International AIDS Society
Stronger Together Against HIV

INDUSTRY LIAISON FORUM
Engaging Experts in HIV

Meeting report

Expanding access to viral load monitoring in resource-limited settings

IAS-ILF Symposium at INTEREST 2014
5 May 2014 - Lusaka, Zambia

Acknowledgements

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Expanding access to viral load monitoring in resource-limited settings

1. Background

The 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection[1] were released at the 7th IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2013) in Kuala Lumpur, Malaysia. These guidelines include recommendations on when to start antiretroviral therapy (ART), what to start with, and how to manage co-morbidities, as well as guidance on optimizing linkages to care so that HIV-infected patients have access to life-saving suppressive ART. Recent studies suggest that a delay in the initiation of second-line ART among people who experienced first-line failure was associated with higher mortality compared with those who had earlier initiation of second-line ART. According to the WHO Global HIV/AIDS 2011 progress report[2], only 2.9% of people on ART in low- and middle-income countries (LMICs), excluding the region of the Americas (i.e., mainly those in Africa and Asia), were on second-line regimens; this contrasts with 27.8% of those in LMICs in the region of the Americas. These data suggest that HIV-infected patients in Africa and Asia might be unnecessarily kept on failing regimens. The appropriate utilization of viral load (VL) monitoring with timely follow up of detectable VLs (e.g., adherence reinforcement and switch to a different regimen if necessary) might be instrumental in addressing this situation and is consistent with the 2013 WHO guidelines[1] recommending implementation of routine VL monitoring.

This symposium, held in conjunction with the 8th INTEREST Workshop 2014 in Lusaka, Zambia, provided an occasion to discuss how to expand access to VL monitoring in resource-limited settings (RLS) and to maximize the benefits, in line with the 2013 WHO guidelines[1]. The session highlighted challenges and solutions in expanding access to VL monitoring. The first two presentations gave an overview of the clinical and financial arguments regarding routine VL monitoring, and the third presentation highlighted laboratory challenges. Following a community perspective to help contextualize this information, a panel discussed solutions to overcome implementation barriers.

The symposium was co-chaired by Linda-Gail Bekker (Desmond Tutu HIV Foundation, South Africa) and Catherine Hankins (Amsterdam Institute for Global Health and Development, AIGHD, The Netherlands). François Venter (University of the Witwatersrand, South Africa) provided the first overview presentation. Nuancing the positive clinical outcomes of using VL for monitoring ART response, Linda-Gail Bekker talked about the financial aspects of VL monitoring (i.e., its questionable cost effectiveness). Sue Aitken (Ndlovu Research Consortium, South Africa) continued the discussion by presenting slides by Trevor Peter (African Society for Laboratory Medicine, ASLM, Botswana) on the laboratory aspects of scaling up VL monitoring in RLS. Michael Gwaba (Community Initiative for TB, HIV/AIDS and Malaria, CITAM+, Zambia) contextualized the need for expanded access to VL monitoring by giving a community perspective. Following these overview presentations, Catherine Hankins facilitated a panel discussion, which included the speakers, as well as a representative from the diagnostics industry (Robert Luo, from Roche Molecular Systems, USA). The audience participated actively in this discussion.

[1] Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection. WHO, Geneva, Switzerland, 2013 (link)
[2] Progress report 2011: Global HIV/AIDS response. WHO, Geneva, Switzerland, 2011 (link)

2. Clinical rationale

HIV VL monitoring, performed by an accurate method, is considered to be the best marker for clinical decision making after initiation of ART. It provides a clinically useful range of values that can indicate the effectiveness of ART and is useful to detect early signs of treatment failure and determine the best time to switch to a second-line treatment. In addition, VL monitoring is a particularly useful tool for monitoring adherence to treatment, performing sentinel surveillance and diagnosing HIV infection in children younger than 18 months (i.e., early infant diagnosis, EID).

In countries where VL monitoring is available, it is standardized for monitoring patients' treatment response and, in combination with CD4 monitoring, for assessing HIV progression. In these settings, a detectable VL systematically triggers an action, including the reinforcement of adherence or the switch to a different regimen, often in conjunction with a resistance test (genotyping), to ensure that the new regimen will be effective. However, in RLS, due to the costs and complexity of VL monitoring, its implementation has been restricted and a public health approach is generally in place. Patients failing clinically or immunologically are switched to a pre-defined regimen, often without prior genotyping. The new WHO guidelines recommend that in situations where VL testing is routinely available, patients' VL is monitored in order to detect potential viral replication and treatment failure (defined as a persistent VL above 1,000 copies/mL).

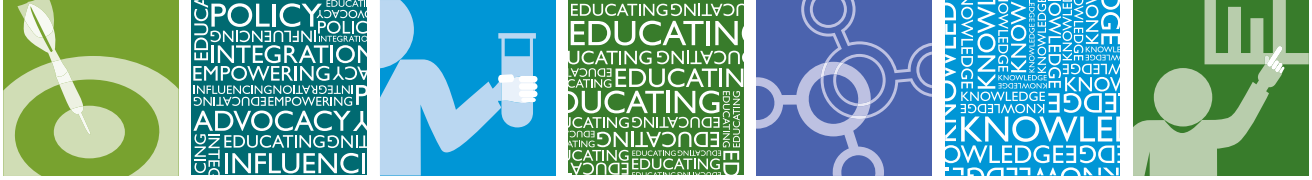
One of the major benefits of routine VL monitoring is that it can limit the amount of time spent on a failing regimen, thus avoiding the selection of resistant viral mutations. The proportion of individuals on ART in LMICs who have been switched from failing first-line ART regimens to second-line regimens is very small relative to the rapidly growing number of people on ART. This suggests that many people who need to switch are either lost to follow up or maintained on failing regimens, a situation that is of particular concern for adolescents, who often have a history of poor virologic suppression.

In an editorial in 2012, Nathan Ford and co-authors stated that there is "little debate about the value of VL in guiding clinical decisions for people on ART"[3]. VL monitoring was mentioned as the preferred tool for monitoring for the first time in the 2013 WHO guidelines[1]. However, there has been a growing inclusion of VL monitoring in the WHO guidelines since 2003 when it was first mentioned as desirable. In 2006, it was recommended for tertiary health care centres and, in 2010, a phased-in approach was proposed for scale up. The current guidelines are as follows:

- "VL is recommended as the preferred monitoring approach to diagnose and confirm antiretroviral treatment failure (strong recommendation, low-quality evidence)"
- "If VL is not routinely available, CD4 count and clinical monitoring should be used to diagnose treatment failure (strong recommendation, moderate-quality evidence)."

Virologic failure, the emergence of viral particles in the blood of a patient on ART, is the first event leading to clinical failure (see Figure 1). Indeed, immunological and clinical failures are delayed after virologic failure, making CD4

[3] Ford N., Roberts T., Calmy A. (2012). Viral load monitoring in resource-limited settings: a medical and public health priority. AIDS 26(13): 1719-1720 (link)



counts and clinical staging less prompt indicators of ART ineffectiveness that has been caused through poor adherence or resistance problems, for example. Consequently, VL monitoring can provide the first indicator of resurgence of viral replication (i.e., active infection) and thus is the best approach for:

- Determining and promoting adherence
- Preventing drug resistance
- Preventing unnecessary switch to second-line regimens
- Measuring the effectiveness of an HIV programme.

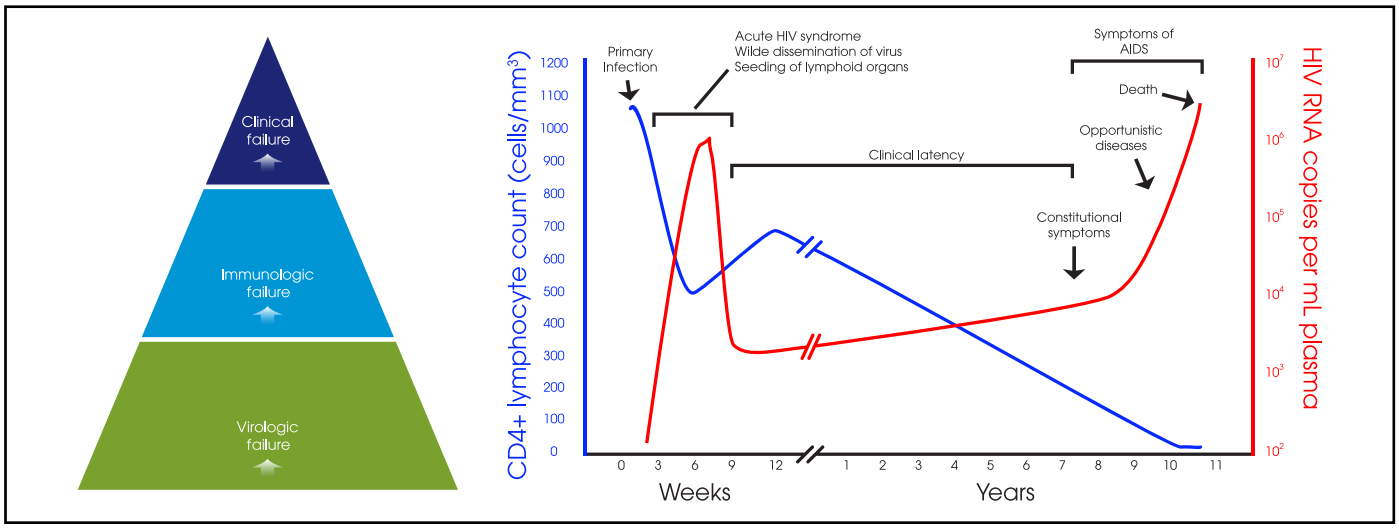


Figure 1. Virologic failure leads to immunologic failure, which leads to clinical failure. There is an inverse relationship between VL and CD4 count in untreated (or failing) HIV-infected patients. Source: François Venter, IAS-ILF Symposium, "Expanding access to viral load monitoring in resource-limited settings", Lusaka, Zambia, 2014 (left image); and Wikimedia Commons file "File:Hiv-timecourse_copy.svg" (right image)

However, given that protease inhibitors (PIs) are used in second-line regimens (with first-line regimens using nucleoside reverse-transcriptase inhibitors, NRTIs, and non-nucleoside reverse transcriptase inhibitors, NNRTIs), the potential for increased resistance in the absence of VL monitoring might not be as detrimental for the individual patient because NRTI/NNRTI resistance does not correlate with PI resistance. However, delayed recognition of drug resistance might have a public health impact through increased onward transmitted resistance.

Importantly, the benefits of VL monitoring depend on timely action following a detectable VL (e.g., adherence reinforcement and a switch to a different regimen). Provided second-line (and also third-line) drugs are available, the availability of affordable point-of-care (POC) technologies can certainly help with same-day decision making (see Section 4).

3. Cost effectiveness

Despite the apparent consensus regarding its clinical benefits, VL monitoring is still not widely used. Costs are a strong argument when comparing the use of VL monitoring and CD4 count monitoring. Indeed, given an approximate price of US$20 per test and the 26 million people eligible for ART, VL monitoring could represent an investment of about US$500 million per year globally, a significant investment, which has to be compared with other comprehensive public health approaches.

Cost-effectiveness models have shown that VL monitoring is not cost effective given current costs for laboratory setups and the tests themselves[4]. This takes into consideration the savings made when sharing or transferring resources (e.g., from CD4 count to VL monitoring), when sparing the use of second-line regimens (and preserving the use of first-line regimens) and when an undetectable VL contributes to the prevention of onward HIV transmission (indirect effect). Models compare VL monitoring at different frequencies with CD4 counts and clinical staging, in combination or alone (see Figure 2, left panel). Although it comes with a high cost, the use of VL monitoring every six or 12 months and without the inclusion of CD4 counts provides the greatest estimated reductions in morbidity and mortality. However, for the same costs, the number of disability adjusted life years (DALYs) averted is also shown in these models to be higher when using the same resources instead for scaling up ART (e.g., through increased coverage or expanded eligibility criteria, see Figure 2, right panel).

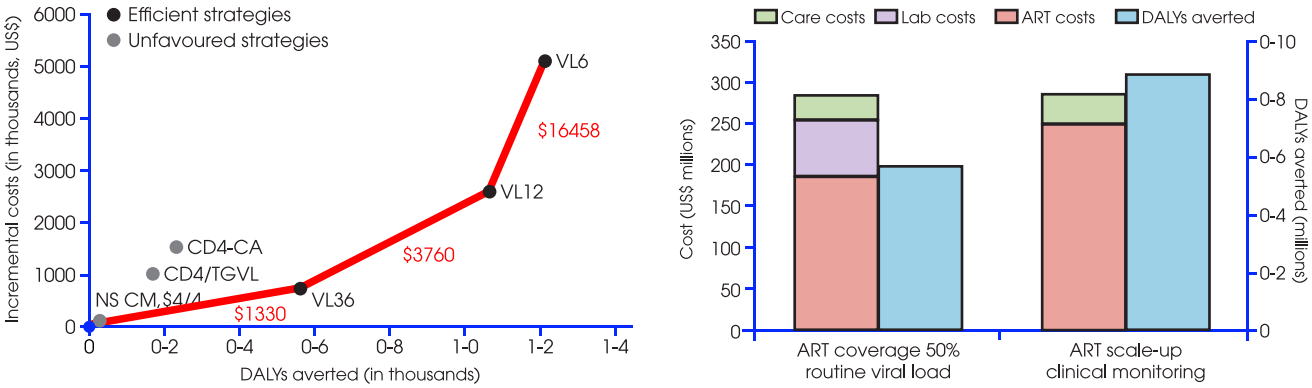


Figure 2. VL monitoring, compared with immunological or clinical monitoring, results in the highest number of DALYs averted. For the same cost, however, the scale up of ART brings more DALYs averted compared with using the same financial resources for scaling up VL monitoring[4]

Although VL monitoring as a routine approach used universally might not be cost effective, different strategies exist to increase its cost effectiveness. One of them is the use of VL monitoring tailored for certain key populations, including individuals with adherence problems. In this case, adherent persons with undetectable VL are followed less frequently and those with detectable viral loads following treatment initiation are followed more closely. Some opportunities for cost savings indeed might lie in the frequency of monitoring. The drawback of this approach is the risk of delaying a needed switch in the case where there is a high probability of resistance emerging. Another approach is the use of selective VL monitoring

[4] Keebler D., Revill P., Braithwaite S., Phillips A., Blaser N., Borquez A., Cambiano V., Ciaranello A., Estill J., Gray R., Hill A., Keiser O., Kessler J., Menzies N.A., Nucifora K.A., Salazar Vizcaya L., Walker S., Welte A., Easterbrook P., Doherty M., Hirnschall G., Hallett T.B. (2014). Cost-effectiveness of different strategies to monitor adults on antiretroviral treatment: a combined analysis of three mathematical models. Lancet Global Health 2(1): e35-e43 (link)

where VL monitoring is used only to confirm virologic failure after its identification by immunological or clinical criteria. This also runs the risk of delays before switching regimens. Another selective approach could prioritize pregnant women, breast-feeding women and persons in serodiscordant couples as virologic failure in these cases carries an increased risk of onward HIV transmission.

The use of different thresholds for the definition of virologic failure (e.g., 1,000 vs. 5,000 copies/mL) and varying frequencies for VL monitoring (e.g., every six, 12 or 24 months) are other approaches to help find an acceptable compromise between benefits and costs. Currently, the 2013 WHO guidelines[1] recommend VL monitoring six months after ART initiation and every 12 months thereafter, with a threshold of 1,000 copies/mL for plasma samples and of 3,000-5,000 copies/mL for dried blood spot (DBS) samples. The threshold of 1,000 copies/mL for virologic failure is based on studies looking at the risk of transmission, as opposed to clinical outcomes, where several studies have shown that even low levels of detectable viraemia (e.g., below 200 copies/mL) can have detrimental clinical effects. In fact, the only truly good VL is when it is undetectable (i.e., below 20-50 copies/mL depending on the technology used).

Although VL monitoring comes with additional costs, these might be balanced by avoidance of unnecessary switches to more expensive second-line regimens, as shown by another modelling study[5]. Follow up after a detectable VL to assess and support improved adherence is another aspect to take into consideration as switching to a second- or third-line regimen obviously involves additional costs. During ART scale up, the involvement of community groups might be key in making sure people are adherent and monitored, and that their VL results are acted upon if virus is detected.

As mentioned earlier, the arguments for VL monitoring are nuanced by the fact that expansion of VL monitoring has to compete for resources with the scale up of ART. In a public health approach, the priority for HIV programmes should thus be first on expanding ART coverage for all those with CD4 counts below 500 cells/mm^3, prioritizing patients with CD4 counts below 350 cells/mm^3, in conjunction with clinical and/or immunological monitoring. Following this scale up, VL monitoring should be considered (and maybe phased in using a selective approach), especially as VL monitoring technologies become cheaper and POC devices are developed. CD4 counts could then be used only for the assessment of the eligibility of patients in the context of ART initiation. In a long-term optic, VL monitoring (in particular using POC devices) might synergize well with other approaches promoting adherence (e.g., adherence clubs and community-based delivery of ART) and lead to even better cost effectiveness. Whereas the scale up of ART should be prioritized, there is also a need to make sure that resources invested in expanding treatment are well utilized (i.e., patients are virologically suppressed). VL monitoring is instrumental for achieving this.

[5] Hamers R.L., Sawyer A.W., Tuohy M., Stevens W.S., Rinke de Wit T.F., Hill A.M., ART-A Consortium (2012). Cost-effectiveness of laboratory monitoring for management of HIV treatment in sub-Saharan Africa: a model based analysis. *AIDS* 26(13):1663-1672 (link)

4. Laboratory challenges

Although the southern part of Africa has started expanding access to VL monitoring, many nations are still lagging in this area, with a large number not yet considering the use of VL monitoring (see Figure 3, which displays data only for continental sub-Saharan African countries). However, models forecast a steady increase in the global use of VL monitoring in the coming years, in particular since the 2013 WHO guidelines[1] recommend its use for routine monitoring. For this to happen, well-planned scale up will be essential to go through the potential laboratory challenges inherent to this technology. Lessons learned from the experience with CD4 counts and EID should be carefully considered. These include the issues of supply chain, sample/specimen logistics (e.g., transport and stability) and the availability of POC tests (see Figure 4).

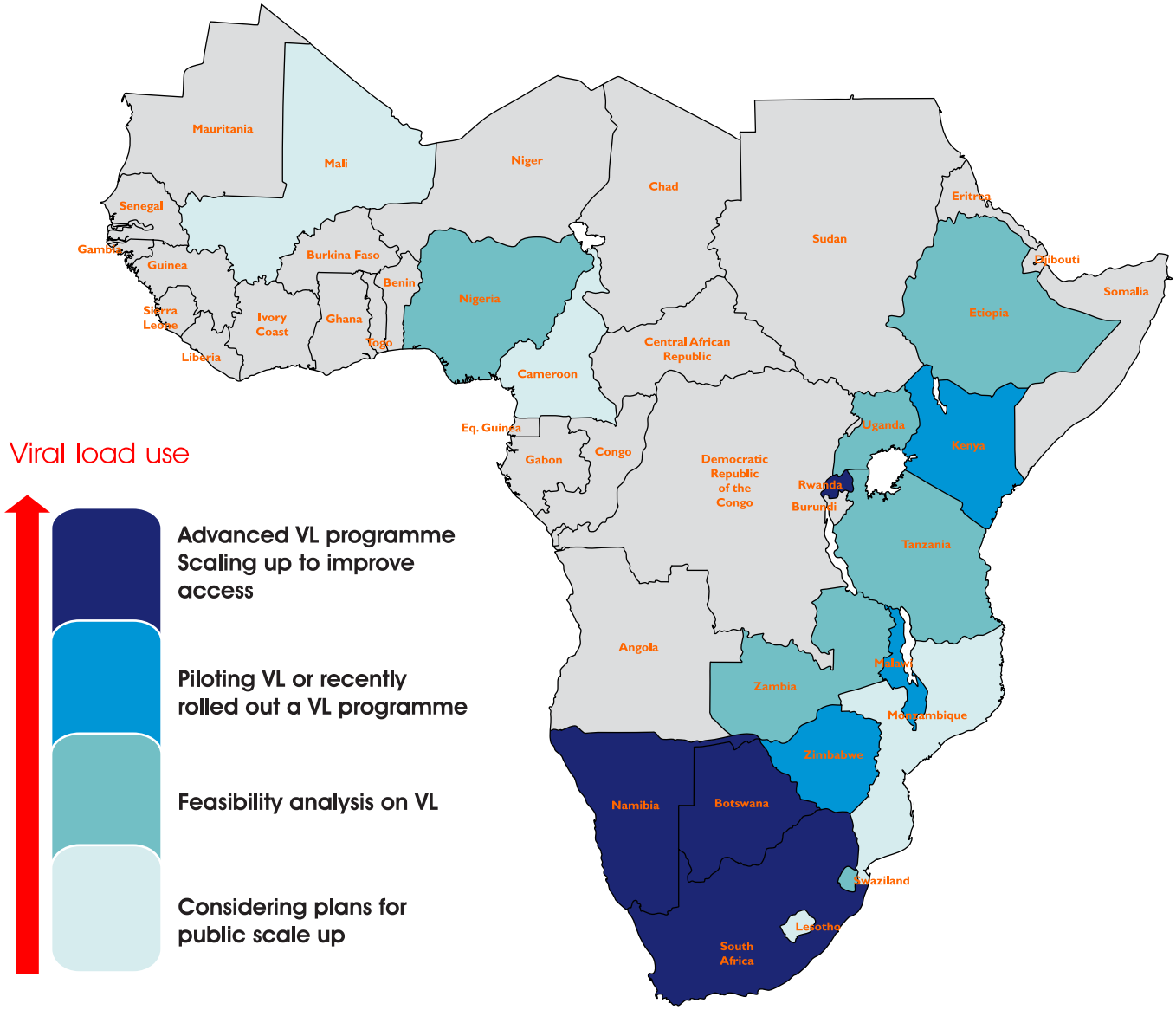


Figure 3. Scale up of VL monitoring in sub-Saharan African countries. Source: Trevor Peter, IAS-ILF Symposium, "Expanding access to viral load monitoring in resource-limited settings", Lusaka, Zambia, 2014

In 2013, ASLM convened an expert meeting to identify consensus strategies and recommendations for increasing access to VL monitoring in Africa[6]. Some of the key findings emerging from this meeting are:

- Laboratories with EID and VL monitoring already in place have spare capacity
- Additional training needs for staff in laboratories are limited
- In addition to several small-scale VL programmes across Africa, South Africa and Botswana have a long experience with high volumes of VL monitoring (both centralized and decentralized).

Compared with CD4 count tests for which costs are stable, costs for VL monitoring vary greatly between countries, ranging from US$10 to $55 per test. Not surprisingly, costs are also consistently higher than for CD4 count tests. To address this issue, standardized, volume-based prices are needed. Consolidating procurement should be prioritized. This is an approach successfully being used for the procurement of antiretrovirals and CD4 tests.

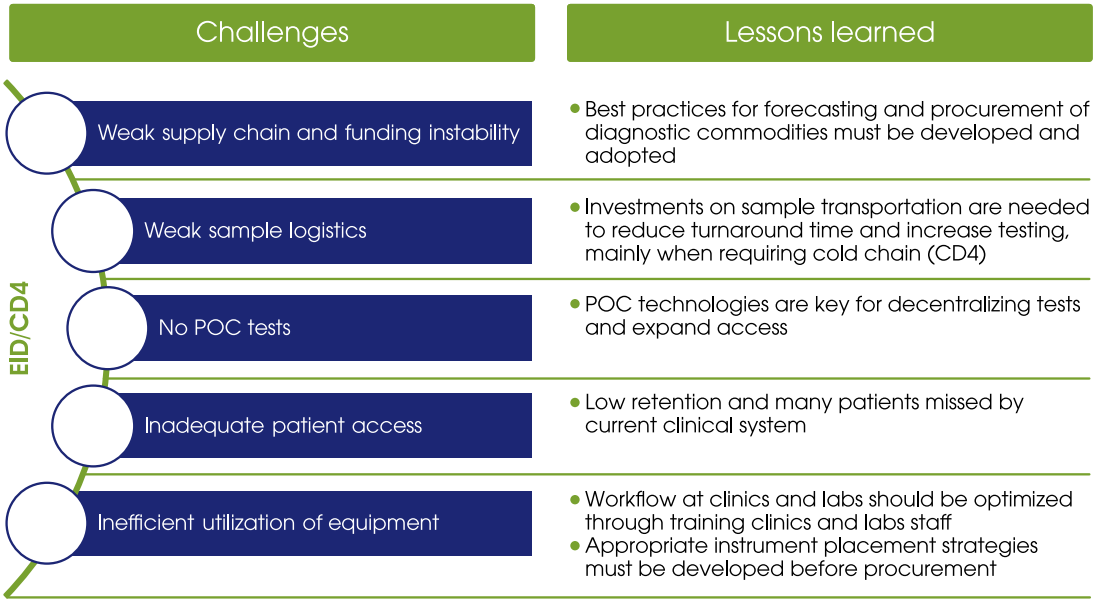


Figure 4. Challenges with and lessons learned from implementation of CD4 count testing and EID. Source: Trevor Peter, IAS-ILF Symposium, "Expanding access to viral load monitoring in resource-limited settings", Lusaka, Zambia, 2014

Current instrument capacity, taking advantage of the unused capacity of platforms for EID, far exceeds the demand for VL monitoring. There is an estimated 86% excess capacity based on the number of instruments and their turnover rates in nine south-eastern African countries (Ethiopia, Kenya, Tanzania, Mozambique, Malawi, Swaziland, Zimbabwe, Zambia, Uganda). Accordingly, more tests should be procured to match current instrument capacity. However, projections for the scale up of VL monitoring show that more instruments will be needed within five years of scale-up efforts. Several other recommendations, a number of which relate to the laboratory, were issued following the ASLM expert meeting (see Figure 5).

[6] Viral load monitoring in African HIV treatment programmes. ASLM, Cape Town, South Africa, 2013 (link)

Once available, POC tools will be a good complement to laboratory-based instruments as POC approaches have the advantage of increasing linkage to care. The Pan African Harmonization Working Party on Medical Devices and Diagnostics is proactively developing standard evaluation protocols for POC VL technology in order to streamline regulatory approval and market access. Guidelines for post-marketing surveillance are also being developed and could include remote device monitoring using wireless technologies. This reflects a need for stronger regulatory systems for diagnostics in general. These are all critical aspects for reliable and accessible VL monitoring, in addition to mentorship of personnel at POC sites and mandatory accreditation of VL laboratories.

The technology for VL monitoring is rapidly evolving and industry faces a diversity of challenges. On the one hand, there are considerable efforts being made to develop POC tools and to improve and validate DBS for stabilization of samples during their transport to centralized laboratories. However, although several companies are investing in the development of POC VL tools, none are currently listed on the WHO list of prequalified diagnostic products (see Table 1). Development is proceeding for centralized, high-sensitivity and high-throughput instruments, as excellence in diagnostics obviously remains a goal. Many tests from several manufacturers are currently under review by the WHO Prequalification of Diagnostics Programme, several being POC tests (see Table 2).
The inclusion of VL monitoring as a routine approach in the 2013 WHO guidelines[1] will hopefully help boost the development of new tests and their prequalification by WHO.

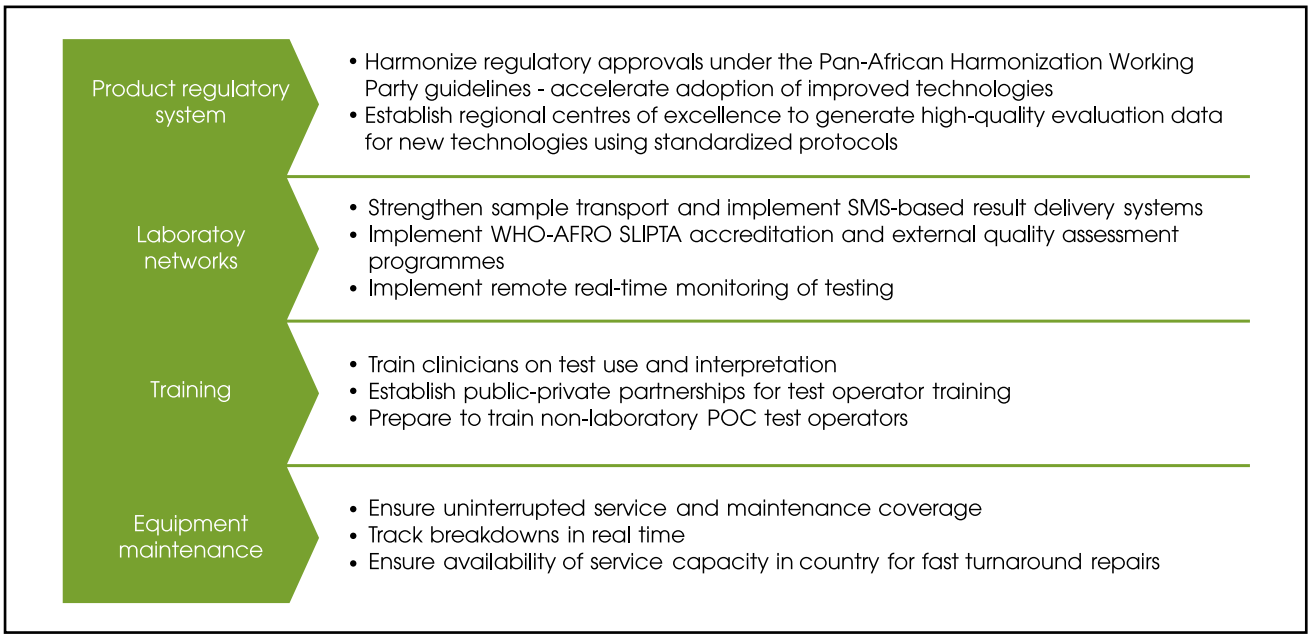


Figure 5. Recommendations for the strengthening of VL laboratory resources. SLIPTA: Stepwise Laboratory Quality Improvement Process Towards Accreditation. Source: Trevor Peter, IAS-ILF Symposium, "Expanding access to viral load monitoring in resource-limited settings", Lusaka, Zambia, 2014

However, one of the challenges lies in the cost effectiveness of low-throughput POC technologies and the continued need for three levels of laboratory: centralized (high throughput), regional and POC (low throughput, rapid turnover). Cost-effectiveness studies are not available on the use of VL POC technologies.

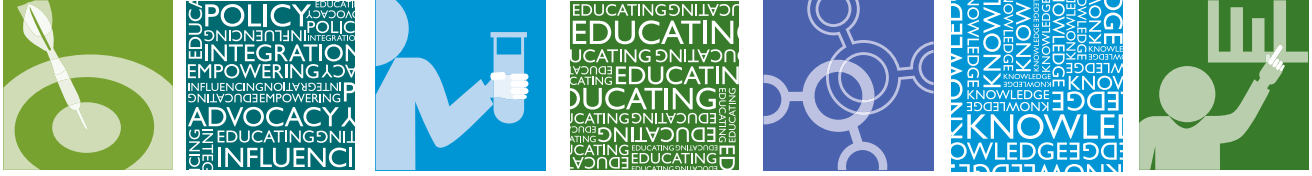
Until POC tools are available, the use of DBS is a potentially good approach to facilitate the transport of samples from remote locations to centralized laboratories. However, their lower sensitivity, as well as contamination from viral DNA (whole blood vs. plasma only), have caused some debate regarding the effective threshold defining virologic failure when using this type of sample. It is hoped that thresholds for the use of DBS samples similar to those for plasma samples could be possible in the future. The same is true, to a lesser extent, for different platforms (i.e., different instruments). Pooled testing, where samples are pooled in groups of five or 10 and only analyzed individually if VL is detectable, is also a promising approach, especially in highly virologically suppressed populations. The use of DBS, pooled testing and, later, POC tools warrants better guidance from normative bodies once enough data on their effectiveness is available.

Company	Product
Abbott Molecular	Abbott RealTime HIV-1 (manual) Abbott RealTime HIV-1 (m2000sp) Abbott RealTime HIV-1 (m24sp) Abbott RealTime HIV-1 Qualitative (manual) Abbott RealTime HIV-1 Qualitative (m2000sp)
bioMérieux	NucliSENS EasyQ HIV-1 v2.0 (automated) NucliSENS EasyQ HIV-1 v2.0 (semi-automated)
Roche Molecular Systems	COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0 (TaqMan 48) COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0 (TaqMan 96)
Siemens Healthcare Diagnostics	VERSANT HIV-1 RNA 1.0 Assay (kPCR)

Table 1. List of VL instruments prequalified by WHO. Source: WHO list of prequalified in vitro diagnostic products, 2014-05-23 (link)

Company	Product
Biocentric	Generic HIV Charge Virale (manual) Generic HIV Charge Virale (automated) Generic HIV DNA Cell
Cepheid	Xpert HIV-1 Quant with GeneXpert Instrument Systems (GeneXpert DX) Xpert HIV-1 Quant with GeneXpert Instrument Systems (GeneXpert Infinity-48s) Xpert HIV-1 Quant with GeneXpert Instrument Systems (GeneXpert Infinity-80) Xpert HIV-1 Quant Assay
Diagnostics for the Real World	SAMBA HIV-1 Semi-Q test
Roche Molecular Systems	COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (Taqman 48) COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative Test, version 2.0 (Taqman 96)
Wave 80 Biosciences	EOSCAPE-HIV Rapid RNA Assay System

Table 2. List of VL instruments under review by the WHO Prequalification of In Vitro Diagnostics Programme. Source: Status of applications to the prequalification of in vitro diagnostics programme, 2014-05-23 (link)



5. Community perspective

Routine VL monitoring is not available in most sub-Saharan African countries. Indeed, except for South Africa, sub-Saharan African countries use VL monitoring, in the few cases where it is available, mainly for confirmation of virologic failure after the patient has reached either immunologic or clinical failure, or both (this is a minimal selective approach). This results in patients (and clinicians) experiencing a lack of awareness concerning VL monitoring. This negatively affects demand and scale up, and the few patients who require VL monitoring often have to pay the high costs themselves in addition to having to travel long distances to a centralized laboratory. This adds to the long response time that many experience, although the problem can be addressed partially by using SMS-based communication.

Countries should move away from considering VL monitoring to be an expensive luxury and rather invest in scaling up. To do so, there is a need for small, decentralized, solar-powered laboratories where samples can safely be stored prior to transport, via an improved cold chain, to centralized laboratories. Needless to say, POC approaches offer a great opportunity for improving access.

6. Closing remarks

VL monitoring is gaining importance in detecting treatment failure in patients on first-line regimens. Appropriate VL monitoring can positively influence the long-term survival of HIV patients in RLS. For better management of patients on ART, it is essential to guarantee early detection of viral resistance, improve adherence and diagnose treatment failure early in order to switch regimens. Some barriers to implementing VL monitoring in RLS are the need for laboratory structures, issues with sample collection and transportation to central laboratories and, obviously, costs of individual tests. Alternatives, including the use of DBS, pooled samples and POC approaches, are being evaluated and can help make the process more manageable, especially for patients living in rural areas. LMICs can help bring prices down by consolidating the demand for VL monitoring and improving procurement practices. As stated in the 2013 WHO guidelines[1], the lack of monitoring capabilities (CD4 and/or VL) should not prevent ART initiation, which should be the priority. However, there should also be no compromise on quality when this is possible. VL monitoring does bring benefits to patients as it is the best predictor of virologic failure. Expanding access to this monitoring tool should be the way forward, but not without systematically acting on detectable VL (i.e., improving adherence and/or switching from a failing regimen to a second- or third-line regimen).

Appendix 1: Agenda

Expanding access to viral load monitoring in resource-limited settings

Symposium in conjunction with INTEREST
Organized by the International AIDS Society-Industry Liaison Forum

Monday, 5 May 2014, 16:00 – 18:00
InterContinental Hotel Lusaka, Lusaka, Zambia

16:00 - 16:05	*Welcome and introduction* *Co-Chairs:* Linda-Gail Bekker (Desmond Tutu HIV Foundation, South Africa) Catherine Hankins (AIGHD, Netherlands)
16:05 - 16:25	*Overview presentation I* *Clinical rationale for VL monitoring in RLS* François Venter (University of the Witwatersrand, South Africa)
16:25 - 16:45	*Overview presentation II* *Cost-effectiveness of VL monitoring in RLS* Linda-Gail Bekker (Desmond Tutu HIV Foundation, South Africa)
16:45 - 17:05	*Overview presentation III* *Laboratory challenges to VL monitoring in RLS* Sue Aitken (Ndlovu Research Consortium, South Africa) *Slides by* Trevor Peter (ASLM, Botswana)
17:05 - 17:15	*Community perspective on VL monitoring in RLS* Michael Gwaba (CITAM+, Zambia)
17:15 - 17:40	*Moderated panel discussion* *Challenges and solutions to VL monitoring in RLS* *Moderator:* Catherine Hankins (AIGHD, Netherlands) *Panellists:* François Venter (University of the Witwatersrand, South Africa) Linda-Gail Bekker (Desmond Tutu HIV Foundation, South Africa) Sue Aitken (Ndlovu Research Consortium, South Africa) Michael Gwaba (CITAM+, Zambia) Robert Luo (Roche Molecular Systems, USA)
17:40 - 17:55	*Questions from the audience*
17:55 - 18:00	*Conclusion* *Co-Chairs:* Linda-Gail Bekker (Desmond Tutu HIV Foundation, South Africa) Catherine Hankins (AIGHD, Netherlands)

IAS-ILF Mission

This meeting was organized by the International AIDS Society-Industry Liaison Forum (IAS-ILF).

The IAS-ILF is a mechanism to inform and support collaboration and partnership between industry and the IAS. Guided by a strong, multi-stakeholder advisory group, it performs this broad task by regularly providing opportunities for industry to understand the IAS's interests and priorities, and vice versa, seeking common ground to enhance the impact of our response to HIV and related co-morbidities.

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