ICAP Approach to Implementation of Routine Viral Load Monitoring

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ABOUT ICAP

ICAP was founded in 2003 at Columbia University's Mailman School of Public Health. A global leader in HIV and health systems strengthening, ICAP provides technical assistance and implementation support to governments and non-governmental organizations in more than 21 countries. ICAP has supported work at more than 5,200 health facilities around the world. More than 2.2 million people have received HIV care through ICAP-supported programs and over 1.3 million have begun antiretroviral therapy.

Preface

This guide was developed as part of a four-part series that aims to support ICAP teams in the implementation of effective strategies that support reaching the global 90:90:90 targets.[1] The four documents describe ICAPs approach to:

1) **Targeted HIV Testing.** This document describes innovations that support an increase in yield in HIV testing, especially among subpopulations that have historically been hard to reach.

2) **Antiretroviral Therapy Initiation in the Era of Treat All.** This document describes approaches to ensuring high uptake and coverage of antiretroviral therapy (ART) in the context of the "treat all" approach.

3) **Differentiated Service Delivery.** This document describes key considerations for the implementation of differentiated service delivery models.

4) **Viral Load Scale-Up.** This document describes key considerations for preparing for national implementation and scale-up of routine viral load monitoring.

These guides can be used to assist countries countries in thinking through successful strategies to increase targeted HIV testing, improve ART coverage and retention in care, and maximize services to ensure viral load suppression. All four documents highlight areas that need to be prioritized, while maintaining a focus on critical issues not adequately covered in other resources. They are intended to complement the "ICAP Package of Care for People Living with HIV" (see Annex 20).

The target audience of this guide includes health managers at the national and sub-national levels and clinical staff supporting the implementation and scale-up of viral load testing and monitoring.

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[1] Targets are that 90 percent of all people living with HIV know their HIV status; 90 percent of all people with diagnosed HIV infection receive sustained ART; and 90 percent of all people receiving ART have viral suppression.

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Acronyms

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral therapy
CDC	U.S. Centers for Disease Control and Prevention
DBS	Dried blood spot
DQA	Data quality assurance
EAC	Enhanced adherence counseling
EMR	Electronic medical records
HF	Health facility
HIV	Human Immunodeficiency Virus
HMIS	Health management information system
LIMS	Laboratory information management system
M&E	Monitoring and evaluation
MDT	Multidisciplinary team
MOH	Ministry of Health
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV
PMTCT	Prevention of mother-to-child transmission of HIV
POC	Point of care
QA	Quality assurance
QI	Quality improvement
SOP	Standard operating procedure
TWG	Technical working group
VL	Viral load
VLM	Viral load monitoring
WHO	World Health Organization

Executive Summary

Routine viral load monitoring (VLM) is an essential part clinical care for individuals receiving antiretroviral therapy (ART). This document describes key considerations for the implementation and scale-up of national VLM systems.

The document is divided into four main sections and includes a number of links to additional resources developed by ICAP country programs, supported ministries of health, and other organizations.

- The first section describes the **principals of, and rationale for, VL measurement** and why VL testing has emerged as the sine qua non method for monitoring response to ART. The recommended timing and frequency for VL testing for different types of individuals (e.g., children, adults, pregnant or breastfeeding women) as well as interpretation of assay results, management of individuals with elevated VL, and criteria for treatment failure based on VL test results are also presented in this section.
- The second section describes **implementation considerations for scaling up VLM services** and includes key information for managers to support informed decisions as they design VL implementation plans. This section also provides a dashboard to support the monitoring of progress toward full-scale uptake.
- The third section addresses **laboratory-related concerns** that must be considered when developing high-quality VL testing services with national coverage. Laboratorians play a key role in all phases of planning and executing VL testing scale-up and must provide technical input into planning for a national VL laboratory network, selection of a VL assay platform, specimen handling, and transport logistics between health facilities and referral laboratories, as well as plans to assure adequate human resource capacity to execute a national plan.
- The fourth section highlights the **monitoring and evaluation** of VLM services, including necessary adaptations to existing monitoring systems and key indicators to monitor during different phases of implementation. The section also includes country examples and monitoring and evaluation resource tools.

Finally, it is important to note that in addition to its importance in monitoring response to ART, proper implementation of differentiated care models relies on accessible, efficient, high-quality VLM (see Figure 1).

Introduction

HIV viral load (VL) is a valuable indicator of an individual's response to ART and risk for clinical progression,[1,2,3] as well as a measure of transmission risk.[4,5] Since 2013, World Health Organization (WHO) guidelines have recommended VL testing as the prefered monitoring approach for all HIV-infected children and adults on ART in order to assess treatment response, detect treatment failure, and determine the need to switch to a second-line regimen in a timely manner.[6]

In 2015, UNAIDS launched the 90:90:90 targets (90% of all people living with HIV with known HIV status, 90% of all people diagnosed with HIV receiving ART, and 90% of all people living with HIV receiving ART with viral suppression by 2020), with the aim of achieving AIDS epidemic control by 2030. Access to uninterrupted, lifelong HIV treatment and high rates of viral suppression are essential to ensuring optimal patient outcomes and population impact for epidemic control.

Viral suppression is also among the key criteria for distinguishing stable and unstable patients on ART, and determining an appropriate level of care in virtually all differentiated service delivery models. Implementation of such models cannot be achieved in the absence of a reliable, high-quality system for routine monitoring of HIV VL. Key decisions regarding the frequency of visits and site of care (e.g. community or health care facility) depend on the availability of timely VL test results.

Operationalization of VL monitoring (VLM) to achieve the third of the 90:90:90 targets will require the combined effort of national and sub-national level governments and key stakeholders to ensure access to VL testing and the availability of new, relevant technologies. Effective implementation will require well-coordinated efforts across many facets of the health care system, including a robust monitoring and evaluation (M&E) system that coordinates data flow across multiple health sector levels to measure outcomes and progress toward the achievement of viral suppression targets.

I. VLM Principles

A. VL Measurement

The goal of ART is to achieve viral suppression, which is associated with better clinical outcomes and a lower risk of HIV transmission. Viral suppression also has implications for durability of ART, as persistent viral replication in persons taking ART can lead to the emergence of resistance to one or more antiretrovirals (ARVs). While it is desirable to have an undetectable VL, the WHO has defined the VL threshold for treatment failure as >1000 copies/ml, given the low risk of HIV transmission and disease progression at or below this level. In most patients taking ART, the VL should be ≤1000 copies/ml after six months of treatment.

Box 1: WHO Definition of Virologic Treatment Failure

- A persistent VL above 1000 copies/ml after at least six months of taking ART.[6]
- "Persistent VL" is defined as two consecutive VL measurements after 3-6 months in an individual with good adherence to ART.

B. Timing and Frequency of VLM

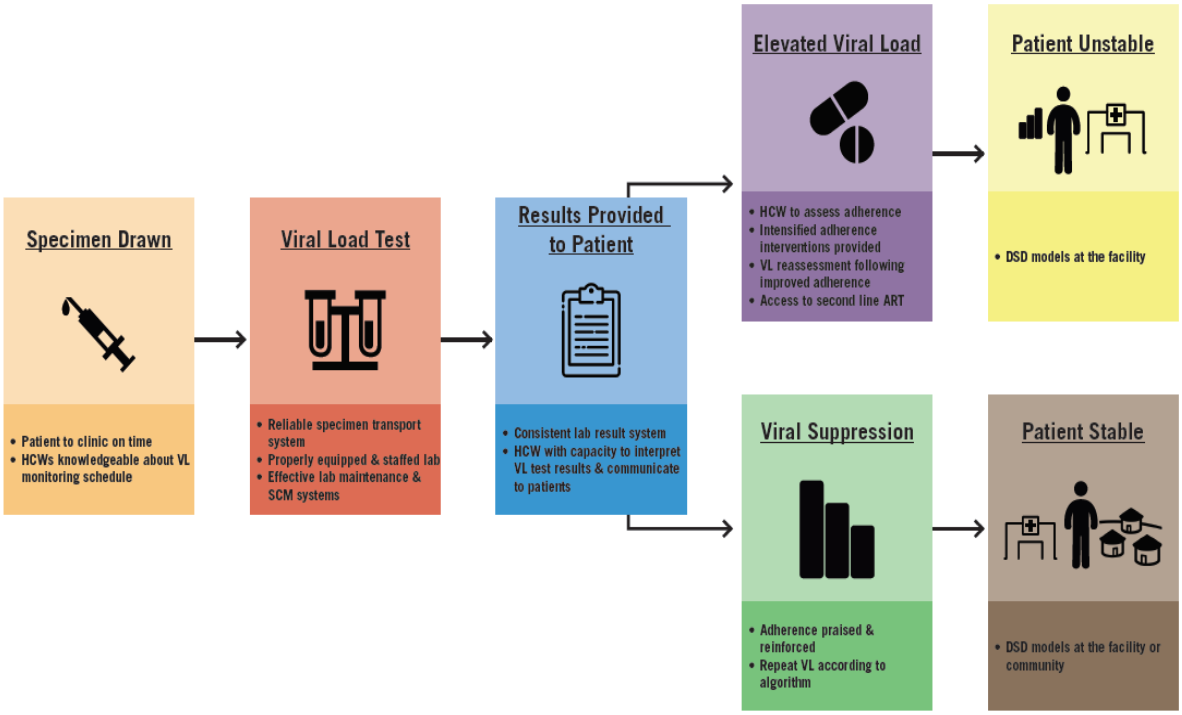
VL testing should ideally be performed at regular intervals for all individuals receiving ART (i.e., routine VLM) in order to monitor treatment response and ensure accurate and timely detection of treatment failure. The optimal timing and frequency of VLM has not been established; however, it is generally recommended that once routine VLM is available at a particular HIV care and treatment facility, a VL test should be performed for all patients who have been on ART for six months or longer at their next clinic visit, or according to the country's VLM phase-in plan. Patients with undetectable VL should repeat the test after six months. Those with two VL test results ≤1000 copies/ml separated by six months (i.e., stable patients) can undergo annual VL testing.

More frequent VL measurement (e.g., every three months) is recommended in many national guidelines for those at high risk for treatment failure (e.g., children and adolescents), as well as in prevention of mother-to-child transmission of HIV (PMTCT) settings (see "Targeted VL Implementation" section).

Figure 1 presents a simplified VLM continuum, showing the pivotal role VL testing plays in a differentiated service delivery model of care. VL results should be coupled with other considerations before determining that a patient is stable and eligible for more or less intensive monitoring at either the health facility (HF) or in the community. Additional details about determining eligibility for differentiated service delivery models can be found in the guide entitled, "ICAP Approach to Differentiated Service Delivery."

For more information on VL principles, results interpretation, and patient management, refer to the "Standard Operating Procedures on Viral Load Monitoring for ICAP Clinical Staff and Health Care Workers" (Annex 4).

Figure 1: Viral Load Continuum, Patient Classification, and Differentiated Service Delivery



* **WHO definition of stable patient**: Received ART for at least one year and has no adverse drug reactions that require regular monitoring, no current illnesses or pregnancy, is not currently breastfeeding, has good understanding of lifelong adherence, and evidence of treatment success (i.e., two consecutive undetectable VL measures). In the absence of VLM, rising CD4 counts or CD4 counts >200 cells/mm^3 and an objective good adherence measure can be used to indicate treatment success.

C. Virologic Treatment Failure

A VL >1000 copies/ml indicates that viral replication is not well-controlled. This may be due to sub-optimal adherence or may indicate that the patient's HIV is resistant to one or more of the drugs in the ART regimen the patient is taking. Individuals with a VL result >1000 copies/ml should promptly undergo a detailed adherence assessment and receive enhanced adherence counseling based on an individualized plan of care, in order to improve adherence (see Figure 1). More intensive follow-up is warranted in almost all such cases, during which time repeat adherence assessments should be conducted and the treatment plan updated to address new or remaining barriers to adherence. After three months of reported good adherence, a repeat VL test should be conducted. Continuous, detectable VL in the face of reported good ART adherence constitutes virologic failure, most commonly due to resistance to one or more of the drugs in the patient's ART regimen. Patients on ART with confirmed, detectable VL (i.e., two consecutive VL measurements >1000 copies/ml within a 3–6 month interval, with enhanced adherence support provided and good adherence reported) will likely need to switch regimens. Individuals with virologic failure should be referred to the relevant decision-making individual(s) or entities (e.g., medical provider, multidisciplinary team, treatment failure committee, etc.) for further management, monitoring, and a switch to a second-line regimen (according to national guidelines). Those whose repeat VL is found to be ≤1000 copies/ml should be offered continued close monitoring and adherence support if concerns remain about possible adherence problems, and should not be considered "stable" until viral suppression is documented on a repeat VL test performed after six months.

In the case of confirmed virologic failure, the goal of switching to second-line ART is to achieve viral suppression or re-suppression (i.e., VL ≤1000 copies/ml). With few exceptions, procedures for managing second-line treatment failure require oversight and monitoring, often relying on centralized approaches. The procedures for decision-making regarding switching from first- to second-line ART for individuals with virologic failure will vary according to a number of factors, including:

- The existing organization of HIV care and treatment services (highly centralized, decentralized, etc.)
- The level of training, experience, and scope of practice of health care providers (ART prescribed by nurses, clinical officers, doctors only, etc.)
- The availability of HIV specialists, the prevalence of treatment failure, clinic volume, and clinic staffing patterns
- The ease of travel to a higher-level facility for patients

Developing systems of stewardship that aim to coordinate efforts to monitor and promote the appropriate use of ARVs, improve patient outcomes, and minimize ART resistance are essential. These systems should support patient-centered management of individuals with confirmed treatment failure (e.g., avoid unnecessary delays and barriers to care, and support shared decision-making between patient and provider), and should provide supportive mentorship to clinicians. These systems and practices may take the form of mandatory formal case reviews by facility, regional, or national specialists/multidisciplinary panels; consulting remote expert clinicians; or, where appropriate, allowing all ART prescribers to obtain certification for switching patients to second-line ART. Monitoring considerations are discussed in Section IV: Monitoring and Evaluation, and Annex 4 provides an example of standard operating procedures (SOP) for viral load monitoring.

Box 2: Examples of Procedures for Switching to Second-line ART

Mozambique

All cases of individuals with confirmed treatment failure undergo review prior to switching to second-line ART by a regional multidisciplinary team (MDT) composed of experts with years of experience with ART management. When a patient with virologic failure is identified, a summary of clinical and lab information is prepared and sent by the facility HIV focal point to the MDT. The MDT convenes to review the information in order to determine if the individual is eligible for a second-line regimen. The request is then sent to the MDT at central level for final approval. Tunaround for switches to second-line regimens has improved over time and the National AIDS Program is working on a decentralization process that will allow decisions to be made by regional MDT (to ensure that switches to second-line regimens happen in a timely manner).

Swaziland

SOPs in Swaziland require that the case history of all patients with confirmed treatment failure be reviewed by a facility-based MDT prior to switching to second-line ART. MDT are typically composed of a doctor, expert client, nurse, and laboratorian. The outcome (e.g., second-line switch) is documented by MDT in a high VL register.

Section 1: Key Points

- VLM is key to monitor response to ARV treatment.
- VLM should be provided as a routine service to all patients on ART.
- A VL >1000 copies/ml indicates that viral replication is not well-controlled, and that the patient should promptly undergo a detailed adherence assessment and receive enhanced adherence counseling. After three months of reported good adherence, a repeat VL test should be conducted.
- In the case of confirmed virologic failure, the goal of switching to second-line ART is to achieve viral suppression or re-suppression (i.e. VL ≤ 1000 copies/ml).

II. Implementation Considerations for VLM

All countries should aim to implement routine VLM to ensure early detection of virologic failure, as well as identification of stable patients who can be referred to less intensive monitoring and clinical follow-up, as described in the guide, "ICAP Approach to Differentiated Service Delivery." As part of preparedness for routine VLM implementation and scale-up, it is essential to ensure proper planning, including full appreciation of the nature of the "VL continuum." A comprehensive assessment of existing systems and detailed plans must be elaborated for each step in the continuum in order to minimize "leakage" and to ensure adequate turnaround time of results so that VLM may influence clinical management.

Important lessons were learned from implementing CD4 monitoring and infant HIV testing programs, including early infant diagnosis. Specifically, inappropriate testing frequency, long turnaround time, poor tracking of test results, and inadequate training and support of health care workers for test interpretation contributed to undermining the potential impact of these lab tests on patient outcomes. Therefore, it is critical to recognize that addressing each step in the VL continuum is a vital part of the initial planning process for VL implementation and scale-up.

A. Implementation Approaches

The Ministry of Health (MOH), National VL Technical Working Group (TWG), key programs within the MOH (HIV, laboratory, M&E), and key stakeholders should assess the systems components related to the VL continuum and consider the country's capacity to implement routine VLM, including available funds and estimated costs for different models of implementation. If national implementation of routine VLM is not feasible, the country should implement a plan for a phased approach to VL testing implementation. Under the phased approach, limited or targeted VL testing is implemented as the needed structure and systems for routine monitoring are developed and applied.

i. Routine VLM Implementation

Countries should aim to offer routine VLM—providing VL testing to all individuals receiving ART at all health facilities offering ART in the country—with the objective of monitoring treatment response. After assessing and evaluating existing country resources and ensuring that adequate resources are available to allow implementation at the national level, MOH should work with key stakeholders to ensure that proper systems are in place for national roll-out.

ii. Targeted VL Implementation

Targeted implementation should be discussed in-country in cases where the needed resources are not available for national implementation of routine VLM for all patients. A targeted approach constitutes a phased implementation, allowing countries to build and strengthen systems and procedures, as well as identify resources for scale-up of national routine VLM implementation. According to the country context, the phased implementation may be on the basis of specific geographic areas or sub-populations as initial steps toward national scale-up.

a. Sub-populations

A phased approach based on sub-populations should focus on groups where treatment monitoring and ensuring viral suppression will have the greatest impact on patient outcomes and the HIV epidemic. In the process of developing and designing the implementation plan, countries should consider their HIV epidemic and identify specific sub-populations on which to focus. A phased approach based on sub-populations will allow the country to create procedures and ensure that systems are in place for eventual implementation of national routine VLM for all patients on ART.

1. Adults With Suspected Treatment Failure

In settings where routine VLM is not feasible, VL testing may be reserved for individuals where treatment failure is suspected based on clinical and/or immunological criteria (see 2016 WHO guidelines and Annex 4). This targeted VLM helps to avoid unnecessary switches to second-line regimens.

2. Infants, Children, and Adolescents

The 2016 WHO guidelines refer to HIV-infected infants and children as a priority group for VLM. In this population, it is important to understand factors that may influence viral suppression, such as the limited ARV drug options available, challenges with the use of protease inhibitor-based regimens (such as supply chain and cold chain for LPV/r syrup), and inadequate dosage for children (with constraints in updating pediatric ART dosage according to age/weight band). In addition, infants exposed to maternal ART and/or postnatal prophylaxis have a higher risk of acquiring and selecting HIV drug resistance mutations and, as a result, are at higher risk of early treatment failure, especially if treated with NNRTI-based regimens[11].

Recent data from national VLM programs, observational cohorts, systematic reviews, and meta-analyses indicate lower rates of viral suppression among HIV-infected infants, children, and adolescents when compared to adults.[11] Further, rates of viral suppression do not appear to have increased substantially as a result of changes in ART regimens (e.g., replacement of D4T with abacavir; use of protease inhibitor-based first-line regimens for all children <3 years).[23]

Adolescents are another priority sub-population described in the 2015 WHO guidelines because they are the only age group in which there has not been a decline in AIDS-related deaths.[12] It is important to recognize that sub-optimal adherence is a major challenge during adolescence, which puts this group at high risk for HIV drug resistance and treatment failure, and can make adherence monitoring particularly challenging.[12,13]

3. Pregnant and Breastfeeding Women on ART

Timely VLM and achieving viral suppression among pregnant and breastfeeding women have concurrent benefits. The woman's health benefits and sexual and mother-to-child transmission is reduced, helping to ensure the long-term health of children and families.

VL testing strategies and algorithms for pregnant and breastfeeding women should consider the urgency and timing of testing, the turnaround time for results, and the options available for patient management. The rationale for an altered VL testing schedule is that pregnancy and breastfeeding are discrete periods with elevated risk of HIV transmission from mother to child and high risk to women's health. Consequently, more frequent monitoring may be warranted; for example, Angola's and Mozambique's VL algorithm for pregnant and breastfeeding women includes the first VL measurement three months after ART initiation to allow for monitoring of viral suppression. Optimal timing and frequency of VLM during pregnancy and breastfeeding remain to be determined.

Special consideration should be given to pregnant and breastfeeding women **already on ART** at arrival at reproductive, maternal, neonatal, and child health services. Adherence to treatment should be assessed for those already on ART for more than six months and a specimen for VL testing should be obtained at their **first visit** to see if viral suppression has been achieved.

b. Geographic Areas

A phased approach based on geographic areas should consider regions where VL implementation would allow for the highest impact, as well as availability of laboratory and specimen transportation systems. In the regions identified for initial VL implementation, the testing algorithm should include all sub-populations as eligible for routine VLM. In order to ensure the highest coverage of VLM and, consequently, the greatest impact on the national HIV epidemic, regions/facilities with the highest HIV prevalence and facilities with the greatest patient volume should be selected for initial implementation.

B. Key Considerations for VL Implementation

A national implementation plan must include detailed procedures for timely identification of patients eligible for VL testing; tracking blood specimens; specimen handling and transport to lab; return of test results to facilities; and clinical decision-making based on test results (see Annex 1 for country examples). Systems are also required for educating patients about VL, providing all patients with test results, "flagging" high VL results and individuals in need of enhanced adherence counseling, and conducting enhanced adherence counseling sessions. Well-defined and expedient procedures for switching ART for those with documented virologic failure must also be formulated.

Demand creation and education strategies for both providers and community are integral to national implementation plans. These should include community sensitization and patient education, as well as training for providers and embedding metrics (process and outcome indicators) for quality assessment and improvement—which are essential to success.

Identification and engagement of relevant stakeholders is a critical part of national implementation planning and typically includes clinical and laboratory experts, implementation partners, the MOH, community partners, and people living with HIV (PLHIV). In most cases, the creation of a separate VL TWG will be required. The following **key milestones** are critical to ensure the seamless implementation of routine VLM in a particular country (see Annex 1 for resources):

- Development of a national VL implementation plan, including demand creation and education strategies
- Technical leadership (which may take the form of a TWG) is in place to monitor the efficiency and effectiveness of the implementation plan at the HF, regional, and national levels
- Appropriate equipment for VL testing is available in relevant laboratories, with appropriately trained individuals who can perform quality testing and optimize workflow to accommodate the required volume of tests over time
- Establishment of a system for commodities management that includes monitoring and alerts for threats (e.g., need for machine maintainence or shortage/stock-out of consumables/reagents), ensuring early interventions and the avoidance of service interruptions
- Creation of job aids and SOPs to ensure access to quality plasma or dried blood spot (DBS) specimens that meet required standards and are collected and shipped to the referral lab
- Establishment of an M&E system that ensures timely and adequate monitoring of: turnaround times of VL test samples and results from/to clinical sites, delivery of results to patients, and clinical outcomes
- Development of SOPs and job aids for VLM, including patient eligibility criteria, when to order the test, how to educate patients on VL, how to interpret results, and how to manage treatment failure (including first- and second- line ART regimens), within a system that ensures the timely identification and management of patients with virologic failure
- Development of a tool and plan to assess facility readiness to inform the design of a VL implementation plan and its procedures
- Training and adequate human resources for all aspects of the VL continuum, including VL test ordering, specimen collection, specimen transport, specimen processing and storage, conducting the VL test, safe disposal of residual specimens, results transmission and documentation, and utilization of results for patient management (including interpretation of VL test results and provision of enhanced adherence counseling)
- Development of a plan for ongoing supportive supervision and regular mentorship of sub-national and implementing HF staff
- Establishment of an M&E framework that includes tools, registers, and a database that are harmonized to ensure accurate documentation of VL test results and that make it possible to measure the progress and outcomes of routine VLM

Regular monitoring of VL implementation is key to ensure that challenges are identified and addressed in a timely manner. Table 2 presents a tool that ICAP developed to help country teams track VL implementation.

Table 1: Key Considerations for the Implementation of Viral Load

	National Level	Regional Level	Health Facility Level
Policy / Political Commitment	• Creation of a functional TWG that includes members of HIV, PMTCT, and laboratory programs and departments; implementing partners; health workers; and PLHIV • Assessment of human resource capacities and M&E system • Estimation of number of eligible patients and samples needed to inform plan for lab structure and consumables • Development of costed, phased implementation plan with targets; determination of criteria to guide phased implementation (e.g., geography, priority populations, etc.) • Development of a demand creation plan for VL testing • Updated national guidelines that integrate VLM, including an algorithm for VLM, SOPs, and job aids • Development of policies outlining VL processes and procedures • Development of standards and processes for the management of patients with virologic failure, including enhanced adherence counseling (EAC) and ART regimen switches	• Creation of a functional TWG to manage and monitor VL implementation, including members of HIV, PMTCT, and laboratory programs; implementing partners; health workers; and PLHIV • Generation of data for program management and national planning	• Identification of a focal point for VL • Development of a sample/results and patient flow SOP with roles and responsibilities • Development of SOP for results and patient management, including second-line changes
Human Resources	• Development of VL curriculum and training materials • Definition of core competencies for each health cadre • Development of a strategy for retaining health workers • Provision of training for molecular lab staff, and re-training plan in place	• Development of a plan for clinical team training • Development of a plan for supportive supervision for VL implementation and patient management • Creation of clinical fora at regional level, such as TWG or MDT (including pharmacists and lab technicians)	• Development of a plan for HF team training • Creation of clinical fora to monitor implementation at HF level, such as TWG or MDT (including pharmacists and lab technicians) • Development of a plan for regular MDT meetings to monitor VL implementation, including case management discussions, specimen collection, and clear roles and responsibilities
Infrastructure	• Creation of facility storage space for additional commodities (ART supplies) at regional level • Expansion of molecular laboratory infrastructure to accommodate increased testing, and of storage facilities for specimens and reagents	• Creation of lab infrastructure, if testing done at regional lab level • Creation of lab structure for HF referring samples	• Creation of dedicated lab space, if high throughput or point of care (POC) VL testing capacity present

Commodities	• Forecasting and quantification of VL reagents and consumables and second-line ARVs • Reliable supply chain (including distribution of inventory, management, and procurement) • Development of commodities forecasting plans	• Reliable supply chain (including distribution of inventory and management)	• Reliable supply chain (including distribution of inventory and management to prevent stock-outs)
M&E / Information Systems	• Definition of M&E framework and agreement on key process and outcome indicators for the VL continuum • Creation of functional management fora for M&E implementation of routine VLM • Updated clinical and lab monitoring tools based on key indicators • Development of cohort monitoring tools to support monitoring the entire VL continuum, including turnaround time • Definition of routine data quality assurance (DQA)	• Creation of a functional TWG to manage M&E implementation of routine VLM, including members of HIV and PMTCT programs; implementing partners; health workers; and PLHIV	• Allocation of tools and registers available at HF level • Development of a plan for regular MDT meetings to monitor VL implementation, including M&E implementation of routine VLM
Laboratory	• Assessment of national VL testing capacity, diagnostics network map, and utilization status, projecting progressive test volume increases and determining needs for new diagnostic platforms to meet national testing demands • Determination of selection criteria and acquisition strategy of new VL platforms • Development of equipment service and maintenance plan • Assessment of existing specimen transport network and result delivery systems • Revision and/or development of lab QA and accreditation plan • Development of algorithm for VLM and lab SOP* • Establishment of VL testing laboratory capacity (specimen collection, processing, results return, training) • Development of commodities forecasting plans • Development of VL testing safety and waste management plan	• Development of VL sample/results transport network • Creation of a structure at peripheral labs for sample processing and preparation prior to sending to referral labs • Development of a training plan for lab technicians/ phlebotomists • Development of a plan for mentorship and supportive supervision of lab staff • Development of a plan for specimen collection, commodities distribution, and inventory monitoring	• Development of sample and results flow, including roles and responsibilities (SOP) • Development of a training plan for lab technicians/ phlebotomists • Development of a plan for regular MDT meetings to monitor VL implementation, including supply chain management and lab procedures • Development of a specimen collection and commodities inventory monitoring tool/system
Quality Assessment and Supervision	• Development of a lab quality management system, including proficiency testing, laboratory mentorship, and supportive supervision	• Development of a supervision plan to monitor VL continuum implementation • Development of functional management fora to monitor VL implementation	• Development of a plan for regular MDT meetings to monitor VL implementation

Acronyms: MDT= multidisciplinary team, **EAC** = enhanced adherence counseling, **HF** = health facility, **QA** = quality assurance
***** Refer to "Standard Operating Procedures on Viral Load Monitoring for ICAP Clinical Staff and Health Care Workers" (Annex 4)

Box 3: The Implications of VLM for CD4 Monitoring

In its 2015 guidelines, the WHO recommends that, in settings where routine VL monitoring is available, CD4 cell count monitoring can be stopped in individuals who are stable on ART and virologically suppressed. As part of the VL implementation scale-up plan, countries should develop a phase-out plan for CD4 monitoring once VL routine monitoring is available.

Although CD4 results are no longer used to determine ART eligibility in countries that have moved to treating all PLHIV, baseline and subsequent CD4 measurements are still important to guide clinical decisions about starting and discontinuing prophylaxis and screening for opportunistic infections. CD4 count may also be helpful in managing ill patients and determining if they are at risk for an opportunistic infection.

Section 2: Key Points

- Identification of a national TWG, including key stakeholders, is a critical part of national implementation planning.
- It is essential to ensure proper planning for routine VLM implementation. This includes conducting a comprehensive assessment of existing systems and developing a national implementation plan that includes detailed procedures for each step in the VL continuum (e.g., sample and results logistics, clinical decision-making based on results, and strategies for patient education and demand creation).
- Routine VLM should be offered to all patients receiving ART; however, if national implementation of routine VLM is not feasible, the country should implement a plan for a phased approach to VL testing implementation.
- A phased approach to VLM implementation allows countries to build and strengthen systems and procedures gradually, and to identify resources for scale-up of national, routine VLM implementation.
- Depending on the country context, phased implementation may be based on specific geographic areas or sub-populations.

Table 2: Viral Load Implementation Monitoring Tool

Guidelines	National HIV treatment guidelines do not include VLM	Discussions and meetings on including VLM in national HIV treatment guidelines are ongoing	National HIV treatment guidelines provide detailed and specific guidance on the implementation of targeted VLM for specific sub-populations or geographic areas	National HIV treatment guidelines provide detailed and specific implementation guidance for universal routine VLM for all populations
National VL Scale-up Plan	None	VL scale-up plan discussions and meetings ongoing	VL scale-up plan draft available and VL implementation commenced	VL scale-up plan approved by MOH and fully implemented
Human Resources (HR)	Limited in-country HR capacity to support VL implementation; roles and responsibilities not clearly defined; no supervision	HR needs assessment is ongoing	HR (HF and lab) hiring process and training ongoing; clear roles, responsibilities, and supervisory structure developed	HF and lab fully staffed (based on needs assessment) and trained using national curricula; ongoing supportive supervision being provided
Laboratory Systems and Capacities	No in-country VL testing capacity	Limited VL testing capacity and networking exists	Sufficient VL testing capacity and networking that supports targeted VLM	Sufficient VL testing capacity and networking that supports universal routine VLM
Demand Creation	None	Discussions and meetings ongoing to develop demand creation for VL, including input from PLHIV representatives, civil society, and other key stakeholders	Demand creation strategy and draft of needed materials available and being piloted in coordination with PLHIV representatives and civil society	Demand creation strategy and supporting materials developed, nationally approved, and fully executed
Training Materials, SOPs, and Job Aids (including EAC materials)	VL clinical and EAC training materials are not available	Some materials have been developed by organizations piloting VL	National, harmonized VL clinical training materials, SOPs, and supporting materials/job aids (including for EAC) are under development	National VL clinical training materials, SOPs, and supporting materials/job aids (including for EAC) have been developed and integrated into pre-service and in-service curricula and are in use; SOPs have been adapted at HF level
VL Coverage	None	Pilot programs only	Regional/specific population VLM coverage (as per national plan)	Universal routine VLM coverage for all populations
M&E System	No M&E system elements/ framework for VLM are in place or in development	Some new or adapted tools (registers, reporting forms) and/or parts of M&E framework for VLM are in development	M&E system elements/framework are in place, but are not comprehensive or fully integrated into routine M&E for HIV/ART	Existing comprehensive VL monitoring M&E systems integrated into national M&E system for HIV care/ART and linked to laboratory and HF data management systems; multi-disciplinary team established and using M&E framework to monitor VL implementation
Quality Management (QA/QI) of VL Implementation	Unknown/not available	Quality management strategy and protocols developed and integrated into clinical materials (e.g., trainings, SOPs)	VLM programs have quality management protocols in place and ongoing quality improvement activities	Demonstrated, consistent, high-quality VL monitoring services across sites
Impact of VL Implementation	Unknown/not available	Process and impact evaluation plans incorporated into M&E framework; monitoring of process indicators or process evaluation of initial phase of VLM implementation underway	Comprehensive process evaluation of national level VLM implementation have been conducted and informed national implementation plan	Impact evaluation conducted; evaluation data show impact of VL implementation on patient outcomes

III. Laboratory Considerations

A. Coordination

Introducing and scaling up routine VLM technologies requires that the laboratory team play a central role in stakeholder engagement. This includes identifying and engaging all relevant national laboratory partners and stakeholders, and designating a focal person who will lead the effort along with other representatives from the national HIV program. The laboratory team should also be represented in the TWG, providing technical guidance on policies, strategies, and implementation workplans for procurement and supply chain management, quality assurance, and diagnostic algorithms. The TWG should also identify existing policies, national health strategies and plans, and HIV testing guidelines that are relevant to HIV VL diagnostics in a specific country, and update them as indicated. Subsequently, these documents should be reviewed whenever new technologies become available.[14]

B. Situation Assessment and Referral Network Mapping

A comprehensive assessment of the national VL laboratory network is key for addressing national diagnostics needs. This activity should be designed to conduct mapping of existing health facilities around the country and current VL testing services that are offered. Understanding the performance of existing VL laboratories will help in the calculation of current throughputs and efficiencies of these labs. Mapping of coverage and access to VL laboratory services across facilities will help to: establish a baseline, strategically determine the ideal placement of new platforms and technologies, and select and periodically revise the specimen referral network map for maximum and efficient utilization of capacities.[14]

C. Specimen Transport and Result Return

To ensure high-quality specimens and test results, specimen transport systems need to operate efficiently. Innovative strategies that are informed by the situation assessment may need to be adopted for the specific context in order to achieve this. Wherever there are well-established early infant diagnosis and CD4 testing programs, national programs should learn from and expand upon existing specimen referral and result delivery systems. The choice of specimen and result transport systems for VL testing should take into consideration the availability of resources and the feasibility, acceptability, confidentiality, security, efficiency, and sustainability of the methods, depending on the type of specimen/s selected and the existing referral network map.

D. Specimen Type and Platform Selection

The choice of specimen type and platform or assay for VL testing is key to all facets of planning. Platform selection should consider performance and operational characteristics to ensure that both the product and specimen are suitable for the setting. Referenced guidelines and technical reports from WHO and other sources should be considered when making these decisions.[14,15,16] Introduction of both high throughput and point of care (POC) VL platforms involve unique challenges related to training, product selection and placement, data management, workflows, performance, and quality assurance.

When introducing HIV VL technologies, countries will need to determine which facilities will benefit the most from the introduction of conventional and POC testing—when products become available—and determine the most appropriate type of POC device, based on the available products and suitability for identified facilities.[17,18] VL testing products should be rationally selected in response to the specific needs and capacity of selected sites, as well as to ensure instruments are fit-for-purpose.[19] Both DBS and plasma specimen types are validated for use on a few common platforms, and selection of the specimen type should take into consideration the existing specimen transport network, laboratory infrastructure, testing modalities, and feasibility on the platform in use (see Table 3).[14] Whereever feasible, plasma is the preferred specimen type for VL testing.

Table 3: Consideration for Selection of Specimen Type

Characteristics	Specimen Type	
	Plasma	DBS
Volume	≥1.5 ml (plasma)	0.25–0.5 ml (whole blood)
Ease of collection	Requires venipuncture	Finger prick (venipuncture optional)
Processing after collection	Requires centrifugation	None
Sample storage / stability	Stringent time (6 to 24 hrs) between collection and processing; cold chain and stringent temperature control depending on duration[13]	Stable at room temperature for 2–4 weeks
Sample transport	Requires cold chain	Room temperature
Biohazard	Triple packaging for shipping	No biohazard after dried
Cost	Stringent storage and transport requirements requiring equipment and time	Consumables for collection and shipping
Platforms	• NucliSENS EasyQ® • Abbott RealTime m2000rt • COBAS® TaqMan® • VERSANT® kPCR • Generic HIV VL • VERSANT HIV RNA 3.0 Assay (bDNA)	• NucliSENS EasyQ® • Abbott RealTime m2000rt • COBAS® TaqMan® • VERSANT® kPCR • Generic HIV VL • VERSANT HIV RNA 3.0 Assay (bDNA)
Assays with WHO prequalification	• NucliSENS EasyQ® HIV-1 v2 • Abbott RealTime HIV-1 (m2000sp) • COBAS® TaqMan® HIV-1 Test, version 2.0 • VERSANT®HIV-1 RNA 1.0 Assay (kPCR)	• NucliSENS EasyQ® HIV-1 v2. • Abbott RealTime HIV-1 (m2000sp)
Assays with CE mark and currently seeking WHO prequalification	• Aptima HIV-1 Quant Dx Assay • Xpert HIV-1 Quant Dx Assay • SAMBA HIV-1 Semi-Q Test • Generic HIV Charge Virale • DxN VERIS HIV-1 Assay	

Table 4: Operational Considerations for High Throughput Platform Selection[14]

Infrastructure	Power supply, climate control, dust, instrument footprint, ancillary equipment, additional rooms for extraction and amplification, and HF tier
Quality assurance	Use with existing external quality assurance and internal quality control
Logistics	Cold-chain requirements (refrigeration vs. freezer), storage requirements, and shelf life
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 laboratory management information system
Durability	Life span of instruments, planned obsolescence, manufacturer 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, hepatitis B and C, gonorrhea, human papillomavirus, chlamydia, outbreak surveillance, etc.

E. Point of Care VL Platforms

Currently, there are two POC VL assays that have secured the European Conformity (CE) mark and Cepheid (Xpert HIV-1 Quant Dx Assay) and Diagnostics for the Real World (SAMBA HIV-1 Semi-Q Test) are actively seeking WHO prequalification (See Table 5). For more on POC platforms that are in the pipeline, see Appendix 4 of the UNITAID-WHO HIV/AIDS Diagnostics Technology Landscape publication.[20]

Similar to high throughput platforms, any selected POC VL platform should undergo both controlled laboratory-based and field evaluations at the intended site of use to assess precision and accuracy compared to a reference technology. Selection of POC VL technology placement sites should weigh the relative importance of the three broad strategies for prioritizing sites for POC deployment: 1) Universal access to testing, defined as prioritizing the most remote sites in the country to ensure that all patients have access to a diagnostic test; 2) Cost efficiency, defined as prioritizing the sites where each POC device can be optimally utilized; and 3) Patient coverage, defined as prioritizing sites to maximize the percentage of patients that have access to a same-day, on-site diagnostic test.

Table 5: Operational Characteristics of (Near) POC VL Platforms with CE Mark That Are Currently Seeking WHO Prequalification

Assay Name	Xpert HIV-1 Quant Dx Assay	SAMBA HIV-1 Semi-Q Test
Manufacturer	Cepheid	Diagnostics for the Real World
Specimen type	Plasma	Plasma
Specimen volume	1.0 ml	0.2 ml
Run size	Up to 403 VL per 8 hours (depending on # of modules)	24–48 VL per 8 hours
Processing	Cartridge–based test; no batching	Cartridge–based test; no batching
Run time duration	90 minutes	90 minutes
Assay shelf life	6 months	9 months
Assay storage temperature	2–8 degrees	2–37 degrees
Eligibility	CE mark	CE mark
Comment	Quantitative (reports actual VL numeric value per ml); instrument displays numeric results	Semi-quantitative (reported as above/below 1000 copies/ml); visual reading

F. Laboratory Quality Management System and Safety

Quality assurance, safety, and waste management plans are essential for safety and efficiency. In particular, procedures for safe disposal of polymerase chain reaction (PCR) products (amplicons) are needed to avoid costly decontamination processes in the case of spillage in any section of the laboratory that is physically linked to the molecular lab.[17,20,21]

i. Laboratory Data Management

Without sufficient data, a VL testing program cannot be accurately evaluated for quality and performance. All testing sites should use standardized electronic or paper-based logbooks documenting quality controls and proficiency tests, test reporting forms, and external quality assessment result forms.[14]

ii. Laboratory Forecasting Needs and Commodities Management

In order to ensure uninterrupted testing service delivery, it is important to strengthen the supply chain management system for VL testing. The country needs to develop a standard list of commodities required for specimen collection and VL testing based on the platforms in use for VLM. In order to avoid partial stock-outs of component consumables shared with other activities, complete sets of specimen collection kits are preferable to bulk distributions. The procurement list, quantity, and schedule need to be informed by close analysis of national and facility-level data. National-level data include consumption data for VL tests, estimated and forecasted needs for VL tests, number of working days in a year, and number of working hours in a day. Facility-level data include patient numbers, current demand for tests at the facility level, distance from facilities, current test turnaround time, current sample transport system, and the availability and type of existing diagnostics.[14,15,22]

Box 4: Supporting Quality VL Testing: The Lab-Clinic-Patient Interface

- Implementing quality VL testing that improves patient outcomes requires extensive site-level support and mentoring, and attending to any gaps between lab and clinical services, as well as between clinical service providers and patients
- All mentoring, clinical SOPs, registers, record keeping, and patient appointment and tracking systems should be reviewed and adapted to maximize the impact of VL testing
- Development of a VL dashboard is important for monitoring and evaluating the effectiveness of program outcomes, and for identifying critical areas for improvement.
  - The VL dashboard should have a data repository for capturing VL test information that will be linked to a visualization tool (i.e., the dashboard).
  - Primary data sources of the dashboard are laboratory information systems and electronic medical records systems (EMRs).
  - The data repository and its visualization tool should be open-sourced, not require heavy computational hardware, and be used by all users on the MOH wide area network, with the possibility to extend its reach to remote sites.
  - The dashboard should provide role-based access: site-level users will have access to specific site data, while national-level users can view all data and analysis.
- Focused quality improvement may be warranted in early phases of VL implementation.

IV. Monitoring and Evaluation

Successful implementation of VLM requires a robust M&E system that coordinates data flow across multiple levels of the health system: 1) Between the HF and laboratory (for transport of specimens to laboratories and for return of results to HF); 2) Communication of results by providers to patients and action by providers based on the VL result (with appropriate patient management and follow-up); and 3) Data transfer from HF and laboratories to sub-national and national levels for reporting and data use. Well-coordinated M&E systems for VLM need to include mechanisms to: monitor initial VLM implementation and scale-up (including the quality of VL testing services); track delivery of results and patient follow-up; and measure outcomes and progress toward the achievement of viral suppression targets. As countries and programs expand VLM and seek to maximize patient follow-up, they will need to incorporate M&E for VLM into existing systems to track performance and achievements in a timely and robust manner.

Steps for inclusion of VLM into M&E systems should include:

1. **Assessment of capacity and gaps** of current M&E systems at the national, sub-national, laboratory, and HF level, in preparation for implementation of VLM
2. Based on the needs assessment results, **development of a national VLM M&E framework** that outlines the M&E systems, tools, data flow, and reporting mechanisms across all levels of the health system, and that includes process and performance indicators for routine reporting
3. **Development or adaptation of existing M&E tools and the Health Management Information System (HMIS)** to adequately capture and feed the necessary data into the VL continuum indicators for tracking of VLM, as described in the M&E framework
4. **Establishment and strengthening of effective data flow** for VLM between new and existing registers, tools, patient medical records, and data management systems for patient-level and aggregate VL data across the different points of service at the laboratory and HF
5. **Development and implementation of aggregate data reporting systems for data visualization and review** to optimize use and tracking of VLM implementation and coverage at the national level, as well as key process and performance indicators at the HF and laboratory levels

Any adaptations and additions to the current M&E system should be developed and implemented in conjunction with all stakeholders, including the MOH and associated national HIV programs, clinical staff representatives, laboratory representatives, M&E experts, patient advocates, and implementing partners. Development of M&E systems should be coordinated with the development of national VLM scale-up plans, clinical guidelines, and SOPs. The two primary foci of developing the M&E system for VLM will be strengthening systems within the HF and improving coordination of M&E systems between HF and laboratories. WHO and UNAIDS have developed global guidance on VL scale-up that includes information on M&E, and the PEPFAR Viral Load Working Group has drafted detailed guidance on the development of M&E frameworks for VLM (see Annex 3). These tools should be utilized as a starting point for developing M&E systems for VLM. Further, lessons learned from infant HIV testing program implementation and from initial phases of implementation of VL testing services may be useful when developing or adapting the M&E system for VLM.

A. Needs Assessment for M&E of VLM

The first step in developing effective systems for M&E of VLM is to assess existing M&E systems, tools, and data flow across the HF, laboratory, sub-national, and national levels. At present, countries are implementing VLM to varying degrees and formal development of corresponding M&E systems may lag behind. A comprehensive assessment of existing systems will help to identify gaps in the current M&E system that must be addressed to standardize and strengthen M&E of VLM, and to ensure robust monitoring of the entire VL continuum. Standardized needs assessment tools have been developed by the PEPFAR Viral Load Working Group and ICAP, and can be adapted to the specific country context (see Figure 2 and Annexes 3 and 8). Needs assessments should be conducted by a team of stakeholders that includes clinical, laboratory, and M&E representatives from the MOH.

Figure 2: Snapshot of Needs Assessment (Annex 3)

SECTION		YES	PARTIAL	NO	Comments	Score/Total (excluding NA)
2.	MONITORING AND EVALUATION (M&E)					Points
Administer this section to the monitoring and evaluation (M&E) officer/data clerk (may need input from an ART clinician).						
6.1	Do current patient cards (and/or electronic medical records) include field(s) to monitor VL test (including test ordered, and results)?					
6.2	Do current ART registers include field(s) to capture VL tests and result data (including Tx initiation month, date test was requested, and result)?					
6.3	Do current reporting tools (paper and/or electronic) from sites include fields to report on key variables including # of patients who received a VL test, # of patients who are virally suppressed, and for routine reporting on VL testing and outcomes?					
6.4	Can M&E systems and tools at sites track VL testing outcomes for cohorts of patients (e.g. VL tests results for patients 6 and 12 months after ART initiation)?					

The needs assessment should serve to map the data flow across all levels of the health system and points of service, and to identify the extent to which data on VL testing is available in existing HF and laboratory registers/tools, patient files and EMR, laboratory information management systems (LIMS), and M&E tools and reports, including both electronic and paper-based tools and systems. Countries have varying types of M&E systems into which M&E of VLM will need to be incorporated. Some countries already have LIMS (data management system designed to capture and display comprehensive laboratory data, such as specimen management, testing, and quality assurance) and VL/infant HIV testing dashboards that utilize LIMS and EMR data to manage specific aggregate laboratory and clinical data. The needs assessment should therefore be used to identify optimal M&E systems and tools for VLM (e.g., identification of the necessity to switch to an electronic system at VL laboratories to ensure management of the additional load created by VLM).

The needs assessment should also inform indicator development to strengthen monitoring of VLM. It should assess what existing indicators are collected as part of routine reporting and whether these indicators allow for effective monitoring of the key steps in the VL continuum (e.g., specimen obtained and processed, results returned to facility, results provided to patient, enhanced adherence counseling performed). Additionally, the needs assessment should determine whether the currently available data can be used to calculate key VLM process and performance indicators, including the U.S. President's Emergency Program for AIDS Relief (PEPFAR), WHO, and MOH indicators and what modifications would be needed to calculate such indicators. This exercise should include identification of data sources and data available at each step in order to determine what additional information is needed to calculate key indicators.

Of special importance is the need to assess the methods and tools used to track specimens and capture the flow of specimens and results between the HF and laboratory, in order to ensure availability of data at each step.

B. Development of VLM M&E Framework

As an expansion of current services, VLM requires the development of a national VL M&E framework that complements the VL scale-up plan. The needs assessment should provide stakeholders with the necessary information to develop the M&E framework, including the monitoring needs along the VL continuum and the corresponding indicators, data sources, and data management systems needed for routine reporting. The M&E framework should, at a minimum, include the following:

- Goals, objectives, and logic model
- Project monitoring plans
- Indicators, including definition, disaggregations, and data sources
- Data flow
- Data collection and reporting procedures
- Reporting mechanisms
- Data management systems
- Data review, analysis, and use
- Data quality assurance plans
- Evaluation

The final M&E framework can be incorporated into the existing national HIV M&E plan, or exist as a stand-alone document to specifically guide M&E of VLM. The VL M&E framework should outline an integrated M&E system across HF, laboratories, transport systems, and national and sub-national levels of the MOH. ICAP in Swaziland supported the MOH with development of their VL implementation plan, which includes an M&E framework (see Annex 10), and the PEPFAR Viral Load Working Group's "Draft M&E Framework for VL Scale-up and Implementation" (see Annex 3) outlines key considerations.

The VL M&E framework should also reflect the strategy for expanding VLM. For example, if a phased approach is planned for implementation of VLM (e.g., implementing targeted VL testing for specific regions or subpopulations before scaling up routine VL testing), then a phased approach should be presented in the M&E plan to ensure that modifications based on early phases are incorporated into the framework. Plans should also be included for enhanced monitoring of implementation at each phase, development of procedures for timely rollout of tools, and the necessary assessments following implementation of each phase to inform scale-up in follow-on phases.

i. Indicator Development

The development of a comprehensive set of indicators for monitoring of VLM should include process indicators to measure implementation and performance and outcome indicators to measure VL coverage and achievement of VL suppression. As part of the development of the VL M&E framework, each of the following must be carefully defined: methods for calculating indicators, data sources, data collection, and reporting (including reporting frequency).

a. Process Measures

During the early phases of VLM implementation, it is essential that M&E systems are developed, in place, and operating in accordance with SOPs. It is prudent for countries to conduct enhanced monitoring of a set of select indicators during initial implementation to support early identification of gaps that need to be corrected. This includes monitoring process indicators to track implementation activities, specific performance indicators along the VL continuum to assess overall quality of VLM implementation, and select outcomes indicators. These indicators should be monitored on a monthly basis (at minimum) during initial implementation at the HF, regional, and national level. For example, in Angola, ICAP developed a detailed SOP on enhanced monitoring to manage this phase of VLM implementation (see Annex 13). As part of the development of the M&E framework, stakeholders should agree on an appropriate length of time for

enhanced monthly monitoring of the implementation process. After this initial period, it is important to continue routine monitoring of the process indicators on a quarterly or semi-annual basis. Table 6 outlines a set of recommended process indicators to monitor VLM implementation.

Table 6: Recommended Process Indicators to Monitor Implementation and Scale-up of VLM

Indicators	Point of Data Collection
1. Number of health care workers trained on VLM and enhanced adherence counseling	HF
2. Number of laboratory technicians/clinical staff trained on VL specimen collection (DBS, plasma, whole blood)	HF
3. Number of laboratory technicians at the VL laboratory trained on VL specimen processing	VL laboratory
4. Number/% of HF that are submitting specimens for VL testing	HF
5. Number of virology laboratories processing VL specimens	VL laboratory
6. Number/% of eligible patients who had VL specimen collected	HF
7. Number of unique VL tests sent to the VL laboratory for processing from the HF	HF
8. Number of specimens received by the VL laboratory from the HF	VL laboratory
9. Number/% of VL specimens rejected by the VL laboratory	VL laboratory
10. Number/ % of VL test results received at the HF	HF laboratory
11. Number/% of eligible patients with a VL result documented in medical record in the past 12 months	HF
12. Number of people with a VL >1000 copies/ml who received enhanced adherence counseling	HF
13. Number of people with a VL >1000 copies/ml who received a follow-up VL test within six months	HF
14. Median/average turnaround time from specimen collection to return of results (time between date of specimen collection to date result received by HF)	HF laboratory
15. Median/ average turnaround time for sending specimen to VL laboratory (time between date of specimen collection to date specimen sent to VL laboratory)	HF laboratory
16. Median/average turnaround time for specimen processing at the VL laboratory (time between date specimen received at VL laboratory to date result sent to the HF)	VL laboratory
17. Median/average turnaround time for return of results to the patient (time between date of receipt of results at the HF and date results are communicated to the patient)	HF
18. Number of days VL specimen not collected due to specimen collection material stock-outs	HF
19. Number of days VL testing service interrupted due to reagent and/or consumable stock-outs at VL laboratory	VL laboratory
20. Number of days VL testing service interrupted due to VL analyzer failure at VL laboratory	VL laboratory
21. Number of days VL testing service interrupted due to power outage at VL laboratory	VL laboratory
22. Number of days VL testing service interrupted due to lack of laboratory staff	VL laboratory

b. Performance and Outcomes Monitoring

To effectively measure performance and outcomes, indicators must cover every step in the VL continuum. This starts by identifying the appropriate cohort of patients currently on ART who are eligible for routine and targeted VL testing during the reporting period (per national VLM guidelines and algorithms on frequency of VLM among subpopulations) and continues with monitoring of the specimen and results flow and turnaround time, as well as patient management based on VL results. Table 7 includes a set of illustrative performance and outcome indicators that countries and programs can use for indicator selection. It includes global indicators from the WHO, UNAIDS, and PEPFAR to assess VL suppression, as well as additional indicators to ensure monitoring of each step in the VL continuum. It is important to include a subset of these indicators (denoted by an asterisk [*] in Table 7) as part of enhanced monthly monitoring from the outset of VL testing implementation, in order to track the quality of VL services. The additional performance and outcome indicators should be monitored on a quarterly, semi-annual, or annual basis during initial implementation and scale-up.

Table 7: Illustrative Performance and Outcome Indicators to Monitor VLM

Indicators
1. **TX_CURR:** Number of adults and children currently receiving ART **(PEPFAR MER Indicator)**
2. Number of patients eligible for VL testing*
3. Number/% of eligible patients who have VL specimen collected*
4. Number/% of patients with VL specimen collected who received their results*
5. **WHO VLS.6:** % of people on ART who had VL monitored at six months
6. **WHO VLS.1:** Number and % of PLHIV on ART with VL suppression (<1000 copies/ml) at 12 months after treatment initiation
7. **WHO VLS.2:** % of people on ART with VL test results at 12 months after ART initiation
8. **WHO VLS.4:** % of PLHIV on ART who obtained at least one VL test result during the past 12 months (cohort or cross-sectional depending on denominator)
9. **TX_PVLS: %** of ART patients with a VL result documented in the medical record and/or LIMS within the past 12 months with a suppressed VL (<1000 copies/ml) **(PEPFAR MER Indicator)**
10. **UNAIDS:** Percentage of people on ART who are virally suppressed (VL level ≤1000 copies/mL) in the reporting period
11. **WHO VLS.3:** Number and % of PLHIV on ART who are virologically suppressed (global indicator for population or program based analysis)
12. **WHO VLS.7:** % of people whose VL is suppressed 48 months after initiating ART
13. **WHO VLS.5:** % of all PLHIV who have suppressed VL (VL suppression coverage)
14. Number of people with a VL >1000 copies/ml who had suppressed VL at follow-up testing*
15. Number of people with two documented VL test results >1000 copies/ml who switched to second-or third-line ART regimens*
* Indicators that should be monitored on a monthly basis during initial VL testing implementation to ensure the quality of VL testing services

Different proposed outcome indicators will answer different questions related to VL monitoring, testing coverage, and suppression. WHO proposed a series of indicators that use the estimated number of PLHIV as the denominator in order to measure population-level coverage of VL testing and VL suppression. WHO and UNAIDS also propose indicators that calculate the percentage of those virally suppressed among those on ART, which can be used to measure program-level coverage and VL suppression. In contrast, the PEPFAR MER indicator, TX_PVLS, measures VL suppression among those who have a documented VL result. Country programs are encouraged to adopt multiple indicators that use different denominators so that they can measure both population and program-level VL testing coverage and viral suppression.

For longitudinal monitoring of the VL continuum, it is recommended that indicators be included to assess cohort-based coverage of VL testing, such as those proposed by WHO for assessing VL coverage and suppression for specific cohorts of patients at six, 12, and 48 months after ART initiation. While calculating and collecting data for these indicators may be more challenging than monitoring and reporting on cross-sectional indicators, doing so allows for additional insight into the quality of VL testing services along the VL continuum as well as patient outcomes.

Box 5: Enhanced Monitoring of VL Implementation in Health Facilities in Mozambique

To track process and performance indicators for VLM—particularly during the initial phases of implementation—ICAP in Mozambique developed two registers for VLM at high-volume HF (see Annexes 18 and 19). The **VL collection register** tracks basic characteristics of the patient, specimen collection, transport to the referral laboratory, and receipt of results. This simple register is effective for monitoring key indicators, such as the number of people receiving VL tests, reasons for VL testing, and turnaround times associated with specimen collection and results delivery.

The **patient follow-up register** is used for more detailed tracking of individual patient follow-up along the VL continuum, including VL test results, referral for EAC, and repeat VL tests.These data are critical for monitoring the quality of VL testing services provided at the HF and are also useful for HF staff to quickly identify patients who require follow-up or who need to be contacted for additional services.

These tools are updated daily by care and treatment officers based at the HF. On a monthly basis, care and treatment officers aggregate the data to produce a monthly report for tracking 16 process and VL continuum indicators. This allows for close monitoring of VL services by ICAP staff in order to quickly identify where additional support is needed.

Countries should consider developing tools similar to these in order to support enhanced monthly monitoring of VLM.

C. M&E Tools for Tracking VLM

In many countries, existing patient medical records (electronic and paper-based), registers, laboratory requisition forms, and other M&E tools likely do not capture all of the necessary information for monitoring VLM implementation and the VL continuum. The data collection and reporting needs at each step of VLM, including VL testing, results transmission, and use of results, should be used to inform the development and adaptation of M&E tools. Table 8 highlights possible electronic and paper-based M&E tools and data sources that could be used to monitor each step in the VL continuum. Countries and programs should determine which data source is most appropriate, based on the considerations and recommendations outlined throughout this section.

Table 8: Illustrative M&E Tools and Data Sources for VL Implementation

VL Continuum Step	Electronic Data Sources	Paper-based Data Sources
Identification of patients eligible for VL testing	• Electronic medical record (EMR)	• Longitudinal ART/antenatal care /postnatal registers • Patient files
Specimen collection	• HF LIMS	• VL laboratory requisition form • HF VL specimen register
Specimen shipment to laboratory	• HF LIMS/VL dashboard • VL Laboratory LIMS/VL dashboard	• VL laboratory requisition form • HF and VL laboratory specimen register
Specimen processing at laboratory	• VL Laboratory LIMS	• VL results form
Return of results to HF	• VL Laboratory LIMS/VL dashboard • HF LIMS/VL dashboard	• VL results form • HF and VL laboratory registers
Delivery of results to patient	• EMR	• Patient files
Unsuppressed VL results and follow-up management of patients, including EAC, confirmation of virologic treatment failure, and switch to second line	• EMR	• Longitudinal ART registers • Patient follow-up form in patient file • Unsuppressed VL register
Suppressed VL results	• EMR	• Patient files • ART register • M&E tools for monitoring differentiated service delivery
Reporting of aggregate data	• VL dashboard • Aggregate HIS/DHIS2	• Monthly reporting forms

i. Monitoring the VL Clinical Continuum

To successfully implement VLM, key steps in the continuum must be monitored to ensure that national guidelines and SOPs are being followed. Thus, M&E systems and tools need to capture the following: whether all eligible patients have a VL specimen collected at appropriate intervals (in accordance with national guidelines); that all patients receive results; and that patients receive appropriate clinical management based on results of VL testing (i.e., patients with unsuppressed VL receive EAC and repeat VL testing, and that patients with virologic treatment failure are switched to second- or third-line regimens, as appropriate).

a. Electronic Medical Records (EMR)

The increased monitoring and reporting needs for robust monitoring of the VL continuum highlight the importance of developing and utilizing EMR to manage patient-level data. In particular, it is critical that clinical staff are able to easily access and review patient-level data in order to effectively manage patient care. With an EMR, key information for each step in the VL continuum (including eligibility, date of VL testing, results, date of return of results to the patient, and patient management based on VL results) can be facilitated (see Table 9). As an EMR should facilitate review of longitudinal trends in VL results for each patient, each of these variables should be entered for each VL testing episode. Inclusion of these variables will allow for automatic flags or alerts that identify when patients are eligible for VL testing, patients who have not yet received their results, and patients with unsuppressed VL who require follow-up care.

Table 9: Key Variables to be Added to EMR to Monitor the VL Continuum

Variables
• Date of eligibility for first VL test
• Date of next VL test (including query to calculate and flag eligibility for VL tests)
• Date of VL specimen collection
• Date when VL assay was done
• VL test result
• Date VL test result was returned to HF
• Date VL test result was given to patient
• Type of differentiated service delivery model for patients with suppressed VL
• Date of VL confirmation test for patients with unsuppressed VL
• Date of provision of EAC
• Date of repeat VL test
• Result of repeat VL test
• Eligibility for second-line regimen
• Date of switch to second-line regimen
• Date of VL test following switch to second-line regimen
• Result of VL test following switch to second-line regimen

The ability to flag eligibility for VL testing is critical for accurate monitoring and reporting on this first step of the VL continuum. Identification of eligibility for VL testing will need to accommodate varying guidelines for different sub-populations. For example, infants, adolescents, and pregnant and breastfeeding women will have different VL testing schedules than non-pregnant adult patients, so it will be necessary to ensure that this information is easily identifiable. This information can more easily be obtained by programming a query into the EMR than by using a paper-based register. It will be particularly useful for flagging eligibility for VL testing among patients receiving differentiated service delivery models of care, or for those in community ART groups who do not return to the HF frequently. The use of EMR will also improve monitoring of turnaround times. In countries with existing EMR, fields and automatic alerts should be updated to monitor VL data prior to implementing VLM.

Effective methods for longitudinal monitoring of patients with unsuppressed VL are also an important consideration in the design of M&E tools. High-quality patient-level data are critical to link information on adherence counseling, confirmatory VL testing, switching to second-line ART regimens, additional follow-up, and final outcomes. High-quality data also allow for the tracking of patients across multiple VL testing episodes, as all VL testing results will be accessible in the EMR. Further, EMR can be used to produce automatic reports on unsuppressed VL and confirmed virologic treatment failure, for review by HF staff and decision-makers. In addition to facilitating individual patient tracking, EMR also facilitate monitoring of and reporting on cohorts of patients with unsuppressed VL and their follow-up care.

b. Adaptation of Registers and Patient Files

1. Elibility for VL Testing

In countries where EMR and/or registers are not in place, it is important that the ART register is longitudinal to monitor patients over time, and that it is organized to allow for easy identification of those eligible for VL testing. With the implementation of VLM, national programs are increasingly including data on VL in ART registers; in some cases, these data are also included in antenatal and postnatal registers. These registers—in particular the ART register—need to have an added space to record VL test results. In longitudinal registers, fields for VL test result should be added to coincide with the period in which the patient is eligible for VL testing (e.g., at six- and 12-month consultations in the ART register) so that staff are able to use the register to quickly identify who is eligible for VLM at time of appointment. SOPs on the completion of registers should also outline this information.

It is important that staff are able to use registers to quickly calculate cohort-based indicators. If registers are not cohort-based, as may be the case at decentralized sites where patients transferring to the HF have a range of ART initiation dates, it may be challenging to identify cohorts of patients eligible for VL testing. One possible approach is to register patients in the new register by cohort. The pages in the register should be labeled sequentially by month and year. When a patient arrives at the HF, they are entered into the register on the page with the month/year that corresponds to their date of ART initiation, as opposed to their date of enrollment at the HF. This will facilitate cohort analysis and easy identification of those eligible for VL testing during a reporting period.

Registers should only include the minimal data necessary to calculate VLM eligibility and record results. Patient forms for follow-up clinical consultations after ART initiation should be inserted in patient files and used for more detailed information on VLM. These forms should be adapted to ensure that there is space to enter information on VL testing and results. At a minimum, fields for specimen collection date, date VL results were delivered to the patient, and VL result must be included. New VLM forms can also be created to track the full VL continuum, particularly follow-up clinical care provided to patients.

2. Tracking Patients with Unsuppressed VL

As noted, robust methods to monitor patients with unsuppressed VL are critical for achieving VL suppression. In the absence of an EMR, tracking patients with unsuppressed VL is more challenging. The options available for longitudinal monitoring of patients with unsuppressed VL using paper-based forms require increased workload for HF staff. To avoid the addition of new registers, longitudinal ART registers (either existing or adapted to longitudinal format) can be used to quickly flag patients with unsuppressed VL results. Using this information, monitoring of individual patients with unsuppressed VL can be done using the patient file. For detailed patient-level data, the existing patient follow-up form should be adapted to include variables on unsuppressed VL results and should be included in the patient file. Additional fields should be used to record follow-up care and clinical decisions for the patient, including EAC, confirmatory VL testing, determination of virologic failure, decisions on switching to second- or third-line regimens, and space for clinical notes and additional explanations regarding specific actions taken by the clinician.

In countries where the ART register is not longitudinal, or where it is not feasible to use patient files for effectively monitoring patients with unsuppressed VL, an additional high VL register should be introduced

to separately track patients with unsuppressed VL. Every time a patient receives additional post-VL testing care, the register should be updated to reflect this new information. This will result in a comprehensive picture of the quality of enhanced adherence and treatment failure support, and will allow for the tracking of final outcomes (viral suppression or virologic failure).

It is important to note that one individual can have multiple "episodes" of unsuppressed VL and can therefore appear in the register multiple times. Thus, final outcome should be understood in terms of completion of that specific episode of unsuppressed VL, until the patient is again eligible for VL testing. The high VL register should include fields for a confirmatory VL test, follow-up clinical appointments and provision of any type of enhanced adherence support, additional VL tests to determine if VL is still unsuppressed, switch to second-line ART, and final patient outcomes (see Figure 3).

Figure 3: Snapshot of Swaziland's High VL Register (See Annex 7)

ART number	ART Start Date (dd/mm/yy)	Names		National ID	DOB (dd/mm/yy)	Sex (M/F)	Current ART	Reason for VL test (R, T)	Date first VL taken	First VL Result (copies/mL)	Date results received by	Date patient received high	Dates of SUAC (dd/mm/yy)				Due date for repeat VL
		First	Surname										1st	2nd	3rd	Additional	

ii. Laboratory VL Continuum

The laboratory portion of the VL continuum includes: specimen collection at the HF laboratory, transport to and processing at the VL laboratory, transport of results back to the HF laboratory for distribution to clinical staff, and delivery to the patient. Tracking turnaround time is an important step for monitoring this part of the VL continuum. Inclusion of key VL variables in the ART register, however, provides little information on the logistics of specimen transport and return of results between HF and VL laboratories. Lessons learned from infant HIV testing implementation reinforce the importance of close monitoring of specimens and results turnaround time, including each step in the flow of the specimen and results within the HF and between the HF and VL laboratory. Therefore, M&E systems for tracking the laboratory portion of the VL continuum must be longitudinal to measure turnaround time and must ensure strong data flow between HF and VL laboratories.

Box 6: Specimen vs. Patient Tracking

In some countries, HF and VL laboratories utilize specimen identification numbers as opposed to patient identification numbers on requisition forms and laboratory registers. When calculating indicators, the number of specimens—not the number of patients—is used as the denominator.

This is particularly problematic for calculating indicators such as the number of patients with unsuppressed VL, as the number of specimens will be used to calculate the indicator and double counting can easily occur. It also prevents tracking of individual patients over time across multiple episodes of VL testing, including between original and confirmatory VL testing for patients with unsuppressed VL.

It is strongly recommended that countries should work to replace specimen ID numbers with patient ID numbers to ensure accurate calculation of indicators and availability of data for tracking individual patients along the VL continuum.

a. Management and Transport of Data from the HF Lab

1. VL Requisition Form

The VL requisition form is the key data source that should be used to link data between HF and VL laboratories. The VL requisition form is completed by the clinician at the HF when a patient is identified as eligible for VL testing. At the HF laboratory, following specimen collection, it will be used to complete the VL specimen register/LIMS. The VL requisition form is then sent with the VL specimen to the VL laboratory. This form is the primary link between the HF and laboratory, and will be used to subsequently complete the patient information on the results form for return of results to the HF. If LIMS or VL dashboards that link HF and VL laboratory systems are in place, the information should also be entered into the electronic platform. At the VL laboratory, the form will be used to complete the register/LIMS and the

VL results form. Therefore, the quality and completeness of data across the laboratory portion of the VL continuum depends on the VL requisition form.

As a critical data source for the completion of additional tools, the following key information—at minimum—should be included:

- HF name
- Patient name
- Unique patient ID number
- Contact information
- Sex
- Age
- Specimen type
- Date of specimen collection
- Time of specimen collection
- Date sent to VL laboratory
- Pregnancy/ breastfeeding status
- Reason for VL testing (routine versus targeted)
- Name of clinician

Box 6 highlights the importance of using unique patient ID numbers. Additional clinical data and treatment information to be included on the requisition form should be determined based on the clinical and monitoring needs in-country. VL requisition forms developed in Angola and Swaziland—with ICAP support—provide additional examples of possible form designs (see Annex 11). It is important to note that some of the form's elements will be completed by the clinician, while others will be completed by HF laboratory staff. Therefore, staff must receive specific training on which elements they are responsible for.

2. HF VL Specimen Register

To manage VL specimen collection and return of results to the HF, a HF VL specimen register needs to be developed and placed at the HF laboratory. The HF VL specimen register should be completed using the requisition form from the HF and the results form received from the VL laboratory. The HF VL specimen register must be designed to allow for longitudinal follow-up of each specimen and result, in particular so that turnaround time can be calculated (see Annex 12). The following key information is to be included in the HF VL specimen register:

- Name of patient
- Patient ID number
- Date and time of specimen collection
- Date and time specimen sent to VL laboratory
- Date results received from VL laboratory

These data points will enable monitoring of median turnaround time at each step in the continuum, and will facilitate early identification of gaps delaying patient management and clinical decision-making. Minimizing turnaround time enables prompt action on the results of VL tests and, consequently, ensures benefit for the patient and community.

The HF VL specimen register also serves a number of other monitoring purposes beyond turnaround time. The HF VL specimen register should include a field to distinguish between routine versus targeted VL testing, in order to facilitate the calculation of routine VL testing coverage and to assess whether HF are actually scaling up routine testing. It should also include VL results (including specimen rejections) in order to monitor the number of patients with unsuppressed VL and the quality of specimen collection at the HF laboratory. By including pregnancy status and basic patient characteristics (age/sex), the register can also be used to monitor the different sub-populations receiving VL testing at the HF—which informs an overall

understanding of VL testing services. Finally, it will allow for rapid tracking of specimen volume to inform stock projections. In HF laboratories with LIMS, an electronic VL specimen register should be integrated into the existing platform, as this will result in stronger data management.

b. Data Management at the VL Lab

As part of the laboratory VL continuum, it is essential that turnaround time and the quality of specimens processed be monitored in the VL laboratory. A laboratory system (either paper-based register or LIMS) is necessary to track data sent and received by the VL laboratory, including:

- Individual specimens and results with associated patient-level information
- The number and type of specimens received
- The esults (including specimen rejection) disaggregated by HF
- Internal turnaround times

If necessary, existing specimen registers at the VL laboratory can be adapted to record VL specimens. An additional VL specimen register should only be introduced at the VL laboratory if absolutely necessary. Rather than developing another register, it is recommended that laboratories use an LIMS to more effectively track the processing of VL specimens. After processing the specimen, the laboratory staff should complete the VL results form, which will then be sent back to the HF or used to deliver results via an LIMS web-portal or VL dashboard, SMS printer placed at the HF, SMS message to patients, or another platform. The key information included on the VL requisition form should be replicated on the results form, so that it is possible to verify the identity of the corresponding patient at the HF for discussion of results.

D. Integrated Data Flow

As part of the initial needs assessment, a mapping exercise will inform the development of data flow. Effective data flow depends on the ability to track an individual patient between multiple points of service. As multiple tools will need to be filled out at each point of service, it is important that a few key data points identifying the patient be entered at every point of service. This will ensure that specimens and results can be individually tracked. This will also ensure that individual patients can be tracked longitudinally to prevent double-counting of patients with unsuppressed VL who receive confirmatory VL testing during indicator calculation. Each register and form (paper-based or electronic) should include, at minimum: the HF name, individual patient name and ID number, age, date of birth, and sex. The necessity for key identifiers that can link individual patient information across multiple points of service is particularly critical if paper-based are used (as opposed to electronic systems). Additional key information on routine versus targeted testing and specimen type can be useful in maintaining data quality across different points of service.

Whenever possible, the use of EMR and LIMS will facilitate linkage of VL testing data between points of service. Depending on the system, it may be feasible to link EMR and LIMS data via the VL dashboard, improving the integration of data. If possible, the two systems should be web-based and interoperable so that limited laboratory information can be imported into or synchronized with the EMR, and vice versa. Transmission of results back to the HF can then be done via the VL dashboard, with data linked directly to the LIMS and EMR. In this case, return of results to the HF will not rely on transport of paper results to the HF, and the turnaround time from processing of the specimen to discussing results with the patient will be reduced. In countries where the LIMS and EMR are not directly linked, results can still be delivered automatically through linkage of the LIMS to SMS printers.

The use of a linked LIMS system allows for data entry from either point of service. HF staff can enter key data points in the HF EMR prior to VL specimen transport, resulting in reduced data entry requirements at the VL laboratory because the key data points will have already been entered at the HF. Additionally, individual patients can be easily tracked longitudinally, eliminating the need for a VL specimen register and unsuppressed VL register. Finally, data from both points of service will be linked in the LIMS, facilitating the creation of VL dashboards that are linked to these data.

An additional option is the use of barcodes to identify and link individual specimens and results to the patient. In this case, data on the patient are entered into the LIMS platform at the HF when the specimen is collected and the barcode on the specimen and laboratory requisition form are entered into the LIMS. At the laboratory, the laboratory staff scan the barcode to pull up the data on the individual patient and report on the results using the VL laboratory LIMS. This reduces the overall amount of data entry required to track the individual patient across the points of service, with the goal of improving data quality and accessibility.

E. Aggregate Data, Reporting Tools, and Data Visualization

Indicators on VLM are being integrated into reporting requirements for national-level programs, and have been added as required indicators in PEPFAR's Monitoring, Evaluation, and Reporting (MER 2.0) Indicator Reference Guide (MERGuide). Without the aforementioned adaptations to registers and tools, it will be challenging to report on VL indicators in countries that do not have electronic databases. In countries with electronic systems, once the necessary fields are included in the EMR or LIMS, aggregate data can be reported through the creation of new queries that automatically calculate and generate reports on aggregate data. The extent to which data can be used for decision-making depends on the timeliness and completeness of data entered into the database, so countries and programs will have to consider the resources necessary to maintain systems for consistent data entry.

Real-time monitoring of key process indicators is crucial for ensuring that VLM scale-up is occurring as planned, that targets are being met, and that the quality of services is maintained. The development of web-based VL dashboards within existing HMIS is an effective method for HF, laboratories, and MOH teams at the national and sub-national level to monitor performance on VL indicators. In addition to conveying test results, as described above, dashboards will serve as data visualization tools for aggregate data captured from VL testing data sources, such as the LIMS and EMR. Linkage of the LIMS and EMR to the VL dashboard will allow for real-time updating of the dashboards.

As part of the initial implementation process, routine monitoring of process indicators and the VL continuum will be critical for assessing data quality, implementation, and progress on performance indicators. For the first six to 12 months of VLM implementation, stakeholders should gather for monthly monitoring meetings to review key process and clinical indicators. The dashboards will serve as an important tool for data review during these meetings. Additionally, the dashboards can be customized for varying levels of user access. While HF staff would be able to access the dashboards for their particular facility, national and sub-national management teams could review data from different levels under their responsibility (e.g., HF, regional, and/or national levels).

F. Other Considerations

Routine Data Quality Assurance (DQA): Regardless of whether paper-based or electronic systems are used to monitor and report on VL scale-up, mechanisms to assess and ensure data quality and completeness must be incorporated into the M&E framework. It is important to conduct more frequent DQA during the first 12 months of VLM scale-up. Data quality and completeness are critical to effectively monitoring the implementation process, using data to decide how to adjust data flow, and preparing for further expansion of VLM. Additionally, with the introduction of new M&E tools and staff responsibilities , DQA results will provide insight into whether staff understand the VLM indicator definitions and how to collect the right data for reporting. If established DQA tools are already in use, they should be updated to include a set of key VL testing indicators, such as the number of individuals that received a VL test during the reporting period and the percentage of those receiving VL testing who are virally suppressed.

Data Confidentiality and Security: In countries with electronic systems, such as in cases where LIMS are installed or linked to EMR to create an integrated HMIS, there are implications for preserving patient confidentiality and data security. It is important to ensure that all endpoints where data can be accessed are appropriately secured. System access should be limited by user type (e.g., HF staff should only be able to access results and dashboards associated with their respective HF). Conversely, sub-national and national-

level staff should be able to review aggregated indicator data for multiple HF or laboratories, but should not be able to access patient-level data or individual results. Specific items on security and patient confidentiality should be included in the original assessment of M&E systems to ensure that these aspects are taken into consideration when designing patient-level and aggregate data systems for VLM. Furthermore, it may be important to include representatives from patient advocacy networks in discussions around privacy and confidentiality considerations, as patients may have a unique perspective on the minimum standards necessary to ensure confidentiality of patient data. It is particularly important to consider the patient perspective on confidentiality when developing guidelines on how patients should be contacted and informed of their VL test results.

Linkage to M&E of Differentiated Service Delivery Models: VL suppression and patient classification (as either stable or unstable) are key considerations when determining the appropriate care to be provided for the individual. Tools for monitoring VLM should be developed in coordination with and considering current M&E systems for differentiated service delivery models. Whenever possible, methods for tracking individual patients over time should link VLM and the differentiated service delivery model of care received, in order to facilitate the longitudinal monitoring of patients.

Routine Quality Assurance (QA)/Quality Improvement (QI) to Monitor Implementation: Specific indicators such as turnaround time at the HF (time from: specimen collection to transport, specimen sent to receipt of results, receipt of results to communication of results to patients; and total time from specimen collected to communication of results to patient) and at the VL laboratory (time from specimen receipt to processing and delivery of results) strengthen monitoring of VLM and warrant additional monitoring at HF and VL laboratories.

One of the key lessons learned from M&E of infant HIV testing and CD4 testing is the necessity of conducting routine QA/QI at the HF level during scale-up to ensure testing is occurring at the appropriate time and frequency; to track turnaround time so that challenges in data flow and along the VL continuum can be identified, and to ensure that results are successfully provided to the patient. HF and laboratories should plan to collect these indicators as part of routine QA/QI activities, for at least a subset of patients or VL tests. In addition, HF should monitor specific quality indicators, such as timely processing of whole blood, which will allow for close monitoring of the quality of VL testing services. HF should develop run charts to monitor and review the frequency and quality of testing according to guidelines, turnaround time, and the delivery of results, and should use these results to identify and remediate gaps along the VL continuum at the HF level. In addition to monitoring turnaround time, it may also be useful for HF to conduct cohort analyses of three-month cohorts, starting at six months after launch of VLM. Monthly data review meetings at the HF level can serve an important function (similar to that of sub-national or national data review meetings) to assess VLM coverage and whether VLM is being implemented as planned.

Evaluation Considerations: The establishment of a successful and sustainable VLM system relies on evaluation. Evaluation helps determine whether VLM implementation is occurring as planned and whether short-, medium-, and long-term objectives are being met. Evaluation of VLM scale-up will also provide a repository of lessons learned and best practices to guide implementation of VLM in other contexts.

Process evaluations should be used to assess VLM implementation. Process evaluation should focus on:

- Whether the gaps identified in the needs assessment have been addressed
- Whether each step in the VL continuum is being implemented in accordance with SOPs and scale-up plans

Box 7: Illustrative VL Testing Evaluation Questions

Examples of VL testing evaluation questions for consideration:

Process: To what extent was VLM implemented in accordance with guidelines and SOPs?

Outcome: What changes occurred in the quality of HIV care and treatment services as a result of the implementation of VLM services?

Impact: What was the impact of VLM on VL suppression?

- The quality of VL testing
- Implementation challenges and successes

Any process evaluation of VLM implementation should include evaluation of the M&E tools and data flow to inform whether they are effectively capturing the necessary data and whether any modifications to the tools are needed. The need for evaluation of implementation is particularly relevant if countries plan to take a phased approach to VL scale-up. In such cases, process evaluations should be planned during the initial phases to inform further expansion of VLM in later phases.

Outcome and impact evaluations are also necessary to evaluate progress toward epidemic control. These evaluations should focus on measuring VL suppression among PLHIV on ART and at population-level among the total estimated number of PLHIV. Illustrative process, outcome, and impact evaluation questions are provided in Box 7. See Annexes 4 and 10 for additional questions for consideration. All evaluation activities must be incorporated into the national M&E framework for VLM.

Section 3: Key points

- A national M&E framework, informed by a needs assessment and developed collaboratively among key stakeholders, is essential to robust M&E of VLM.
- Identification of a comprehesive set of indicators, including process, performance, and outcome indicators, is a key component of the M&E framework for VLM.
- Enhanced monitoring of key indicators during the initial implementation phase of VLM is recommended to ensure that activities are implemented as planned and that the quality of services is maintained.
- M&E tools will need to be adapted or created to ensure successful monitoring of each step in the VL continuum and reporting on key indicators.
- It is essential that M&E systems be designed in such a way that creates integrated data flow from the HF to the laboratory and back to the HF. LIMS and EMR can facilitate linkage of data between points of service.
- Developing web-based VL dashboards within existing HMIS is an effective method for real-time monitoring of indicators.
- Early development of process evaluations is highly recommended as a way to address gaps, identify lessons learned, and inform future scale-up.

V. Resources and Tools

To access these resources and tools, copy and paste the URL below into your web browser. Note that not all hyperlinks will work directly from Word.

Annex 1: Meeting Report: Reaching the Third 90: Implementing High Quality Viral Load Monitoring at Scale
http://icap.columbia.edu/resources/detail/reaching-the-third-90-implementing-high-quality-viral-load-monitoring-meeti

Annex 2: Clinical Training Material from Angola (Portuguese)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 3: Draft Monitoring and Evaluation Framework for Viral Load Scale-Up and Implementation (PEPFAR Viral Load Working Group)
http://www.aslm.org/?wpdmdl=14690

Annex 4: Standard Operationg Procedures on Viral Load Monitoring for ICAP Clinical Staff and Health Care Workers
http://icap.columbia.edu/resources/detail/standard-operating-procedures-on-viral-load-monitoring

Annex 5: High Viral Load Form
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 6: High Viral Load Register
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 7: High Viral Load Register (Swaziland)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 8: Site Readiness Assessment Checklist (Swaziland)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 9: Viral Load Monitoring and Enhanced Adherence Counseling Flipchart
http://icap.columbia.edu/resources/detail/viral-load-toolkit

Annex 10: National Operational Plan for Scaling-Up Routine HIV Viral Load Monitoring (Swaziland)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 11: Laboratory Requisition Form (Swaziland)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 12: Health Facility Laboratory Specimen Register (Angola / Portuguese)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 13: SOP for VL Implementation Monitoring Meetings (Angola / Portuguese)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 14: High Viral Load Register (Angola / Portuguese)
http://icap.columbia.edu/resources/detail/viral-load-toolkit

Annex 15: High Viral Load Patient Monitoring Form (Angola / Portuguese)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 16: Site Readiness Assessment Checklist (Angola / Portuguese)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 17: National Readiness Assessment (Angola / Portuguese)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 18: Viral Load Collection Register (Mozambique / Portuguese)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 19: Patient Follow-up Register (Mozambique / Portuguese)
http://icap.columbia.edu/resources/detail/sample-viral-load-tools

Annex 20: ICAP Package of Care for People Living with HIV
http://icap.columbia.edu/resources/detail/icap-package-of-care-for-people-living-with-hiv

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