Monitoring and Evaluation of HIV Viral Load Programs

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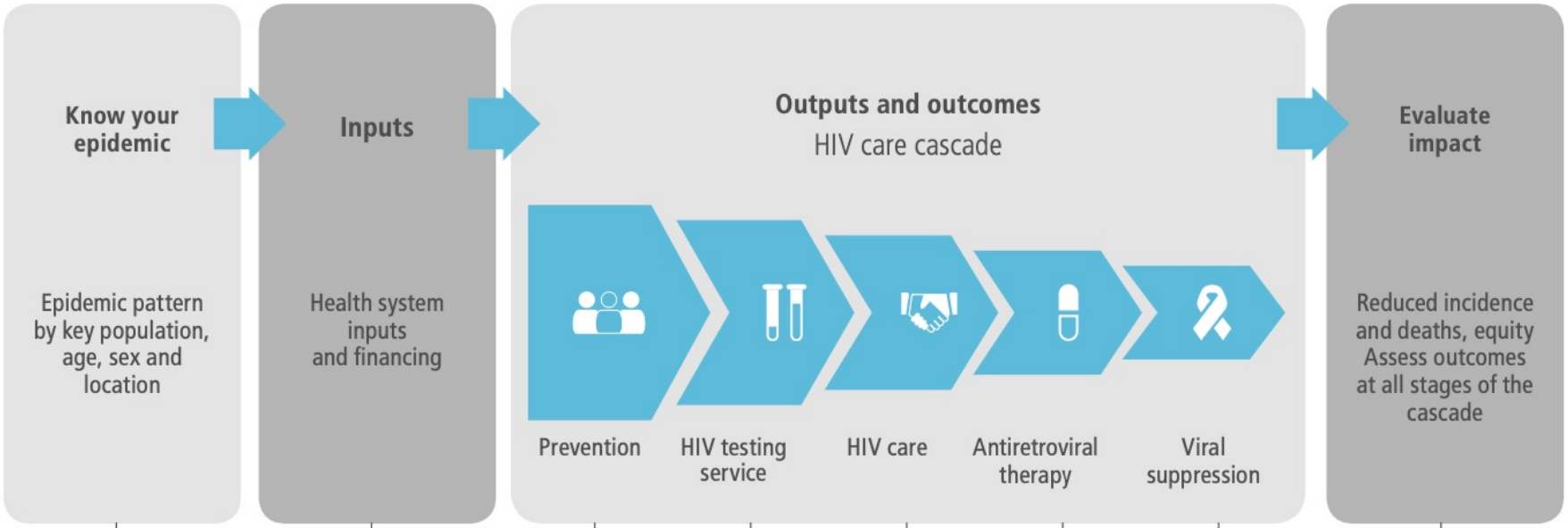
World Health Organization

Global Indicators for HIV Monitoring and Evaluation



1. People living with HIV
Number and % of people living with HIV

2. Domestic funding
% of the HIV response funded domestically

3. Prevention by key populations
% condom use among key and general populations or sterile needles per person who injects drugs (including the use of pre-exposure prophylaxis (PrEP) where relevant)

4. Knowing HIV status
Number and % of people living with HIV who have been diagnosed

5. HIV care
Number and % of people living with HIV receiving HIV care (including antiretroviral therapy)

6. Currently receiving antiretroviral therapy
Number and % of people living with HIV receiving antiretroviral therapy or antiretroviral medicine for preventing mother-to-child transmission

7. Antiretroviral therapy retention
Number and % of people living with HIV retained and surviving receiving antiretroviral therapy

8. Viral suppression
Number and % of people receiving antiretroviral therapy with suppressed viral loads

9. People dying from AIDS-related causes
Deaths per 100 000 population

10. People newly infected with HIV
Number of people newly infected per 1000 uninfected population

World Health Organization

Key Variables for Laboratories to Consider

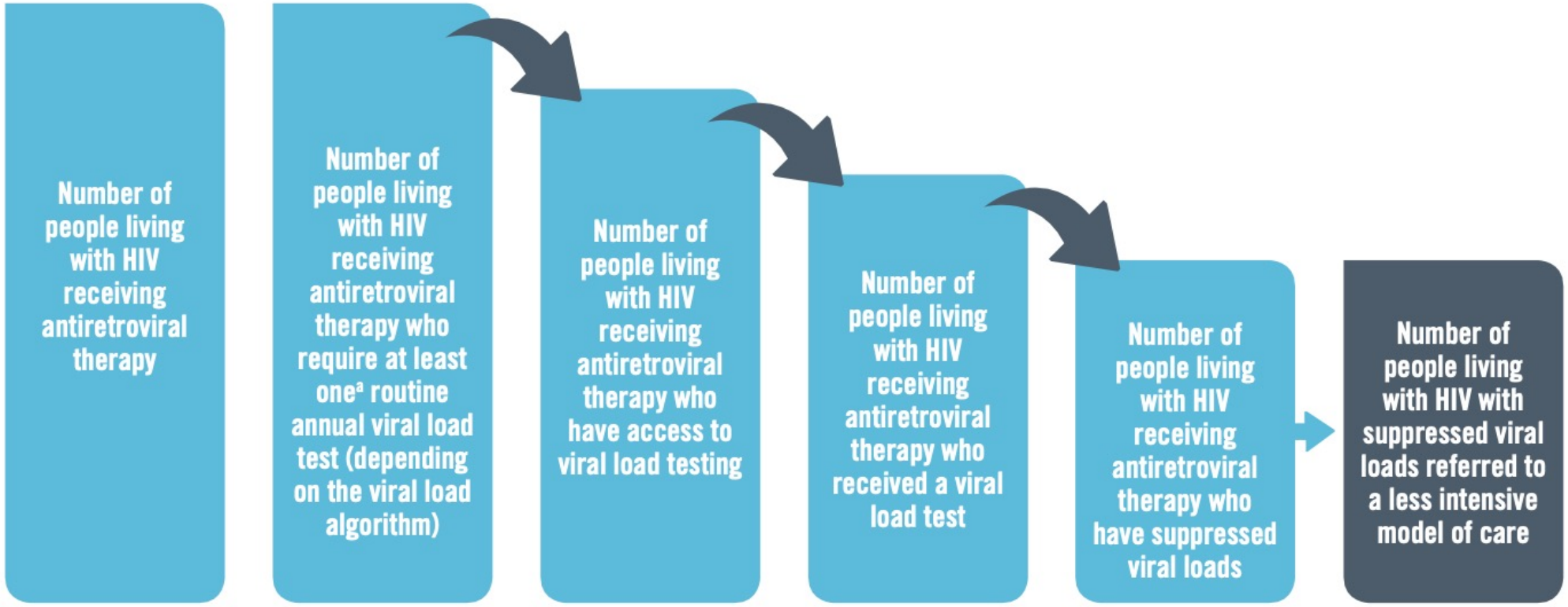
Specimen requisition form (entered at the clinic)

- 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

Viral Load Testing Cascade



Core Indicators Along the 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

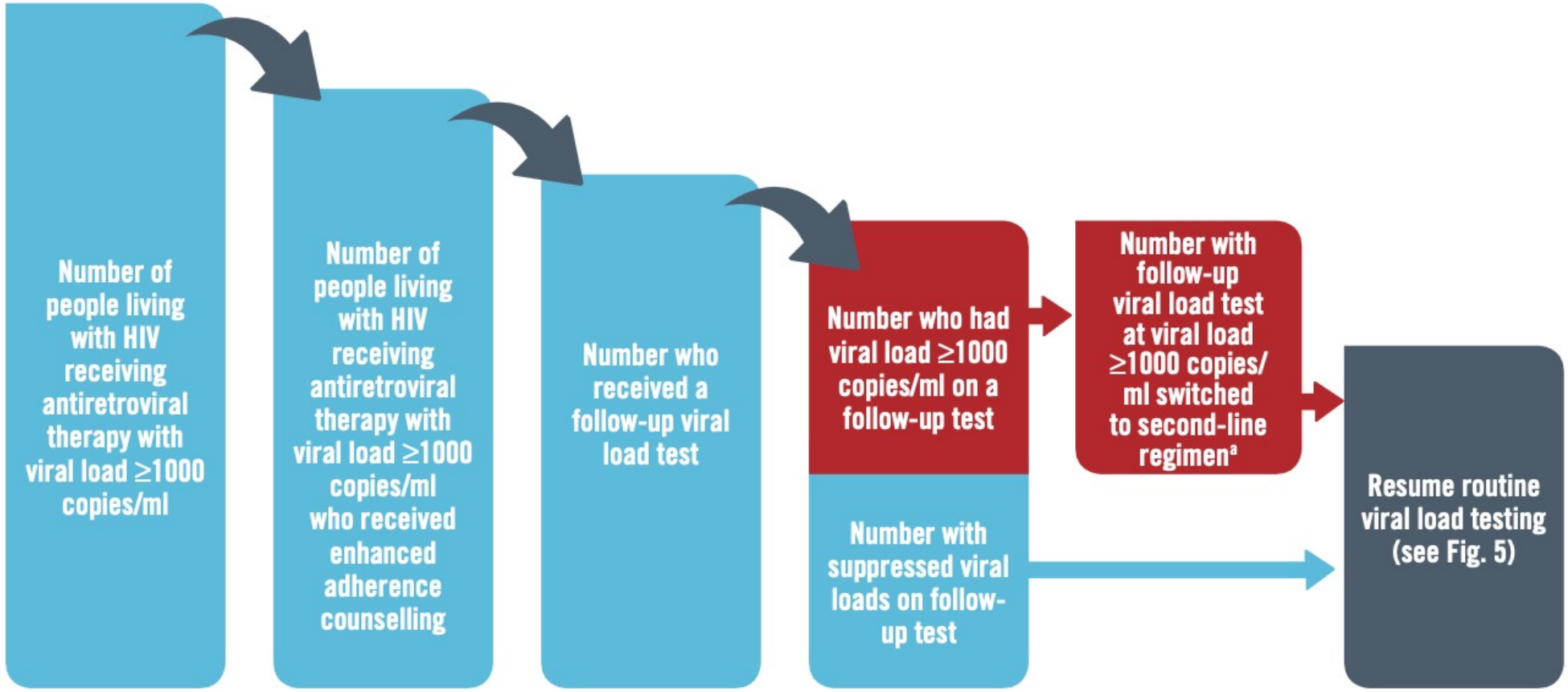
Core Indicators Along the Cascade

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

Core Indicators Along the Cascade

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

Viral Load Testing Cascade



Evaluating Service Quality and Viral Load Testing

- Assess compliance with national guidelines on viral load monitoring
  - Site level with viral load testing, follow-up and referrals

- Assess compliance with national guidelines on managing treatment
  - If treatments are being changed in a timely manner to second-line regimens when necessary in accordance with guidelines

Process Evaluations

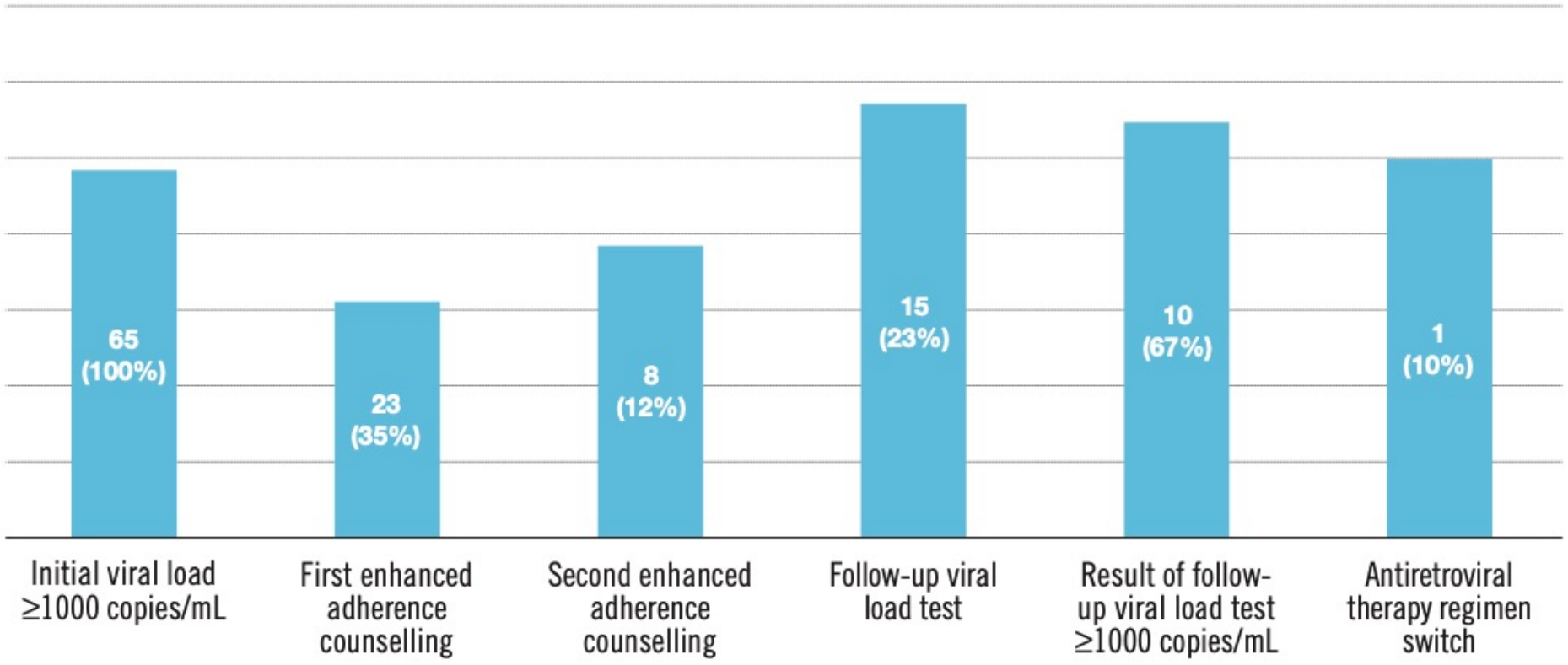
Examples of questions	Use of results
• Were target populations reached? Why not? • Was the programme implemented as planned? Why? What worked? What did not work? • What were the kinds of problems encountered in delivering the programme – were there enough resources from the beginning to do it well? Was 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 Evaluations

- 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

Example Data Summary



Sample Patient 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* *2nd: Reason/ Date*	*1st: Reason/ Date* *2nd: Reason/ Date*	*1st: Reason/ Date* *2nd: Reason/ Date*
															Preg 1	Preg 2	Preg 3	Preg 4				
				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
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				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
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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
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Sample Laboratory Reporting Form

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

Lab

Sample High Viral Load Follow-Up Register

	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.																

Planning for Monitoring and 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)