INTERIM TECHNICAL UPDATE

TECHNICAL AND OPERATIONAL CONSIDERATIONS FOR

IMPLEMENTING HIV VIRAL LOAD TESTING

JULY 2014

ACCESS TO HIV DIAGNOSTICS

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ABBREVIATIONS

ART	antiretroviral therapy
CAP	College of American Pathologists
CD4	cluster of differentiation 4
CE	European conformity
EDTA	ethylenediaminetetraacetic acid
IVD	in vitro diagnostic medical device
PCR	polymerase chain reaction
SLIPTA	Stepwise Laboratory Quality Improvement Process towards Accreditation
SLMTA	Strengthening Laboratory Management towards Accreditation
TB	tuberculosis

EXECUTIVE SUMMARY

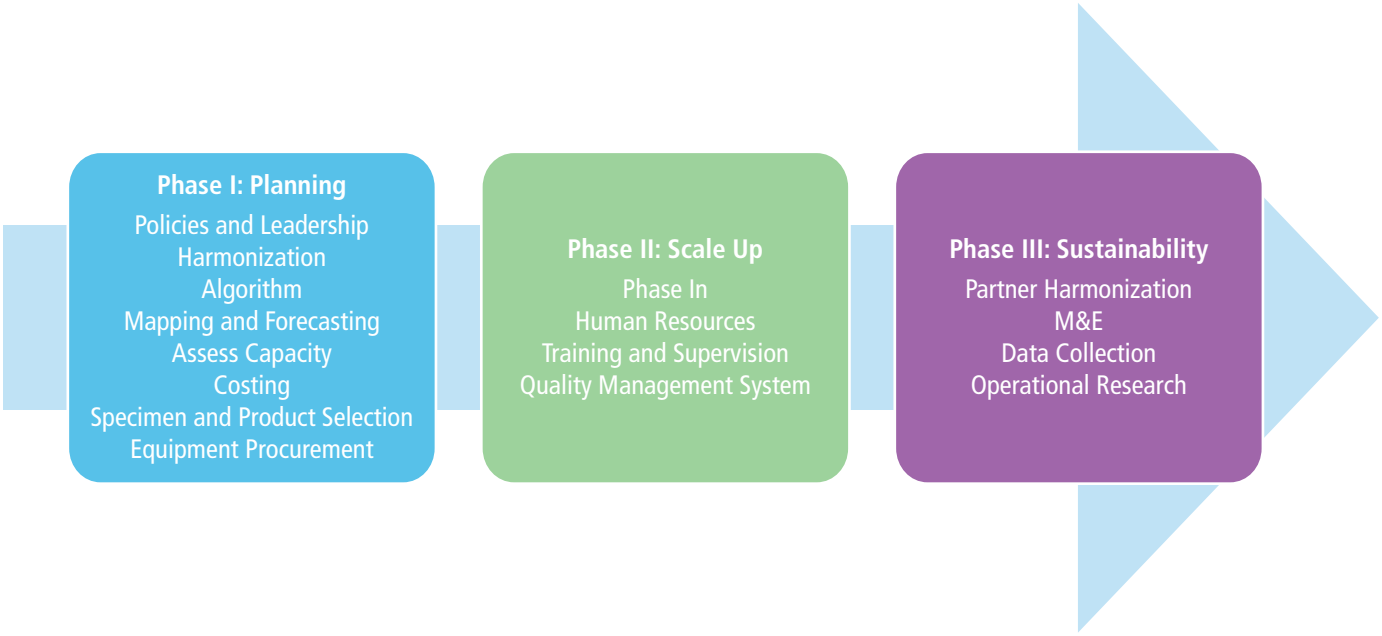
This publication provides high-level guidance on implementing and scaling up HIV viral load testing programmes for health ministries and implementation partners, using a three-phased approach: (1) planning; (2) scale-up; and (3) sustainability. The guidelines for managing antiretroviral therapy (ART) issued by WHO have recognized the importance of viral load monitoring since 2003. Routine viral load monitoring is now strongly recommended as the monitoring strategy of choice. In 2013, WHO recommended viral load as the preferred monitoring approach to diagnose and confirm ART failure and using the reduced threshold of viral failure of 1000 copies/ml based on two consecutive viral load measurements using plasma specimens within 12 months, with adherence support between measurements. There are many challenges to implementing viral load monitoring in resource-limited settings, including complex technical requirements to perform the test, the logistics of specimen transport and cost. This publication addresses strategies to plan and implement a logical viral load testing network, including engaging leadership, mapping and forecasting, product and specimen selection, algorithm development, human resources and infrastructure requirements, monitoring and evaluation, maintenance, quality management systems and training. A key inclusion is technical guidance on using dried blood spot specimens. This publication is intended to serve as a reference point for countries, whether they are commencing implementation or scaling up existing viral load testing capacity. Thoughtful consideration and planning of all areas covered in this publication will assist in developing a robust and sustainable HIV viral load testing network.

INTRODUCTION

The 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection *(1)* recommend viral load testing as the preferred monitoring tool for diagnosing and confirming the failure of antiretroviral therapy (ART). In accordance with these guidelines, many countries are investing in viral load testing to monitor people receiving ART (Fig. 1). Viral load monitoring is the gold standard practice in resource-rich countries for detecting treatment failure among people receiving ART; however, its availability in resource-limited settings has been severely restricted because of prohibitively high costs (US$ 40–85 per test solely for reagents and consumables), complex specimen collection and transport requirements and the need for well-established laboratory infrastructure and well-trained personnel. Because of these financial and operational barriers, the WHO treatment guidelines, while recognising viral load as the gold standard for ART monitoring, have historically focused on using clinical and immunological criteria for determining treatment failure. However, numerous studies have demonstrated the poor predictive value of the WHO immunological criteria for identifying viral failure and have shown that delayed detection of treatment failure leads to accumulation of HIV drug resistance *(2,3)*. The 2013 WHO consolidated antiretroviral guidelines *(1)* recommend viral load testing six months after initiating ART and then annually for people receiving ART; for the people with detectable viraemia, targeted adherence support followed by confirmatory viral load testing is recommended to distinguish poor adherence from true treatment failure. Those with treatment failure would then be switched to second-line ART.

This publication provides high-level guidance on implementing and scaling up viral load testing programmes for health ministries and implementing partners. It aims to inform national HIV programme managers and laboratory managers using a three-phased approach: (1) planning; (2) scale-up; and (3) sustainability.

Fig. 1. Phased implementation of viral load testing



The significant challenge to successfully implementing and scaling up viral load testing to reach everyone receiving ART is adequate strategic planning. This publication provides a framework for key areas to be considered and addressed during the planning phase for implementing and scaling up viral load testing and highlights the elements critical to supporting a sustainable viral load testing network. Each area discussed presents its own new challenges, especially if viral load testing is being scaled up within a weak and uncoordinated laboratory network. Some of the more critical challenges are discussed below, but countries are encouraged to share the lessons learned so that others can incorporate these in their plans for implementing viral load testing. Annex 1 provides one example of a framework from the African Society for Laboratory Medicine.

PHASE 1: PLANNING

POLICIES, LEADERSHIP AND GOVERNMENT COMMITMENT

Enabling universal access to viral load testing for everyone receiving ART requires careful planning, with agreed contributions from all involved stakeholders, a realistic but robust timeline and placement strategies for introducing and disseminating the new technologies nationwide. Even with careful planning, reaching everyone receiving ART (especially as ART delivery is decentralized to lower-level health facilities) with capacity to perform viral load testing may take several years. National governments are best placed to convene stakeholders, organize the response and lead working groups dedicated to developing, implementing and monitoring programmes for viral load testing. Revising and updating national guidelines on ART and monitoring for HIV infection and developing national policies and plans for implementing viral load testing are essential to reduce the time to achieve universal access to viral load testing, since many of the essential activities described below (such as selecting and procuring machines, building laboratory capacity, training health care personnel and developing specimen transport networks) need to be developed and implemented simultaneously. In addition, a high level of government commitment and leadership to lead the response and align plans for implementing viral load testing with national laboratory strategic plans is important for mobilizing national and international stakeholders to support the response. To achieve this, national governments should convene technical working groups, composed of appropriate national and international stakeholders, to develop agreed national plans for implementing viral load testing with clear timelines and deliverables for scaling up access to viral load testing for everyone receiving ART.

Country-specific policies and guidelines for viral load testing should be clear and should include clinical algorithms and strategies to reach target populations. The availability of financial, human and infrastructural resources needs to be considered and addressed as resources permit during the implementation process. However, existing limitations should not block the adoption of viral load testing, since stepwise solutions and capacity-building embedded within an implementation strategy can be developed.

Senior health ministry officials and key government departments must be engaged in developing and implementing their national strategies for viral load testing, especially in:

- policy and clinical guidelines
- building viral load testing capacity
- generating demand for viral load testing
- enabling systems for viral load testing
- integrating viral load testing into the health system
- programme management.

HARMONIZATION

Leadership at the national level is critical to optimize both the implementation of programmes and management of laboratories. From a programmatic standpoint, standards for service provision at facilities should be clearly established and integrated with all levels of programme management, including: preservice and in-service training, published guidelines and clinical algorithms, workforce standards, targets, monitoring and evaluation, reporting requirements, quality improvement and supervision objectives. All these programmatic standards need to be conveyed to regional and district-level programme coordinators, who can then ensure that facilities meet the expectations of the national programme. It is also important for national programme managers to maintain open lines of communication and opportunities for programme review so that regional and district coordinators can provide valuable feedback from the field to the national programme and corrective adjustments can be made at the national level.

Likewise, the role of the central or national reference laboratory will also be to establish standards for laboratory management, training, quality assurance and troubleshooting measures, documentation and reporting, which can then be translated to operations at the regional laboratory level. At earlier stages of implementation, the central or national reference laboratory probably plays a backstopping role if and when regional laboratories encounter issues such as supply shortages, instrument failure, need for additional training and inaccurate results. The lines of communication and support also need to be open between central and regional laboratories so that issues can be raised as they arise and the national laboratory programme can be strengthened throughout implementation and beyond.

DEVELOPING A CLINICAL ALGORITHM FOR VIRAL LOAD MONITORING

Revising the national algorithm for monitoring ART is a cornerstone of planning for expanding viral load testing, since it significantly influences numerous subsequent

decisions, especially the volume of testing and programme costs (Box 1). The 2013 WHO consolidated antiretroviral drug guidelines provide a general algorithm for consideration, but programme managers should collaborate closely with local clinicians experienced in providing ART to determine whether modifications are needed to best fit the national epidemic and context.

Box 1. Developing an algorithm for monitoring viral load

- Frequency of targeted and routine viral load testing (such as six months after initiating ART and then yearly)
- Definition of viral failure based on testing platform
- Repeat testing interval among people with viral failure (three or six months) and adherence counselling requirements before repeat testing
- Specimen type for testing and repeat testing (plasma or dried blood spots)
- Need for population-specific testing algorithms (such as children, pregnant women and people for whom treatment is suspected to have failed)
- Current and projected numbers for people receiving ART (first-, second- and third-line regimens)

MAPPING AND FORECASTING THE VIRAL LOAD TESTING NETWORK

Planning is key to successfully implementing and scaling up viral load testing programmes. The planning phase should include mapping the needs for viral load testing by assessing needs, assessing existing resources and building the necessary capacity. In addition to determining the numbers of current and expected people receiving ART and tests needed, planning is also required to accurately assess and forecast the viral load laboratory network needed to support the programme. Countries should review national ART plans and determine the number of people who will require viral load testing during the coming years, taking into account high-priority populations and the anticipated numbers of repeat tests to confirm treatment failure.
As programmes for viral load testing are scaled up, the clinical algorithm for viral load testing must not exceed the sustainable capacity for such testing such that viral load testing is sustainable across the entire health system to provide the best care.

VIRAL LOAD TESTING NETWORK

To ensure high-quality specimens and test results, specimen transport systems need to operate efficiently. New models and innovative strategies may need to be developed to achieve this. In countries that already have well-established early infant diagnosis and CD4 programmes and specimen referral networks, this can provide the basis for implementing viral load testing. Baseline assessments of country resources, needs and targets should map to existing early infant diagnosis and viral load resources and networks and current testing demands to best integrate services. This will aid in further mapping the facilities collecting specimens for viral load testing and the testing laboratories. Support systems for viral load testing networks should be developed and strengthened in parallel. Components of the assessment should include:

- the number of laboratories that can carry out molecular techniques (early infant diagnosis or viral load testing), existing volumes of testing for early infant diagnosis, available capacity for viral load testing and potential for expansion;
- the geographical distribution of testing needs and target populations (ART sites), including areas currently under- or over-served;
- opportunities for integrating diagnostic services (CD4, early infant diagnosis, tuberculosis (TB), etc.);
- factors limiting the use of available capacity and/or testing expansion;
- specimen referral network and transmission of results;
- information management systems;
- equipment service and maintenance;
- quality systems and external quality assessment programmes;
- supply chain and logistics infrastructure and capacity;
- monitoring and evaluation systems; and
- adoption of new high-quality technologies, such as technologies to be used at the point of care.

Because disease programmes beyond HIV use laboratory network systems, viral load testing programme managers should work closely with other disease programmes, such as those focusing on hepatitis C and B and TB, to pool technical and financial resources and collectively communicate programme and policy needs to ensure sustainability. Viral load testing programmes will not improve patient care and treatment outcomes unless they are integrated into the national health system.

ASSESSING CAPACITY FOR VIRAL LOAD TESTING

Data on existing capacity for viral load testing and information on existing systems to support viral load testing (early infant diagnosis and CD4 counts) should be aggregated during baseline assessment. Existing capacity is defined as operational molecular laboratories processing viral load and early infant diagnosis specimens with excess capacity available immediately; this should include the capacity of implementing partners if appropriate. Back-up capacity should also be included in planning to compensate for interruptions in the viral load testing network (such as equipment downtime). As the number of tests expands, additional testing platforms and/or sites may be required as determined by ongoing monitoring of the viral load testing programme. As viral load testing is scaled up to support routine monitoring, CD4 counting may be scaled back for monitoring the response to ART; CD4 will still be needed in the foreseeable future for initiating ART *(4)*. Planning for additional capacity should address limitations in equipment, infrastructure, funding, policies and human resources.

COSTING VIRAL LOAD TESTING

The price per viral load test can range widely (US$ 10 to US$ 60) depending on the manufacturer and country (based on reports by the Clinton Health Access Initiative, UNITAID and Médecins Sans Frontières). Recently, several manufacturers have committed to regional agreements in which reduced pricing for viral load reagents may be obtained for as low as US$ 10.50 per test. Negotiations with manufacturers for agreements that do not require outright purchase of platforms, especially on a reagent rental or lease basis in which instruments are leased and reagents purchased at a set price, may improve responsiveness for maintenance needs and therefore minimize interruptions from platform downtime. Further, these types of arrangements rely on more accurate and reliable forecasting estimates for the number of tests required, are therefore key to reducing the costs of viral load tests and should therefore be pursued if possible. Such reduced-cost agreements should include access to the reduced cost for all national implementing partners or even regional costing agreements.

To coordinate procurement, identify funding gaps and ensure a consistent supply of commodities, national quantification and two-year forecast for viral load, early infant diagnosis and CD4 commodities should be undertaken using demographics, instrument service statistics (including downtime), consumption data and national ART targets; specific consideration should be given to changes in the use of CD4 within the clinical algorithm as viral load testing is scaled up. Current statistics on CD4 testing services should be used to determine the resources needed by facility in alignment with the phased roll-out of the viral load testing programme. A supply plan for procurement with pooled orders for reagents and consumables on a quarterly basis should be considered. If an annual order is desired, provision should be made for staggered deliveries to take into account the short shelf life of reagents and the requirement for refrigerating test kits.

SPECIMEN TYPE AND PRODUCT SELECTION

The choice of specimen type and platform or assay for viral load testing is key to all facets of planning. Product selection should consider performance characteristics as well as operational characteristics to ensure that both the product and specimen are suitable for the setting of use. The operational characteristics of each specimen type must be considered given the existing specimen transport network, laboratory infrastructure and testing modalities. In some programmes, combining specimen types and testing platforms may be optimal to best suit different settings. Each platform or assay and specimen type should be validated to ensure high-quality results.

The following commercially available molecular, laboratory-based viral load platforms are capable of measuring HIV viral load (RNA or total nucleic acids): COBAS® TaqMan® (Roche Molecular Systems), Abbott RealTime m2000rt (Abbott Molecular), NucliSENS EasyQ® (bioMérieux), VERSANT® kPCR (Siemens Healthcare Diagnostics), Generic HIV Viral Load (Biocentric), VERSANT HIV RNA 3.0 Assay (bDNA), artus® HI Virus-1 RG RT-PCR and artus® HI Virus-1 QS-RGQ Kit (QIAGEN). Although standardizing equipment is recommended to avoid the co-management of multiple testing platforms, selecting an appropriate mix of platforms for specific health care settings may enhance competitive pricing and avoid downtime related to one type of instrument. In addition, some manufacturers offer special local or regional pricing programmes with specific eligibility criteria (tiered or differential pricing). Programme managers should carefully investigate these offers together with their neighbouring countries.

Although continual advancement is being made with existing and new technologies, some viral load testing platforms still have limitations in viral load measurement using dried blood spot specimens. National programme managers are encouraged to use scientific evidence and to assess their programmatic needs to select an appropriate platform or assay for their viral load testing network.

Key points include the following:

- Using plasma specimens for viral load testing is the preferred monitoring approach to determine viral failure at the threshold of 1000 copies/ml among people living with HIV in accordance with the 2013 WHO consolidated antiretroviral drug guidelines *(1)* and remains the gold standard.
- However, where logistical, infrastructural or operational barriers to performing viral load testing using plasma specimens have not yet been resolved, dried blood spot specimens for viral load testing can be used effectively at the threshold of 1000 copies/ml on most laboratory-based platforms (Table 1).
- Dried blood spot specimens can be prepared using EDTA and venous blood pipetted onto dried blood spot collection cards or finger-stick blood delivered by microcapillary tube.
  - Available dried blood spot collection cards that have been demonstrated for use with viral load include Whatman 903, Munktell TNF or Ahlstrom Grade 226. Other cards may be used if sufficient evidence becomes available for their performance.
- All manufacturers of laboratory-based viral load assays should provide a protocol including dried blood spot specimens and pursue regulatory approval for in vitro diagnostics using dried blood spot specimens.

A meta-analysis of available published and unpublished comparative data (to be published soon) suggests that the performance of dried blood spot specimens for HIV viral load testing varies by platform compared with plasma specimens. Table 1 summarizes current data for performance characteristics using dried blood spot specimens according to commercially available viral load testing platforms.

Most studies performed used dried blood spot specimens prepared from EDTA–whole blood specimens were prepared in the laboratory using precision pipettes. Two very recent studies *(5,6)* evaluated dried blood spot specimens prepared from finger-stick using microcapillary tubes by laboratory technicians in one and by laboratory technicians and health care workers in the other. The results indicated that finger-stick collection under these conditions works well compared with venous blood dried blood spots or plasma specimens for viral load testing, but further research is required. Unpublished data (Mary E. Schmitz et al., United States Centers for Disease Control and Prevention, unpublished poster presentation, 20th International AIDS Conference, Melbourne, Australia, 20–25 July 2014) have also demonstrated that dried blood spot specimens prepared directly from hanging drop finger-prick blood perform well compared with plasma.

Table 1. Provisional data on performance characteristics for commercially available molecular HIV viral load assays using dried blood spot specimens compared with plasma at 1000 copies/ml cut-off

Assay assessed	Sensitivity (mean %)	Specificity (mean %)	*n*
Abbott Molecular: Abbott RealTi*m*e HIV-1 (manual, m24sp and m2000sp) assays with m2000rt platform	95.24[a]	91.67[a]	1529
Biocentric: Generic HIV Charge Virale	94.86[a]	55.16[a]	531
bioMérieux: NucliSENS EasyQ® HIV-1 v2.0	84.37[a]	94.52[a]	1062
Roche Molecular Systems: COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, version 2.0 [free virus elution protocol]	81.02[b]	96.74[b]	229
HIV-1 RNA 1.0 Assay (kPCR)	90.97[a]	87.76[a]	144

Sources: [a]Lara Vojnov et al., Clinton Health Access Initiative, unpublished manuscript on dried blood spot specimens with highly variable performance compared with plasma across the five available viral load technologies, 15 June 2014. [b]Sergio Carmona and Zukiswa Mahlumba, South African National Health Laboratory Service, unpublished raw data using the new Roche COBAS® Ampliprep/TaqMan® system version 2.0 with the revised free virus elution (FVE) protocol and specimens processed within one week of collection, 18 June 2014; further research is required. Using the existing Roche COBAS® Ampliprep/TaqMan® system version 2.0 (SPEX) protocol, the results were different: sensitivity: 99.33%, specificity 43.86%, *n* = 2314 (Lara Vojnov et al., Clinton Health Access Initiative).

OPERATIONAL CHARACTERISTICS OF VIRAL LOAD TECHNOLOGIES

Although detailed technical specifications of commercially available viral load technologies have been published *(6–9)*, practical guidance outlining the programmatic considerations that need to be considered in selecting and implementing viral load assays has been lacking Although current viral load technologies share common technical features that make them comparable in terms of analytical performance (lower limit of detection, linear range and HIV subtype detection), they differ in terms of test principle, specimen throughput capability, costs, infrastructure, human resources required and ability to use dried blood spots collected from ART-experienced populations. Being aware of these differences is particularly important for laboratory managers from resource-limited settings advising on implementing and scaling up of viral load testing nationwide. Annex 2 provides detailed operational characteristics for selecting products according to the five commercially available platforms (summarized in Box 2).

The selection of viral load technologies should not rely solely on the technical specifications and characteristics of a viral load platform but also specimen type specificities (Box 3) and operational considerations, such as efficiency of specimen transport system, expected testing volumes, human resources and technical support. It is also important when planning specimen transport systems to consider the maximum time that is advised for specimen transport and storage, which differs according to specimen type (whole blood, plasma or dried blood spot) and the transport and storage temperature. It is important to consider the maximum amount of time plasma and dried blood spot can be kept at room temperature during transport and where and how specimens will be stored at testing facilities or

Box 2. Operational considerations for selecting products

Regulatory approvals and donor procurement policies are critical for the eligibility of products for procurement with public money. The Global Fund to Fight AIDS, Tuberculosis and Malaria allows eligibility for procurement for products that are WHO prequalified or approved by regulatory authorities that are founding members of the Global Harmonization Task Force, including the European Union, United States Food and Drug Administration, Health Canada, Therapeutic Goods Administration Australia and Ministry of Health and Welfare of Japan.

Company experience and track record in resource-limited settings and capacity for post-market surveillance

Operational characteristics for consideration:

- infrastructure requirements: power supply, climate control, dust, instrument footprint, ancillary equipment, additional rooms for extraction and amplification and health facility tier;
- quality assurance: use with existing external quality assurance, internal quality control and quality control;
- logistics: cold-chain requirements (refrigeration versus freezer), storage requirements and shelf life;
- technical support: availability in the country or region, especially for automated systems: training, maintenance, service, warranty and help desk;
- ease of use: number of steps, automation, protocol, job aids, existing human resources (early infant diagnosis), workflow, cross-contamination risk, barcoding system and maintenance and cleaning required;
- safety and waste: biohazard risk (closed or open system), solid and liquid waste;
- data management: connectivity, back-up and storage, results reporting and a laboratory management information system; and
- durability: life span of instruments, planned obsolescence, company experience and track record.
- Considerations for cost set-up: cost of ancillary equipment, infrastructure changes required, consumables, controls, quality assurance material, maintenance contracts, staff time, reagent rental, consortium pricing and multiple platforms for competitive pricing
- Polyvalence (utility for other purposes): early infant diagnosis, tuberculosis (TB), hepatitis B and C, gonorrhoea, human papillomavirus, chlamydia, outbreak surveillance, etc.

holding hubs. Table 2 summarizes published results for specimen stability at a range of typical transport and storage temperatures.

There are many approaches to phasing the scaling up of viral load testing using plasma or dried blood spot specimens or a matrix of both that may change over time as the programme's capacity for collecting and transporting specimens develops. One approach to consider is a phased approach initially scaling up plasma specimens in urban and peri-urban areas and to reserve scaling up of dried blood spots for hard-to-reach areas in which phlebotomy and the processing of venous blood within 6 hours are not possible. A phased scale-up approach will also enable the implementation and/or strengthening of a system for transporting specimens and returning results. Consider hubs (testing and specimen referral centres) strategically placed in remote areas with high throughput and linked to clinics, mapped to increase catchment areas and maximize the efficiency of specimen transport and result reporting to increase access to viral load testing. Strengthening the viral load testing network also strengthens the overall specimen transport system for integrating other specimen types (CD4, clinical chemistry, viral hepatitis, TB, external quality assessment panels, etc.) and builds capacity at lower-level laboratories for cold-chain storage facilities, centrifugation of venous blood and capacity for storing specimens.

Box 3. Specimen type and operational considerations

Plasma specimens

- The gold standard to determine viral failure
- Must be prepared from anticoagulated EDTA–whole blood (venous) within six hours of blood collection (if left at room temperature, 24 hours at 2–8°C) or according to the manufacturer's instructions
- Prepared plasma can be stored at room temperature for up to 24 hours, at 2–8°C for up to 5 days and –20°C to –80°C for longer periods
- Can be used accurately on all the existing laboratory-based platforms

Dried blood spot specimens

- Not considered biohazardous once dried
- Easier to transport and are not as time and temperature sensitive as EDTA–whole blood or plasma specimens
- Can be prepared using a precision pipette/ microcapillary EDTA-venous blood or finger-prick blood specimen prepared using a measured microcapillary tube
- Can be prepared using Whatman 903, Munktell TNF, Ahlstrom Grade 226 DBS collection cards depending on the manufacturer's instructions

Table 2. Summary of published studies and manufacturer recommendations for time of transport and storage at various conditions for plasma, whole-blood and dried blood spot specimens for HIV viral load testing

Temperature	37°C (humid conditions)	15–30°C (room temperature)	4°C	–20°C	–70°C
Time	**Whole blood (venous EDTA)**				
	6 hours	6 hours	Not applicable	Not applicable	Not applicable
	Plasma				
	24 hours	24 hours	5 days	1 year	5 years
	Dried blood spot				
	1–2 weeks	1–2 weeks	2–52 weeks	3–36 months	1 year

For the COBAS® AmpliPrep/ COBAS® TaqMan® HIV-1 Test, version 2.0 with the revised free virus elution protocol, the results shown were from dried blood spots that were prepared, transported and processed within one week. Care should therefore be taken to ensure that the storage of dried blood spot cards at room temperatures does not exceed one week until more evidence is available for the effect of longer transport periods.

Sources: Cassol et al. *(10)*, Leelawiwat et al. *(11)*, Mitchell et al. *(12)*, Reigadas et al. *(13)*, Van Deursen et al. *(14)*, *WHO manual for HIV drug resistance testing using dried blood spot specimens (15)*.

PROCURING EQUIPMENT

There are three common methods of acquiring laboratory equipment: purchase, lease and reagent rental (Table 3). The method dictates the type of maintenance support provided, and each method involves different invoices and payment terms.

If a reagent rental agreement is negotiated, it must detail the terms by which the manufacturers will place instruments and the volumes or percentage of throughput capacity used that will trigger the placement of additional instruments, also at no additional cost. Training of laboratory personnel in how to preventively and correctively maintain and operate the equipment must be explicitly requested when the purchase is negotiated.

Laboratory scientists and manufacturers are jointly responsible for a good preventive maintenance strategy, but the level of effort and time commitment of these two groups may vary depending on the method of acquiring the equipment. The frequency and type of service maintenance (preventive, repair, calibration and software updates) and/or replacement of equipment must be detailed in any agreement signed with a company.

Table 3. Ways to procure laboratory equipment

Purchase	Lease	Reagent rental
Can result in discounted cost	Total cost is higher than purchasing because of the offset of the cost of instruments versus the cost of reagents	Total price is higher than purchase but monthly cost is predictable
Reagent cost may be less	Reagent pricing may be negotiated separately	Reagent cost is higher because cost of equipment, reagents and service is spread across each test for the duration of the contract.
Extended warranty is negotiated separately and is an added cost to the purchase price	Equipment warranty is included in the negotiated price for the duration of the lease or contract	
No volume commitment	No volume commitment if reagents are negotiated in a separate contract	Requires accurate volume commitment
Equipment expense can be depreciated	Not applicable	
Can be used as trade-in for upgraded models	At the end of the lease, the equipment can be returned or exchanged for a newer model (not in all countries)	
Equipment is owned by country	Buy-out option at the end of the lease or contract	
Requires significant initial cash outlay	Requires minimum initial cash outlay	
Risk of obsolescence in 5–7 years	Risk is low, since the leasing period is less than five years	
Disposal of used equipment may become difficult	The manufacturer owns the equipment and will reclaim it at the end of the lease	

PHASE 2: SCALE-UP

PHASING IN VIRAL LOAD MONITORING

Phased scale-up is recommended to efficiently and successfully expand viral load testing. This approach avoids overwhelming specimen transport networks, laboratory staff and clinical staff and enables programmatic and operational data to be collected that can inform and optimize national expansion. Countries should develop detailed, country-specific strategies to systematically transition to routine viral load monitoring for everyone receiving ART; this will probably include a mix of technologies as expansion progresses. The approach may be phased based on several factors (such as geographical distribution and existing capacity), a focus on priority populations *(4)* or a combination. For example, Uganda's national programme has focused on priority populations within key geographical areas. Priority populations that may be considered for the initial phase include children, pregnant women and their partners, people for whom treatment failure is suspected (based on either clinical or immunological criteria) and/or people receiving second-line ART. Determining the priority populations requires close collaboration and discussion to develop consensus among key stakeholders and depends on current national guidelines for expanding treatment. Decisions about expanding from priority populations to the general population are ideally based on data from initial phases (including input from laboratory and site staff, programme managers, specimen transport coordinators, etc.) so that expansion can be orderly and successful.

Planning for phased scale-up should include careful costing and funding analyses at each phase. If countries decide to concurrently phase out CD4 monitoring for people receiving ART *(4)*, commodity procurement, staffing and budgeting for CD4 testing can be diverted into viral load testing.

As the viral load testing network expands, connectivity among ART sites, laboratories and health care providers will pose another critical challenge. Innovative connectivity modalities for programme managers to monitor and manage the viral load testing network to ensure high-quality testing and care should also be considered. In addition, improved monitoring and evaluation processes will help to continually identify programmatic gaps and bottlenecks to be shared with programme managers.

New technologies are rapidly being introduced to meet the demand for increased viral load testing. One of the greatest challenges is balancing evaluation of performance and operational characteristics that will ensure accurate results and aligning with regulatory approval. It is recommended that countries harmonize evaluations and regulatory approval processes within the region. The WHO Prequalification of In Vitro Diagnostics Programme offers independent assessment of the safety, quality and performance of commercially available viral load technologies. These technical data should be used to accelerate national registration of assays with local validation of operational characteristics to ensure optimal placement of the different types of technologies, including those that are suitable for point-of-care testing that are still in the development pipeline.

HUMAN RESOURCES

Effectively managing the scaling up of viral load testing and ensuring routine monitoring with no disruption to other services requires investing in human resources to ensure continual quality testing and care. Additional human resource needs may include: laboratory staff, data clerks, phlebotomists, transport drivers, repository managers, coordinators, trainers, mentors and procurement specialists. Mapping existing human resource capacity for each type of worker involved is strongly encouraged. This would entail aligning the existing resources and services currently being provided, such as CD4 and early infant diagnosis, while forecasting future viral load targets and needs to accommodate a phased-in approach for viral load testing.

Existing laboratory staff may be able to have their workload transitioned as monitoring needs transition from CD4 counting to viral load testing; however, people in pre-ART care still require CD4 testing for monitoring eligibility for ART (in accordance with WHO guidelines), and staff time will probably have to be increased in the early months of implementing viral load testing. Strong training, mentorship and oversight are needed; ideally, one experienced laboratory staff member functions as a viral load coordinator to oversee the implementation of viral load testing.

Sustainable laboratory networks and referral laboratories for HIV viral load and other specialized laboratory tests require highly skilled laboratory scientists, who are in low supply in many low- and middle-income countries. The formal training for laboratory technicians (or technologists) varies from country to country, ranging from a diploma to a university degree. A comprehensive framework for human resources for health to address the needs for specialized laboratory staff significantly helps in planning human resource needs and allocating the required resources. The human resource framework for viral load testing should not be treated as a stand-alone approach but rather included in the overall framework for human resources for health. Each country has different human resource challenges, given their sociopolitical structures and experiences, health system structure, organization and resourcing. The

context of each country should guide the human resource framework and supporting policies. An initial assessment identifying critical human resource elements is encouraged, keeping in mind that growing numbers of tests increases the need for human resources.

At the service delivery level, viral load testing should be incorporated into the existing scopes of work for health care workers and into the service delivery processes at health care facilities. Human resource capacity should also be mapped at this level so that adequate staffing can be ensured, since many countries have long-standing challenges in this critical area. Additional nursing staff, adherence counsellors, outreach workers, phlebotomists and laboratory technicians may be needed to support the implementation of viral load testing and the associated clinical services. Key operational questions at various levels of decision-making (national, district, facilities and departments) should be considered, and should engage leadership of all types of human resources for health.

TRAINING AND SUPERVISION

Because scaling up routine viral load testing represents a paradigm shift in ART monitoring for many countries, detailed training and communication plans are required to ensure the dissemination of accurate information to all stakeholders, including relevant clinical, laboratory, strategic information, supply chain and community workers. Training plans for each type of worker should include a preservice curriculum, provision for repeated training as required by staff turnover and refresher and competence training. Training should also incorporate clear supporting materials such as laboratory standard operating protocols, job aids, supportive supervision and mentoring guides and patient and community communication posters. Care should be taken to ensure that materials are aligned and harmonized to avoid confusion and fragmented implementation.

Before training, all relevant clinical and laboratory materials (such as laboratory standard operating protocols, patient chart documentation, ART registers, laboratory requisition forms and facility standard operating protocols) should be reviewed and updated to maximize the practical utility of training and ensure that staff can document data, interventions and results related to viral load testing.

Laboratory staff

For laboratory staff, training should focus on proper handling and processing of specimens to ensure accurate test results. Laboratory training should be driven by standard operating protocols that have been reviewed and approved by laboratory and quality assurance management. All laboratory staff must be properly trained and deemed competent to perform their duties, noting a mix of activities that often include specimen handling (reception and accessioning, processing and testing, transporting and storage), data and technical support, etc.

Training should clearly address criteria for accepting and rejecting specimens but also include follow-up communication with collection sites and possibly transporters if poor specimen quality is detected. Standard operating protocols should also include troubleshooting protocols and be highlighted during training, with laboratory management providing continual oversight and mentorship.

In addition to the training required for laboratory staff, the following priority groups require targeted training: clinical health care workers, adherence counsellors, people living with HIV, community outreach workers and other stakeholders and national and regional mentors.

Clinical health care workers (such as doctors, clinical officers, nurses and midwives)

Clinical health workers play a central role in the uptake of viral load testing; training should therefore focus on ensuring that providers understand the advantages of viral load testing (such as increased simplicity of interpretation compared with immunological monitoring) and the implications for improving patient management. Training should include guidance on providing clear messages on the reasons for viral load testing, complying with the viral load clinical algorithm, interpreting results for clinical management, documenting follow-up and promoting adherence to ART and retention in care. Clear communication protocols and documents can assist in training health care workers to relay important messages to the people receiving ART on understanding viral load results and the next steps in care and treatment. Training providers to provide excellent counselling to the people receiving ART on viral load testing and results can empower and motivate these people to adhere to ART and invest in their own health outcomes. In countries that have recently transitioned to lifelong ART for pregnant and breastfeeding women (formerly "option B+"), many health care workers in maternal, newborn and child health with limited experience in monitoring and managing ART are now tasked with providing comprehensive treatment services; additional support for these health care workers may therefore be necessary to ensure that patient management is not compromised in the transition to viral load monitoring. Training should include numerous

practical case studies to ensure that participants gain understanding of common clinical scenarios in interpreting viral load results. In addition, sites should be encouraged to develop a facility-specific structured approach for switching people to second-line ART (such as multidisciplinary team discussions and enhanced follow-up).

Adherence counsellors

Adopting routine viral load monitoring will significantly affect the frequency, intensity and content of adherence counselling sessions. Adherence counsellors play a critical role in any routine viral load testing strategy: studies have shown that up to 70% of the people with detectable viral loads can be resuppressed with improved adherence, avoiding costly switches to second-line ART. Instead of standardized routine adherence counselling for everyone receiving ART, counsellors should be provided with materials and training to provide more intensified counselling and targeted assistance to people identified as potentially non-adherent through the results of viral load testing. This should include a standardized algorithm of adherence sessions before repeating viral load or switching to second-line ART.

People living with HIV, community outreach workers and other stakeholders (such as local leaders, peer mentors and family support groups)

Educating people on the value and utility of viral load testing is key to a successful viral load testing programme. Many people living with HIV and community stakeholders have traditionally focused on CD4 as a marker of their treatment success, and introducing routine viral load testing requires clear messages to people living with HIV and communities about the advantages of viral load testing, how it relates to adherence and general understanding of results (detectable versus undetectable). This may be especially important in programmes that discontinue CD4 testing among people receiving ART. Mobilizing facility and community support by ensuring understanding of the advantages and interpretation of viral load testing is key to successfully rolling out and maintaining the trust of people living with HIV and communities in the quality of service delivery. This may also help garner support for enhanced tracking and other adherence activities among people with a detectable viral load. Individuals and communities who understand viral load testing may be more motivated to adhere to medication and invest in positive health outcomes.

National and regional mentors

Expanding routine viral load testing and ensuring that the scale-up plan is systematically and accurately implemented requires close supervision at the facility and laboratory level to prevent misinterpretation and deviation from standard operating protocols. Training for mentors should include providing guidance on site-level supportive supervision to multiple types of health workers (with corrective actions where needed), recognizing high-performing sites and collecting data on the implementation of viral load testing at the site to inform the national programme on the progress in roll-out. Mentors should use a structured approach that includes checklists, reviewing medical records and standardized visit templates, including a site supervisory logbook that remains at the facility.

QUALITY MANAGEMENT SYSTEM

Maintaining testing quality as viral load testing is scaled up requires strengthening quality assurance systems and the viral load testing network (Box 4). Each country should have a quality management system and external quality assurance plan to ensure that all laboratory testing is available, accurate and timely. A national quality system should be in place, encompassing all tiers of the health care system, to support the viral load programme and monitor and evaluate the capacity of the viral load testing network to support the programme goals. A comprehensive quality management system comprises an ongoing cycle of quality assessment and improving the process and programme at all functional programme levels, including the organizational and individual levels, equipment and reagent stock management, the use of quality control, data management and documentation, occurrence management, specimen management and safety and waste management. This system should incorporate national standards for testing and training staff involved in external quality assurance and laboratory management and non-technical staff involved in testing services. Innovative external quality assurance strategies (such as new quality control materials) may need to be developed to adequately ensure that the quality of viral load testing and other HIV diagnostic testing is maintained.

To ensure that the viral load testing network is strengthened and integrated as part of the overall health system, the quality management system should focus developmental efforts on achieving international accreditation of testing laboratories. As such, a stepwise approach using internationally accepted standards (such as Strengthening Laboratory Management towards Accreditation (SLMTA) or Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA) or

another equivalent programme) should be implemented to encourage, support and recognize the implementation of a quality management system in laboratories. Full accreditation is defined by meeting standard criteria to receive accreditation by a nationally, regionally or internationally recognized accreditation body, such as the College of American Pathologists, International Organization for Standardization, South African National Accreditation System and Southern African Development Community Accreditation Service.

Box 4. Considerations for a quality management system for a viral load testing network

- External quality assessment programmes that include proficiency testing and quality control
- Continual training and competence assessment
- Quality managers
- Data quality checks
- A monitoring and evaluation system, such as a management dashboard, that tracks progress towards accreditation, performance in external quality assessment programmes, corrective action steps, inventory and procurement

PHASE 3: SUSTAINABILITY – MAINTAINING A VIRAL LOAD TESTING NETWORK

HARMONIZATION AMONG PARTNERS AND IMPLEMENTING PARTNERS

Implementing a high-quality national viral load testing programme requires coordination among all stakeholders (donors and implementing partners) providing support for HIV service delivery. In most cases, some existing capacity in the country may already be contributing to a viral load testing programme. Virological testing may be occurring at regional referral centres, selected ART clinics or through the private sector. Since viral load testing provides one of the most robust measures of the quality of national ART programmes (the proportion of people with viral suppression), it is important to harmonize how viral load testing is performed, reported and monitored at the national level to ensure consistency in reporting this quality indicator. This need not involve harmonizing all elements of viral load testing supported by implementing partners. In fact, having a mix of platforms and settings (such as public and private) in which viral load testing is performed may be advantageous; this can enable continued testing when particular instruments need preventive or corrective maintenance and foster healthy competitive markets to reduce the prices for viral load equipment and reagents. However, having common understanding (across partners) of the platforms, thresholds, quality assurance standards, networks for referring specimens and returning results and procedures for reporting results is important for programme oversight and properly interpreting results.

MONITORING AND EVALUATION AND INFORMATION SYSTEMS

Centralized monitoring and evaluation are critical tools to inform the expansion and maintenance of viral load testing and evaluate the quality of existing viral load testing programmes at the laboratory and clinic level. The health ministry should collect and analyse data on programme efficiency, performance and access using a standardized set of metrics within the context of a broader monitoring and evaluation plan. These data should be reported and shared with all stakeholders for review to enable programmes to be improved. Programmes are strongly recommended to routinely review viral load testing data as part of data quality assessment so that corrective action can be taken as needed.

The viral load laboratory requisition and reporting forms represent a significant opportunity for collecting comprehensive data on key components of the national viral load testing programme that can be used to monitor the progress of implementing viral load testing and the quality of clinical service delivery. The requisition and reporting forms should be simple, clear and succinct to ensure that they can be completed accurately and rapidly, and training on completing them should be incorporated into training modules for both service providers and laboratory staff to ensure standardized interpretation of results and optimal data quality. Annex 3 provides an example of a viral load laboratory requisition form. Table 4 lists elements to consider incorporating into the form.

Table 4. Elements to consider for laboratory requisition and report forms

Specimen requisition form (entered at the clinic)

- Patient identification number
- Collection site
- Date of birth (age)
- Sex
- Whether currently pregnant or breastfeeding
- If receiving ART, current regimen (first, second or third line)
- Previous exposure to ARV drugs, such as for preventing mother-to-child transmission, post-exposure prophylaxis or pre-exposure prophylaxis
- Date ART started (time receiving ART)
- Reason for the test
- Date and time specimen collected
- Specimen type
- Adherence assessment
- WHO clinical staging and CD4 count

Testing report form (entered at the laboratory)

- Demographic information (patient identification number, specimen identification number, date of birth, current ART regimen)
- Result of the viral load test, including which assay (copies/ml)
- Specimen quality
- Temperature at which the specimen was received
- Date and time the specimen was received
- Date the specimen was tested
- Date the result was reported

Data aggregated from viral load requisition forms can provide key information, such as the pace of clinical and laboratory roll-out, types of people receiving viral load testing, viral suppression rates in different populations, turnaround time at various levels of the system and specimen rejection rates. Consider using existing systems for programmes for early infant diagnosis testing as a starting template for monitoring and evaluating viral load testing. Electronic and innovative technologies (such as Global System for Mobile Communication (GSM) printers and a centralized national data platform) should be used where available to facilitate and ensure transfer of quality information. The sites chosen in the initial stages of implementing the programme should be evaluated for optimal performance using standard metrics used for continual site monitoring and further planning. These metrics should inform the readiness of sites for expanding the viral load testing network.

DATA COLLECTION AND ANALYSIS

Continual data collection and routine review are needed to inform programme managers of the volume and quality of viral load services being implemented and provided. Planning should include process evaluation measures (such as the availability and distribution of commodities, the costs and the progress in training) to monitor and evaluate the scaling up of clinical and laboratory services. A reporting template or dashboard that highlights the performance of facilities, districts or partners may be useful for highlighting areas needing targeted support and should be available for regular review. Data collected from ongoing supervision efforts are also a source of important feedback on progress and challenges in implementation. As implementation progresses, evaluation should be planned or ongoing to assess programme outcomes. Quarterly or semiannual reviews with stakeholders can provide critical opportunities for correcting course and keep partners engaged and invested in outcomes. The data collected and lessons learned are important information for reporting to stakeholders and advocating to policy-makers and funders. Ideally, viral load testing data should be incorporated into currently available national registries, reporting forms and databases.

ONGOING OPERATIONAL RESEARCH

Countries should consider possible areas for operational research to improve the viral load testing network. Current broad questions revolve around the cost, impact and sustainability of routine viral load testing; impact and outcomes for priority populations; uptake and outcomes for programme, clinical and laboratory systems; non-adherence; and transmitted and acquired HIV drug resistance. Operational research efforts should be considered in the early stages of programme planning so that data may be collected throughout implementation and may inform later stages of implementation and may benefit other country programmes. Other research questions to be answered may revolve around the costs, benefits and accuracy of new technologies (especially technologies for point-of-care testing) as they become available.

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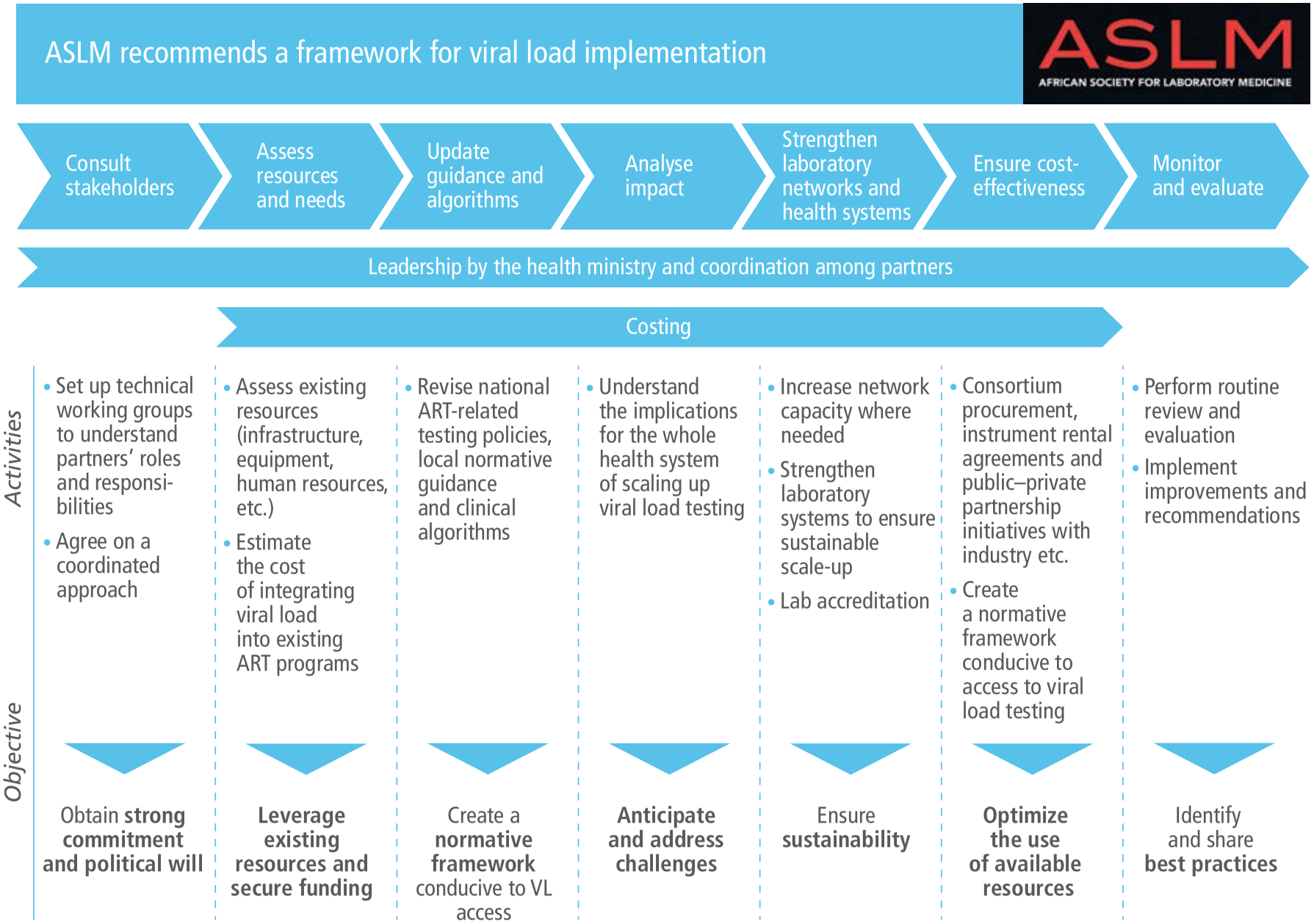
ANNEX 1. STRATEGIC PLANNING FRAMEWORK FOR IMPLEMENTING VIRAL LOAD TESTING OF THE AFRICAN SOCIETY FOR LABORATORY MEDICINE



ANNEX 2. SUMMARY OF COMMERCIALLY AVAILABLE HIV VIRAL LOAD TESTING TECHNOLOGIES BASED ON NUCLEIC ACID TESTING

	Abbott	Biocentric	bioMérieux S.A.	Roche	Siemens Healthcare Diagnostics
Assay name	Abbott RealTi*me* HIV-1	Generic HIV viral load (research use only)	NucliSens EasyQ® HIV-1 v2.0	COBAS®AmpliPrep/ COBAS® TaqMan® (CAP/ CTM) HIV-1 Test v2.0	VERSANT® HIV RNA 1.0 (kPCR)
Type of assay	Real-time reverse-transcriptase polymerase chain reaction (RT-PCR), quantitative	Real-time PCR	Real-time nucleic acid sequence–based amplification (NASBA)	Real-time RT-PCR, quantitative	Real-time RT-PCR, quantitative
Dynamic range (copies/ml)	40–10 000 000	100–50 000 000	25–10 000 000	20–10 000 000	37–11 000 000
Specimen type	EDTA and ACD Plasma, dried blood spot (research use only)	Plasma, dried blood spots	Plasma, dried blood spots	Plasma or dried blood spot (research use only)	Plasma, serum, dried blood spots (research use only)
Specimen volume required	200 – 500 – 600 – 1000 µl	Regular protocol: 200–500 µl Ultra-sensitive protocol: 400–1200 µl	100, 500 and 1000 µl of plasma Two dried blood spots (2 x 50 µl)	1 ml of plasma 60–70 µl of dried blood spot (research use only)	500 µl (plasma, serum) One dried blood spot (50–100 µl) (research use only)
Area of HIV genome amplified	Pol/INT	Long terminal repeat genes	Gag	Gag and long terminal repeat	Pol (Integrase)
HIV-1 subtypes amplified	Group M (subtypes A, B, C, D, CRF01-AE, F, CRF02-AG, G and H), Group O and Group N	B and non-B subtypes including circular recombinant form (CRF) (ANRS and WHO panels)	A, B, C, D, CRF01-AE, F, G, CRF02-AG, H and J	Group M, subtypes A–H Group O	Group M (A–H, CRF01-AE and CRF02-AG); Group O
Time to result	5 hours	4 hours including RNA isolation	2.5–3 hours including extraction	5–6 hours	5–6 hours
Cost per test (US dollars)[1]	US$ 12.50–70	US$ 14	US$ 18	US$ 20–30 per test US$ 35–90 per test	US$ 20–75 (includes all consumables)
Number of specimens per run	21–93 patient specimens (plus 3 external controls)	1–96	8–48 per run	21–63 for batch loading (168 per 8-hour day continuous loading)	89 (plus 7 calibrators and controls)
Extraction method available	Manual and automated	Manual only	Semi-manual and automated	Automated	Automated only
Equipment required[2]	Extraction: M2000sp or M24sp Amplification: M2000rt: US$ 50 250	Real-time thermocycler and small consumables	NucliSens miniMAG system or NucliSens easyMAG system, NucliSens EasyQ Analyser and Strip centrifuge	COBAS® AmpliPrep with COBAS® TaqMan® 96 (docked or undocked) or COBAS® TaqMan® 48	Main system: VERSANT™ kPCR Molecular System

1 Prices vary considerably with quantities and special negotiations.

2 All assays require pipettes, vortex mixers and refrigerators.

	Abbott	Biocentric	bioMérieux S.A.	Roche	Siemens Healthcare Diagnostics
Equipment cost (US dollars)	M2000sp: US$ 100 000 or M24sp: US$ 90 000 M2000rt: US$ 50 250	US$ 40 000	**miniMAG: US$ 12 900** **EasyQ: US$ 57 400** **easyMAG: US$ 114 100**	**COBAS® TaqMan® 48/96: US$ 45 000–100 000/US$ 80– 150 000** **AmpliPrep: US$ 80–150 000**	**VERSANT™ kPCR Molecular System: US$ 180 000**
Infrastructure required	Three dedicated areas for performing the assay with the Abbott *m*1000sp/ m24sp Systems and manual specimen preparation, Abbott *m*Sample Preparation System and Abbott *m*2000*rt*. Two dedicated areas, specimen preparation area and amplification area, for the Abbott *m*2000*sp* and Abbott *m*2000*rt*	None stated, but given the manual nature of the assay, three dedicated areas should be recommended	**Three dedicated areas**	**Two or three dedicated areas are required depending on the workflow chosen**	**Deep-freezing** **Three dedicated areas**
Storage conditions	mSample Preparation System RNA (4 x 24 preps) must be stored at 15–30°C The Abbott RealTime HIV-1 Calibrator A and Calibrator B must be stored at –10°C or colder. The Abbott RealTime HIV-1 Negative and Positive Controls must be stored at –10°C. The Abbott RealTime HIV-1 Amplification Reagent Pack and Internal Control vials must be stored at –10°C or colder when not in use	–20°C	**2–8°C for amplification reagents** **For extraction reagents: buffers 1, 2 and lysis buffer: 2–30°C** **Buffer 3 and magnetic silica: 2–8°C**	**2–8°C for all reagents**	**VERSANT™ HIV-1 RNA (kPCR) Kit, IVDD Box 1: –30°C to –10°C** **VERSANT™ HIV-1 RNA (kPCR) IVDD Box 2: –90°C to –60°C** **VERSANT™ Sample Preparation 1.0 Reagents Box 1: 15–30°C** **VERSANT™ Sample Preparation 1.0 Reagents Box 2: 2–8°C**
Regulatory status	WHO prequalification, Therapeutic Goods Administration, CE-IVD, US-IVD, Canada-IVD, Japan-IVD for plasma	None	**WHO prequalification, CE-IVD (plasma and EDTA dried blood spot)**	**WHO prequalification, CE-IVD, US-IVD, Japan-IVD, Canada-IVD for plasma**	**WHO prequalification, CE-IVD for plasma**

LABORATORY REQUEST FORM FOR HIV VIRAL LOAD TESTING

Specimen identification information: *to be completed by laboratory staff*

Facility name:	Date specimen collected (DD/MM/YYYY):
Facility code:	Specimen type (please tick one): ☐ DBS ☐ Plasma ☐ Whole blood
District:	

Patient information: *to be completed by a clinician*

Unique identifier:	Date of birth (DD/MM/YYYY):
ART number:	If unknown, age in years: Sex: ☐ Male ☐ Female
	If <1 year, age in months:
Current regimen (use code below):	Date treatment initiated (DD/MM/YYYY):
Is the patient receiving second-line therapy? ☐ Yes ☐ No	Is the patient pregnant or breastfeeding? ☐ Yes ☐ No
Reason for failure: ☐ Viral ☐ Immune ☐ Clinical	Is the patient receiving ARV drugs for preventing mother-to-child transmission? ☐ Yes ☐ No
Does the patient have active TB? ☐ Yes ☐ No	Patient's telephone number:
If yes, is he or she on ☐ initiation ☐ continuation phase	ARV adherence ☐ Good ≥95% ☐ Fair (85–94%) ☐ Poor <85%

Indication for viral load testing (please tick one): *to be completed by a clinician*

☐ **Routine monitoring**
Date of last viral load test (DD/MM/YYYY): Value: (copies/ml)

☐ **Repeat viral load test after detectable viraemia and six months of adherence counselling**
Date of last viral load test (DD/MM/YYYY): Value: (copies/ml)

☐ **Suspected treatment failure**
Date of last viral load test (DD/MM/YYYY): Value: (copies/ml)

Requesting clinician: *Date requested (DD/MM/YYYY):*
Signature:

ART regimen codes

INSERT LATEST HEALTH MINISTRY CODES

For more information, contact:

World Health Organization
Department of HIV/AIDS
20, avenue Appia
1211 Geneva 27
Switzerland

E-mail: hiv-aids@who.int

www.who.int/hiv

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