TECHNICAL UPDATE

CONSIDERATIONS FOR

DEVELOPING A MONITORING AND EVALUATION FRAMEWORK FOR VIRAL LOAD TESTING

SEPTEMBER 2018

COLLECTING AND USING DATA FOR SCALE-UP AND OUTCOMES

PEPFAR

CDC Centers for Disease Control and Prevention

World Health Organization

ASLM African Society for Laboratory Medicine

USAID From the American People

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TABLE OF CONTENTS

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ABBREVIATIONS

ART	Antiretroviral therapy
DHIS2	District Health Information System
EAC	Enhanced Adherence Counseling
EID	Early Infant Diagnosis
LIMS	Laboratory Information Management System
M&E	Monitoring and Evaluation
MER	Monitoring, Evaluation, and Reporting Guidance
PEPFAR	President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV
SOP	Standard Operating Procedures
SQA	Service quality assessment
UNAIDS	Joint United Nations Programme on HIV/AIDS
UID	Unique Identifier
VF	Virologic failure
VL	Viral load
WHO	World Health Orga

EXECUTIVE SUMMARY

The 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection recommend viral load as the preferred monitoring approach to diagnose and confirm ART failure. As countries invest in the scale-up of routine viral load testing, it is critical to measure the impact and progress towards achieving the UNAIDS target of 90% viral suppression amongst patients on ART by 2020. This document presents key considerations and examples of tools (provided in the appendices) to assist countries in developing a national viral load (VL) monitoring and evaluation (M&E) plan.

Section 1 describes the process of assessing M&E data systems and tools and understanding how data flows to and from facilities, sample transport networks and laboratories. Stakeholders from lab, HIV care and treatment, and M&E need to review and update systems and tools to adequately capture and utilize data at site, district and national levels of their program. Section 2 outlines a set of indicators that M&E systems are encouraged to collect in order to measure key program and patient outcomes along the VL testing cascade. Section 2 also includes a discussion on how to monitor patients who are not virally suppressed and suggests tools for longitudinally following cohorts of non-suppressed patients. Appendix 3 includes examples of data collection tools that country programs can adapt for their setting and Appendix 5 includes a menu of possible indicators that can be integrated into an M&E Framework or plan for VL. Section 3 provides methods for evaluating viral load implementation plans and examples of evaluation questions.

To reach the third 90, country programs must delve into their data and understand how it represents the quality of VL testing services. We hope that these considerations provide practical tools and examples for how to measure and document outcomes as countries scale-up routine VL monitoring. Careful planning and consideration of all areas covered in this document will inform the development of an M&E system that accurately tracks and reports national viral load coverage and suppression rates.

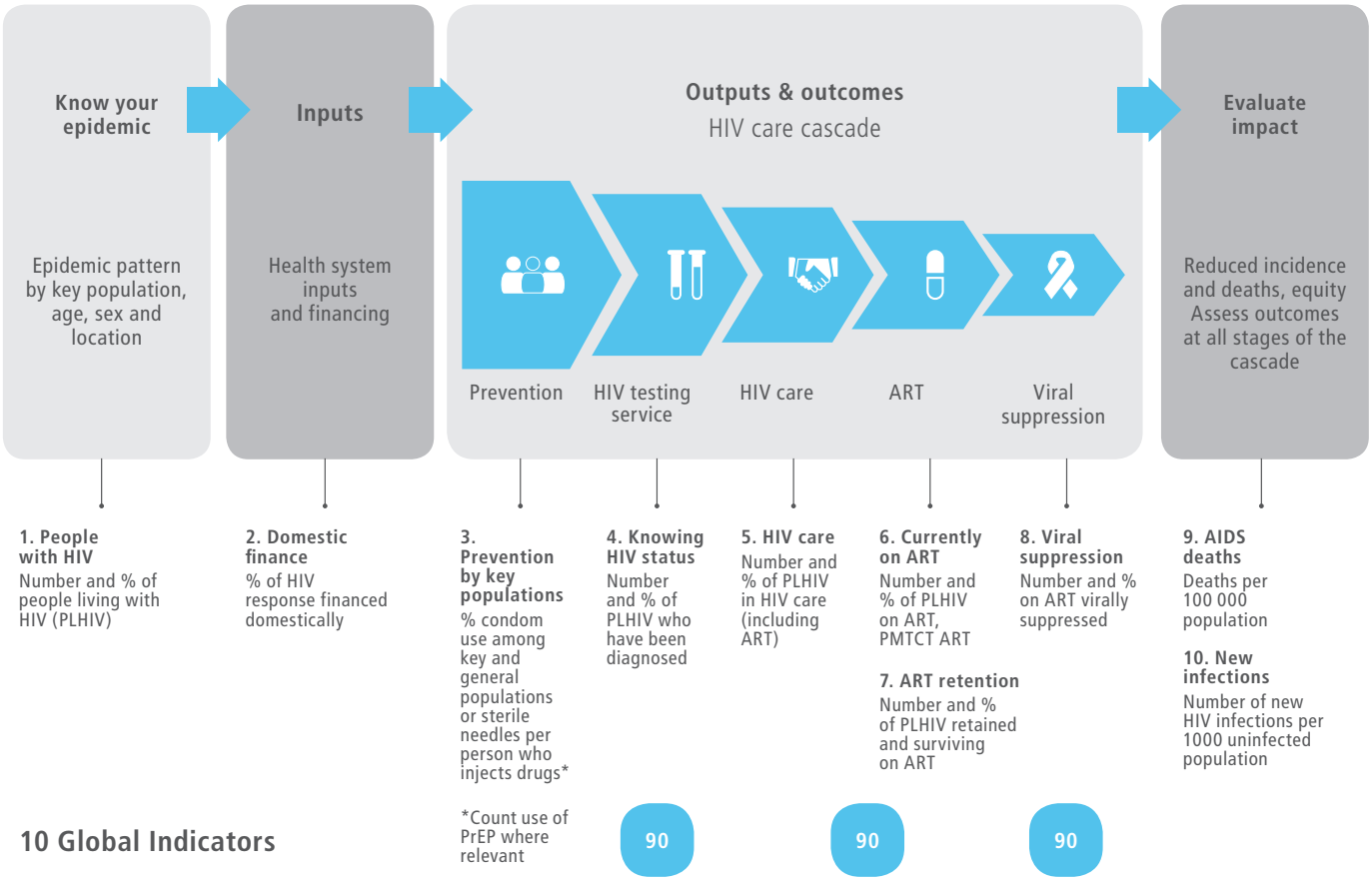
INTRODUCTION

Monitoring the continuum of the HIV response is critical for ensuring high quality of care and optimal clinical outcomes for HIV-infected individuals. The recent scale-up of routine viral load monitoring has played an integral role in tracking both the individual response to antiretroviral therapy (ART) and performance towards programmatic goals.

Viral load testing encompasses more than conducting the test within the laboratory; it requires functioning sample referral networks, data systems, healthcare provider-driven processes, and quality control and improvement mechanisms to handle specimen collection and transport, data management and analysis, and accurate and timely interpretation of results by clinical staff. As countries scale-up viral load testing and track viral suppression in people living with HIV (PLHIV) on ART, monitoring and evaluation (M&E) plans are needed to measure the success of program implementation and clinical outcomes. Utilizing routine viral load M&E data and systems for VL testing requires coordination, collaboration, and communication between a) laboratory, clinical, and M&E staff, b) data systems at facilities, laboratories, and above-site levels, and c) data capture/M&E tools. Strong M&E plans also require clarity on data flow, data elements, and indicators for VL monitoring. Utilization of viral load data is essential for patient-level and program-level decision making, and should be stressed in M&E plans.

WHO and various stakeholders released the "Consolidated Strategic Information (SI) Guidelines for HIV in the Health Sector" in 2015, and more recently "Consolidated guidelines on person-centred HIV patient monitoring and case surveillance Guidelines" in 2017. These documents highlight the importance of monitoring the HIV cascade at the program and individual levels to track progress to the ambitious UNAIDS targets known as '90-90-90' (90% of

Fig. 1. Global indicators for the monitoring and evaluation of the health sector response to HIV



Source: *Consolidated strategic information guidelines for HIV in the health sector*, WHO, May 2015.

PLHIV know their status, 90% of PLHIV who know their status are on ART, and 90% of those on ART are virally suppressed). Figure 1 illustrates the HIV cascade, the key cascade indicators, and the UNAIDS 90-90-90 targets.

While the WHO Consolidated SI guidelines provides a hierarchy of indicators for a high-level view of the HIV response, and further national indicators, a more detailed M&E approach is needed to measure VL testing scale-up and its clinical impact in real world settings. To measure progress towards the third 90, indicators related to processes (e.g. samples/results transport, turnaround time, and sample testing), patient outcomes (e.g. viral suppression, follow-up VL testing after high result), and quality (e.g. sample rejection) are required.

The main objective of this document is to provide considerations for developing a framework for a national VL M&E plan as one component of a national M&E plan for the HIV sector. The document focuses on key considerations and tools to assist countries as they scale-up routine VL monitoring, including:

- Assessing M&E systems for VL testing and clinical outcomes (including examples of M&E tools for monitoring VL implementation and outcomes that can be adapted by country teams)
- Potential indicators for routine and enhanced monitoring to measure progress towards achieving the third 90
  - Key M&E considerations for patients who are **not** virally suppressed
- Considerations for evaluating VL implementation and outcomes

SECTION 1: ASSESSING AND STRENGTHENING VIRAL LOAD M&E SYSTEMS

Assessing the current data collection, reporting and management systems in place for implementation of VL testing is one of the first steps to ensuring that countries have robust systems for high quality VL testing data. This assessment of the M&E systems will provide a review of how systems collect and move data from sites and labs for patient management and program oversight. Even countries that have more mature VL testing programs can benefit from a comprehensive review of their M&E systems to ensure that M&E data for VL testing and outcomes are being optimally collected, analyzed, and used for program improvement. Ideally, a comprehensive review of the entire HIV M&E system or routine data systems, of which VL is a part, will be conducted. This will minimize multiple, parallel reviews of systems. Given the complexities of monitoring VL testing, conducting a broader, more comprehensive M&E systems review may be beneficial for a country program. Please refer to WHO's "Consolidated Guidelines on Person-Centred HIV Patient Monitoring and Case Surveillance for more information and recommendations for conducting comprehensive reviews of systems and updating patient monitoring tools.

Creating and maintaining an M&E system to track the VL testing cascade involves numerous stakeholders: laboratory staff, HIV care and treatment program managers, health care workers, supply chain management staff, and strategic information/M&E specialists. All stakeholders should be engaged in the assessment and programs should work closely to ensure that data sources and tools are tailored for VL monitoring and include relevant fields to record and report VL testing data and clinical outcomes. Appendix 1 includes a logic model for routine VL testing that incorporates clinical guidelines, testing algorithms and standard operating procedures (SOPs).

Appendix 2 provides an assessment tool to assist with evaluating readiness of M&E systems to monitor VL testing; this can be part of a more comprehensive M&E system review. Appendix 3 includes examples of M&E tools specific to VL data capture. If introducing new VL M&E tools is not feasible, required data variables should be integrated into existing M&E tools.

VIRAL LOAD TESTING CASCADES

There are two key VL testing cascades that should guide an assessment of M&E systems and tools for VL:

- Coverage and outcomes of routine VL testing – This cascade tracks the number of individuals currently on ART who received a VL test, had a result documented in the medical record, and were found to be virally suppressed.
- Follow-up of patients that are not virally suppressed – This cascade tracks the number of individuals with a VL result above the threshold (e.g., VL ≥1000 copies/mL), how many received enhanced adherence counseling (EAC) and a follow-up VL test, and how many were suppressed on follow-up testing. It also tracks whether those who were non-suppressed on follow-up had a switch in ART regimen.

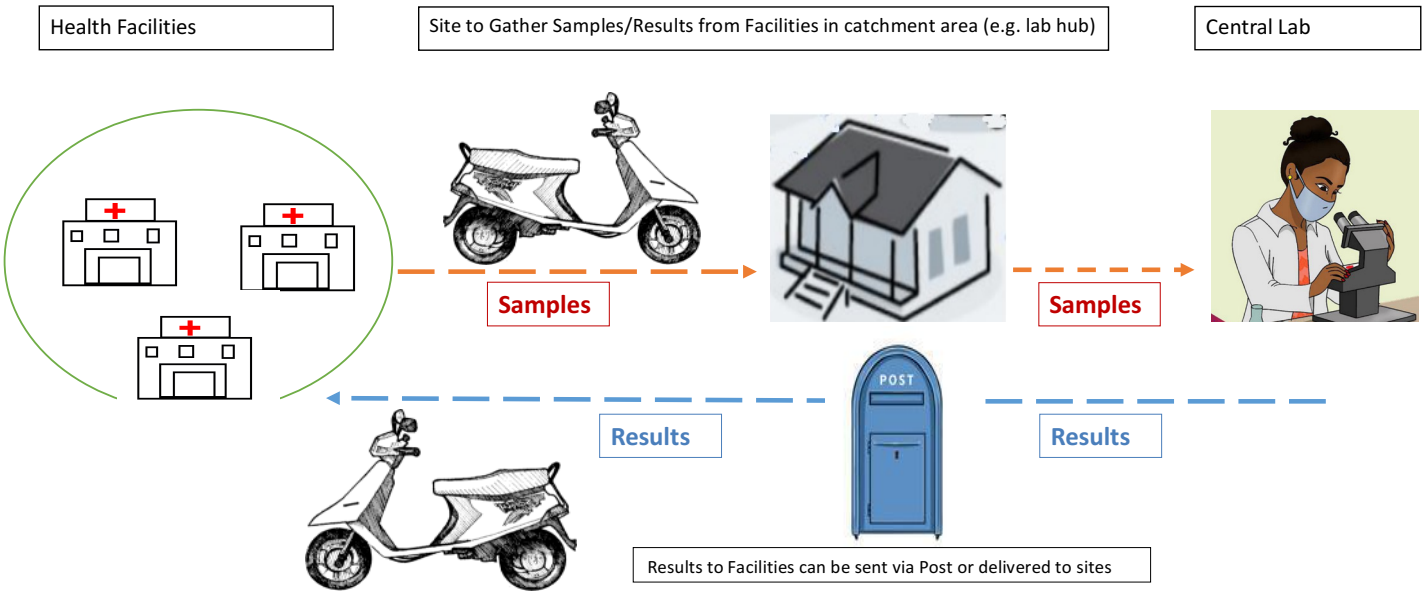
Understanding VL testing cascades will help guide assessments of M&E systems, including review, revision, and development of new M&E tools for data capture to ensure that teams have the capacity to create VL cascades at the site, sub-national, and national levels. Section 2 of the document presents core indicators to consider for monitoring processes, quality, and patient outcomes along both cascades. It will also be important to routinely review these data for completeness to ensure that both coverage of VL testing and quality of follow-up with patients is being done. For example, reviewing the data from these cascades will highlight patients who are not receiving a VL test or who may not have a VL test result documented in their record. These reviews can be done during more in-depth service quality assessments (see section 3).

MAPPING THE FLOW OF DATA AND DATA CAPTURE FOR THE VIRAL LOAD TESTING CASCADE

Understanding the flow of VL data is one of the first steps of conducting an assessment of the VL M&E system. An effective VL M&E system should have a clear map of how data flows from one source to another and how data is captured at each step. Most VL testing will rely on a specimen transport system that moves samples from facilities to more centralized molecular laboratories for VL testing. The sample and results transport network is an especially complex system, and M&E tools are generally required at every step.

One successful sample transport model from Uganda involves a sample transport network in which motorbike riders collect samples from health facilities in a designated catchment area and deliver them to a "lab hub"; samples are then sent from the hubs to the central lab for VL testing. Figure 2 summarizes the flow of samples and

Fig. 2. Example of map of sample transport network and results return for VL testing



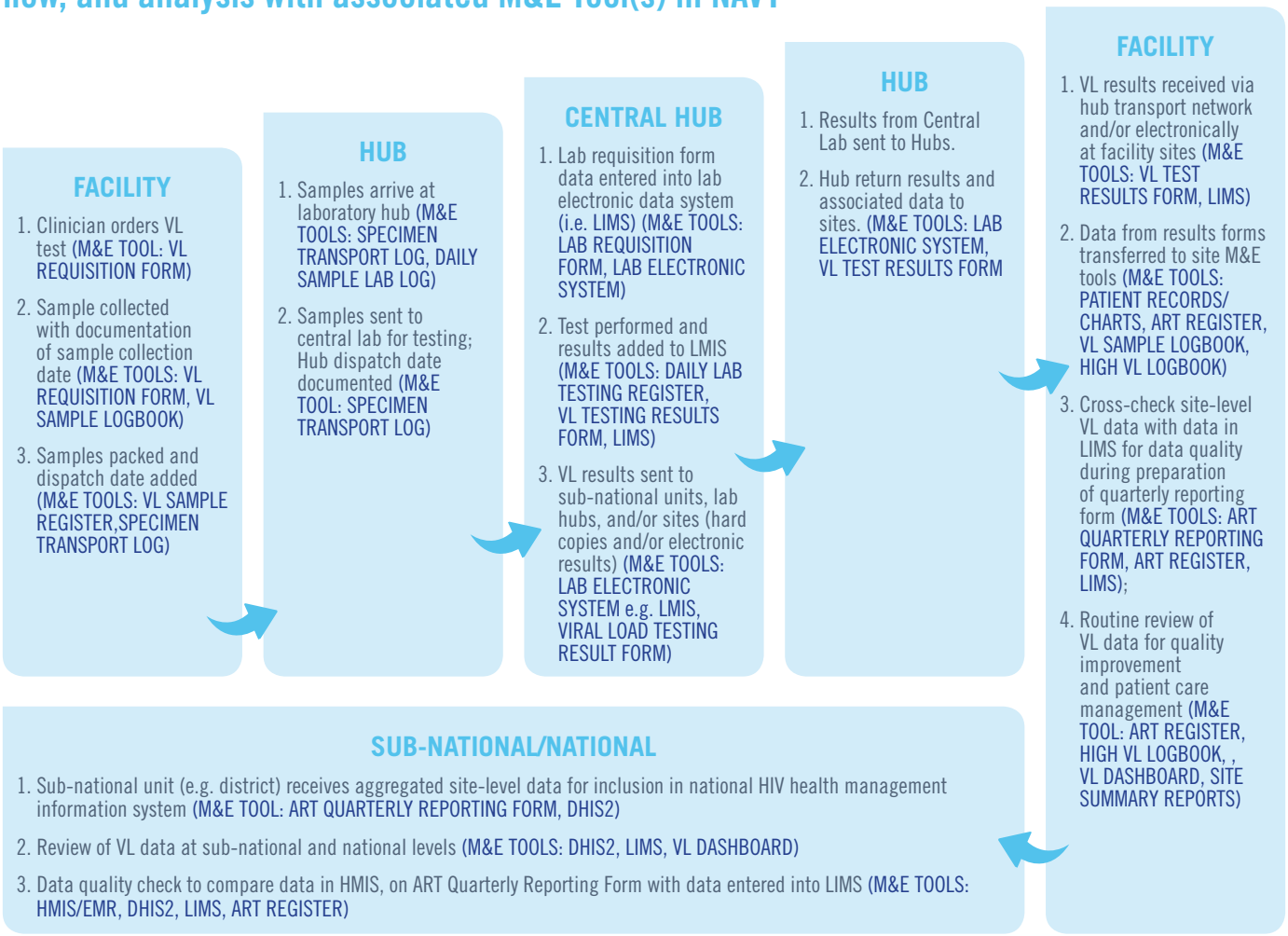
results. Results can be returned to sites via post or motorbike riders who deliver results back to sites. Programs should continue to develop innovations to improve rapid and more direct return of results.

During the mapping exercise, programs should also note the M&E tools used for recording data from sample collection to return of results to aggregation of site-level results. Figure 3 is an example of a high-level process map that shows key VL testing processes with the M&E tools used to capture key data at each step, from VL sample collection to return of results to review and reporting of VL data. Country programs can adapt Figure 3 to reflect their own processes, systems, and M&E tools.

Mapping out this process, including the main M&E tools being used to capture key data, will clearly highlight where data should be captured as samples and results flow from the facility to the centralized or regional lab(s) back to facilities. Working on the process map with inclusion of the M&E tools may also help programs develop or refine SOPs for VL testing and VL M&E. This will also stress the importance of activities that should occur at multiple levels. For example, data quality checks are key to review consistency of data between unlinked systems. Please refer to Appendix 3 for examples of VL M&E tools that capture data along the entire VL testing cascade.

The considerations in this document are based on the assumption that programs are using a specimen transport network that move samples from facilities to a centralized lab for VL testing. As countries scale-up VL testing and/or new technologies (e.g., point of care VL) become available, programs may shift to decentralized models that may require modification of these considerations.

Fig. 3. Example of High-Level Standard Operating Procedure (SOPs) for data capture, flow, and analysis with associated M&E Tool(s) in NAVY



UPDATING/DEVELOPING M&E TOOLS FOR CAPTURING VL RELATED DATA

Effective tracking of VL testing and patient outcomes requires multiple M&E tools and systems from multiple locations (i.e. facilities, specimen transport networks, and labs); Country programs may have existing tools that may simply require some updating to effectively track VL. It is essential that programs understand how all of the M&E tools and systems collect, link, and report VL-related data. Data sources and M&E systems that are needed to track VL testing include:

- Viral Load Test Requisition Forms
- Viral Load Sample Register/Logbook
- Viral Load Results Form
- High Viral Load Registers or Logbooks to follow-up patients who are not virally suppressed (i.e. VL≥1000 copies/mL)
- Patient Monitoring Systems (electronic and/or paper): Patient charts, ART registers, ART cards, ANC registers, Postnatal Registers
- Aggregate health information systems (e.g. District Health Information Systems 2 (DHIS2))
- Lab Information Management Systems (LIMS) and other systems at viral load testing labs and laboratory hubs

During the VL M&E assessment, country programs may need to update or develop new M&E tools to ensure that key variables are being collected.

Figure 4 provides a list of variables that should be included in VL lab requisition and VL results forms. Some of these variables should also be integrated into other M&E tools such as patient cards/charts, ART registers, high VL registers, and VL sample logbooks. Note that all of the variables (i.e. those entered at the clinic and at the lab) should be included in the LIMS maintained at the lab and also reflected in M&E tools at the site.

Fig. 4. Key Variables to consider for laboratory requisition forms and other M&E Tools

SPECIMEN REQUISITION FORM (entered at the clinic)

- Patient identification number
- Collection site
- Date of birth (age)
- Sex
- Whether currently pregnant or breastfeeding
- If receiving ART, current regimen (first, second or third line)
- Previous exposure to ARV drugs, such as for preventing mother-to-child transmission, post-exposure prophylaxis or pre-exposure prophylaxis
- Date ART started (time receiving ART)
- Reason for the test
- Date and time speciment collected
- Specimen type
- Adherence assessment
- WHO clinical staging and DC4 count

TESTING REPORT FORM (entered at the laboratory)

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

Source: *Technical and Operational Considerations for Implementing HIV Viral Load Testing*, WHO, July 2014.

It is likely that country programs will need a specific M&E tool such as a register or logbook to track patients with VL≥1000 copies/mL (i.e. High VL Register or Logbook). While country programs may understandably have concerns about adding tools to sites and increasing the burden on site staff, a tool for longitudinal tracking of patients with high VL is essential for appropriate and timely clinical management. Furthermore, using this tool should not be overly burdensome because it is likely that only a small proportion of patients will have a VL≥1000 copies/mL and require tracking. Key variables to track in the High VL Register or Logbook include:

- Unique Identifier (UID), if it is available
- ART Number
- ART Start Date
- Contact Information
- Date and result of first high VL test
- Dates for Enhanced Adherence Counseling (EAC)
- Date and result of Follow-up VL Test
- Outcome (i.e. switch in ART Regimen or remain on same ART regimen)

Please see Appendix 3 for an example of a High VL Register and refer to Section 3 for specific considerations for tracking patients with VL≥1000 copies/mL.

KEY VL M&E CHALLENGES TO CONSIDER DURING M&E SYSTEMS ASSESSMENTS

There are several common M&E challenges to consider and address when assessing M&E systems and developing M&E tools to monitor implementation of VL testing. Main challenges include:

- Accessing and utilizing VL testing data for patient management from unlinked lab, facility, and/or national aggregate reporting systems
- Tracking and reporting data on VL tests vs. individual patients due to lack of a unique identifier
- Tracking patients over time (including those with VL≥1000 copies/mL)
- Tracking VL coverage and VL suppression rates for individuals
- Estimating VL testing need

Many programs, particularly in the scale-up phases of VL testing, may rely heavily on lab information systems that are not electronically linked to site-level and/or aggregate HIV health information systems used to track and report on individuals on ART. These systems are often fragmented, with different data architecture, and thus data do not move seamlessly between the systems. Therefore, understanding how information will move between unlinked facility and lab systems is critical. For many sites, this will involve manually transferring test results received from labs to

Table 1. Summary and suggestions to address VL M&E key challenges

Challenge	Suggestions
Utilizing data from unlinked lab, facility, and/or national aggregate reporting systems	• Map out flow of samples and results to/from facilities • Identify key indicators for routine monitoring that align with VL testing guidelines, clinical algorithms and SOPs • Overlay key indicators on the flow map of samples and results to/from facilities • Ensure that M&E tools with appropriate fields are available to capture these data • Develop SOPs, training materials, mentorship protocols, and data quality assessment processes for labs, facilities, and SI/M&E staff for data capture; train staff in an interdisciplinary way so that all staff understand each other's roles in capturing data and how various systems will be used to monitor VL testing and suppression rates. • Pilot test all changes in tools and training materials to identify challenges before launching on a larger scale • If relying primarily on LIMS for VL monitoring and reporting, ensure that unique individuals can be tracked over time and that data are accurately reflected in patient charts and being utilized for patient management
Tracking and reporting VL data on tests vs. individual patients	• Clarify which systems track tests and/or individual patients • Assess the degree to which individual patients and their outcomes can be tracked • Ensure that individual patients can be identified through age groups and key clinical information such as pregnancy and breastfeeding status. Populations such as pregnant and breastfeeding women would require particular focus since a lack of VL suppression could threaten PMTCT • Be clear about which indicators track tests vs. individuals (see Section 2 for more information) • Summarize the limitations with reporting tests and individuals; to the extent possible, develop methodology to de-duplicate results to report on individual patients • Ensure that M&E tools, systems, and processes are designed to track individual patients (e.g. consistent use of UIDs) • Tracking coverage of patients who routinely receive VL tests to ensure that all patients who should receive a VL test are receiving them
Tracking patients over time (including those with VL≥1000 copies/mL)	• Determine the extent to which M&E systems can track cohort-based and cross-sectional groups of patients over time (see Section 2 for more details) • Example of groups of individuals that require longitudinal tracking: – Cohorts of patients who have been on ART for specified periods of time receiving VL tests and their result (longitudinal) – Patients who are not virally suppressed (longitudinal) • Assess the M&E tools, systems, and processes to track all groups of patients and revise them as needed; ensure that patients who have VL>1000 copies/mL are tracked appropriately and switched to 2nd line, if needed • Consider how pregnant and breastfeeding women will be tracked if they transfer between sites in the peripartum or postpartum period • Pilot test all changes to identify key challenges and issues before rolling out nationally.
Tracking VL coverage and VL suppression rates for individuals	• Be clear about tracking the number of patients and tests along the 'cascade of VL testing' so that programs are using the appropriate denominator to assess both coverage and VL suppression rates. • For tracking VL coverage, the denominator should be # of PLHIV on ART for at least 12 months. This denominator may be disaggregated by age/sex, pregnant women, breastfeeding women, and other sub-populations so that programs can track VL testing coverage among various sub-populations. • For routine program reporting on VL suppression rates, the denominator should be specifically defined as the number of individuals who received a VL test. Ideally, programs should track a cascade: # of individuals currently on ART, # who received a VL test, and # virally suppressed. Furthermore, programs should review the data by various sub-populations
Estimating VL testing need	• Key data include the number of patients new and current on ART who should receive VL test(s) in a 12-month period. Consider: – Patients new on ART who may require two tests in a 12-month period (i.e. 6 months after initiation and again at 12 months after initiation) – Repeat tests due to the first VL≥1000 copies/mL. This will depend on VL testing guidelines and prevalence of viral suppression in key age groups and populations. – Timing and location of when and where pregnant and breastfeeding women receive VL tests

patient charts/cards, ART registers, High VL registers (for VL≥1000 copies/mL), and other facility-level M&E tools. Furthermore, there may be a wide variety of facility patient management systems. This variability impacts how and when results are transferred from VL lab results forms to patient and site records. Country programs should carefully assess the process of transferring data between systems to ensure that the source of patient data used for reporting is accurate. Data for sites on numbers of individuals who received a VL test and their results should be compared between site-level records/systems and lab management information systems to ensure that there are no major discrepancies. Different data sources (e.g. LIMS, patient charts, and registers) should be cross-checked for data quality and consistency. This highlights the importance of ensuring strong linkages between health management information systems (HMIS) at facilities and LIMS to track all outcomes for a patient for clinical management and aggregate data for reporting and program oversight.

While VL reporting during scale-up may rely predominantly on LIMS, WHO and other key stakeholders note that some VL data reporting should come from sites providing patient care. This also stresses the need for site staff to adhere to SOPs on transfer of data from VL lab results form to patient and site records to ensure that data are being used for patient management, and eventually for reporting.

Another key consideration is tracking outcomes for individual patients rather than tests. For example, the LIMS may only be able to track the number of VL tests conducted, sample types and the associated results for tests, and cannot de-duplicate repeat tests for individual patients. While M&E systems and tools may have been designed to track individuals (e.g. including ART number on lab requisition form), staff at sites must consistently enter individual patient information in all fields on the form and this data must be accurately and completely entered into LIMS. Longitudinal tracking of patients will require M&E systems to track individual patients over time through UIDs. Please refer to WHO's Consolidated guidelines on person-centred HIV patient monitoring and case surveillance Guidelines", for more comprehensive considerations for UIDs and recommendations to develop systems for UIDs.

As routine VL testing is scaled up, it is critical that there is a system in place for longitudinal tracking of patients; examples in which this is important for programmatic and individual tracking include:

- Cohorts of patients who have been on ART for specified periods of time receiving VL tests and their result (e.g. VL test and result 6 and 12 months after ART initiation)
- Patients who are not virally suppressed (i.e. VL ≥1000 copies/mL)

Using unlinked M&E systems from facilities and labs requires that individual tracking information is consistent across all data sources. Fields on the sample requisition form completed by the facility (e.g. ART number, Patient name, ART start date etc.), must consistently match with fields entered by the lab, such that the electronic lab information system will correctly identify patients. Programs can improve the interaction between facility and lab systems and their ability to report on individual outcomes by monitoring the completeness of data on lab requisition forms at sites and completeness of these data in LIMS. Data quality exercises should also be routinely conducted to compare and link data in LIMS to site-level data on patient charts and/or ART registers to ensure that data are accurately reflected in patient charts. Please see the "Data Quality, Analysis, and Use" in Section 2 below for more information on conducting routine data quality checks.

Finally, M&E data will inform estimations of VL testing needs. As country programs scale-up VL, forecasting commodities, estimating financial and human resource needs, and tracking overall VL testing coverage will be increasingly important. Given the complexities of tracking patients and ensuring that testing follows guidelines, country programs will need to plan accordingly and ensure that M&E systems are providing helpful data to inform VL testing needs estimates. Table 1 is a summary of the major challenges and considerations on how to address to them. Section 2 provides more details and considerations on several of the challenges listed below.

TRAINING AND CAPACITY BUILDING IN M&E FOR VIRAL LOAD MONITORING

Assessment of M&E tools may highlight the need to revise current forms and develop new tools. Country programs should pilot test all tools for data capture, entry, reporting, and use to ensure that they are complete, user-friendly, and capable of generating the data for monitoring and reporting VL testing processes and outcomes.

Training and onsite mentorship will be essential to ensure that data capture forms and M&E tools are correctly and completely filled out at sites, and if required, entered into LIMS and patient records. Data should be routinely reviewed at the site-level and above-site-level to ensure that patient management is in line with SOPs and reflected in the quality of data. Trainings should emphasize the following:

- Accurate and complete documentation in forms, registers, and/or databases
- Clarity about individual roles and responsibilities in data collection and reporting

- Review of testing algorithms, SOPs and processes
- Correct methodology to aggregate data for reporting
- Consistent data capture at sites using M&E tools (e.g., patient cards, ART registers, lab results forms etc.)
- Clinical guidelines that inform various fields on the forms (e.g., distinguishing whether the VL test is routine or targeted)
- Adherence to M&E protocol (e.g. transfer of results at facility from VL result form to VL registers, patient cards/ charts, ART Registers, facility-based electronic systems)

Country programs and implementing partners must plan for on-going data quality assessments, especially in the early phase of rolling out tools, to identify challenges and to ensure that staff are receiving appropriate training and mentorship.

Training and ongoing site mentorship on data use will also be essential. Trainings should address data use at both the patient and program levels. Trainings on data use at the patient-level should address feedback to patients, adherence to SOPs, including M&E tracking, and follow-up monitoring for non-suppressed patients. Trainings on data use at the program-level should address analysis of data at aggregate levels to identify and address programmatic issues to improve overall outcomes and program quality.

SUMMARY OF CONSIDERATIONS:

- Engage stakeholders from all disciplines (e.g., laboratory staff and directors, HIV care and treatment program managers, healthcare workers, supply chain managers, and M&E specialists) in the assessment and reform of VL M&E systems
- Assess capacity of M&E systems and tools to routinely track and report on the entire VL testing cascade (from collecting samples at sites to returning results to patients and routinely reporting results through M&E tools and systems)
- Map data flow for VL monitoring to guide review of current M&E tools
- Update existing M&E tools (e.g., patient cards, facility ART registers, lab requisition forms, etc.) and develop new ones (as needed) to ensure that VL testing and results are captured (e.g. High VL Register/logbooks). Pilot test all updated and new tools before finalizing and rolling out nationally
- Consider key challenges and ways to address them during assessment of M&E systems and tools. Use this process to guide a critical review of VL M&E plans and indicators
- Develop a training and mentorship plan to strengthen capacity to routinely collect, analyze, and use VL data at sites, subnational levels, and national levels to improve quality of services and patient outcomes

SECTION 2: INDICATORS IMPLEMENTATION AND OUTCOMES OF VIRAL LOAD TESTING

Several key VL indicators from multiple sources including the WHO Consolidated Strategic Information Guidelines, PEPFAR Monitoring, Evaluation, and Reporting (MER) Guidance v2.0, and considerations from the PEPFAR Task Force for Viral Load and Infant Virologic Testing are compiled and presented in this document. Country programs can adapt relevant indicators appropriate for their country VL program monitoring and reporting systems and develop additional ones that reflect their priorities. Where possible, programs should try to align their indicators and disaggregations with those in the WHO Consolidated Strategic Information Guidelines and MER guidance. Collection and analysis of data that is disaggregated by age -and population, with attention to priority population VL outcomes (i.e. pregnant women, children, adolescents, and key populations) is key to focus interventions and improve clinical care.

Stakeholders should identify key indicators and expected outcomes for regular review at the national level; these indicators and outcomes should also be reflected in National M&E Plans for HIV programs. Appendix 4 includes a template of a national viral load M&E Plan that countries may use or adapt.

INDICATORS FOR ROUTINE MONITORING OF THE VL CASCADE

Routine monitoring involves the routine collection of data from all ART sites and all patients. Data sources for routine monitoring should include ART sites, hubs and labs in the lab/specimen transport network, and labs where VL samples are processed.

After reviewing the overall data flow and M&E tools associated with data capture and recording, one helpful approach for selection of routine monitoring indicators is to list the key steps in the VL testing cascade and define how each step would be measured. When reviewed together, the routine monitoring indicators should reflect how well the country is implementing VL scale-up and progressing towards the third 90.

Table 2 presents a list of core indicators that are considered essential for routine VL cascade monitoring and program implementation, including monitoring of patients with a non-suppressed viral load. Some indicators are dependent upon the completion of multiple steps in the cascade, in which case the indicator is listed with the step that is

Table 2. Core Indicators along VL Testing Cascade

Key steps in the cascade of VL testing	**Core indicators for routine monitoring** (See Appendix 5 for more detailed indicator information, including numerator and denominator guidance)
Order VL Test	• % of sites in the specimen transport network that are submitting samples for VL testing • # VL tests submitted by sites to the lab/specimen transport network
Process VL Test Sample	• # VL tests received by lab from sites • # VL tests run by lab
Returned VL Test Result	• % of VL tests results returned to sites within one month of sample being taken
Coverage, Documentation, and Outcome of VL Test Result	• % of people on ART with VL results at 12 months after ART initiation [WHO VLS.2] • % of people on ART tested for VL with VL level < 1,000 copies at 12 months after ART initiation [WHO: VLS.1] • % of patients with a VL result documented in the medical record and/or laboratory information systems (LIS) within the past 12 months with a suppressed VL (<1000 copies/ml) [PEPFAR MER: TX_PVLS] • % of PLHIV on ART who are virologically suppressed [WHO VLS.3] • % of PLHIV with suppressed VL (<1000 copies/ml) who have been referred to a less intense model of care/differentiated service delivery
Intervene on VL Test Result if VL≥1000 copies/ml	• % of people on ART with VL≥1000 copies/mL who have received enhanced adherence counselling (EAC)
Order Follow-up VL Test if VL≥1000 copies/ml	• % of people on ART with VL≥1000 copies/mL who received a follow-up VL test within 3–6 months after enhanced adherence counseling (or according to national guidelines) • % of people on ART who had VL≥1000 copies/mL and then suppressed to VL <1000 copies/ml on follow-up testing
Modify ART regimen after two consecutive results of VL≥1000 copies/ml	• % of PLHIV on ART with two documented VL test results ≥ 1,000 copies/mL switched to 2nd or 3rd line ART regimens

furthest along in the sequence. Appendix 5 contains a more comprehensive list of potential indicators for country programs to consider, including those suggested by WHO. Appendix 5 also contains more detailed information about each indicator, including defined numerators and denominators and suggestions for sources of data collection and disaggregation. The indicators in Appendix 5 are organized by process/systems and health outcomes. Indicators to track specimen management and testing should be applicable to both centralized lab testing as well as any near-POC or POC VL testing that is included in national VL monitoring programs.

These core indicators measure site and system-level processes, coverage, quality, and patient outcomes related to VL testing. Countries may be in different stages of implementation of VL scale-up and should prioritize which indicators from the core list are required for routine collection and review. For indicators, particularly patient outcomes, that require patient chart review or allow access to identifiable patient information, counsel of national institutional review board should be sought to determine any possible necessary ethical considerations.

The indicators in Table 2 consist of both cohort-based indicators and cross-sectional. It is important to distinguish between longitudinal tracking of cohort-based patients versus conducting a cross-sectional cascade analysis of patients who are virally suppressed. A cohort-based analysis follows patients who initiated ART at the same time to a specified period of time (e.g. 6 months, 12 months, 24 months etc.) to examine patient outcomes.

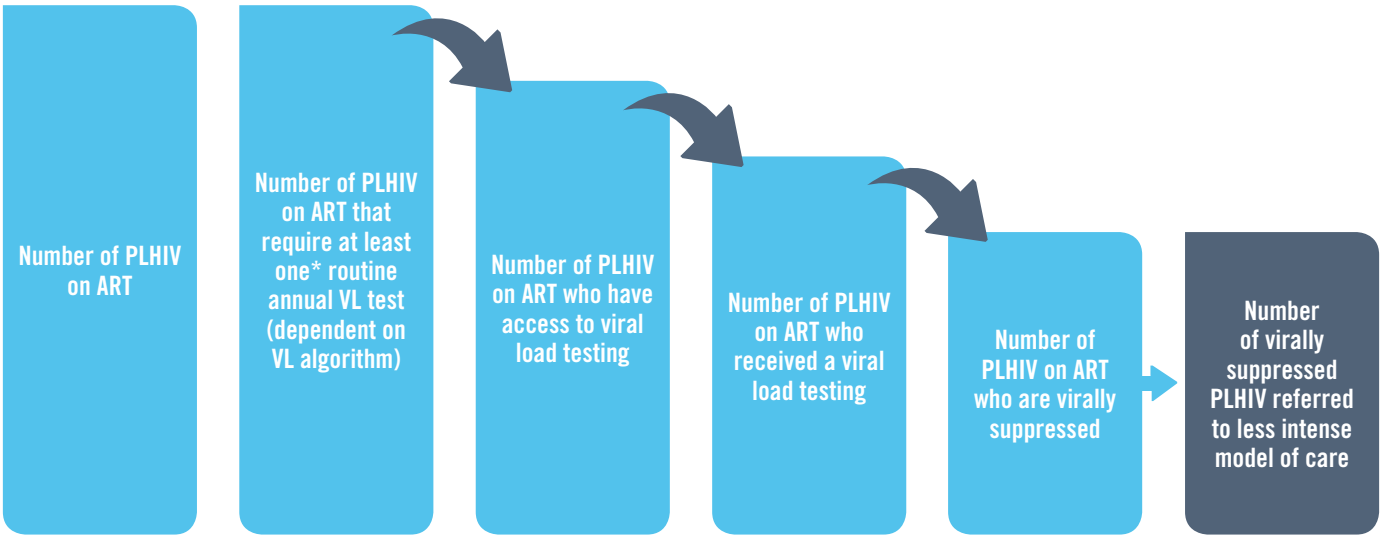
Cohort-based testing can answer key programmatic questions, but it can be costly and requires standard UIDs to track patients over time, especially in areas of high mobility. Cross-sectional cascade analysis looks at aggregate data across variables linked in a cascade at a specific time; all the people counted across the cascade may not be the same person. Thus, this type of analysis can help to identify overall systems issues. It is important to note the key caveats and limitations of the data when conducting the different types of analyses.

TRACKING COVERAGE OF ROUTINE VIRAL LOAD TESTING AND RATES OF VL SUPPRESSION

Tracking scale-up of routine VL testing is essential to understand VL testing coverage and outcomes. Until all patients on ART receive routine VL tests according to national testing guidelines, the proportion of patients on ART who have access to and receive a VL test should tracked to monitor VL testing coverage and outcomes. Developing cascades with associated indicators are important to monitor VL testing coverage and maturation of systems and processes so that VL suppression rates can be interpreted accordingly.

Figure 5 illustrates the relationship between key indicators along the VL testing cascade, and who are found to be virally suppressed. Tracking outcomes for patients who receive a VL test (i.e. those patients who are suppressed

Fig. 5. Cascade of Routine Viral Load Testing and Key Indicators to Track Virally Suppressed Patients



*A patient generally requires a VL test 6 and 12 months after ART initiation, and then once every 12 months thereafter.

and those who are not suppressed) is key for clinical management. Utilization of suppressed VL results to refer virally suppressed patients to a less intense model of care (e.g. receiving 3+ months refills, attending a clinical visit every 6+ months etc.) is essential for implementation of differentiated service delivery. Patients who are not virally suppressed require additional tracking and have another cascade for tracking (see figure 6 below).

Figure 5 illustrates the cascade that programs should consider when assessing and tracking routine VL testing coverage and outcomes. The proportion of ART patients who require a VL test in one year per the national VL testing algorithms must be considered in calculating the denominator for virologic suppression rates. Some national testing algorithms may stipulate a VL test once every two years, thereby decreasing the denominator compared to the entire pool of ART patients on ART. If there are gaps in VL testing coverage, using PLHIV on ART who received a VL test (vs. PLHIV on ART who require a VL test) as the denominator for suppression rate would be more appropriate; using those who received a VL test as the denominator will exclude patients who did not even receive a test.

Tracking the proportion of ART patients who had access to a VL test (e.g. patients in specific geographies, sub-populations etc.) and the proportion of ART patients who received a VL test are examples of a system and process indicators that can be measured to track scale-up of coverage and also improve interpretation of virologic suppression rates. As programs reach 100% coverage of routine VL testing for all populations across the entire country, tracking 'access' to a VL test becomes less essential for monitoring VL testing coverage.

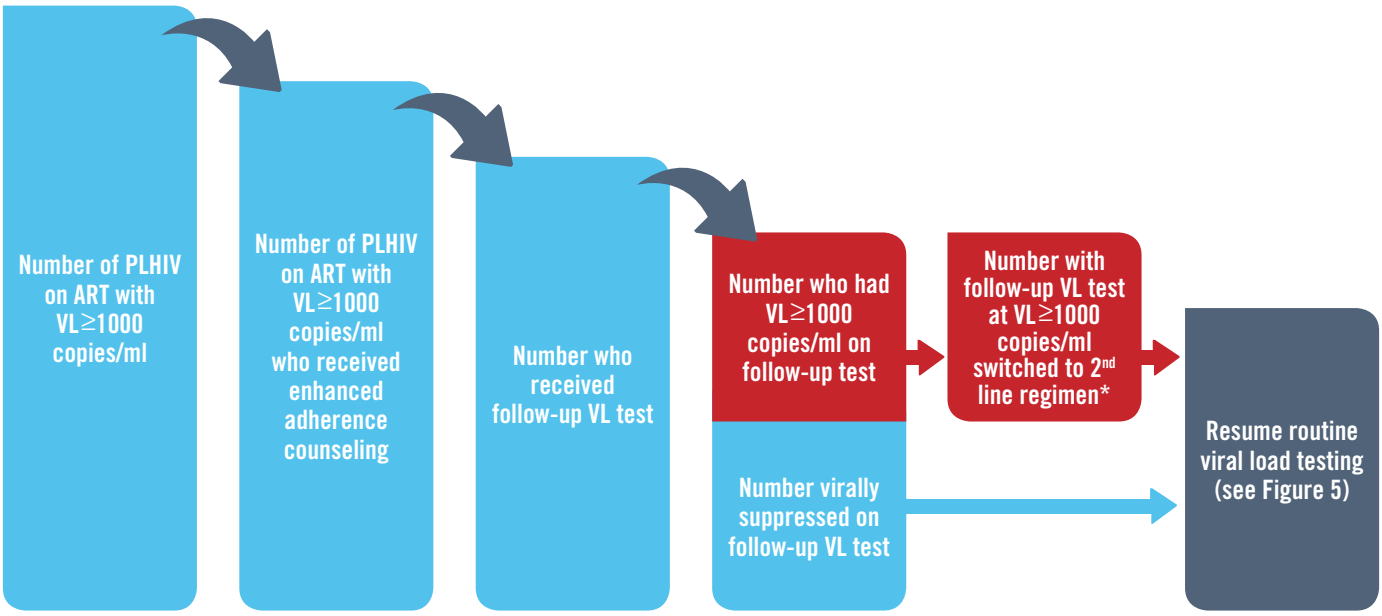
The cascade in Figure 5 can be used to conduct a cohort-based analysis or a cross-sectional based analysis. To conduct a cohort-based analysis, the data in the cascade could follow patients who initiated ART at the same time to a specified period of time (e.g. 6 months, 12 months, 24 months etc.) to examine patient outcomes. To conduct a cross-sectional cascade analysis, the data in the cascade would reflect aggregate data for the variables for a specific period. While this is helpful, it is important to note however, that not all the people counted across the cascade may be the same person. As was noted above, it is important to note the key caveats and limitations of the data when conducting the different types of analyses.

M&E CONSIDERATIONS FOR MONITORING PATIENTS WHO ARE NOT VIRALLY SUPPRESSED

Patients with a non-suppressed VL will require more intensive monitoring and specific tools and systems to track interventions. Figure 6 illustrates the cascade for patients with VL≥1000 copies/mL.

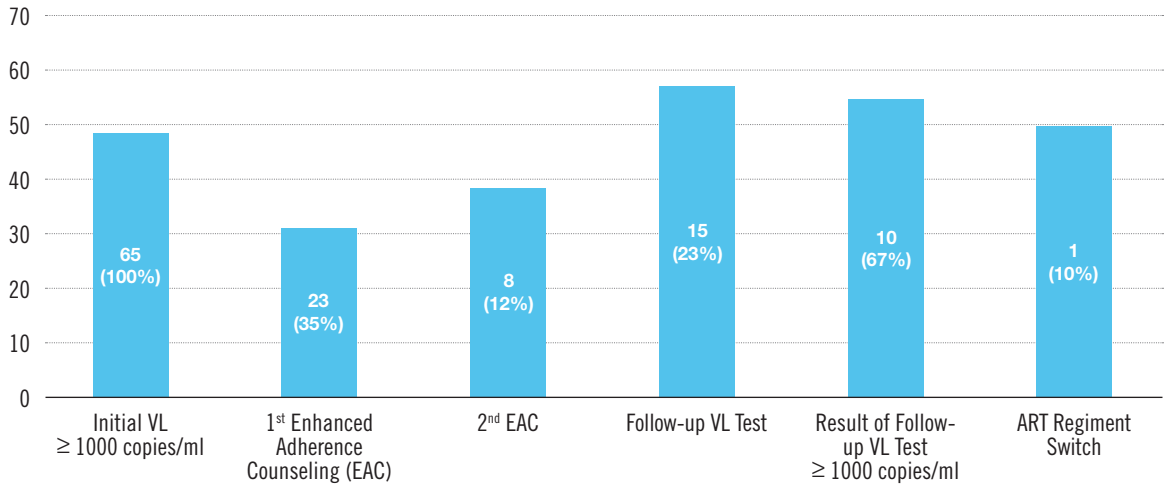
Country programs should ensure M&E tools (e.g. high VL register) are available for closely tracking patients with non-suppressed tests (≥1000 copies/mL). Data from a high

Fig. 6. VL cascade for patients with a non-suppressed VL test result (VL>1000 copies/mL)



*In general, a patient switching to 2nd line will receive a VL test 6 months after 2nd line initiation, and again at 12 months, and once every 12 months thereafter.

Fig. 7. Example of Utilizing Routinely Collected Data to Understand the Leaks in the VL Cascade in PLHIV with non-suppressed VL: From VL ≥1,000 to 2nd Line ART



viral load register or logbook (Appendix 3) can be used to track patients who have a VL result ≥ 1000 copies/mL, and review the proportion of individuals who received the recommended clinical management (i.e., enhanced adherence counseling interventions, VL testing, and switch of ART regimens for continued non-suppression).

It is expected that the volume of patients with VL≥1000 copies/mL requiring longitudinal tracking to create the VL cascade (Figure 6) will be relatively low since program data has shown that the majority of ART patients are virally suppressed. Figure 7 is an example of a cascade analysis that can be displayed if comprehensive data are collected in a logbook or register. Data from multiple sites can be aggregated and reviewed for and leaks stemming from non-adherence to guidelines or patient loss to follow-up. This type of data should be used to improve clinical follow-up and routinely reviewed at both the facility and above-site levels.

Data from the cascade may also inform discussions on HIV drug resistance. Tracking patients with VL≥1000 copies/mL along the entire cascade will help with quantification of patients that did not re-suppress after completing EAC and are at higher risk of having HIV drug resistance.

While Figure 7 is useful at displaying the VL cascade for VL patients, it is worth noting that patients who received the EAC sessions and those who received a follow-up VL test could be different patients. However, the example of the high VL register that is provided in Appendix 3 would allow programs to also conduct a longitudinal analysis of the same group of patients.

In summary, core indicators along the VL cascade attempt to measure site and system-level:

- Performance of initial VL in patients post-ART initiation
- Performance of routine VL in patients on ART
- VL suppression rate in ART patients, with disaggregations for sub-populations and age/sex
- Interventions for ART patients with non-suppressed VL i.e., documented enhanced adherence counseling (EAC)
- Performance of follow-up VL in ART patients with non-suppressed VL
- Modification of ART regimens based on repeat values of VL≥1000 copies/ml as per national guidelines

With the appropriate and robust M&E systems and tools in place, data can be used to examine other monitoring questions related to service delivery. For example:

- What are the differences in virologic suppression rates between men and women on ART?
- Which sites have particularly poor rates of virologic suppression?
- What percent of samples collected are rejected due to improper or insufficient collection (including incorrect lab requisition form completion)?
- What percent of pregnant or breastfeeding women on ART are virologically suppressed?

- What percent of children on ART are virologically suppressed?
- What percent of non-suppressed patients underwent some adherence counseling interventions? What proportion completed the prescribed amount before being re-tested?
- What proportion of non-suppressed patients received a follow-up (i.e. 2nd) VL test?
- What percent of patients with a first non-suppressed VL test re-suppress after receiving adherence counseling interventions? How does this vary by population (e.g., men vs. women, children vs. adults)?What percent of patients with persistently high VL have been switched to 2nd line ART?

The ability for country programs to examine these monitoring questions will depend on both the availability and quality of VL data. Data from multiple indicators may be required to answer one question.

DATA QUALITY

Data quality should be a priority for programs, especially with the complexities of monitoring and reporting routine VL data from multiple locations and sources. Data quality must be regularly reviewed at sites, labs, and within the aggregate M&E system used to monitor the overall HIV program (e.g. DHIS2). Dimensions of data quality include:

- Validity: the degree to which the data measure what they are intended to measure
- Accuracy: the percentage of data fields containing correct data
- Availability: ability of the system to report the data, including availability of registers to validate reported data and percentage of facilities submitting monitoring reports
- Completeness: the proportion of data fields that are complete (not missing data)
- Timeliness: the proportion of reports submitted on time.

Ensuring data quality starts before data are collected through the development of high level protocols or standard operating procedures for ensuring data quality at the service delivery, district, and national levels. Data quality protocols provide standard guidelines for data management procedures to ensure accuracy, completeness and timeliness of data being transmitted; ensures consistency in indicator definitions; and defines responsibilities for data quality at each level of the health information system.

Routine VL data quality assessments (DQAs) should be incorporated into the VL M&E Plan. Routine data assessments can be as simple as recreating site-level values for specified indicators at selected sites that were reported in the previous reporting period to conducting a more thorough assessment of comparison of reported data through multiple unlinked systems (e.g. site registers/ electronic medical records, DHIS2, and LIMS). More in-depth DQAs can include close review of recorded data to ensure that correct data are being recorded (e.g. comparing results data from LIMS to data in the patient chart to data recorded for the patient in a register. Both ends of the spectrum are routinely needed for monitoring VL data quality.

Protocols for the implementation of routine DQAs are also needed; these should assess adherence to data collection, aggregation, and reporting protocols that were defined in data quality quality protocols developed before data collection started. The DQA protocol includes instructions on when assessments should be conducted; who is responsible for conducting assessments; and how data from assessments should be reviewed and used to inform action plans to improve data quality.

Please refer to WHO's "Consolidated Guidelines on Person-Centred HIV Patient Monitoring and Case Surveillance for more information and recommendations for conducting data quality reviews and assessments.

DATA ANALYSIS AND DATA USE FOR PROGRAM IMPROVEMENT

Developing a clear plan for data analysis and use in the early phases of scale-up can motivate staff to collect, review, and analyze VL testing data. The data analysis plan should include analysis of overall VL testing coverage and outcomes at the site and above-site levels, review of data by age groups and for various priority and key populations, and data analysis of VL cascades. Data analysis may also be cohort-based or cross-sectional, depending upon the question and available data. Research studies and program data have shown a significant variability in VL suppression by age group, with children and adolescents having virologic failure rates up to 3 times higher than adults (Boerma et. all, 2016). For this reason, it is imperative that VL outcome indicators be analyzed by age group (e.g., standard disaggregations for children plus ages 10-19 for adolescents). Priority populations such as pregnant and breastfeeding women should also be analyzed separately to inform programmatic activities around elimination of maternal to child transmission. Viral load suppression rates among HIV/TB co-infected populations and key populations (e.g. female sex workers, men who have sex with men, and people who inject drugs) should also be analyzed to inform program implementation. Even if data on some sub-populations are not routinely collected, programs should plan to review data at sites for sub-populations during

routine service quality assessments and/or supportive supervision site visits.

Country programs have increasingly been utilizing 'dashboards' to conduct routine data analysis and use among stakeholders. Routine and frequent availability and review of data for key metrics, displayed with graphics and visuals have been essential to promote data use and understanding. While dashboards are generally developed outside of the primary VL data collection systems, country programs are moving more towards integration of dashboards in existing data systems such as LIMS and DHIS2.

Data should be used to answer key technical and programmatic questions and provide key stakeholders (e.g., MOH, district/regional/province staff, facility staff, implementing partners, etc.) with information to inform program implementation, identify challenges, and initiate corrective action for quality improvement. Quality improvement is a continuous and iterative process. Data analysis of the VL cascade indicators is essential to identify challenges and inform strategies for improvement. Program data should be routinely reviewed and used at multiple levels to update strategic plans, program implementation and improvement plans, and commodities forecasting. Tools (e.g. dashboards, clinical cascade templates, action plans) should be informed by successful models used in other program areas to assist with routine analysis, track progress, and identify new and ongoing program challenges.

SUMMARY OF MONITORING CONSIDERATIONS:

- Identify indicators, processes, and tools for routine monitoring
- Develop dashboards or standard reports to aid in routine data analysis and use
- Routinely monitor data quality with stakeholders and follow-up with sites to improve collection, analysis, and use of data
- Update national HIV M&E plans to reflect VL testing and scale-up monitoring. This may involve developing the M&E section of the national plan for VL implementation *and* updating national HIV M&E plans to include VL testing indicators, targets, and planned evaluations. Include only high-level routine VL targets and indicators in the national M&E HIV plan. Ensure that there is a clear plan for data analysis and use, and that site staff are engaged in the review of data from their sites
- Ensure that dashboards include key steps in alignment with the VL testing cascade. It will be important to monitor how many individuals receive routine VL tests per the national algorithm to identify any early issues with demand creation and/or provider compliance with VL testing guidelines
- Data analysis and use of tools should support stakeholders and program implementers to utilize data to inform:
  - Strategic Planning
  - Program Implementation and Improvement (including quality of testing and clinical services)
  - Commodities Forecasting

SECTION 3: SERVICE QUALITY ASSESSMENTS AND EVALUATION OF VIRAL LOAD TESTING

Country programs may want to conduct enhanced monitoring of VL implementation, particularly during scale-up so that issues can be identified promptly and corrective actions can be taken as soon as possible. Furthermore, evaluations should be planned early on to ensure robust data are collected and reviewed to inform program implementation and improvement.

ENHANCED MONITORING AND SERVICE QUALITY ASSESSMENTS

Enhanced monitoring may involve more frequent review of routine monitoring indicators, or it may involve a limited set of key indicators, in addition to the core set of indicators, which are collected from a subset of sites. These data should be reviewed by interdisciplinary teams on a more frequent basis to assess adherence to SOPs and quality of services provided. Enhanced monitoring may also highlight some key issues with data quality.

In addition to enhanced monitoring of key indicators, country programs should consider conducting service quality assessments (SQAs). SQAs provide in-depth site-level assessments of programs using implementation standards to identify areas that need further improvement. As a result, SQAs provide constructive feedback to site-level and national programs on how well sites are meeting standards of care. While the focus of the SQA is on service provision, there is a heavy reliance on reviewing site-level data. Thus, it is important for M&E systems to be in place to capture key data that can be reviewed during SQAs.

Objectives of a VL SQA include:

1) Assess compliance with national guidelines on VL monitoring in patients who have initiated ART or are already on ART through measurement of:
   a. site-level compliance with initial VL performance in patients post-ART initiation
   b. site-level compliance with interventions for individuals with virologic failure (as defined by national guidelines)
   c. site-level compliance with routine follow-up VL testing in ART patients
   d. site-level compliance with VL testing of ART patients in the last 12 months
   e. site-level compliance with referral of stable patients to less intense model of care/differentiated service delivery
2) Assess compliance with national guidelines on the management of virologic failure through the determination of:
   a. whether ARV regimens are changed in a *timely* manner to a 2nd-line regimen based on repeatedly detectable VL values per national guidelines
   b. whether ARV regimens are being changed to an *appropriate* 2nd-line regimen based on a repeatedly detectable VL values per national guidelines

During SQAs, more in-depth DQAs can also be performed at sites. Data quality assessments alone generate vital information for program monitoring, and quality improvement but provide a limited context for investigators to fully understand the reasons for the findings. By combining an SQA activity with a DQA, programs will have a more complete context for understanding the data collected and reported by the site, and any discrepancies between indicator values..

Appendix 5 provides a list of indicators that can be included in an enhanced monitoring plan or VL SQA/DQA.

CONDUCTING EVALUATIONS OF VL IMPLEMENTATION

Country programs are encouraged to collaborate with stakeholders to complete high-quality evaluations of their VL implementation plans.

Types of Evaluations

There are several types of evaluations that can be conducted to inform and improve program implementation and outcomes. Appendix 7 outlines the differences amongst process evaluation, outcome evaluation, economic evaluation, and operations research. This section primarily focuses on process and outcome evaluations.

Process evaluations are conducted to evaluate if VL scale-up is being implemented as planned. Process evaluations identify facilitators and barriers to VL testing from multiple perspectives (e.g. patient, provider, specimen transporter, lab technician, M&E officer, etc.), and identify lessons learned to inform further scale-up efforts.

Examples of Process Evaluation Questions:

- Was VL testing scaled-up and implemented as planned? Why? What worked? What did not work?
- How are M&E, program/clinical, and lab staff working together to review and use data on VL testing performance?
- Were staff adequately trained to implement VL testing for patient monitoring? Was there adequate support for VL testing (including providers at sites, lab transporters, lab technicians, and M&E staff)?
- Which models of sample transport result in more people receiving VL tests and results?
- As a measure of quality of VL services, how effective is the centralized system at returning test results to facilities in a timely manner?
- How effective is the hub and transport network at returning results to facilities?
- How effective are electronic transfers of results compared with physical return of results in ensuring that results are used at sites for patient management?
- What are the best practices to ensure patients receive VL testing and results in a timely fashion, understand VL results, and receive adherence counseling to improve ART adherence and documentation of viral suppression?

Outcome evaluations are conducted to determine program effectiveness. Outcome evaluations require the collection of baseline data from which to measure change and therefore should be planned before or during the early stages of VL implementation. If programs begin an outcome evaluation mid-way through implementation, they will not be able to answer critical questions due to limited or poor quality baseline data. By planning ahead, country programs can articulate evaluation questions, develop protocols, collect baseline data, and plan for subsequent data collection for a high-quality outcome evaluation.

Examples of Outcome Evaluation Questions:

- Which sub-populations had the most success with VL testing? What were the significant differences in VL test results between different sub-populations? Why?
- How has quality of HIV services, particularly adherence counseling and support, changed as a result of routine VL testing?
- What are the optimal models of enhanced adherence counseling to ensure patients are adhering to HIV treatment and are virally suppressed?
- How well do self-reported adherence rates predict viral suppression?
- How has the implementation of VL testing impacted the timely switch of patients to appropriate second-line ART?

It is critical that the national M&E plan allocates an appropriate budget for the execution of an effective evaluation plan to support effective VL implementation. Engaging stakeholders early in the implementation planning process will help programs prioritize evaluation questions and resources required to execute the evaluation (i.e. technical, budget, and staff time). Once there is agreement on evaluation priorities and resources have been allocated, plans to execute the evaluation can move forward. Evaluation protocols should be developed as soon as possible so that programs have adequate time to collect baseline data, where required.

SUMMARY OF CONSIDERATIONS

- Adhere to evaluation standards and reporting requirements of funder
- Engage stakeholders to develop evaluation questions, priorities, and budgets.
- Identify and categorize the type of evaluations that may be conducted; distinguish between process, outcome and operations research
- Develop evaluation protocols as early as possible to guide collection of baseline data as a foundation for measuring change

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APPENDIX 1: LOGIC MODEL FOR ROUTINE VIRAL LOAD TESTING

OUTPUTS	ACTIVITIES	OUTPUTS	OUTCOMES		
			SHORT-TERM	MID-TERM	LONG-TERM (IMPACT)
• Funding • Staff (e.g. Lab Techs, Transport Network, Clinic Staff etc.) • Policies • Partnerships • Equipment, Supplies, Reagents etc. • Lab/Specimen Transportation Network	**PLANNING** • Assess capacities of staff, existing specimen transport network, infrastructure, molecular labs, testing modalities, IPs, and M&E system • Assess clinical site and program readiness • Select specimen type and platform or assay, and VL technologies for VL testing • Develop clinical algorithms and quality standards for VL monitoring • Review and update clinical and lab monitoring and reporting (M&R) tools for VL monitoring • Develop training materials and plan for training staff at national, sub-national, and site levels • Develop costed, phased implementation plan with targets; determine criteria to guide phased implementation (e,g, geography, priority pops etc.) • Develop/Revise plan for lab accreditation and Quality Improvement/Quality Assurance system to ensure quality of VL testing • Identify current and future limitations of equipment, infrastructure, funding, policies, and HR • Identify and prioritize evaluation questions (process and outcomes) for VL monitoring and health outcomes	**PLANNING** • Comprehensive costed, phased , and strategic VL testing implementation plan with targets developed • Training materials and training plan for staff at labs and facilities developed • Revised M&R forms, and updated M&R SOPs for national, sub-national, and site levels to ensure complete and quality data available for VL monitoring • M&E Plan for VL testing developed • Quality mngmt system and external QA plan in place **IMPLEMENTATION OF VL MONITORING** **Systems and Capacity Strengthening** • Quality Standards and SOPs established • M&R Forms and SOPs updated • Molecular labs identified for VL testing and lab/specimen transport network strengthened • Staff trained in VL testing procedures, including completion of M&R tools • Clinical and program readiness assessed for phased implementation of VL testing **Service Delivery** • Viral Load Testing available and scaled up for all PLHIV on ART	**System outcomes** • Increased capacity of lab techs. HCWs, data clerks etc. to request, conduct, verify, and/or monitor outcomes of VL testing • Increased ability to consistently provide supplies, transport specimens, and return results to sites for VL testing **Health outcomes** • Increased access of HIV+ patients on ART to routine VL testing • Increased %age of patients with documented VL results • Improved treatment recommendations and quality of care for HIV+ patients	**System outcomes** • Increased volume of VL testing • Increased quality of VL testing • Increased routine and strategic use of quality data **Health outcomes** • Increased coverage of VL testing among HIV+ patients on ART • Increased patient adherence to ART regimen • Improved quality of care for ART patients • Improved ART outcomes	• Reduction in morbidity and mortality • Decreased numbers of AIDS-related deaths • Reduction of new HIV infections • Increased survival of patients on ART • Increased numbers of infections averted

APPENDIX 2: TOOL AND CHECKLIST FOR ASSESSMENT OF VIRAL LOAD M&E SYSTEMS

Purpose: The purpose of this tool is to guide the assessment of M&E systems and their capacity to routinely monitor and track VL testing. The process of collecting data from M&E tools should be well-aligned with the goal of informing and improving program implementation. This tool may be utilized throughout the process of VL implementation to inform scale-up efforts and to monitor implementation. Ideally, this tool would be used as part of a broader, more comprehensive M&E system assessment/review.

Appendix 2 (continued)

Area of System to Review	Assessment Questions	Findings	Recommendation
Data Flow and Data Capture	• Has sample flow from the site to lab been clearly mapped out? • Has data flow from the site to lab and back to site (e.g., results return) been clearly mapped out? • Have data capture forms been mapped to data and sample flow? Is it clear what form will be used at which point in sample transport and flow of data results? • Have data capture forms/data sources been mapped to indicators? Is it clear where the data will come from for the various indicators?		
Data Collection (Paper and Electronic M&E Tools)	• Do current patient cards (or electronic medical records) include field(s) to document VL testing (including when ordered, received, and results reported)? • Do current ART registers include field(s) to record VL test results (including month when test was requested and test results)? Ideally this would be clearly noted in the ART register at 6 months after initiation and 12 months thereafter (or per national VL testing algorithms). • Do current M&E tools include the required fields for key variables for routine reporting on VL testing and outcomes? • Is there a clear process for recommending changes to existing M&E tools (or creation of new tools) to capture data for VL testing and results? • Is there a plan to pilot test all updated tools? • Is there an existing lab electronic system (e.g. Laboratory Information Management System (LIMS))? Does it include fields to capture data for VL testing? Are these fields clearly linked to the paper-based M&E tools that may be used for sample transport? Is there interoperability of lab electronic systems with national electronic systems that are used for monitoring and reporting on HIV? If not, how often is the data from each respective system reviewed for discrepancies? • Is the data captured in service delivery site and patient-level M&E tools the same as the data captured in Laboratory Information Systems? If not, what are the discrepancies? Should the tools and systems be harmonized? • Can the systems track only tests, not individuals? For example, if relying on a lab electronic information system for reporting, can that system report results for unique individuals or only report tests conducted? • Can systems track unique individuals over time? For example, if relying on a lab electronic information system for reporting, can the system report results for the individual over time (e.g. annual routine VL tests over time, follow-up VL test after initial test showed detectable VL etc.)? • Can M&E systems and tools track VL testing outcomes for cohorts of patients (e.g. VL test results for patients 6 and 12 months after ART initiation)?		

Appendix 2 (continued)

Area of System to Review	Assessment Questions	Findings	Recommendation
Data Reporting	• Have routine data reporting forms been updated to include required fields for key VL testing indicators? • Have electronic reporting systems been updated to integrate required fields for reporting and monitoring VL testing and results? • Can the program report on tests and/or individuals? Can the program only track tests, and not individuals? What is required to be able to track and report both tests and individuals?		
Data Analysis and Use	• Have M&E Plans been updated to reflect scale-up of VL testing? Have national indicators to monitor 90-90-90 been clearly defined? • Is there a clear plan for data analysis on routine and enhanced VL monitoring indicators that includes disaggregations by age and patient population? • Is there a plan with tools and materials for more frequent monitoring of VL testing during scale-up? • Has there been input from service providers, program managers, M&E staff, and other key stakeholders on plans for data analysis and use, tools, and processes? • Has a dashboard or template for displaying, tracking, and reviewing indicator results been developed with input from all stakeholders? • Have regular meetings with stakeholders been established to review data and discuss corrective/follow-up action?		
Data Quality	• Is there a strategy to monitor data quality at sites and labs and resolve discrepancies between unlinked systems (e.g. LIMS, site registers/ electronic medical records, and DHIS2)? • Have variables on VL testing been integrated into data quality assessment (DQA) tools? • After implementing VL testing, have there been DQAs to review data at sites and compare data from unlinked data systems such as LIMS, paper registers/electronic systems,, and ART aggregate reporting systems (e.g. DHIS2)? Does data from all three sources match?		
Service Quality	• Is there a strategy to monitor quality of VL implementation at the facility level (e.g., timely and accurate use of VL results for patient management)? • Is there a plan to follow-up on service quality findings to ensure that data are of the highest quality?		

Appendix 2 (continued)

Area of System to Review	Assessment Questions	Findings	Recommendation
Capacity	• Is there a plan being developed to train service providers, lab staff, M&E staff, and others on the correct completion of tools? Is this training also incorporating elements of the clinical cascade so that it is clear how the data relate to the three 90s? • Is there a plan and schedule to provide ongoing on-site training and mentorship to ensure compliance with national guidelines for VL testing and documentation? • Is there a plan to follow-up on DQA results to ensure that data are of the highest quality? • Is there a forum where lessons learned, challenges, and recommendations on M&E for VL testing can be communicated and tracked?		

APPENDIX 3: EXAMPLES OF KEY M&E TOOLS FOR VIRAL LOAD MONITORING

LAB REQUISITION FORM AND VL RESULTS FORM: Example from Government of Uganda: Lab Requisition Form. The front side is the Lab Requisition Form that accompanies the VL sample from the facility to the lab hub and the centralized lab for testing and processing. The back side is the VL Results Form that reports results back to the facility.

MINISTRY OF HEALTH UGANDA
CENTRAL PUBLIC HEALTH LABORATORIES
P.O. Box 7272, Plot 1062-106 Butabika Road, Luzira
Toll free line 0800-221100
Email: customercare@cphl.go.ug

Lab Request Form for HIV Viral Load Analysis

Name of Health Facility: _____ Health Facility Code: _____
District: _____ Hub: _____

PATIENT DETAILS

Date of Birth DD/MM/YYYY
Patient Clinic ID/ART #: _____ If DOB Unknown Age in Years _____ Sex: ☐ Female ☐ Male
Other ID: _____ If < 2 years, Age in Months _____ Phone Number: _____

TREATMENT INFORMATION

Date of Treatment Initiation: DD/MM/YYYY Current WHO Stage ☐ I ☐ II ☐ III ☐ IV

How long has this patient been on treatment ☐ 6 months - < 1yr ☐ 1 – 2yrs ☐ 2 - <5yrs ☐ > 5yrs

Which treatment line is patient on? ☐ First ☐ Second ☐ Third Current Regimen (use code below) _____

Is mother pregnant? ☐ No ☐ Yes If Pregnant, enter the ANC #: _____

Is mother breastfeeding? ☐ No ☐ Yes

Patient has active TB? ☐ No ☐ Yes If Yes, are they on ☐ Initiation Phase ☐ Continuation Phase

ARV Adherence ☐ Good >95% ☐ Fair 85 – 94% ☐ Poor <85%

Treatment care approach(DSDM) ☐ FBIM ☐ FBG ☐ FTDR ☐ CDDP ☐ CCLAD

INDICATION FOR VIRAL LOAD TESTING (please tick one): To be completed by Clinician

☐ Initial ☐ Routine ☐ Repeat (after IAC) ☐ Suspected Treatment Failure ☐ 1st ANC For PMTCT ☐ CCLAD entry

Date of last VL	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY

ART Regimen Codes

1st line children <10 years	1st line Adolescents 10-19 years	1st line Adults ≥20 years	2nd line children <10 years	2nd line Adolescents 10-19years	2nd line Adults ≥20 years	3rd line children <10 years	3rd line Adolescents 10-19 years	3rdline Adults ≥20 years
4C=ABC-3TC-NVP	3A=TDF-3TC-EFV	1C=AZT-3TC-NVP	5D=TDF-3TC-LPV/r	8A=TDF-3TC-LPV/r	2B=TDF-3TC-LPV/r	7B=DAR/r-RAL-AZT-3TC	9A=DAR/r-RAL-TDF-3TC	6A= DAR/r-RAL-TDF-3TC
4D=AZT-3TC-EFV	3B=ABC-3TC-NVP	1D=AZT-3TC-EFV	5K=ABC-3TC-LPV/r	8B=AZT-3TC-ATV/r	2C=AZT-3TC-ATV/r	7E=DAR/r-RAL-ABC-3TC	9B=DAR/r-RAL-AZT-3TC	6B=DAR/r-RAL-AZT-3TC
4E=ABC-3TC-NVP	3C=AZT-3TC-NVP	1E=TDF-3TC-NVP	5L=AZT-3TC-ATV/r	8C=AZT-3TC-LPV/r	2E=AZT-3TC-LPV/r	7F=OTHERS	9C=DAR/r-ETV-TDF-3TC	6C=DAR/r-RAL-ABC-3TC
4F=ABC-3TC-EFV	3D=AZT-3TC-EFV	1F=TDF-3TC-EFV	5M=ABC-3TC-ATV/r	8D=TDF-3TC-ATV/r	2F=TDF-3TC-ATV/r		9E=DAR/r-RAL-ABC-3TC	6E=DAR/r-ETV-TDF-3TC
4G=ABC-3TC-LPV/r	3E=ABC-3TC-NVP	1H=ABC-3TC-NVP	5P=AZT-3TC-ABC	8E=ABC-3TC-LPV/r	2G=ABC-3TC-LPV/r		9F=OTHERS	6D=OTHERS
4H=AZT-3TC-LPV/r	3F=ABC-3TC-EFV	1I=ABC-3TC-EFV	5Q=ABC-3TC-RAL	8F=ABC-3TC-ATV/r	2H=ABC-3TC-ATV/r			
4I=TDF-3TC-EFV	3M=ABC-3TC-DTG	1M=ABC-3TC-DTG	50=AZT-3TC-LPV/r	8G=OTHERS	2I=OTHERS			
4J=TDF-3TC-NVP	3N=TDF-3TC-DTG	1N=TDF-3TC-DTG	5R=AZT-3TC-RAL					
4L=AZT-3TC-ABC	3K=OTHERS	1G=OTHERS	5N=OTHERS					
4M=ABC-3TC-DTG								
4N=TDF-3TC-DTG								
4K=OTHERS								

INFORMATION FOR HIV DRUG RESISTANCE TESTING ONLY

Past Regimen	(use code above)	(use code above)	(use code above)	(use code above)	(use code above)	Body Weight: _____ kg
Start Date	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	Patient on Rifampicin?
Stop Date	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	DD/MM/YYYY	☐ Yes ☐ No

Requesting clinician: ..... Phone number: ..... Date: .....

Sample Identification Information: To be completed by Health Facility Laboratory Staff

SAMPLE DETAILS
Date of Sample Collection: _____ Sample Type: ☐ DBS ☐ Plasma

Name of Lab Person: _____ Phone: _____

MINISTRY OF HEALTH UGANDA

CENTRAL PUBLIC HEALTH LABORATORIES

FACILITY DETAILS

Name: _____

District:_____ l Hub:_____

SAMPLE DETAILS

Form #: _____

Sample Type: ☐ DBS ☑ Plasma

PATIENT INFORMATION

ART Number: _____

Other ID: _____

Sex: ☑ Female ☐ Male ☐ Left Blank

Date of Birth: _____

Phone Number:

SAMPLE TEST INFORMATION

Sample Collection Date: _____

Reception Date: _____

Test Date: _____

TREATMENT INFORMATION

Treatment Initiation date: _____

Treatment Line: ☐ First ☑ Second ☐ Third

Pregnant?: ☐ NO ☑ YES ANC #: ____

Breastfeeding? : ☑ NO ☐ YES

VIRAL LOAD RESULTS

Method Used: HIV-1 RNA PCR Roche

Location ID: _____

Viral Load Testing #: _____

Result of Viral Load: _____

RECOMMENDATIONS

Suggested Clinical Action based on National Guidelines:
≥ 1,000 copies/mL. Patient has unsuppressed viral load.

- Please screen/test for OI- crag and initiate intensive adherence counseling
- Repeat viral load test within 4 - 6 months.
- Next VL test Expected in Oct, 2016. Send 2 samples. One for VL test. One for HIVDR test

Lab Technologist: _____

Lab Manager: _____

CENTRAL PUBLIC HEALTH LABORATORIES MINISTRY OF HEALTH virology Lab

DATE RELEASED

"a SANAS Accredited Medical Laboratory, No. M0589"

ART REGISTER WITH FIELDS FOR RECORDING VIRAL LOAD RESULTS: Example from Government of Uganda: ART Register that can track cohorts of patients. This shows an example of a field to document VL test results. Per guidelines, a VL test result is expected to be documented at 6 months after initiation, 12 months after ART initiation, and then annually thereafter. Fields in the ART register for recording VL results are essential for monitoring cohorts of ART patients.

The registry has been broken into two tables to fit the pages of this document; the first table corresponds to the left side of the registry, and the second table corresponds to the right page of the registry for longitudinal tracking of patients. Although not shown here, fields for tracking VL have also been integrated into ANC, labor, and postnatal registers in Uganda.

Left side of register

HMIS FORM 081: ART REGISTER

MINISTRY OF HEALTH

COHORT: Year.................................... Month..................................Name of Health Unit..

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	11	(12)	(13)	(14)	(15)	(16)					(17)	(18)	(19)
Registration and personal information								Status at start ART				CLINICAL STAGE (Insert date)			eMTCT				Original Regimen	1st-line regimen	2nd-line regimen	3rd-line regimen
ART start date	Unique ID No.	TI / eMTCT	Patient clinic ID	Name *Surname* *Given name*	Sex	Age (yrs) (Write age in months if 2 yrs)	Address (District, sub-county, parish, LC1)	Function status	Weight/ MUAC	WHO clinical stage	CD4 #/%	CPT/ Dapsone Start Month /year Stop Month /year	INH (H) Start Month/ year Stop Month/ year	TB Rx District TB reg # Start Month / year Stop Month / year	For each pregnancy, record EDD, ANC# and HIV-exposed infant # Preg 1	Preg 2	Preg 3	Preg 4		*1st: Reason/ Date* *2nd: Reason/ Date*	*1st: Reason/ Date* *2nd: Reason/ Date*	*1st: Reason/ Date* *2nd: Reason/ Date*
				Surname Given name			District Sub-County, Parish/ Village / Cell					Start Date Stop Date	Start Date Stop Date	REG # Start Date Stop Date	EDD ANC Infant #	EDD ANC Infant #	EDD ANC Infant #	EDD ANC Infant #		1st: .... Reason / Date 2nd: .... Reason / Date	1st: .... Reason / Date 2nd: .... Reason / Date	1st: .... Reason / Date 2nd: .... Reason / Date
				Surname Given name			District Sub-County, Parish/ Village / Cell															
				Surname Given name			District Sub-County, Parish/ Village / Cell					Start Date Stop Date	Start Date Stop Date	REG # Start Date Stop Date	EDD ANC Infant #	EDD ANC Infant #	EDD ANC Infant #	EDD ANC Infant #		1st: .... Reason / Date 2nd: .... Reason / Date	1st: .... Reason / Date 2nd: .... Reason / Date	1st: .... Reason / Date 2nd: .... Reason / Date
				Surname Given name			District Sub-County, Parish/ Village / Cell															
				Surname Given name			District Sub-County, Parish/ Village / Cell					Start Date Stop Date	Start Date Stop Date	REG # Start Date Stop Date	EDD ANC Infant #	EDD ANC Infant #	EDD ANC Infant #	EDD ANC Infant #		1st: .... Reason / Date 2nd: .... Reason / Date	1st: .... Reason / Date 2nd: .... Reason / Date	1st: .... Reason / Date 2nd: .... Reason / Date
				Surname Given name			District Sub-County, Parish/ Village / Cell															

Right side of register

HMIS FORM 081: ART REGISTER

MINISTRY OF HEALTH

COHORT: Year.................................... Month..................................Name of Health Unit..

	Year............................Fill in Months										Fill in Months								
Patient ID	Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Clinical stage	Wgt	CD4# CD4% VIRAL LOAD	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Clinical stage	Wgt	CD4# CD4% VIRAL LOAD
	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT			CD4# CD4% VIRAL LOAD	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT			CD4# CD4% VIRAL LOAD
	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT			CD4# CD4% VIRAL LOAD	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT			CD4# CD4% VIRAL LOAD
	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT			CD4# CD4% VIRAL LOAD	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT			CD4# CD4% VIRAL LOAD
	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT			CD4# CD4% VIRAL LOAD	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT	ARVs/FU Status TB Status / Nutrition Status ADH CPT			CD4# CD4% VIRAL LOAD

VIRAL LOAD SAMPLE REGISTER/LOGBOOK AT FACILITY: *Optional* tool to document all samples sent from the facility and all results returned to the facility for individual patients. Key fields include: Date sample collected, ART number, patient name, date of birth (DOB), sex, pregnant (yes/no), contact information, reason for test (e.g., routine vs. targeted, follow-up after non-suppressed viral load), date result received at facility, and information related to reasons for sample rejection (if applicable). This log is usually maintained by lab staff at sites, but this responsibility may be shared with other staff depending site size and staff availability.

DATE VL SAMPLE TAKEN (DD/MM/YYYY)	ART NUMBER	FIRST NAME	SURNAME	DOB	SEX	PREGNANT (Y/N)	CONTACT INFORMATION	REASON FOR TEST (ROUTINE VS. TARGETED)	DATE VL RESULT RECEIVED AT FACILITY	IF SAMPLE REJECTED, DATE FACILTY NOTIFIED OF REJECTION	REASON FOR SAMPLE REJECTION

HIGH VL RESULTS FORM: Optional form to record follow-up actions for patients with viral load ≥1000 copies/mL. This would be maintained in the patient chart or incorporated into electronic medical record systems, but can also be used to complete the High VL register/logbook (see next tool example). Key fields include: patient contact information, ARV information, enhanced adherence counseling session data, follow-up VL test date, VL test result, and if patient was switched to another ART regimen.

HIGH VIRAL LOAD FORM

(For Enhanced adherence counselling (EAC) and Second Line ART Consideration)

A. Patient Information

Name		**Facility**	
DOB *(DD/MM/YYYY)*		**Age**	
Sex		**ART Number**	

ARV Information		***Viral Load Results***	
ARV Regimen	**Date of initiation** (DD/MM/YYYY)	**Recent VL** (c/ml)	**Date** (DD/MM/YYYY)
		Previous VL(s) (if any) (c/ml)	**Date** (DD/MM/YYYY)

Current WHO T-staging	**I**	**II**	**III**	**IV**

B. **Present illness (if any)**			**Comments**
Is this patient currently a presumptive TB?	☐ **Y**	☐ **N**	
History of chronic diarrhoea or vomiting?	☐ **Y**	☐ **N**	
Any other OI or signs of immunosuppression?	☐ **Y**	☐ **N**	
History of side-effects with ARV?	☐ **Y**	☐ **N**	

Patient's adherence history *before* EAC	☐ Good	☐ **Fair**	☐ **Poor**

C. **EAC sessions *(To be filled by the Adherence counsellor):***

For <u>each</u> session, assess major barriers for possible poor adherence (cognitive, behavioural, emotional, socio-economic as shown above).

Treatment supporter present: ☐ Y ☐ N

Enhanced adherence counselling (EAC) (To be filled by the Adherence Counsellor) session 1:

*For <u>each</u> session, assess **major** barriers for possible poor adherence (cognitive, behavioural, emotional, socio-economic as shown below).*

Date (DD/MM/YYYY):	Barriers:	Interventions:
__/__/_____ Adherence over last month ☐ Good ☐ Fair ☐ Poor **Pill count done?** Y ☐N ☐ *Pill intake: ___%*	☐ Knowledge ☐ Forgot ☐ Feeling better ☐ concurrent illness ☐ Alcohol/drugs ☐ Health beliefs/alternative remedies ☐ Depression ☐ Fear disclosure ☐ Lack of family/partner support ☐ Pill burden ☐ Child behaviour/refusing for children on ART ☐ Side effects ☐ Ran out of medication ☐ Lost/ damaged ☐ Sharing medications ☐ Transport ☐ Scheduling ☐ Failure to adjust Food insecurity ☐ Drug stock out ☐ Long wait ☐ Stigma ☐ Political crisis	*<u>Services</u>* ☐ Clinical ☐ Education ☐ Counselling (ind) ☐ Counselling (grp) ☐ Peer support ☐ Treatment buddy ☐ Drug pick-up ☐ DOT ☐ Case mgmt. *<u>Tools</u>* ☐ Pill box ☐ Calendar ☐ Journal/log ☐ Written instructions ☐ Phone calls ☐ SMS ☐ Alarms ☐ Other: _____

1st EAC session ***Identified adherence barrier/s***	***Agreed plan of action***
ARV-intake demonstration by patient/caretaker done? ☐Y ☐N Counsellor: _____ Date (DD/MM/YYYY): ____/____/_____	

2nd EAC session Counsellor: _____ Date (DD/MM/YYYY): ____/____/_____ Adherence since last session (e.g, over last month) ☐ Good ☐ Fair ☐ Poor **Pill count done?** Y ☐N ☐ *Pill intake: ___%*	
Identified adherence barrier/s	***Agreed plan of action***

3rd EAC session Counsellor: _____ Date (DD/MM/YYYY): ____/____/_____ Adherence since last session (e.g, over last month) ☐ Good ☐ Fair ☐ Poor **Pill count done?** Y ☐N ☐ *Pill intake: ___%*	
Identified adherence barrier/s	***Agreed plan of action***

Your impression about patient's adherence during and after EAC: ☐ Likely to be good
☐ Likely to **NOT** be good
☐Barriers identified not cleared
☐Missed appointment(s)* (*) *If patient has missed appointments, repeat Viral Load should be deferred and EAC extended. Share decision with the team.*

Major remaining barriers identified after EAC sessions:

- Behavioural **Y ☐N ☐If yes:** _____
- **Cognitive ☐Y ☐N** If yes: _____
- Socio-economic **☐Y ☐N If yes:**_____
- **Emotional ☐Y ☐N** If yes: _____
- Other barriers (e.g., Disclosure, Religion...) **Y ☐N ☐**If yes: specify_____ _____

Comments: _____
Extend adherence sessions **Y ☐N ☐**

Additional EAC session
Counsellor: _____ Date (DD/MM/YYYY): ____/____/_____
Adherence since last session (e.g, over last month)

- ☐ Good
- ☐ Fair
- ☐ Poor

Pill count done? Y ☐N ☐ *Pill intake: ___%*

Identified adherence barrier/s	***Agreed plan of action***

Additional EAC session
Counsellor: _____ Date (DD/MM/YYYY): ____/____/_____
Adherence since last session (e.g, over last month)

- ☐ Good
- ☐ Fair
- ☐ Poor

Pill count done? Y ☐N ☐ *Pill intake: ___%*

Identified adherence barrier/s	***Agreed plan of action***

D. **Date repeat Viral Load due** DD/MM/YYYY: ____/____/_____
(Complete 3-6 months **AFTER good** *adherence is achieved)*

Counsellor: _____ Date of assessment: ____/____/_____

E. **Repeat Viral Load result**: Date (of sample collection DD/MM/YYYY): ____/____/____

☐ <1000c/ml ☐ **≥1000c/ml**

F. OUTCOME for patients with persistently high Viral Load ≥ 1000c/ml (To be filled by the ART provider)

What is the plan for this patient? (tick all that apply)

Plan:	Date
☐ Remain on current regimen	___/___/_____
☐ Switch to second-line regimen	___/___/_____
New regimen : _____	
☐ Extend adherence sessions	
☐ Repeat viral load in 3 months	___/___/_____

Comments:_____

ART provider name:_____

ART provider signature: _____

ART provider contact number: _____

Date: ____/____/_____

HIGH VL RESULTS FOLLOW-UP REGISTER: Examples of longitudinal register to track patients with VL ≥1000 copies/mL. Country programs can adapt the register for their settings. Sites should complete these registers for all patients with an initial VL ≥1000 copies/mL to track EAC, follow-up VL test, result, outcome (e.g. maintained on regimen, switched etc.), and VL test result post-outcome.

The register has been broken into two tables in order to fit the pages of this document. The first table corresponds to the left side of the register, and the second table corresponds to the right page of the register for longitudinal tracking of patients.

	PATIENT SURNAME	PATIENT FIRST NAME	ART NUMBER	ART START DATE	DOB	SEX	CURRENT ART REGIMEN	REASON FOR VL TEST	DATE FIRST VL TAKEN	DATE RESULTS RECEIVED BY FACILITY	DATE PATIENT RECEIVED HIGH VL RESULT	FIRST EAC SESSION DATE	SECOND EAC SESSION DATE	THIRD EAC SESSION DATE	ADDITIONAL EAC SESSION DATE	ADDITIONAL EAC SESSION DATE
1.																
2.																
3.																
4.																
5.																
6.																
7.																

	DUE DATE FOR 1st FOLLOW-UP VL TEST	DATE 1st FOLLOW-UP VL TEST TAKEN	DATE RESULTS RECEIVED BY FACILITY	RESULT OF 1st FOLLOW-UP VL TEST (mL/copies)	DATE CLIENT RECEIVED REPEAT VL RESULT	MDT CASE REVIEW DATE	OUTCOME: ① SWITCHED REGIMEN ② REMAINED ON CURRENT REGIMEN ③ OTHER (E.G., TRANSFERRED OUT, DECEASED, REFERRED)	ART REGIMEN, IF SWITCHED	OUTCOME DATE	DUE DATE FOR FOLLOW-UP VL TEST DATE POST ART SWITCH	DATE OF FOLLOW-UP VL TEST TAKEN POST ART SWITCH	FOLLOW-UP VL RESULTS (COPIES/mL) POST ART SWITCH	COMMENTS
1.													
2.													
3.													
4.													
5.													
6.													
7.													

APPENDIX 4: EXAMPLE TEMPLATE FOR NATIONAL VIRAL LOAD M&E PLAN

Key sections that should be included in National Viral Load M&E Plans include:

Program Monitoring:
- Main Stakeholders
- Indicators that include definitions, disaggregations, data sources, frequency of reporting
  - Baseline Data and Targets to be Achieved with timeframe
  - Responsible Parties
- Data Systems and Management
- Data Quality Assessments
- Data Analysis
- Data Use
- Estimated Budget to conduct program monitoring

Evaluation:
- Purpose of the evaluation
- Evaluation Question
- Type of Evaluation
- Individuals and roles in evaluation team
- Users of the evaluation findings (i.e. stakeholders)
- Timeline
- Budget

It is recommended that country teams clearly develop two parts of an M&E plan: a performance monitoring plan and an evaluation plan. The following is an example of a template that can be used or adapted for an M&E Plan.

PART 1: PERFORMANCE MONITORING PLAN

Monitoring Question	Performance Measure & Target	Data Source	Frequency of Collection and Reporting	Responsibility
What is the the monitoring question? (See Appendix 5 for several monitoring questions) For example, what are outcomes of patients who received a VL test?	What performance measure (i.e. indicator) will be used? Specify disaggregations (e.g. <1 Male, <1 Female etc.) Define the target, as needed. ? For example, X individuals on ART will receive a VL test in Year 1.	Where will the data be obtained? For example, the LIMS, ART Registers, Patient Charts, VL Testing Registers/Logbooks etc.	When will the data be gathered and reviewed? For example, data will be recorded during VL sample collection from a patient and reported to MOH monthly.	Who will capture the data? For example, data will be captured on the VL Lab Requisition form by site staff. Data from the form and results will be entered into LIMS by lab staff. (Site Staff and Central Lab Staff)

Data Systems and Management

Specify how data will be managed. For example, briefly describe how data will be entered from sites and labs into the Lab Information System (LIS) and managed in the LIS for analysis and reporting.

Data Analysis and Quality

Briefly describe data analysis and data quality assurance plans for VL data. For example, specify how data will be analyzed at the site, district, and national level and by subpopulations (e.g., pregnant women, breastfeeding women, age/sex disaggregations etc.). Data quality assurance plans can include description of checks to compare data between unlinked systems (e.g. LIS, DHIS) and/or comparing data on sites to LIS and/or DHIS.

Data Use and Results Dissemination

Specify how data will be used. For example, describe how data will be reviewed monthly by districts to assess site performance, and district offices will follow-up with sites quarterly to present data and address gaps, underperformance, and other quality issues. Describe how there may be monthly meetings by multiple stakeholders from facilities, labs, districts etc. to review key data.

PART 2: EVALUATION PLAN

Evaluation Plan Narrative

Stakeholders involved in the evaluation: List stakeholders involved in the evaluation.

Purpose of the evaluation: List the purpose of the evaluation.

Program goals and objectives: List the program goal(s) and objectives to be addressed through the evaluation.
- Goal:
- Objectives:

Program Logic Model: Attach logic model (See Appendix 1 for an example of a VL specific logic model)
Individuals and roles in evaluation team: List individuals and roles on the evaluation team.

Users of the evaluation findings: List the users and uses of the evaluation findings.

Timeline: Attach the timeline for completing the evaluation.

Budget: Attach the budget for completing the evaluation.

Evaluation Plan Matrix

Evaluation Question(s)	Type of Evaluation	Variables/ Indicators	Data Source	Data Collection Method	Dissemination and Utilization
What do we need to know/ evaluate (fidelity, effectiveness) about the program?	What type of evaluation is it? Process? Outcome? Both?	What specific variables/ indicators are needed to answer your evaluation question?	What will the data source be for the variables/ indicators?	How will the data be gathered/ collected? Will it be through qualitative, quantitative or mixed methods? Will interviews, document reviews, and/or review of program data occur?	What dissemination and utilization strategies will be used to share evaluation findings and how will they be used by stakeholders for program improvement? Make sure to include where evaluation findings will be publically available (for PEPFAR supported evaluations)

Additional Resource to assist with development of a comprehensive evaluation plan and evaluation:

Salabarría-Peña, Y, Apt, B.S., Walsh, C.M. *Practical Use of Program Evaluation among Sexually Transmitted Disease (STD) Programs*, Atlanta (GA): Centers for Disease Control and Prevention; 2007. Available at: http://www.cdc.gov/std/program/pupestd.htm

PEPFAR Evaluation Standards of Practice (ESoP) v2 (September 2015). Available at: http://www.pepfar.gov/documents/organization/247074.pdf

APPENDIX 5: CORE PROGRAM INDICATORS FOR VIRAL LOAD TESTING SCALE-UP AND IMPLEMENTATION

Country programs should select relevant and helpful indicators for their programs from Appendix 5 (in addition to their own indicators, as applicable); programs are not required or expected to monitor all indicators below. Furthermore, programs should edit/adapt indicators suggested by this framework for their settings (indicator guidance source "Considerations for Developing a Monitoring and Evaluation Framework for VL Testing.")

Please note that PEPFAR Monitoring, Evaluation, and Reporting (MER) indicators are from MER 2.0, which went into effect in October 1 2016 and are reported annually, per current guidance. WHO indicators reflected are from the WHO Consolidated SI Guidelines and can be found at: http://apps.who.int/iris/bitstream/10665/164716/1/9789241508759_eng.pdf?ua=1&ua=1

It is important to specify the timeframe for each indicator when reporting results (e.g. 30,000 VL tests were received by regional labs for processing between January and March 2016)

APPENDIX 5: System and Process Indicators for Monitoring VL Scale-Up and Implementation

Monitoring Question	Indicator	Numerator/ Denominator	Disaggregation	Data Source Considerations	Program Relevance/Importance	Indicator Guidance Source
What is the access/ coverage of VL samples submitted by ART sites to the lab/ specimen network?	**Percentage of unique VL tests submitted by sites to the lab/specimen transport network**	**N:** # of unique VL tests submitted by sites to the lab/specimen transport network **D:** # of PLHIV on ART	• Age • Sex • Pregnant • Breastfeeding Type of VL sample: • DBS • Plasma	VL Sample Daily Log (retained at site where sample was collected)	This indicator allows programs to track progress in scaling up VL testing coverage at the site-level and above. This indicator tracks data from sites and sub-populations (e.g., adults, adolescents, children, pregnant, breastfeeding). This data will show if the number of samples submitted is low in proportion to the number of patients on ART, or the number of VL tests expected per reporting period. Sites should explore reasons for the low proportion of samples collected. While it is challenging to track samples for unique individuals, it is important that both the numerator and denominator track this data because it is most accurate for programs to use for monitoring scale-up of coverage and forecasting commodities. This can be examined during service and data quality assessments and/or during routine site visits until systems may be able to routinely collect and track.	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing
What is the volume of VL samples received by each VL testing lab?	**Number of VL samples received by lab from sites**	Total # of VL samples received by lab	Lab level • Regional • Central Site name Site level (e.g. Hospital, Clinic, etc.) SNU/Geographic Area Type of VL sample: • DBS • Plasma Reason for VL Test: • Routine VL • Targeted VL (i.e. Suspected Treatment Failure) • Follow-up VL (after a previous VL≥1000 copies/ml) • Other Demographic: • Age/Sex • Pregnant • Breastfeeding	• VL requisition form completed at ART sites • LIMS	This indicator assesses the total number of tests, type of sample and reason for VL test of samples received by labs for processing. It may inform management of commodities, and should be monitored more frequently if it helps with forecasting.	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing

APPENDIX 5: System and Process Indicators for Monitoring VL Scale-Up and Implementation (continued)

Monitoring Question	Indicator	Numerator/ Denominator	Disaggregation	Data Source Considerations	Program Relevance/Importance	Indicator Guidance Source
What proportion of VL samples is rejected for processing by each lab or hub?	**Percentage of VL tests rejected by each lab**	**N:** # VL samples rejected at each lab **D:** # VL samples received at each lab	Lab level • Regional • Central Site name SNU/Geographic Area Type of VL sample: • DBS • Plasma Reason for VL Test: • Routine VL • Targeted VL (i.e. Suspected Treatment Failure) • Follow-up VL (after a previous VL≥1000 copies/ml) • Other Rejection reason: • Incomplete Form • Poor Sample Quality (disaggregated DBS or Plasma sample) Demographic: • Age • Sex • Pregnant • Breastfeeding	LIMS	This indicator will account for tests collected and received that were rejected at the hub or lab and not processed and reasons for rejection. It will help inform the expected number of VL test results to be returned to sites and target sites that need refresher training on specimen collection.	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing
What is the proportion of VL test results returned to ART sites?	**Percentage of VL test results received at sites within one month of sample taken**	**N:** # of VL test results received at site within one month of sample taken **D:** # of VL samples that were sent to lab for testing in past month	Site name Site level (e.g. Hospital, Clinic, etc.) SNU/Geographic Area Type of VL sample: • DBS • Plasma	Patient Charts, ART and/ or VL Testing Registers at sites VL Sample Daily Log at sites	This indicator will track the proportion of VL results that were returned to sites within one month of sample taken. This will allow programs to track the receipt of test results at sites. This can be examined during service and data quality assessments and/or during routine site visits. Laboratory equipment and maintenance should be monitored closely, as this will impact processing and return of VL results. For example, it is important for laboratories to document the duration of any breakdown in VL instruments, as well as the reasons for the breakdown(s).	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing

APPENDIX 5: System and Process Indicators for Monitoring VL Scale-Up and Implementation (continued)

Monitoring Question	Indicator	Numerator/ Denominator	Disaggregation	Data Source Considerations	Program Relevance/Importance	Indicator Guidance Source
What proportion of VL test results returned to ART sites were recorded in patient charts and/ or ART registers?	**Percentage of PLHIV on ART with a VL result documented in the medical record within the past 12 months**	**N:** # of adult and pediatric ART patients with a viral load result documented in the patient medical record within the past 12 months **D:** # of VL test results received at site		ART and/ or VL Testing Registers at sites VL Sample Daily Log at sites	This indicator will track the proportion of VL results that were received at sites and documented in patient records and/or ART registers on site. One of the common challenges is that results that are returned are often not documented or acted upon at sites. This can be examined during service and data quality assessments and/or during routine site visits since these data will be hard to routinely collect.	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing
What proportion of lab staff dedicated to VL testing has been appropriately trained to process VL samples?	**Percentage of lab staff dedicated to VL testing that has been trained on SOPs for VL testing**	**N:** # of lab staff that are dedicated to VL testing that have been trained on SOPs for VL testing **D:** # of lab staff eligible for training in VL SOPs and VL algorithms	Training on: • DBS • Plasma Lab level: • Site • Regional • Central SNU/Geographic Area	MOH HR systems PEPFAR Implementing Partner HR Systems	This indicator will track the proportion of lab staff performing VL tests who have been properly trained on SOPs for VL testing. Since high staff turnover is a common challenge, this is an important quality indicator that can inform the need for ongoing, frequent staff trainings. This can be examined during service and data quality assessments and/or during routine supportive supervision site visits.	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing
What proportion of clinical staff responsible for ordering VL tests has been appropriately trained to order and interpret VL test results?	**Percentage of clinical staff responsible for VL testing that has been trained on SOPs for VL testing**	**N:** # of clinical staff that have been trained on SOPs for VL testing **D:** # of clinical staff eligible for training on VL SOPs and VL algorithms	Staff cadre: • Physician • Nurse • Clinical officer Site level (e.g. Hospital, Clinical etc.) SNU/Geographic Area	MOH HR systems PEPFAR Implementing Partner HR Systems	This indicator will track the proportion of clinical staff who have been properly trained on SOPs for VL testing and that are performing VL tests. Since high staff turnover is a common challenge, this is an important quality indicator that can inform the need for ongoing, frequent staff trainings. This can be examined during service and data quality assessments and/or during routine supportive supervision site visits.	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing

APPENDIX 5: Health Outcome Indicators for Monitoring VL Scale-Up and Implementation

Monitoring Question	Indicator	Numerator/ Denominator	Disaggregation	Data Source and Considerations	Program Relevance/Importance	Indicator Guidance Source
What proportion of ART patients received a VL test at 6 months after ART initiation and were virally suppressed?	**Percentage of people on ART and who had VL monitored at 6 months [WHO: VLS.6]**	**N:** # of PLHIV and on ART with at least one VL test result in their medical record within the first 6 months after ART initiation **D:** # of PLHIV and on ART for at least 6 months	Demographic: • Age • Sex • Pregnant • Breastfeeding Of those tested, # that were virally suppressed	Program records, e.g. ART and/or VL testing registers, cohort reporting forms, patient medical records, electronic medical record (EMR). LIMS (If treatment information and unique patient identifier is available on VL test requisition form and entered into LIMS) This data is based on a cohort of patients alive and on ART who are virally suppressed 6 months following their initiation on treatment. De-duplicate records to avoid double-counting when calculating the numerator. Denominator should exclude patients who have died, transferred to another clinic or been classified as lost to follow-up.	This indicator, WHO VLS.6, tracks coverage and outcomes of early VL testing of patients on ART at 6 months. This indicator assesses the extent to which VL is available in the country. By 6 months after ART initiation, all patients on ART should have received at least one VL test. This indicator also monitors VL suppression of patients 6 months after initiation on treatment. VL suppression is a disaggregation of WHO VLS.6. This may be examined during service quality assessments or site visits, if not collected routinely.	WHO Consolidated Strategic Information Guidelines for the HIV Sector
What proportion of ART patients is virally suppressed at 12 months after ART initiation?	**Percentage of people on ART tested for viral load (VL) with VL level <1,000 copies at 12 months after ART initiation [WHO: VLS.1]**	**N:** # of PLHIV on ART with VL<1000 copies/ml at 12 months after ART initiation **D:** # of PLHIV and on ART with VL test result available at 12 months	Demographic: • Age • Sex • Pregnant • Breastfeeding	Program records, e.g. ART and/or VL testing registers, cohort reporting forms, patient medical records, EMR. LIMS (If treatment information and unique patient identifier is available on VL test requisition form and entered into LIMS) This data is based on a cohort of patients alive and on ART who are virally suppressed 12 months following their initiation on treatment.	This indicator will allow programs to monitor VL suppression of patients 12 months after initiation on treatment and also to estimate the percent of PEPFAR supported PLHIV who are virally suppressed.	WHO Consolidated Strategic Information Guidelines for the HIV Sector

APPENDIX 5: Health Outcome Indicators for Monitoring VL Scale-Up and Implementation (continued)

Monitoring Question	Indicator	Numerator/ Denominator	Disaggregation	Data Source and Considerations	Program Relevance/Importance	Indicator Guidance Source
What is the coverage of VL testing?	**Percentage of ART patients receiving a VL test in the last 12 months**	**N:** # of PLHIV and on ART with at least one VL test result in their medical record in the last 12 months **D:** # of PLHIV and on ART for at least 12 months	Demographic: • Age • Sex • Pregnant • Breastfeeding	Program records, e.g. ART and/or VL testing registers, cohort reporting forms, patient medical records, EMR. LIMS (If treatment information and unique patient identifier is available on VL test requisition form and entered into LIMS) De-duplicate records to avoid double-counting when calculating the numerator. Denominator should exclude patients who have died, transferred to another clinic or been classified as lost to follow-up.	This indicator is a cross-sectional measure of the proportion of ART patients who received at least one VL test in the last 12 months.	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing
What proportion of ART patients who received a VL test in the last 12 months is virally suppressed?	**% of ART patients with a viral load result documented in the medical record and/ or laboratory information systems (LIS) within the past 12 months with a suppressed viral load (<1000 copies/ml) [PEPFAR MER: TX_ PVLS]**	**N:** # of adult and pediatric patients on ART with suppressed viral load results (<1,000 copies/ml) documented in medical records and /or laboratory records within the past 12 months **D:** Number of adult and pediatric ART patients with a viral load result documented in medical records and / or laboratory records in the past 12 months.	Age/Sex/Indication: • <1 M/F Routine, 1-9 M/F Routine, 10-14 M/F Routine, 15-19 M/F Routine, 20-24 M/F Routine, 25-29 M/F Routine, 30-34 M/F Routine, 35-39 M/F Routine, 40-44 M/F Routine, 45-49 M/F Routine,, 50+ M/F Routine • <1 M/F Targeted, 1-9 M/F Targeted, 10-14 M/F Targeted, 15-19 M/F Targeted, 20-24 M/F Targeted, 25-29 M/F Targeted, 30-34 M/F Targeted, 35-39 M/F Targeted, 40-44 M/F Targeted, 45-49 M/F Targeted,50+ M/F Targeted • Pregnant Routine; Breastfeeding Routine; Pregnant Targeted; Breastfeeding Targeted	Program records, e.g. ART and/or VL testing registers, electronic patient medical records, EMR. LIMS (If treatment information and unique patient identifier is available on VL test requisition form and entered into LIMS) MER 2.0 revised Indicator combines TX_VIRAL and TX_UNDETECT. The indicator now requires the suppressed viral load result to be documented in the clinic patient record and only use the laboratory system for results if it can be linked back to the individual patient file. This indicator is required for PEPFAR annual reporting starting in FY17 Routine refers to VL tests obtained at standard intervals following ART initiation to monitor virologic response to ART. Targeted refers to VL tests obtained based on a specific clinical indication (e.g. concern about disease progression or failure to respond to ART).	This indicator is a cross-sectional measure of proportion of documented viral load tests from adult and pediatric ART patients with a suppressed result (<1,000 copies/ml), allowing ART programs to monitor individual and overall programmatic response to ART as measured by virologic suppression.	PEPFAR Monitoring, Evaluation, and Reporting 2.0 Guidance (PEPFAR MER 2.0)

APPENDIX 5: Health Outcome Indicators for Monitoring VL Scale-Up and Implementation (continued)

Monitoring Question	Indicator	Numerator/ Denominator	Disaggregation	Data Source and Considerations	Program Relevance/Importance	Indicator Guidance Source
What proportion of PLHIV with suppressed VL (<1000 copies/ml) has been referred to a less intense model of care/ differentiated service delivery in the last 12 months?	**Percentage of PLHIV with suppressed VL (<1000 copies/ ml) who have been referred to a less intense model of care/ differentiated service delivery in the last 12 months**	**N:** # of adult and pediatric patients on ART with suppressed viral load results (<1,000 copies/ml) referred to less intense model of care **D:** # of adult and pediatric patients on ART with suppressed viral load results (<1,000 copies/ml) within the past 12 months	Demographic: • Age • Sex • Pregnancy • Breastfeeding • Key Population DSD Model	Program records, e.g. ART registers, patient medical records, EMR.	This indicator measures the referral of stable clients to a less intense model of care or differentiated service delivery (DSD) model. A "stable patient" is determined by receiving a suppressed viral load result (<1,000 copies/ml) after at least 12 months of being on ART. Monitoring the referral of stable patients to DSD models will help gauge how well sites are implementing DSD protocols for stable patients. This may be examined during service quality assessments or site visits, if not collected routinely. However, it is important for country programs to closely monitor adherence and implementation of guidelines for differentiated service delivery.	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing
What proportion of ART patients with a VL ≥ 1000 copies/ mL received enhanced adherence counseling (EAC)?	**Percentage of people on ART with a VL ≥ 1000 copies/mL who received enhanced adherence counselling (EAC) and support**	**N:** # of PLHIV on ART with a VL ≥1000 during a 12 month period who received enhanced adherence counselling (EAC) and support **D:** # of PLHIV on ART who received VL≥1000 copies/ml and were due for a follow-up VL test within the reporting period	Demographic: • Age • Sex • Pregnancy • Breastfeeding EAC Completion: • EAC#1 • EAC#2 • EAC#3	High VL and/or Enhanced Adherence Counseling(EAC) registers/logbooks/ longitudinal tools at sites LIMS (if unique patient identifier is implemented and utilized) Electronic Medical Records, if available at sites and can track EAC visits The denominator should represent the # of patients with VL≥1000 copies/ml before they initiated any EAC sessions, and the numerator should represent the # of patients with VL≥1000 copies/ ml who received any EAC. Longitudinal tracking of patients who are not virally suppressed identifies which patients received interventions and the outcomes of those interventions. The disaggregation captures how many EAC sessions the patient completed.	This indicator measures the number of PLHIV on ART with VL≥1000 copies/ ml that have partially or fully received enhanced adherence counseling (EAC). Poor adherence is often a contributing factor to virologic failure in ART patients. **Country programs should adapt this indicator to reflect their guidelines for EAC for patients with non-suppressed VL.**	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing

APPENDIX 5: Health Outcome Indicators for Monitoring VL Scale-Up and Implementation (continued)

Monitoring Question	Indicator	Numerator/ Denominator	Disaggregation	Data Source and Considerations	Program Relevance/Importance	Indicator Guidance Source
What proportion of ART patients with a VL ≥ 1000 copies/ mL received a follow-up VL within 6 months?	**Percentage of people on ART with VL ≥1,000 mL who received a follow-up VL test within 6 months after enhanced adherence counseling (or according to national guidelines)**	**N:** # of PLHIV on ART who received a follow-up VL test within 6 months after a VL≥1000 copies/ml **D:** # of PLHIV on ART with VL≥1000 copies/ml during the reporting period	Demographic: • Age • Sex • Pregnancy • Breastfeeding ART Treatment Regimen: • 1st Line • 2nd Line • 3rd Line	High VL and/or Enhanced Adherence Counseling (EAC) registers/logbooks/ longitudinal tools at sites LIMS (if unique patient identifier is implemented and utilized) Electronic Medical Records, if available at sites This indicator measures the compliance with re-testing patients with VL≥1000 copies/mL. This is ideally a cohort-based indicator that measures the proportion of patients who were due to and actually received a follow-up test in the reporting period. The result of the follow-up VL test can be included as a disaggregation (i.e. # of individuals with VL result <1000 copies/ mL and # of individuals with VL result ≥1000 copies/mL) under this indicator if programs find it easier to track as a disaggregation and can ensure data quality. If reported this way, VL results should be collected and reported by demographic disaggregations.	This is a quality control indicator to measure the follow-up of patients with non-suppressed VL who should have received a follow-up VL test. Generally, patients are re-tested within 3–6 months of a VL≥1000 copies/ml and after they have received some EAC. ART regimen should be noted so that programs can be clear which ART regimen the non-suppressed patient is currently on.	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing

APPENDIX 5: Health Outcome Indicators for Monitoring VL Scale-Up and Implementation (continued)

Monitoring Question	Indicator	Numerator/ Denominator	Disaggregation	Data Source and Considerations	Program Relevance/Importance	Indicator Guidance Source
What proportion of ART patients with VL≥1000 copies/mL during the reporting period had a follow-up VL that showed virologic suppression <1000 copies/mL?	**Percentage of people on ART with VL≥1000 who then suppressed to VL <1000 copies/ml on follow-up testing**	**N:** # of PLHIV on ART with follow-up VL <1000 copies/ml **D:** # of PLHIV on ART with a VL ≥1000 copies/ml during the reporting period and received a follow-up VL test within 6 months	VL Test Result by Demographic: • Age • Sex • Pregnancy • Breastfeeding ART Treatment Regimen: • 1st Line • 2nd Line • 3rd Line EAC Completion: • EAC#1 • EAC#2 • EAC#3	High VL and/Enhanced Adherence Counseling (EAC) registers/logbooks/ longitudinal tools at sites LIMS (if unique patient identifier is implemented and utilized) Electronic Medical Records, if available at sites The inclusion of EAC Completion as a disaggregation will depend on which indicators are selected and how databases are structured to reconstruct the cascade for VL cascade for patients whose initial VL test result VL≥1000 copies/mL (see Figure 6 in the VL M&E Framework). This indicator can be amended and integrated as a disaggregation under the indicator "Percentage of people on ART with a VL ≥ 1000 copies/mL during a 12-month period who received a follow-up VL test within 6 months." Please see "Data Source and Considerations" under the indicator for more information.	This indicator measures the proportion of patients who suppress after a VL test result of ≥1000 copies/ml. This helps measure the potential impact of intervention after a non-suppressed viral load. This also informs the prevalence of HIVDR.	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing
What proportion of ART patients with repeat VL≥1000 copies/ml are switched to second or third line ART regimens?	**Percentage of PLHIV on ART with two documented VL test results ≥ 1,000 copies/ mL switched to 2nd or 3rd line ART regimens**	N: # of PLHIV on ART with two consecutive VL test results ≥ 1,000 copies/ mL switched to 2nd or 3rd line ART regimens D: # of PLHIV on ART with two consecutive VL test results ≥ 1,000 copies/ mL during the reporting period	Demographic: • Age • Sex • Pregnancy • Breastfeeding ART Treatment Regimen: • 1st Line • 2nd Line • 3rd Line EAC Completion: • Partial Completion of EAC • Full completion of EAC	High VL and/or Enhanced Adherence Counseling (EAC) registers/logbooks/ longitudinal tools at sites LIMS (if unique patient identifier is implemented and utilized) Electronic Medical Records, if available at sites	This indicator measures clinical follow-up and management of VF. This may help inform forecasting and budgeting for procurement of second and third-line ART regimens.	Considerations for Developing a Monitoring and Evaluation Framework for VL Testing

APPENDIX 5: Health Outcome Indicators for Monitoring VL Scale-Up and Implementation (continued)

Monitoring Question	Indicator	Numerator/ Denominator	Disaggregation	Data Source and Considerations	Program Relevance/Importance	Indicator Guidance Source
What proportion of ART patients are virologically suppressed?	**Percentage of PLHIV and on ART who are virologically suppressed [WHO VLS.3]**	**N:** # of PLHIV on ART who have a suppressed VL (<1000 copies/mL) **D: Population-level denominator:** # of PLHIV who have been on ART for at least 6 months **D: Program-based denominator:** # of PLHIV on ART who have a VL measurement in the past 12 months	Demographic: • Age • Sex • Pregnancy • Breastfeeding	ART registers and cross-sectional reports, patient records, EMR. LIMS Population-based survey, such as the HIA surveys, that collects data on ART coverage and viral suppression.	With the programme-based denominator, measures virologic suppression achieved among all those currently on treatment who received a VL measurement, regardless of when they started ART. Corresponds to the third 90 of the 90–90–90 target (90% of those on ART have suppressed viral loads).	WHO Consolidated Strategic Information Guidelines for the HIV Sector

APPENDIX 6: PEPFAR EVALUATION STANDARDS OF PRACTICE

1. ENGAGE STAKEHOLDERS
2. CLEARLY STATE EVALUATION QUESTIONS, PURPOSE, AND OBJECTIVES
3. USE APPROPRIATE EVALUATION DESIGN, METHODS, AND ANALYTICAL TECHNIQUES
4. ADDRESS ETHICAL CONSIDERATIONS AND ASSURANCES
5. IDENTIFY RESOURCES AND ARTICULATE BUDGET
6. CONSTRUCT DATA COLLECTION AND MANAGEMENT PLANS
7. ENSURE APPROPRIATE EVALUATOR QUALIFICATIONS AND EVALUATION INDEPENDENCE
8. MONITOR THE PLANNING AND IMPLEMENTATION OF AN EVALUATION
9. PRODUCE QUALITY EVALUATION REPORTS
10. DISSEMINATE RESULTS
11. USE FINDINGS FOR PROGRAM IMPROVEMENT

PEPFAR Evaluation Standards of Practice (ESoP) v2 (September 2015). Available at: http://www.pepfar.gov/documents/organization/247074.pdf

APPENDIX 7: DIFFERENCES BETWEEN TYPES OF EVALUATION AND OPERATIONS RESEARCH[1]

Types	Description	Examples of Questions	Use of Results
Process Evaluation	Determines whether the program is reaching the right target populations, how a program is being implemented, and what factors help or hinder program implementation to inform program planning and development and take corrective action	• Were target populations reached? Why not? • Was the program implemented as planned? Why? What worked? What did not work? • What were the kinds of problems encountered in delivering the program – were there enough resources from the beginning to do it well? Was it well managed? • Were staff trained or educated to the right level of the program design? Is there skill at facilitating the program processes from beginning to end? Was there adequate support to the program?	• Decision making • Resource allocation • Program improvement • Understand how program impact and outcome were achieved (i.e. program implementation) and to inform program replication
Outcome Evaluation	Determines if and by how much intended short-term, intermediate and long-term program effects have been achieved in the target populations or organizations after implementing a program or intervention. Short-term outcomes are the initial expected changes (e.g., knowledge, awareness, attitudes, skills). Intermediate outcomes are those interim changes (e.g., behavior, policy, norms, coverage, quality) that provide a sense of progress toward reaching long-term outcomes. Long-term outcomes or impact includes changes in the ultimate program goals (e.g., mortality, morbidity)	• Were the intended effects (outcomes) achieved? What contributed to that? • Was the program more successful with certain groups of people than with others? • What aspects of the program did participants find gave the greatest benefit? • Did the implementation of the intervention result in changes in knowledge, attitudes, and skills among the members of the target population? • Did the program have any unintended (beneficial or adverse) effects on the target population(s)? • How has quality of services changed as a result of the intervention?	• Decision making • Resource allocation • Program improvement • Determine if program effectiveness has been demonstrated and if program objectives were met
Impact Evaluation	Measures changes attributable to a defined intervention by comparing actual impact to what would have happened in the absence of the intervention (the counterfactual scenario). IEs are based on models of cause and effect and require a rigorously defined counterfactual to control for factors other than the intervention that might account for the observed change.[2]	• What could have happened in the absence of the program/ intervention?	• Decision making • Resource allocation • Provides a comparison between what actually happened and what would have happened in the absence of the intervention
Economic Evaluation[3]	Systematic way to identify, measure, value, and compare the costs and consequences of various programs, policies, or interventions. Assess the cost factors related to different interventions, enabling comparisons to be made among potential strategies	• How do the costs compare across the interventions or settings? • Which model is the most cost-effective?	• Decision making • Resource allocation • Provides a review of program effectiveness with economic resources (e.g. cost and benefit) to inform budgetary planning

[1] Adapted from: Salabarría-Peña, Y. (2008). Draft: Difference between Monitoring, Program Evaluation, Operational Research, Health Services Research and Public Health Evaluations. Unpublished paper.

[2] PEPFAR 2014 Country Operational Guidance and 2012 supplemental guidance on Implementation Science/Impact Evaluation.

[3] Dunet, D. (2012). CDC Coffee Break: Introduction to Economic Evaluation [PowerPoint Slides]. Retrieved from: http://www.cdc.gov/dhdsp/pubs/docs/cb_january_10_2012.pdf.

Appendix 7 (continued)

Types	Description	Examples of Questions	Use of Results
Operations Research	Operational research aims to develop solutions to current operational problems of specific health programs or specific service delivery components of the health system, e.g., a health district or a hospital. This research is characterized by a strong problem-solving focus and an urgency to find solutions. Its demand-driven nature and close association with health care delivery and routine health care operations ensure operational relevance of the research activities and rapid uptake and local utilization of research findings.[4]	• How to best generalize interventions that have shown to be effective in a small scale for widespread and sustainable use? • How to best implement existing or new program strategies? [Note: Similar to Process Evaluation]	• Improve service delivery or to strengthen other aspects of programs • Focus attention and resources on problem solving • Integrate and disseminate solutions into programs

[4] Remme JHF, Adam T, Becerra-Posada F, D'Arcangues C, Devlin M, et al. (2010) Defining Research to Improve Health Systems. PLoS Med 7(11): e1001000. doi:10.1371/journal.pmed.1001000.

Notes

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