1

Learning objectives:

By the end of the module, participants will be able to:

- Follow the national algorithm or WHO's algorithm
 - o Determine when a viral load test should be ordered
 - Interpret results of viral load and switch patients to a second line ARV regimen appropriately
- Identify clinic-based strategies to improve implementation at each step of the algorithm

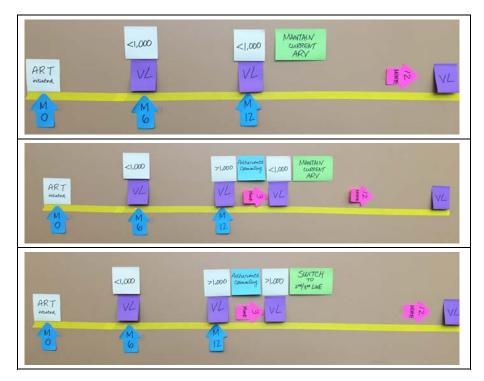
Target audiences: all cadres: Clinicians, Counsellors, and Laboratorians

Pre-requisites: Module 1

Participant handouts: 2-1, 2-2, 2-3, 2-4, 2-5, 2-6, 2-7, 2-8

Special preparations before facilitating:

Gather enough scissors, yellow tape, and scotch tape/glue for Activity 2-A (see below for examples)



Icon	Meaning
	Refer to Handout
$\boldsymbol{\times}$	Customize the slide for local context

3 **Module-at-a-glance**

Segment		What you do	Time	Handouts
Module ope	ening		0:05	
Slides 1	1-2	State the module objective.		
Slide 3		Gauge participants' knowledge with the Knowledge Check. You may need to refresh some key concepts from Module 1 before you proceed to teaching this module.		
1. Accurate	ly follo	wing a national algorithm	1:00	
Slides 4	4-6	Explain the slides according to the content notes.		2-1, 2-2
Slides 7	7-8	Demonstrate how to apply the Viral Load Algorithm using 2 real-life scenarios.		
		*You may use either the animated slides (projected on the screen), or masking tapes and cut-outs (on the wall).		
Slides	9-12	Conduct activity 2A: Applying the National Viral Load Algorithm according to content notes.		2-3, 2-4
2. Choosing result	the ap	propriate course of action given a patient's viral load	0:30	
Slides 1	13-26	Explain the slides according to the content notes.		2-2, 2-5
3. Identifyi	ng prog	rammatic strategy to enhance uptake of viral load	1:15	
Slides 2	27-34	Explain the slides according to the content notes.		2-6, 2-7
Slides 3	35-38	Conduct activity 2B: Algorithm Case Studies according to content notes.		2-8
Module clo	sing		0:10	
Slides 3	39-40	Invite participants to supply words to complete each key message		
		TOTAL MODULE DURATION:	3:00	

4	DRAFT
Slide Number	Content Notes for PowerPoint Slides
0	Heading - Knowledge Check
3	Gauge participants' knowledge with the Knowledge Check question.
_	Heading - Three Scenarios for Viral Load Results
5	There are only three possible viral load results:
	1. Viral load <1,000 copies/ml - The virus is suppressed and the ART is working.
	Patients should continue the current regimen.
Handout	2. Viral load is undetectable - The virus is suppressed and the ART is working. But this
2-1	does <u>not</u> mean HIV has disappeared. HIV is still present in reservoirs (i.e., hiding place
	or safe zone for the virus to hide), which include lymph nodes, genitalia, central
	nervous system, and gastrointestinal system – in these places, the virus is still
	present, even with treatment. Because of this viral reserve, the ARV regimen must be
	continued to maintain a low or undetectable viral load. With a continued
	low/undetectable viral load and appropriate treatment and monitoring, the patient
	will continue to be asymptomatic (i.e. not develop opportunistic infections)
	3. Viral load >1,000 copies/ml The virus is NOT suppressed because the current ART
	is working but the patient is not taking it properly OR the current ART is not working
	due to resistance or treatment failure.
6	Heading - National Viral Load Algorithm
0	There are two types of monitoring:
	• <u>Targeted viral load monitoring</u> : Any patient with clinical or immunological failure
	should have a viral load to confirm treatment failure. The exact point (i.e. which
	clinical stage) at which a viral load should be measured should be determined based
	on national guidelines
Handout	• <u>Routine viral load monitoring</u> (Early detection of virological failure): this type of
2-2	monitoring should begin at 6 months, then 12 months after initiating treatment.
	Afterwards, if viral load result is <1,000 copies, refer to national guidelines
	According to the algorithm, when viral load is >1,000 copies/ml, you should evaluate the
	patient for any adherence concerns and initiate viral load counselling. The patient should
	repeat the viral load test 3-6 months later.
	• If the repeat viral load is <1,000, the patient should continue 1 st line therapy.
	 If the repeat viral load is >1,000, switch the patient to 2nd line therapy.
	in the repeat vital load is 7 1,000, switch the patient to 2 - the therapy.
	Customization – use country-specific algorithm, if available
7-8	Heading – Applying the National Viral Load Algorithm
70	Demonstrate how to apply the Viral Load Algorithm using 2 real-life scenarios.
	*You may use either the animated slides (projected on the screen), or masking tapes and cut-
	outs (on the wall).
9-12	Heading – Activity 2A: Applying the National Viral Load Algorithm
~ 14	1. Explain the activity using slide 9
	2. Refer participants to handout 2-3
	3. Divide participants into 3 groups
	 Provide each group with necessary materials*
	5. Monitor group activity (15 minutes)
Handout 2-3. 2-4	6. Debrief each scenario using slides 10-12
<i>L</i> J. <i>L</i> ⁻ T	

Slide Number	Content Notes for PowerPoint Slides
	*If scissors, yellow tape, and scotch tape/glue are not available, ask participants to draw the scenarios on the flipchart paper.
14	 Heading - All viral loads >1,000 copies/ml need further investigation When a viral load is > 1000 copies/ml, there are two possibilities: The current ARV regimen is still working but the patient is not taking it properly The current ART is no longer working due to resistance or treatment failure The most common reason is poor adherence. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/15/virologic-failure
15	 Heading - Reasons for Viral Load >1,000 copies/ml Possible reasons for <i>Resistance</i> or <i>Treatment Failure</i> include: Drug interactions causing sub-therapeutic levels of ARVs e.g., rifampicin, traditional medicines, anti-epileptics (any enzyme-inducing drug) GI intolerance leading to sub-therapeutic levels of ARVs (i.e., chronic diarrhoea o vomiting) Side effects—due to unpleasant effects, the patient is not taking their drugs as prescribed Previous exposure to ART (including PMTCT) resulting in pre-existing resistance Not changing the ARV dose according to weight change in pediatric patients
16	 Heading - Reasons for Viral Load >1,000 copies/ml Common challenges leading to <i>Poor Adherence</i> include: Non-disclosure Economic barriers for accessing care – patient cannot afford their ARVs or must use their resources for food, housing, other sick relatives Alcohol or drug abuse – leads to forgetting to take ARVs, money is used for alcoh or drugs instead of ARVs, etc Feeling better so they think they don't need the ARVs – patients need to understand why they must continue treatment even though they may be feeling better Pregnancy and breastfeeding mothers possible at high risk of poor adherence – mothers may be concerned that the ARVs could harm the baby, mothers may forget to take daily medications with the demands of an infant Changing guardian for pediatric ART care – during the transition, ARV regimen may not be communicated effectively, medications could be missed while getting used to a new routine Side-effects causing patients to stop their medication – patients do not feel good when taking their medication and would rather not take the ARVs
17 & 18	 Heading - All viral loads >1,000 copies/ml require action Action to be taken by each of the following roles: <u>Clinics</u>: Flag the patient's record so that all clinic staff is aware the patient requires close follow up and repeat VL testing Assure that the patient completes their adherence training and repeat VL testing Contact the patient to remind them if the patient misses a counseling session or VL testing, <u>Clinicians</u>:

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6	DRAFT
Slide Number	Content Notes for PowerPoint Slides
	 Explore the medical reasons impacting the patient's adherence to treatment – i.e. they feel better and don't think they need to keep taking the ARV's, side effects of ARV's, drug or alcohol abuse, etc. and explain reasoning for medication adherence Complete VL documentation in patient's chart, including the high viral load form or equivalent
	- Advise patient on when to return for repeat VL testing <u>Counsellors</u>
	 Explore the possible psychosocial factors impacting the patient's adherence – i.e. poverty, drug/alcohol abuse, poor understanding, changing guardianship for pediatric patients, etc. Complete the enhanced adherence intervention with the patient – assure that patient has appropriate education regarding why they should and how to take their medication Patients
	 Attend enhanced adherence counseling Complete VL testing 3-6 months after viral load test results given so that treatment can be adjusted appropriately Take ARVs daily
19	Heading - Why is adherence so important? For ARVs to work effectively you need to take all 3 drugs, regularly (not missing doses or taking them very late) for three to six months to achieve virological suppression < 1000 copies/ml. If ARVs are taken daily, adherence issues can be ruled out if the repeat viral load is >1,000 copies/ml.
20	Heading - Why is adherence counselling important?Counseling helps the patient improve adherence to the treatment regimen and improvetreatment outcome. Between 54-89% of patients will resuppress (Bonner, Kimberly, AlyssaMezochow, Teri Roberts, Nathan Ford, and Jennifer Cohn. "Viral Load Monitoring as a Tool to ReinforceAdherence." JAIDS Journal of Acquired Immune Deficiency Syndromes: 74-78.)Providers should explain to the patients that if they can improve their adherence, it is likely
	that they will bring the viral load below 1,000. This will allow them to stay asymptomatic for longer, prevent the development of resistance, and stay on the first line treatment regimen instead of switching to the more expensive 2 nd line treatment.
21	Heading - When to take the repeat viral load The second (repeat) viral load should be taken 3-6 months after the first viral load result is given and first counselling session is completed –this should happen at the same patient visit. Observe if the patient is clinically unwell or sick. The timing of the algorithm should be adapted to the clinical urgency If the patient is clearly non-adherent 3 months after the receiving the first viral load result
	 and completing the adherence counselling: Do not take a repeat viral load at this time Review adherence issues and continue adherence counselling – focus on key adherence issues for each individual patient and explore any new adherence issues (i.e. new financial issues?) Ask the patient to return in 3 months for repeat viral load testing (this is 6 months after the first viral load result/first adherence counselling session)

7	DRAFT
Slide Number	Content Notes for PowerPoint Slides
22 Handout 2-2	 Heading - If the REPEAT viral load is <1,000 copies/ml: Congratulate the patient and explain the result of the second VL to the patient The virus is suppressed, meaning that the immune system can recover and there's a low risk of becoming ill or symptomatic If the virus is undetectable, there's a low risk of the virus becoming resistant to the current treatment and there's a reduced risk of passing the virus to someone else However, the VIRUS IS STILL PRESENT within reservoirs Patient should continue first line treatment and return to routine schedule of VL monitoring per the national algorithm Emphasize that if they continue their treatment, they will continue to suppress the virus and allow their immune system to recover ***In some settings, a plasma-based viral load is used and there may be more resources for counselling. In these settings, a result between 50-1,000 copies/ml may still require an intervention – consult national guidelines ***VL is not just a monitoring tool to switch patients correctly to 2nd line, it is also helping people to stay on 1st line
23	Heading - If the Repeat VL is >1,000 copies/ml : Before seeing the patient, review the medical and psychosocial factors and discuss the case in
Handout 2-2	 a team meeting (including the clinicians and counsellors) before the patient returns for their results. If adherence issues were addressed prior to the repeat viral load, assume likelihood of resistance and plan to switch the patient to a second line regimen. If adherence issues remain, review case to assess if switch can be delayed and VL repeated in 3 months (factors to be assessed, CD4, clinical condition, likelihood of resistance). For 2nd line failure, follow local guidelines regarding access to genotyping and 3rd line regimens
24	Heading - Viral Load >1,000 copies/ml means treatment failure when Only when a viral load result is more than 1000 copies/ml on two consecutive results with three months apart can treatment failure be ruled. The 1,2,3 rule helps us to work out whether we should consider switching to second line drugs.
25	Heading - Resistance can be Resistance can be caused by several factors. It can be due to inadequate drug levels as a result of poor adherence, drug interactions or GI intolerance, or the patient has been infected with a resistant virus.
26 Handout 2-5	 Heading - Second line regimen After the patient has demonstrated treatment failure per algorithm, a clinician (physician or nurse) with appropriate training can then order switching from 1st to 2nd line HIV treatment. Refer to Handout for WHO guidelines on 2nd line ARV regimens. Customization – revise the handout per any available national guidelines
28	Heading - Programmatic strategies to improve viral load uptake Despite VL being routine in guidelines, uptake is often below 100%. In some settings that have recently moved to routine viral load, uptake has been slow.

3	DRAFT
Slide Number	Content Notes for PowerPoint Slides
	Customization – replace chart with national statistics on viral load uptake
29	Heading - Enhancing Uptake of Viral Load Monitoring
29	Here are some example strategies to enhance uptake of viral load:
	Educate patients on when and why viral load should be taken
	 Clearly document in patient's file/notebook that VL is due at next appointment in order to allow triage of patients needing VL in the waiting area
	 Develop SOPs to ensure each patient's viral load is taken according to the national
	algorithm
	• Follow up with patients who have missed a viral load testing. A viral load register will be a great monitoring tool.
30	Heading - Enhancing Uptake of Viral Load Monitoring
30	Additionally, patient forms should include a column to record viral load results. It is
	important to track each patient's viral load, especially when initiating ART and when viral
	load is measured >1,000 copies/ml – with close monitoring, patients receive optimal care.
04	Heading - Enhancing Uptake of Viral Load Monitoring
31	Sometimes it's difficult to remember to take the viral load, even when there's a column to
	record it. A <i>trigger</i> , or reminder, is often a helpful tool to help clinic staff remember when a
	viral load is due for a patient. These triggers should be created based on what type of medical chart is used. For example,
	• If a computer system is in place, schedule automatic reminders that pop up when the
	patient's chart is opened
	• If paper charts are used, the best time to create the trigger may vary based on the
	work flow at each clinic site - this should be part of the clinic SOP
	Heading - Example of a Standard Operating Procedure (SOP)
32	Standard Operating Procedures are protocols that are followed by a clinic to ensure patients
	receive appropriate care. Everyone in the clinic must be familiar with these procedures.
	Presented here is an example of what procedures to follow when a patient arrives to the
	clinic for an appointment. SOPs can be customized to fit the needs of each clinic so that patient care is optimal and efficient.
	Customization – Provide country-specific SOP
33	Heading - Use a High Viral Load Form for each patient requiring a repeat viral load
	For individual patient management, a "High Viral Load form" is a detailed record
	summarizing the viral load test results and adherence counselling sessions. It should be used for each patient requiring a repeat viral load test and kept in the patient chart/medical file.
Handout	This High Viral Load Form includes two important sections:
2-6	 <u>Viral Load Results</u>: this is where the initial VL result >1,000 is recorded with the date
	that it was taken; space for previous VL is provided
	• <u>Outcome</u> : this is where the repeat VL result is recorded with the date; the subsequent
	treatment plan is also recorded here
	This form can then be used as a summary to review and discuss the case for possible switch to second line if needed.

9	DRAFT
Slide Number	Content Notes for PowerPoint Slides
	Customization – Provide relevant country form
34 Handout 2-7	 Heading - Use an Enhanced Adherence Register to capture and monitor all patients with repeat viral load This tool will enable clinic staff to ensure that clients at risk of treatment failure are followed up according to the algorithm. This Register should be updated at each clinic appointment and when viral load results are received. If patients default from enhanced adherence they should be actively contacted by an appointed clinic staff member to ensure they follow-up for their repeat viral load testing. The maintenance of this register should be a part of the clinic SOP. Refer to handout for further explanation. In this example: Patient A came to the clinic on October 20th and had a viral load >1,000. He returned 3 months later for his repeat viral load test is <1,000 he can return to routine viral load test are recorded. Since his repeat test is <1,000 he can return to routine viral load monitoring per the national algorithm. Patient B came to the clinic on October 22nd and had a viral load >1,000. He did not return to the clinic. He should be contacted by the clinic so that he comes in for his repeat viral load testing Refer to the handout for an example of how the enhanced adherence register is set-up and what information should be included. This tool may be customized to best meet the needs of the clinic.
35-38 Handout 2-8	 Heading - Activity 2B: Algorithm Case Studies 1. Explain the activity using slide 35 2. Refer participants to handout 2-8 3. Divide participants into 3 groups 4. Monitor group activity (20 minutes) 5. Debrief each scenario using slides 36-38
39-40	Heading – Module 6: Key messages Invite participants to supply words to complete each key message.

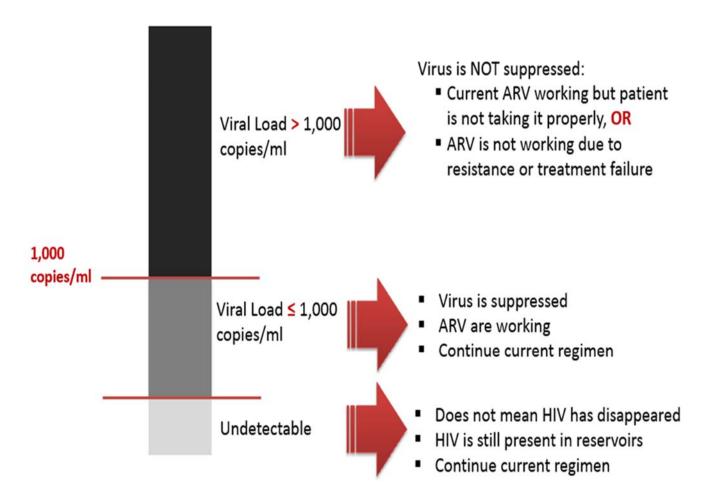
References

Bonner, Kimberly, Alyssa Mezochow, Teri Roberts, Nathan Ford, and Jennifer Cohn. "Viral Load Monitoring as a Tool to Reinforce Adherence." *JAIDS Journal of Acquired Immune Deficiency Syndromes*: 74-78.

WHO 2013 Consolidated Guidelines On The Use Of Antiretroviral Drugs For Treating And Preventing HIV Infection (<u>http://www.who.int/hiv/pub/guidelines/arv2013/download/en/</u>)

NIH. Virologic Failure (April, 2015). <u>https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/15/virologic-failure</u>

Three Scenarios for Viral Load Results



The Three Scenarios for Viral Load Results summarizes the possible situations after a viral load result returns and what these situations mean. Please refer to the Viral Load Algorithm for next steps when a result is >1,000 copies/ml.

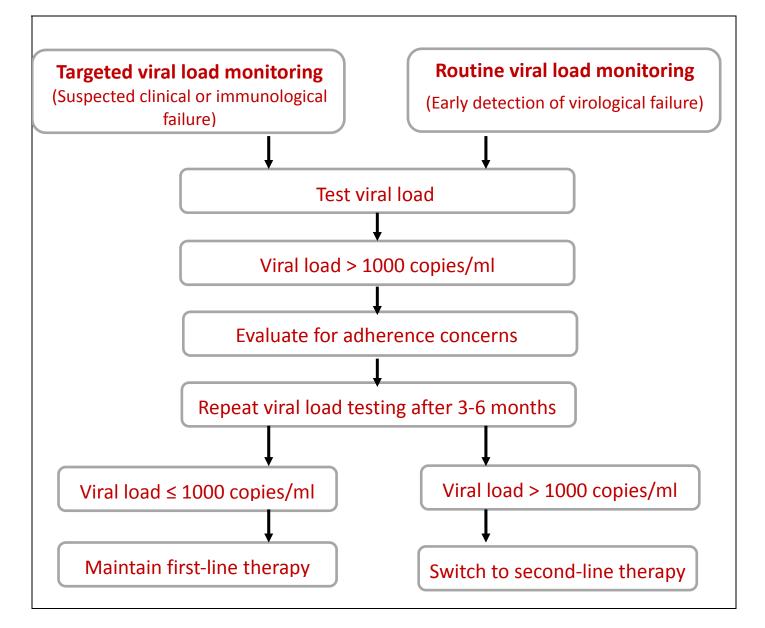
<u>Reservoir</u> = a hiding place or safe zone for the virus to reside.

HIV reservoirs include: lymph nodes, genital mucosa, gastrointestinal system, central nervous system (brain, cerebrospinal fluid [CSF])

National Viral Load Algorithm

Based on the WHO 2013 Consolidated Guidelines on the Use of Antiretroviral Drugs and Preventing HIV Infection, Chapter 7.3

http://www.who.int/hiv/pub/guidelines/arv2013/download/en/



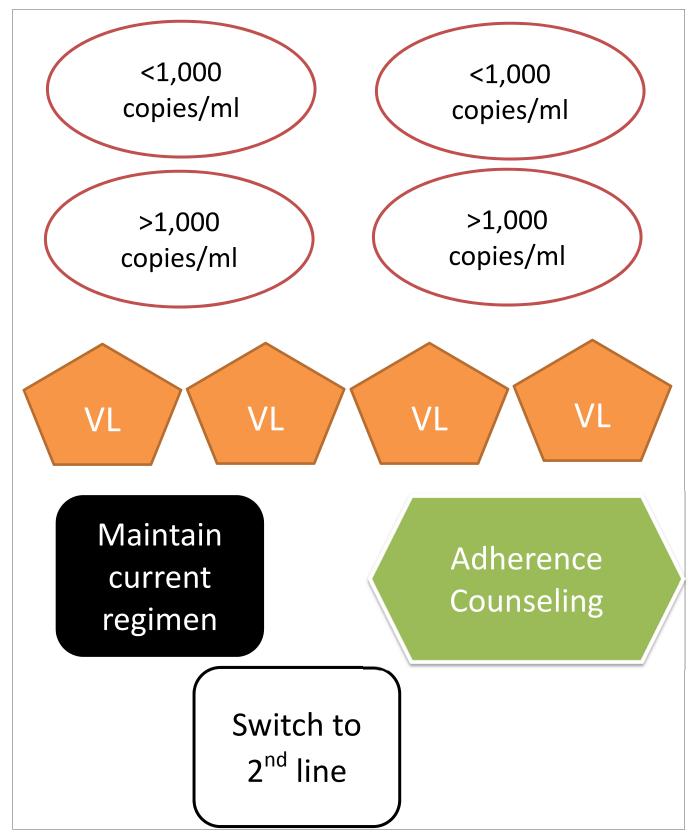
What to Do with Re	peat Viral Load Results
If the Viral Load is <1,000 copies/ml	If the Viral Load is >1,000 copies/ml
Congratulate the patient	BEFORE seeing patient, discuss case in team meeting
 Explain that the virus is still present and 	If adherence issues were resolved:
suppressed by current treatment	Assume resistance
Continue current treatment regiment	Switch to 2nd line
Return to routine viral load monitoring per	If adherence issues remain:
national algorithm	 Assess if switch can be delayed and
	viral load repeated in 3 months

Activity 2A - Applying the National Viral Load Algorithm

Scenario A 25 year old female patient had her first viral load test performed after 6 months Α on ART. The result was **<1,000** copies/ml. What should be the next steps? Assuming another Viral Load test was done according to the national algorithm and the result was **10,000** copies/ml, what should be the next steps? Assuming the next Viral Load test result was **5,000** copies/ml, what should be the next steps? When should the next Viral Load test be? Select the appropriate cut-outs and map the scenario. **Scenario** A 45 year old male patient had his first viral load test performed after 6 months on B ART. The result was **<1,000** copies/ml. What should be the next steps? Assuming another Viral Load test was ordered according to the national . algorithm and the result was **7,500** copies/ml. what should be the next steps? Another Viral Load test was done and the result was **<1,000** copies/ml. What should be the next steps? When should the next Viral Load test be performed? Select the appropriate cut-outs and map the scenario. **Scenario** A 15 year old female patient had her first viral load test performed after 6 months С on ART. The result was 150,000 copies/ml. What should be the next steps? Assuming another Viral Load test was ordered according to the national algorithm and the result was 10,000 copies/ml, what should be the next steps? When should the next Viral Load test be? Select the appropriate cut-outs and map the scenario.

Scenario Sheet

Activity 2A – Cut-Outs



Handout 2-5

Second-Line Regimen Choices

The table below outlines the second line regimen choices dependent on the current first line the patient is failing. Please consult national guidelines for any variation to this.

Source: WHO 2013 Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection, Chapter 7.5 http://www.who.int/hiv/pub/guidelines/arv2013/download/en/

Table 7.18 Summary of preferred second-line ART regimens for adults, adolescents, pregnant women and children

Second-li	ine ART		Preferred regimens	Alternative regimens
	d adolescents (≥ pregnant and b		AZT + 3TC + LPV/r ^a AZT + 3TC + ATV/r ^a	TDF + 3TC (or FTC) + ATV/r TDF + 3TC (or FTC) + LPV/r
	If a NNRTI-bas regimen was u		ABC + 3TC + LPV/I ^b	ABC + 3TC + LPV/r ^b TDF + 3TC (or FTC) + LPV/r ^b
Children	If a PI-based first-line	<3 years	No change from first- line regimen in use ^c	AZT (or ABC) + 3TC + NVP
	regimen was used	3 years to less than 10 years	AZT (or ABC) + 3TC + EFV	ABC (or TDF) + 3TC + NVP

^a DRV/r can be used as an alternative PI and SQV/r in special situations; neither is currently available as a heatstable fixed-dose combination, but a DRV + RTV heat-stable fixed-dose combination is currently in development.

^bATV/r can be used as an alternative to LPV/r for children older than six years.

^c Unless failure is caused by lack of adherence resulting from poor palatability of LPV/r.

15 **Handout 2-6**

High Viral Load Form (Example)

The High Viral Load Form is used when a viral load is measured >1,000 copies/ml and is kept in the patient's medical record. A clinic staff member documents the viral load before enhanced adherence counselling is done in the "Viral Load Results" section at the top of the form. In the "Outcome" section at the bottom of the form, the results of the repeat viral load test are recorded. The planned treatment regimen may also be recorded there.

(For Enhanced Adherence Counselling and Second Line Consideration)	
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e: Health Centre:	_ ٦
Sex: M F Pt Number:	-
Information Viral Load Popula	
Regimen: Date of initiation: Viral Load before EAC: c/ml Date://	
Previous VI (if any) : c/ml Date: / /	
// // // // // // // // //// //// //_//_///_////	
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anced Adherence Counselling (To be filed by the Counsellor) ach session, assess major barriers for possil a poor adherence (cognitive, behavioral, emotional, socio, economic) of 1 st session: /_/Summary:	-
of 1" session: / / Summary:	-
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impression about patient's adherence <u>during and after</u> EAC: ely to be good	
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Handout 2-7

Enhanced Adherence Register (Example)

The enhanced adherence register is a clinic tool that can be used to keep track of patients with a viral load >1,000 copies/ml. A clinic staff member in charge of the register enters the patient's name, medical record number, previous viral load result and date, when the repeat viral load was done, and the results of the repeat viral load and when they were received.

Patients due for Repeat Viral Load Testing This Week: Jan 17 - 23

Patient Name	Previous Viral Load:	Repeat Viral Load:	Repeat Viral Load: Results
Medical Record #	Date and Result	Date completed	and Date Received
Name:	copies/ml	Date:	copies/ml
MRN:	Date:		Date:
Name:	copies/ml	Date:	copies/ml
MRN:	Date:		Date:
Name:	copies/ml	Date:	copies/ml
MRN:	Date:		Date:

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Activity 2B - Algorithm Case Studies

Case Study Sheet

Scenario A	Joseph has been on ART for 6 months and has his first viral load test completed at the clinic. The result comes back as 3500 copies/ml.		
	 What is the meaning of this result? 		
	\circ What is the next step for this patient?		
	 When should the next Viral Load be drawn? 		
	 Joseph receives enhanced adherence counseling and a repeat viral load after 6 months is <1000 copies/ml 		
	• What is the meaning of this result?		
	• What is the next step for this patient?		
	 When should the next Viral Load be drawn? 		
Scenario B	 Mary has been on ART for 2 years. Her CD4 was 150 cells/µl when she started ART and most recently was 300 cells/µl. Routine Viral Load monitoring recently became available at the clinic she is attending and was found to be 14,000 copies/ml. During her adherence assessment she was found to have had poor adherence during the 3 months prior to the Viral Load test. She received enhanced adherence counseling and repeat Viral Load after 3 months was 8000 copies/ml. What is the meaning of these results? Does Mary have drug resistance? Should she be started on a second-line regimen? 		
Scenario C	 Harry has been on ART for 6 months and has his first viral load test completed at the clinic. The result comes back as 2.0 log10 copies/ml What is the real number of copies per ml? Is Harry experiencing treatment failure or viral suppression? Would you suspect he has diligently taken his anti-retrovirals or do you suspect he has missed some doses? What is the next step for this patient? When should the next Viral Load be drawn? 		