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MINISTRY OF HEALTH

Guidance to the Operational Implementation of HIV Viral Load Routine Testing

August, 2017

National Center for HIV/AIDS, Dermetology and STD

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Acknowledgement

The guidance was prepared based on the National HIV clinical management guidelines for Adults and Adolescents, officially approved by the ministry of health, dated on 09 August, 2016. This document will provide details guidance on clear description of Its implementation process, supply chain management, co-ordination, and monitoring and evaluation.

The National Center for HIV/AIDS, Dermatology and STD (NCHADS) would like to express its appreciation and thank all relevant NCHADS Units including AIDS Care, Laboratory and Data Management; and development partners including WHO and US-CDC who actively contributed to the successful development of the Guidance to the Operational Implementation of HIV Viral Load Routine Testing for the use in Cambodia.

Our special thank to Mr. Mam Sovatha, Dr. Samreth Sovannarith, Dr. Ngauv Bora, Dr. Kaoen Chetra, Mr. Mom Chandara , Dr. Laurent Ferradini, Dr. Deng Serongkea, Dr. Lori Newman, Dr. Ahmed Saadani, Dr. Chan Sodara, Mr. Hy Chayly and Ms. Soch Kunthea for taking their effort in coordinating and revising for this important guidance.

Phnom Penh, 07 / Sept. / 2017
Director of NCHADS

Dr. Ly Penh Sun

1. Introduction

Cambodia has made great progress in responding to HIV epidemic. HIV prevalence in general population aged 15-49 years was estimated to decline from 1.6% in 1998 to 0.6 in 2015 (AEM-SPECTRUM). Number of HIV infected patients on ART increased from 71 in 2001 to 54,769 by the end of 2015 (NCHADS ART Report). Rapid scale up of ART service started in 2003 when NCHADS and partners introduced and expanded the continuum of care (CoC) model for people living with HIV (PLHIV).

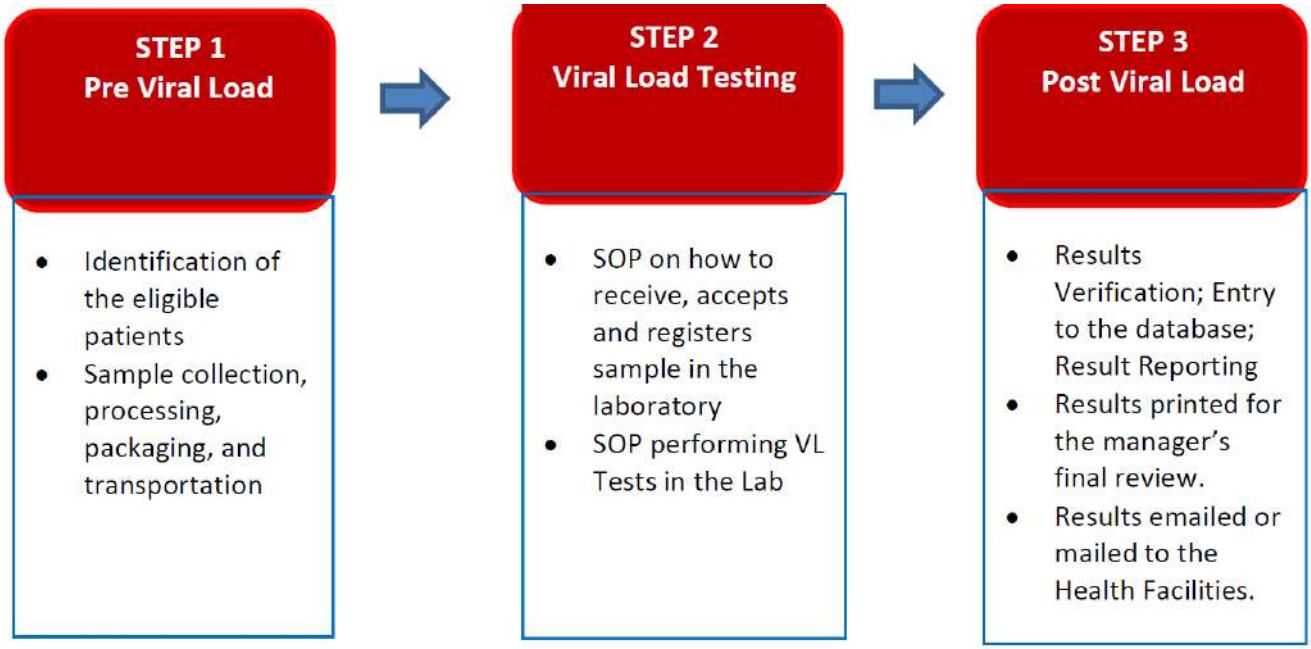
NCHADS started the viral load testing program to support the scaled-up ART program in 2011. However, the use of viral load testing was first only limited to the identification and management of treatment failure. The 2012 Cambodia ART guidelines recommended routine viral load testing for ART monitoring. The implementation of routine viral load testing started in 2013, prioritizing patients enrolled in the ART cohort for the longest time.

Remarkable increase in viral load testing among ART cohort patients has been observed in the last few years. The number of viral load tests increased from 9,290 in 2013 to 22,027 in 2014, and to 37,568 in 2015 (NCHADS Laboratory Report). This figure, although showed a progress in scaling up viral load tests, indicates the need for further efforts to increase viral load testing coverage to support the last 90 of the 90-90-90 global and national targets.

This document provides guidance to ART teams and stakeholders in implementing and scaling up viral load tests to support the ART program. It describes the implementation process, supply chain management, co-ordination, and monitoring and evaluation for viral load tests in Cambodia.

2. Process for the Implementation of HIV1-Viral Load Tests

In Cambodia, viral load testing usually start when HIV clinicians make a request for the test to monitor the effectiveness of ART in their HIV infected patients. Upon request by HIV clinicians, blood samples are drawn from patients and transported to a laboratory for running the viral load tests. The test results are then sent back to ART sites where they are evaluated and used to guide treatment. Therefore, the process and arrangement for HIV viral load testing can be divided into 3 steps, including pre-viral load test (step 1), viral load test (step 2), and post-viral load test (step 3).



2.1 Step 1: Pre-viral Load Test

This step refers to necessary arrangement or activities occurring before samples arrive at a laboratory where the viral load tests are performed.

2.1.1 Identification of the eligible patients

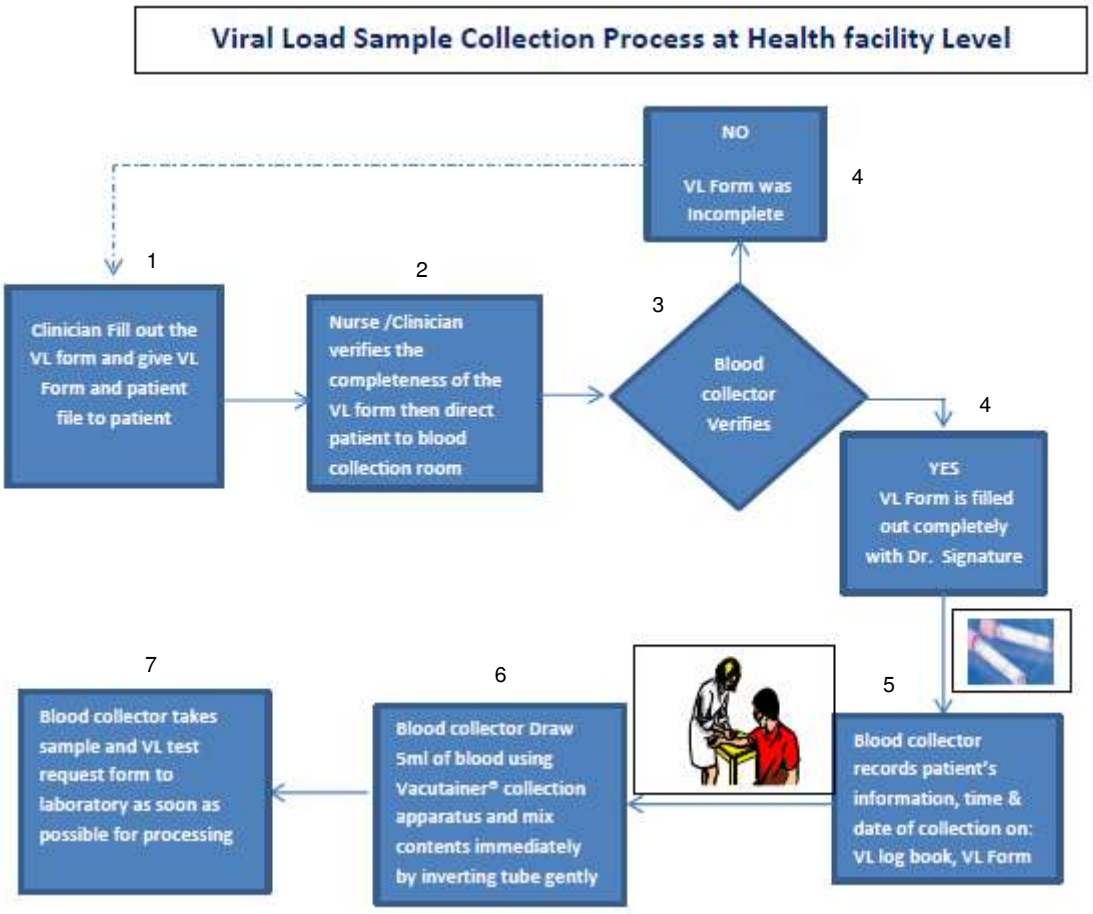
The eligibility criteria for HIV viral load testing are defined in the National ART Guidelines. The most updated Cambodia ART guidelines recommend routine HIV viral load monitoring testing as follows: 6 months after ART initiation, 12 months after ART initiation, and then annually after starting ART (Annex 1 - viral load monitoring algorithm).

In addition, HIV viral load testing can be requested for suspected treatment failure and management of patients. HIV viral load testing can also be requested for HIV-infected pregnant women who are at high risk of transmitting HIV to their exposed babies (please see national ART and PMTCT guidelines for more information).

At every visit, ART patients should be assessed for the viral load testing eligibility criteria, as documented in the patient form (Annex 2). The assessment should be done by ART clinicians, but supportive staff such as data entry officers, PLHIV peer counselors, and ART nurse counselors may help to identify patients who are eligible for routine viral load monitoring testing. Those who are eligible, should be prescribed the viral load test during the visit.

2.1.2 Sample collection

ART patients who are required to be tested for viral load should obtain and carry their patient files and the completed laboratory request form with them when going to the sample collection room.



- Every ART site should have a room or a designated area for blood collection that provides privacy, comfortable space, and safety for staff and patients. Staff responsible for sample collection should be trained before performing this task.
- SOPs & job aides for sample collection should be available. Viral Load Sample Collection and Shipment to Testing Laboratory at Health facility Level form (Annex 3) must be available at site.
- Every viral load test should be requested by HIV clinicians using a standard laboratory request form provided by NCHADS (Annex 4). The form should be fully completed and signed by the clinician. If a barcode sticker is available, it should be placed on the appropriate space indicated in the form. If barcode label is not available, the full patient clinic ID or ART number should be clearly written on the box provided in the form.

- At the consultation, the clinician fills out the test request form and provides the patient's file to patient. The Nurse or clinic personnel indicates where the patient should go for blood collection. The Nurse or clinic personnel verifies the completeness of the test request form and adds any missing information.
- The patient brings the test request and the patient's file to the sample collection site. The staff collecting the blood ensures that the VL test request form is complete with clinician's signature and contact information. If the test request form is not completely filled out, blood should not be collected and the patient should return to the clinic to obtain the missing information.
- Blood collection staff records the individual patient's necessary information in a standard viral load test "Sample Collection Form" provided by NCHADS (Annex 3).
- Blood collection staff verifies the information written on the request form, the patient file, and on the tubes to make sure that all the information are correctly matched.
- Following patient preparation per standard SOP for blood collection, use 5ml BD Vacutainer® Plasma Preparation Tubes (PPT™), or 5ml BD Vacutainer® EDTA tubes and Vacutainer® apparatus for blood collection. If the barcode is available, stick the barcode taken from the patient file on the tube. If the barcode is not available, write the patient's clinic ID or ART number and the patient's name on the tube using a permanent marker pen. Draw **5ml** of blood using Vacutainer® collection apparatus and mix contents **immediately by inverting tube gently back and forth 8-10 times**.
- The staff who collects the blood, takes the sample and the test request form to the laboratory as soon as possible for processing. The staff might collect the blood from a few patients before taking a batch of samples to the laboratory.

2.1.3 Sample processing and storage at site level

- Laboratory staff verifies the quality of the sample and the completeness of the test request form before registering the sample in the standard sample receipt's logbook provided by NCHADS (Annex 5). In case the sample does not meet the acceptance criteria, it will not be accepted by the laboratory. The sample rejection will be documented in the logbook and sample and test request form will be returned to the clinic.

- As soon as possible following blood collection and **up to six hours**, plasma shall be separated from cells by centrifugation **at 250g or 2500rpm/10 minutes**. In case of using a regular Vacutainer® blood collection tube with EDTA, plasma sample is transferred to a new vial after centrifugation. Alternatively, plasma can be maintained in the PPT™ after centrifugation, as a gel keeps plasma and cells separated. Samples can be stored at 2-8°C for up to one week, until batches of samples are transported to VL testing laboratory.
- Test request forms are kept in a safe location until samples are transported for VL testing.

2.1.4 Sample Transport

- Laboratory staff annotates on Viral Sample Tracking Form (Annex 6) date and time of sample pickup and name of person transporting the samples.
- Specimen transportation routes and schedules from ART clinics/laboratories to NCHADS and Siem Reap laboratories should be arranged. Courier information is documented at laboratory referring the samples and at NCHADS Lab.
- A specific SOP for sample packaging and transportation, based on guidelines for clinical specimens, detailing the following:
    - Responsible couriers for each route with contact numbers
    - Days and times of sample pick up from ART clinic/laboratory
    - Days and times of sample delivery to laboratory
    - Packaging instructions (double packaging)
    - Safety procedures in the event of spills and broken sample tubes
    - ART clinic and laboratory contact numbers for emergencies or other problems
- Include sample batch list and test request forms inside container, protected by a plastic cover
- As a rule, **sample collection on Fridays should be avoided** unless the sample package can reach VL testing sites before 10:00 AM.
- **Courier operators must be trained** in how to manage spills and how to prevent excessive shaking and exposure to sun light/heat during transport as per contract.

2.2 Step 2: HIV1- Viral Load Test

- A SOP describes how the laboratory staff receives, accepts, and registers samples in the viral load Logbook (refer to Laboratory SOP). This SOP includes:
    - Specimen acceptance/rejection criteria
    - Sample registration in electronic database
    - Laboratory number assignment
    - Storage and disposal of test request forms
    - Sample storage and disposal
- The procedures describe how to perform the VL test is in a separate laboratory SOP. This SOP includes:
    - How to prepare samples for testing
    - How to set up instrument for run
    - How to load samples in instrument
    - How to retrieve results
    - How to dispose consumables, reagents, and clean up instrument after run
    - How to troubleshoot problems
    - How to perform instrument's maintenance
    - How to export results from the instrument to the laboratory database
- After the run, technician analyzes results to check for any invalid results. If invalid results have occurred, error codes are analyzed and corrective actions are performed to remediate problems

2.3 Step 3: Post HIV-1 Viral Load Test

- After VL run is verified for valid/invalid results, the results of each run are exported as an Excel file and saved on a storage medium with the name and date of the run.
- The storage medium is inserted in a computer running the database and results are transferred. The date of each run is entered in the database.
- Another authorized technician reviews results to avoid transcription errors.
- Results are printed for laboratory's manager final review and signature on test reporting forms.

2.3.1 Delivery and use of viral load result

- Viral load results are reported to ART sites in copies and log/ml, using a standard viral load result form (Annex 7). Printed individual results with the signature of laboratory's manager can be sent to ART sites by courier or can be picked up by assigned persons who bring the blood sample to the laboratory. The result can also be reported to ART sites by email in PDF file.
- ART sites should assign a person to follow up and support the management of VL results. The assigned person should ensure that their site gets the VL results from Laboratory and that the results are documented in patients' file.
- When the results arrive ART sites, the assigned person should alert clinicians on detectable viral load results. For detailed information on how to interpret viral load result to improve patient outcome and actions to be taken refer to viral load algorithm in Annex 1.

3. Supply Chain Management

3.1. The Forecasting at the National Level

By using the current laboratory commodity quantification system (Excel tool), LMU forecasts for viral load reagent and consumables as required by GF to meet the grand budget period. From previous costing exercise it is expected that the viral load volume for 2016 is 40,840 and 2017 is 43,630 at NCHADS and Siem Rep laboratory (See Table below):

Approximate testing volumes at the two VL/EID sites are as follows: Based on number of patients

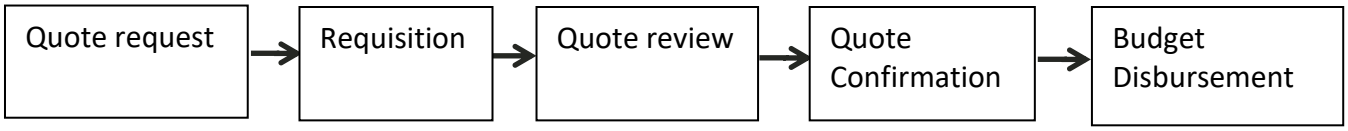
	Lab	2015 expected	2016 expected	2017 expected	2018 expected	2019 expected	2020 expected
VL	PP	34,893	40,840	43,630	35250	37500	39750
	Siem Reap				11750	12500	13250
	Siem Reap				405	405	405
TOTAL		36,620	46,620	46,620	48,620	51,620	54,620

3.2 The Forecasting at the Site Level

Site estimate their need for consumables such as tubes, catheters, etc. related to routine viral monitoring using the national algorithm in Annex 1 and their present active ART patients.

3.3 Ordering and procurement procedure for viral load reagents

The ordering and procurement of viral load reagents consist of four steps:



3.3.1. Requisition: The Logistics Management Unit (LMU) at NCHADS performs the quantification of the viral load reagents using Excel laboratory quantification tool four times per year to avoid expired stocks due to short self-life of viral load reagents. LMU sends the requisition to Procurement Unit at NCHADS.

3.3.2. Quote request: Procurement Unit will communicate directly to the supplier (Abbott) to get the quotation and share with LMU, NCHADS laboratories.

3.3.3. Quote review: LMU, NCHADS and Lab review the specifications and shelf life for all the requested items in the quote and respond to the Procurement Unit.

3.3.4. Quote confirmation and budget disbursement: Procurement Unit confirms the quote and sends the official purchase order to the supplier and then requests Finance Unit to disburse the required funds to the supplier's account after shipment of goods arrived. Once the commodities are arrived and cleared by the NCHADS and the local cleaning agent, the viral load commodities (Abbott reagents and proprietary consumables) are directly delivered to NCHADS and laboratories.

4. Viral load Testing Coordination

At national level, relevant Units of NCHADS, including AIDS Care Unit (ACU), Data Management Unit (DMU), and Lab Unit (LU) are jointly responsible for coordinating the implementation of VL scale up activities with the support and guidance of the TWG on care and treatment and the TWG on laboratory. Progress in VL scale up and rational use of VL tests will be overseen by these TWG. At provincial and site level, B-IACM co-ordination mechanism should be used to support the implementation of VL scale up activities.

5. Viral Load Testing Monitoring Framework

Monitoring the continuum of the HIV response is critical for tracking performance towards achieving goals ensuring high quality of care and optimal clinical outcomes, and improving services for HIV-infected individuals.

As countries scale-up viral load testing and track viral suppression in people living with HIV (PLHIV) on antiretroviral therapy (ART), monitoring and evaluation (M&E) plans need to measure the success of program implementation and clinical outcomes. Utilizing routine viral load (VL) M&E data and systems for VL testing requires coordination, collaboration, and communication between a) laboratory, clinical, and M&E staff, b) data systems at facilities, laboratories, and above-site levels, and c) data capture/M&E tools. Clarity on data flow, data elements, and indicators for VL monitoring is required for strong M&E plans.

WHO and various stakeholders recently developed "Consolidated Strategic Information (SI) Guidelines for HIV in the Health Sector." The document highlights the importance of monitoring the HIV cascade and reaching ambitious UNAIDS targets known as 90-90-90 to ensure that 90% of PLHIV know their status, 90% of PLHIV are on ART, and 90% of those on ART are virally suppressed. **Figure 1** illustrates the HIV cascade, the key cascade indicators, and the UNAIDS 90-90-90 targets.

The routine monitoring indicators should reflect how well the country is implementing VL scale-up and progressing towards the third 90.

Table 1 illustrates this approach and presents a recommended list of core indicators for routine VL monitoring, including monitoring of patients with a VL >1000 copies/m. Some indicators are dependent upon the completion of multiple steps in the cascade, in which case the indicator is listed with the step that is furthest along in the sequence.

A more comprehensive list of indicators for the country to consider and more details about each indicator, including defined numerators and denominators is shown below.

Table 1: Core Indicators for VL M&E along VL Testing Cascade

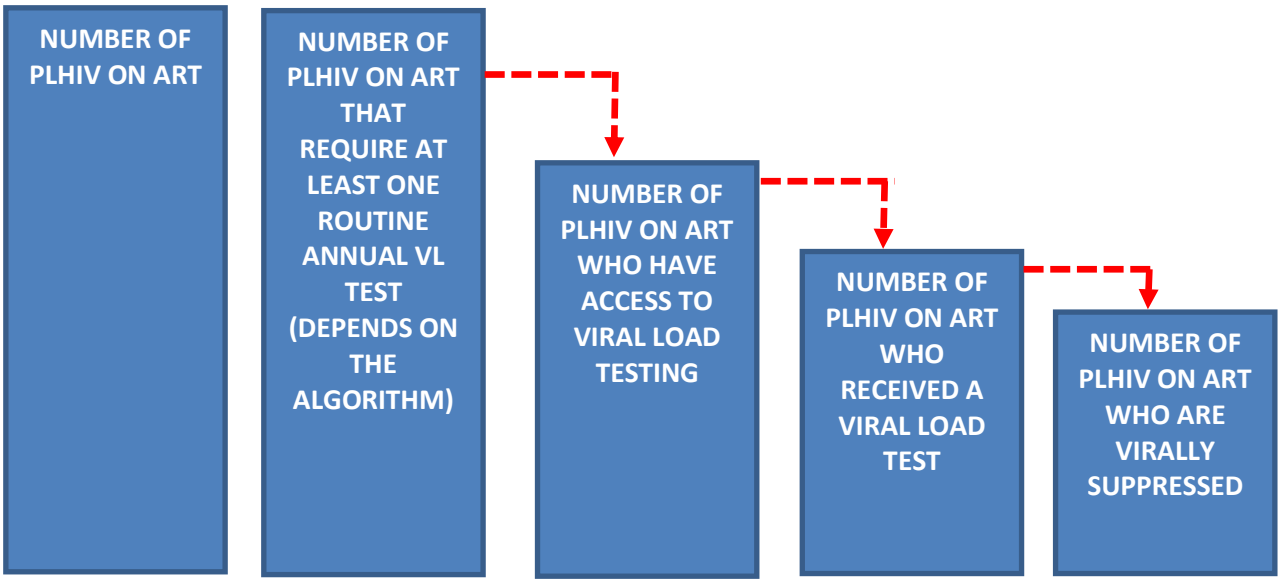
KEYS STEPS IN THE CASCADE OF VL TESTING	CORE INDICATORS FOR ROUTINE MONITORING
Process VL Test Sample	• # of samples for VL tests received by lab from sites
Receive VL Test Result	• % of VL tests results returned to sites
Document VL Test Result	• % of people on ART with VL results at 6months after ART initiation • % of people on ART tested for VL with VL level <1,000 copies at 12 months after ART initiation
Intervene on VL Test Result if VL≥1000 copies/ml	• % of people on ART with non-suppressed VL who have received enhanced adherence counselling (EAC)
Order Follow-up VL Test if VL≥1000 copies/ml	• % of people on ART with non-suppressed VL who received a follow-up VL test within 3-6 months • % of people on ART who were non-suppressed and then suppressed to VL <1000 copies/ml on follow-up testing
Modify ART regimen after two consecutive results of VL≥1000 copies/ml	• % of PLHIV on ART with two documented VL test results ≥ 1,000 copies/mL switched to 2nd or 3rd line ART regimens

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

- **Coverage and outcomes of routine VL testing (figure 1)**:

This cascade tracks the number of individuals' current on ART who received a VL test, had a result documented in the medical record, and were found to be virally suppressed.

Figure 1: Cascade of Viral Load Testing and Key Indicators to Track Virally Suppressed Patients



- **Follow-up of patients that are not virally suppressed (figure 2, and 3):**

Figure 2: VL cascade for patients whose initial VL test result VL≥1000 copies/mL

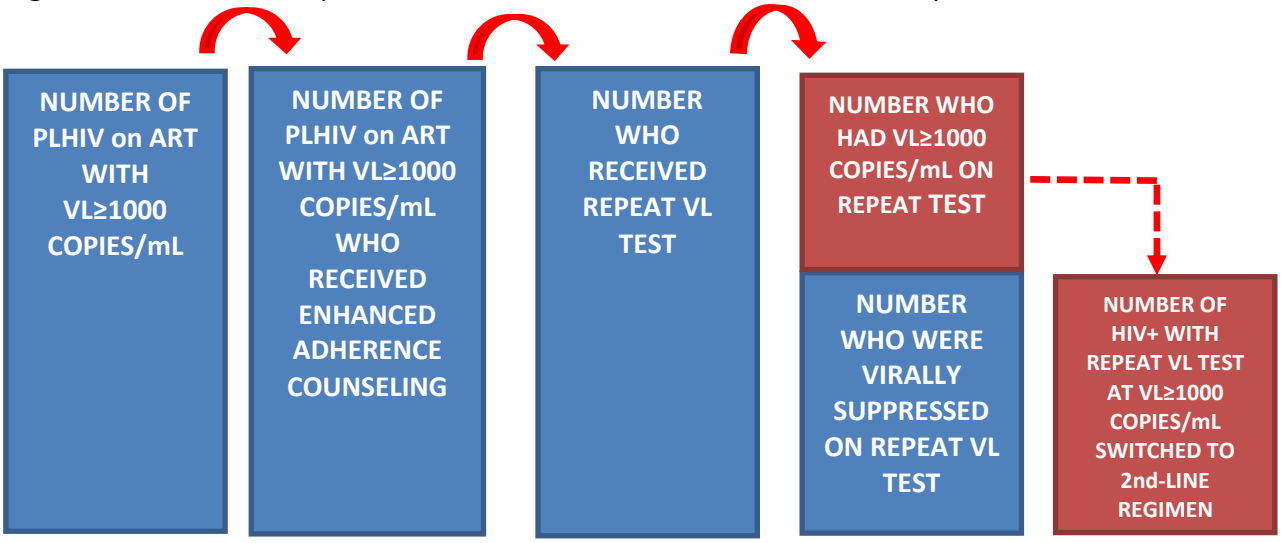
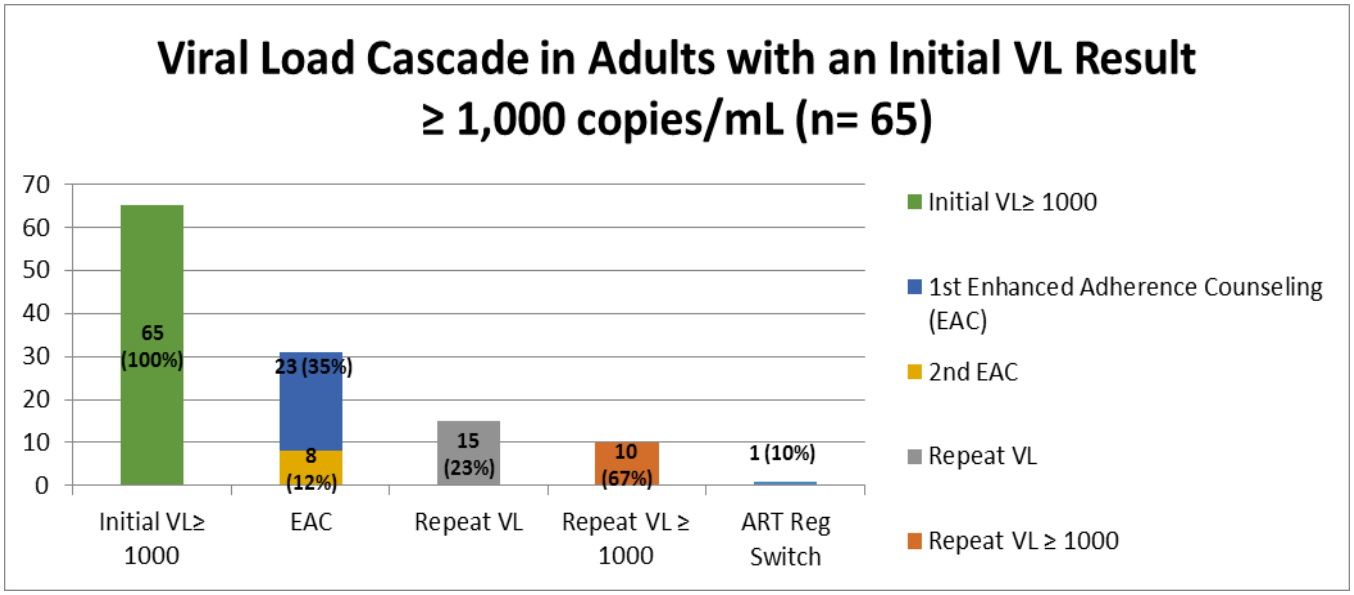


Figure 3: Example VL cascade and interventions for detectable VL



This cascade tracks the number of individuals with a VL result above the threshold (e.g., VL ≥1000 copies/mL) and how many received enhanced adherence counseling (EAC) and a follow-up VL test, and were either suppressed or non-suppressed on follow-up testing. It also tracks whether the follow-up test led to a switch in ART regimen.

6. List of Indicators:

Indicator # 01	**% (Volume) of VL samples received at the lab from ART sites**
Definition	% of unique VL samples received at the lab, from ART sites
Rationale/Purpose	This indicator allows programs to track progress at the site-level and above in scaling-up coverage of VL testing at the site level. This indicator will provide data from sites and various populations (e.g., adults, adolescents, children, pregnant, breastfeeding) reasons if a site is submitting a low proportion of samples; for example, track the number of VL samples submitted with respect to current number of patients on ART or expected number of VL tests per period and explore reasons if proportion is low It will be important to ensure that the numerator and denominator are both tracking data for individuals to analyze the proportion. It is recognized that it may be challenging to track samples for unique individuals; however, accurate data for this indicator will support programs to monitor scale-up of coverage and inform forecasting of commodities etc.
Numerator	# of unique VL samples submitted by sites to the lab/specimen transport network
Denominator	# of PLHIV on ART
Disaggregation(s):	• Age/Sex: <15 Male, 15+ Male, <15 Female, 15+ Female • Type of VL sample: -DBS -Plasma
Data Source	NCHADS VL Sample Daily Log/database
Method of measurement	Data for this indicator can be collected from the labs processing VL testing in the country. For the analysis, compare, ART site by ART site, the number of VL submitted to the number of VL anticipated based on the number of ART patients who are eligible for VL testing in the reporting period
Interpretation	This indicator will provide data from sites and various populations (e.g., adults, adolescents, children, pregnant, breastfeeding) reasons if a site is submitting a low proportion of samples; for example, track the number of VL samples submitted with respect to current number of patients on ART or expected number of VL tests per period and explore reasons if proportion is low It will be important to ensure that the numerator and denominator are both tracking data for individuals to analyze the proportion. It is recognized that it may be challenging to track samples for unique individuals; however, accurate data for this indicator will support programs to monitor scale-up of coverage and inform forecasting of commodities etc.
Responsibility	ART sites and Labs performing VL testing
Frequency	Quarterly or bi-annually

Indicator # 02	**Proportion of VL samples is rejected for processing by each lab processing VL testing**
Definition	Percentage of VL samples rejected by each lab processing VL testing
Rationale/Purpose	This indicator will account for tests collected and received that were rejected at the lab and not processed and reasons for rejection. It will help inform the expected number of VL test results to be returned to sites.
Numerator	# VL samples rejected at each lab processing VL testing
Denominator	# VL samples received at each lab processing VL testing
Disaggregation(s):	Lab level: Type of VL sample: -DBS -Plasma Reason for VL Test: -Routine VL -Targeted (i.e. Suspected Treatment Failure) -Follow-up VL (after a previous VL≥1000 copies/ml) -Other Demographic: • Age/Sex: <15 Male, 15+ Male, <15 Female, 15+ Female • Type of VL sample: -DBS -Plasma
Data Source	NCHADS VL Sample Daily Log/database
Method of measurement	
Interpretation	This indicator will account for tests collected and received that were rejected at the lab and not processed and reasons for rejection
Responsibility	ART sites and Labs performing VL testing
Frequency	Quarterly or bi-annually

Indicator # 03	% (volume) of VL test results returned to and documented at ART sites within the lab/specimen network
Definition	% of VL test results received at sites
Rationale/Purpose	One of the common challenges is that results are returned to sites, but not documented or acted upon at sites. This will allow programs to track the receipt of test results at sites. This can be examined during service and data quality assessments and/or during routine site visits.
Numerator	# of VL test results received and documented at site
Denominator	# of VL test results received at ART site
Disaggregation(s):	Site name Type of VL sample: -DBS -Plasma
Data Source	Patient Charts, ART and/or VL Testing Registers at sites VL Sample Daily Log at sites
Method of measurement	Compute for percentage using numerator and denominator above
Interpretation	This indicator will track the proportion of VL results that were received at sites. This will inform the process of addressing specific challenges across the VL cascade
Responsibility	ART sites
Frequency	Quarterly or biannually

Indicator # 04	% (volume) of VL test results returned and received at ART sites within the lab/specimen network
Definition	% of PLHIV on ART with a VL result documented in the medical record within the past 12 months
Rationale/Purpose	One of the common challenges is that results are returned to sites, but not documented or acted upon at sites. This will allow programs to track the receipt of test results at sites. This can be examined during service and data quality assessments and/or during routine site visits.
Numerator	# of VL test results received at site
Denominator	# of VL samples that were sent to lab for testing
Disaggregation(s):	Site name Type of VL sample: -DBS -Plasma
Data Source	Patient Charts, ART and/or VL Testing Registers at sites VL Sample Daily Log at sites
Method of measurement	Compute for percentage using numerator and denominator above
Interpretation	This indicator will track the proportion of VL results that were received at sites. This will inform the process of addressing specific challenges across the VL cascade
Responsibility	ART sites
Frequency	Quarterly or bi-annually

Indicator # 05	% of people on ART who had VL monitored at 6 months
Definition	% of people on ART who had VL monitored at 6 months
Rationale/Purpose	This indicator tracks coverage and outcomes of early VL testing of patients on ART at 6 months. This indicator assesses the extent to which VL is available in the country. By 6 months after ART initiation, all patients on ART should have received at least one VL test. This indicator also monitors VL suppression of patients 6 months after initiation on treatment. VL suppression is a disaggregation of this indicator. This may be examined during service quality assessments or site visits, if not collected routinely.
Numerator	Number of PLHIV who had their VL measured at 6 months after ART initiation
Denominator	# of PLHIV who initiated ART 6 months before the start of the reporting period
Disaggregation(s):	• Age/Sex: <15 Male, 15+ Male, <15 Female, 15+ Female • VL Suppression: Of those tested, # that had VL<1000 copies/mL by age/sex • Recommended: <1, 1-<5, 5-<10, 10-<15, 15-<20, 15+ • Recommended: By Key populations: SW, MSM, and PWID in concentrated and mixed epidemics only.
Data Source	ART database/ART register
Method of measurement	Data for this indicator can be collected from the ART registers/patient records from all ART facilities/clinics. For the analysis, sort it by latest 6 months, before the beginning of the reporting period
Interpretation	VL is expected to be suppressed 6 months after treatment initiation
Responsibility	Provincial HIV Program/NCHADS
Frequency	Bi-annually or annually

Indicator # 06	**% of adult (who were) on ART, who received viral load testing, at least once in the last 12 months**
Definition	The percentage of adult (who were) on ART for 12 months who received viral load testing at least once per year.
Rationale/Purpose	this indicator with the result for 'number of PLHIV active on ART by the end of the reporting period', can be used to estimate viral load testing coverage
Numerator	Number of adults who have been active on ART by the end of the reporting period, who received viral load testing at least once in the last 12 months.
Denominator	Total number of adult PLHIV who have been on ART for over 12 months.
Disaggregation(s):	• Age/Sex: <15 Male, 15+ Male, <15 Female, 15+ Female • Recommended: <1, 1-<5, 5-<10, 10-<15, 15-<20, 15+ • Recommended: By Key populations: SW, MSM, and PWID in concentrated and mixed epidemics only.
Data Source	ART database
Method of measurement	Data for this indicator can be collected from the ART registers/patient records from all ART facilities/clinics. For the analysis, sort it by latest records as of the end of the reporting period (all patients who initiated AR, since the beginning of the program/recording)
Interpretation	If the value of this indicator is low, assess the reasons of the low coverage.
Responsibility	Provincial HIV Program/NCHADS
Frequency	Bi-annually or annually

Indicator # 07	**% of PLHIV on ART tested for viral load with suppressed viral load <1000 copies /ml in the last 12 months**
Definition	% of PLHIV on ART tested for viral load with suppressed viral load <1000 copies /ml in the last 12 months.
Rationale/Purpose	To assess the progress toward viral suppression, which is the outcome of effective ART treatment.
Numerator	Number of PLHIV on ART tested for viral load with suppressed viral load <1000 copies /ml in the last 12 months
Denominator	Total number of PLHIV on ART tested for viral load in the last 12 months.
Disaggregation(s):	• Age/Sex: <15 Male, 15+ Male, <15 Female, 15+ Female • Recommended: <1, 1-<5, 5-<10, 10-<15, 15-<20, 15+ • Recommended: By Key populations: SW, MSM, and PWID in concentrated and mixed epidemics only.
Data Source	ART database
Method of measurement	Data for this indicator can be collected from the ART registers/patient records as of the end of the reporting period from all ART facilities/clinics. For the analysis, sort it by latest 12 months.
Interpretation	This indicator measures viral suppression, which has a significant impact on patient survival, morbidity, and ongoing transmission of HIV.
Responsibility	Provincial HIV Program/NCHADS
Frequency	Bi-annually or annually

Indicator # 08	**% of people on ART tested for viral load (VL) with VL level <1,000 copies at 12 months after ART initiation**
Definition	% of people on ART tested for viral load (VL) with VL level <1,000 copies at 12 months after ART initiation
Rationale/Purpose	This indicator will allow programs to monitor VL suppression of patients 12 months after initiation on treatment and also to estimate the percent of PLHIV who are virally suppressed.
Numerator	# of PLHIV on ART with VL<1000 copies/ml at 12 months after ART initiation
Denominator	# of PLHIV and on ART with VL test result available at 12 months
Disaggregation(s):	• Age/Sex: <15 Male, 15+ Male, <15 Female, 15+ Female • Recommended: <1, 1-<5, 5-<10, 10-<15, 15-<20, 15+ • Recommended: By Key populations: SW, MSM, and PWID in concentrated and mixed epidemics only.
Data Source	ART database
Method of measurement	Program records, e.g. ART and/or VL testing registers, cohort reporting forms, patient medical records. This data is based on a cohort of patients alive and on ART who are virally suppressed 12 months following their initiation on treatment.
Interpretation	This indicator measures viral suppression, which has a significant impact on patient survival, morbidity, and ongoing transmission of HIV.
Responsibility	Provincial HIV Program/NCHADS
Frequency	Bi-annually or annually

Indicator # 09	**% of PLHIV with detectable VL who have received enhanced adherence counselling (EAC) and support (EAC 1, 2 and 3)**
Definition	% of PLHIV with detectable VL who have received enhanced adherence counselling three times with one month interval (EAC) and support (EAC 1, 2 and 3)
Rationale/Purpose	EAC is key to salvaging existing regimens and minimizing the risk of HIVDR, factor to virological failure in ART patients.
Numerator	Number of PLHIV with detectable VL who have received enhanced adherence counselling (EAC) and support
Denominator	Number of PLHIV with detectable VL, throughout the 3-6 month period of time prior to the beginning of the current reporting period
Disaggregation(s):	• Age/Sex: <15 Male, 15+ Male, <15 Female, 15+ Female • EAC Completion: Attended EAC#1, Attended EAC #2, Attended EAC#3 • Recommended: <1, 1-<5, 5-<10, 10-<15, 15-<20, 15+ • Recommended: By Key populations: SW, MSM, and PWID in concentrated and mixed epidemics only.
Data Source	ART database/High viral load register
Method of measurement	Data for this indicator can be collected from the ART registers/patient records. For the analysis, sort it by latest records as of the end of the reporting period, up until 3 to 6 months before the beginning of the reporting period
Interpretation	This indicator measures the promptness/timeliness to take action, per indicated protocol, in addressing High VL results
Responsibility	Provincial HIV Program/NCHADS
Frequency	Bi-annually or annually

Indicator # 10	**Percentage of people on ART with a VL ≥ 40 copies/mL during a 12-month period who received a follow-up VL test within 6 months**
Definition	Proportion of ART patients with a VL ≥ 40 copies/mL during a 12-month period received a follow-up VL within 6 months
Rationale/Purpose	Quality Indicators monitors the adequate and prompt VL testing follow-up and effective receipt of results, to maximize the chances to salvage the current regimen
Numerator	# of PLHIV on ART who received a follow-up VL test within 6 months after a VL≥ 40 copies/ml
Denominator	of PLHIV on ART with VL≥ 40 copies/ml during 12-month period

Disaggregation(s):	• Age/Sex: <15 Male, 15+ Male, <15 Female, 15+ Female
	• VL result: Of those who received a follow-up VL test within 6 months,
	  ○ # that had VL≤40 copies/mL, by age/sex
	  ○ that had VL between 40 and 1000 copies/mL, by age/sex
	  ○ # that had VL≥1000 copies/mL, by age/sex
	• Recommended: <1, 1-<5, 5-<10, 10-<15, 15-<20, 15+
	• Recommended: By Key populations: SW, MSM, and PWID in concentrated and mixed epidemics only.

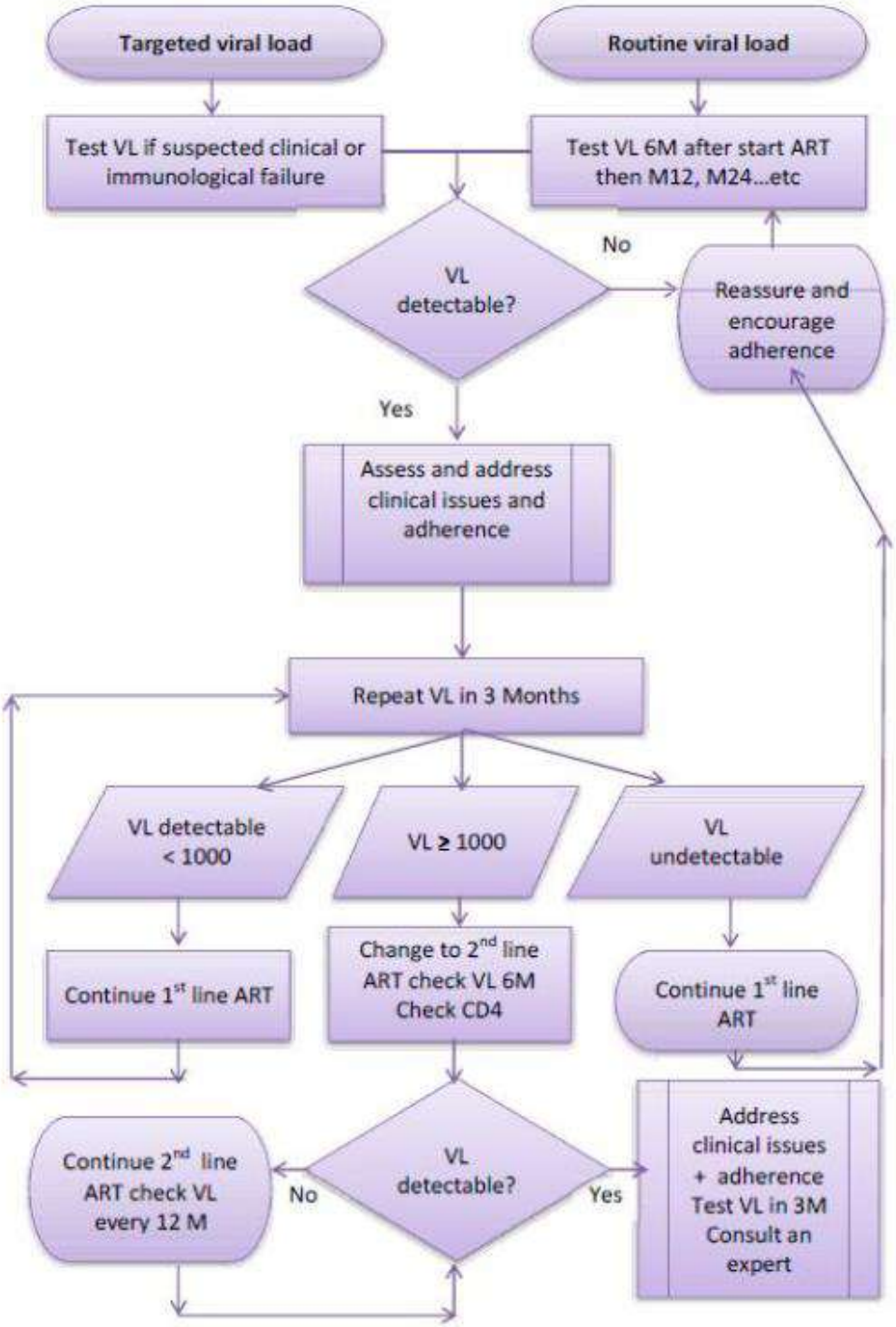
Data Source	ART database
Method of measurement	Data for this indicator can be collected from the ART registers/patient records from all ART facilities/clinics. For the analysis, sort it by latest records as of the end of the reporting period, up until 3 to 6 months before the beginning of the reporting period
Interpretation	This indicator measures the promptness/timeliness to take action, per indicated protocol, in addressing High VL results This indicator measures also the proportion of patients whose VL goes back to an undetectable status after a VL test result of ≥1000 copies/ml. This helps measure the potential impact of intervention after a non-suppressed viral load. This also informs the prevalence of HIV Drug Resistance (HIVDR).
Responsibility	Provincial HIV Program/NCHADS
Frequency	Bi-annually or annually

Indicator # 11	(%) of ART patients with two documented VL test results ≥ 1,000 copies/mL switched to 2nd
Definition	Number of ART patients with two documented VL test results ≥ 1,000 copies/mL switched to 2nd
Rationale/Purpose	Quality Indicators monitor the adequate and prompt VL testing and switch to 2nd line
Numerator	Number of ART patients with two documented VL test results ≥ 1,000 copies/mL switched to 2nd line ART
Denominator	Number of ART patients with two documented VL test results ≥ 1,000 copies/mL, throughout the 3-month period of time prior to the beginning of the current reporting period.
Disaggregation(s):	• Age/Sex: <15 Male, 15+ Male, <15 Female, 15+ Female • Recommended: <1, 1-<5, 5-<10, 10-<15, 15-<20, 15+ • Recommended: By Key populations: SW, MSM, and PWID in concentrated and mixed epidemics only.
Data Source	ART database
Method of measurement	Data for this indicator can be collected from the ART registers/patient records from all ART facilities/clinics. For the analysis, sort it by latest records as of the end of the reporting period, up until 3 months before the beginning of the reporting period
Interpretation	Low switch to 2nd line rate (per pre-set target) will inform corrective action
Responsibility	Provincial HIV Program/NCHADS
Frequency	Bi-annually or annually

Indicator # 12	Proportion of ART patients are virologically suppressed
Definition	(%) Percentage of PLHIV and on ART who are virologically suppressed
Rationale/Purpose	Corresponds to the third 90 of the 90–90–90 target (90% of those on ART have suppressed viral loads)
Numerator	# of ART patients with documented repeat VL test results < 1,000 copies/mL
Denominator	# of ART patients with two documented VL test results throughout the 6-12 month period of time prior to the beginning of the current reporting period
Disaggregation(s):	• Age/Sex: <15 Male, 15+ Male, <15 Female, 15+ Female • Recommended: <1, 1-<5, 5-<10, 10-<15, 15-<20, 15+ • Recommended: By Key populations: SW, MSM, and PWID in concentrated and mixed epidemics only. • Pregnancy • Breastfeeding
Data Source	ART database
Method of measurement	Data for this indicator can be collected from the ART registers/patient records from all ART facilities/clinics. For the analysis, calculate rate: number of PLHIV with VL<1000 copies/Ml, at their latest VL testing, among the total number of PLHIV on ART for 6 months or longer by the end of the reporting period
Interpretation	With the program-based denominator, measures virological suppression achieved among all those currently on treatment who received a VL measurement, regardless of when they started ART
Responsibility	NCHADS
Frequency	Annually, ad-hoc surveys and studies

7. Annexes

Annex 1: Viral load monitoring algorithm



Annex 2: Patient Form

ចំណាត់ថ្នាក់ជំងឺតាម WHO ថ្ងៃ ? ○ 1 ○ 2 ○ 3 ○ 4

ការណែនាំសម្រាប់ប្រើ ART (Eligible for ART) : ○ បាទ Yes ○ ទេ No

ស្ថានភាពអ្នកជំងឺ : (Function): ○ ធ្វើការបាន Work ○ ដើរមិនបានឆ្ងាយ (Ambulatory) ○ សំរាកមួយកន្លែង Bed bound

ប្រសិនបើកើតរបេង : (If TB) : ○ របេងសួត (PTB) : ○ របេងក្រៅសួត (EP-TB) : ○ វិជ្ជមានបេក្ទា (BK +) ○ អវិជ្ជមានបេក្ទា/ គ្លីនិក (BK - / Clinic)

ការព្យាបាលជំងឺរបេង : TB Treatment : ○ ចាប់ផ្តើម Start ○ ឈប់ Stop ○ កំពុងព្យាបាល Ongoing ថ្ងៃ-ខែ-ឆ្នាំ ...../...../.....

ត្រូវធ្វើតេស្តមន្ទីរពិសោធន៍: (Prescribing Laboratory Test)

CD4:

☐ បាទ Yes ☐ ទេ No

Viral Load:

☐ បាទ Yes ☐ ទេ No

ការវាយតំលៃ និង គំនិតការ Assessment and Plan

Medication Toxicities :

☐ Moderate/ severe anemia (AZT, CTX) ☐ Renal toxicity (TDF) ☐ Rash (NVP, EFV, CTX, ABC) ☐ Hepatitis (NVP, EFV, INH)

☐ Peripheral neuropathy (d4T, ddI, INH) ☐ Neutropenia (AZT) ☐ Hyperlipidemia (PI/r) ☐ Lactic acidosis (d4T, AZT, ddI)

☐ Hypersensitivity (ABC) ☐ Jaundice/ Hyperbilirubinemia (NVP, INH, ATV/r) ☐ Other _____

ថ្នាំសង្កត់ធ្ងន់បច្ចុប្បន្ន Current medication

ឱសថ Medication	កំរិត Dose	បរិមាណ Quantity	ពេលវេលាប្រើប្រាស់ Freq	ទំរង់ Form	ចាប់ផ្តើម Start	ឈប់ Stop	បន្ត Continue	ថ្ងៃខែឆ្នាំ Date	មូលហេតុនៃការបញ្ឈប់ (កូដ) Reason for discontinuation (Code)	កំណត់ចំណាំ Remarks
ARV drugs										
○ TDF + 3TC + EFV					○	○	○	/ /		
○ AZT + 3TC+ NVP					○	○	○	/ /		
○ TDF + 3TC+					○	○	○	/ /		
○ LPV/r					○	○	○	/ /		
○ ATV/r					○	○	○	/ /		
					○	○	○	/ /		
OI drugs										
○ Cotrimoxazole					○	○	○	/ /	○1° ○2° ○3°*	
○ Fluconazole					○	○	○	/ /	○1° ○2° ○3°*	
○ Isoniazid					○	○	○	/ /		
○ B6					○	○	○	/ /		
					○	○	○	/ /		
					○	○	○	/ /		
TB drugs										
					○	○	○	/ /		
					○	○	○	/ /		
					○	○	○	/ /		

លទ្ធផល/ទិសដៅ Outcome / Actions

○ លះបង់ Lost ○ ស្លាប់ Dead ទីកន្លែង: Place ☐ នៅផ្ទះ Home ☐ នៅមន្ទីរពេទ្យ at Hospital ☐ ផ្សេងៗ ..... Other

ថ្ងៃខែឆ្នាំ Date: / /

មូលហេតុនៃការស្លាប់ : Cause of death : .....

ផ្ញើរទៅ: Referred to: ○ PMTCT ○ CBPCS ○ TB ○ Inpatient ○ Other: .....

○ ផ្ទាស់ចេញទៅកន្លែងដែលមានសេវាART ផ្សេងទៀត (ឈ្មោះ) Transfer out to another ART site : (Name)

ថ្ងៃណាត់ជួបលើកក្រោយ Next appointment: / /

ហត្ថលេខា និង ឈ្មោះ អ្នកស្រង់ពត៌មាន

* 1° (Primary Prophylaxis), 2° (Secondary Prophylaxis), 3° (Treatment Only)

Last updated 20/04/2016

Annex 3: ART Site Sample Collection Form

ART Site Sample Collection From										
S/ No	Patient Name	ART Number	Age	Sex	Date Sample Collected at Health Facility	Sample Collected By	Date of Dispatch From Health Facility	Batch Number	Results Received by	Comments

Annex 4: Laboratory Request Form

មន្ទីរសុខាភិបាល ..... មន្ទីរពេទ្យ .....

បំណុលស្នើសុំធ្វើតេស្ត

ឈ្មោះអ្នកជម្ងឺ : ..... អាយុ :.....ឆ្នាំ, ភេទ :.....

លេខកូដអ្នកជម្ងឺ/ Barcode:

ថ្ងៃ-ខែ-ឆ្នាំ បូមឈាម : ...../ ...../..... ម៉ោងបូមឈាម : .....

ប្រភេទតេស្ត

☐ CD4

☐ HIV-1 Viral Load: ○ First Line Patient
○ Second Line Patient

☐ DNA PCR: ○ នៅពេលកើត ○ នៅអាយុ ៦ សប្តាហ៍
○ ៦ សប្តាហ៍ក្រោយពេលផ្តាច់ដោះ ○ តេស្តបញ្ជាក់

ថ្ងៃ-ខែ-ឆ្នាំ : ...../...../២០១.....

អ្នកបូមឈាម: ..... គ្រូពេទ្យស្នើសុំ:.....

ហត្ថលេខា : ..... ហត្ថលេខា : .....

Annex 5: Viral Load Logbook at Hub

Viral Load Sample Tracking From									
Facility Name / Lab Name:									
Shipping date and Time:						Sent to Lab By:			
S/ No	**Site Name**	**Site ID**	**Number of Sample**	**Site Batch Number**	**Date Sample Received From ART Sites**	**Date Sample Shipping to NCHADS or Siem Reap Lab**	**Date Recived Results from NCHADS or Siem Reap Lab**	**Responsible Person**	**Comments**
Responsible Person Name & Signiture									

Annex 6: Viral Sample Tracking Form

Viral Load Sample Tracking Form : Used to Track Samples From Sites and Hubs to Lab						
Facility Name /Lab Name:						
Shipping Date and Time:						
Sent to Lab By:				Tel No:		
S/ No	**Site Name**	**Site ID**	**Number of Sample**	**Site Batch Number**	**Date Results received**	**Comments**

Annex 7: Viral load result form

មជ្ឈមណ្ឌលជាតិប្រយុទ្ធនឹងជំងឺអេដស៍សើស្បែកនិងកាមរោគ
មន្ទីពិសោធន៍ HIV និង STI

លេខកូដមន្ទីរពិសោធន៍ Lab ID:..... ថ្ងៃខែឆ្នាំបូមឈាម (DD-MM-YYYY): .....

លេខកូដអ្នកជំងឺ Clinic ID: ..... ថ្ងៃខែឆ្នាំធ្វើតេស្ត (DD-MM-YYYY): .....

លេខកូដអ្នកជំងឺART: ..... ថ្ងៃខែឆ្នាំទទួលឈាម (DD-MM-YYYY): .....

អាយុ: ..... ភេទ: ..... មន្ទីរពេទ្យ: .....

ឈ្មោះអ្នកស្នើសុំ: .....

លទ្ធផលមន្ទីរពិសោធន៍

HIV-1 Viral Load by Abbott m2000sp system (Low Detection limit <40 copies/ml)		
Viral Load Results	Log	Copies/ml

ថ្ងៃ ខែ ឆ្នាំ (DD-MM-YYYY): .....

ប្រធានមន្ទីរពិសោធន៍៖

ឧបត្ថម្ភបោះពុម្ពដោយ

អង្គការ UNAIDS