

Programming of laboratory investments - with a focus on viral load testing

New Funding and Reprogramming

Version 3: August 2014

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This document has been developed by the Global Fund in the context of an initiative with PEPFAR to produce a joint action plan covering programmatic, finance and procurement areas to support the expansion of viral load testing as recommended by WHO in 2013.

The main objective of the document is to complement the guidance on the implementation of viral load technologies which has been published by WHO and partners¹. It has been reviewed internally and externally by a range of partners and collaborating institutions (CDC, PEPFAR, UNITAID, USAID, WHO).

Please direct any requests for clarification or in-depth information - or suggestions for improvement to Martine Guillerm (Martine.Guillerm@theglobalfund.org) or Martin Auton (Martin.Auton@theglobalfund.org).

¹ Technical and Operational Considerations for Implementing HIV Viral Load Testing. 2014. WHO. Available at: <http://www.who.int/hiv/pub/arv/viral-load-testing-technical-update/en/>

1. Purpose of the document

This document has been developed to help prepare and/or review robust, prioritized and costed funding requests; to support grant design; and support grant implementation for investments in laboratory technologies.

Focused on the 2013 WHO recommendation for the expanded use of viral load (VL) testing as the preferred monitoring approach to diagnose and confirm ARV treatment failure², the approach can be applied to funding requests for other laboratory investments – and it is planned to evolve the document to have broader applicability over the next few months. The document particularly supports the development of funding requests where comprehensive Viral Load Implementation Plans and/or National Laboratory Strategic Plans are not developed or are outdated.

Section 4: “Gathering information related to Viral Load Testing” is organized in three specific sections that detail the elements to consider and describe when defining the scope and shape of funding requests and implementation plans – this document builds on the 2014 WHO recommendation on viral load testing³ which advises that expansion should be context specific; that a phased approach to VL testing is implemented; and that there are various technical choices that can be combined. It is expected that a detailed analysis of the context where VL testing will be implemented is attached to any funding proposal, highlighting the gaps and the barriers to be overcome.

Complementary actions also being undertaken involve negotiations with suppliers for improved procurement and contracting modalities including better service and support. In this light, grant recipients are encouraged to model different scenarios of test unit pricing as proposed in section 4i) so that during any prioritization of interventions, it can be determined at what level viral load testing may become affordable according to the specific context and other priorities. The aggregated numbers for different scenarios and strong implementation plans will also facilitate the negotiation for optimal pricing and contracting conditions with the manufacturer.

2 Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. WHO. 2013. <http://www.who.int/hiv/pub/guidelines/arv2013/en/index.html>

3 Supplement to the 2013 Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. WHO 2014. http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013supplement_march2014/en/

It is recommended that funding proposals should include the following:

- Current and up-coming revised testing algorithms for the ARV population (with or without priority segments of population)
- Summary of testing targets for the 4 coming years
- Mapping of existing testing capacities for molecular technologies (EID and VL) and CD4
- **Draft phased VL implementation plan (pilot or broader)**
- List of the proposed equipment (lab based and/or lower throughput POC testing platforms as relevant) with quantities, and placement approach
- Comprehensive budget with various costing scenarios for implementation

2. Background information

WHO recommendations

In March 2014, WHO issued additional guidance⁴ :

That re-confirms HIV viral load testing is the preferred monitoring approach to diagnose ART treatment failure and scale-up is context specific, and programme managers and laboratory experts need to collaborate closely at the national level.

- That recommends a phased approach for implementation; and that there are options for phasing in viral load testing that will increase as new technologies become available or are approved - including sample-collection and transportation tools and launch of lower throughput (more-point of care) technologies.
- That CD4 testing for treatment monitoring can be reduced except where viral load is not available. CD4 testing is still necessary to guide ART initiation.
- That selection of a platform should include in addition to cost: robustness, accuracy at threshold of clinical importance (less than or equal to 1000 copies/ml).
- That the testing or collection site (depending on sample transport system) has the ability to ensure expeditious delivery of samples to the viral load laboratory.
- That the availability of point-of-care technologies over the next several years may impact early infant diagnosis and treatment monitoring.
- That further detailed technical guidance will be provided.

Global Fund and PEPFAR support to the scale-up of viral load testing

As part of the joint initiative with PEPFAR to support the scale-up of viral load testing as recommended by WHO, the following principles were developed which can be translated to programmatic, financing and procurement considerations for viral load investments:

1. Do no harm to existing programmes
2. Analyse the impact of scale-up on existing budgets
3. Optimize existing equipment and investments
4. Understand the current diagnostic marketplace
5. Develop a quality management/assurance programme that supports scale-up
6. Consider the context of the programme as introduction and scale-up take place

More details about these principles are provided in Annex 1.

Existing limitations should not block the whole VL adoption process as stepwise solutions and capacity building embedded within an implementation strategy can be laid out. Therefore, countries can start programs commensurate with existing resources and grow their programs as additional capacity becomes available.

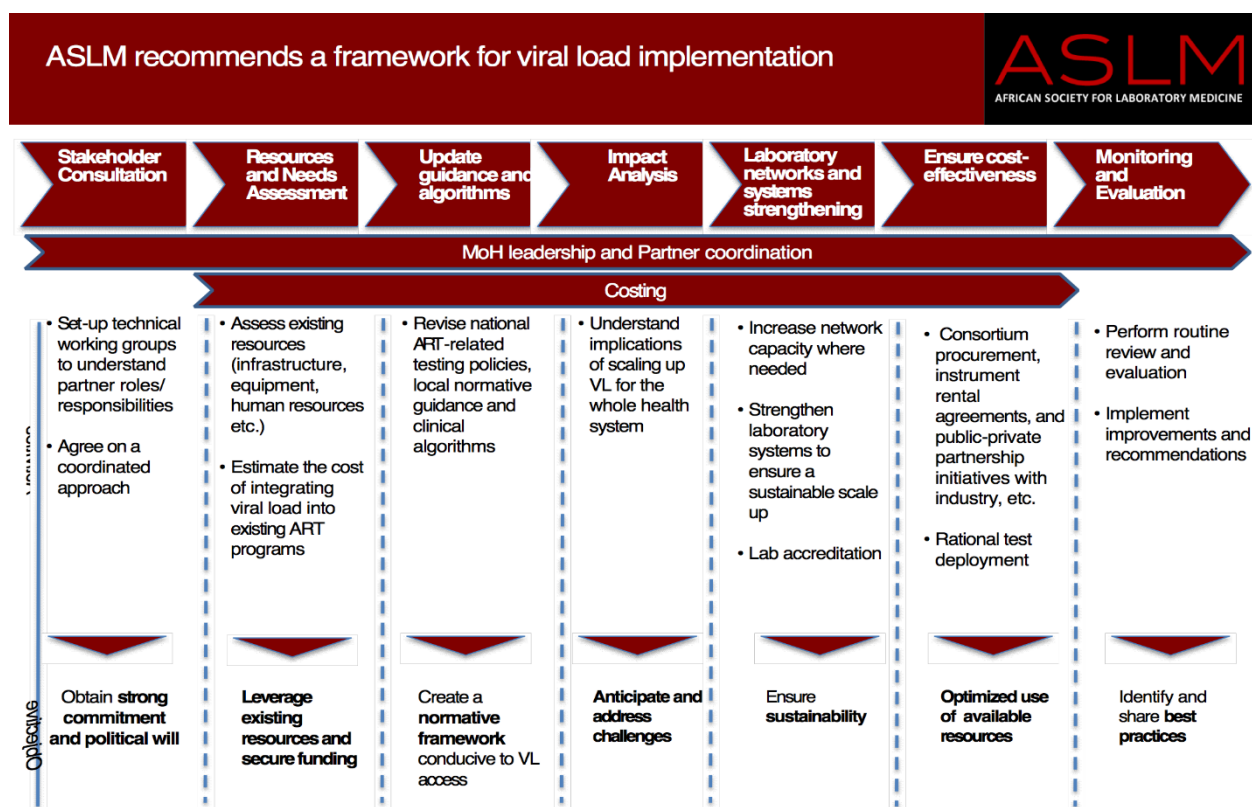
⁴ It is highly recommended to refer to section 7 of the referred document. Supplement to the 2013 Consolidated Guidelines on the use of antiretroviral drugs for treating and Preventing HIV infection. WHO.2014; http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013supplement_march2014/en/

3. Integration and Programmatic Approach

As described above, viral load testing has been recognized as a critical component of HIV programmes by WHO. It is however essential that programmes should be built on the needs for treatment monitoring and adherence support to either serve the general ART population or initially target specific vulnerable groups of patients on ARVs. Viral load services should also be properly integrated into laboratory and clinical services to ensure that increased access to VL testing results in clinical decisions and improved linkages to care.

A strategic vision using a framework for activities is strongly recommended. The document developed by the African Society for Laboratory Medicine (ASLM) for implementation of a VL testing plan is proposed here for advice. Good preparation, clear policies/guidance on use of viral load consistent with the WHO 2013 guidelines and strong commitment of the team in charge of the project are key components of success.

Figure 1: Framework for Viral Load Implementation⁵



⁵ ASLM. Viral Load Testing Consultation meeting, 2013. <http://www.aslm.org/resource-centre/hiv-viral-load-testing/>

In addition to the selection of appropriate technologies, the funding requests and implementation plans should consider:

- the needs and investments in laboratory infrastructure;
- the needs for general lab equipment and related reagents and consumables;
- staff training;
- transportation system for the samples or referral system for the patients to reach the lab or sample collection facilities;
- results delivery;
- routine maintenance of equipment;
- and supportive quality assurance systems⁶.

Even if the first phase of an implementation plan is initially limited to a portion of the population or a specific geographical area, the lessons learned during the preparation and launching phases will provide an in depth understanding of the many challenges to be overcome. Progressively the full range of components of such a plan will be introduced and the different stakeholders involved in the process will capture a refined understanding of the benefits of a viral load testing program.

Technology components and available systems

The measurement of HIV viral load can be quantitative to monitor the efficacy of the treatment and/or qualitative to diagnose HIV paediatric infection. Dual testing platforms offer capacity for both EID and VL testing. VL commodities include a set of equipment, consumables and reagent kits. The current laboratory-based equipment is generally expensive (high capital cost) and demanding in terms of maintenance, staff qualification, quality assurance processes, and procurement and supply management.

The market offerings for laboratory-based VL testing systems are quite diverse:

- Closed high-throughput testing platforms are the most common, which can be used only with proprietary reagent kits and consumables. In this case, the proprietary equipment, reagents and consumables are procured from the same company. This approach also requires some third party consumables that can be procured from general laboratory vendors.
- Open testing platforms involve a generic piece of equipment that can be used with reagent kits and consumables produced by several third party suppliers. Choice among open testing platforms is currently limited due to the lack of stringently evaluated and approved products. Typically an open platform system includes specific equipment for extraction and amplification/detection.
- Some lower-throughput/point-of-care systems are currently reaching the final steps of development, and undergoing evaluations and regulatory assessment.

It is important to recall that viral load technologies are sophisticated pieces of equipment and the reagent kits need to be properly stored, maintained and used by trained staff in well-organized lab facilities – it is also essential that provisions are made to procure adequate maintenance contracts with manufacturers for the life of the testing platform.

Further descriptions of current and pipeline technologies are described by UNITAID⁷ and Médecins sans Frontières⁸ in their publications and updates.

⁶ See Global Fund Information Note on Health Systems Strengthening for Global Fund Applicants: “Improving laboratory infrastructures and systems”; March 2014; <http://www.theglobalfund.org/en/fundingmodel/support/infonotes/>

⁷ HIV/AIDS diagnostics technology landscape annual report with semi-annual update. UNITAID. <http://www.unitaid.eu/en/resources/publications/technical-reports>

⁸ Putting HIV Treatment to the Test: A Product Guide for Viral Load and Point-of-Care CD4 Diagnostic Tools. MSF. 2013; <http://www.msfacecess.org/our-work/hiv-aids>

Understanding and comparing viral load pricing and contracting

Presentation of pricing and contracting can often be complex with many permutations of what is included or excluded. This section provides an overview of the elements to consider when trying to understand and compare pricing quotations from suppliers and contracting information – this section will evolve with subsequent versions of the support document.

Special attention should be paid to the following elements:

- What is included/excluded in the quotation
- Type of acquisition; ownership vs leasing vs bundled pricing (including service and maintenance – or other running costs into the price of reagents)
- Incoterms: trade terms outline the responsibilities of the manufacturer and purchasers with regards to transport, international freight and insurance costs
- Currency
- Different levels of pricing based on country income level and/or geographical location (tiered pricing)
- Pricing presented per test
- Differences in equipment and reagent kits specifications
- Minimum commitments or volumes associated with test pricing or other terms
- Included equipment with ancillary equipment required to run testing

These are further detailed in Annex 2.

4. Gathering information related to Viral Load Testing

Investments in viral load should be supported by a robust implementation plan. The following sections include the elements to consider, shape the flow of thinking and describe when defining the scope of funding requests and implementation plans. Not all the features outlined below are relevant for all the countries/context, investment case for VL testing platform should be framed accordingly.

Investment in VL testing platform when properly devised is expected to be counter balanced by a medical and public health impact in a mid-term perspective.

i) Contextual information

The starting point for the development of an implementation plan for VL testing should be the pace of progress of the national HIV/AIDS programme in the country. The key aspects to consider are listed below. Adequacy between the needs for VL testing, the capacities of the laboratory services and the established treatment and testing targets are of critical importance.

A. The HIV disease burden in the country

- Country total population
- Prevalence of HIV infection
- Distribution (geographical, urban vs rural, at risk populations)
- Prevalence of resistance

B. The national HIV/AIDS programme

- Number of patients under ARV treatment
- Number of patients currently under first-line ARV treatment
- Number of patients currently under second-line ARV treatment
- Current national treatment coverage: percentage of patients treated over the total number of patients in need of treatment
- Current protocol for treatment monitoring:
 - CD4 testing: frequency; type of equipment
 - VL testing: initiation date if currently implemented; number of VL test performed last year(s)
 - For suspected treatment failures only
 - For routine treatment monitoring, if so with which frequency
- If VL testing has been introduced, describe the accompanying activities related to

- clinician/patient literacy and adherence support
- Collection and transportation of samples for VL testing: describe methodology (sample types) and geographical coverage
- Testing for HIV Early Infant Diagnostic (EID): number of EID tests performed last year and testing coverage.
- Tuberculosis, Hepatitis B/C and Sexually Transmitted Infections (STI) testing already offered to the patients under ARV treatment: provide detail on lab strategy. Are the testing platforms being used for VL in the country polyvalent, with capacities to conduct TB, Hepatitis and STI testing?
- Links, if existing, between settings involved in routine VL testing and the ones focusing on research purposes

C. Laboratory services and experiences with HIV testing and monitoring

This section reflects that VL testing services are not built in isolation from the national laboratory system. Implementation of VL services should derive from the organization and the role played by the laboratory services and Ministry of Health. A number of implementing partners (agencies and stakeholders) may also be involved in the provision of similar or related laboratory services. This will have an impact on the strategy meant to offer viral load testing.

- Number of testing sites with functional capacities for HIV diagnostics
 - For adults (rapid diagnostic tests -RDTs, ELISA)
 - For children (EID)
- Average number of working hours/ day in the laboratories to be involved in the VL plan
 - In the laboratories with VL capacities
- Number of laboratories in the country (or region being supported)
 - with capacities for CD4 testing
 - with capacity for viral load testing (public sector and private/NGOs)
- Current strategy for deployment of VL capacities/utilization in the country:
 - Centralized with one reference centre linked to peripheral sites via sample transportation system(s)
 - Decentralized to regional or district level together with multiple testing sites
- Number of technicians trained for VL testing; number trained for EID testing
- Sources of VL testing equipment:
 - VL assay(s) that have been adopted in the country program: explain what VL testing system is being used (indicate the commercial name of the platform)
 - Indicate what are the molecular testing platforms available in the country (used to test other pathologies such as hepatitis, TB, etc.). Indicate if GeneXpert machines are already present⁹
- Country plan for introduction of lower throughput/Point-of Care equipment for VL testing: provide information if this has been already investigated and planned.
- Current average timeline for reception of VL testing results after sample collection:
 - At reference level
 - At district level
- Open source testing platforms for VL testing or other molecular testing (extraction systems, thermocyclers, centrifuge, ELISA plate reading, etc.). Provide details if that strategy has been implemented in the country.
- Main problems encountered and overcome regarding the following procurement steps for VL testing platforms:
 - choice of testing platform,
 - choice of contracting options among the ones offered by commercial companies (an outline of some of these can be found in Annex 2)

⁹ GeneXpert machines have been introduced in many countries for diagnostic of tuberculosis and detection of Rifampicin resistance. The company is developing specific cartridges for VL testing, the product is not yet available commercially nor stringently evaluated.

- training for the use of viral load and EID testing platforms
- in country support by commercial companies (maintenance and servicing)
- stock-out of reagents, forecast of needs
- breakdown of equipment
- definition of a pricing strategy, negotiations with commercial companies
- accreditation process for the laboratory settings: explain whether this process has been initiated.
- National registration: process, envisaged challenges

ii) Viral Load implementation and scale-up plan

An implementation plan for VL testing at country level should be based on a multi-component approach. A logical organization and well prepared phased approach will enhance the uptake of VL testing by the various stakeholders in the country: clinicians, patients, lab personnel and staff responsible for procurement and supply.

- A. Plan for implementation or scale-up of VL testing prepared at national level
 - Brief description of the existing plan or plan being prepared in the country
Implementation plan should be devised through consultation with stakeholders and in-depth analysis of specific strengths and weaknesses.
 - Scheduled initiation date
 - Time period covered by the plan
- B. Testing algorithm clearly defined.
 - Intended use for VL testing (detection of treatment failure and/or routine monitoring)
 - Frequency of VL testing
- C. Targets for implementation and/or scale up of VL testing
 - Target for treatment coverage for the next 3 years
 - Target population for VL testing: describe the specific segments of the population (geographical and/or specific populations) who will benefit from the viral load testing capacities
- D. Revision of protocol for adherence support or scaled-up in relation to the expansion of VL testing capacities. Provide information.
- E. Second line treatment options
 - Options for 2nd line treatment available in the country
 - Financing and procurement provisions to cover more patients on 2nd line treatment with the expanded monitoring based on viral load testing: provide details
- F. Strategy for implementation/scale up of viral load testing
 - VL testing laboratory strategy: centralized testing vs decentralized. Explain rationale.
 - Testing sites: provide mapping of identified future testing sites.
 - Preparation of the testing sites: HR (quantification for additional trained laboratory technicians), training, rehabilitation of lab spaces if required, refurbishment of labs especially for air conditioning, availability of centrifuges, storage capacities and cold chain; description of planned or completed activities.
 - CD4 testing is now recommended to be phased out in the context of treatment monitoring except where there is no viral load testing¹⁰. Therefore a plan to progressively transition from CD4 testing to VL testing (redirection of funding between CD4 and VL testing, of lab workforces, of testing algorithms, etc.) is required. Briefly explain the scheduled steps. Synergies and alignment with the UNITAID Accelerating Access to Innovative Point-of-Care HIV Diagnostics project including transition to other funding sources for the procurement of consumables¹¹

¹⁰ Supplement to the 2013 Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. WHO. 2014. http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013supplement_march2014/en/

¹¹ Ethiopia, Kenya, Malawi, Mozambique, Tanzania, Uganda and Zimbabwe. <http://www.unitaid.eu/en/accelerating-access-to-innovative-point-of-care-hiv-diagnostics>

might be of interest.

- Provide brief description of sample transportation system (new or enhanced) together with the selected tools (use of DBS or other sampling techniques).
 - Enhancement of delivery of the testing results to the relevant recipients: describe the considered strategy (communication tools, referral systems).
 - Describe the QA components for the VL testing activities.
 - Optimization of the use of the existing testing platforms in the country to reach their full capacity: describe what options have been considered (by modifying the referral system of the patients/samples, by modifying the workflow of the laboratories, etc.). Creating a link between the existing capacities for EID testing and the plans for VL testing is recommended, typically by using the equipment for EID to scale-up the capacities for VL testing using relevant reagent kits. Describe how this linkage has been considered in the plan
 - Phased roll-out of testing capacities through a tiered approach¹² between the different levels of laboratory services; describe the steps included in the strategy.
- G. Point of care (POC) VL testing is considered as complementary to conventional laboratory-based equipment (existing technologies). Up-coming POC technologies will have the capacity to enhance a VL plan mainly built on laboratory based testing platforms¹³
- If this point has been considered in the implementation plan, provide information on the preferred technologies and their intended uses.

iii) Selection, procurement and contracting

Selection and purchase of the appropriate Viral Load testing platform is a challenging phase of implementation. The features of the various systems should be carefully evaluated to understand which best meets the needs of a specific context and demonstrates best value. The information collected in this section will be critical for the establishment of a functional supply chain linking the company to the laboratory services, the patients and the testing results.

While standardization and rationalization are critical at country level, the selection of an appropriate mix of platforms presents some advantages in terms of procurement and lab management. Typically the combination will depend on the feasible testing demand; specifications of the platforms (and associated sample collection medium); utilization of existing testing capacity; functionality of referral and transport mechanisms; robustness; and cost.

A. Selection

- Simplified descriptions of the main commercial technical options together with an analysis of their characteristics have been published¹⁴.
- Forecast of testing numbers for the next 3 years will help in assessing specific technical requirements.
- Not all the VL laboratory based technologies can be deployed outside of central/reference laboratories. Describe the tiered approach for the laboratory system and the corresponding selected equipment including sample transport system and deployment of lower throughput/point of care systems.
- Is the throughput of the selected equipment proportional to the number of tests forecasted? Have lower throughput open systems for VL testing requiring a lower initial investment been considered?
- VL technologies may have variable performance on specific HIV subtypes. A

12 Supplement to the 2013 Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. WHO. 2014. http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013supplement_march2014/en/

13 UNITAID technical reports. HIV/AIDS Technology Landscape. 2013. <http://www.unitaid.eu/en/resources/publications/technical-reports>

14 UNITAID Technical Reports. HIV/AIDS Technology Landscape. 2013. <http://www.unitaid.eu/en/resources/publications/technical-reports>

search for data related to the evaluation of the selected testing systems in the country or region is recommended to consolidate the choice of equipment. Nevertheless the multiplication of local/regional evaluations is not recommended.

- The selected VL technology should be validated¹⁵ for each sample type intended to be used. Reviewing the information related to the performance of the selected equipment for the selected sampling strategies is important.
- Choice of the required VL testing system(s) and global policy:
 - Assess whether the selected VL testing system(s) comply with the Global Fund's QA policy¹⁶
 - Assess if the selected VL testing system(s) has already been prequalified by WHO or approved by a SRA¹⁷
- Provide details about the provision and budget for QA systems and staff training.
- Description of the distribution channels for equipment and reagent kits.
- Cold chain requirements (fridges, freezers, deep-freezers, space for storage) supporting the use of the selected systems and corresponding sample collection and transportation systems: describe corresponding provisions.
- Requirements for maintenance of the equipment. Some pieces of equipment are self-maintained or require a generic approach but others can only be maintained by the manufacturer or by specialized staff trained by the company. This should be covered by a maintenance contract.
- Registration of the equipment in the nationally approved list of equipment (if required)

B. Contracting and pricing strategy. The following options which are further detailed in annex 2 should be carefully assessed prior to signature of any contractual agreement with a company:

- Specific provisions for staff training, routine maintenance for:
 - The equipment already being used in the country
 - Any new equipment to be procured
- Contracting options for the equipment: purchasing or leasing.
- Provisions for a start-up package including installation, pre-service, calibration, in-service training and a 3 month reagent kit and for replenishment packages including reagents and consumables.
- Specific provisions for preventive maintenance, spare parts, replacement strategy of defective equipment if appropriate
- Supplier's capacity in terms of country support.
- A situation in which there is some degree of competition¹⁸ for the procurement of the main items (technical platforms and/or reagents) is strongly promoted. A minimum of two different VL testing platforms are recommended in each country. Some specific contexts might sustain a rationale for a unique testing platform to be used in the country.
- Specific language about INCOTERMS, committed testing volumes, assistance provisions included in the price per test or price per equipment proposed.
- Pricing scenarios: As mentioned in the background section the Global Fund and PEPFAR are undertaking negotiations with suppliers for improved procurement and contracting modalities including better service and support that are targeted to be

15 Validation should be conducted as stipulated in the Global Fund's QA policy.
http://www.theglobalfund.org/documents/psm/PSM_QADiagnostics_Policy_en/

16 Global Fund's policy for procurement of diagnostic products requires the VL testing equipment to be authorized for use by one of the Regulatory Authorities of the Founding Members of the GHF when stringently assessed (high risk classification). For comprehensive information please consult the following link :
http://www.theglobalfund.org/documents/psm/PSM_QADiagnostics_Policy_en/

17 http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

18 ASLM Viral Load Testing Consultation meeting report. 2013. available at <http://www.aslm.org/resource-centre/hiv-viral-load-testing/>

developed during quarter 3 and 4 of 2014. In this light, grant recipients are encouraged to model different scenarios of test pricing so that during any prioritization of interventions, it can be seen at what level viral load testing may become affordable according to the specific context and other priorities. Recipients are therefore encouraged to develop budget projections based on at least 3 or 4 different pricing levels between USD 10 and USD 50 per test.

Annex 1: Guiding principles for the scale-up of Viral Load testing

1. Do no harm to existing programmes: expanding viral load should not jeopardize scale-up of ART services to those currently eligible under WHO guidance. It is expected that not all countries will introduce or scale-up at the same rate. The introduction of virologic monitoring should not detract from Early Infant Diagnosis (EID) testing that uses the same platforms.
2. Analyse the impact of scale-up on existing budgets: the scale-up should have as little impact on overall laboratory and treatment budgets as possible. Careful consideration of a variety of trade-offs will need to be made including clinical monitoring protocols, machine placement and choice of technology. Consideration of budgetary impacts for virologic testing should span several years, as initial costs may be higher, with benefits accruing later.
3. Optimize existing equipment and investments: expanding the capacity for virologic monitoring will require optimal use of current diagnostics and platforms and maximizing previous investments. Innovative approaches to support laboratories, transfer specimens and communication of results should be adopted to support both previous and future investments.
4. Understand the current diagnostic marketplace: the introduction of additional technologies should take place in a rational manner, optimizing the opportunities of pooled volume negotiations of the large current large financiers/ purchasers (Global Fund, PEPFAR and the Government of South Africa).
5. Develop a quality management/assurance programme that supports scale-up: the platforms, testing algorithms and lab systems should be embedded within an appropriate system for quality assurance at the global and national levels
6. Consider the context of the programme as introduction and scale-up take place: The expansion of viral load should take into consideration local HIV treatment guidelines and epidemiology. Virologic testing could be phased-in through prioritization of special populations or geographic areas. Additionally the role and amount of donor supported CD4 testing needs to be considered both in the short and long term.

Annex 2: Understanding viral load pricing and contracting

Below is an overview of the elements to consider when understanding and comparing pricing and contracting information including when receiving information from commercial companies. Offers should be simple and transparent to enable a proper evaluation of value for money. Importantly the differences in specifications of the testing platforms should be kept in mind when making comparisons:

- Automated/manual machine
- Throughput: number of samples per run; time for results
- Value of ability to run other tests on the same platform (polyvalent systems)

Main provisions to assess:

- What is included/excluded
 - Equipment – for purchase; or non-purchase placement
 - Reagents – are all reagents included? What other consumables are necessary¹⁹?
 - Installation and training; initial warranty
 - Extended warranties; maintenance; ongoing support and training
 - Insurance for rental/placement models
 - Other items offered – e.g. laboratory equipment; refrigerators; freezers
 - Additional cost levied by distributors (travels, training, etc...)
- Type of acquisition; ownership
 - Purchase vs lease
 - Reagent rental with analyser placement
 - Threshold pricing depending on output; consequences of not meeting the anticipated or contracted thresholds
- Shelf life of reagents kits and storage temperature requirements
- Incoterms are trade terms that outline the responsibilities of the manufacturer and purchasers with regards to transport, international freight and insurance costs - the price difference between different incoterms could be 10-20% or more depending on the weight, volume, shipping method; and temperature control requirements. The main incoterms are described below:
 - EXW: EX -Works: The selling price reflects the price at the manufacturing site – the buyer is responsible for all insurance and freight costs.
 - FOB: Free on Board: The seller is responsible for transport to the port of shipment (in the exporting country); the buyer is responsible for international shipping and insurance.
 - FCA Free Carrier (named place of delivery): The seller to deliver goods to a named airport, terminal, or other place where the carrier operates. Costs for transportation and risk of loss transfer to the buyer after delivery to the carrier.
 - CIF: Cost, Insurance, and Freight: The seller is responsible for freight to the destination port and includes this cost in the selling price; the buyer is responsible for insurance once goods are loaded on the carrier and all costs after arrival in port.
 - DAP: Delivered at Place: The seller is responsible for insurance and freight to a named place of destination; the buyer assumes responsibility for insurance and transport, import duties.
- Currency
 - Conversion to one currency for comparison purposes
 - Contractual management of currency fluctuations
- Different levels of pricing based on country income level and/or geographical location (tiered/differential pricing)
- Price per test: which incoterm is used; does it include the total price of all reagents, buffers, and controls needed; what other consumables are necessary.
http://www.who.int/entity/diagnos_of_diagnostics_finalversion.pdf?ua=1

¹⁹ For information, consult WHO. 2014. Manual for Procurement of Diagnostics and Related Laboratory Items and Equipment;

http://www.who.int/entity/diagnostics_laboratory/procurement/131024_procurement_of_diagnostics_finalversion.pdf?ua=1

Annex 3: References

WHO

Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. WHO. 2013. <http://www.who.int/hiv/pub/guidelines/arv2013/en/index.html>

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