



## Setting the scene:

# What questions remain in scaling up viral load?

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# MSF IMPLEMENTATION OF INFANT, VIRAL LOAD AND POC CD4 DIAGNOSTIC TOOLS

## Point-of-Care (POC) testing:

 MSF has implemented POC CD4 diagnostics\*\*

 MSF is implementing or planning to implement POC VL / infant diagnostics

\*\*Implementation in at least one MSF project in the country

## Laboratory-based testing:

 MSF has installed its own VL laboratory\*\*

 MSF conducts referrals to a non-MSF VL laboratory

 MSF conducts referrals to a non-MSF infant diagnostics laboratory

Bangladesh	Malawi  
Cameroon 	Mali  
Central African Republic  	Mozambique    
Chad  	Myanmar  
Congo 	South Africa 
Democratic Republic Congo*     	South Sudan  
Guinea  	Swaziland   
Haiti	Uganda 
India   	Ukraine
Kenya  	Yemen
Kyrgyzstan* 	Zimbabwe   
Lesotho*  	

\*MSF VL lab implementation planned

\*\*MSF provides diagnostics but not treatment



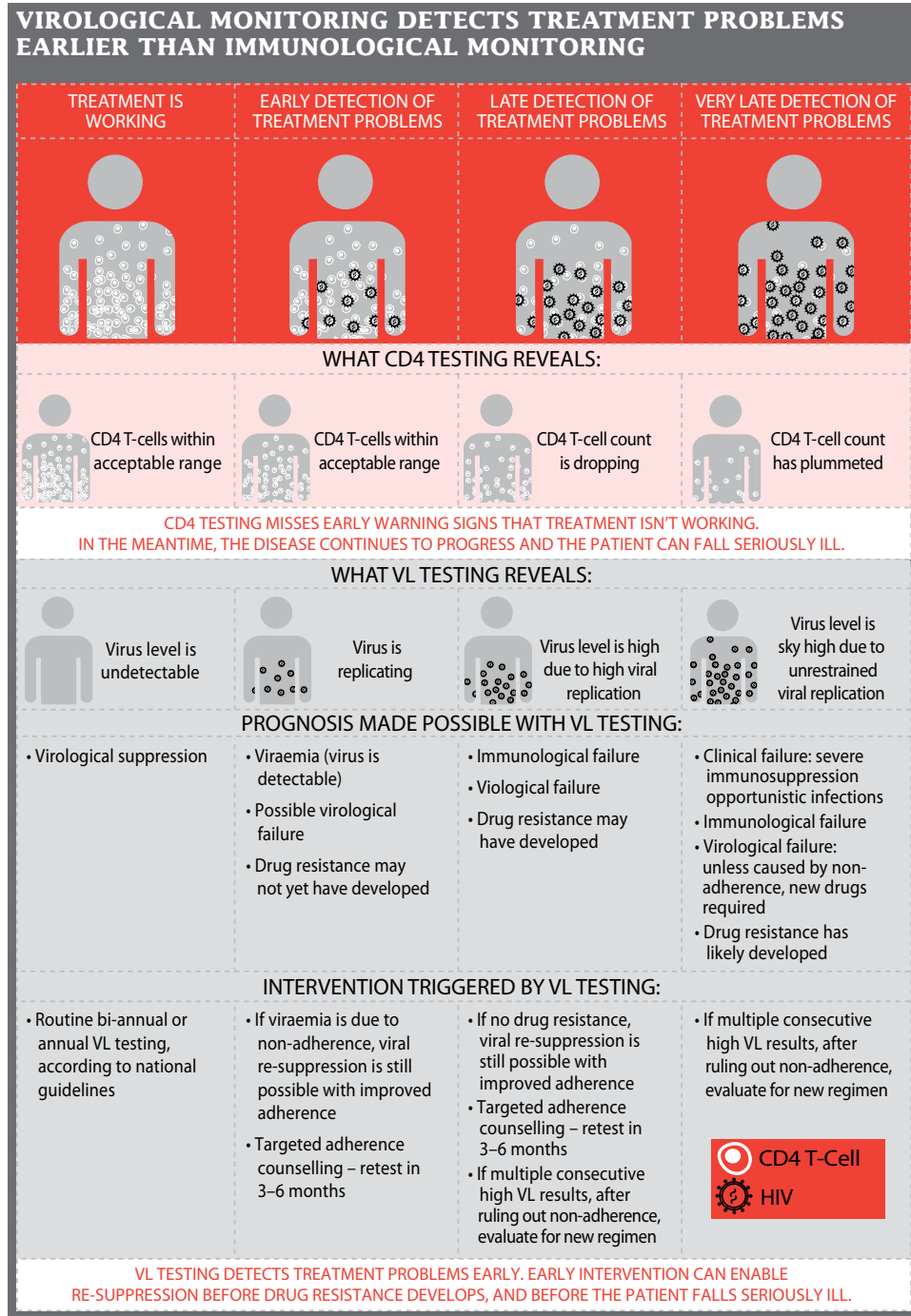
Co-funding from Unitaid in DRC, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Uganda, Zimbabwe

# What are the current recommendations and targets for viral load?

- **WHO strongly recommends VL** for ART monitoring (6 and 12 months and yearly thereafter) as it is the **gold standard** & much more accurate than clinical or immunological monitoring
- **CD4 testing** still important to inform **ART eligibility and risk of OIs** **BUT not needed in addition to VL for stable people on ART** (CD4 doesn't drop if person is virally suppressed)
- → **countries should use resources for VL scale-up!**
- E.g. South Africa dropping CD4 testing 12 months post ART = **51%**  
↓ **in cost** (\$68 mil) over 5 years
- → **redirect money elsewhere for better HIV care!**
- **UNAIDS targets:** 90% know status; 90% HIV+ receiving ART; 90% on ART virally suppressed
- → **two of these rely on lab testing!**

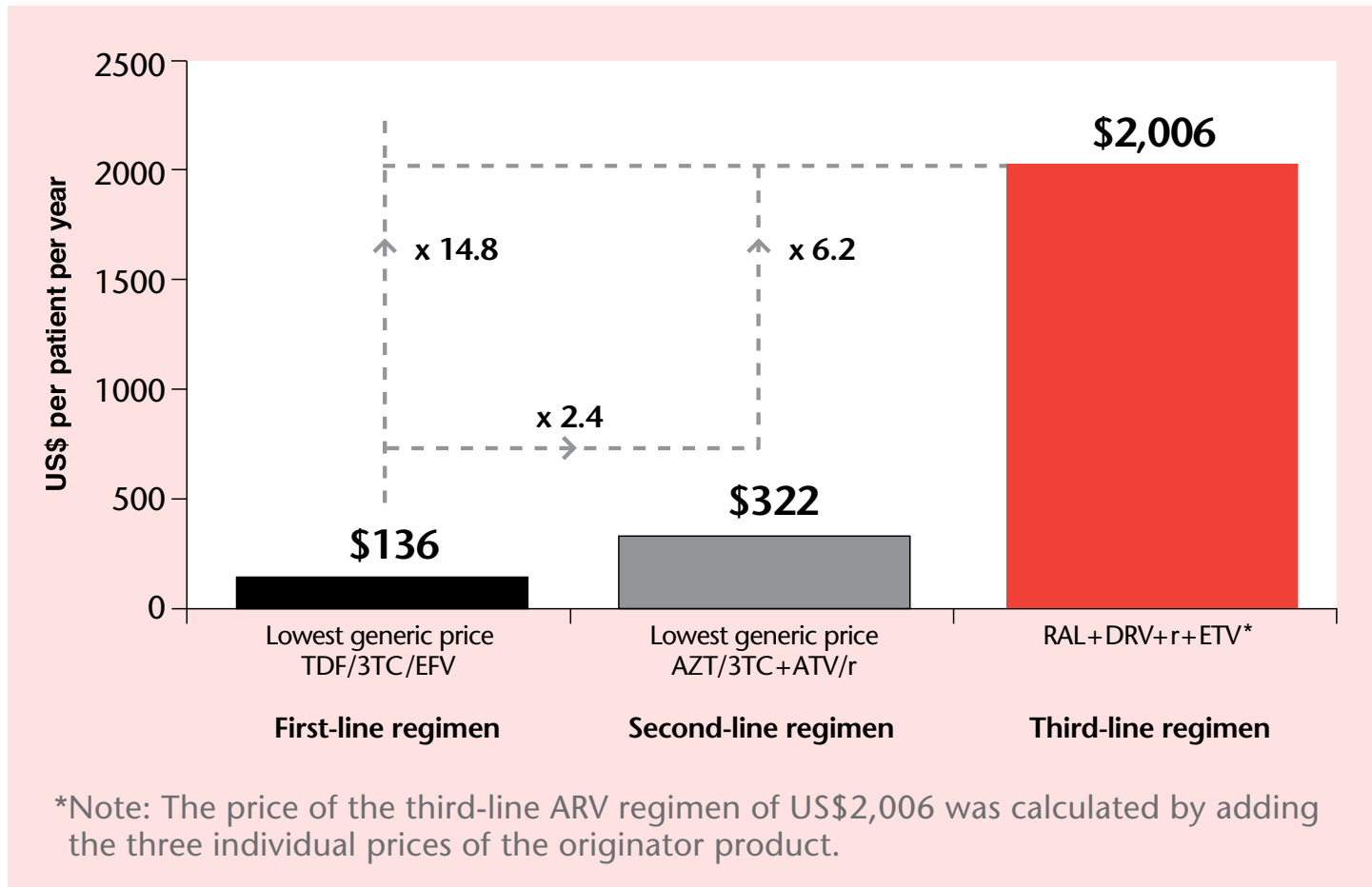
# How can routine HIV testing help improve HIV care?

- Virally suppressed on ART = **treatment is working**
- WHO recommended **virological failure threshold = 1,000 copies/mL**
- **<1,000 copies/mL** = unlikely to develop resistance or transmit the virus
- **>1,000 copies/mL** = treatment failure due to either non-adherence or drug resistance
- **Viral load undetectable** = below limit of detection of test (varies depending on sample volume etc)



# The importance of preserving first line, affordable, robust, one-pill-a-day regimens

**GRAPH 6: PRICE COMPARISON OF TREATMENT REGIMENS**



# Are we getting there at national level?

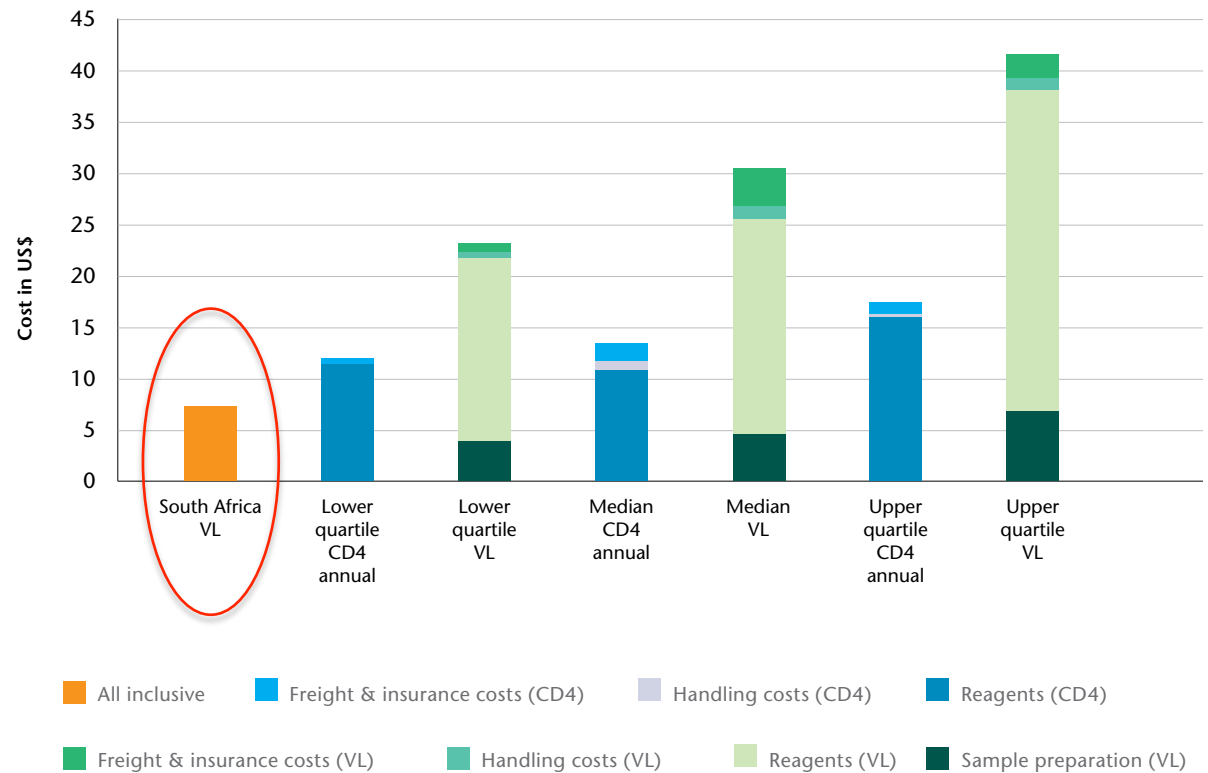
- **Viral load testing:**
  - 39/52 (**75%**) countries **recommend routine viral load** for ART monitoring
  - 10/52 (**19%**) countries **recommend targeted viral load** for confirming ART failure after clinical or immunological failure
  - 3/52 (**6%**) **do NOT recommend viral load** monitoring
- **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
- → **big gap between country guidelines and implementation on the ground**

# What is the cost of viral load testing in countries?

## 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)

CD4 AND VIRAL LOAD ANNUAL COSTS BY QUARTILE



**Costs vary enormously within and between countries**

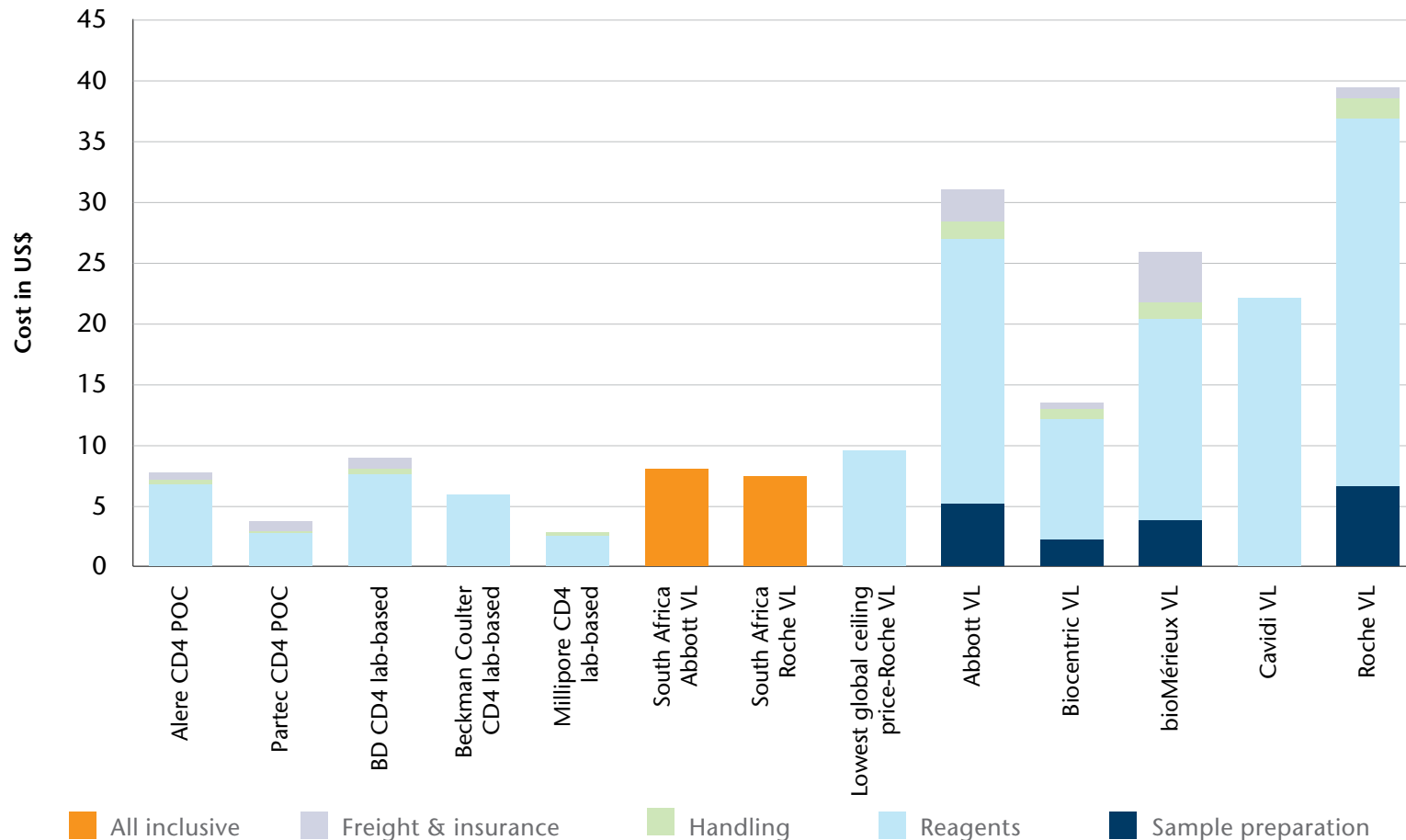
Facility type	Cost in USD (range)	Cost (local currency) - where known	Reagents	Consumables	Maintenance	Instrument	Lab HR	Sample transport	Blood collection
India viral load									
Private labs	\$96.33 (65.13 - 130.25)	INR 5,916 (4750 - 8000)	x	x	x	x	x	x	x
For an NGO	\$41.56 (29.31 - 57.99)	INR 2,552 (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					

Source: MSF five country survey



# What are the test suppliers charging?

## CD4 AND VIRAL LOAD COSTS BY COMPANY



Sources: (i) analysis of GF's PQR database; (ii) South African tender Oct 2014; (iii) Roche global ceiling price

# What is the manufacturing cost of viral load tests? (estimated based on 1 million tests produced/year)

	Reagent costs	Moulding costs	Reagent container costs	Final assembly costs	Total without IP	IP costs	Total with IP (IP as % of total cost)
<b>LAB-BASED TESTS (COMMERCIALY AVAILABLE)</b>							
Abbott RealTime HIV-1 assay	\$2.38	\$0.02	\$0.07	\$0.06	\$2.52	\$4.25	\$6.77 (63%)
Roche CAP/CTM HIV-1 assay	\$4.37	\$0.07	\$0.03	\$0.04	\$4.51	\$1.80	\$6.31 (29%)
BioMerieux NucliSens EasyQ HIV-1 assay	\$1.23	\$0.00	\$0.35	\$0.04	\$1.61	\$0.00	\$1.61 (0%)
Cavidi ExaVir Load assay	\$2.49	\$0.00	\$0.22	\$0.05	\$2.76	\$0.00	\$2.76 (0%)
<b>POINT-OF-CARE TESTS (NOT YET MARKET LAUNCHED)</b>							
Alere Q HIV Test	\$1.56	\$4.01	\$0.00	\$1.50	\$7.07	\$2.26	9.33 (24%)
DRW SAMBA test	\$1.62	\$3.29	\$0.00	\$1.50	\$6.41	\$2.26	\$8.67 (26%)
Wave80 EOSCAPE-HIV test	\$1.56	\$3.50	\$0.00	\$0.00	\$5.06	\$1.20	\$6.26 (19%)
Lumora "BART" test	\$1.62	\$0.00	\$1.27	\$0.95	\$3.84	\$1.00	\$4.84 (21%)

**Armored RNA (Ambion)**

**Moulding costs for POC**

**POC = x2**

**IP costs based on 10% royalty fee of net average selling price in LMICs**

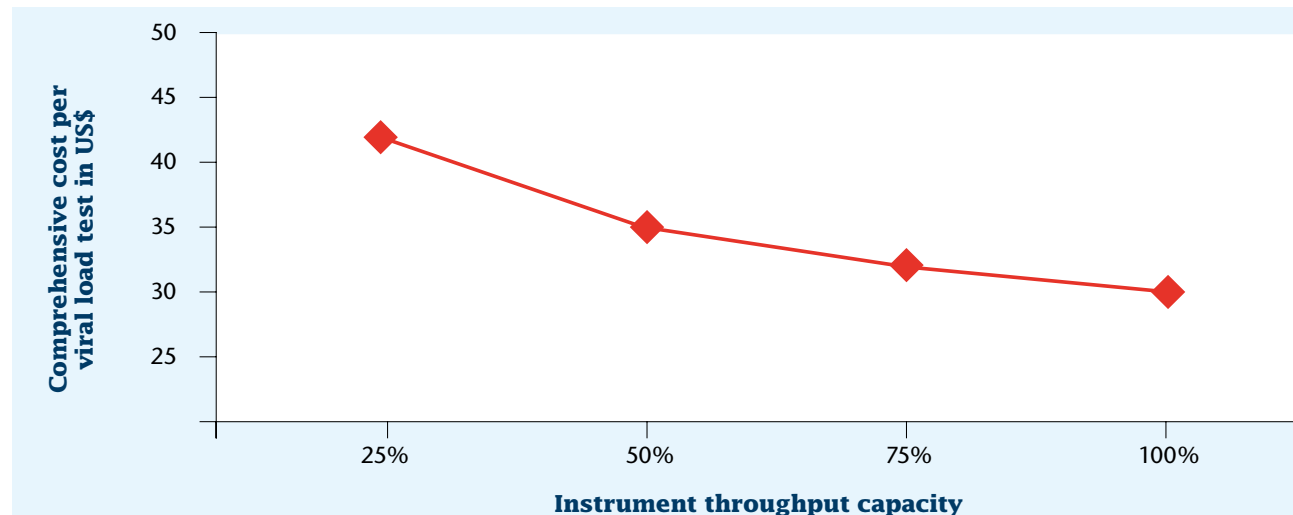
# Can we improve efficiency in contracting and use of machines?

- **Purchasing options**

- Purchase instrument outright / lease equipment / **reagent rental / agreement plan (RAP)** (reagents & consumables purchased for a higher price **ALL INCLUSIVE** of instrumentation, repairs, parts, labour, maintenance, replacement of equipment & training)
- **RAP is best option** but requires known volumes for length of contract

- **Optimising use of machines**

- Throughput
- Polyvalency



# 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>



*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).<sup>1</sup> Measuring VL six months after ART initiation and annually thereafter is strongly recommended as the

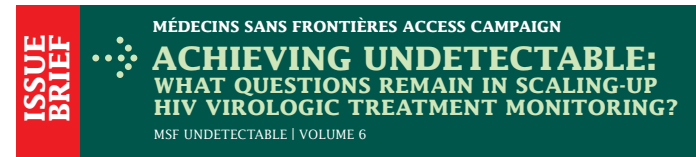
best treatment monitoring protocol to enable the timely detection of adherence problems and provide the opportunity for early adherence interventions that may prevent the development of treatment failure, thus prolonging the use of first line regimens, and to facilitate the accurate detection of treatment failure.<sup>2</sup>

But, according to a 2013 survey by WHO, access to HIV diagnostic and monitoring services is poor across low- and middle-income countries (LMICs).<sup>3</sup> 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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*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.



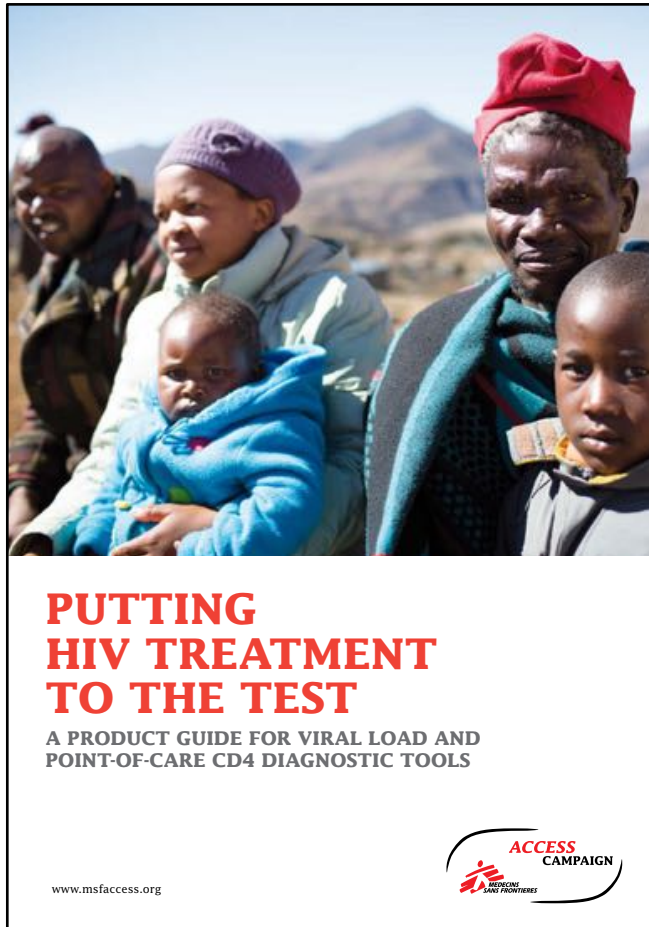
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[msfaccess.org/achieving-undetectable](http://msfaccess.org/achieving-undetectable)

# Implementation & Training Tools

<http://msfaccess.org/undetectable>



## Viral Load Testing Training for Health Care Workers



World Health  
Organization



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



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