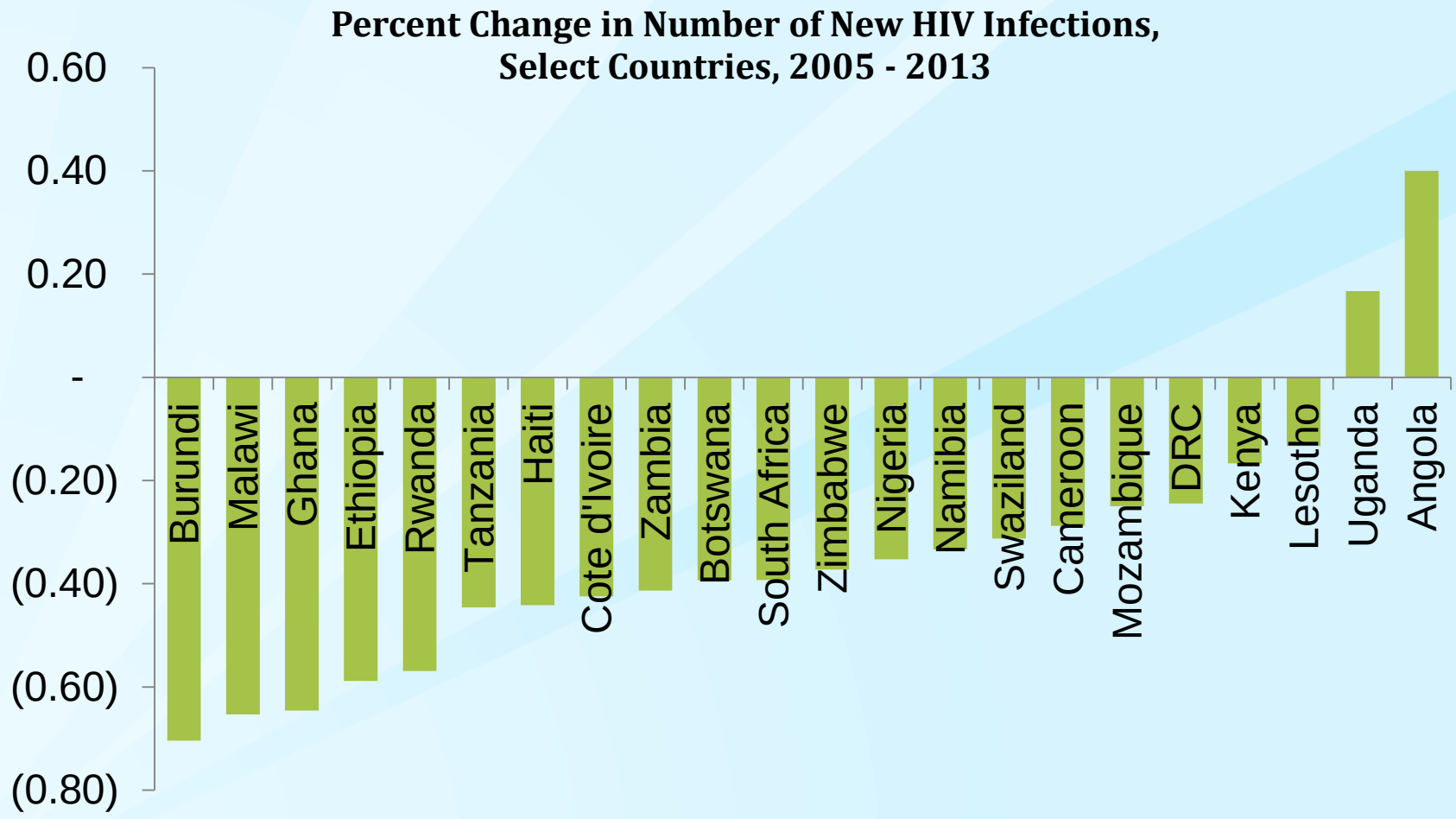
2008 – 2012: PEPFAR 2

- Shift from emergency to sustainable response
- Shared responsibility & country-driven programs
- Scaling up core interventions (ART, PMTCT & VMMC) for impact

2013-2018: PEPFAR 3

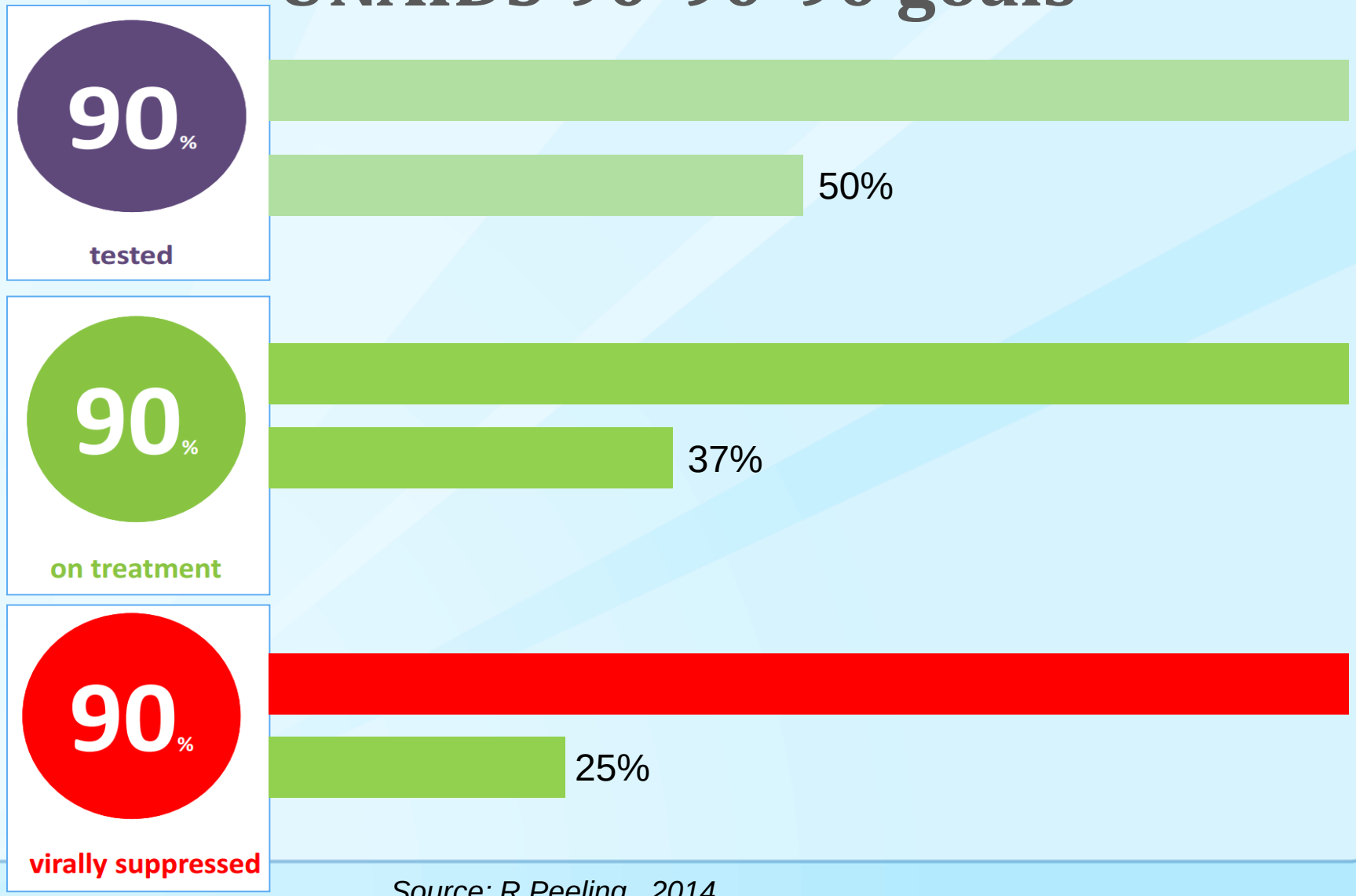
- Sustainability & shared responsibility
- Quality, oversight, transparency, & accountability for impact
- Accelerating core interventions for epidemic control

Progress is Unequal : Decline in New HIV Infections Varies By Country



Source, UNAIDS 2014

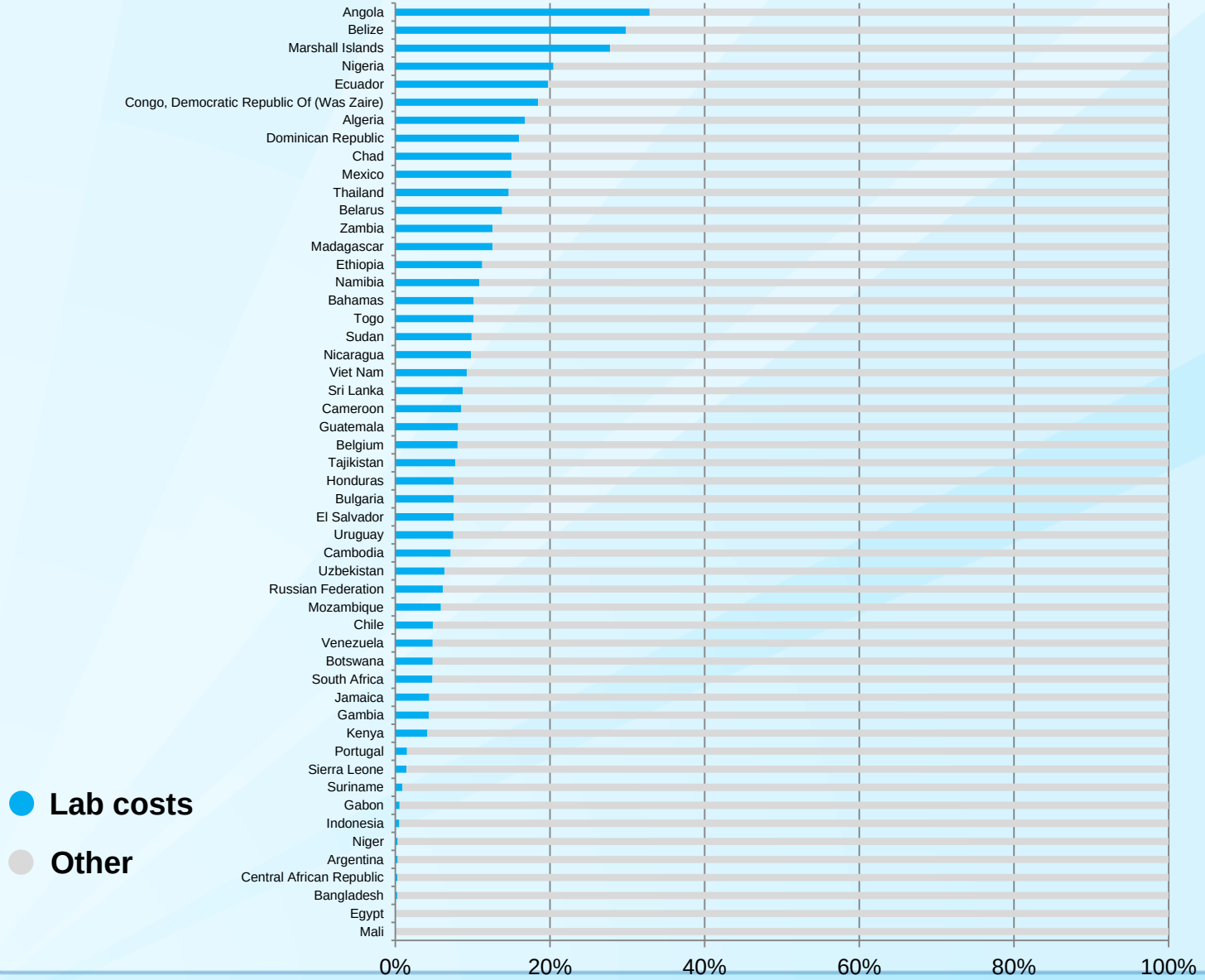
The Diagnostics Gaps to Meet the UNAIDS 90-90-90 goals



Source: R Peeling , 2014

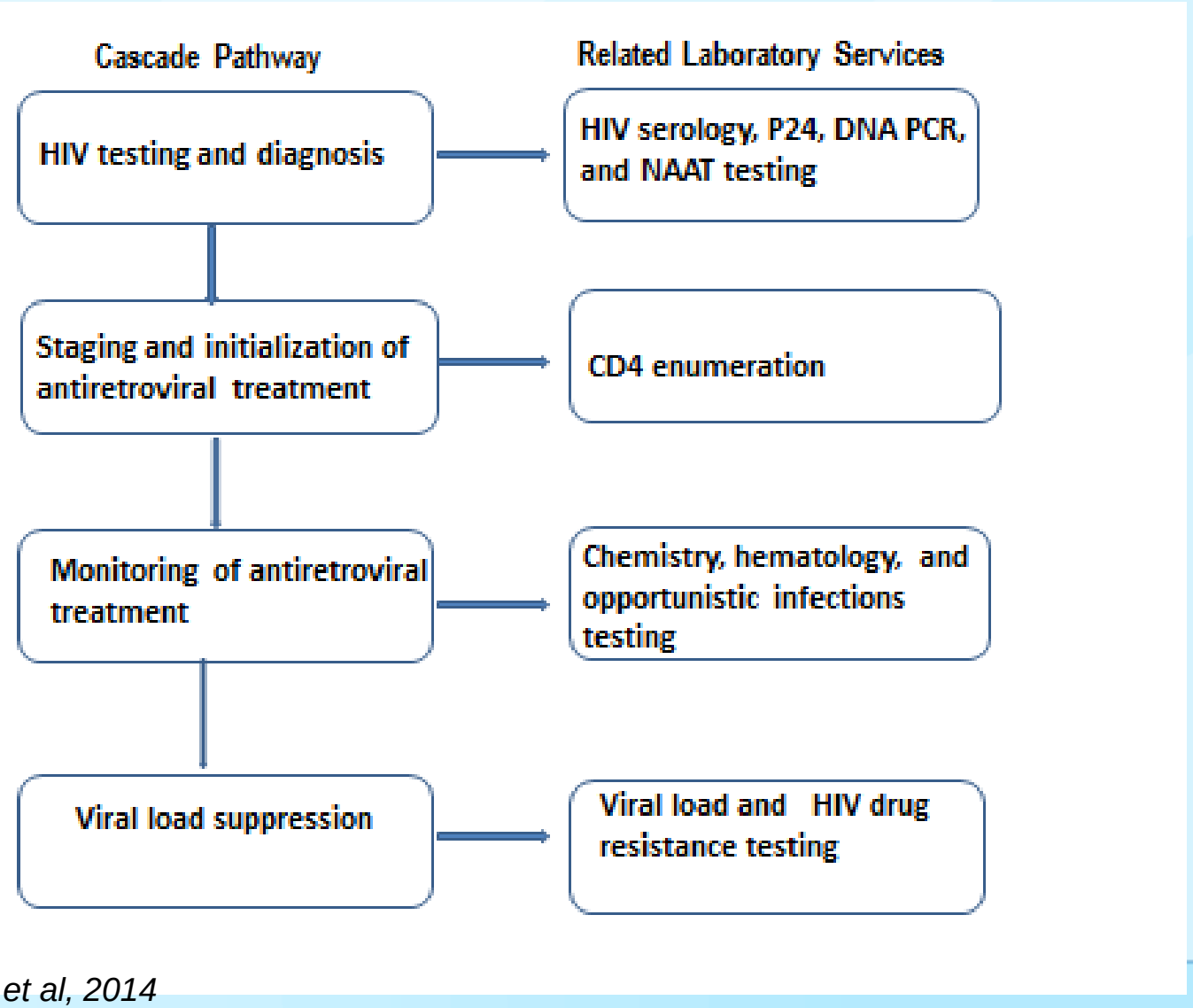
1 Gaps in Diagnostics

Lab Costs as a Proportion of Treatment and Care Costs



Source: UNAIDS 2013

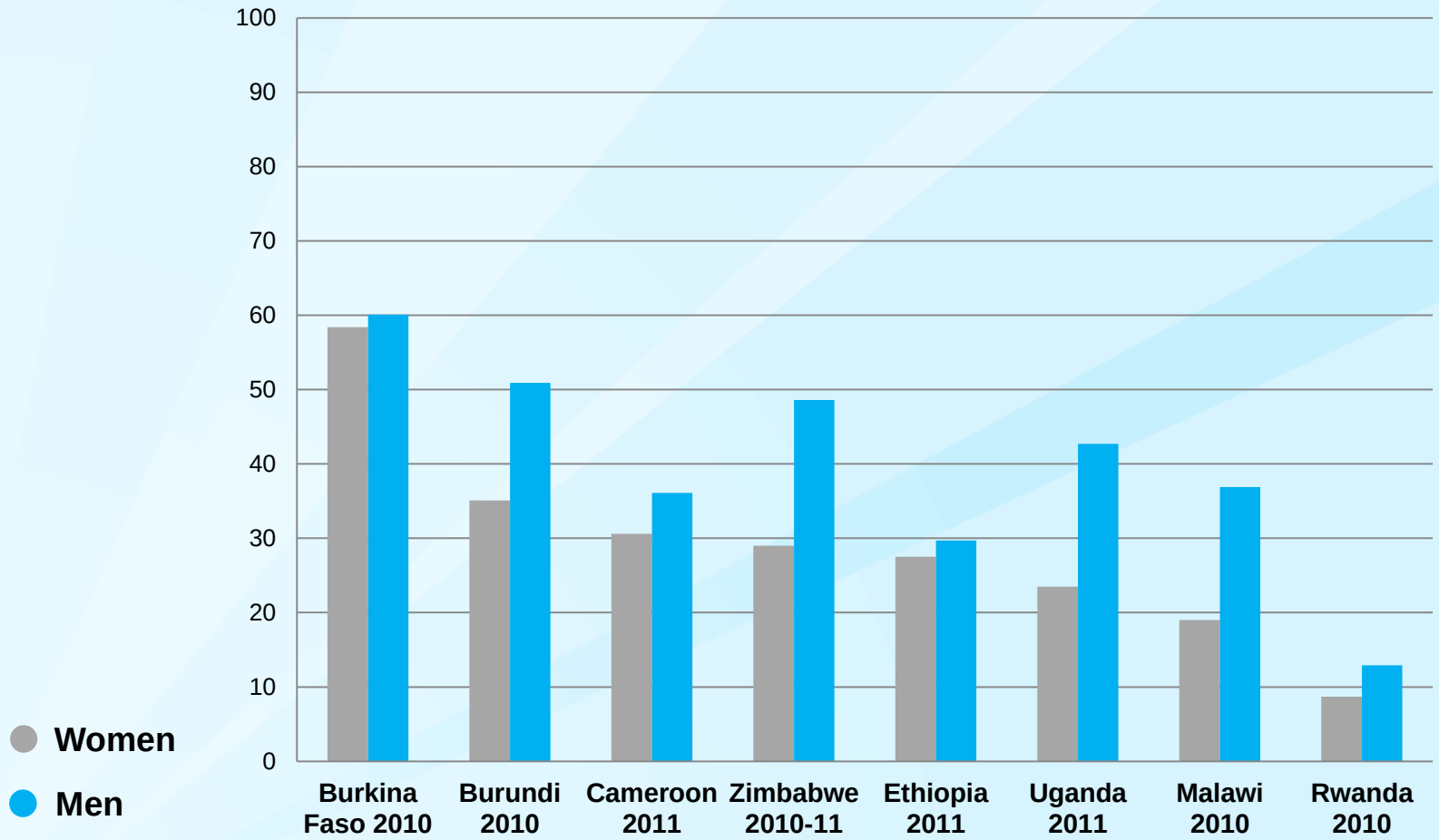
Access to Diagnostics in the Treatment Cascade



Source: Alemnji et al, 2014

HIV Testing Offered In PEPFAR-Supported Countries Between 2004-2013

Proportion of Individual Never Tested for HIV



Source: Demographic and Health Surveys

HIV Rapid Testing Sites

Published Reports of Misdiagnosis

OPEN ACCESS Freely available online

2009 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

OPEN ACCESS Freely available online

2013 PLOS | ONE

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

JOURNAL OF THE INTERNATIONAL AIDS SOCIETY

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RESEARCH

Indeter
results
centres

Debrah I Boeras[1],
Elwyn Chomba[6],
Angela M Calien

EXPERT REVIEWS

Causes of false-positive HIV rapid diagnostic test results

Expert Rev. Anti Infect. Ther. 12(1), 49–62 (2014)

Derryck Klarkowski[1], Daniel P O'Brien[2,3], Leslie Shanks[1] and Kasha P Singh*[4,5]

HIV rapid diagnostic tests have enabled widespread implementation of HIV programs in resource-limited settings. If the tests used in the diagnostic algorithm are susceptible to the same cause for false positivity, a false-positive diagnosis may result in devastating consequences. In resource-limited settings, the lack of routine confirmatory testing, compounded by incorrect interpretation of weak positive test lines and use of tie-breaker

Accuracy of Test Results is Critical - Quality Assurance Cycle

Tools Developed by WHO and Partners to Support Reliable HIV Related Point of Care Testing

2010

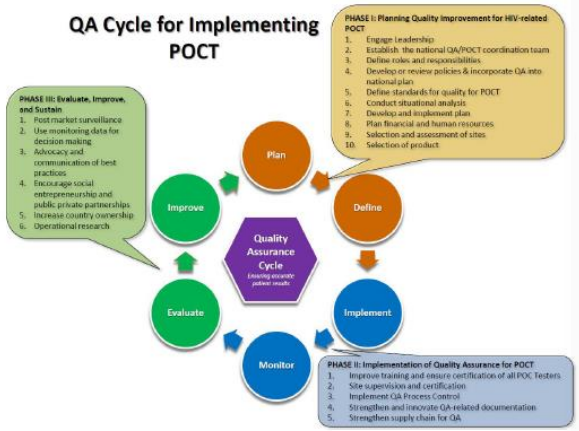
A Handbook for Improving HIV Testing and Counselling Services

Field-test ver

World He
Organiza

Handbook for Improving the Quality of HIV-related Point-of-Care Testing:

Ensuring Reliability and Accuracy of Test Results

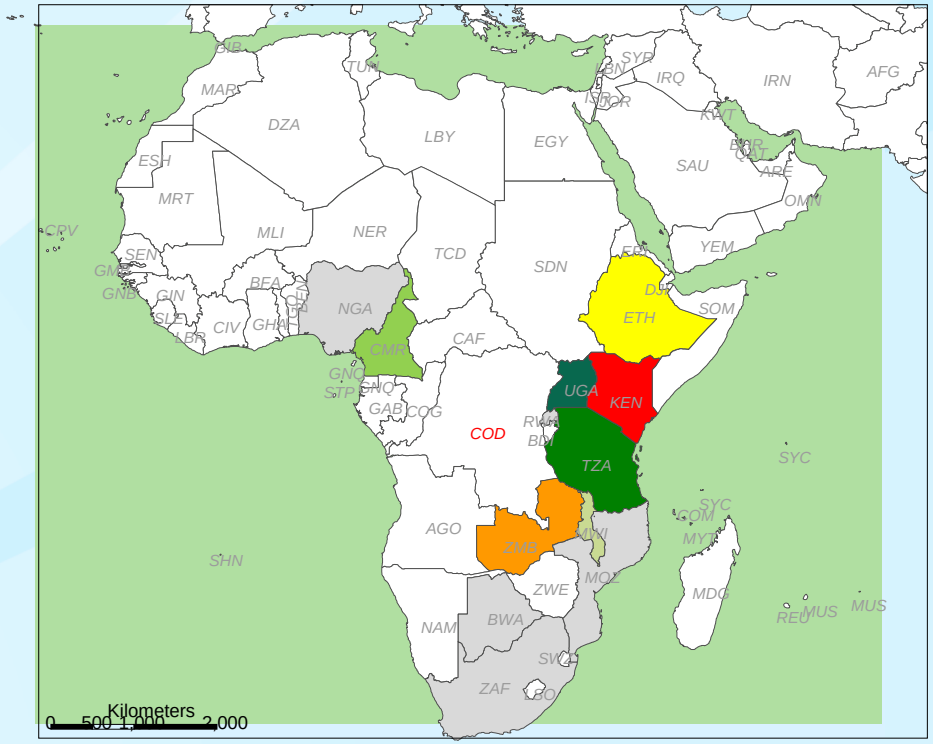


Framework for the Development of HIV-Related Point of Care Testing Policy for Implementation and Quality Assurance

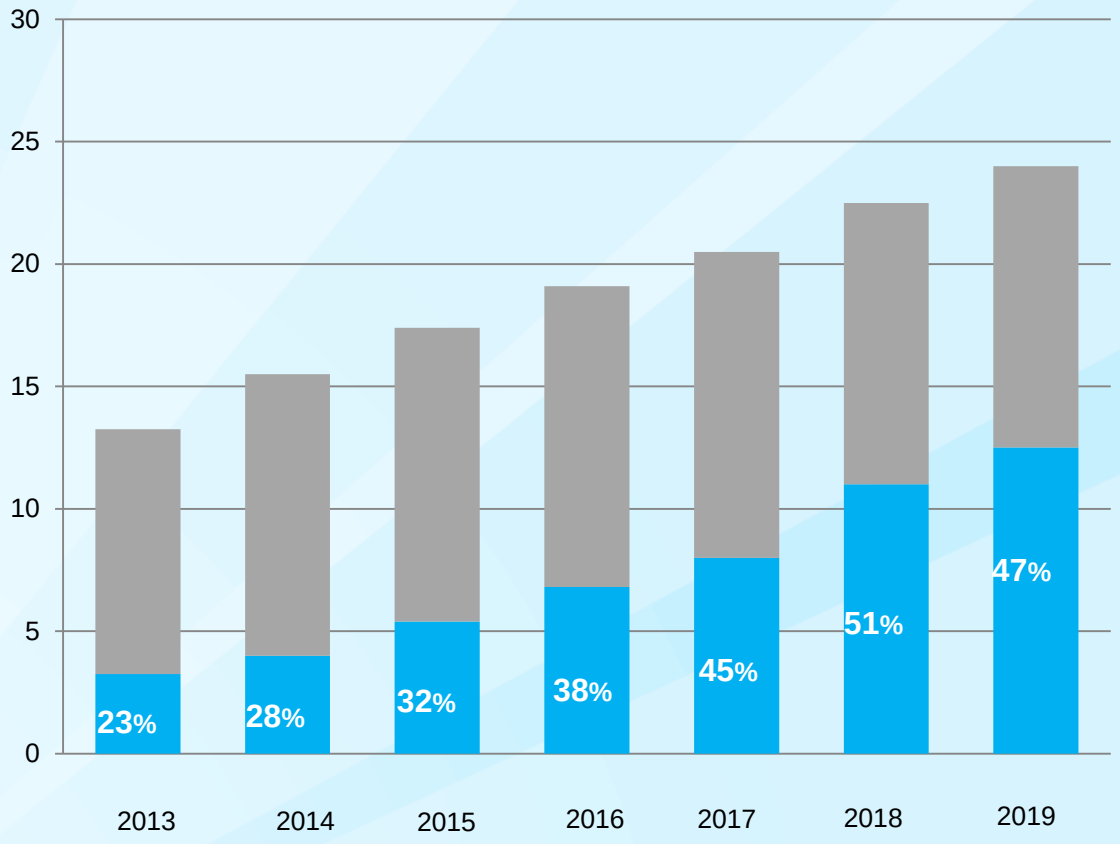
Ensuring Reliable and Accurate Test Results

Rapid Testing Quality Improvement Initiative (RTQII)

- $40 million OGAC-funded initiative for 2 years
- Target 7 PMTCT Option B+ countries
- Promote critical QA elements and completion of QA cycle



Predicted Viral Load Needs



Global Viral Load forecast

Global Viral Load need

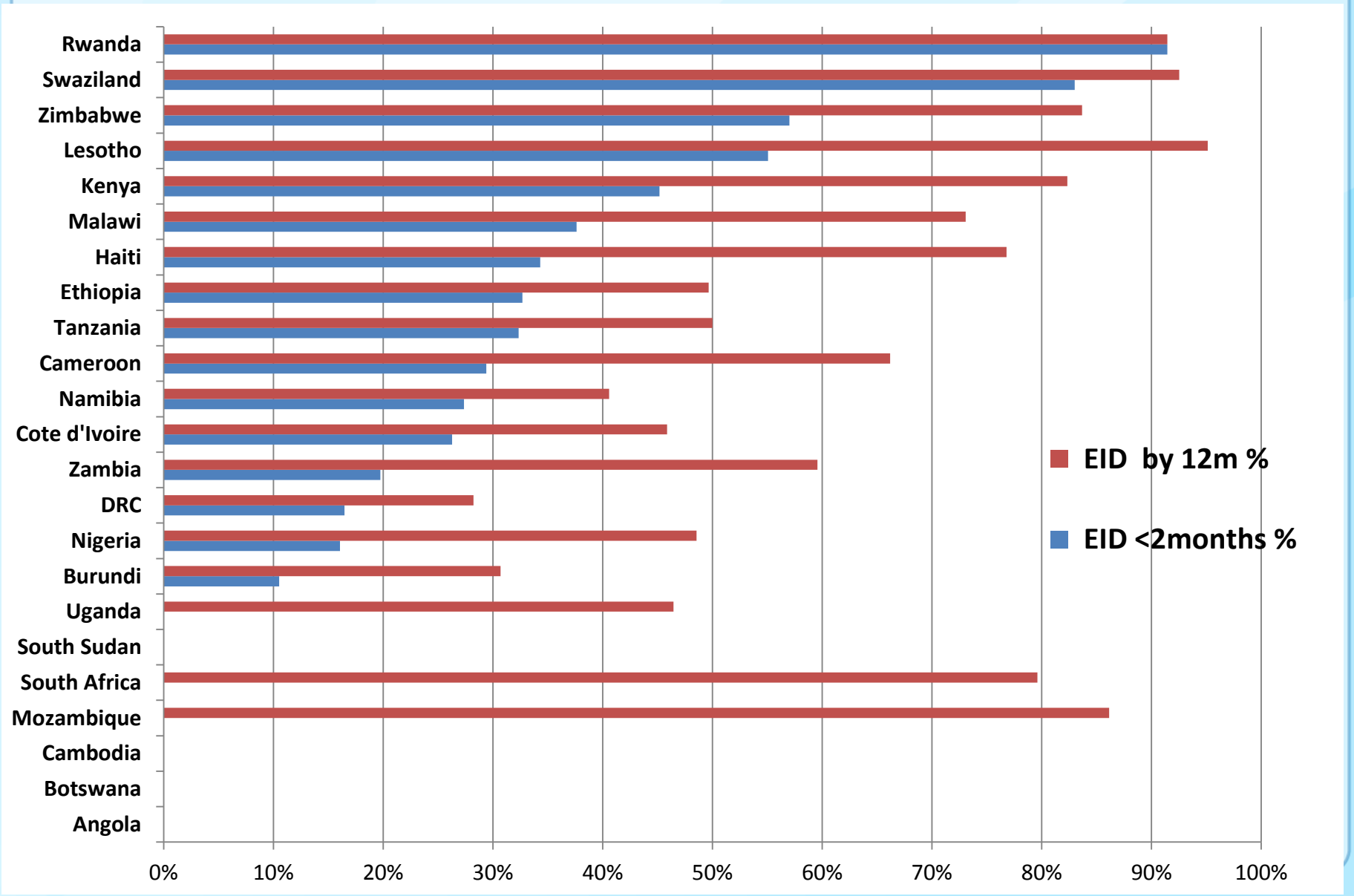
Source: Clinton Health Access Initiative, 2013

Capacity for CD4 and Viral Load Testing

Geographical region (number of countries surveyed = 97)	Number of responding countries	CD4	Viral load
		Average number of people receiving antiretroviral therapy per laboratory [range]	Average number of people receiving antiretroviral therapy per laboratory [range]
Sub-Saharan Africa	20	2 287 [10–10 745]	39 539 [5257–326 241]
Middle East and North Africa	8	150 [15–439]	183 [15–531]
East, South and South-East Asia and Oceania	12	897 [23–5350]	5 125 [256–55 686]
Europe and Central Asia	4	1 025 [309–1419]	1 025 [523–1419]
Latin America and the Caribbean	22	1 913 [61–5843]	2 773 [156–20 042]

Source: Yves Souteryand, WHO 2011

Infant HIV Testing: PEPFAR APR Data 2013



2 Access and Coverage

Diagnostics

Rapid Test
CD4
Viral Load

+

Access

Uptake
Coverage

=

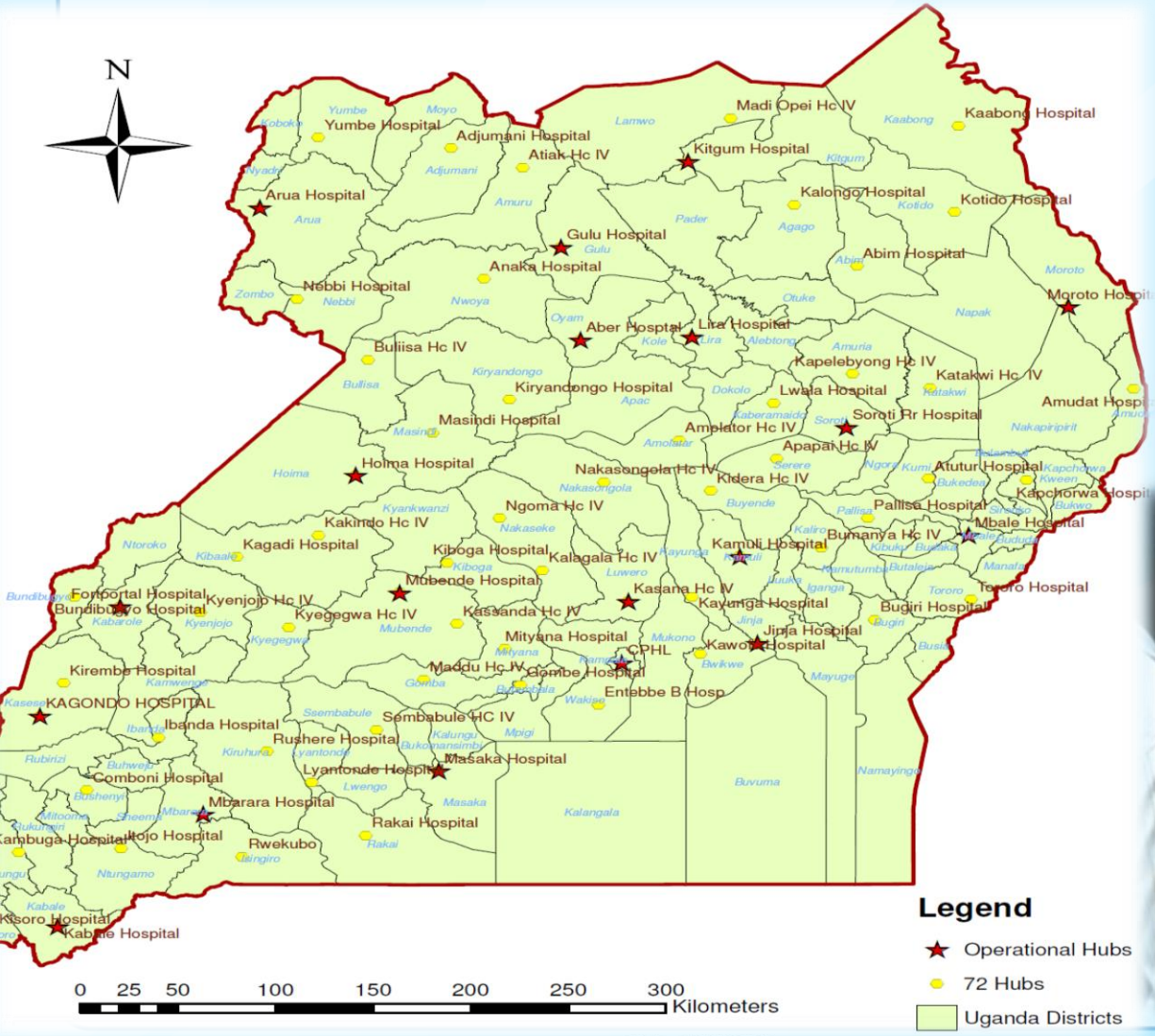
Impact of Treatment Cascade

Quality of Treatment Prevention Cascade

Factors Influencing Access

- Role of Point of Care Testing
- Policy
- Funders
- Public Private Partnerships
- Laboratory health systems and networks

Strengthening Sample Transport Networks - Uganda



- Initial pilot of 19 hubs reached 625 health facilities.
- Scaled up to 60 hubs serving 1700 health facilities launched.

Sample Transport Costs For DBS Decreased By 62% After Setting Up The Sample Referral System

Source: Kiyaya, PlosOne, 2013

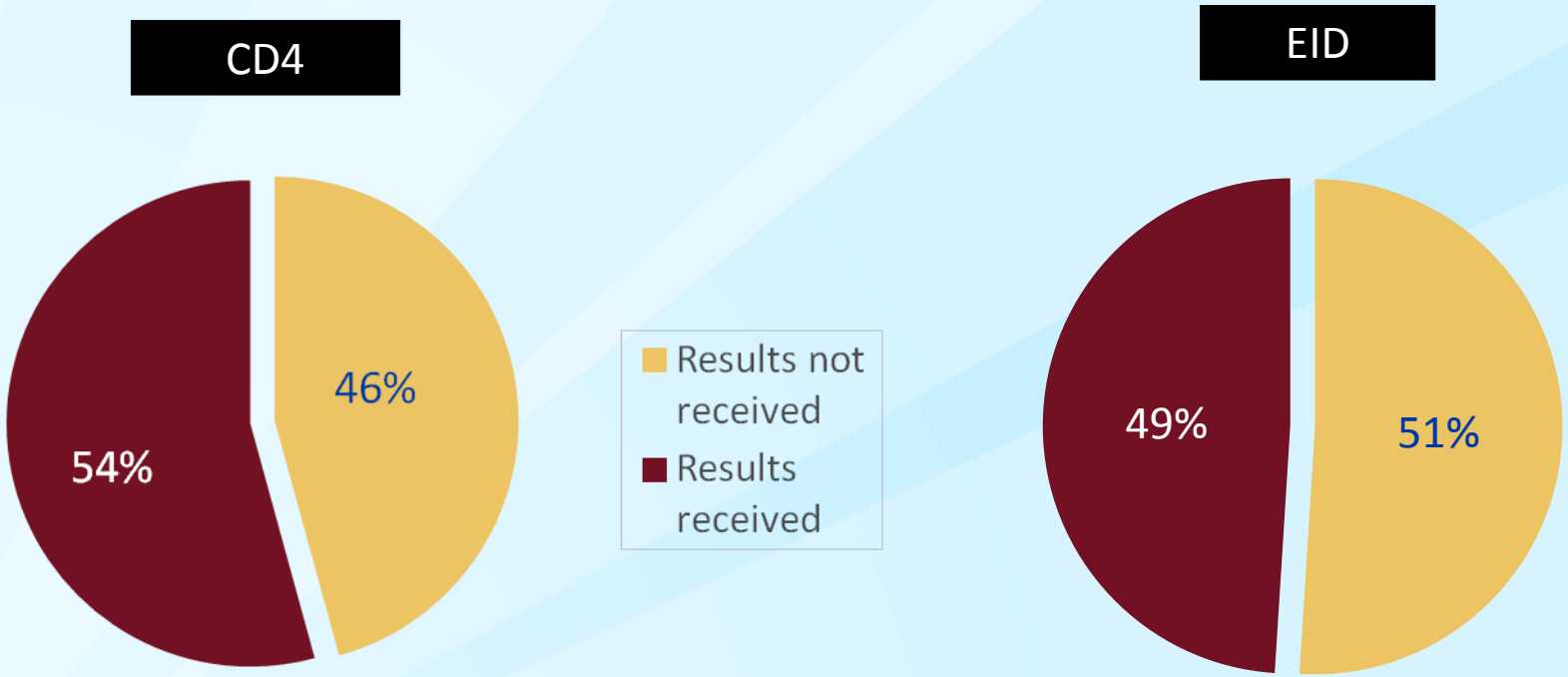
3 Impact and Role of Clinicians

Country X: Example Of The CD4 PIMA Point of Care Utilization, 2012

• Total number of sites	269
• Sites with “0” consumption	46
• Sites with consumption ≤ 1/day	91
• % of sites with 0 or consuming ≤ 1/day	34%
• % of sites with access to referral lab	30%

Source: Jason Williams, SCMS

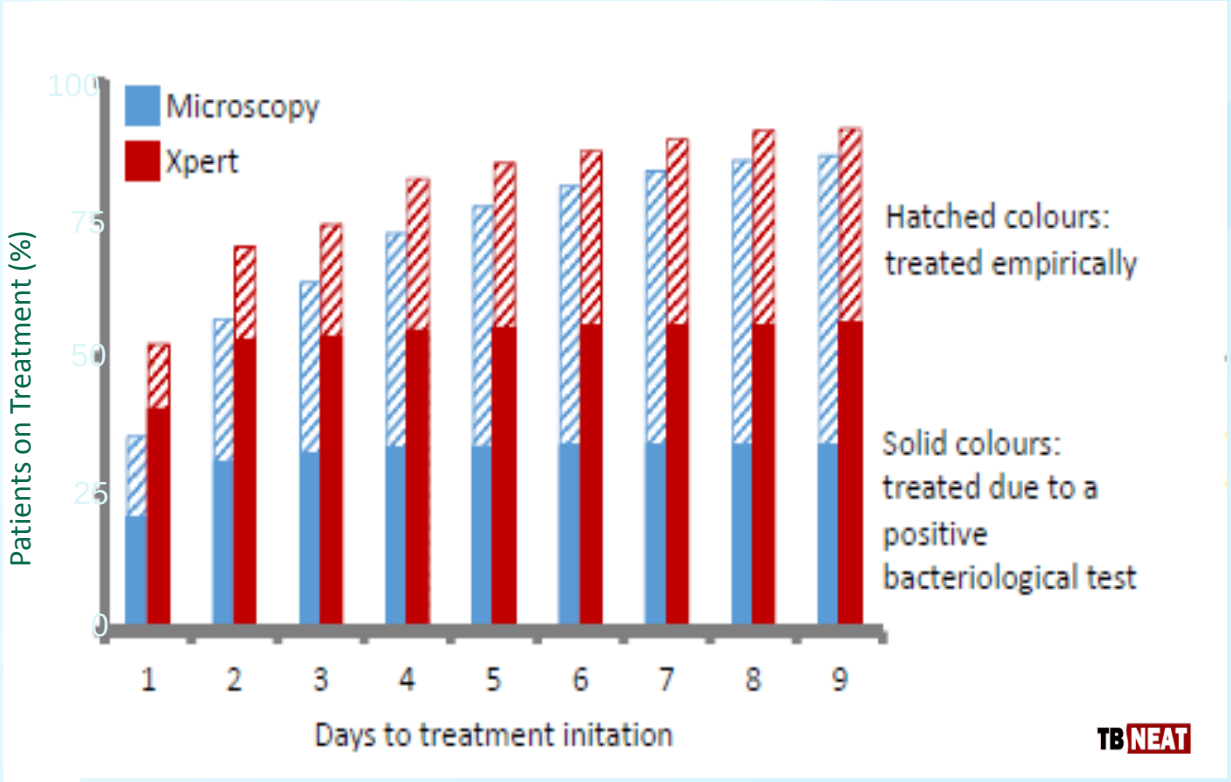
Many Tests are Performed but Results are Never Delivered to Patients



Sources: National volumes for Mozambique, Malawi and South Africa based on CHAI data

Role of Clinicians - TB Treatment Initiation

Even when Xpert MTB/RIF is available, many patients treated empirically



Source: Theron et al. Lancet. 2014.; 383

4 Key Partnerships

Key Partnerships to Improve Access to Diagnostics

- Clinicians
- Policy
- Program managers
- Implementing partners
- Donors
- Multi-laterals

Power of Partnership - Public Private Partnerships are Critical for increasing Access to Quality Diagnostics

U.S. President's Emergency Plan for AIDS Relief

SUPPORT *for* COUNTRIES

Activities will be implemented through three primary means:

- Country-specific laboratory strengthening programs that offer PEPFAR and

New Public-Private Partnership to Strengthen Laboratory Systems

In a pioneering public-private partnership, the U.S. President's Emergency Plan for AIDS Relief (Emergency Plan/PEPFAR) and BD (Becton, Dickinson and Company) will support the improve services in African countries severely af (TB).

Through this five-year, public-private pa the Emergency Plan and BD will work laboratories, Ministries of Health, and

Building Tanzania's laboratory capacity through public-private partnership

Christina MWANGI[1], Christy WISTAR[2], Kenneth LEMA[2], Charles MASSAMBU[3], Ralph TIMPERI[4], Vincent MGAYA[1], Jeffery MINTON[5], Scott KREITLEIN[5]
[1]CDC Tanzania [2]Abbott Fund Tanzania [3]Ministry of Health and Social Welfare [4]Association of Public Health Laboratories [5]Design 4 Others

Ministry of Health and Social Welfare
United Republic of Tanzania

Abbott Fund

CDC

APHL

design 4 others

State of many health laboratories in Tanzania

Nationwide Modernisation of 23 Regional Laboratories in Tanzania

Regional laboratory modernised by Abbott Fund in 2007

Conclusions

- **Remarkable progress in scaling up HIV prevention and treatment programs**
- **Laboratory services and access to diagnostics critical in achieving AIDS-free generation and UNAIDS 90-90-90 goals**
  - Quality central to expanding diagnostics
  - Strategies needed to scale – up viral load testing
- **Key partnerships central to achieve access to diagnostics**
- **Central role of clinicians**

Thanks!

For more information please contact Centers for Disease Control and Prevention
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Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov