



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).

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Médecins Sans Frontières, Rue de Lausanne 78, CP 116, CH-1211 Geneva 21, Switzerland
Tel: + 41 (0) 22 849 84 05 Fax: + 41 (0) 22 849 84 04 Email: access@msf.org

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However, the survey also showed that many machines were being underutilised; and that 10% of machines were not in operation due to lack of installation, repair or staff training. Thus, only an estimated 20% of those on treatment in LMICs receive VL testing.^{4,5} To increase coverage, much more work has to be done to improve access to VL testing, including scaling up capacity and improving affordability.

Although the lack of access to VL testing in LMICs is well recognised, the in-country

market dynamics that serve to drive the demand for test commodities is not well understood. This issue brief includes top-line findings from an in-depth qualitative survey in five countries (India, Kenya, Malawi, South Africa and Zimbabwe) on the current state of CD4, infant^{*} diagnostic and VL testing, along with future scale-up plans and barriers to implementation.

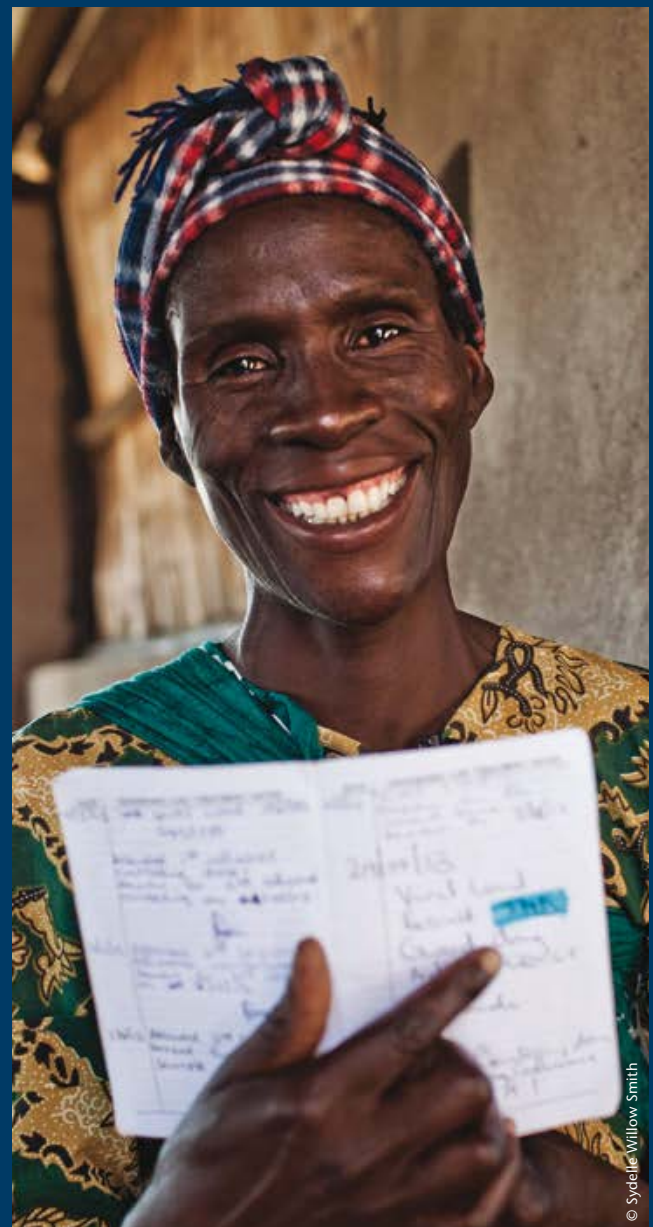
Using a semi-structured questionnaire, extensive interviews were carried out between March and mid-May 2014 with

16-20 experts from each country (almost all face-to-face), including: government health officials; laboratory directors and technicians; representatives of key donor agencies; doctors and other healthcare workers; staff from non-governmental and community-based organisations working in HIV treatment, care and support; private-sector firms that supply diagnostics equipment for VL testing; and people living with HIV/AIDS.

^{*}referring to a child under the age of 18 months, whereby a virological test is needed for HIV diagnosis¹

“There’s no greater motivating factor for people to stick to their HIV treatment than knowing the virus is ‘undetectable’ in their blood. Viral load testing is the optimal way of maintaining people on first-line treatment and knowing when to switch them to second-line drugs, so it’s high time it’s made available in countries with a heavy burden of disease. With new WHO guidelines, our collective goal should now be to scale up without messing up: to reach more people, retain them on treatment, and with an undetectable viral load.”

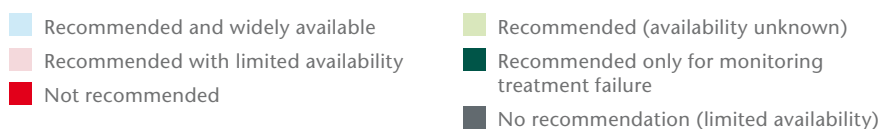
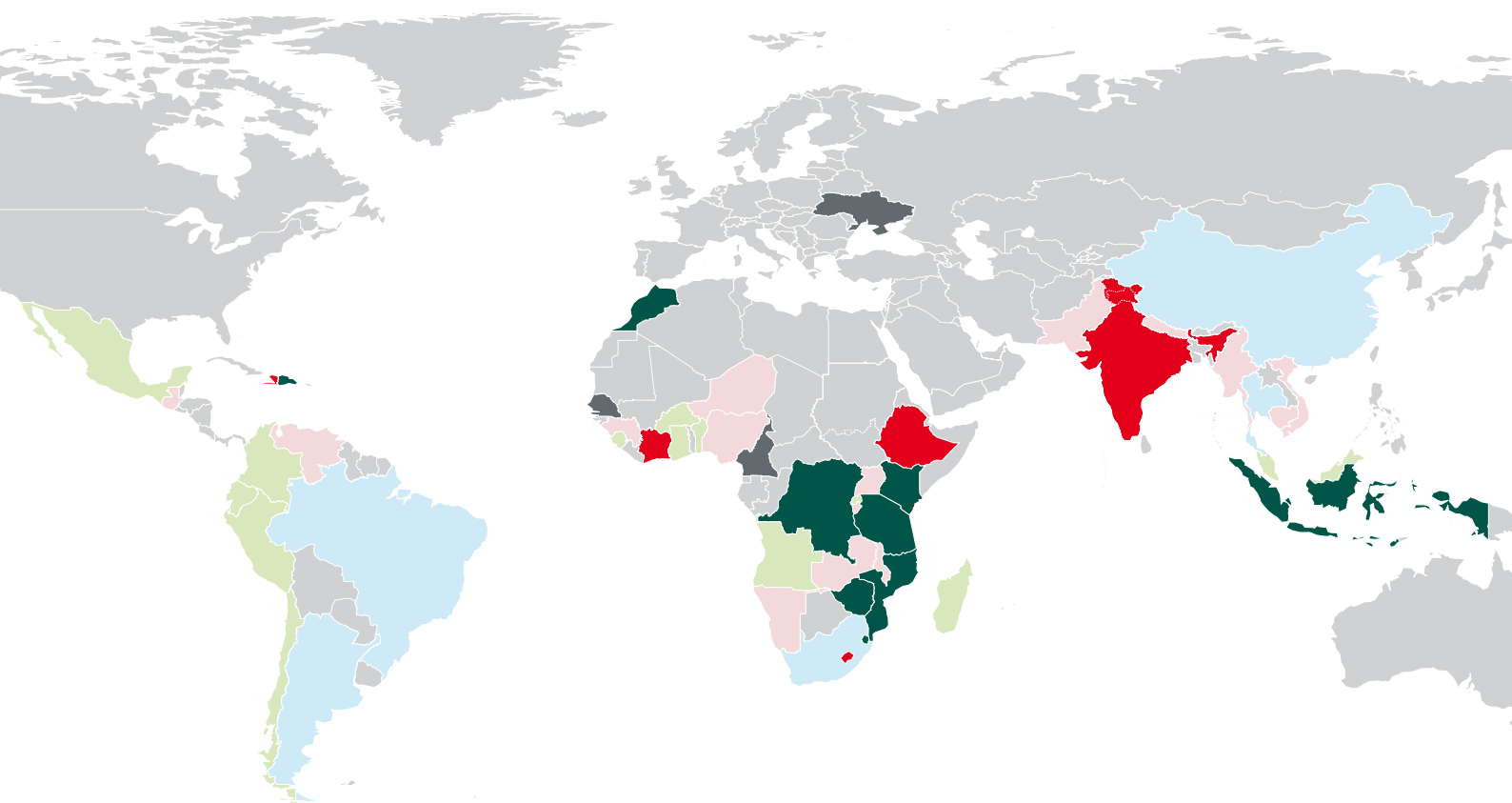
Gilles van Cutsem, Medical Coordinator,
MSF South Africa and Lesotho



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NATIONAL VIRAL LOAD RECOMMENDATIONS

GUIDELINES ON THE USE OF ROUTINE VL MONITORING ACROSS 51 LOW- AND MIDDLE-INCOME COUNTRIES, AND THE LEVEL OF IMPLEMENTATION*



GUIDELINES AND IMPLEMENTATION GLOBALLY

While many LMICs recommend routine VL monitoring for people on ART, in line with WHO recommendations, in reality only a minority of those who need it have access to this service. Routine VL testing is only widely available in a handful of countries, while some countries still do not recommend routine VL testing at all, or recommend it only in the case of suspected treatment failure. Where VL testing does occur, the systems and clinical capacity to act promptly on the findings (e.g., to switch to second- or third-line ART) is rarely in place.

* (ref: UNAIDS)

MSF AND CD4, INFANT AND VIRAL LOAD DIAGNOSTICS

Through co-funding from UNITAID, MSF is working with government health facilities in eight countries (Democratic Republic of the Congo, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Uganda and Zimbabwe) to facilitate VL scale up, to introduce point-of-care (POC) testing for VL, CD4 and infant diagnosis, and to determine the optimal and most feasible use of different technologies in HIV projects in these countries.

MSF is piloting the implementation of the first POC VL test, Diagnostics for the Real World's SAMBA I, in Chiradzulu, Malawi, and in Arua, Uganda. Specifically in Chiradzulu, the aim is to offer decentralised community access to routine VL monitoring through implementation of the VL POC test into nine rural health facilities. Furthermore, task-shifting the operation of the device to trained community workers would overcome the severe staff shortage of laboratory technicians nationwide, and allow clinical staff to focus on clinical tasks and the care of complex patients. The cost-effectiveness of the strategy is maximised by simplifying and shortening the cascade from blood draw, to result, to patient, to clinical decision making.^{6,7}

In Thyolo, Malawi, MSF has introduced routine VL testing, based on dried blood spot (DBS) samples run on the bioMérieux NucliSENS platform, and has also validated the use of pooled VL testing, where five DBS samples are pooled into a single sample, yielding significant cost savings.⁸ Only positive samples need to be retested individually. MSF has also validated the preparation of DBS samples from finger-prick blood by health surveillance assistants based at clinics.⁹

This overcomes not only the lack of phlebotomy services but also allows the use of an easy-to-transport sample that is stable at ambient temperature.¹⁰

Data from Homa Bay, Kenya, comparing POC CD4 and laboratory based VL show that clinical and immunological criteria are poorly predictive of virological failure.¹¹ In Kibera, a recent data analysis showed that stable people on ART with a VL below 1,000 copies/mL do not require additional CD4 monitoring as their CD4 counts don't drop below 200 cells/ μ L.¹²

Although routine VL services are offered in South Africa, MSF supports interventions, such as adherence counselling, to help people improve adherence to treatment and thus to reduce their viraemia. In addition, similar to the Kenya data, MSF research has shown that concomitant CD4 testing is not necessary when routine VL monitoring is available, as, when VLs remain undetectable after initial immune reconstitution, CD4 counts do not drop below 200 cells/ μ L.¹³

MSF has supported the implementation of VL testing in Zimbabwe, including installing a bioMérieux NucliSENS

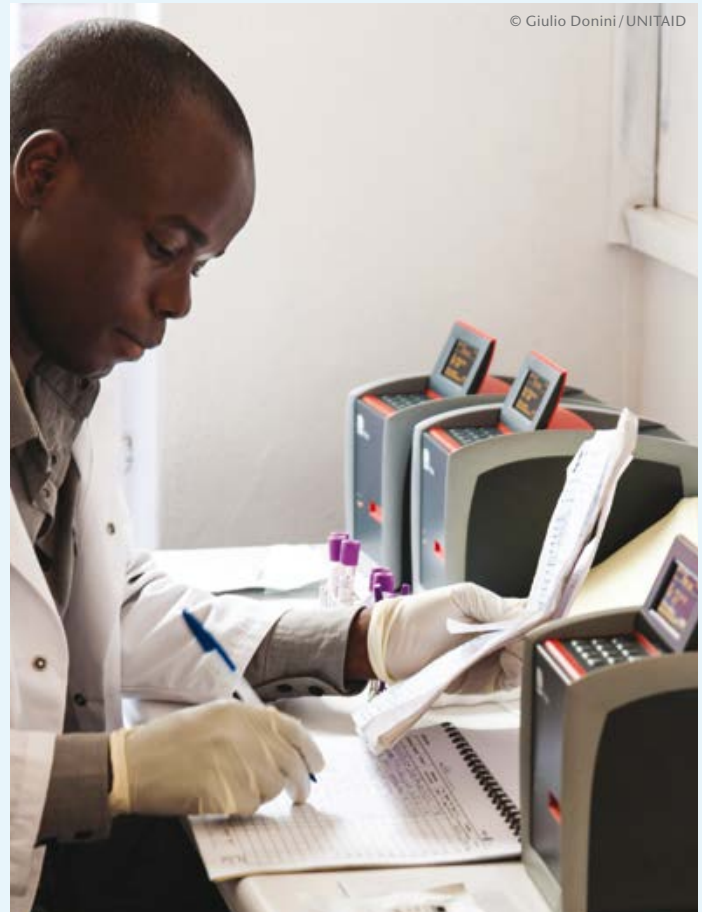
platform at the National Microbiology Reference Laboratory in Harare, with the use of DBS samples. A recent cost analysis, although only based on the reagent cost per test rather than a more comprehensive cost calculation, showed that dropping CD4 monitoring for a cohort of 14,000 stable people on ART would generate a cost saving of US\$94,212, and would consequently free up sufficient money to perform 9,421 VL tests, at \$10 per test.¹²

Lastly, MSF has decentralised care to clinics in Shiselweni, Swaziland, including the provision of POC CD4 testing using the Alere PIMA device. In addition, routine VL testing is provided through the hospital, two health centres and the 22 clinics of the whole Shiselweni region, using a lower cost, open, multiple manufacturer testing platform supplied by Biocentric that uses plasma samples, with timely sample transport and results delivery. Access to VL testing has allowed for the introduction of enhanced adherence support to help people on ART reach undetectable status, or to switch them to another regimen, if needed.¹⁴



“With viral load monitoring and intensive adherence support, we were able to prevent 31 out of 40 people from unnecessary switches to expensive and sparsely available third-line regimens. However, there is an increasing need for access to medications that can be used in third-line antiretroviral regimens. The cost of such medications and inadequate access to HIV viral load monitoring and drug-resistance testing are major barriers to the management of people failing second-line ART.”

Petros Isaakidis, Medical Epidemiologist and Senior Operational Research Fellow, MSF India



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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

Cameroon

Central African Republic

Chad

Congo

Democratic Republic Congo*

Guinea

Haiti

India

Kenya

Kyrgyzstan*

Lesotho*

Malawi

Mali

Mozambique

Myanmar

South Africa

South Sudan

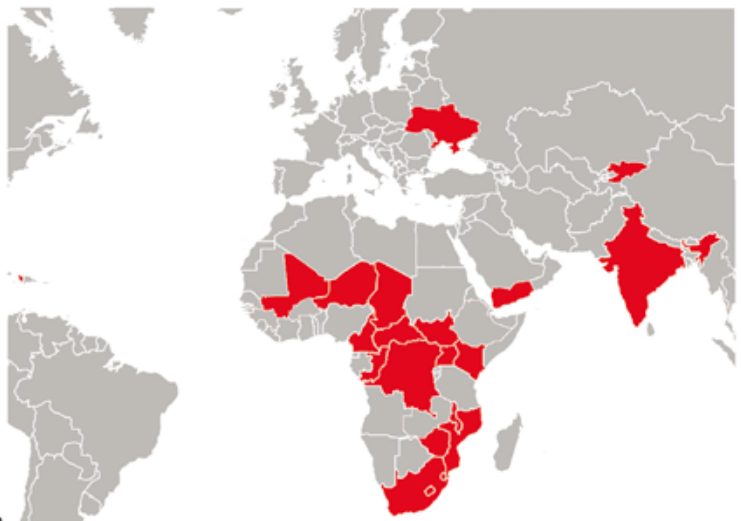
Swaziland

Uganda

Ukraine

Yemen

Zimbabwe



*MSF VL lab implementation planned

*MSF provides diagnostics but not treatment

RESULTS OF THE FIVE-COUNTRY SURVEY

THE CURRENT STATE OF ACCESS TO, PROVISION OF, AND SCALE-UP PLANS FOR VIRAL LOAD TESTING ACROSS FIVE COUNTRIES

	India	Kenya	Malawi	South Africa	Zimbabwe
Number of people living with HIV/AIDS (ref: UNAIDS, year 2012)	2,085,008	1,646,012	1,129,768	6,070,751	1,368,128
Number of people on ART (ref: UNAIDS, year 2012)	~750,000 (year 2014)	604,000	405,100	2,200,000	565,700
Viral load testing in national protocols to confirm treatment failure or offered routinely based on WHO 2013 guidelines (including adherence support)	confirm failure	confirm failure	routine and confirm failure (biennially, and 5,000 copies/ml failure threshold due to use of DBS)	routine and confirm failure	confirm failure
Viral load testing available for this purpose in the public sector	limited	yes	limited	yes	limited
Number of viral load tests provided in 2013	6,000 - 7,000	53,000 (up from 15,000 in 2012; already 53,000 by May 2014)	37,000	2,400,000	30,000 - 48,000
Viral load monitoring to replace immunological treatment monitoring	not currently	not currently	not applicable (CD4 monitoring never recommended)	yes	yes, once routine viral load testing is fully implemented
Number of government laboratories offering viral load testing (number of instruments)	9 (20)	7 (~15)	5 (6 Abbott)	17 (8 Abbott, 9 Roche)	1 (NMRL, Harare; 1 bioMerieux [supplied by MSF])
Scale-up of viral load testing planned	yes, to approximately 30 laboratories	no official targets but aiming for 150,000 tests in 2014 (already achieved 54,000 = 20% of need)	2 new machines in 2014; no official targets but aiming for 300,000 tests annually by 2016 (80,000 in 2014 = 30% of need)	20% increase per year	5 instruments by end 2014 (= 54,000 tests or 7.7% coverage for routine testing); ultimately 2 instruments per each of the 10 provinces by end 2016
Priority groups during viral load testing scale-up	1) on ART >5 years 2) opportunistic infections 3) immunological decline	piggy-back on infant diagnostic testing using existing labs that could scale up capacity	piggy-back on infant diagnostic testing, beginning with high volume sites, prioritising high burden facilities (>5,000 on ART) and district hospitals	not applicable (sufficient capacity)	those suspected of failing treatment
Cost of viral load test at government lab	test: \$29; with lab overheads: \$35	test: \$10.50; with lab overheads: about \$20 (estimate)	test: \$15 with lab overheads about \$22 (estimate) (ref: CHAI)	test: \$10; with lab overheads (subsidised): \$29	test: \$23 (ref: MSF); with lab overheads: \$35
Cost of CD4 test at government lab	test: \$8	test: \$7-8 (ref: CHAI)	unknown	test with lab overheads (subsidised): \$5	unknown
Use of DBS as a sample type (in addition to plasma)	only for infant diagnosis; needs validation for viral load use	yes, for infant diagnosis and viral load - although viral load is still controversial and requires further validation due to accuracy issues	yes, for infant diagnosis and, from 2014, for viral load (with a subsequent validation at 1,000 copies/ml)	only for infant diagnosis	yes, for both infant diagnosis and viral load

Disclaimer:

The data is cross-sectional and refers only to government programmes and facilities, unless otherwise indicated. Data collected from March to mid-May 2014. Figures in US\$

VL IN NATIONAL GUIDELINES

Although all five countries surveyed before mid-May 2014 indicated interest in providing routine VL monitoring, only Malawi and South Africa recommend routine VL monitoring in their guidelines. VL access in these two countries is still not universal, with MSF respondents reporting that only about a quarter of the South African population regularly receive routine VL monitoring, based on the guideline algorithm. For example, a monitoring and evaluation report by the Department of Health in the second quarter of 2013 indicated that only 41% of adults, and 34% of children, on ART for eight years had a viral load test (with 83% of adults, and 82% of children, virally suppressed below 400 copies/mL).¹⁵

HEALTH SYSTEMS CONSTRAINTS

••• Human resources

All countries reported insufficient personnel availability, with overburdened and inadequate numbers of health care professionals in front line

facilities, as well as insufficient training and a lack of up-to-date knowledge.

••• Logistical barriers

Logistical constraints are, universally, a major limiting factor, including weak sample transport systems and supply chain, and poor maintenance and infrastructure requirements of VL machines. In particular, sample transport is a significant limitation and turn-around-times are long (often more than a month).

••• Procedures

Few countries have adequate systems for tracking people on ART and, in the absence of these, loss to follow-up and poor recall is common. In addition, systems for review and decision-making can complicate the matter further. For example, in India, barriers to accessing VL for confirmation of treatment failure include the requirement that a VL test first be approved by the State AIDS Clinical Research Panel (SACEP). People have to travel long distances and present themselves personally before the SACEP

committee to obtain this approval, increasing the bureaucratic delays in the clinical assessment of people on ART.

DROPPING CD4 MONITORING

A 2014 supplement to the WHO 2013 guidelines and other evidence indicate that CD4 testing of those with an undetectable VL is likely unnecessary.^{12,16,17} Currently only South Africa and Malawi do not recommend routine CD4 treatment monitoring. Other countries would need to scale-up their VL testing capacities in order to drop CD4 monitoring. Given that this could take some time, countries are faced with the decision of whether to spend resources scaling-up CD4 testing in the short- to medium-term, even though it may ultimately be a redundant test for monitoring stable people on ART once virologically suppressed, or investing in VL testing scale-up. It would be preferable to focus on CD4 testing capacity for treatment initiation while concentrating on scaling-up VL testing services for treatment monitoring.

FUNDING SHORTAGES

Respondents from most countries cited financial resource constraints as one of the reasons for incomplete or slow implementation of VL monitoring, alongside the substantial health systems barriers. For example, Malawi has changed its VL monitoring recommendation from once every 12 months to once every 24 months, and implementation of VL testing has been slow.

In Zimbabwe, taking into account committed support to date, the estimated funding gap for VL testing is \$3.26 million for 2014, and \$2.9 million for 2015.



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USE OF DRIED BLOOD SPOTS

DBS samples were developed to reduce the complexity of sample collection and transport and thus can be prepared by less skilled health workers. DBS is already used extensively in surveyed countries for infant diagnosis. However, most surveyed countries expressed hesitation about using DBS for VL testing due to concerns about accuracy of this method (most available VL technology has higher thresholds for detectability, and results do not correlate well with plasma-based measurements, at the WHO recommended 1,000 copies/mL threshold for virological failure). Malawi has plans to use DBS routinely for VL testing for more remote facilities (possibly along with POC testing), with the first DBS kits arriving in January 2014. The lessons learned from the Malawi experience will be critical to inform the use of DBS in additional countries.

PLANS FOR POINT OF CARE VIROLOGICAL TESTS

While most countries noted that there were very few clinical situations where POC VL testing would provide significant added value, POC was noted as a potential solution to address concerns around weak sample transport, especially in very remote areas. Based, in part, on the implementation of POC CD4 testing, countries expressed concerns about accuracy; high rates of invalid results; health worker training; additional burden placed on clinic-based health workers; and the difficulty of assuring quality in a decentralised system. Countries also noted that, in general, the per-test cost (including only reagents and other commodities needed to perform the test, as more comprehensive costs are unknown) of high-throughput systems was likely to be lower than for POC. Thus, surveyed countries indicated a preference for strengthening centralised VL testing

facilities and the supporting sample transport infrastructure, which would have the added benefit of strengthening sample transport for other diseases as part of health system strengthening. The use and scale-up of POC technologies for VL testing on a national level was not being planned by any of the countries surveyed. More respondents indicated a potential role for POC for infant diagnosis due to lack of performance of existing centralised services for timely early infant diagnosis and the increased clinical relevance of obtaining immediate test results.

DRIVING DOWN THE PRICES

There is considerable opportunity to decrease the price of VL testing. In Kenya, negotiations supported by the Clinton Health Access Initiative (CHAI) have resulted in an all-inclusive (reagents and consumables, instrumentation, training and service and maintenance, although not including human resource



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costs) selling price of US\$10.50 per test, currently supplied by Abbott and Roche. Kenya has already increased its VL testing and, from January until mid-May 2014, provided more than 53,000 VL tests – as many as were provided in the entire year in 2013 – as reported on the online National AIDS & STI Control Programme VL dashboard. According to CHAI, the price is a result of negotiations based on projections of increased volumes (although, importantly, no volume commitments were made) and competition between manufacturers, with Abbott and Roche each taking an initial 50/50 split in the tender. South Africa has also used competition, with a 50/50 tender split between Abbott and Roche, and large volumes as mechanisms to reduce pricing. They also rent (rather than buy) the instruments to allow space for innovative products, use the instruments at close to maximal capacity through high volumes, and could expand capacity with existing infrastructure, if needed, using 24-hour shifts. In order to help drive prices down globally, South Africa's current tender aims to harness its large market by requesting companies to provide a ceiling price it would offer to other governments and the Global Fund to Fight AIDS, TB, and Malaria (GFATM).

INSUFFICIENT AWARENESS AND DEMAND FOR VL

For the most part, people living with HIV/AIDS and civil society groups were not well informed about the importance of VL monitoring and, as a consequence, there is limited demand and advocacy for access to VL monitoring in countries, and for accurate treatment switching. A notable exception is the Indian Network of People Living with HIV/AIDS, who are demanding that people with suspected

treatment failure who are referred by ART centres to SACEPs should present with accompanying viral load test results, requested by the referring doctor, to increase the efficiency of the process and reduce unnecessary delays in their assessment. In addition, there seems to be a lack of awareness from clinicians and people living with HIV/AIDS about the importance of VL testing, with poor uptake and a lack of correct clinical follow-up, even when VL testing is available.



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BRAZILIAN CASE STUDY: LESSONS FOR THE SCALE-UP OF VL TESTING

Brazil provides CD4-independent treatment (test and treat) and a baseline and six-monthly routine VL test for people on ART, with approximately one million VL tests performed in 2013. They will stop using CD4 as a treatment monitoring tool from mid-2015 but retain baseline testing for clinical decision-making. Brazil's size and remote areas present some logistical challenges, but people on ART are able to access treatment that includes VL testing.

An interview with the coordinator of the general laboratory at the Department of STDs, AIDS and Hepatitis reveals several examples of successful practices to increase access to VL monitoring.

VL (and infant diagnostic) testing is accessible at 85 laboratories throughout Brazil, each with a platform supplied by

Abbott, and this is expected to increase to 100 laboratories in 2015. Like South Africa, Brazil uses a tender system to select products, using competition at the bidding stage. Their volumes are large so suppliers have an incentive to compete. In the past it has been seen as easier to grant the tender to just one company, as volumes are higher and prices better, and laboratories can be standardised and results compared. In 2013, the cost per VL test was \$10, including all laboratory-associated costs (reagents and consumables, instrumentation, training, and service and maintenance), except for labour, and this price is lower than the \$13 per CD4 test. The terms of the tender are quite firm, including a service agreement that specifies repair or replacement of instrumentation within 24 hours.

Test results are tracked through a single database that uses a unique identifying number. Access to the database is available to the laboratories, as well as to programme coordinators as a management and monitoring tool. Paper copies are sent to remote sites where access to the database is limited. People receive care at specialised HIV reference centres around the country.

Although they will mainly continue to rely on high-throughput laboratory-based platforms using plasma as a sample type (they have sufficient phlebotomy services and sample transportation), Brazil is considering validating POC VL testing to serve remote areas.



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ADDITIONAL INFORMATION

More detailed information on CD4, infant diagnostic and VL testing, as part of the five-country survey and UNAIDS database analysis, is available online in supplementary material, which may be accessed at www.msfast.org/content/usage-hiv-viral-load-monitoring-5-countries.

ACKNOWLEDGEMENTS

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DISCLAIMER

The information and observations provided in this document are based on notes taken during in-person discussions with respondents and (in a handful of cases) responses provided by email. No fact checking, validation or verification has taken place. In some cases, different respondents provided conflicting data or gave different assumptions, observations and impressions. No effort was made to resolve such variances; where relevant, such differences in opinion and/or details are noted.

PREVIOUS MSF UNDETECTABLE PUBLICATIONS

Available at: www.msfast.org/undetectable



Volume 1 – Undetectable: How Viral Load Monitoring can Improve HIV Treatment in Developing Countries; July 2012



Volume 3 – How Low Can We Go? Pricing for HIV Viral Load Testing in Low- and Middle-Income Countries; December 2013



Volume 2 – Putting HIV Treatment to the Test: a Product Guide for Viral Load and Point-of-Care CD4 Diagnostic Tools; July 2013



Volume 4 – HIV Status? Undetectable: Four Essential Interventions to Improve HIV Treatment, Save Lives, and Reduce Transmission; December 2013

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WHAT NEEDS TO HAPPEN

Despite significant barriers, most respondents, from government officials to clinicians to people living with HIV/AIDS, reported that VL would confer significant added value in ensuring the provision of quality care. Respondents identified a number of promising opportunities to address barriers to bring down VL test prices and facilitate scale-up. Respondent data, combined with MSF's experience providing VL, has informed the following recommendations:

❖ Secure financial resources

Financing was identified as a major barrier to upgrading from CD4 to VL for treatment monitoring, so obtaining additional funding is crucial. Countries eligible for GFATM support should submit robust concept notes that reflect the costs of rolling out VL monitoring as well as adherence support systems.

❖ Replace routine CD4 treatment monitoring with VL testing

With earlier treatment initiation, the need for CD4 testing is declining and, in the near future, may only be needed to inform clinical decisions at enrolment into care of people newly identified with HIV infection, define time of ART initiation, and confirm immune reconstitution. Therefore countries can prioritise resources for scaling-up VL rather than increasing CD4 testing capacity.

❖ Decrease the cost of VL testing and move to rental contracts

Using competition and negotiation, the selling price per laboratory-based test has dropped to approximately \$10 in Brazil, Kenya and South Africa, and, in all instances, instrument rental and service and maintenance were included (although not human resources or transport services). Competition, especially at the tendering stage, has helped decrease costs. Testing efficiencies, such as processing larger volumes per day, instituting shift work, and using VL sample pools for stable patients, allows for maximal use of instrumentation and decreased costs. Donor organisations and countries with large VL volumes should work together to leverage their power to get better prices and service agreements for all countries involved; for example, by using pooled procurement and moving to instrument rental options rather than purchasing expensive equipment that does not allow for flexibility in platform choice in the future.

❖ Improve knowledge about the use and benefits of VL

Training for both clinicians, to be better able to provide optimal care, and people living with HIV/AIDS, to know how best to monitor their health, is critical. In addition, since civil society has advocated for many of the most important tools and policies that have improved the HIV response globally, their voice is critical to demonstrating demand and ensuring the rapid and appropriate rollout of VL testing.

❖ Improve health systems constraints

MSF pilots on routine VL monitoring reveal programmatic challenges for implementation, that were echoed in the results of the five country survey. The issues with sample transport may be significantly alleviated with the use of DBS, and new advances in DBS technology are expected to increase accuracy. Countries and WHO must rapidly respond to advances in DBS technology with appropriate guideline updates and country-level implementation. Even with new tools such as improved DBS, improvements in sample transport systems are needed. Although courier services may exist to transport samples and results to the VL testing laboratory, which is often centrally located, alternate and reliable transport must be put in place to service the "last mile." Human resources are constrained, but the burden of sample collection may be alleviated through task shifting. For example, MSF has validated fingerprick blood collection performed by community workers.



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Médecins Sans Frontières, Rue de Lausanne 78, CP 116, CH-1211 Geneva 21, Switzerland
Tel: + 41 (0) 22 849 84 05 Fax: + 41 (0) 22 849 84 04 Email: access@msf.org

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