2023 ART Clinical Guidelines

for the Management of HIV in Adults, Pregnancy and Breastfeeding, Adolescents, Children, Infants and Neonates

June 2023 Version 4

Republic of South Africa National Department of Health

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Foreword

South Africa is committed to attaining the UNAIDS 95-95-95 targets to control the HIV epidemic by providing quality healthcare services using highly effective antiretroviral treatment (ART). The principal goal of ART is to attain and maintain viral suppression, which will prevent new HIV infections, increase life expectancy, decrease morbidity and mortality as well as improve the quality of lives of all South Africans, thus contributing to realising the vision of A LONG AND HEALTHY LIFE FOR ALL.

The "Test and Treat All" approach has allowed people living with HIV (PLHIV) to access ART timeously.

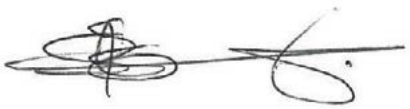
South Africa is committed to using available technology and evidence to continue the fight against HIV. The 2019 guidelines have been revised to include more optimised treatment regimens for all clients, including pregnant and breastfeeding women and children. The National Health Council (NHC) has adopted the new World Health Organization (WHO) recommended first, second and third-line regimens that include Dolutegravir (DTG) as the preferred antiretroviral drug.

I am introducing the 2023 ART guideline, which introduces simplified ART provision and harmonised methods of management of children, adolescents and adults, as well as pregnant women living with HIV/AIDS, TB and other common opportunistic infections. The guidelines also provide guidance on the use of Dolutegravir (DTG) dispersible tablets for children from 3 kg and 4 weeks old.

These guidelines have been revised with the Differentiated Models of Care SOPs to ensure simultaneous consideration and alignment of clinical, adherence and service delivery updates. The Differentiated Models of Care SOPs form part of this guidance to enable optimal use of decentralised and integrated service delivery to promote a patient-centred approach. Effective implementation of these guidelines will increase access to ART services, advance South Africa's ability to control the epidemic and help to achieve the 2030 SDG goals.

I urge all clinicians at PHC clinics, community health centres and hospitals across the board to use these guidelines diligently to offer quality, comprehensive services to the public.

I would like to sincerely thank all the internal and external stakeholders who actively contributed to developing these guidelines.



Dr SSS Buthelezi
Director-General: Health
Date: 24-04-2023

Managing the Client on ART

Monitoring on ART

! Remember to check adherence at every clinical follow-up visit, in a non-judgemental way. Ask open ended questions e.g. "Is there anything that makes it difficult for you to take your treatment?" See also the 'Adherence' section of the ***"ABCDE assessment of an Elevated Viral Load" on page 22***

Providing quality care at the follow-up visit is essential to promote adherence, achieve and sustain viral suppression, minimise side-effects and toxicities, and promote quality of life. A client on ART should be monitored to:

1 Determine clinical response to ART

2 Determine the virological and immunological response to ART

3 Detect and manage any side-effects and toxicities

The following components should be included in the **clinical assessment:**

Weight (adults)
An assessment of trends in weight in adults

Growth and neurodevelopment (children)
An assessment of trends in weight, height, head circumference, and neurodevelopment

! Remember to increase the ART dosage as weight increases!

Screen for TB (see below *) **and other OIs:**
to diagnose and provide treatment; to adjust ART regimen if required; to provide a package of care for AHD if required; to determine if TB preventive therapy is required

WHO clinical staging
to determine response to ART, and CPT eligibility

Screen for pregnancy and ask if planning to conceive as outlined in the table for ***"Baseline Clinical Evaluation" on page 5***

Viral load should be measured to timeously detect problems with adherence or treatment failure

! Remember, any elevated VL > 50 c/mL is a medical emergency!

Assess and manage according to the algorithm ***"VL Monitoring for Clients on TLD" on page 21***

The CD4 count monitors susceptibility to opportunistic infections, identifies clients with advanced HIV disease and informs eligibility for OI prophylaxis.

Monitor routinely after 10 months/DCs on ART (aligned with VL).

Thereafter, stop CD4 monitoring unless:

- CD4 still ≤ 200 cells/mm^3: repeat every 6 months until CD4 > 200
- VL ≥ 1000 c/mL: repeat CD4 every 6 months until VL < 1000 c/mL
- A clinical indication arises, such as a new WHO Stage 3 or 4 condition in a previously well client

Repeat CD4 for clients returning > 90 days after missing a scheduled appointment (see ***"re-engagement algorithm" on page 12***)

Side-effects and ART toxicities can affect adherence and endanger the client's health:

Drug side-effects
Ask about side-effects at each visit (e.g. sleep or gastrointestinal disturbances)

TDF-induced nephrotoxicity
If on TDF, do creatinine and eGFR* at months 3 and 10 (aligned with VL monitoring schedule)
Thereafter, repeat every 12 months
See also ***"Assessing Renal Function" on page 8***

Dyslipidaemia
If on a PI-based regimen, do total cholesterol and triglycerides (TGs) at month 3
If above acceptable range, do fasting cholesterol and TGs and if still above acceptable range, obtain expert advice

Anaemia and neutropaenia
If on AZT, do a full blood count and differential white cell count at months 1 and 3
Thereafter, repeat if clinically indicated

* Screening for TB at follow-up Visits

At every routine follow-up visit:	At every 12-monthly clinical review on ART (aligned with 12-monthly VL)	For symptomatic PLHIV admitted to hospital [in addition to the MTB/Rif Ultra (Xpert)]	For symptomatic PLHIV seen in an outpatient setting [in addition to the MTB/Rif Ultra (Xpert)]
• Do a TB symptom screen. If symptomatic, do a MTB/Rif Ultra (Xpert)	• Routine MTB/Rif Ultra (Xpert) (regardless of TB symptoms)	• Do a U-LAM test	• Do a U-LAM test if: - CD4 count <200 within the last 6 months, or - advanced HIV disease, or - current serious illness.

For more information on the package of care for AHD and the management of specific OIs, please refer to the ***Consolidated ART guideline***

! When monitoring on ART, also integrate monitoring for other chronic conditions (HPT, DM, and mental health) and routinely offer reliable contraception and cervical cancer screening to female clients.

2023 ART Clinical Guidelines (Part II)

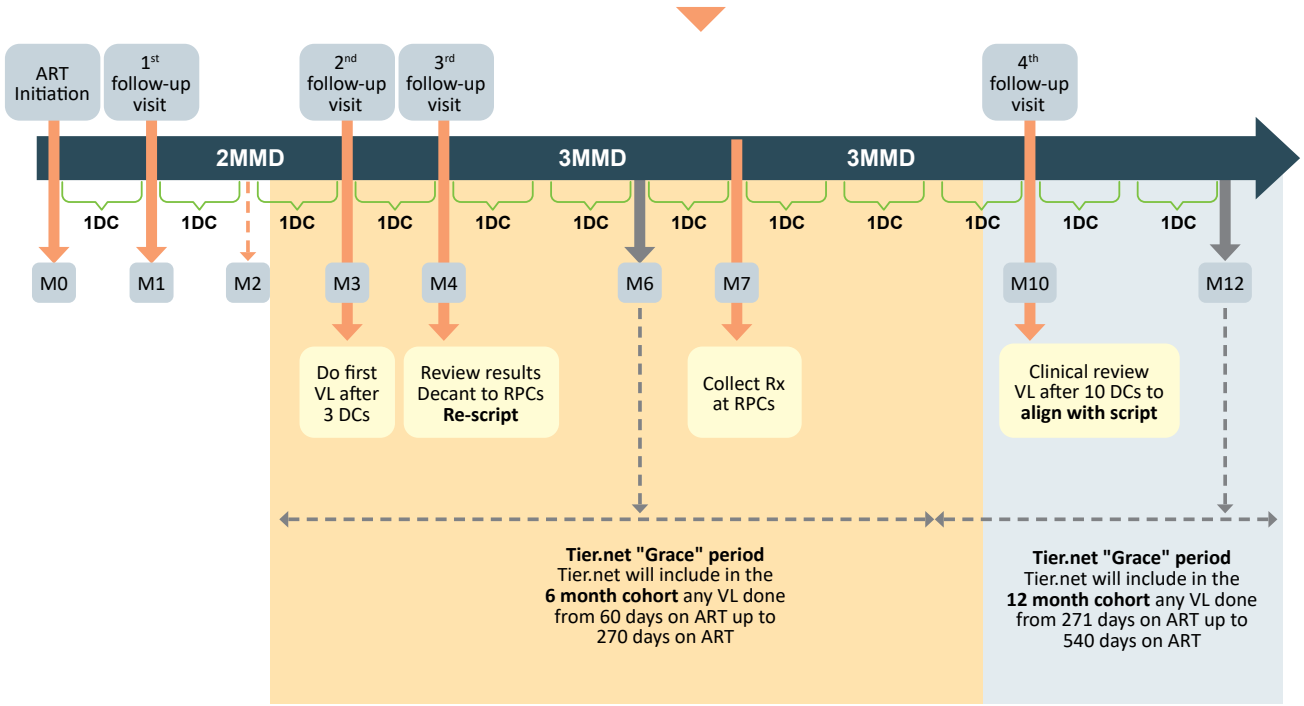
June 2023 Version 4

Republic of South Africa National Department of Health

Routine HIV VL Monitoring Schedule on ART

A dispensing cycle is defined as the number of days for which a client would have treatment if a single standard "monthly" quantity of tablets was dispensed. The term 'dispensing cycle (DC)' is preferred to the previously used term 'month' due to the potential discrepancy that may arise between the days of treatment dispensed (if 28 day pack sizes are used) and the days in a month (on average, 30 days). However, the term dispensing cycle can be applied to single pack sizes of 28 tablets (1DC) or larger pack sizes of 90 tablets (3 DCs).

Routine VL monitoring	Intervention	Comments
First VL after ART initiation	Do 1st VL after **3 dispensing cycles**	• Allows for earlier detection of factors influencing viral suppression • Allows for earlier decanting for suppressed clients to minimise visits and promote continued engagement in care • This VL will form part of the **6 month VL completion cohort** in Tier.net
Second routine VL after ART initiation (in clients who remain virally suppressed)	This VL can be done from **10 dispensing cycles** but should be aligned with the clients scripting cycle	• This VL will form part of the **12 month VL completion cohort** in Tier.net
Third routine VL after ART initiation (in clients who remain virally suppressed)	This VL can be done **from 22 dispensing cycles**, but should be aligned with the clients scripting cycle	• This VL will form part of the 24 month **VL completion cohort** in Tier.net
Fourth and all subsequent VLs	VLs will be taken at intervals of 12 dispensing cycles for all clients who remain virally suppressed	
The timing of dispensing cycles, follow-up visits, and VL monitoring is illustrated in the diagram below		



- For the 1st VL taken after 3 dispensing cycles, clients should be requested to return to the facility one DC later to review results and so that the client can be assessed for RPCs eligibility.
- For all subsequent VL monitoring (and other routine monitoring investigation) in clinically well clients: Clients should be rescripted at the same visit that their VL is taken. Clients should not be required to come back to the facility the following month for VL result review prior to rescript. Rather, recall to the facility only those clients with an elevated VL or other abnormal result.
- Facilities should ensure that results management processes are in place to ensure that results are reviewed by a clinician, that abnormal results are identified, and the client is appropriately actioned. The NHLS Results for Action (RfA) reports are a useful tool to facilitate the review of results.

! Breastfeeding women should have their VL monitored every 6 months starting from the time of delivery

VL Monitoring Algorithm for Clients on TLD

(also applicable to ALD and other DTG-containing regimens)

Routine VL monitoring for virally suppressed clients as outlined in the algorithm
"Routine HIV VL Monitoring on ART" on page 20
VL monitoring should happen every 6 DCs in a breastfeeding woman

VL < 50 c/mL

VL unsuppressed (VL ≥ 50 c/ml)
(This includes previous VL level of 50–999 and VL > 1 000 c/ml)

Do a thorough assessment of the cause of an elevated VL. Consider the possibility of:
A. **A**dherence problems (see *"Enhanced Adherence Support" on page 22*)
B. **B**ugs (Intercurrent infections)
C. In-**C**orrect ART dosage (see Annexure 5 *"Drug Dosing Chart" on page 34*)
D. **D**rug Interactions (see *"Drug Interactions with DTG and Rifampicin-containing TB Treatment" on page 13*)
E. R**E**sistance (if > 2 years on treatment)

Implement interventions to re-suppress the VL, including **Enhanced Adherence Support** if indicated
(See Annexure 3 Enhanced Adherence Counselling)
Recommend **condom use and contraception** as appropriate

Repeat VL after 3 months

Repeat **VL unsuppressed**[1] **(VL > 50 c/ml)**

Re-assess and resolve adherence issues![2]
(See *"ABCDE assessment of an Elevated Viral Load" on page 22*
and Annexure 3 *"Enhanced Adherence Support" on page 22*)

On TLD for **at least 2 years**

On TLD **less than** 2 years[3]

If **Adherence > 80%**[4], and **Two** or more consecutive **VLs ≥ 1 000 c/mL** taken two or more years after starting TLD regimen or at least one VL ≥ 1 000 c/mL and either CD4 < 200 cells/mm^3 or an opportunistic infection

If adherence still suboptimal[4], or persistent low-level viraemia (2 or more consecutive VLs between 50 and 999 c/mL)

Go to the algorithm for
"Management of Confirmed Virological Failure on TLD" on page 23

Repeat VL at next scheduled routine VL
(i.e., in 6 months' time) Intensify efforts to **resolve adherence issues** [2]

1. Due to their high genetic barrier, resistance to a first-line DTG-containing (TLD1) regimen is extremely rare. If other reasons for an unsuppressed VL have been addressed or excluded, e.g., drug interactions, and the client remains unsuppressed at their repeat VL, suboptimal adherence remains the most probable cause for non-suppression. The highest probability of improving adherence would be to remain on a once-daily, well-tolerated, fixed-dose combination regimen (TLD) while identifying and addressing the underlying root causes of non-adherence. 99,9% of these clients will re-suppress on TLD if adherent!
2. Repeat ABCDE assessment as outlined on *"ABCDE assessment of an Elevated Viral Load" on page 22*. Remember to ask about treatment side-effects, the potential cost of transport or loss of income related to clinic visits, non-disclosure, gender-based violence (GBV), and current or prior drug interactions. Current or previous drug interactions with rifampicin, carbamazepine, phenytoin, phenobarbital, or the polyvalent cations may have resulted in the development of resistance.
3. Drug interactions may also warrant an expert discussion and authorisation of a resistance test earlier than 2 years on the regimen. If necessary, discuss with an expert
4. Objective measures of good adherence include at least one of:
   a. Pharmacy refills > 80% in the last 6–12 months (if this is known)
   b. Attendance of > 80% of scheduled clinic visits in the last 6–12 months (if this is known)
   c. Detection of current antiretroviral drug/s in the client's blood or urine, if available

Note: Self-reported adherence is not considered a measure of good adherence!

ART, Antiretroviral therapy; DTG, Dolutegravir; LLV, Low-level viraemia; SOP, Standard operating procedure; TL, Third-line; TLD, fixed-dose combination of tenofovir, lamivudine, DTG; VL, Viral load.

Assessing an Elevated Viral Load

A thorough assessment is essential for any client with a viral load measuring ≥ 50 c/ml			
Adherence	A	Is adherence to medication poor? Ask about factors that may influence adherence e.g. Direct cost of clinic visits to patient, e.g. transport, loss of income, cost of paying another person to take on social responsibilities • Taking time away from existing work, finding work and/or social care responsibilities • Needing to travel for extended periods of time • Medication side-effects • Unpalatable medications • Depression or other mental health conditions • Alcohol or substance abuse • Poor social support and/or GBV • Non-disclosure Pregnant women may experience nausea/vomitting, heartburn, and constipation. Assess the need for symptomatic treatment with an anti-emetic, anti-diarrhea agent, or fiber supplement. Adherence difficulties in young children are often linked to poor tolerability of unpalatable formulations, particularly LPV/r solution. It is important to ask the caregiver about how the child tolerates the medication e.g., does the child refuse to swallow the medicine or spit, or vomit the medicine out?	**Tips** Ask open ended questions e.g. "What makes it difficult for you to collect or take your treatment?", and "How many doses have you missed this week?" Statements like "we all miss a dose now and then" can encourage a client to be more open. Create a safe and non-judgemental space for your client to discuss challenges.
Bugs	B	Check for symptoms and signs of infection. Do a TB and STI screen.	Remember that immune compromised, malnourished, and pregnant clients may not exhibit overt symptoms of TB. If in doubt, do a TB GXP.
Correct Dose	C	Is the client on the correct dose for their weight? This is especially applicable to growing children, or clients with deteriorating renal function or previous renal impairment	
Drug Interactions	D	Are there any potential drug interactions? Consider: • Other prescribed treatment e.g. rifampicin, anti-epilepsy drugs and pregnancy supplements (iron, calcium) • Over the counter treatment e.g., antacids, multivitamins • Other supplements and herbal/traditional medications e.g. St John's wort	See also ***"Drug Interactions with DTG and Rifampicin-containing TB Treatment" on page 13*** If in any doubt, call the **HIV Hotline 0800 212 506** or one of the ***"Helplines" on page 23***
REsistance	E	Consider HIV drug resistance if other causes of virological failure have been excluded and the client is adherent to their medication by an objective measure.	Refer to the algorithm ***"Management of Confirmed Virological Failure on TLD" on page 23***

Clinician considerations for providing Enhanced Adherence Counselling (EAC)

Barrier to adherence	Intervention	EAC indicated?
Difficulty getting to facility to collect treatment	Reduce unnecessary visits through enrolling client in a RPCs model or providing multi-month dispensing (MMD)	No need for EAC
Drug side effects or unpalatability impacting adherence?	Change to more palatable regimen	No need for EAC
Challenges with taking/remembering to take treatment	Provide EAC	

Enhanced Adherence Support

Enhanced Adherence Counselling (EAC) is aimed at non-stable clients presenting with adherence issues or poor treatment response and/or signs of treatment failure. Enhance Adherence Counselling focuses on:

- Providing education on the outcome of their latest clinical assessment and VL results
- Understanding what the client already knows or doesn't know regarding their treatment and the importance of VL suppression
- Doing a mental health screen
- Correcting any misconceptions and allowing flexibility around the most common barriers to adherence (such as alcohol/drug consumption, forgetting doses due to a rigid schedule, etc.).
- Assessing and understanding the barriers that affect the client's adherence
- Developing adherence strategies to overcome these

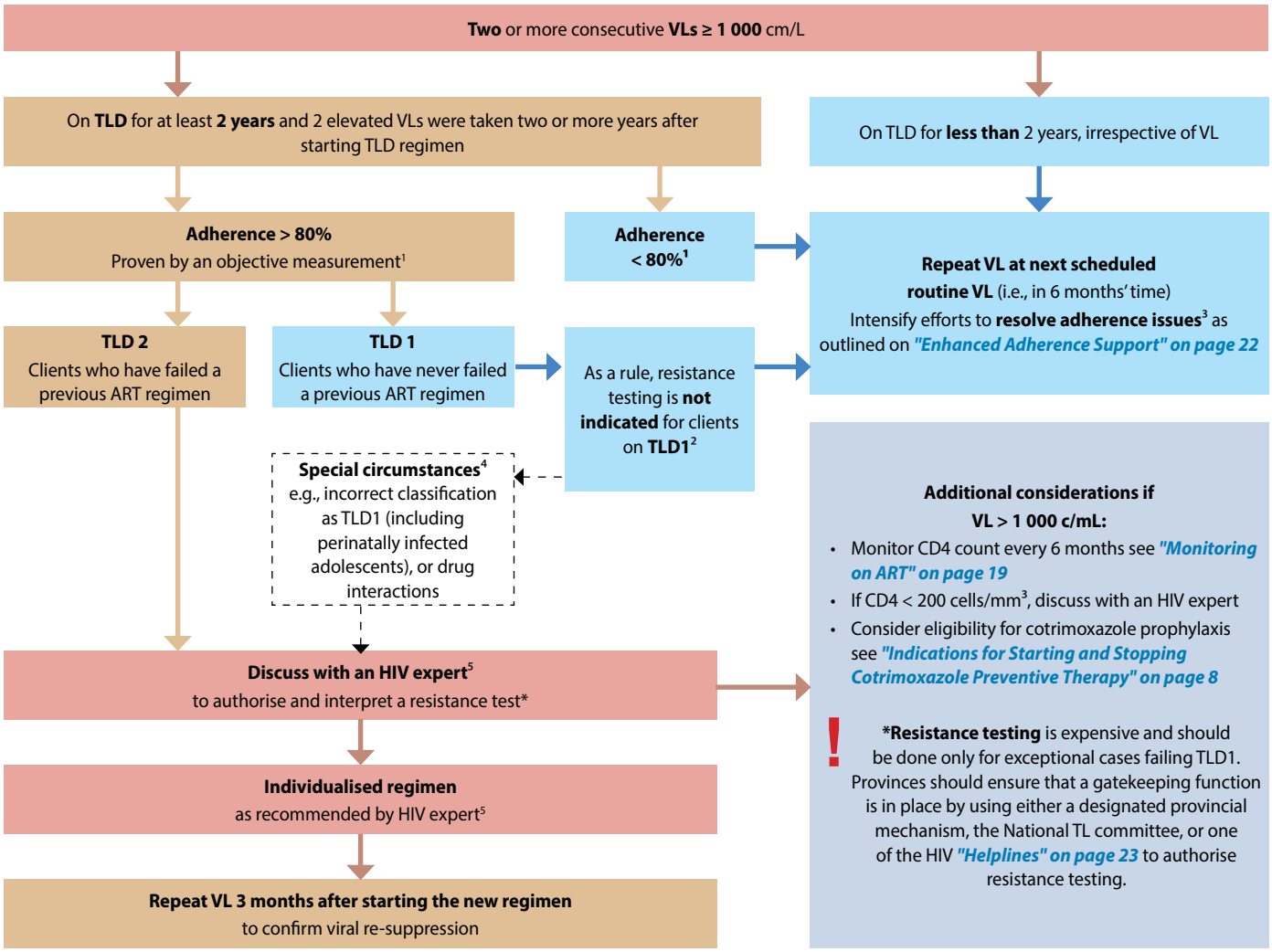
To support the above processes, the following useful tools extracted from the Differentiated Care Models Standard Operating Procedures 2023 included in the annexures:

- SOP 2 Enhanced Adherence Counselling (Annexure 3)
- Mental Health Screen (Annexure 4)
- Child and adolescent disclosure counselling for children living with HIV (Annexure 7)

'better late than never': clients should be counselled they can take their ARVs up to several hours late if they miss their chosen time

Management of Confirmed Virological Failure on TLD

(also applicable to ALD and other DTG-containing regimens)



1. Objective measures of good adherence include at least one of:
   - Pharmacy refills > 80% in the last 6-12 months (if this is known)
   - Attendance of > 80% of scheduled clinic visits in the last 6-12 months (if this is known)
   - Detection of current antiretroviral drug/s in the client's blood or urine, if available
   - Note: Self-reported adherence is not considered a measure of good adherence!
2. Due to their high genetic barrier, resistance to a first-line DTG-containing regimen (TLD1) is extremely rare. If other reasons for an unsuppressed VL have been addressed or excluded, e.g., drug interactions and the client remains unsuppressed at their repeat VL, suboptimal adherence remains the most probable cause for non-suppression. The highest probability of improving adherence would be to remain on a once-daily, well-tolerated, fixed-dose combination regimen (TLD) while identifying and addressing the underlying root causes of non-adherence. 99,9% of these clients will re-suppress on TLD if adherent!
3. Repeat the ABCDE assessment as outlined on *"ABCDE assessment of an Elevated Viral Load" on page 22*. Remember to ask about treatment side-effects, the potential cost of transport or loss of income related to clinic visits, mental health conditions, non-disclosure, poor social support, or substance abuse. If necessary, discuss with an expert or refer to other multidisciplinary team members, if available.
4. Special circumstances that may warrant a resistance test for clients on TLD1 include:
   - Incorrect classification as TLD1 (clients who declare themselves as never having had ART before, but who have actually been exposed to ART and may have failed a regimen in the past)
   - Perinatally infected adolescents: Unless a clearly documented drug history is available, perinatally infected adolescents should be classified as TLD2 due to the high likelihood of ART exposure and virological failure in the past
   - Current or previous drug interactions with rifampicin, carbamazepine, phenytoin, phenobarbital, or the polyvalent cations may have resulted in the development of resistance. Drug interactions may also warrant an expert discussion and authorisation of a resistance test earlier than 2 years on the regimen.

   In these types of exceptional circumstances, TLD1 clients with persistent virological failure despite confirmed good adherence may be discussed with an expert to authorise a resistance test on a case-by-case basis.
5. For advice from an HIV expert, approach an HIV Hotline, an infectious disease specialist, or the Third Line ART committee

If in doubt about any aspect of viral load management or switching to second-line, contact one of the following resources:

National HIV & TB Health Care Worker Hotline: **0800 212 506**

Right to Care Paediatric, Adolescent and Adult HIV Helpline: **082 352 6642**

KZN Paediatric Hotline: **0800 006 603**

ART, Antiretroviral therapy; DTG, Dolutegravir; LLV, Low-level viraemia; TL, Third-line; TLD, fixed-dose combination of tenofovir, lamivudine, DTG; VL, Viral load.

Visit Schedule for Integrated Care for the Mother-baby Pair Living with HIV

Age group	Age of child	Routine visits as per RTHB	Dispensing cycle (DC)	ART Follow-up for baby	ART Follow-up for mother	Immunisations	Feeding advice	Growth monitoring	Development	Head circumference	Vit A	Deworming	Oral Health	TB Screen	Mother's Family planing (FP)
Neonate (birth PCR positive)	1–3 week	3–6 days postnatal visit for mother and baby	1	Follow up 1 week ART initiation, then 1–2 weekly thereafter **Clinical review and renew script Switch to ABC/3TC/DTG if eligible.** Give TCA date in 2 weeks to align with 6-week well-baby visit	2 months ART provided at discharge from labour ward which will last mother until 6 week PN visit		x	x							x
	4 weeks														x**
2–6 months (monthly follow-up)	6 weeks*	6 weeks	2*	Clinical review Repeat script for 1DC for baby*	Postnatal clinical review and adherence check-in. Provide breastfeeding support. Provide treatment for 2 DCs (2MMD) for mother	x	x	x						x	
	10 weeks	10 weeks	3	Clinical review Repeat script for 1DC for baby	If mother received either DMPA (Depo Provera®) or NET-EN (Nur Isterate®) after delivery, give repeat injection at this visit***	x	x	x						x	x
	14 weeks	14 weeks	4	Clinical review **and VL** Repeat script for 1DC for baby	Adherence check-in for mother Provide breastfeeding support. Provide treatment for 3 DCs (3MMD) for mother	x	x	x	x	x				x	
	18 weeks	4 months	5	Clinical review and **VL results review** Repeat script for 1DC for baby			x	x						x	
	22 weeks	5 months	6	Clinical review Repeat script for 1DC for baby			x	x						x	
	26 weeks	6 months	7	Clinical review Renew script and provide treatment for 3DCs at a time (3MMD) If any concerns, follow up at shorter intervals	Clinical review and '6-month' VL. Provide breastfeeding support. Script for and provide treatment for 3DCs at a time (3MMD). Alternatively, if VL suppressed, offer RPCs options, if this suits the PCGs needs.	x	x	x	x		x			x	x

HIV can be diagnosed at any age, and the date of ART initiation and timing of VL monitoring will depend on the date of diagnosis. The example below is for an infant with a positive birth PCR and illustrates an ART visit schedule that aligns with the well-baby visit schedule in the RTHB. However, the principles applied here also apply to children with a positive 10-week HIV PCR or a positive 6-month HIV PCR (and HIV tests done at any other time)

The principles are as follows:

1. Wherever possible, try to align the child's ART follow-up visits with the routine well-baby visit schedule in the RTHB
2. Wherever possible, try to align the mother's ART, VL monitoring, and family planning visits with that of the child's visit schedule so the mother-baby pair need only attend the facility once for both consultations on the same day
3. Wherever possible, allow the mother and baby to receive ART at the same facility

* At week 4, switch to DTG if eligible and dispense treatment for the full dispensing cycle (28 days). Review and repeat script at 6 weeks (rather than 8 weeks) to align with the RTHB visit schedule. The additional 2 weeks treatment that the mother-baby pair will have in reserve will allow for alignment with the 6-month RTHB appointment which usually happens around week 26 (compared to 6 DCs of treatment which will only provide enough treatment for 24 weeks)

** Confirm the mother's FP method choice. Inform her that the DMPA injection or the combined oral contraceptive pill (COCP) can be repeated 3-monthly, and will align well with the ART and well- baby visit schedules. Using the NET-EN 2-monthly injection will require additional visits by the mother, as a 2-monthly repeat injection will not always align with the visit schedule outlined above.

*** As per WHO recommendations[1], the repeat injection of DMPA and NET-EN can be given up to 2 weeks early. The repeat DMPA injection can be given up to 4 weeks late without requiring additional contraceptive protection. The repeat NET-EN injection can be given up to 2 weeks late without requiring additional contraceptive protection.

[1]WHO. Selected practice recommendations for contraceptive use. World Health Organization Department of Reproductive Health and Research; 2016.

Age group	Age of child	Routine visits as per RTHB	Dispensing cycle (DC)	ART Follow-up for baby	ART Follow-up for mother	Immunisations	Feeding advice	Growth monitoring	Development	Head circumference	Vit A	Deworming	Oral Health	TB Screen	Mother's Family planing (FP)
6–12 months **3 monthly follow-up**	**30 weeks**	**7 months**	8		Recall to the facility only if the VL is ≥ 50 c/mL		x	x						x	
	34 weeks	**8 months**	9				x	x						x	
	38 weeks	**9 months**	10	Clinical review Renew script and provide treatment for 3DCs at a time (3MMD) If any concerns, follow up at shorter intervals	Provide treatment for 3DCs at a time (3MMD) unless in RPCs Provide breastfeeding support.	x	x	x	x					x	x
	42 weeks	**10 months**	11				x	x						x	
	46 weeks	**11 months**	12*				x	x						x	
	52 weeks*	**12 months (of 30 days)**	13	Clinical review and VL Renew script and provide treatment for 3DCs at a time (3MMD) If any concerns, follow up at shorter intervals	Clinical review and VL Provide breastfeeding support Renew script and provide treatment for 3DCs at a time (3MMD) or offer RPCs options/rescript for RPCs	x	x	x	x	x	x	x	x	x	x
13–24 months **3 monthly follow-up**	**56 weeks**		14	Recall to the facility only if the VL is ≥ 50 c/mL											
	60 weeks		15												
	64 weeks	**15 months**	16	Clinical review Renew script and provide 3DCs of treatment at a time (3MMD) If any concerns, follow up at shorter intervals	Provide treatment for 3DCs at a time (3MMD) Provide breastfeeding support.		x	x	x		x	x		x	x
	68 weeks		17												
	72 weeks		18												
	76 weeks	**18 months**	19	Clinical review Renew script and provide 3DCs of treatment at a time (3MMD) If any concerns, follow up at shorter intervals	6-monthly VL if breastfeeding. Renew script and provide treatment for 3DCs at a time (3MMD) or offer RPCs options/rescript for RPCs. Try to align ART for mother and baby with the well-baby visit schedule	x	x	x	x		x	x		x	x
	80 weeks		20												
	84 weeks		21												
	88 weeks	**21 months**	22	Clinical review Renew script and provide 3DCs of treatment at a time (3MMD) If any concerns, follow up at shorter intervals	Provide treatment for 3DCs at a time (3MMD) Provide breastfeeding support.		x	x						x	x
	92 weeks		23												
	96 weeks		24												
2 until < 5 years **3 monthly follow-up**	**24–59 months**	**At 24 months and 6-monthly thereafter**		**Follow-up visits at 3DC intervals** Renew script and provide treatment for 3DCs at a time (3MMD) Repeat VL at 12 DC intervals If any concerns, follow up at shorter intervals	6-monthly VL if breastfeeding. Renew script and provide treatment for 3DCs at a time (3MMD) or offer RPCs options/rescript for RPCs **Try to align with child's yearly well-baby visit schedule**		Up to 2 years	6-monthly	At 3 years		6-monthly	6-monthly	yearly	3-monthly	3-monthly

Visit Schedule for Integrated Care for Clients already on ART when diagnosed with Drug-sensitive TB

GENERAL PRINCIPLES

- Clinicians should provide integrated TB management at clinical consultation visits. Failure to combine care leads to increased visit schedules and significantly increases the risk of disengagement and loss-to-follow-up (LTF).
- This schedule is for a standard DS-TB treatment (Rx) regimen consisting of 2 months of intensive phase Rx (IP) and 4 months of continuation phase (CP) Rx after a negative smear at the end of the IP.
- This schedule applies to a client already on ART when diagnosed with drug-sensitive TB. A client diagnosed with HIV and TB can also benefit from 2-months supply of ART and TB continuation phase to support adherence and retention.

Integrated visit schedule for a client on ART who develops DS-TB (not in RPCs)		**Months (M) on TB Treatment (Rx)**						
		Intensive Phase (IP) (months 1-2)				**Continuation Phase (CP) (months 3-6)**		
		TB M0	**TB M1 (4 completed weeks)**	**7 wks**	**TB M2 (8 completed weeks)**	**TB M4 (16 completed weeks)**	**23 wks**	**TB M6 (24 completed weeks)**
Integrated TB/ ART clinical consult	TB screening as part of routine care	TB diagnosis and TB Rx initiation	Clinician-managed care at facility		Assess smear conversion and transition to CP of TB Rx, if smear result is negative	Clinician-managed care at facility		Confirm TB Rx completion Assess for RPCs enrolment
Investigations	TB GeneXpert and any other investigations as clinically indicated	Review result		Smear	Review result		Smear	Review end-of-Rx result
ART/TB script	Script ART for 1 month	Combined script for 1 month of IP TB Rx and ART	Combined script for 1 month of IP TB Rx and ART		Combined script for 2 months** of CP TB Rx and ART	Combined script for 2 months** CP of TB Rx and ART"		If eligible for RPCs: RPCs ART script for 6 months
ART-TB drug supply dispensed by facility	Dispense ART for 1 month	Dispense 1 month of IP TB Rx and DTG boosted ART	Dispense 1 month of IP TB Rx and DTG boosted ART		Dispense 2 months of CP TB Rx and 2 months DTG boosted ART	Dispense 2 months of CP TB Rx and 2 months DTG boosted ART		Dispense 3 months of ART
Ask client to return:	If client has TB symptoms or is unwell, ask client to return in 5-7 days for review *	After 4 weeks for clinical review	After 3 weeks for sputum smear	After 1 week for smear results	After 8 weeks for clinical review	After 7 weeks for end of Rx smear	After 1 week for smear results	If eligible and enrolled in RPCs: return for next ART supply at RPCs pick-up point after 3 months

OVERVIEW OF PRINCIPLES FOR TB MANAGEMENT IN PLHIV WHO ARE RECEIVING ART THROUGH AN RPCS MODEL

- If an RPCs client screens positive for TB symptoms at their RPCs clinical review visit but is not acutely unwell, the clinician will rescript for RPCs.
- **If acutely unwell, return to clinician-managed care and do not script for RPCs again. Follow approach in table above.**
- Results (TB investigations and VL) should be reviewed in 5-7 days, or sooner if possible*
- If the patient is diagnosed with TB and/or their VL is ≥ 50c/mL, the patient will return to regular clinician-managed care and should be re-assessed for RPCs enrolment when TB Rx is completed and/or their VL is < 50 c/mL again).
- If the patient **is not diagnosed** with TB (and their VL was suppressed), the patient will continue in RPCs.

Integrated visit schedule for a client in RPCs who develops DS-TB		Months (M) on TB Treatment (Rx)						
		Intensive Phase (IP) (months 1-2)				Continuation Phase (CP) (months 3-6)		
		TB M0 (Rx initiation)	TB M1 (4 completed weeks)	7 wks	TB M2 (8 completed weeks)	TB M4 (16 completed weeks)	23 wks	TB M6 (24 completed weeks)
Integrated TB/ ART clinical consult	RPCs clinical visit with clinician consultation	TB diagnosis and TB Rx initiation De-register from RPCs and continue care at a facility	Clinician-managed care at facility		Assess smear conversion and transition to CP of TB Rx, if smear result is negative	Clinician-managed care at facility		Confirm TB Rx completion Assess for RPCs. If eligible for RPCs: Re-enrol in RPCs
Investigations	VL, eGFR, TB symptom screen and routine TB GeneXpert Any other investigations as clinically indicated	Review result		Smear	Review result		Smear	Review end-of-Rx result
ART/TB script	Repeat 6 month ART script for RPCs (unless acutely unwell)	Script 1 month of IP TB Rx and additional DTG****	Script 1 month of IP TB Rx and additional DTG****		Combined script for 2 months** of CP TB Rx and ART	Combined script for 2 months** of CP TB Rx and ART		If eligible for RPCs: RPCs ART script for 6 months
ART-TB drug supply dispensed by facility	Dispense first 3 months of ART supply from facility***	Dispense 1 month of IP TB Rx	Dispense 1 month of IP TB Rx		Dispense 2 months of CP TB Rx and 2 months of DTG boosted ART	Dispense 2 months of CP TB Rx and 2 months of DTG boosted ART		Dispense 3 months of ART
Ask client to return:	If the client has TB symptoms ask the client to return in 5-7 days for review*	After 4 weeks for clinical review	After 3 weeks for sputum smear	After 1 week for smear results	After 8 weeks for clinical review	After 7 weeks for end of Rx smear	After 1 week for smear results	If eligible and enrolled in RPCs: return for next ART supply at RPCs pick-up point after 3 months

* If the facility does not have a reliable results management and/or recall system in place, it will require the patient to return to the facility within 5-7 days for a combined review of their TB and VL results. If the facility has an effective result management and recall system in place, it may recall only those clients with a positive TB diagnosis and/or a VL ≥ 50 c/mL.

** For TB with longer continuation phases, a 3-month supply can be considered (see DMOC SOP 4) to align TB/ART Rx supply length between investigations and clinical consultations.

*** Clients in RPCs who screen positive for TB but are not acutely unwell can remain in their RPCs until their TB diagnosis is confirmed. After a positive TB screen, the client will continue to be scripted for RPCs with the facility providing the first 3 months ART supply and the RPCs providing the second three month ART supply. Where a facility has an ART stock shortage concern, the script can be adjusted to the facility providing the first 2 months ART supply and the RPCs providing the second 4 months ART supply (4MMD). If the client is subsequently diagnosed with TB, the client will be returned to facility-based care. As they have already received a 3-month supply of ART, they will have ART on hand to cover their intensive phase, and will only require boosted DTG to be scripted. Thereafter ART to be dispensed again at TB M2 (i.e. after 2 completed months of TB treatment). However, where the patient only received a 2-month ART supply because of facility stock shortages, the ART supply on hand will not be sufficient for the full intensive phase of TB treatment, as the ART would have been dispensed a number of days before TB treatment was initiated. ART will need to be topped up at TB M1 to ensure sufficient supply to TB M2. The table accounts for when ART will need to be supplied again with TB treatment based on the patient having received a 3 month ART supply.

**** DTG boosting is required when the client is on rifampicin containing TB treatment. In adults and adolescents, the dosing frequency of DTG should be increased to 50 mg 12-hourly. If on TLD FDC, then add DTG 50 mg 12 hours after TLD dose. For DTG-boosting in children, see "Drug Dosing Chart" on page 34. DTG boosting should continue until 2 weeks after TB treatment has been completed.

Annexures available online at: https://ojs.sabinet.co.za/index.php/sapj/article/view/273/148