TECHNICAL UPDATE

CONSIDERATIONS FOR

DEVELOPING A MONITORING AND EVALUATION FRAMEWORK FOR VIRAL LOAD TESTING

APRIL 2019

COLLECTING AND USING DATA FOR SCALE-UP AND OUTCOMES

World Health Organization

Considerations for developing a monitoring and evaluation framework for viral load testing

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DEVELOPING A MONITORING AND EVALUATION FRAMEWORK FOR VIRAL LOAD TESTING

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CONTENTS

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ABBREVIATIONS

DHIS2	District Health Information System
MER	PEPFAR Monitoring, Evaluation and Reporting
PEPFAR	United States President's Emergency Plan for AIDS Relief
UNAIDS	Joint United Nations Programme on HIV/AIDS

EXECUTIVE SUMMARY

The WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection recommend viral load as the preferred monitoring approach to detect and confirm the failure of antiretroviral therapy. As countries invest in scaling up of routine viral load testing, measuring the impact of and progress towards achieving the UNAIDS target that 90% of people receiving antiretroviral therapy have suppressed viral loads by 2020 (as part of the 90–90–90 targets) is critical. This publication presents key considerations and examples of tools (provided in the annexes) to assist countries in developing a national viral load monitoring and evaluation plan.

Section 1 describes the process of assessing monitoring and evaluation data systems and tools and understanding how data flow to and from facilities, sample transport networks and laboratories. Stakeholders from laboratories, HIV care and treatment and monitoring and evaluation need to review and update systems and tools to adequately capture and use data at the site and at the district and national levels of their programme. Section 2 outlines a set of indicators that monitoring and evaluation systems are encouraged to collect in order to measure key programme and patient outcomes along the viral load testing cascade.

Section 2 also includes a discussion on how to monitor people whose viral loads are not suppressed and suggests tools for longitudinally following cohorts of non-suppressed people. Annex 3 includes examples of data collection tools that country programmes can adapt for their setting, and Annex 5 includes a menu of possible indicators that can be integrated into an monitoring and evaluation framework or plan for viral load testing. Section 3 provides methods for evaluating viral load implementation plans and examples of evaluation questions.

To reach the third 90 of the 90–90–90 targets, country programmes must delve into their data and understand how they represent the quality of viral load testing services. These considerations hopefully provide practical tools and examples for how to measure and document outcomes as countries scale-up routine viral load monitoring. Careful planning and consideration of all areas covered in this publication will inform the development of a monitoring and evaluation system that accurately tracks and reports national rates of viral load coverage and suppression.

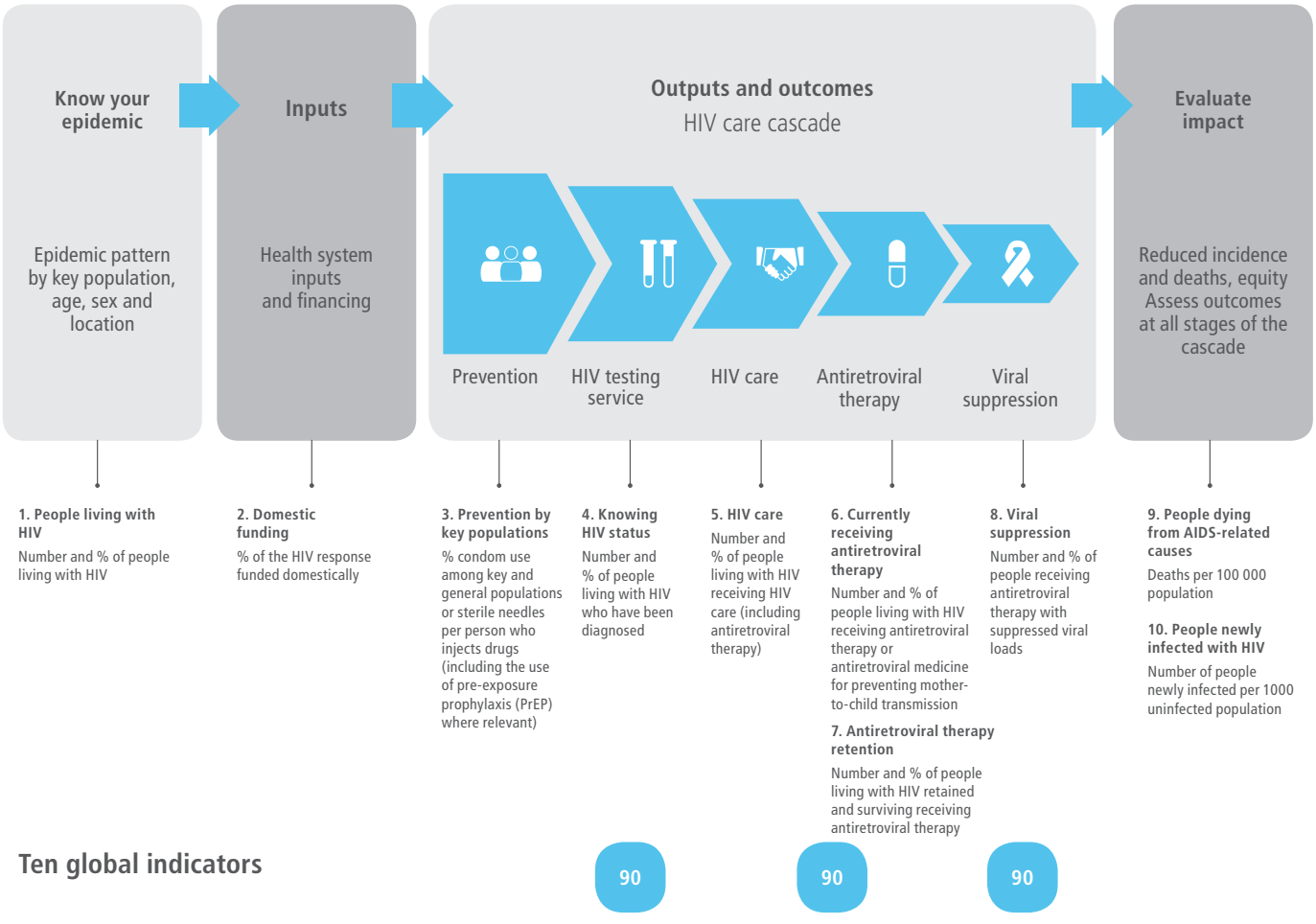
INTRODUCTION

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

Viral load testing encompasses more than conducting the test within the laboratory; it requires functioning sample referral networks, data systems, processes driven by health-care providers 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 suppression of viral loads among people living with HIV receiving antiretroviral therapy, monitoring and evaluation plans are needed to measure the success of programme implementation and clinical outcomes. Using routine viral load monitoring and evaluation data and systems for viral load testing requires coordination, collaboration and communication between (1) laboratory, clinical, and monitoring and evaluation staff, (2) data systems at facilities, laboratories and above-site levels and (3) data capture and monitoring and evaluation tools. Strong monitoring and evaluation plans also require clarity on data flow, data elements and indicators for viral load monitoring. Using viral load data is essential for patient-level and programme-level decision-making and should be emphasized in monitoring and evaluation plans.

WHO published the consolidated strategic information guidelines for HIV in the health sector in 2015 *(1)* and consolidated guidelines on person-centred HIV patient monitoring and case surveillance guidelines in 2017 *(2)*. These highlight the importance of monitoring the HIV cascade at the programme and individual levels to track

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 (1)*

progress in achieving the ambitious UNAIDS 90–90–90 targets: 90% of the people living with HIV know their HIV status, 90% of the people who know their HIV-positive status are receiving antiretroviral therapy and 90% of the people receiving antiretroviral therapy have suppressed viral loads. Fig. 1 illustrates the HIV cascade, the key cascade indicators and the UNAIDS 90–90–90 targets.

Although the WHO consolidated strategic information guidelines provide a hierarchy of indicators for a high-level view of the HIV response and further national indicators, a more detailed monitoring and evaluation approach is needed to measure the scaling up of viral load testing and its clinical impact in real-world settings. To measure progress towards achieving the third 90, indicators related to processes (such as transport of samples and results, turnaround time and sample testing), patient outcomes (such as suppressed viral loads and follow-up viral load testing after a high result) and quality (such as sample rejection) are required.

The main objective of this publication is to provide considerations for developing a framework for a national viral load monitoring and evaluation plan as one component of a national monitoring and evaluation plan for the HIV sector. The publication focuses on key considerations and tools to assist countries as they scale up routine viral load monitoring, including:

- assessing monitoring and evaluation systems for viral load testing and clinical outcomes, including examples of monitoring and evaluation tools for monitoring viral load implementation and outcomes that country teams can adapt;
- potential indicators for routine and enhanced monitoring to measure progress towards achieving the third 90;
- key monitoring and evaluation considerations for patients who do not have suppressed viral loads; and
- considerations for evaluating viral load implementation and outcomes.

1. ASSESSING AND STRENGTHENING VIRAL LOAD MONITORING AND EVALUATION SYSTEMS

Assessing the current data collection, reporting and management systems in place for implementing viral load testing is one of the first steps in ensuring that countries have robust systems for high-quality viral load testing data. This assessment of the monitoring and evaluation systems will provide a review of how systems collect and move data from sites and laboratories to manage patients and oversee programmes. Even countries that have more mature viral load testing programmes can benefit from comprehensive review of their monitoring and evaluation systems to ensure that monitoring and evaluation data for viral load testing and outcomes are being optimally collected, analysed and used to improve programmes. Ideally, the entire HIV monitoring and evaluation system or routine data systems, of which viral load is a part, will be comprehensively reviewed. This will minimize multiple, parallel reviews of systems. Given the complexities of monitoring viral load testing, conducting a broader, more comprehensive review of monitoring and evaluation systems may benefit a country programme. WHO's consolidated guidelines on person-centred HIV patient monitoring and case surveillance *(2)* provide more information and recommendations for conducting comprehensive reviews of systems and updating patient monitoring tools.

Creating and maintaining a monitoring and evaluation system to track the viral load testing cascade involves numerous stakeholders: laboratory staff, HIV care and treatment programme managers, health-care workers, supply chain management staff and strategic information and monitoring and evaluation specialists. All stakeholders should be engaged in the assessment, and programmes should work closely to ensure that data sources and tools are tailored for viral load monitoring and include relevant fields to record and report viral load testing data and clinical outcomes. Annex 1 includes a logic model for routine viral load testing that incorporates clinical guidelines, testing algorithms and standard operating procedures.

Annex 2 provides an assessment tool to assist in evaluating the readiness of monitoring and evaluation systems to monitor viral load testing; this can be part of a more comprehensive review of the monitoring and evaluation system. Annex 3 includes examples of monitoring and evaluation tools specific to capturing viral load data. If introducing new viral load monitoring and evaluation tools is not feasible, the required data variables should be integrated into existing monitoring and evaluation tools.

VIRAL LOAD TESTING CASCADES

Two key viral load testing cascades should guide assessment of monitoring and evaluation systems and tools for viral load:

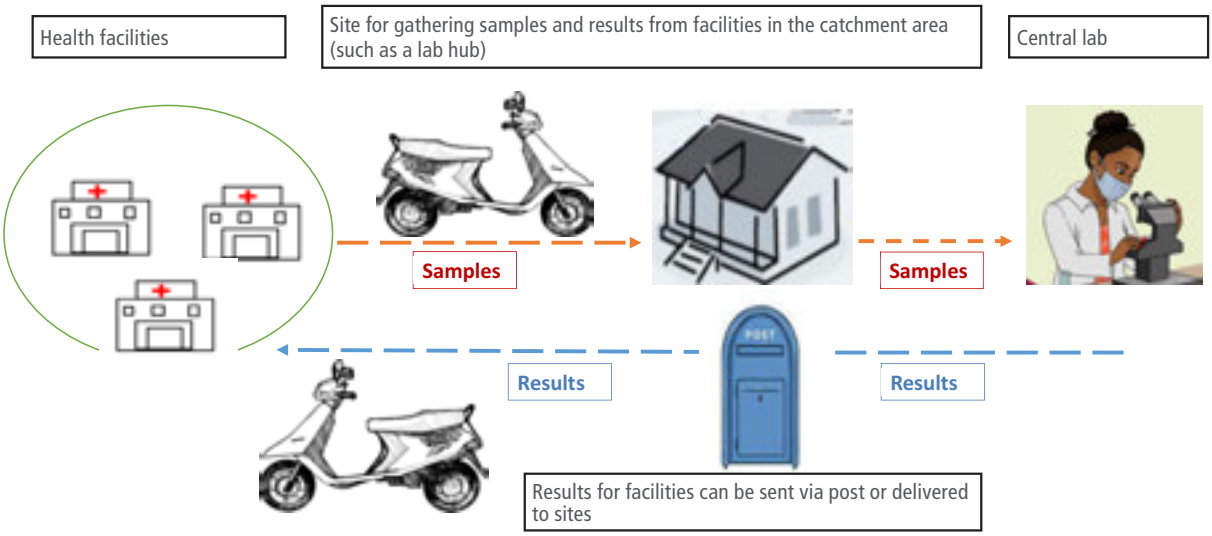
- coverage and outcomes of routine viral load testing, which tracks the number of people currently receiving antiretroviral therapy who received a viral load test, had a result documented in the medical record and had suppressed viral loads; and
- follow-up of people without suppressed viral loads, which tracks the number of people with a viral load result above the threshold (such as ≥1000 copies/mL), how many received enhanced adherence counselling and a follow-up viral load test, how many were suppressed on follow-up testing and whether the people who were not suppressed on follow-up had switched antiretroviral therapy regimen.

Understanding viral load testing cascades will help guide assessments of monitoring and evaluation systems, including reviewing, revising and developing new monitoring and evaluation tools for data capture to ensure that teams have the capacity to create viral load cascades at the site, subnational and national levels. Section 2 presents core indicators to consider for monitoring processes, quality and patient outcomes along both cascades. Routinely reviewing these data for completeness is also important to ensure both the coverage of viral load testing and quality of follow-up with patients. For example, reviewing the data from these cascades will highlight people who have not received a viral load test or who may not have a viral load 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 viral load data is one of the first steps in assessing a viral load monitoring and evaluation system. An effective viral load monitoring and evaluation system should have a clear map of how data flow from one source to another and how data are captured at each step. Most viral load testing rely on a specimen transport system that moves samples from facilities to more centralized

Fig. 2. Example of a map of a sample transport network and the return of results for viral load testing



molecular laboratories for viral load testing. The network for transporting sample and results is an especially complex system, and monitoring and evaluation tools are generally required at every step.

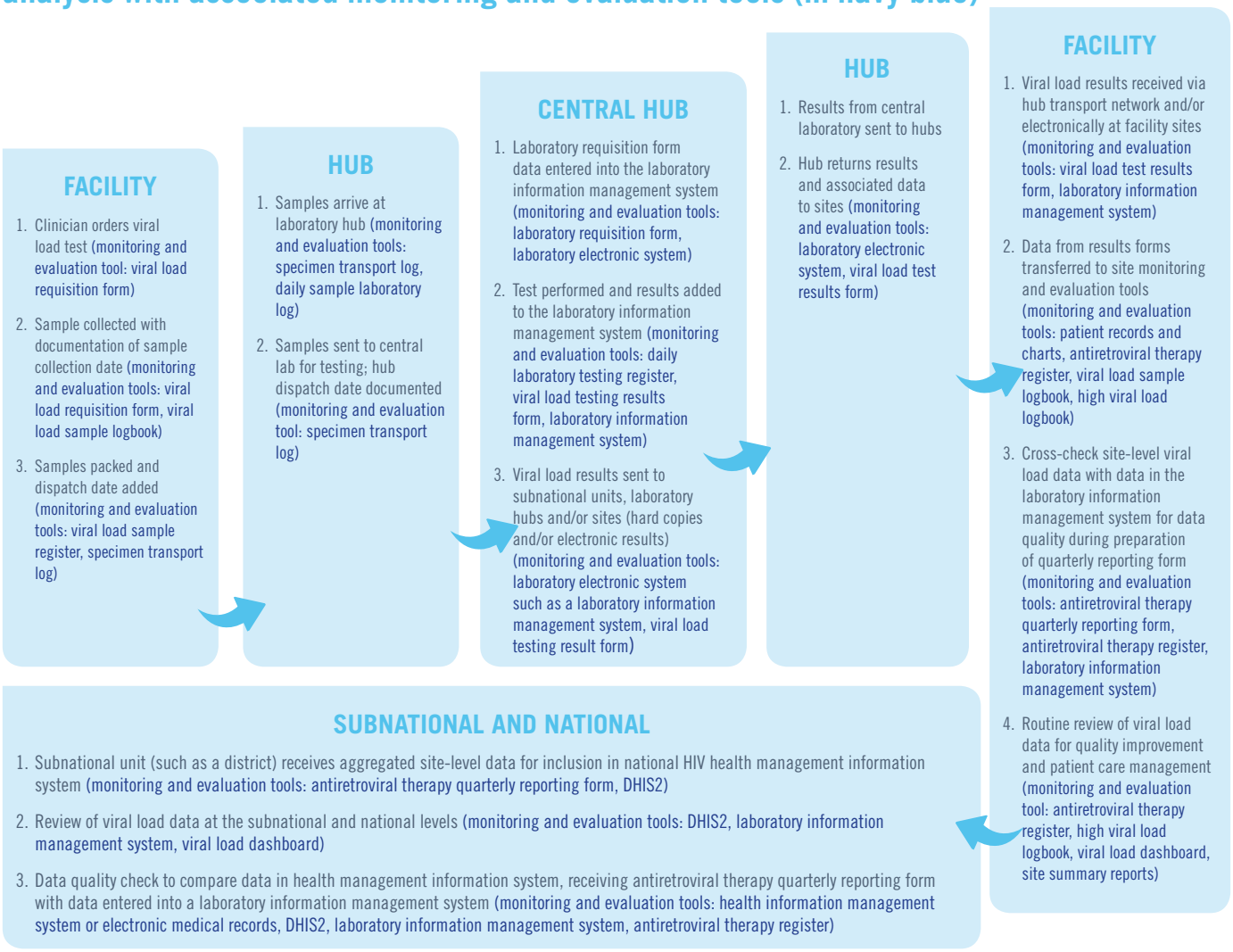
One successful sample transport model from Uganda involves a sample transport network in which motorbike riders collect samples from health facilities in a designated catchment area and deliver them to a laboratory hub; samples are then sent from the hubs to the central laboratory for viral load testing. Fig. 2 summarizes the flow of samples and results. The results can be returned to sites via post or motorbike riders. Programmes should continue to develop innovations to improve rapid and more direct return of results.

During the mapping exercise, programmes should also note the monitoring and evaluation tools used for recording data from collecting samples to returning results to aggregating site-level results. Fig. 3 is an example of a high-level process map that shows key viral load testing processes with the monitoring and evaluation tools used to capture key data at each step, from collecting viral load samples to returning results to reviewing and reporting viral load data. Country programmes can adapt Fig. 3 to reflect their own processes, systems and monitoring and evaluation tools.

Mapping out this process, including the main monitoring and evaluation tools being used to capture key data, clearly highlights where data should be captured as samples and results flow from the facility to the centralized or regional laboratories back to facilities. Working on the process map including the monitoring and evaluation tools may also help programmes in developing or refining standard operating procedures for viral load testing and viral load monitoring and evaluation. This will also stress the importance of activities that should occur at multiple levels. For example, data quality checks are key to reviewing the consistency of data between unlinked systems. Annex 3 provides examples of viral load monitoring and evaluation tools that capture data along the entire viral load testing cascade.

The considerations in this publication are based on the assumption that programmes are using a specimen transport network that moves samples from facilities to a centralized laboratory for viral load testing. As countries scale up viral load testing and/or new technologies (such as point-of-care viral load testing) become available, programmes may shift to decentralized models that may require modifying these considerations.

Fig. 3. Example of high-level standard operating procedures for data capture, flow and analysis with associated monitoring and evaluation tools (in navy blue)



UPDATING AND DEVELOPING MONITORING AND EVALUATION TOOLS FOR CAPTURING DATA RELATED TO VIRAL LOAD

Effective tracking of viral load testing and patient outcomes requires multiple monitoring and evaluation tools and systems from multiple locations (facilities, specimen transport networks and laboratories). Country programmes may have existing tools that may simply require some updating to effectively track viral load. It is essential that programmes understand how all the monitoring and evaluation tools and systems collect, link and report data related to viral load. Data sources and monitoring and evaluation systems that are needed to track viral load testing include:

- viral load test requisition forms;
- a viral load sample register or logbook;
- a viral load results form;
- high viral load registers or logbooks to follow up patients who do not have suppressed viral loads (≥1000 copies/mL);
- patient monitoring systems (electronic and/or paper): patient charts, antiretroviral therapy registers, antiretroviral therapy cards, anternatal care registers and postnatal registers;
- aggregate health information systems (such as District Health Information System 2 (DHIS2)); and
- laboratory information management systems and other systems at viral load testing laboratories and laboratory hubs.

During the assessment of viral load monitoring and evaluation, country programmes may need to update or develop new monitoring and evaluation tools to ensure that key variables are being collected.

Fig. 4 provides a list of variables that should be included in viral load laboratory requisition and viral load results

Fig. 4. Key variables to consider for laboratory requisition forms and other monitoring and editing 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 antiretroviral therapy, current regimen (first, second or third line)
- Previous exposure to antiretroviral drugs, such as for preventing mother-to-child transmission, post-exposure prophylaxis or pre-exposure prophylaxis
- Date antiretroviral therapy started (time receiving antiretroviral therapy)
- Reason for the test
- Date and time specimen collected
- Specimen type
- Adherence assessment
- WHO clinical staging and DC4 count

Testing requisition form (entered at the laboratory)

- Demographic information (patient identification number, specimen identification number, date of birth, current antiretroviral therapy 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 (3).*

forms. Some of these variables should also be integrated into other monitoring and evaluation tools such as patient cards or charts, antiretroviral therapy registers, high viral load registers and viral load sample logbooks. Note that all the variables (those entered at the clinic and at the laboratory) should be included in the laboratory information management system maintained at the laboratory and also reflected in monitoring and evaluation tools at the site.

Country programmes will probably need a specific monitoring and evaluation tool such as a register or logbook to track patients with viral load ≥1000 copies/mL (high viral load register or logbook). Although country programmes may understandably have concerns about adding tools to sites and increasing the burden on site staff, a tool for longitudinally tracking people with high viral load is essential for appropriate and timely clinical management. Further, using this tool should not be overly burdensome because only a small proportion of people probably have a viral load ≥1000 copies/mL and require tracking. Key variables to track in the high viral load register or logbook include:

- unique identifier, if available;
- antiretroviral therapy number;
- antiretroviral therapy start date;
- contact information;
- date and result of first high viral load test;
- dates for enhanced adherence counselling;
- date and result of follow-up viral load test; and
- outcome (switch in antiretroviral therapy regimen or remain on same antiretroviral therapy regimen).

Annex 3 provides an example of a high viral load register, and Section 3 discusses specific considerations for tracking people with viral load ≥1000 copies/mL.

KEY CHALLENGES IN VIRAL LOAD MONITORING AND EVALUATION TO CONSIDER IN ASSESSING MONITORING AND EVALUATION SYSTEMS

Several common monitoring and evaluation challenges should be considered and address in assessing monitoring and evaluation systems and developing monitoring and evaluation tools to monitor the implementation of viral load testing. The main challenges include:

- accessing and using viral load testing data for patient management from unlinked laboratory, facility and/or national aggregate reporting systems;
- tracking and reporting data on viral load tests for individual people because a unique identifier is lacking;
- tracking individuals over time, including those with viral load ≥1000 copies/mL;
- tracking viral load coverage and viral load suppression rates for individuals; and
- estimating the viral load testing needed.

Further, there may be a wide variety of facility patient management systems. This variability affects how and when results are transferred from viral load laboratory result forms to patient and site records. Country programmes 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 the numbers of individuals who received a viral load test and their results should be compared between site-level records and systems and laboratory management information systems to ensure that there are no major discrepancies. Different data sources (such as laboratory information management system, patient charts and registers) should be cross-checked for data quality and consistency. This highlights the importance of ensuring strong links between health management information systems at facilities and laboratory information management systems to track all outcomes for a patient for clinical management and aggregate data for reporting and programme oversight.

Although viral load reporting during scale-up may rely predominantly on laboratory information management system, WHO and other key stakeholders note that some viral load data reporting should come from sites providing patient care. This also stresses the need for site staff to adhere to standard operating procedures on transferring data from viral load laboratory result forms 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 individuals rather than tests. For example, the laboratory information management system may only be able to track the number of viral load tests conducted, sample types and the associated results for tests and cannot de-duplicate repeat tests for individuals. Although monitoring and evaluation systems and tools may have been designed to track individuals (such as including the antiretroviral therapy number on the laboratory requisition form), staff at sites must consistently enter individual patient information in all fields on the form, and these data must be accurately and completely entered into the laboratory information management system. Longitudinal tracking of patients will require monitoring and evaluation systems to track individuals over time through unique identifiers. See the WHO consolidated guidelines on person-centred HIV patient monitoring and case surveillance *(2)* for more comprehensive considerations for unique identifiers and recommendations to develop systems for unique identifiers.

As routine viral load testing is scaled up, a system is needed for longitudinally tracking patients; examples in which this is important for programmatic and individual tracking include:

- cohorts of individuals who have been receiving antiretroviral therapy for specified periods of time and receiving viral load tests and their result (such as viral load tests and results six and 12 months after initiating antiretroviral therapy); and
- individuals who do not have suppressed viral loads (≥1000 copies/mL).

Using unlinked monitoring and evaluation systems from facilities and laboratories requires that individual tracking information be consistent across all data sources. Fields on the sample requisition form completed by the facility (such as antiretroviral therapy number, patient name and antiretroviral therapy start date) must consistently match the fields entered by the laboratory, such that the electronic laboratory information system will correctly identify patients. Programmes can improve the interaction between facility and laboratory systems and their ability to report on individual outcomes by monitoring the completeness of the data on laboratory requisition forms at sites and the completeness of these data in laboratory information management systems. Data quality exercises should also be routinely conducted to compare and link data in laboratory information management systems to site-level data on patient charts and/or antiretroviral therapy registers to ensure that data are accurately reflected in patient charts. Please see the subsection on data quality, analysis and use in Section 2 for more information on conducting routine data quality checks.

Finally, monitoring and evaluation data will inform estimations of viral load testing needs. As country programmes scale up viral load testing, forecasting commodities, estimating financial and human resource needs and tracking overall viral load testing coverage will be increasingly important. Given the complexities of tracking patients and ensuring that testing follows guidelines, country programmes will need to plan accordingly and ensure that monitoring and evaluation systems are providing helpful data to inform estimates of the viral load testing needed. Table 1 summarizes 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 MONITORING AND EVALUATION FOR VIRAL LOAD MONITORING

Assessment of monitoring and evaluation tools may highlight the need to revise current forms and develop new tools. Country programmes 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 viral load testing processes and outcomes.

Training and on-site mentorship are essential to ensure that data capture forms and monitoring and evaluation tools are correctly and completely filled out at sites and, if required, entered into laboratory information management systems and patient records. Data should be routinely reviewed at the site level and above-site level to ensure that patient management is in accordance with standard operating

Table 1. Summary and suggestions to address key challenges in viral load monitoring and evaluation

Challenge	Suggestions
Using data from unlinked laboratory, facility and/or national aggregate reporting systems	• Map out the flow of samples and results to and from facilities • Identify key indicators for routine monitoring that align with viral load testing guidelines, clinical algorithms and standard operating procedures • Overlay key indicators on the flow map of samples and results to and from facilities • Ensure that monitoring and evaluation tools with appropriate fields are available to capture these data • Develop standard operating procedures, training materials, mentorship protocols and data quality assessment processes for laboratories, facilities, and strategic information and monitoring and evaluation staff for data capture; train staff in an interdisciplinary way so that all staff members understand each other's roles in capturing data and how various systems will be used to monitor viral load testing and suppression rates • Pilot test all changes in tools and training materials to identify challenges before launching on a larger scale • If the laboratory information management system is primarily relied on for viral load monitoring and reporting, ensure that unique individuals can be tracked over time and that data are accurately reflected in patient charts and being used for patient management
Tracking and reporting viral load data on tests for individuals	• Clarify which systems track tests and/or individuals • Assess the degree to which individuals and their outcomes can be tracked • Ensure that individuals 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 viral load suppression could threaten the prevention of mother-to-child transmission • Be clear about which indicators track tests for individuals (see Section 2 for more information) • Summarize the limitations with reporting tests and individuals; to the extent possible, develop methods to de-duplicate results to report on individuals • Ensure that monitoring and evaluation tools, systems and processes are designed to track individuals (such as consistently using unique identifiers) • Tracking coverage of individuals who routinely receive viral load tests to ensure that everyone who should receive a viral load test is receiving it
Tracking patients over time (including those with viral load ≥1000 copies/mL)	• Determine the extent to which monitoring and evaluation systems can track cohort-based and cross-sectional groups of individuals over time (see Section 2 for more details) • Example of groups of individuals that require longitudinal tracking: – Cohorts of individuals who have been receiving antiretroviral therapy for specified periods of time receiving viral load tests and their results (longitudinal) – Individuals who do not have suppressed viral loads (longitudinal) • Assess the monitoring and evaluation tools, systems and processes to track all groups of individuals and revise them as needed; ensure that individuals with viral load >1000 copies/mL are tracked appropriately and switched to second-line therapy, 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 viral load coverage and viral load suppression rates for individuals	• Be clear about tracking the number of individuals and tests along the cascade of viral load testing so that programmes are using the appropriate denominator to assess rates of both coverage and viral load suppression • For tracking viral load coverage, the denominator should be the number of people living with HIV receiving antiretroviral therapy for at least 12 months; this denominator may be disaggregated by age and sex, pregnant women, breastfeeding women and other subpopulations so that programmes can track viral load testing coverage among various subpopulations • For routine programme reporting on rates of viral load suppression, the denominator should be specifically defined as the number of individuals who received a viral load test; ideally, programmes should track a cascade: number of individuals currently receiving antiretroviral therapy, number who received a viral load test and number with suppressed viral loads. Further, programmes should review the data by various subpopulations
Estimating the need for viral load testing	• Key data include the number of individuals new to and currently receiving antiretroviral therapy who should receive viral load tests in a 12-month period. Consider: – Individuals new to antiretroviral therapy who may require two tests in a 12-month period (six months after initiation and again at 12 months after initiation) – Repeat tests because the first viral load ≥1000 copies/mL; this will depend on viral load testing guidelines and the prevalence of viral suppression in key age groups and populations – The timing and location of when and where pregnant and breastfeeding women receive viral load tests

procedures and reflected in the quality of data. Training 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, standard operating procedures and processes;
- correct methods to aggregate data for reporting;
- consistent data capture at sites using monitoring and evaluation tools such as patient cards, antiretroviral therapy registers and laboratory result forms;
- clinical guidelines that inform various fields on the forms such as distinguishing whether the viral load test is routine or targeted; and
- adherence to the monitoring and evaluation protocol such as transferring results at the facility from the viral load result form to viral load registers, patient cards and charts, antiretroviral therapy registers and facility-based electronic systems.

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

Training and ongoing site mentorship on data use will also be essential. Training should address data use at both the patient and programme levels. Training on data use at the patient level should address feedback to patients, adherence to standard operating procedures, including monitoring and evaluation tracking, and follow-up monitoring for patients without suppressed viral loads. Training on data use at the programme level should address analysis of data at aggregate levels to identify and address programmatic issues to improve overall outcomes and programme quality.

SUMMARY OF THE CONSIDERATIONS

- Engage stakeholders from all disciplines (such as laboratory staff and directors, HIV care and treatment programme managers, health-care workers, supply chain managers and monitoring and evaluation specialists) in assessing and reforming viral load monitoring and evaluation systems.
- Assess the capacity of monitoring and evaluation systems and tools to routinely track and report on the entire viral load testing cascade: from collecting samples at sites to returning results to patients and routinely reporting results through monitoring and evaluation tools and systems.
- Map data flow for viral load monitoring to guide the review of current monitoring and evaluation tools.
- Update existing monitoring and evaluation tools (such as patient cards, facility antiretroviral therapy registers and laboratory requisition forms) and develop new ones (as needed) to ensure that viral load testing and results are captured (such as high viral load registers or logbooks). Pilot test all updated and new tools before finalizing and rolling out nationally.
- Consider challenges and ways to address them in assessing monitoring and evaluation systems and tools. Use this process to guide a critical review of viral load monitoring and evaluation plans and indicators.
- Develop a training and mentorship plan to strengthen capacity to routinely collect, analyse and use viral load data at sites, subnational levels and national levels to improve the quality of services and patient outcomes.

2. INDICATORS OF THE IMPLEMENTATION AND OUTCOMES OF VIRAL LOAD TESTING

This publication compiles and presents several key viral load indicators from multiple sources, including the WHO consolidated strategic information guidelines for HIV in the health sector *(1)* and PEPFAR Monitoring, Evaluation and Reporting (MER) Guidance v2.0 *(4)*. Country programmes can adapt relevant indicators appropriate to their country viral load programme monitoring and reporting systems and develop additional ones that reflect their priorities. Where possible, programmes should try to align their indicators and disaggregation with those in the WHO consolidated strategic information guidelines for HIV in the health sector and MER guidance. Collecting and analysing data that are disaggregated by age and population, with attention to priority population viral load outcomes (pregnant women, children, adolescents and key populations) are key to focusing interventions and improving 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 monitoring and evaluation plans for HIV programmes. Annex 4 includes a template of a national viral load monitoring and evaluation plan that countries may use or adapt.

INDICATORS FOR ROUTINELY MONITORING THE VIRAL LOAD CASCADE

Routine monitoring involves routinely collecting data from all antiretroviral therapy sites and all patients. Data sources for routine monitoring should include antiretroviral therapy sites, hubs and laboratories in the laboratory and specimen transport network and laboratories where viral load samples are processed.

After reviewing the overall data flow and monitoring and evaluation tools associated with data capture and recording, one helpful approach for selecting routine monitoring indicators is to list the key steps in the viral load testing cascade and define how each step would

Table 2. Core indicators along the viral load testing cascade

Key steps in the cascade of viral load testing	**Core indicators for routine monitoring** (see Annex 5 for more detailed indicator information, including numerator and denominator guidance)
Order viral load test	• % of sites in the specimen transport network that are submitting samples for viral load testing • Number of viral load tests submitted by sites to the laboratory and specimen transport network
Process viral load test sample	• Number of viral load tests received by the laboratory from sites • Number of viral load tests run by the laboratory
Returned viral load test result	• % of viral load tests results returned to sites within one month of the sample being taken
Coverage, documentation and outcome of viral load test result	• % of people receiving antiretroviral therapy with viral load results at 12 months after initiating antiretroviral therapy [WHO: VLS.2] • % of people receiving antiretroviral therapy tested for viral load with level <1000 copies/mL at 12 months after antiretroviral therapy initiation [WHO: VLS.1] • % of people with a viral load result documented in the medical records and/or laboratory information systems within the past 12 months with a suppressed viral load (<1000 copies/mL) [PEPFAR MER: TX_PVLS] • % of people living with HIV receiving antiretroviral therapy who have suppressed viral loads [WHO VLS.3] • % of people living with HIV with suppressed viral loads (<1000 copies/mL) who have been referred to a less intense model of care or differentiated service delivery
Intervene on viral load test result if viral load ≥1000 copies/mL	• % of people receiving antiretroviral therapy with viral load ≥1000 copies/mL who have received enhanced adherence counselling
Order follow-up viral load test if viral load ≥1000 copies/mL	• % of people receiving antiretroviral therapy with viral load ≥1000 copies/mL who received a follow-up viral load test within 3–6 months after enhanced adherence counselling (or according to the national guidelines) • % of people receiving antiretroviral therapy who had viral load ≥1000 copies/mL and then had suppressed viral load <1000 copies/mL on follow-up testing
Modify antiretroviral therapy regimen after two consecutive results of viral load ≥1000 copies/mL	• % of people living with HIV receiving antiretroviral therapy with two documented viral load test results ≥1000 copies/mL switched to second- or third-line antiretroviral therapy regimens

be measured. When reviewed together, the routine monitoring indicators should reflect how well the country is implementing viral load scale-up and progressing towards achieving the third 90 of the 90–90–90 targets.

Table 2 presents a list of core indicators that are considered essential for routine viral load cascade monitoring and programme implementation, including monitoring patients with a non-suppressed viral load. Some indicators depend on completing multiple steps in the cascade, in which case the indicator is listed with the step that is furthest along in the sequence. Annex 5 contains a more comprehensive list of potential indicators for country programmes to consider, including those suggested by WHO. Annex 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 Annex 5 are organized by process and systems and health outcomes. Indicators for tracking specimen management and testing should be applicable to both centralized laboratory testing as well as any near-point-of-care or point-of-care viral load testing that is included in national viral load monitoring programmes.

These core indicators measure site and system-level processes, coverage, quality and patient outcomes related to viral load testing. Countries may be in different stages of implementing viral load scale-up and should give priority to the indicators from the core list required for routine collection and review. For indicators, especially patient outcomes, that require patient chart review or allow access to identifiable patient information, advice from a national institutional review board should be sought to determine any possible necessary ethical considerations.

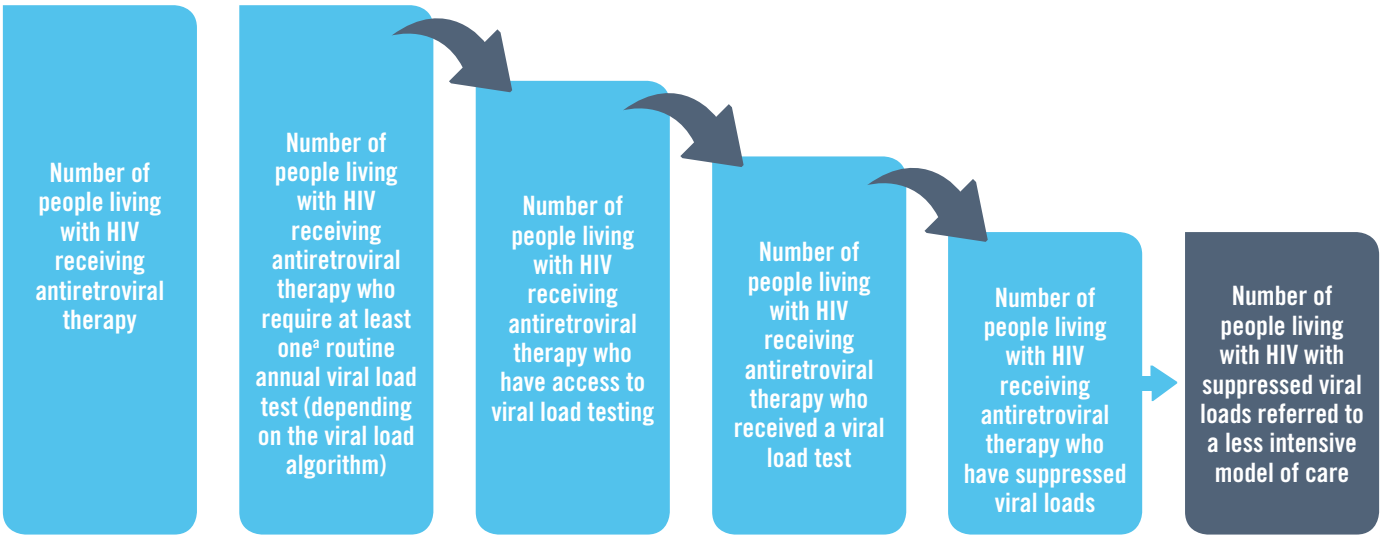
The indicators in Table 2 comprise both cohort-based indicators and cross-sectional ones. Distinguishing between longitudinal tracking of cohort-based patients versus conducting a cross-sectional cascade analysis of patients with suppressed viral loads is important. A cohort-based analysis follows patients who initiated antiretroviral therapy at the same time to a specified period of time (such as six, 12 or 24 months) to examine patient outcomes.

Cohort-based testing can answer key programmatic questions, but it can be costly and requires standard unique identifiers to track patients over time, especially in areas of high mobility. Cross-sectional cascade analysis examines 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 system issues. Noting the key caveats and limitations of the data is important in conducting the different types of analyses.

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

Tracking the scaling up of routine viral load testing is essential to understanding viral load testing coverage and outcomes. Until everyone receiving antiretroviral therapy

Fig. 5. Cascade of routine viral load testing and key indicators to track people with suppressed viral loads



[a] A person generally requires a viral load test six and 12 months after initiating antiretroviral therapy and then once every 12 months thereafter.

receives routine viral load tests according to national testing guidelines, the proportion of people receiving antiretroviral therapy who have access to and receive a viral load test should be tracked to monitor viral load testing coverage and outcomes.

Developing cascades with associated indicators are important to monitor viral load testing coverage and the maturation of systems and processes so that rates of viral load suppression can be interpreted accordingly.

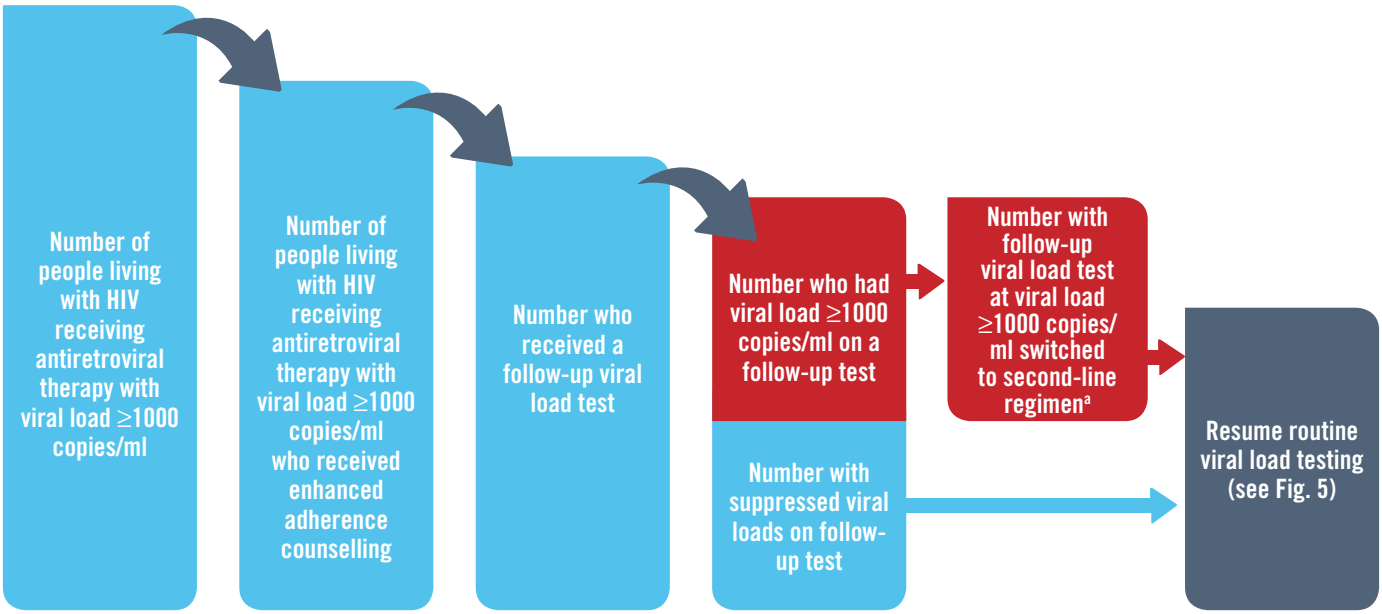
Fig. 5 illustrates the relationship between key indicators along the viral load testing cascade among people with suppressed viral loads. Tracking outcomes for people who receive a viral load test (those with suppressed viral loads and those without) is key for clinical management. Using viral load results to refer people with suppressed viral loads to a less intensive model of care (such as receiving refills every three months or more or attending a clinical visit every six months or more) is essential for implementing differentiated service delivery. People without suppressed viral loads require additional tracking and have another cascade for tracking (Fig. 6).

Fig. 5 illustrates the cascade programmes should consider when assessing and tracking routine viral load testing coverage and outcomes. The proportion of people receiving antiretroviral therapy who require a viral load test in one year in accordance with the national viral load testing algorithms must be considered in calculating the denominator for rates of suppressed viral loads. Some national testing algorithms may stipulate a viral load test once every two years, thereby decreasing the denominator compared with the entire pool of people receiving antiretroviral therapy. If there are gaps in viral load testing coverage, using people living with HIV receiving antiretroviral therapy who received a viral load test (vs. people living with HIV receiving antiretroviral therapy who require a viral load test) as the denominator for the rate of suppressed viral load would be more appropriate; using those who received a viral load test as the denominator will exclude people who did not even receive a test.

Tracking the proportion of people receiving antiretroviral therapy who had access to a viral load test (such as people in specific geographical locations or subpopulations) and the proportion of people receiving antiretroviral therapy who received a viral load test are examples of system and process indicators that can be measured to track the scaling up of coverage and also improve the interpretation of the rates of suppressed viral loads. As programmes reach 100% coverage of routine viral load testing for all populations across the entire country, tracking access to a viral load test becomes less essential for monitoring viral load testing coverage.

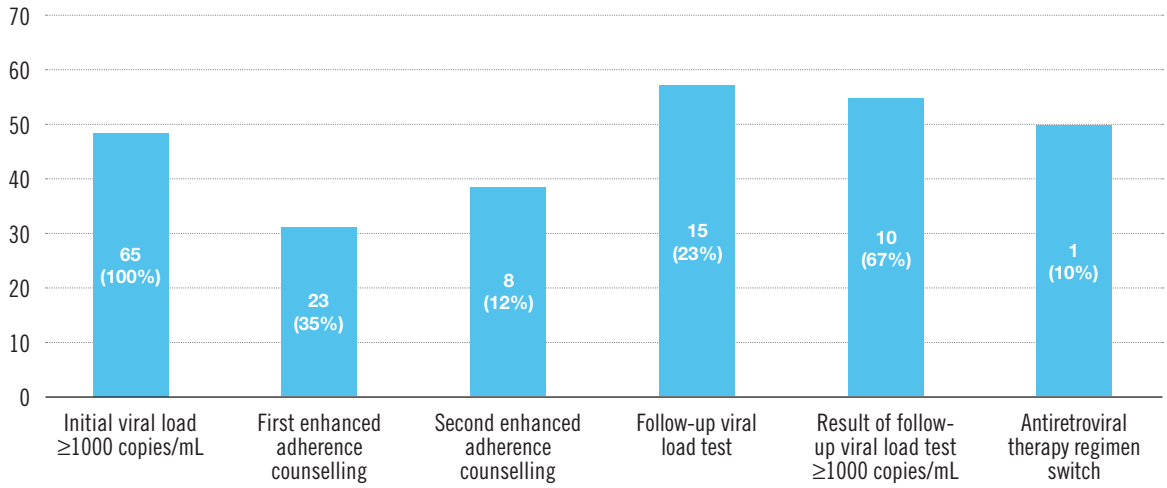
The cascade in Fig. 5 can be used to conduct a cohort-based analysis or a cross-sectional analysis. To conduct a cohort-based analysis, the data in the cascade could follow people who initiated antiretroviral therapy at the same time to a specified period of time (such as six, 12 months or 24 months) to examine outcomes. To conduct a cross-sectional cascade analysis, the data in the cascade would reflect aggregate data for the variables for a specific period. Although this is helpful, not all the people counted across the cascade may be the same person. As was noted above, noting the key caveats and limitations of the data is important in conducting the different types of analysis.

Fig. 6. Viral load cascade for people with a non-suppressed viral load test result (≥1000 copies/mL)



[a] In general, people switching to second-line therapy will receive a viral load test six months after initiation and again at 12 months and once every 12 months thereafter.

Fig. 7. Example of using routinely collected data to understand the leaks in the viral load cascade for people living with HIV with non-suppressed viral load: from viral load ≥1000 copies/mL to second-line antiretroviral therapy



MONITORING AND EVALUATION CONSIDERATIONS FOR PEOPLE WITHOUT SUPPRESSED VIRAL LOADS

People without suppressed viral loads require more intensive monitoring and specific tools and systems to track interventions. Fig. 6 illustrates the cascade for people with viral load ≥1000 copies/mL.

Country programmes should ensure that monitoring and evaluation tools (such as a high viral load register) are available for closely tracking people without suppressed viral loads (≥1000 copies/mL). Data from a high viral load register or logbook (Annex 3) can be used to track people with a viral load result ≥1000 copies/mL and to review the proportion of individuals who received the recommended clinical management, including enhanced adherence counselling interventions, viral load testing and switching antiretroviral therapy regimens if non-suppression continues.

The number of people with viral load ≥1000 copies/mL requiring longitudinal tracking to create the viral load cascade (Fig. 6) is expected to be relatively low since programme data has shown that most people receiving antiretroviral therapy have suppressed viral loads. Fig. 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 leaks stemming from non-adherence to guidelines or loss to follow-up. These 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 people with viral load ≥1000 copies/mL along the entire cascade will help in quantifying the people who did not re-suppress viral load after completing enhanced adherence counselling and are at higher risk of having HIV drug resistance.

Although Fig. 7 is useful for displaying the viral load cascade for people tested for viral load, the people who received the enhanced adherence counselling sessions and those who received a follow-up viral load test could be different. However, the example of the high viral load register provided in Annex 3 would allow programmes to also longitudinally analyse the same group of people.

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

- performance of initial viral load among people after initiating antiretroviral therapy;
- performance of routine viral load among people receiving antiretroviral therapy;
- rate of viral load suppression among people receiving antiretroviral therapy disaggregated for subpopulations and age and sex;
- interventions for people receiving antiretroviral therapy with non-suppressed viral load: documented enhanced adherence counselling;
- performance of follow-up viral load testing among people receiving antiretroviral therapy with non-suppressed viral load; and
- modification of antiretroviral therapy regimens based on repeat values of viral load ≥1000 copies/mL in accordance with national guidelines.

With appropriate and robust monitoring and evaluation systems and tools in place, data can be used to examine other monitoring questions related to service delivery.

- What are the differences in rates of suppressed viral loads between men and women receiving antiretroviral therapy?
- Which sites have especially poor rates of suppressed viral loads?
- What percentage of samples collected are rejected because of improper or insufficient collection, including incorrectly completed laboratory requisition forms?
- What percentage of pregnant or breastfeeding women receiving antiretroviral therapy has suppressed viral loads?
- What percentage of children receiving antiretroviral therapy has suppressed viral loads?
- What percentage of people receiving antiretroviral therapy with non-suppressed viral loads underwent some adherence counselling interventions? What proportion completed the prescribed amount before being retested?
- What proportion of people receiving antiretroviral therapy with non-suppressed viral loads received a follow-up (second) viral load test?
- What percentage of people receiving antiretroviral therapy with a first non-suppressed viral load test has suppressed viral loads after receiving adherence counselling interventions? How does this vary by population (such as men versus women and children versus adults)?
- What percentage of people with persistently high viral loads switched to second-line antiretroviral therapy?

The ability of country programmes to examine these monitoring questions depends on both the availability and quality of viral load data. Data from multiple indicators may be required to answer one question.

DATA QUALITY

Data quality should be a priority for programmes, especially given the complexities of monitoring and reporting routine viral load data from multiple locations and sources. Data quality must be regularly reviewed at sites and laboratories and must be used within the aggregate monitoring and evaluation system to monitor the overall HIV programme (such as 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 the availability of registers to validate reported data and the percentage of facilities submitting monitoring reports;
- completeness: the proportion of data fields that are complete (not missing data); and
- timeliness: the proportion of reports submitted on time.

Ensuring data quality starts before data are collected by developing 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 the accuracy, completeness and timeliness of the data being transmitted; to ensure consistency in indicator definitions; and to define the responsibilities for data quality at each level of the health information system.

Routine quality assessments of viral load data should be incorporated into the viral load monitoring and evaluation 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 more thoroughly comparing the reported data through multiple unlinked systems, such as site registers and electronic medical records, DHIS2 and laboratory information management systems. More in-depth data quality assessments can include closely reviewing recorded data to ensure that the correct data are being recorded, such as comparing data from laboratory information management systems with data in the patient chart and data recorded for the patient in a register. Both ends of the spectrum are routinely needed for monitoring the quality of viral load data.

Protocols for implementing routine data quality assessment are also needed; these should assess adherence to the data collection, aggregation and reporting protocols defined in data quality protocols developed before data collection started. The data quality assessment 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.

The WHO consolidated guidelines on person-centred HIV patient monitoring and case surveillance *(2)* provide more information and recommendations for reviewing and assessing data quality.

ANALYSING AND USING DATA FOR IMPROVING PROGRAMMES

Developing a clear plan for analysing and using data in the early phases of scale-up can motivate staff to collect, review and analyse viral load testing data. The data analysis plan should include analysing overall viral load testing coverage and outcomes at the site and above-site levels, reviewing data by age groups and for various priority and key populations and analysing data from viral load cascades. Data analysis may also be cohort-based or cross-sectional, depending on the question and available data. Research studies and programme data have shown a significant variation in viral load suppression by age group, with children and adolescents having rates of viral load non-suppression up to three times higher than adults *(5)*. For this reason, it is imperative that viral load outcome indicators be analysed by age group (such as standard disaggregations for children plus for adolescents 10–19 years old). Priority populations such as pregnant and breastfeeding women should also be analysed separately to inform programmatic activities around eliminating mother-to-child transmission. Rates of viral load suppression among people coinfected with HIV and TB and among key populations (such as female sex workers, gay men and other men who have sex with men and people who inject drugs) should also be analysed to inform programme implementation. Even if data on some subpopulations are not routinely collected, programmes should plan to review data at sites for subpopulations during routine assessment of service quality and/or supportive supervision site visits.

Country programmes have increasingly been using dashboards for routinely analysing and using data among stakeholders. Routine and frequent availability and review of data for key metrics, displayed with graphics and visuals, have been essential in promoting the use and understanding of data. Although dashboards are generally developed outside the primary systems for collecting viral load data, country programmes are moving more towards integrating dashboards into existing data systems such as laboratory information management systems and DHIS2.

Data should be used to answer key technical and programmatic questions and provide key stakeholders (such as the health ministry, district, regional or provincial staff facility staff and implementing partners) with information to inform programme implementation, identify challenges and initiate corrective action for improving quality. Quality improvement is a continual and iterative process. Analysing data from the viral load cascade indicators is essential to identify challenges and inform strategies for improvement. Programme data should be routinely reviewed and used at multiple levels to update strategic plans, plans for implementing and improving programmes and plans for forecasting demand for commodities.

Such tools as dashboards, clinical cascade templates and action plans should be informed by successful models used in other programme areas to assist with routine analysis, track progress and identify new and ongoing programme 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 the collection, analysis and use of data.
- Update national HIV monitoring and evaluation plans to reflect monitoring of viral load testing and scale-up. This may involve developing the monitoring and evaluation section of the national plan for implementing viral load testing and updating national HIV monitoring and evaluation plans to include viral load testing indicators, targets and planned evaluations.
- Include only high-level routine viral load targets and indicators in the national HIV monitoring and evaluation plan. Ensure a clear plan for analysing and using data and that site staff are engaged in reviewing data from their sites.
- Ensure that dashboards include key steps in alignment with the viral load testing cascade. Monitoring how many individuals receive routine viral load tests in accordance with the national algorithm is important to identify any early problems with demand creation and/or provider compliance with viral load testing guidelines.
- Data analysis and the use of tools should support stakeholders and programme implementers in using data to inform:
  - strategic planning;
  - programme implementation and improvement, including the quality of testing and clinical services; and
  - forecasting the demand for commodities.

3. ASSESSING SERVICE QUALITY AND EVALUATING VIRAL LOAD TESTING

Country programmes may want to enhance the monitoring of viral load implementation, especially during scale-up, to promptly identify problems and take corrective action. Further, evaluation should be planned early to ensure that robust data are collected and reviewed to inform the implementation and improvement of programmes.

ENHANCED MONITORING AND SERVICE QUALITY ASSESSMENT

Enhanced monitoring may involve more frequent review of routine monitoring indicators or a limited set of key indicators, in addition to the core set of indicators, which are collected from a subset of sites. Interdisciplinary teams should review these data more frequently to assess adherence to standard operating procedures and the quality of the services provided. Enhanced monitoring may also highlight some key problems with data quality.

In addition to enhanced monitoring of key indicators, country programmes should consider conducting service quality assessment. Service quality assessment provides in-depth site-level assessment of programmes using implementation standards to identify areas that need to be improved further. As a result, service quality assessment provides constructive feedback to site-level and national programmes on how well sites are meeting standards of care. Although service quality assessment focused on the services provided, it relies heavily on reviewing site-level data. Thus, monitoring and evaluation systems should be in place to capture key data that can be reviewed during service quality assessment.

The objectives of assessing viral load service quality include:

1) Assess compliance with national guidelines on viral load monitoring among people who have initiated antiretroviral therapy or are already receiving antiretroviral therapy by measuring:
   a. site-level compliance with initial viral load performance among people who have initiated antiretroviral therapy;
   b. site-level compliance with interventions for individuals with viral failure (as defined by national guidelines);
   c. site-level compliance with routine follow-up viral load testing among people receiving antiretroviral therapy;
   d. site-level compliance with viral load testing of people receiving antiretroviral therapy in the past 12 months; and
   e. site-level compliance with referral of stable people living with HIV to a less intensive model of care or differentiated service delivery.

2) Assess compliance with national guidelines on managing viral failure by determining:
   a. whether antiretroviral therapy regimens are changed in a timely manner to a second-line regimen based on repeatedly detectable viral load values in accordance with national guidelines; and
   b. whether antiretroviral therapy regimens are being changed to an appropriate second-line regimen based on repeatedly detectable viral load values in accordance with national guidelines.

During service quality assessment, more in-depth data quality assessment can also be performed at sites. Data quality assessment alone generates vital information for monitoring programmes and improving quality but provide a limited context for investigators to fully understand the reasons for the findings. Combining service quality assessment with data quality assessment will provide programmes a more complete context for understanding the data collected and reported by the site and any discrepancies between indicator values.

Annex 5 provides a list of indicators that can be included in an enhanced monitoring plan or viral load service quality assessment and data quality assessment.

EVALUATING THE IMPLEMENTATION OF VIRAL LOAD TESTING

Country programmes are encouraged to collaborate with stakeholders to conduct high-quality evaluation of their viral load implementation plans.

Types of evaluation

Several types of evaluation can be conducted to inform and improve programme implementation and outcomes. Annex 7 outlines the differences among process evaluation, outcome evaluation, economic evaluation and operations research. This subsection primarily focuses on process and outcome evaluations.

Process evaluation evaluates whether the scaling up of viral load testing is being implemented as planned. Process evaluation identifies facilitators and barriers to viral load testing from multiple perspectives (such as those of patients, providers, specimen transporters, laboratory

technicians and monitoring and evaluation officers) and identify lessons learned to inform further scale-up efforts.

Examples of process evaluation questions

- Was viral load testing scaled up and implemented as planned? Why? What worked? What did not work?
- How are monitoring and evaluation, programme or clinical and laboratory staff working together to review and use data on the performance of viral load testing?
- Were staff members adequately trained to implement viral load testing for patient monitoring? Was there adequate support for viral load testing, including providers at sites, laboratory transporters, laboratory technicians and monitoring and evaluation staff?
- Which models of sample transport result in more people receiving viral load tests and results?
- As a measure of the quality of viral load 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 is the electronic transfer of results versus the physical return of results in ensuring that sites use results for managing patients?
- What are the best practices to ensure that patients receive viral load testing and results in a timely fashion, understand the viral load results and receive adherence counselling to improve antiretroviral therapy adherence and the documentation of suppression of viral loads?

Outcome evaluation is conducted to determine programme effectiveness. Outcome evaluation requires collecting baseline data from which to measure change and should therefore be planned before or during the early stages of implementing viral load testing. If programmes begin outcome evaluation midway through implementation, they will not be able to answer critical questions because of limited or poor-quality baseline data. By planning ahead, country programmes can articulate evaluation questions, develop protocols, collect baseline data and plan for subsequent data collection for high-quality outcome evaluation.

Examples of outcome evaluation questions

- Which subpopulations had the most success with viral load testing? What were the significant differences in viral load test results between subpopulations? Why?
- How has the quality of HIV services, especially adherence counselling and support, changed as a result of routine viral load testing?
- What are the optimal models of enhanced adherence counselling to ensure that people adhere to HIV treatment and have suppressed viral loads?
- How well do self-reported adherence rates predict suppressed viral loads?
- How has the implementation of viral load testing affected the timely switch to appropriate second-line antiretroviral therapy?

The national monitoring and evaluation plan must allocate an appropriate budget for executing an effective evaluation plan to support effective viral load implementation. Engaging stakeholders early in the implementation planning process will help programmes in setting priorities for evaluation questions and the resources required to execute the evaluation (technical resources, budget and staff time). Once agreement is reached on evaluation priorities and resources have been allocated, plans for evaluation can move forward. Evaluation protocols should be developed as soon as possible so that programmes have adequate time to collect baseline data, when required.

SUMMARY OF CONSIDERATIONS

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

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ANNEX 1. LOGIC MODEL FOR ROUTINE VIRAL LOAD TESTING

OUTPUTS	ACTIVITIES	OUTPUTS	OUTCOMES		
• Funding • Staff such as laboratory technicians, transport network and clinic staff • Policies • Partnerships • Equipment, supplies, reagents etc. **Laboratory and specimen transport network**	**PLANNING** • Assess the capacity of staff, the existing specimen transport network, infrastructure, molecular laboratories, testing modalities, IPs and the monitoring and evaluation system • Assess the readiness of clinical sites and programmes • Select the specimen type and platform or assay and the technologies for viral load testing • Develop clinical algorithms and quality standards for monitoring viral load testing • Review and update clinical and laboratory monitoring and reporting tools for monitoring viral load testing • Develop training materials and a plan for training staff at the national, subnational and site levels • Develop a costed, phased implementation plan with targets; determine the criteria for guiding phased implementation such as geography or priority populations • Develop or revise a plan for laboratory accreditation and a quality improvement or quality assurance system to ensure the quality of viral load testing • Identify current and future limitations of equipment, infrastructure, funding, policies and human resources **Identify and set priorities for process and outcome evaluation questions for monitoring viral load testing and health outcomes**	**PLANNING** • A comprehensive costed, phased and strategic viral load testing implementation plan with targets are developed • Training materials and a training plan for staff at laboratories and facilities are developed • Revised monitoring and reporting forms and updated standard operating procedures for monitoring and reporting for the national, subnational and site levels are in place to Ensure that complete and high-quality data are available for viral load monitoring • A monitoring and evaluation plan for viral load testing is developed • A quality management system and an external quality assurance plan are in place **IMPLEMENTING THE MONITORING OF VIRAL LOAD TESTING** **Strengthening systems and capacity** • Quality standards and standard operating procedures are established • Monitoring and reporting forms and standard operating procedures are updated • Molecular laboratories are identified for viral load testing and the laboratory and specimen transport network strengthened • Staff trained in viral load testing procedures, including completion of monitoring and reporting tools • Clinical and program readiness assessed for phased implementation of viral load testing **Service delivery** **Viral load testing available and scaled up for all people living with HIV receiving antiretroviral therapy**	**SHORT TERM** **System outcomes** • Increased capacity of laboratory technicians, health-care workers, data clerks etc. to request, conduct, verify and/or monitor the outcomes of viral load testing • Increased ability to consistently provide supplies, transport specimens and return results to sites for viral load testing **Health outcomes** • Increased access of people living with HIV receiving antiretroviral therapy to routine viral load testing • Increased percentage of people living with HIV receiving antiretroviral therapy with documented viral load results **Improved treatment recommendations and quality of care for people living with HIV**	**MID-TERM** **System outcomes** • Increased volume of viral load testing • Improved quality of viral load testing • Increased routine and strategic use of high-quality data **Health outcomes** • Increased coverage of viral load testing among people living with HIV receiving antiretroviral therapy • Increased adherence to antiretroviral therapy regimens • Improved quality of care for people living with HIV receiving antiretroviral therapy **Improved antiretroviral therapy outcomes**	**LONG TERM (IMPACT)** • Reduction in morbidity and mortality • Fewer people dying from AIDS-related causes • Fewer people newly infected with HIV • Improved survival of people living with HIV receiving antiretroviral therapy • Increased numbers of people averting HIV infection

ANNEX 2. TOOL AND CHECKLIST FOR ASSESSING MONITORING AND EVALUATION SYSTEMS FOR VIRAL LOAD TESTING

Purpose: The purpose of this tool is to guide the assessment of monitoring and evaluation systems and their capacity to routinely monitor and track viral load testing. The process of collecting data by using monitoring and evaluation tools should be well aligned with the goal of informing and improving programme implementation. This tool may be used throughout the process of implementing viral load testing to inform scale-up efforts and to monitor implementation. Ideally, this tool would be used as part of a broader, more comprehensive assessment and review of the monitoring and evaluation system.

Annex 2 (continued)

Area of system to review	Assessment questions	Findings	Recommendation
Data flow and data capture	• Has the sample flow from the site to the laboratory been clearly mapped? • Has the data flow from the site to laboratory and back to the site (such as returning results) been clearly mapped? • 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 the flow of data results? • Have data capture forms and data sources been mapped to the indicators? Is it clear where the data will come from for the various indicators?		
Data collection (paper and electronic monitoring and evaluation tools)	• Do current patient cards (or electronic medical records) include fields to document viral load testing, including when ordered, received and the results reported? • Do current antiretroviral therapy registers include fields to record viral load test results, including the month when the test was requested and the test results? Ideally, this would be clearly noted in the antiretroviral therapy register at six months after initiation and 12 months thereafter (or in accordance with the national algorithms on viral load testing). • Do current monitoring and evaluation tools include the required fields for key variables for routine reporting on viral load testing and outcomes? • Is there a clear process for recommending changes to existing monitoring and evaluation tools (or creating new tools) to capture data for viral load testing and results? • Is there a plan to pilot test all updated tools? • Is there an existing laboratory electronic system (such as a laboratory information management system? Does it include fields to capture data for viral load testing? Are these fields clearly linked to the paper-based monitoring and evaluation tools that may be used for sample transport? Are the laboratory electronic systems interoperable with the national electronic systems that are used for monitoring and reporting on HIV? If not, how often are the data from each respective system reviewed for discrepancies? • Are the data captured in service delivery site and patient-level monitoring and evaluation tools the same as the data captured in laboratory information management systems? • If not, what are the discrepancies? Should the tools and systems be harmonized? • Can the systems track only tests and not individuals? For example, if a laboratory electronic information system is relied on for reporting, can that system report results for unique individuals or only report the tests conducted? • Can systems track unique individuals over time? For example, if a laboratory electronic information system is relied on for reporting, can the system report results for the individual over time (such as annual routine viral load tests over time or follow-up viral load tests after an initial test showed detectable viral load)? • Can monitoring and evaluation systems and tools track viral load testing outcomes for cohorts (such as viral load test results six and 12 months after initiating antiretroviral therapy)?		

Annex 2 (continued)

Area of system to review	Assessment questions	Findings	Recommendation
Data reporting	• Have routine data reporting forms been updated to include the required fields for key viral load testing indicators? • Have electronic reporting systems been updated to integrate the required fields for reporting and monitoring viral load testing and results? • Can the programme report on tests and/or individuals? Can the programme 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 monitoring and evaluation plans been updated to reflect the scaling up of viral load testing? Have national indicators to monitor the 90–90–90 targets been clearly defined? • Is there a clear plan for analysing data on routine and enhanced viral load monitoring indicators that includes disaggregation by age and population? • Is there a plan with tools and materials for more frequent monitoring of viral load testing during scale-up? • Have service providers, programme managers, monitoring and evaluation staff and other key stakeholders provided input 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 or follow-up action?		
Data quality	• Is there a strategy to monitor data quality at sites and laboratories and resolve discrepancies between unlinked systems such as a laboratory information management systems, site registers and electronic medical records and DHIS2? • Have variables on viral load testing been integrated into data quality assessment tools? • After viral load testing has been implemetned, has there been data quality assessment to review data at sites and compare data from unlinked data systems such as laboratory information management systems, paper registers and electronic systems and antiretroviral therapy aggregate reporting systems (such as DHIS2)? Do the data from all three sources match?		
Service quality	• Is there a strategy to monitor the quality of viral load testing implementation at the facility level (such as timely and accurate use of viral load results for patient management)? • Is there a plan to follow up on service quality findings to ensure that the data are of the highest quality?		

Annex 2 (continued)

Area of system to review	Assessment questions	Findings	Recommendation
Capacity	• Is a plan being developed to train service providers, laboratory staff, monitoring and evaluation staff and others on the correct completion of tools? Does this training also incorporate elements of the clinical cascade to clearly show how the data relate to the three 90–90–90 targets? • Is there a plan and schedule to provide ongoing on-site training and mentorship to ensure compliance with national guidelines for viral load testing and documentation? • Is there a plan to follow up on the results of data quality assessment to ensure that the data are of the highest quality? • Is there a forum for communicating and tracking lessons learned, challenges and recommendations on monitoring and evaluation for viral load testing?		

ANNEX 3. EXAMPLES OF KEY MONITORING AND EVALUATION TOOLS FOR VIRAL LOAD MONITORING

Laboratory requisition form and viral load results form. An example from from the Government of Uganda: lab request form. The front side is the lab request form that accompanies the viral load sample from the facility to the laboratory hub and the centralized laboratory for testing and processing. The back side is the viral load 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 y <2 , 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 - < 1 _ <1yrs] 1 – 2yrs ☐ 2 - 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 approa 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"

Antiretroviral therapy register with fields for recording viral load results. Example from the Government of Uganda: an antiretroviral therapy register that can track cohorts of people receiving antiretroviral therapy. This shows an example of a field to document viral load test results. In accordance with the guidelines, a viral load test result is expected to be documented at six months after antiretroviral therapy initiation, 12 months afterwards and then annually thereafter. Fields in the antiretroviral therapy register for recording viral load results are essential for monitoring cohorts of people receiving antiretroviral therapy.

The register has been broken into two tables 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 registry for longitudinal tracking. Although not shown here, fields for tracking viral load have also been integrated into antenatal care, labour 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 #					*1st: Reason/ Date*	*1st: Reason/ Date*	*1st: Reason/ Date*
															Preg 1	Preg 2	Preg 3	Preg 4		*2nd: Reason/ Date*	*2nd: 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 or logbook at facility. This is an 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, antiretroviral therapy number, patient name, date of birth, sex, pregnant (yes or no), contact information, reason for test (such as routine versus targeted or 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 laboratory staff at sites, but this responsibility may be shared with other staff depending on the 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 viral load results form. This is an optional form to record follow-up actions for people 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 viral load register or logbook (see the next tool example). Key fields include: patient contact information, antiretroviral therapy regimen information, data on enhanced adherence counselling session, follow-up viral load test date, viral load test result and whether the person switched to another antiretroviral therapy 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 viral load results follow-up register. Examples of a longitudinal register to track patients with viral load ≥1000 copies/mL. Country programmes can adapt the register for their settings. Sites should complete these registers for all patients with an initial viral load ≥1000 copies/mL to track enhanced adherence counselling, follow-up viral load test, result, outcome (such as maintained on regimen or switched) and viral load test result after outcome.

The register has been divided into two tables 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.													

ANNEX 4. EXAMPLE OF A TEMPLATE FOR A NATIONAL MONITORING AND EVALUATION PLAN FOR VIRAL LOAD TESTING

The following key sections should be included in a national monitoring and evaluation plan for viral load testing.

Programme monitoring
- Main stakeholders
- Indicators that include definitions, disaggregation, data sources and frequency of reporting
  - Baseline data and targets to be achieved with time frame
  - Responsible parties
- Data systems and management
- Data quality assessment
- Data analysis
- Data use
- Estimated budget to conduct programme monitoring

Evaluation
- Purpose of the evaluation
- Evaluation questions
- Type of evaluation
- Individuals and roles in the evaluation team
- Users of the evaluation findings (stakeholders)
- Timeline
- Budget

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

PART 1: PERFORMANCE MONITORING PLAN

Monitoring question	Performance measure and target	Data sources	Frequency of collection and reporting	Responsibility
What is the monitoring question (Annex 5 provides several monitoring questions)? For example, what are the outcomes of people who received a viral load test?	What performance measure (indicator) will be used? Specify disaggregation (such as <1 male, <1 female etc.) Define the target as needed. For example, X individuals receiving antiretroviral therapy will receive a viral load test in year 1.	Where will the data be obtained? For example, the laboratory information management system, antiretroviral therapy registers, patient charts, viral load testing registers or logbooks etc.	When will the data be gathered and reviewed? For example, data will be recorded during viral load sample collection from a patient and reported to the health ministry monthly.	Who will capture the data? For example, site staff will capture data by using the viral load laboratory requisition form. Laboratory staff will entered data from the form and results into the laboratory information management system. (site staff and central laboratory staff)

Data systems and management

Specify how data will be managed. For example, briefly describe how data will be entered from sites and laboratories into the laboratory information system and managed in the laboratory information system for analysis and reporting.

Data analysis and quality

Briefly describe the data analysis and data quality assurance plans for viral load data. For example, specify how data will be analysed at the site, district and national levels and by subpopulations (such as pregnant women, breastfeeding women and age and sex disaggregation). Data quality assurance plans can include description of checks to compare data between unlinked systems (such as a laboratory information system or DHIS) and/or comparing data on sites to the laboratory information system and/or DHIS.

Using the data and disseminating the results

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

PART 2: EVALUATION PLAN

Evaluation plan narrative

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

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

Programme goals and objectives: List the programme goals and objectives to be addressed through the evaluation.
- Goals:
- Objectives:

Programme logic model: Attach the logic model (see Annex 1 for an example of a logic model for viral load).

Individuals and roles in the evaluation team: List the 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 questions	Type of evaluation	Variables and indicators	Data sources	Data collection method	Dissemination and use
What do we need to know or evaluate (fidelity and effectiveness) about the programme?	What type of evaluation is it? Process? Outcome? Both?	What specific variables and indicators are needed to answer your evaluation question?	What will the data source be for the variables and indicators?	How will the data be collected? Qualitative, quantitative or mixed methods? Will interviews, document reviews and/or reviews of programme data occur?	What dissemination and use strategies will be used to share evaluation findings? How will stakeholders use them to improve programmes? Make sure to include where the evaluation findings will be publicly available (for PEPFAR-supported evaluations)

Additional resources to assist in developing a comprehensive evaluation plan and evaluation

Salabarría-Peña Y, Apt BS, Walsh CM. Practical use of program evaluation among sexually transmitted disease (STD) programs. Atlanta: United States Centers for Disease Control and Prevention; 2007 (http://www.cdc.gov/std/program/pupestd.htm).

PEPFAR evaluation standards of practice v2. Washington (DC): PEPFAR; 2015 (http://www.pepfar.gov/documents/organization/247074.pdf).

ANNEX 5. CORE PROGRAMME INDICATORS FOR SCALING UP AND IMPLEMENTING VIRAL LOAD TESTING

Country programmes should select relevant and helpful indicators for their programmes from Annex 5 (in addition to their own indicators, as applicable); programmes are not required or expected to monitor all indicators below. Further, programmes should edit or adapt indicators suggested by this framework for their settings.

Please note that PEPFAR monitoring, evaluation and reporting indicators are from MER 2.0, which went into effect on 1 October 2016 and are reported annually in accordance with current guidance. WHO indicators reflected are from: Consolidated strategic information guidelines for HIV in the health sector. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/164716/1/9789241508759_eng.pdf?ua=1&ua=1).

It is important to specify the time frame for each indicator when reporting results (for example, regional laboratories received 30 000 viral load tests for processing between January and March 2016).

ANNEX 5. System and process indicators for monitoring viral load scale-up and implementation

Monitoring question	Indicator	Numerator and denominator	Disaggregation	Data sources and considerations	Programme relevance and importance	Indicator guidance source
What is the access and coverage of viral load samples submitted by antiretrovir al therapy sites to the laboratory or specimen?	Percentage of unique viral load tests submitted by sites to the laboratory or specimen transport	**Numerator:** number of unique viral load tests submitted by sites to the laboratory or specimen transport network **Denominator:** number of people living with HIV receiving antiretroviral therapy	• Age • Sex • Pregnant • Breastfeeding Type of viral load sample: • Dried blood spot • Plasma	Viral load sample daily log (retained at the site, where the sample was collected)	This indicator allows programmes to track progress in scaling up viral load testing coverage at the site level and above. This indicator tracks data from sites and subpopulations (such as adults, adolescents, children, pregnant women and breastfeeding women). These data will show whether the number of samples submitted is low in proportion to the number of people receiving antiretroviral therapy or the number of viral load tests expected per reporting period. Sites should explore the reasons for the low proportion of samples collected. Although tracking samples for unique individuals is challenging, it is important that both the numerator and denominator track these data because it is most accurate for programmes 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 the systems may be able to routinely collect and track.	
What is the volume of viral load samples received by each viral load testing laboratory?	Number of viral load samples received by the laboratory from sites	Total number of viral load samples received by the laboratory	Laboratory level • Regional • Central Site name Site level (such as hospital, clinic, etc.) Subnational unit or geographical area Type of viral load sample: • Dried blood spot • Plasma Reason for viral load test: • Routine viral load test • Targeted viral load test (suspected treatment failure) • Follow-up viral load test (after a previous viral load ≥1000 copies/mL) • Other Demographic: • Age and sex • Pregnant • Breastfeeding	• Viral load requisition form completed at antiretroviral therapy sites • Laboratory information management system	This indicator assesses the total number of tests, the type of sample and reason for viral load testing samples received by laboratories for processing. It may inform the management of commodities and should be monitored more frequently if it helps with forecasting.	

ANNEX 5. System and process indicators for monitoring viral load scale-up and implementation (continued)

Monitoring question	Indicator	Numerator and denominator	Disaggregation	Data sources and considerations	Programme relevance and importance	Indicator guidance source
What proportion of viral load samples is rejected for processing by each laboratory or hub?	Percentage of viral load tests rejected by each laboratory	**Numerator:** number of viral load samples rejected at each laboratory **Denominator:** number of viral load samples received at each laboratory	Laboratory level • Regional • Central Site name Subnational unit or geographical area Type of viral load sample: • Dried blood spot • Plasma Reason for viral load test: • Routine viral load • Targeted viral load (suspected treatment failure) • Follow-up viral load test (after a previous viral load ≥1000 copies/ml) • Other Rejection reason: • Incomplete form • Poor sample quality (disaggregated dried blood spot or plasma sample) Demographic: • Age • Sex • Pregnant • Breastfeeding	Laboratory information management system	This indicator will account for tests collected and received that were rejected at the hub or laboratory and not processed and the reasons for rejection. It will help to inform the expected number of viral load test results to be returned to sites and target sites that need refresher training on specimen collection.	
What proportion of viral load test results are returned to antiretroviral therapy sites?	Percentage of viral load test results received at sites within one month of sample taken	**Numerator:** number of viral load test results received at site within one month of the sample **Denominator:** samples that were sent to the laboratory for testing in the past month	Site name Site level (such as a hospital or clinic) Subnational unit or geographical area Type of viral load sample: • Dried blood spot • Plasma	Patient charts, antiretroviral therapy and/or viral load testing registers at sites Viral load sample daily log at sites	This indicator will track the proportion of viral load results that were returned to sites within one month of the sample being taken. This will allow programmes 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, since this will affect the processing and return of viral load results. For example, it is important for laboratories to document the duration of any breakdown in viral load instruments and the reasons for the breakdowns..	

ANNEX 5. System and process indicators for monitoring viral load scale-up and implementation (continued)

Monitoring question	Indicator	Numerator and denominator	Disaggregation	Data sources and considerations	Programme relevance and importance	Indicator guidance source
What proportion of viral load test results returned to antiretroviral therapy sites were recorded in patient charts and/or antiretroviral therapy registers?	Percentage of people living with HIV receiving antiretroviral therapy with a viral load result documented in the medical record within the past 12 months	**Numerator:** number of adults and children receiving antiretroviral therapy with a viral load result documented in the medical record within the past 12 months **Denominator:** number of viral load test results		Antiretroviral therapy and/or viral load testing registers at sites Viral load sample daily log at sites	This indicator will track the proportion of viral load results that were received at sites and documented in patient records and/or antiretroviral therapy registers on site. One of the common challenges is that the results returned are often not documented or acted on 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.	
What proportion of laboratory staff dedicated to viral load testing have been appropriately trained to process viral load samples?	Percentage of laboratory staff dedicated to viral load testing that have been trained on standard operating procedures for viral load testing	**Numerator:** number of laboratory staff dedicated to viral load testing that have been trained on standard operating procedures for viral load testing **Denominator:** number of laboratory staff eligible for training in viral load standard operating procedures and viral load algorithms	Training on: • Dried blood spot • Plasma Lab level: • Site • Regional • Central Subnational unit or geographical area	Health ministry human resources systems PEPFAR implementing partner human resources systems	This indicator will track the proportion of laboratory staff performing viral load tests who have been properly trained on standard operating procedures for viral load testing. Since high staff turnover is a common challenge, this is an important quality indicator that can inform the need for ongoing, frequent staff training. This can be examined during service and data quality assessments and/or during routine supportive supervision site visits.	
What proportion of clinical staff responsible for ordering viral load tests have been appropriately trained to order and interpret viral load test results?	Percentage of clinical staff responsible for viral load testing that have been trained on standard operating procedures for viral load testing	**Numerator:** number of clinical staff members that have been trained on standard operating procedures for viral load testing **Denominator:** number of clinical staff members eligible for training on viral load standard operating procedures and viral load algorithms	Staff cadre: • Physician • Nurse • Clinical officer Site level (such as a hospital or clinic) Subnational unit or geographical area	Health ministry human resources systems PEPFAR implementing partner human resources systems	This indicator will track the proportion of clinical staff who have been properly trained on standard operating procedures for viral load testing and are performing viral load tests. Since high staff turnover is a common challenge, this is an important quality indicator that can inform the need for ongoing, frequent staff training. This can be examined during service and data quality assessments and/or during routine supportive supervision site visits.	

ANNEX 5. Health outcome indicators for monitoring viral load scale-up and implementation

Monitoring question	Indicator	Numerator and denominator	Disaggregation	Data sources and considerations	Programme relevance and importance	Indicator guidance source
What proportion of people receiving antiretroviral therapy received a viral load test at six months after initiating antiretroviral therapy and had suppressed viral loads?	Percentage of people receiving antiretroviral therapy who had viral load monitored at six months [WHO: VLS.6]	**Numerator:** number of people living with HIV and receiving antiretroviral therapy with at least one viral load test result in their medical record within the first six months after initiating antiretroviral therapy **Denominator:** number of people living with HIV and receiving antiretroviral therapy for at least six months	Demographic: • Age • Sex • Pregnant • Breastfeeding Of those tested, number with suppressed viral loads	Programme records, such as antiretroviral therapy and/or viral load testing registers, cohort reporting forms, patient medical records and electronic medical records Laboratory information management system (if treatment information and unique patient identifier are available on the viral load test requisition form and entered into the laboratory information management system) These data are based on a cohort of people who are alive and receiving antiretroviral therapy who have suppressed viral loads six months after initiating treatment De-duplicate records to avoid double-counting when calculating the numerator The denominator should exclude people who have died, transferred to another clinic or been classified as lost to follow-up	This indicator, WHO VLS.6, tracks the coverage and outcomes of early viral load testing of people receiving antiretroviral therapy at six months This indicator assesses the extent to which viral load testing is available in the country By six months after initiating antiretroviral therapy, everyone receiving it should have received at least one viral load test This indicator also monitors viral load suppression six months after initiating treatment. Viral load 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 (1)*
What proportion of people receiving antiretroviral therapy have suppressed viral loads at 12 months after initiating antiretroviral therapy?	Percentage of people receiving antiretroviral therapy tested for viral load at <1000 copies/mL at 12 months after initiating antiretroviral therapy [WHO: VLS.1]	**Numerator:** number of people living with HIV receiving antiretroviral therapy with viral load <1000 copies/mL at 12 months after initiating antiretroviral therapy **Denominator:** number of people living with HIV receiving antiretroviral therapy with a viral load test result available at 12 months	Demographic: • Age • Sex • Pregnant • Breastfeeding Of those tested, number with suppressed viral loads	Programme records, such as antiretroviral therapy and/or viral load testing registers, cohort reporting forms, patient medical records and electronic medical records Laboratory information management system (if treatment information and unique patient identifier are available on the viral load test requisition form and entered into laboratory information management system) These data are based on a cohort of patients alive and receiving antiretroviral therapy who have suppressed viral loads 12 months after initiating treatment The denominator should exclude people who have died, transferred to another clinic or been classified as lost to follow-up	This indicator will allow programmes to monitor viral load suppression of patients 12 months after initiating treatment and to estimate the percentage of PEPFAR-supported people living with HIV who have suppressed viral loads	WHO *Consolidated strategic information guidelines for the HIV sector (1)*

ANNEX 5. Health outcome indicators for monitoring viral load scale-up and implementation (continued)

Monitoring question	Indicator	Numerator and denominator	Disaggregation	Data sources and considerations	Programme relevance and importance	Indicator guidance source
What is the coverage of viral load testing?	Percentage of people receiving antiretroviral therapy receiving a viral load test in the past 12 months	**Numerator:** number of people living with HIV receiving antiretroviral therapy with at least one viral load test result in their medical record in the past 12 months **Denominator:** number of people living with HIV receiving antiretroviral therapy for at least 12 months	Demographic: • Age • Sex • Pregnant • Breastfeeding	Programme records, such as antiretroviral therapy and/or viral load testing registers, cohort reporting forms, patient medical records and electronic medical records Laboratory information management system (if treatment information and unique patient identifier are available on the viral load test requisition form and entered into the laboratory information management system) De-duplicate records to avoid double-counting when calculating the numerator The 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 people receiving antiretroviral therapy who received at least one viral load test in the past 12 months.	
What proportion of people receiving antiretroviral therapy who received a viral load test in the past 12 months have suppressed viral loads?	Percentage of people receiving antiretroviral therapy with a viral load result documented in the medical record and/or laboratory information systems within the past 12 months with a suppressed viral load (<1000 copies/mL) [PEPFAR MER: TX_PVLS]	**Numerator:** number of adults and children receiving antiretroviral therapy with suppressed viral load results (<1000 copies/mL) documented in medical records and/or laboratory records within the past 12 months **Denominator:** Number of adults and children receiving antiretroviral therapy with a viral load result documented in medical records and/or laboratory records in the past 12 months	Age (years), sex and 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	Programme records, such as antiretroviral therapy and/or viral load testing registers, electronic patient medical records and electronic medical records Laboratory information management system (if treatment information and unique patient identifier are available on the viral load test requisition form and entered into the laboratory information management system) The 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 the laboratory system can only be used for results if it can be linked back to the individual patient file This indicator is required for PEPFAR annual reporting starting in fiscal year 2017 Routine refers to viral load tests obtained at standard intervals following antiretroviral therapy initiation to monitor viral load response to antiretroviral therapy Targeted refers to viral load tests obtained based on a specific clinical indication (such as concern about disease progression or failure to respond to antiretroviral therapy)	This indicator is a cross-sectional measure of the proportion of documented viral load tests from adults and children receiving antiretroviral therapy with a suppressed viral load (<1000 copies/mL), allowing antiretroviral therapy programmes to monitor individual and overall programmatic response to antiretroviral therapy as measured by suppression of viral loads	*PEPFAR monitoring, evaluation, and reporting guidance (2)*

ANNEX 5. Health outcome indicators for monitoring viral load scale-up and implementation (continued)

Monitoring question	Indicator	Numerator and denominator	Disaggregation	Data sources and considerations	Programme relevance and importance	Indicator guidance source
What proportion of people living with HIV with suppressed viral loads (<1000 copies/ml) have been referred to a less intensive model of care or differentiated service delivery in the past 12 months?	Percentage of **people living with HIV** with suppressed **viral loads** (<1000 copies/ml) who have been referred to a less intensive model of care or differentiated service delivery in the past 12 months	**Numerator:** number of adults and children receiving antiretroviral therapy with suppressed viral loads (<1000 copies/ml) referred to a less intensive model of care **Denominator:** number of adults and children receiving antiretroviral therapy with suppressed viral loads (<1000 copies/ml) within the past 12 months	Demographic: • Age • Sex • Pregnancy • Breastfeeding • Key population Model of differentiated service delivery	Programme records, such as antiretroviral therapy registers, patient medical records and electronic medical records	This indicator measures the referral of stable clients to a less intense model of care or differentiated service delivery model. A "stable patient" is determined by receiving a suppressed viral load result (<1000 copies/ml) after at least 12 months of receiving antiretroviral therapy. Monitoring the referral of stable patients to differentiated service delivery models will help gauge how well sites are implementing differentiated service delivery 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 programmes to closely monitor adherence and implementation of guidelines for differentiated service delivery	
What proportion of people receiving antiretroviral therapy with a viral load ≥1000 copies/mL received enhanced adherence counselling?	Percentage of people receiving antiretroviral therapy with a viral load ≥1000 copies/mL who received enhanced adherence counselling and support	**Numerator:** number people living with HIV receiving antiretroviral therapy with a viral load ≥1000 copies/mL during a 12-month period who received enhanced adherence counselling and support **Denominator:** number of people living with HIV receiving antiretroviral therapy who had viral load ≥1000 copies/mL and were due for a follow-up viral load test within the reporting period	Demographic: • Age • Sex • Pregnancy • Breastfeeding Enhanced adherence counselling completion: • Enhanced adherence counselling 1 • Enhanced adherence counselling 2 • Enhanced adherence counselling 3	High viral load and/or enhanced adherence counselling registers, logbooks or longitudinal tools at sites Laboratory information management system (if a unique patient identifier is implemented and used) Electronic medical records, if available at sites, can track enhanced adherence counselling visits The denominator should represent the number of people with viral load ≥1000 copies/ml before they initiated any enhanced adherence counselling sessions, and the numerator should represent the number of people with viral load ≥1000 copies/ml who received any enhanced adherence counselling. Longitudinal tracking of people who are not have suppressed viral loads identifies which patients received interventions and the outcomes of those interventions. The disaggregation captures how many enhanced adherence counselling sessions each person completed	This indicator measures the number of people living with HIV receiving antiretroviral therapy with viral load ≥1000 copies/ml who have partly or fully received enhanced adherence counselling. Poor adherence is often a contributing factor to viral failure among people receiving antiretroviral therapy Country programmes should adapt this indicator to reflect their guidelines for enhanced adherence counselling for people with non-suppressed viral loads.	

ANNEX 5. Health outcome indicators for monitoring viral load scale-up and implementation (continued)

Monitoring question	Indicator	Numerator and denominator	Disaggregation	Data sources and considerations	Programme relevance and importance	Indicator guidance source
What proportion of people receiving antiretroviral therapy with a viral load ≥1000 copies/mL received a follow-up viral load test within six months?	Percentage of people receiving antiretroviral therapy with viral load ≥1000 copies/mL who received a follow-up viral load test within six months after enhanced adherence counselling (or according to national guidelines)	**Numerator:** number of people living with HIV receiving antiretroviral therapy who received a follow-up viral load test within six months after a viral load ≥1000 copies/ml **Denominator:** number of people living with HIV receiving antiretroviral therapy with viral load ≥1000 copies/ml during the reporting period	Demographic: • Age • Sex • Pregnancy • Breastfeeding Aniretroviral therapy regimen • First line • Second line • Third line	High viral load and/or enhanced adherence counselling registers, logbooks or longitudinal tools at sites Laboratory information management system (if a unique patient identifier is implemented and used) Electronic medical records, if available at sites This indicator measures the compliance with retesting people with viral load ≥1000 copies/mL. This is ideally a cohort-based indicator that measures the proportion of people who were due to and actually received a follow-up test in the reporting period The result of the follow-up viral load test can be included as a disaggregation (number of individuals with viral load result <1000 copies/mL and number ≥1000 copies/mL) under this indicator if programmes find it easier to track as a disaggregation and can ensure data quality. If reported this way, viral load results should be collected and reported by demographic disaggregation	This is a quality control indicator to measure the follow-up of people with nonsuppressed viral load who should have received a follow-up viral load test Generally, patients are retested within 3–6 months of a viral load ≥1000 copies/ml and after they have received some enhanced adherence counselling The antiretroviral therapy regimen should be noted so that programmes know which antiretroviral therapy regimen the person with non-suppressed viral loads is currently receiving	
What proportion of **people receiving antiretroviral therapy** with **viral load** ≥1000 copies/mL during the reporting period had a follow-up **viral load test** that showed <1000 copies/ml	Percentage of people **receiving antiretroviral therapy** with **viral load** ≥1000 **copies/mL** who then suppressed to <1000 copies/ml on follow-up testing	**Numerator: number of people living with HIV receiving antiretroviral therapy with follow-up viral load test <1000 copies/ml** **Denominator: number of people living with HIV receiving antiretroviral therapy with a viral load ≥1000 copies/ml during the reporting period and receiving a follow-up viral load test within six months**	Viral load test result by demographic: • Age • Sex • Pregnancy • Breastfeeding Antiretroviral therapy regimen: • First Line • Second Line • Third Line Enhanced adherence counselling completion: • Enhanced adherence counselling 1 • Enhanced adherence counselling 2 • Enhanced adherence counselling 3	High viral load and enhanced adherence counselling registers, logbooks or longitudinal tools at sites Laboratory information management system (if a unique patient identifier is implemented and used) Electronic medical records, if available at sites Including the completion of enhanced adherence counselling as a disaggregation depends on which indicators are selected and how databases are structured to reconstruct the viral load cascade for people whose initial viral load test result was ≥1000 copies/mL (see Fig. 6 in the main text) This indicator can be amended and integrated as a disaggregation under the indicator "Percentage of people receiving antiretroviral therapy with a viral load ≥1000 copies/mL during a 12-month period who received a follow- up viral load test within six months." Please see "Data sources and considerations" under the indicator for more information	This indicator measures the proportion of people with suppressed viral loads after a test result of ≥1000 copies/mL, which helps to measure the potential impact of intervention after a non-suppressed viral load and informs about the prevalence of HIV drug resistance	

ANNEX 5. Health outcome indicators for monitoring viral load scale-up and implementation (continued)

Monitoring question	Indicator	Numerator and denominator	Disaggregation	Data sources and considerations	Programme relevance and importance	Indicator guidance source
What proportion of people receiving antiretroviral therapy with repeat viral load ≥1000 copies/ml switch to second- or third-line antiretroviral therapy regimens?	Percentage of people living with HIV receiving antiretroviral therapy with two documented viral load test results ≥1000 copies/mL switching to second- or third-line antiretroviral therapy regimens	**Numerator:** number of people living with HIV receiving antiretroviral therapy with two consecutive viral load test results ≥1000 copies/mL switching to second- or third-line antiretroviral therapy regimens **Denominator:** number of people living with HIV receiving antiretroviral therapy with two consecutive viral load test results ≥1000 copies/ mL during the reporting period	Demographic: • Age • Sex • Pregnancy • Breastfeeding Antiretroviral therapy regimen: • First Line • Second Line • Third Line Enhanced adherence counselling completion: • Partial completion • Full completion	High viral load and/or enhanced adherence counselling registers, logbooks or longitudinal tools at sites Laboratory information management system (if a unique patient identifier is implemented and used) Electronic medical records, if available at sites	This indicator measures clinical follow-up and management of viral load. This may help to inform forecasting and budgeting for procuring second- and third-line antiretroviral therapy regimens	
What proportion of the people receiving antiretroviral therapy have suppressed viral loads?	Percentage of people living with HIV and receiving antiretroviral therapy who have suppressed viral loads [WHO VLS.3]	**Numerator:** number of people living with HIV receiving antiretroviral therapy who have a suppressed viral load (<1000 copies/mL) **Denominators** **Population-level denominator:** number of people living with HIV who have been receiving antiretroviral therapy for at least six months **Programme-based denominator:** number of people living with HIV receiving antiretroviral therapy who have a viral load test in the past 12 months	Demographic: • Age • Sex • Pregnancy • Breastfeeding	Antiretroviral therapy registers and cross-sectional reports, patient records and electronic medical records Laboratory information management system Population-based survey, such as the HIV impact assessment surveys, that collects data on antiretroviral therapy coverage and viral suppression	With the programme-based denominator, measures suppression of viral loads achieved among all those currently receiving treatment who received a viral load test, regardless of when they started antiretroviral therapy Corresponds to the third 90 of the 90–90–90 targets (90% of the people receiving antiretroviral therapy have suppressed viral loads)	WHO Consolidated strategic information guidelines for the HIV sector *(1)*

REFERENCES

1. Consolidated strategic information guidelines for HIV in the health sector. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/164716/1/9789241508759_eng.pdf?ua=1&ua=1, accessed 8 March 2019).
2. PEPFAR monitoring, evaluation, and reporting indicator reference guide. Washington (DC): PEPFAR; 2015 (http://www.pepfar.gov/documents/organization/240108.pdf, accessed 8 March 2019).

ANNEX 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 a 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 high-quality evaluation reports

10. Disseminate the results

11. Use the findings to improve programmes

Source: PEPFAR evaluation standards of practice 3.0. Washington (DC): PEPFAR; 2017 (https://www.pepfar.gov/reports/guidance/c61317.htm, accessed 8 March 2019).

ANNEX 7. DIFFERENCES BETWEEN TYPES OF EVALUATION AND OPERATIONS RESEARCH[a]

Type	Description	Examples of questions	Use of results
Process evaluation	Determines whether the programme is reaching the right target populations, how a programme is being implemented and what factors help or hinder programme implementation to inform programme planning and development and take corrective action	• Were target populations reached? Why not? • Was the programme implemented as planned? Why? What worked? What did not work? • What were the kinds of problems encountered in delivering the programme – 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 programme design? Is there skill at facilitating the programme processes from beginning to end? Was there adequate support for the programme?	• Decision-making • Resource allocation • Programme improvement • Understand how programme impact and outcome were achieved (programme implementation) to inform programme replication
Outcome evaluation	Determines whether and by how much intended short-term, intermediate and long-term programme effects have been achieved in the target populations or organizations after implementing a programme or intervention. Short-term outcomes are the initial expected changes (such as knowledge, awareness, attitudes and skills). Intermediate outcomes are the interim changes (such as behaviour, policy, norms, coverage and quality) that provide a sense of progress toward reaching long-term outcomes. Long-term outcomes or impact includes changes in the ultimate programme goals (such as mortality and morbidity)	• Were the intended effects (outcomes) achieved? What contributed to that? • Was the programme more successful with certain groups of people than with others? • What aspects of the programme did participants find gave the greatest benefit? • Did implementing the intervention result in changes in knowledge, attitudes and skills among the members of the target population? • Did the programme have any unintended (beneficial or adverse) effects on the target populations? • How has the intervention changed the quality of services?	• Decision-making • Resource allocation • Programme improvement • Determine whether programme effectiveness has been demonstrated and whether the programme 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). Impact evaluation is based on models of cause and effect and requires a rigorously defined counterfactual scenario to control for factors other than the intervention that might account for the observed change.	• What could have happened in the absence of the programme or intervention?	• Decision-making • Resource allocation • Compares what actually happened and what would have happened in the absence of the intervention
Economic evaluation[a]	Systematic way to identify, measure, value and compare the costs and consequences of various programmes, policies or interventions. Assesses the cost factors related to various interventions, enabling potential strategies to be compared	• How do the costs compare across the interventions or settings? • Which model is the most cost-effective?	• Decision-making • Resource allocation • Reviews programme effectiveness with economic resources (such as cost and benefit) to inform budgetary planning

[a] Dunet D. CDC coffee break: introduction to economic evaluation [slide presentation]. Atlanta: United States Centers for Disease Control and Prevention; 2012 (http://www.cdc.gov/dhdsp/pubs/docs/cb_january_10_2012.pdf, accessed 8 March 2019).

Annex 7 (continued)

Type	Description	Examples of questions	Use of results
Operations research	Operations research aims to develop solutions to current operational problems of specific health programmes or specific service delivery components of the health system, such as 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 the operational relevance of the research activities and rapid uptake and local use of research findings.[b]	• How can interventions that have shown to be effective in a small scale be best generalized for widespread and sustainable use? • How can existing or new programme strategies best be implemented? (similar to process evaluation)	• Improve service delivery or to strengthen other aspects of programmes • Focus attention and resources on problem solving • Integrate and disseminate solutions into programmes

[b] Remme JHF, Adam T, Becerra-Posada F, D'Arcangues C, Devlin M et al. Defining research to improve health systems. PLoS Med. 2010;7:e1001000.

Sources: adapted from: Salabarría-Peña Y. Difference between monitoring, program evaluation, operational research, health services research and public health evaluations. Unpublished, 2008.

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