VIRAL LOAD MONITORING: Challenges and Innovation in Laboratory Diagnostic Implementation

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Gaborone, BOTSWANA
Presentation Format

I. Background information
II. Current situation
III. Successes
IV. Challenges
V. Lessons
VI. Departing thoughts
Viral Load Testing in Africa

• Is Africa ready for viral load testing?

• Is Africa committed to viral load testing?

• Will we ever see viral load testing included in routine monitoring of ART patients in Africa?
• Botswana is a landlocked country in the centre of southern Africa.

• Population
  • 2,024,904
    (2011 Pop. Census)

• First case of AIDS
  • Reported in 1985
VARIOUS POPULATIONS

• Adults aged 15 – 49 years
  • 25%

• Pregnant women
  *(Ministry of Health ANC Surveillance Report, 2011)*
  • 30.4%

• Female sex workers (FSW)*
  • 61.9% (95% CI, 56.7-69.2)

• Men who have sex with other men (MSM)*
  • 13.1% (95% CI, 10.0-16.2)
  • Adjusted HIV prevalence - 9.2%

HIV EPIDEMIC IN BOTSWANA

- Botswana has a generalized HIV epidemic.
  - One of the countries with highest levels of HIV prevalence in the world,
    - Higher than any other country except Swaziland.

- BAIS I  – 2000  -  No HIV testing
- BAIS II  – 2004  -  17.1%
- BAIS III – 2008  -  17.6%
- BAIS IV  – 2013  -  18.5% (18 months and above)
If it was so easy...

New infections

Prevalence

Deaths
If it was so easy...

New infections

Prevalence

Deaths
If it was so easy...

New infections

Prevalence

Deaths
If it was so easy...

- New infections
- Prevalence
- Deaths
Viral Load Testing in Botswana
Botswana’s Clinical Care Guidelines

• Since 2002, STRONG POLITICAL WILL allowed Botswana to improve upon WHO recommendations by adding:

  ▪ Routine Viral Load Monitoring
  ▪ Resistance Testing
  ▪ Optimal ART Regimens
  ▪ Universal HAART/Triple ARV Prophylaxis
  ▪ Approaches in Integrative Care

The 2012 Revisions build upon these strengths including improved eligibility criteria.
Laboratory Monitoring in Botswana


• Standard of Care
  • CD4 testing
  • Viral Load Testing
  • HIV Drug Resistance Testing

• HIV Diagnosis
  • HIV serology
    • ELISA
    • Rapid HIV Tests
  • HIV DNA PCR – mainly for early infant diagnosis (EID) of HIV infection in children
Down the Memory Lane

• In 2000, a pilot treatment program launched in Princess Marina Hospital (concept of IDCC)

• 01 Dec 2001 - The Botswana Harvard HIV Reference Laboratory (BHHRL) was opened in Gaborone.

• In January 2002, MASA (ART) program was launched; one of the first in Africa.

• ART services started with four sites (Gaborone, Serowe, Maun and Francistown) in 2002/03 with 3500 patients
Botswana started laboratory monitoring with 2 HIV Reference Laboratories with CD4 and Viral Load Capabilities 2002-2004

BHHRL – Botswana Harvard HIV Reference Laboratory

NHHRL – Nyangagbwe Hospital HIV Reference Laboratory
Challenges Of Rapidly Growing Program

• Long Turn-Around-Times

• Specimens were transported for long distances and under extreme weather conditions
  • Road transportation is the main mode of transport

• Specimen integrity compromised, thus affecting the quality of results
• The Laboratory was creating a ‘bottleneck’ in the provision of quick ARV services.

• Roll out the laboratory services (CD4 and Viral Load) to the district /primary hospital – i.e. taking the services to the people rather people coming to the services.
Factors affecting turn-around-times (TAT)

- Laboratory supplies
- Equipment Service and Maintenance
- Scarce Human Resources
- Communication between facilities
- Specimen transport Delivery
- Sample tracking system

Fish bone chart: High Turnaround time of results
“Solution to Laboratory Problems”

- Roll out the laboratory services to the district/primary hospitals and eventually to the clinics

- “Taking the services closer to the people rather people coming to the services”.

Masa
Antiretroviral Therapy
Lectura la Maneño ya pa Rúbëntë Mwogu wa Hiv/Aids
Which Viral Load Platforms?
The answer to which viral load platforms depends among other things:

- **Infrastructure**

- **Pricing** – cost of machine/reagents or leasing

- **Population of patients to be served**

- **Equipment throughput**
The HIV/AIDS epidemic in Botswana has affected all districts; rural areas are affected with equal (and in some cases, greater) intensity as urban areas (National AIDS Coordinating Agency, 2003).

The challenge for Botswana has always been how to best reach those who need treatment urgently in both rural and urban areas.
The High HIV Prevalence Districts in Botswana

<table>
<thead>
<tr>
<th>District</th>
<th>Total population prevalence (%)</th>
<th>PLWHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kweneng East</td>
<td>21.5</td>
<td>57,154</td>
</tr>
<tr>
<td>Gaborone</td>
<td>17.0</td>
<td>38,647</td>
</tr>
<tr>
<td>Central - Serowe</td>
<td>17.1</td>
<td>32,178</td>
</tr>
<tr>
<td>Central- Mahalapye</td>
<td>23.1</td>
<td>27,141</td>
</tr>
<tr>
<td>Central- Tutume</td>
<td>18.2</td>
<td>26,371</td>
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<tr>
<td>Francistown</td>
<td>24.3</td>
<td>24,319</td>
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<tr>
<td>Kgalagadi</td>
<td>20.2</td>
<td>21,234</td>
</tr>
<tr>
<td>Kgalagadi South</td>
<td>18.9</td>
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<tr>
<td>Kgatleng</td>
<td>19.9</td>
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<tr>
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<tr>
<td>Selibe Phikwe</td>
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<td>13,674</td>
</tr>
<tr>
<td>Central- Bobonong</td>
<td>19.3</td>
<td>13,666</td>
</tr>
</tbody>
</table>
1st Viral Load Platform used in Botswana

Roche COBAS AMPLICOR
Cavidi Viral Load System introduced in 2007 for the district labs

1. Vacuum Pump
2. Vacuum Tubing
3. Waste Container and lid
4. Buffer Dispenser
5. Metal-plug plate handle
6. Buffer Dispenser legs
7. Column
8. Column Holder
9. Tube Connector
10. Waste Collector
11. Storage Tube
12. Collector Tube Rack
13. Lysate Collector
COBAS Ampliprep & Taqman 48 (CAP CTM)
Biomeriux-Easy Mag/Easy Q

Easy Mag

Easy Q
Cavidi Viral Load System-Exavir load version 3
COBAS Ampliprep & Taqman 96 (CAP CTM)
Where are we now with ART?
Laboratory Capacity in 2015
Number of patients on ART

- **Total of 245,340** patients currently receiving HAART in Botswana by October 2014.
  - Treatment in the public sector – 226,767
    - 63% women
    - children under the age 13 years - 3.6% (8,398)
  - Government’s Out-sourcing Program - 5,860
  - Medical Aid Schemes and Work-place Programs – 8,129
  - Cumulative death (since 2002) – 23,959
Lessons Learned
“Strategic Partnerships”
Collaboration between Ministry of Health and Partners

**Partnerships**

- **Purchase of Equipment**
  - PEPFAR (CDC Bots) ACHAP MoH

- **Development of Infrastructure**
  - PEPFAR (CDC Bots) ACHAP Ministry of Health

- **Short Term Training and Capacity Development**
  - BHP

- **Recruitment of Personnel and Long Term Training**
  - Ministry of Health
BHP-PEPFAR Laboratory Master Trainer Program

- Centralized training at the HIV Reference Laboratory
- On-Site Training at Decentralized Laboratory
- Launch Testing
  Enroll Laboratory in EQA Program
• Political Leaders have shown unparalleled commitment to:

  • Openly addressing the HIV crisis

  • Avail funds to deal with the ever growing pressure on the health and social sectors.
Lessons learned cont’d

- Leadership
- Management
- Political will
- Courage
- Information
- Accountability and
- Capability

-are more critical than money in the broader scheme
Botswana Responded to the:

- HIV/AIDS Death epidemic
33,000 deaths estimated due to HIV / AIDS (2003)

“We are threatened with extinction. People are dying in chilling numbers. It is a crisis of first magnitude.”

His Excellency the President of Republic of Botswana - Festus Mogae
“The need for treatment far outstrips our ability to deliver it. There is a lot of pressure on us, because if we fail, people will say: Botswana had everything going for it and it failed, so why should we help anyone else in Africa?”

Dr Howard Moffat - Superintendent of the Princess Marina clinic. ‘Botswana battles against ‘extinction’, The Guardian, 8 July 2002’
Strength of Laboratory System in Botswana

• Laboratory Services Quality Assurance System in the country

• National Quality Manager at MoH Level
  – National Quality Policy
  – National Quality Manual
  – Laboratory Quality Manuals and SOPs

• Laboratory Quality Officer in each laboratory

• Laboratory Staff trained in Good Clinical Laboratory Practices (GCLP)
Challenges of Decentralization Process

• Sustained Quality Control and Quality Assurance (QC/QA)

  • Enrolment in EQA program can be expensive

  • Generate panels at the HIV Reference Lab for local QA assessment
What is the Role of Point of Care (POC) in Viral Load Testing?
POC Viral load & EID products: available and pipeline

Ref: Maurine M. Murtagh, UNITAID Consultant

The Current Pipeline for Point-of-Care Virologic Testing for HIV/AIDS
22 July 2014

*Estimated as of May 2014 - timeline and sequence may change. No market launch date set by company.
Parting thoughts

• Focus must remain on saving lives; do not overburden the issue

• Is our story to provide routine viral load testing in Africa convincing enough for the political leadership.

• Success is largely dependent on building true local capacity/capability at all levels (attract & retain the best for public sector work)

• Coordination and alignment between and among local and international partners is critical
Acknowledgements

• Government of Botswana - Ministry of Health

• CDC Botswana

• ACHAP

• Botswana Harvard Partnership – PEPFAR Track 1.

• Roche for sponsorship
Thank You for Attention

Keep The Promise. Stop AIDS