Progress in HIV Viral Load Testing and Point of Care Tests

John N. Nkengasong, Ph.D
Associate Director for Laboratory & Chief, International Laboratory Branch
Division of Global HIV/AIDS & Tuberculosis
Center for Global Health, CDC Atlanta
Outline

• Introduction
• Where are we?
• Barriers to Scaling up Viral Load and Uptake
• Platforms and Quality of testing
• Demand Creation
• Point of Care Test
Introduction

90% diagnosed
90% on treatment
90% virally suppressed
Guidelines Matter

World Health Organization

HIV/AIDS Programme

GUIDELINES

CONSOLIDATED GUIDELINES ON THE USE OF ANTIRETROVIRAL DRUGS FOR TREATING AND PREVENTING HIV INFECTION

RECOMMENDATIONS FOR A PUBLIC HEALTH APPROACH

JUNE 2013
Viral Load Monitoring in African HIV Treatment Programmes

Cape Town, South Africa, 18-20 April 2013

ASLM unites and rallies public health community
Addis Ababa Sept 2014-ASLM/PEPFAR Workshop

- Developed country-specific plans for scaling-up HIV viral load testing using a network approach
- Identification of tools for scaling up viral load
Where are we?
Guidelines Matter – Implementation is Challenging

The error of a top-down approach

“I have shared my vision, so now we have a shared vision”
Cartoon by Mark de Koning
WHO’s 2013 Guidelines Established Momentum for HIV Viral Load Testing in National Programs Across Africa

### 1. Feasibility Analysis and Planning
- Tanzania
- Ethiopia
- Zambia
- Cote d’Ivoire
- Mozambique
- Mali
- Cameroon

### 2. Piloting or Recently Rolled out VL Programs
- Malawi
- Rwanda
- Swaziland
- Uganda
- Lesotho
- Zimbabwe

### 3. Well-Established VL Program
- Botswana
- Kenya
- South Africa
- Namibia

Source: CHAI
Global Estimates (2014-15) vs the Gap to reach 90-90-90 Targets

- **HIV Positive People**: 36.9 million
- **Diagnosed**: 19.8 million
- **On ART**: 15.0 million
- **Viral Suppression <1000 (ITT)***: 11.6 million

Breakpoints:
- **Breakpoint 1**: 13.4 million Undiagnosed
- **Breakpoint 2**: 14.9 million not treated
- **Breakpoint 3**: 15.3 million Not Virally Suppressed

Forecasted HIV Viral Load Testing Demand, 2015-2020

Source: WHO/CHAI
3 Barriers to scaling up viral load and uptake
Five Key Barriers to Scale up of Viral Load at National Levels

1. Viral Load Networks - Sample Referral Systems
2. Demand Creation and Uptake of Results – Role of Clinicians & Patients
3. Financing and Supply Chain Management
4. Monitoring and Evaluation
5. Human Resources
Scale-up of HIV Viral Load Monitoring — Seven Sub-Saharan African Countries

Shirley Lecher, MD; Dennis Ellenberger, PhD; Andrea A. Kim, PhD; Peter N. Fonjungo, PhD; Simon Agolory, MD; Marie Yolande Borget MS; Laura Broyles, MD; Sergio Carmona, MBBC; Geoffrey Chipungu, MBBS; Kevin M. De Cock, MD; Varough Deyde, PhD; Marie Downer, MD; Sundeep Gupta, MD; Jonathan E. Kaplan, MD; Charles Kiyaga, MPhil; Nancy Knight, MD; William MacLeod, Sc.D; Boniface Makumbi; Hellen Muttai, MBChB; Christina Mwangi, MMed; Jane W. Mwangi, MMed; Michael Mwasekaga; Lucy W. Ng’Ang’A, MBChB; Yogan Pillay, PhD; Abdoulaye Sarr, DSc; Souleymane Sawadogo; Daniel Singer, MD; Wendy Stevens, MBBC; Christiane Adje Toure, PhD; John Nkengasong, PhD
Barriers at Site Level

1. Laboratory data (VL test results) are neither reviewed nor analyzed for program improvement
2. Laboratory requisition forms capture limited information
3. Unique IDs do not exist or not recorded
4. SOPs do not exist at clinics and laboratories
5. Workflows are far from being optimized
6. Major inconsistency for VL test reporting to clinicians:
   - target not detected
   - below level of detection
   - <20 copies/ml
   - <1000 copies/ml and undetectable
Two SMS printer messages

No unique ID such as ART Number

What if two patients have same name?
Strategic Approach

Improve Efficiencies for Viral Load Testing and Uptake of Test Results
Our process is extremely efficient!

Yes, but you're not actually going anywhere.
Improving Efficiencies Across the Viral Load Testing Spectrum

Demand Creation

Pre-Test

Specimen Collection and Processing

Sample Transport

Human Resources

Quality Management System

Assay Validation

Lab Testing

Result Reporting

Uptake of Results and Patient Management

M&E

Post-Test

3rd 90-90-90 target achieved
Tools Developed

1. Quantification/Forecasting Tools
   - Quantimed...
2. Guidelines for Training Clinicians/Nurses on Viral Load Testing
3. Guidelines for Sample Referral Systems
4. Costing framework
5. M&E Framework
Doing More with Less – Optimizing Viral Load Workflow in Swaziland

- **Current capacity**: 2275/mo in 2015
  - Viral load testing target: 13,333/mo in 2016 and 2017
- **Doubling of current workflow from 35% to 70% in 2016**
  - Barcoding & sample QC at reception area
  - Use of 2ml pipets and vortex within BSC
  - Use of perforated cards
Viral Load Specimen
Referral Web Maps

Distribution of ART patients by Zone
Viral Load Specimen Referral Web Maps

Distribution of VL referral sites and ART patients
A Platform not Pipeline Approach: Specimen Referral and Transport Systems

Boda boda to aid sample and result delivery

Integrated sample referral

Rif resistant TB samples

Post office

NTRL LPA/culture

Toll free line
Efficient Specimen Referral System Decreased Cost of DBS Transportation by 62% Up

Source: Kiyaga et al. PlosOne 2014
Platforms and Quality of Testing is Key
## Viral Load Platform by Countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Platform</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uganda</td>
<td>Abbott, Roche</td>
</tr>
<tr>
<td>Kenya</td>
<td>Abbott, Roche</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Abbott, Roche</td>
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<td>Roche</td>
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<tr>
<td>South Africa</td>
<td>Abbott, Roche</td>
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<tr>
<td>Zimbabwe</td>
<td>Roche, Biomerieux, Cavidi</td>
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<tr>
<td>Botswana</td>
<td>Roche, Biomerieux</td>
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<tr>
<td>Nigeria</td>
<td>Abbott, Roche</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Roche</td>
</tr>
<tr>
<td>Cote D’Ivoire</td>
<td>Abbott, Roche, Biomerieux, Biocentric</td>
</tr>
</tbody>
</table>
Figure 1. Dried Blood Spot (DBS) sample collection methods used in Kenya DBS VL study
Dried blood spot samples can be used for HIV-1 viral load testing with most currently available viral load technologies: a pooled data meta-analysis

Lara Vojnov1*, Sergio Carmona2, Clement Zeh3, Jessica Markby4, Debrah Boeras3, Marta R. Prescott1, Jessica A. Joseph1, Anthony L.H. Mayne5, Souleymane Sawadogo3, Maria Mercedes Perez Gonzalez6, Wendy S. Stevens2, Meg Doherty6, Trevor F. Peter1, Chunfu Yang3, and the DBS for VL Diagnostics Investigation Consortium#

Field evaluation of Dried Blood Spots for HIV-1 viral load monitoring in adults and children receiving antiretroviral treatment in Kenya, 2013: Implications for scale-up in resource limited settings

Mary E. Schmitz, MPH1; Simon Agolory, MD2; Muthoni Junghae, PhD1; Laura N. Broyles, MD2; Muthusi Kimeu, MSc3; Joseph Ombayo, BSc4; Mamo Umuro, MSc4; Irene Mukui, MD5; Kennedy Alwenya, MA3; Moses Baraza, BSc3; Kenneth Ndiece, BSc3; Samuel Mwalili, PhD1; Emilia Rivadeneira, MD2; Lucy Ng’ang’a, MD1; Chunfu Yang, PhD2; Clement Zeh, PhD, MPH1; for VL-DBS Study Group.

Submitted to JAIDS for consideration of publication
Viral Load Proficiency Testing Programs

Viral Load PT using Dried Tube Specimens
Performance of Laboratories enrolled in Proficiency Testing for Viral Load Testing

Source - Garcia et al. Journal of Clinical Microbiology 2014
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Demand Creation and Monitoring and Evaluation
Creating the Demand for Viral Load

**Challenge**
- Lack of effective dissemination and translation of the guidelines into accessible job aids
- Awareness campaigns for patients on the benefits of VL testing and its difference from CD4

**Solutions**
- Tools to help countries increase demand for viral load and to educate patients and clinicians on the use of viral load

**Demand generation drivers**

**Clinician education**

**Patient education**
Lower than detectable limit
1.058
mL
• Even when routine viral load monitoring was in place, around 44% of patients with confirmed virological failure were not switched.

• 22% of patients under routine viral load monitoring and 30% of those receiving targeted viral load monitoring switched regimen without any evidence of virological failure.
It's not my problem, the hole is in their side of the boat!
Improving Efficiency by Scorecard Approach – What is measured gets done

Survey Score: Uganda

- Uganda Total Score (light green bar)
- Information Management System & M&E
- Human Resources
- Specimen Referral Network
- Product Selection & Placement
- Advocacy & Education
- Policy, Leadership, & Management
- Forecasting

Legend:
- Total Possible Score
- Country Score
- Country Score for Pillar

Survey Score: 0 to 100
6 Viral Load Point of Care tests
Scaling up Viral Load will Require Combination Platforms

Lab-Based Testing

POC

Near-POC
POC Viral load & EID products: available and pipeline*

Source: M. Murtagh
Improve Uptake, Access and Quality of POCT for
HIV/AIDS, tuberculosis, malaria, cryptococcus, sexually transmitted infections

Laboratory systems
- National policy/Role of institutions
- Evaluation/Regulation
- Quality Management System
- Human resources training, Certification and retention
- Equipment Maintenance System
- Supply Chain Management System
- Laboratory Information System and Connectivity
- Post market surveillance

Effective Deployment of POCT

POCT Services
- POCT Serology (HIV, rapid test)
- POCT Molecular testing (GeneXpert)
- POCT Hematology
- POCT Chemistry
- POCT Cytology (CO4 enumeration)
- POCT Microscopy (AFB test)
Conclusions

- Focus on improving efficiencies
- Collaborative approach to scaling up viral load in National Plans
- Scorecard to measure progress
- Demand creation - Clinicians and Patients as drivers
Remember that the happiest people are not those getting more, but those giving more.

H. Jackson Brown, Jr.