A Market Assessment of HIV Immunological and Virological Testing Across Low- and Middle-Income Countries

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ASLM, 4 December 2014

Introduction

- **Viral load** monitoring of people on ART is **strongly recommended** by the WHO
- Viral load is the **best ART monitoring tool** (superior to clinical and CD4 monitoring)
- Barriers, such as cost and complexity, mean that **most countries have not implemented routine viral load testing** for all people on ART, but things are slowly improving
- **Supply-side** of the viral load testing market has been fairly **well mapped** (e.g. MSF and Unitaid reports)
- Country-specific, **demand-side information requires more in-depth study**
- **Aimed to investigate the market dynamics** of viral load, CD4 and infant diagnostic testing in 5 LMICs

Methodology

- **1. UNAIDS database analysis** of guidelines across 55 countries
- **2. Qualitative market assessment** of 5 countries: India, Malawi, Kenya, South Africa and Zimbabwe
- In-country surveys performed by **consultants**: AIDS Strategy, Advocacy and Policy (ASAP)
- Between **March – mid-May 2014**, with a targeted update in October
- Semi-structured **questionnaire** was used as a guide to interview 16-20 respondents per country
- **Respondents included**, for example:
  - heads of national HIV programs
  - procurement managers
  - laboratory directors
  - people from NGOs and civil society
- **Questions covered**, for example:
  - procurement, pricing and funding
  - testing targets and country guidelines (and the extent to which they were being implemented)
  - impact and implications of scaling up viral load testing
  - challenges or obstacles
  - stakeholder input

UNAIDS database analysis of 55 higher prevalence LMICs

- **Viral load testing:**
  - 39/52 (**75%**) countries **recommend routine viral load** for ART monitoring
  - 10/52 (**19%**) countries **recommend targeted viral load** for confirming ART failure after clinical or immunological failure
  - 3/52 (**6%**) **do NOT recommend viral load** monitoring
- **CD4 testing:**
  - Only **4 countries** (Kenya, Malawi, South Africa and Uganda) **do NOT recommend routine CD4 testing** for ART monitoring
  - The reasoning behind this is that CD4 testing is not needed as an additional test for stable, virologically suppressed people on ART
- **Early infant diagnosis:**
  - Majority of countries recommend a test at **4-6 weeks** (WHO guideline)
  - **<30%** of HIV exposed infants receive a **test within 2 months of birth** in 17/43 **(40%) countries**
  - **>70%** of HIV exposed infants receive a **test within 2 months of birth** in only 5 **(12%) countries**

- Additional information: www.msfaccess.org/achieving-undetectable

Highlights from 5-country survey results

	India	Kenya	Malawi	South Africa	Zimbabwe
No. of PLWHA	2,085,008	1,646,012	1,129,768	6,070,751	1,368,128
No. on ART (% of all PLWHA)	750,000 (36%)	604,000 (37%)	405,100 (36%)	2,200,000 (36%)	565,700 (41%)
VL in nat. guidelines	confirm failure	routine	routine	routine	confirm failure
Available for this purpose	limited	limited	limited	yes	limited
No. VL tests 2013	6,000 - 7,000	53,000	37,000	2,400,000	30,000 - 48,000
CD4 - ART eligibility	350	500	500	350	500
CD4 – routine ART monitoring	yes	no	no	no (only at 12 months)	yes

	India	Kenya	Malawi	South Africa	Zimbabwe
No. gov. labs offering VL (no. & type instruments)	9 (20 Abbott & Roche)	7 (˜15 Abbott & Roche)	5 (6 Abbott)	17 (17 Abbott & Roche)	1 (1 bioMerieux)
Sample transport and results (improvement needed in all cases)	local to town, courier to lab	local to town, courier to lab, some m-health	Informal gov.	local to town, courier to lab, internet and SMS	local to town, courier to lab
Scale-up of VL testing planned	yes (to ˜30 labs)	yes (150,000 for 2014)	yes (300,000/yr by 2016)	yes (20% increase/yr)	yes (2 machines/province by end 2016)
Priority grps during scale-up	1) on ART >5 yrs; 2) OIs, 3) CD4 drop	piggy-back on EID set-up	piggy-back on EID set-up; high volume sites	N/A	Confirming suspected ART failure
Third-line ART	no, in progress	extremely limited	no	yes	no

	India	Kenya	Malawi	South Africa	Zimbabwe
POC tests (only Alere PIMA)	none (20 ordered)	˜100 (but not in operation)	˜125 (30% of need)	very limited	>250 (mostly for ART initiation)
Interest in CD4 POC tests	yes, to augment lab	unsure	depends if CD4 testing is phased out	awaiting field evaluations	yes, to overcome transport pb
Interest in VL POC tests	limited, to augment lab	limited, to augment lab	limited, to augment lab	limited, to augment lab	limited, to augment lab
No. gov labs offering EID	7	7	5	9	1
EID test turn around time	sample transport: >3d; lab: 6d; result: email	>2-4 wks; some web-based & SMS	3 wks – 2 mnths; some SMS	1-10 wks; internet otherwise SMS or paper	1-4 mnths
DBS used	only for EID	EID & VL	EID & VL	EID	EID & VL
Funding source	GF & domestic	PEPFAR, DFID, UNITAID	GF, UNITAID, World Bank, MSF	GF & 70% domestic	GF, UNITAID, MSF

Costs vary enormously

SA VL price:

- **Reagent agreement plan - all inclusive** of:
  - Reagents & consumables
  - Service & maintenance
  - Instrumentation
- **Based on large volumes** (2mil/yr scaling to 4mil/yr) & a **competitive tender system** (3 years)

Facility type	Cost in USD (range)	Cost (local currency) - where known	Reagents	Consumables	Maintenance	Instrument	Lab HR	Sample transport	Blood collection
India viral load									
Private labs	$96.33 (65.13 - 130.25)	INR 5,916 (4750-8000)	x	x	x	x	x	x	x
For an NGO	$41.56 (29.31 - 57.99)	INR 2,552 (1,800 - 3,562)	x	x	x	x	x	x	x
Government lab	$22.79	INR 1,400	x	x	x				
NGO lab	$24.69	INR 1,350	x	x	x				
South Africa viral load									
Private labs	$105.40 (90 - 126.21)		x	x	x	x	x	x	x
For an NGO	$18.09	ZAR 200	x	x	x	x	x	x	x
NHLS to health departments	$27.58	ZAR 305	x	x	x	x	x	x	
NHLS contract with test suppliers	$7.58	ZAR 82.51	x	x	x	x			
Zimbabwe viral load									
For an NGO	$35		x	x	x	x	x	x	x
Private labs	$70 - $90		x	x	x	x	x	x	x
Public sector	$14.50		x	x					
Malawi viral load									
Public sector	$20.76 (20 - 41.28)		x	x	x	x	x	x	x
Public sector	$14.25		x	x					
Kenya viral load									
Private labs	$79.62 (40.90 - 100)		x	x	x	x	x	x	x
Public sector	$46.82 (40 - 51.64)		x	x	x	x	x	x	x
CHAI-negotiated price (public sector)	$10.50		x	x	x	x			
India CD4									
Private lab	$24.42		x	x	x	x	x	x	x
NGO lab	$19.05		x	x	x	x	x	x	x
Government lab	$2.93		x	x					

Access barriers to viral load testing and subsequent intervention

- In most but not all countries:
  - India: State AIDS Clinical Expert Panels (SACEPs) as “gate-keepers” for VL testing
  - High cost
  - Lack of funding
  - Limited human resources (and training)
  - Poor procurement management e.g. stock outs
  - Lack of awareness among civil society, PLWHA, clinicians etc on importance of VL testing
  - Geography and distance e.g. sample transport and results delivery
  - Poor lab infrastructure and equipment maintenance
  - No validation of DBS and POC tests
  - Poor record keeping and patient tracking
  - Poor follow-up on results and high patient loss to follow-up
  - Unequal access within the same country e.g. urban versus rural
  - Weak adherence counseling

What needs to happen?

- **Financial resources must be secured** for the sustainable scale-up of routine viral load testing
- Countries require **implementation support**, beyond the lab, for this new and unfamiliar test
- Countries should be encouraged to spend resources **scaling up viral load testing for ART monitoring in preference to CD4**
- Countries need to **negotiate better prices** (e.g. through pooled procurement and competition) and ensure **all inclusive contracts** (reagents and consumables, instrumentation, service and maintenance, training etc)

More information
(including supplementary material)
http://msfaccess.org/undetectable

ISSUE BRIEF

MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN

GETTING TO UNDETECTABLE: USAGE OF HIV VIRAL LOAD MONITORING IN FIVE COUNTRIES

MSF UNDETECTABLE | VOLUME 5

This issue brief is the fifth in a series produced by MSF to equip policymakers, people living with HIV/AIDS, and communities with information on the products, costs, and operational strategies to help realise scale-up of viral load monitoring, which we believe is an essential tool, along with adherence support, to help as many people on ART as possible to reach and maintain viral suppression.

Viral load (VL) testing for routine treatment monitoring is a key recommendation of the World Health Organization's (WHO) 2013 consolidated guidelines on the use of antiretroviral therapy (ART).[1] Measuring VL six months after ART initiation and annually thereafter is strongly recommended as the best treatment monitoring protocol to enable the timely detection of adherence problems and provide the opportunity for early adherence interventions that may prevent the development of treatment failure, thus prolonging the use of first line regimens, and to facilitate the accurate detection of treatment failure.[2]

But, according to a 2013 survey by WHO, access to HIV diagnostic and monitoring services is poor across low- and middle-income countries (LMICs).[3] The survey found that there was only one VL instrument, on average, per 8,706 people on ART (a laboratory-based instrument can typically perform at least 100 tests per day or 25,000 tests a year).

Continued overleaf

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ISSUE BRIEF

MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN

ACHIEVING UNDETECTABLE: WHAT QUESTIONS REMAIN IN SCALING-UP HIV VIROLOGIC TREATMENT MONITORING?

MSF UNDETECTABLE | VOLUME 6

With the 2013 WHO consolidated HIV treatment guidelines, and further evidence from operational and cost-effectiveness research supporting the use of viral load monitoring in low- and middle-income countries (LMICs), there is a need to rapidly scale-up this important technology to strengthen the provision of quality and effective HIV treatment and care.

A number of barriers may be hindering scale-up, including the price of viral load testing, logistical and implementation barriers, and even potential costs incurred from the higher price of second-line antiretrovirals (ARVs) as more patients failing first-line treatment are identified.

When addressing the task of introduction and use of routine virological monitoring, national HIV programmes and other implementers are faced with competing priorities, limited resources and logistical barriers. In this briefing document, Médecins Sans Frontières (MSF) Access Campaign presents further evidence from a five-country study of viral load implementation and MSF's own operational experience, to help respond to questions and concerns countries may face when planning viral load scale-up.

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Thank you — Dankie — Ngiyabonga — Enkosi — Ke a leboga

Acknowledgements:

- MSF colleagues, PLWHA, Ministries of Health and Laboratories with which we work
- AIDS Strategy, Advocacy and Policy (ASAP) for performing the 5-country survey
- Unitaid as co-funders

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