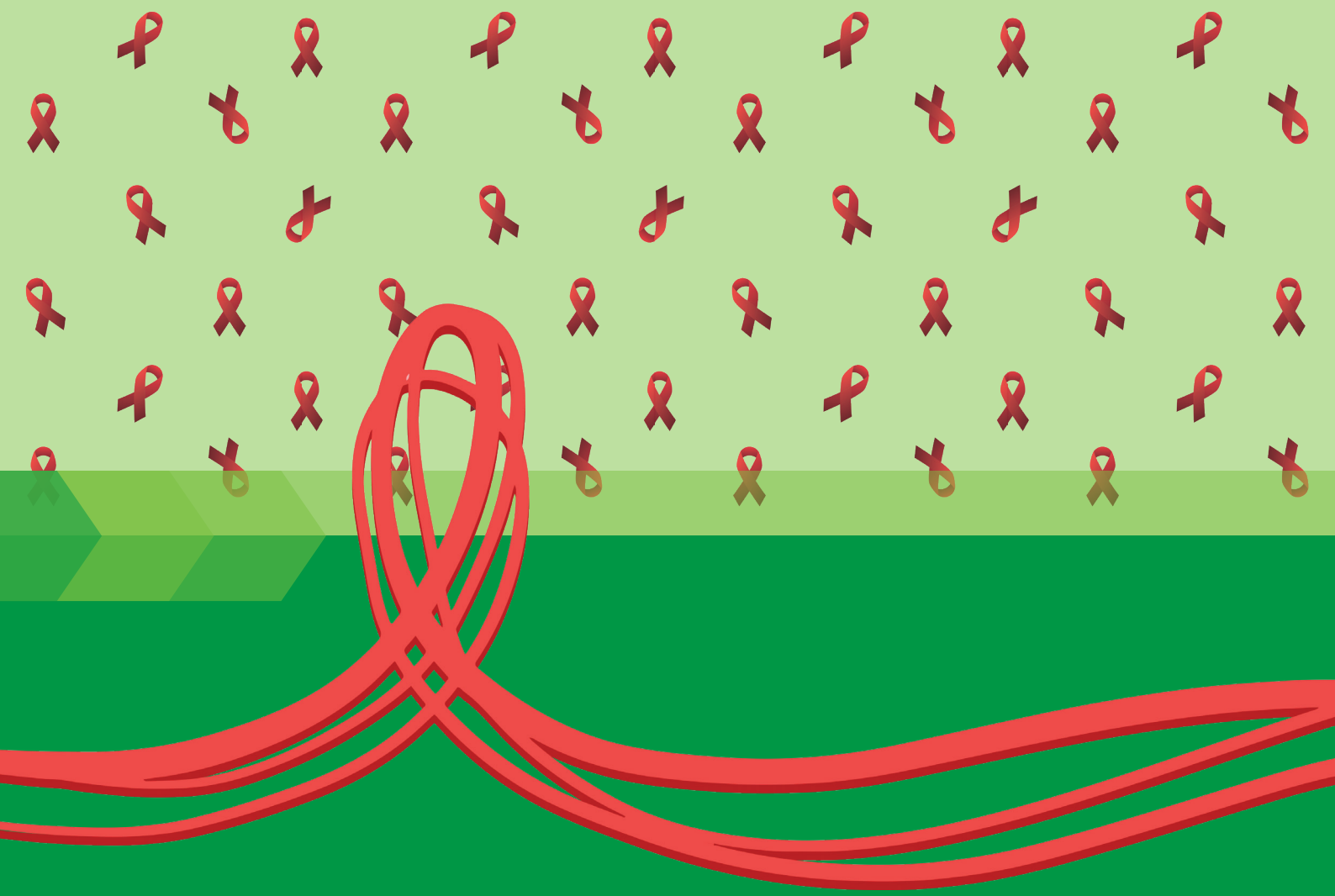


2023 ART Clinical Guidelines

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

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

World Health Organization

2030 NDP

Contents

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 3kg 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

What is New in this Guideline?

Terminology	**TLD 1** (or ALD 1 in children)	Clients on a DTG-containing regimen, who have **never failed** any other regimen (previous "first-line" terminology)
	TLD 2 (or ALD 2 in children)	Clients on a DTG-containing regimen, who **have failed** an earlier regimen (previous "second-line" terminology)
	Dispensing cycle:	A dispensing cycle (DC) is defined as the number of days for which a client would have treatment if a single standard "monthly" quantity of tablets were dispensed. The term 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)
ART Regimens	**All adult and adolescent clients > 30 kg and > 10 years of age, including pregnant and breastfeeding women**	• The preferred first-line ART regimen is **tenofovir disoproxil fumarate-lamivudine-dolutegravir (TLD)** for those adult and adolescent clients initiating ART. • TDF weight-related eligibility criteria decreased from **35 kg to 30 kg** • All clients already on ART and not on dolutegravir (DTG), whether on first-line or second-line regimens, should be evaluated for a switch to a dolutegravir-containing regimen.
		• TDF may safely be reused in 2nd-line therapy following 1st-line failure with TDF-containing regimens. TLD will therefore be used as both first (TLD 1) and second (TLD 2) line regimens and in certain cases, 3rd line regimens as well • Simplified **switching from TEE to TLD not dependant on VL**
	New formulations	• **DTG 10 mg dispersible tablets** for children from ≥ 3kg and ≥ 4 weeks of age • DTG-containing fixed-dose combination: Abacavir (ABC) 600 mg + lamivudine (3TC) 300 mg + DTG 50 mg (ALD FDC). ALD FDC can be prescribed for clients ≥ 25 kg
	Children ≥ 3 kg and ≥ 4 weeks of age until 29,9 kg or 9 years of age	• The preferred first-line ART regimen is **abacavir-lamivudine-dolutegravir (ALD)**. • All paediatric clients already on ART and not on dolutegravir (DTG), whether on first-line or second-line regimens, should be evaluated for a switch to a dolutegravir-containing regimen.
	Other antiretrovirals	• **Abacavir** is the preferred alternative agent if TDF cannot be used • Zidovudine (AZT) no longer part of any standard ART regimen. AZT will be reserved only for cases with **both** renal failure **and** ABC hypersensitivity • **Atazanavir/r** replaces lopinavir/r as the preferred protease inhibitor except when on TB treatment
Monitoring on ART	**VL monitoring**	**First VL** after ART initiation to be done after 3 dispensing cycles
	Creatinine and eGFR	eGFR previously done at 'month' 6 moves to 'month' 3 (i.e. after 3 dispensing cycles) to align with the new VL monitoring schedule
Virological Failure	• **Definition:** two or more VLs ≥ 1000 c/mL taken two or more years after starting a DTG/PI-containing regimen and adherence > 80% • **Focus on improved adherence:** Resistance to DTG is very uncommon. If other reasons for an unsuppressed VL (including drug interactions) have been addressed or excluded, 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. • **No regimen changes without a resistance test:** Switching off a DTG-containing regimen should only happen if InSTI resistance has been confirmed by a resistance test • Resistance testing can only be authorised by a member of the National Third-line committee, one of the helpline consultants, or a nominated provincial expert	

Other updates	• 2 high quality counselling sessions at ART start and at follow-up a month later
	• Reduces health facility visits in the first year on ART to support continued engagement in care, including visit schedule for first year on treatment.
	• Removes time on ART from repeat prescription collection strategies (RPCs) eligibility criteria, enabling access as soon as first VL is suppressed.
	• Reduces visits once enrolled in RPCs with a maximum of 2 visits per 6-month scripting cycle.
	• Returns clients in RPCs with VL 50-1000 c/mL to clinician care for TLD switch and VL management
	• Enables multi-month dispensing (MMD) by the facility between clinical visits including for people not eligible for RPCs - children from 6 months of age, post-natal women, people co-infected with TB, with elevated viral loads or re-engaging in care.
	• Introduces a differentiated approach to management on re-engagement.
	• Integrates contraception and TB preventative therapy into all service delivery models
	• Aligns ART visit schedules to TB management and infant EPI schedules to enable integration
	• Incorporates tools for:
	  • enhanced adherence counselling
	  • mental health assessment	

Overview

This ART Clinical Guideline is intended to serve as a quick reference guide for antiretroviral treatment (ART) in adults, pregnant and breastfeeding women, adolescents and paediatric clients, and as a job aide for healthcare workers and implementing partners. This document is not intended to be exhaustive; for more information or details on any recommendations, or on the prevention of vertical transmission, please refer to the comprehensive Consolidated HIV Guidelines document and the Guideline for Family-Centred Transmission Prevention of Communicable Infections (HIV, Hepatitis, Listeriosis, Malaria, Syphilis and TB) 2023.

These guidelines have been revised with the Differentiated Models of Care (DMOC) Standard Operating Procedures (SOPs) to ensure simultaneous consideration and alignment of clinical, adherence and service delivery updates. The DMOC SOPs form part of this guidance to enable optimal use of decentralised and integrated service delivery and should be read concurrently with this clinical guideline.

The objectives of this document are to:

- Provide guidance on initiation of ART in antiretroviral-naïve clients as well as those returning to care in the era of dolutegravir (DTG)
- Provide guidance for switching of clients already on ART to DTG-containing regimens
- Provide guidance on routine management of clients on ART to promote viral suppression
- Highlight critical areas for provision of integrated ART, TB, and family planning services, and the use of differentiated models of care

The preferred first-line ART regimen is tenofovir disoproxil fumarate-lamivudine-dolutegravir (TLD) for those adult and adolescent clients initiating ART, and abacavir-lamivudine-dolutegravir (ALD) in children . All clients already on ART and not on dolutegravir (DTG), whether on first-line or second-line regimens, should be evaluated for switch to a dolutegravir-containing regimen.

In the new ART era of dolutegravir, TLD will be used as a first-line and a second-line ART regimen, and as part of certain third-line regimens with other medicines. This has necessitated a change of the previous “first-line” and “second-line” terminology to the following:

TLD1: Clients on a DTG-containing regimen, having never failed a previous regimen (old “first-line” terminology)

TLD2: Clients on a DTG-containing regimen, who have failed a previous regimen (old “second- line” terminology)

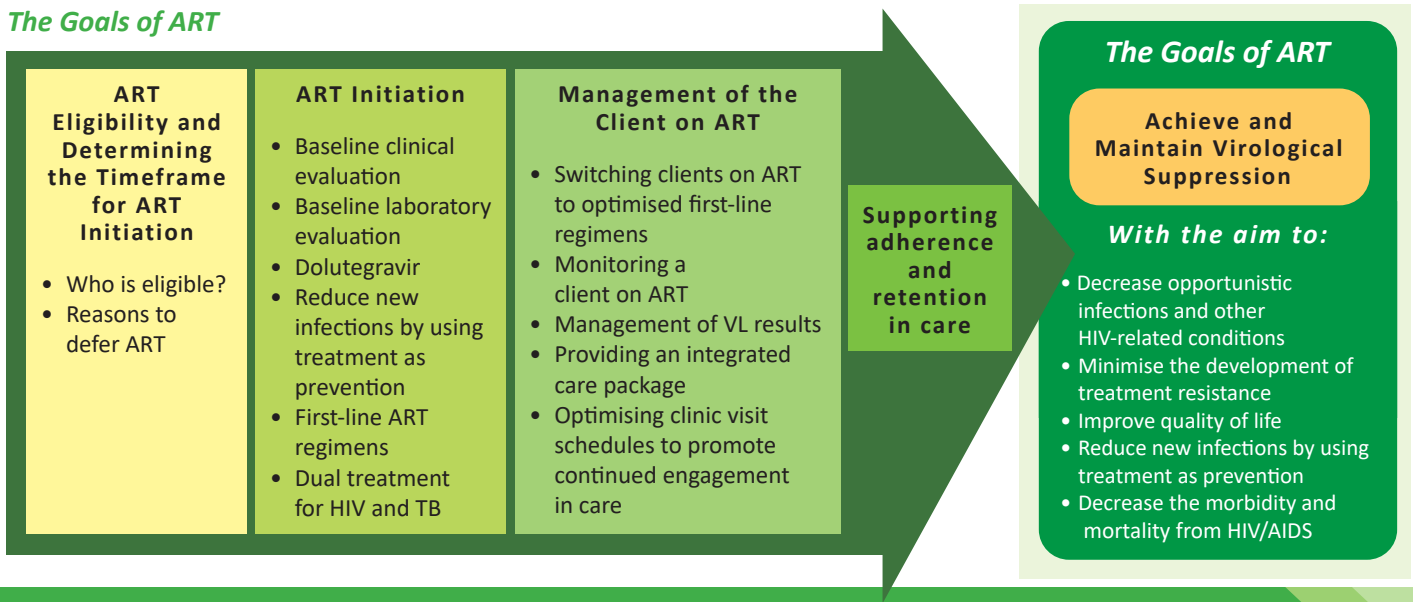
The safety of DTG in women of childbearing-potential has been firmly established and neural tube defects are no longer a concern that influences regimen choice in women. However, the integration of family planning and ART services remain of paramount importance, and issues of family planning and contraception should be discussed at every clinical interaction to understand the client’s current fertility desires and healthcare needs.

All people either currently on ART, or newly initiated on ART, should be screened for TB and assessed for TB preventive therapy (TPT) as indicated. All individuals should be assessed for advanced HIV disease (AHD) and provided with a comprehensive package of care, including cotrimoxazole prophylaxis, as needed.

The guideline broadly follows the process of care, namely:

1) ART eligibility and determining the timeframe for ART initiation
2) ART initiation
3) Management of the client on ART
4) Supporting adherence, sustained viral suppression and retention in care

The Goals of ART



ART Eligibility

All people living with HIV (PLHIV) are eligible to start ART regardless of age, CD4 cell count and clinical stage. For all clients without contra-indications, ART should be initiated within 7 days, and on the same day if possible. Pregnant women, infants and children under five years, and clients with advanced HIV disease should be prioritised for rapid initiation. Many clients (including pregnant women) may be able to initiate ART on the same day as their HIV diagnosis, provided that they are clinically well, and are motivated to start ART. While rapid, and same-day ART initiation is encouraged where possible, all clients, particularly those with advanced HIV disease, should be carefully assessed for opportunistic infections (OIs) that may necessitate ART deferral.

Medical Indications to Defer ART

Medical Indications to Defer ART	
Indication	**Action**
TB symptoms (cough, night sweats, fever, recent weight loss)	Investigate symptomatic clients for TB before initiating ART. If TB is excluded, proceed with ART initiation and TB preventive therapy (after excluding contra-indications to TPT). If TB is diagnosed, initiate TB treatment and defer ART. The timing of ART initiation will be determined by the site of TB infection and the client's CD4 cell count
Diagnosis of drug-sensitive (DS) TB at a non-neurological site (e.g. pulmonary TB, abdominal TB, or TB lymphadenitis)	Defer ART initiation as follows: • If CD4 < 50 cells/µL – initiate ART within 2 weeks of starting TB treatment, when the client's symptoms are improving, and TB treatment is tolerated • If CD4 ≥ 50 cells/µL – initiate ART 8 weeks after starting TB treatment • In pregnant and breastfeeding women (PBFW) initiate ART within 2 weeks of starting TB treatment, when the client's symptoms are improving, and TB treatment is tolerated. Defer ART for 4-6 weeks if symptoms of meningitis are present. For further details, refer to the Family-Centered Transmission Prevention Guideline 2023
Diagnosis of drug-resistant (DR) TB at a non-neurological site (e.g. pulmonary TB, abdominal TB, or TB lymphadenitis)	Initiate ART after 2 weeks of TB treatment, when the client's symptoms are improving, and TB treatment is tolerated
Diagnosis of DS-TB or DR-TB at a neurological site (e.g. TB meningitis or tuberculoma)	Defer ART until 4-8 weeks after start of TB treatment
Signs and symptoms of meningitis	Investigate for meningitis before starting ART
Cryptococcal antigen (CrAg) positive in the absence of symptoms or signs of meningitis and if lumbar puncture is (LP) negative for cryptococcal meningitis (CM)	No need to delay ART. ART can be started immediately.
Confirmed cryptococcal meningitis	Defer ART until 4-6 weeks of antifungal treatment has been completed
Other acute illnesses e.g. *Pneumocystis jirovecii* pneumonia (PJP) or bacterial pneumonia	Defer ART for 1-2 weeks after commencing treatment for the infection
Clinical symptoms or signs of liver disease	Confirm liver injury using ALT and total bilirubin levels. ALT elevations > 120 IU/L with symptoms of hepatitis, and/or total serum bilirubin concentrations > 40 µmol/L are significant. Investigate and manage possible causes including TB, hepatitis B, drug-induced liver injury (DILI), or alcohol abuse
Note: Clients who are already on ART should NOT have their treatment interrupted upon diagnosis of the above conditions	

ART Initiation

A clinical assessment and laboratory baseline investigations should be done in order to initiate ART. However, laboratory results do not need to be available to start clients on ART on the same day, provided they have no clinical evidence of TB, meningitis or renal disease. In addition, all clients, and caregivers of paediatric clients, must receive counselling on how to administer medication, monitor side-effects and deal with challenges to adherence.

Baseline Clinical Evaluation for Adults and Adolescents, Pregnant Women, and Children < 10 Years

The baseline clinical evaluation of a client about to start ART requires a thorough **history and clinical examination**. The minimum components of the baseline clinical evaluation are outlined in the table below.

Interventions to support adherence to ART
ART literacy education and fast-track initiation counselling (FTIC) empower clients to adhere to treatment, and positively influence clinical outcomes. Adherence counselling at ART initiation and first follow-up visit should focus on:

- providing the client with an understanding of HIV, ART, and the importance of VL suppression
- providing the client with practical skills to adhere to ART
- identifying any potential risk factors for adherence in the future
- An individualized adherence plan should be developed with clear treatment milestones, including an undetectable viral load

Component of the Baseline Clinical Evaluation	Purpose	Further Action Required		
		Adolescents (10-19 years) and Adults	Pregnant Women	Children (< 10 years)
Recognise the client with respiratory, neurological, or abdominal **danger signs needing urgent care**	To identify opportunistic infections and conditions needing urgent care or referral See also the section on ***"Advanced HIV Disease" in the 2023 Consolidated ART Guideline***	Identify respiratory, neurological, or abdominal danger signs as outlined in Adult Primary Care (APC) guideline	Identify danger signs as outlined in the Maternity Care guidelines	Identify danger signs as classified in the IMCI Chart booklet
Nutritional Assessment	To identify recent weight loss that may indicate an active opportunistic infection (OI) or other pathology. To identify underweight/ obese clients requiring nutritional and lifestyle support	Measure weight and height and determine BMI (kg/m^2): < 18.5 = underweight; 18.5 to 25 = normal; > 25 to < 30 = verweight; ≥30 = obese	Measure mid upper arm circumference (MUAC) Women with MUAC < 23 cm require additional nutritional support/ referral	Plot weight, height and head circumference (if < 2 years) on growth chart, and measure MUAC to identify moderate and severe malnutrition
Test for TB	To identify clients who require treatment for TB To identify clients who do not have active TB and who may be eligible for TPT ***see "TB Preventive Therapy" on page 9***	At enrolment into care/ ART start: • TB symptom screen and clinical examination • Routine MTB/Rif Ultra (Xpert) on all PLHIV at enrolment into ART care (regardless of TB symptoms)	For all HIV-positive women at first visit in antenatal clinic, do a: • TB symptom screen and clinical examination • Routine MTB/ Rif Ultra (Xpert) (regardless of TB symptoms)	Identify symptoms of cough, night sweats, fever, failure to thrive as outlined in the TB screening tool Attempt sputum testing (and Xpert) where feasible Enquire about TB contacts

Additional TB Investigations for Symptomatic Clients:

For symptomatic PLHIV admitted to hospital
[in addition to the MTB/Rif Ultra (Xpert)]

- Do a U-LAM test
- Do a chest X-ray if clinically indicated
- Do other investigations for extra-pulmonary TB if clinically indicated

Enquire about TB contacts

For symptomatic PLHIV seen in an outpatient setting
[in addition to the MTB/Rif Ultra (Xpert)]

- Do a U-LAM test if:
  - CD4 count <200 within the last 6 months, or
  - advanced HIV disease, or
  - current serious illness.
- Do a chest X-ray if clinically indicated

Component of the Baseline Clinical Evaluation continued	Purpose	Further Action Required		
		Adolescents (10-19 years) and Adults	Pregnant Women	Children (< 10 years)
Screen for symptoms of meningitis	To diagnose and treat clients with cryptococcal and other forms of meningitis and reduce associated morbidity and mortality	**Identify symptoms of headache, confusion** or **visual disturbances.** With cryptococcal meningitis, clients may only present with a recurrent headache. Other symptoms may include fever, neck stiffness or coma. Do/refer the client for a **lumbar puncture**. Defer ART if meningitis is confirmed as outlined in ***"Medical Indications to Defer ART" on page 4***		
Screen for active depression, other **mental health** issues or substance abuse	Mental health conditions and substance use can affect adherence and the client's quality of life. In general, ART can be initiated, and cautiously monitored see also ***"Mental Health Assessment" on page 31***	Screen for symptoms of depression, psychosis, and substance abuse		Screen for symptoms of depression in older children
Screen for major chronic **non-communicable diseases (NCDs)** (diabetes, hypertension, epilepsy)	To identify and manage clients with major chronic NCDs and/or comorbidities. To identify and prevent potential drug interactions with ART e.g. metformin and anti-epileptic medications	Do blood pressure (BP), and urine dipstix for proteinuria and glucose. Identify other risk factors (smoking, increased waist circumference, age) and determine cardiovascular (CVS) risk. Manage NCDs and CVS risk factors as outlined in the PHC EML	Do blood pressure (BP), and urine dipstix for proteinuria and glucose	Identify the child with epilepsy and be aware of potential drug interactions of anti-epileptic treatment and ART
Screen for **pregnancy** and ask if planning to conceive	To identify pregnancy and facilitate early referral for antenatal care (ANC) and measures to prevent vertical transmission. To assess fertility intentions and contraceptive needs if not pregnant.	Ask if the client is currently using contraception and if her last menstrual period occurred at the expected time. If she answered "no" to either question, do a urine pregnancy test	N/A	N/A
Symptom screen for **sexually transmitted infections** (STIs)	To identify and treat STIs in sexually active clients	STI screening should include the following three questions: "Do you have any genital discharge?" "Do you have any genital ulcers?" "Has/have your partner(s) been treated for an STI in the last 8 weeks?		N/A
Neurodevelopmental screen	To identify children with neurodevelopmental delay requiring intervention/referral and follow-up	N/A	N/A	Screen for developmental delays as outlined in the child's Road to Health Booklet (RTHB)
WHO clinical stage	**After the baseline clinical evaluation has been completed by means of a thorough history and clinical examination, the client's WHO clinical stage can be determined:** **At ART initiation**, WHO clinical stage helps us to: Understand the severity of the client's clinical condition and the associated risk of mortality Determine the urgency and timing of ART initiation Determine if cotrimoxazole prophylaxis (CPT) is indicated see ***"Indications for Starting and Stopping Cotrimoxazole Preventive Therapy" on page 8***			

Baseline Laboratory Evaluation for Adults and Adolescents, Pregnant Women, and Children

The following baseline laboratory investigations should be performed routinely before a client initiates ART. Clients are not required to wait for the results of the baseline investigations prior to starting ART, but results should be checked at the next visit.

Laboratory evaluation	Purpose	Adolescents (10-19 years) and Adults	Pregnant Women	Children (< 10 years)
Confirm HIV test result	To confirm HIV status for those without documented HIV status	✓	✓	✓
CD4 cell count/ %	To identify eligibility for CPT	See ***"Indications for Starting and Stopping Cotrimoxazole Preventive Therapy" on page 8***		
	To identify eligibility for cryptococcal antigen (CrAg) screening	A reflex CrAg test will be done automatically by the laboratory on all CD4 counts < 100 cells/µL		N/A
Creatinine and eGFR if TDF used	To assess renal insufficiency	See table titled ***"Assessing Renal Function" on page 8***		N/A
Haemoglobin (Hb)	To identify and manage anaemia; to determine eligibility for zidovudine (AZT) where necessary	If Hb is low, do a full blood count (FBC). Characterise according to mean corpuscular volume (MCV) as either microcytic, normocytic, or macrocytic and manage accordingly[1]	Treat with ferrous sulphate tds if Hb < 10 g/dL. Refer if < 8 g/dL and symptoms, if anaemia diagnosed at 36 weeks gestation or later, or if no response to treatment	Children < 5 years: Treat with iron supplements and deworm the child[1] Children ≥ 5 years: Do FBC. Characterise according to MCV and manage accordingly[1]
GeneXpert (MTB/Rif Ultra)	To diagnose TB	For any client with a positive TB symptom screen For people living with HIV, regardless of TB symptoms: • At the time of HIV diagnosis • On enrolment in antenatal care for pregnant women		
Cryptococcal antigen test (CrAg) if CD4 < 100 cells/ µL	To identify asymptomatic clients who need pre-emptive fluconazole treatment	A reflex CrAg test will be done automatically by the laboratory on all CD4 counts < 100 cells/µL If CrAg-negative, no fluconazole is required If CrAg-positive, the client will require treatment of the infection All CrAg-positive clients should be referred for a lumbar puncture, regardless of symptoms	All pregnant women with a positive CrAg should be referred for a lumbar puncture, regardless of symptoms. The results of the lumbar puncture and further management should be discussed with an expert, or one of the ***"Helplines" on page 23***	N/A
Cervical cancer screening	To identify women with cervical lesions and manage appropriately	All HIV-positive women should be screened for cervical cancer at diagnosis and subsequently every 3 years if the screening test is negative. If the cervical screening results suggest a possible abnormality of the cervical cells, then a clear plan for further investigation and treatment (e.g. colposcopy and LLETZ procedure) should be determined according to the local referral guidelines.	Pregnancy does not preclude screening for cervical cancer and it can be performed up to 20 weeks of gestation. If the cervical screening results suggest a possible abnormality of the cervical cells, then a clear plan for further investigation (e.g., colposcopy) should be determined according to the local referral guidelines	N/A
HBsAg	To identify those co-infected with hepatitis B (HBV)	If positive, exercise caution in stopping TDF-containing regimens, to prevent hepatitis flares		N/A

[1] As outlined in the PHC EML 2020

Assessing Renal Function

> **!** A low absolute creatinine level is of no concern and needs no intervention. It may be an indication of low muscle mass. However, a low creatinine clearance (eGFR) is of concern and indicates reduced renal function.

Assessing Renal Function

Age/pregnancy Status	What must be measured?	Acceptable level for TDF use
≥ 10 and < 16 years of age	eGFR using Counahan Barratt formula	> 80 mL/min/1.73 m^2
Adults and adolescents ≥ 16 years	eGFR using MDRD equation[1]	> 50 mL/min/1.73m^2
Pregnant women	Absolute serum creatinine level	< 85 µmol/L

Counahan Barratt formula

$$\text{eGFR (mL/min/1.73 m}^2\text{)} = \frac{\text{height [cm] x 40}}{\text{creatinine [µmol/L]}}$$

DTG is known to decrease tubular secretion of creatinine without affecting glomerular filtration. Serum creatinine concentrations increase early in treatment (by less than 15%), remain stable throughout therapy, and are not an indication to stop DTG. A creatinine level that keeps on rising, is however a cause for concern and could indicate TDF toxicity or other underlying pathology.

[1] Modification of Diet in Renal Disease Study (MDRD) equation. The MDRD formula is automatically calculated by the laboratory for those 18 years and older. For assistance in manually calculating the eGFR for adolescents between 16 and 18 years of age, please contact one of the ***"Helplines" on page 23.*** Alternatively, use the calculator provided at https://www.mdcalc.com/mdrd-gfr-equation, or one of numerous smartphone applications available for this purpose. Ensure that the website/application uses the correct unit of measurement (i.e. µmol/L) for the creatinine level

Indications for Starting and Stopping Cotrimoxazole Preventive Therapy (CPT)

Age and HIV status	When to Start	When to Stop
HIV-positive infant under 1 year of age	All children under 1 year should be on cotrimoxazole irrespective of CD4% or clinical stage	
HIV-positive child 1-5 years of age	CD4% ≤ 25 %, WHO Stage 2, 3, and 4	Discontinue if CD4 count > 25 %, regardless of clinical stage
HIV-positive child under 5 years of age with PJP infection	Start CPT after PJP treatment is completed	Continue CPT until 5 years of age and stop thereafter only if CD4 criteria in the older-than-five category are met
HIV-positive adults and children older than 5 years	CD4 count ≤ 200 cells/µL, WHO Stage 2, 3 and 4	Discontinue if CD4 count > 200 cells/µL, regardless of clinical stage

TB Preventive Therapy

All clients starting ART, or already on ART, and who have not yet received TB Preventive Therapy (TPT), should be considered for TPT. Prior to initiating TPT, active TB should be ruled out through a clinical evaluation and by testing for TB. If the client is asymptomatic, TPT initiation need not be delayed if TB GeneXpert results are outstanding. TPT and ART can be initiated on the same day. A Tuberculin skin test (TST) is not required prior to starting TPT. TB testing strategies will vary by age as younger children cannot spontaneously expectorate sputum. In well children without symptoms, neither sputum testing nor CXR are therefore requirements to start TPT. Sputum testing should be attempted in children who can expectorate spontaneously (typically > 25kg), but if they are well (without symptoms) and unable to expectorate, they should start TPT, even if no CXR or sputum testing is available.

Category of Client	Specific Eligibility Criteria	Treatment and Duration
Adult or adolescent ≥ 15 years (non-pregnant)	Any CD4 count. Exclude active liver disease, alcohol abuse, or known hypersensitivity to isoniazid	Isoniazid, oral, 300 mg daily for 12 months (12H) and pyridoxine 25 mg daily Rifapentine and isoniazid weekly (3HP) may be available in selected locations*
Children living with HIV who are < 15 years of age	• Children undergoing their first evaluation for HIV and ART, from 14 weeks of age • All children (including neonates) with significant exposure to TB	Isoniazid, oral, 10 mg/kg/day for 6 months (maximum dose 300 mg daily) and pyridoxine daily
Pregnant women	Any CD4 count. Exclude active liver disease, alcohol abuse, or known hypersensitivity to isoniazid	Isoniazid, oral, 300 mg daily for 12 months and pyridoxine 25 mg daily

* Alternative TPT regimen for adults, adolescents and children ≥ 25 kg: Where available, 3HP (weekly isoniazid and rifapentine) can be used in clients on a DTG-containing regimen who have a VL < 50 c/mL in the last 6 months. 3HP should NOT be used in new clients initiating a DTG-containing regimen. In these clients, 12H is still the preferred TPT regimen. Where 12H/3HP is prescribed for a client in an RPCs, no additional clinician review visits are required (the full 3 months 3HP supply/6 months of 12H can be scripted).

Dolutegravir

Dolutegravir (DTG) Overview

For further detail on switching **existing stable clients on ART** between regimens, see ***"Switching existing clients to DTG-containing regimens" on page 14***

Class of ARV: Integrase Inhibitor (InSTI)

Benefits: DTG is a potent antiretroviral that provides rapid viral suppression, has a high genetic barrier to resistance, and has minimal side effects and drug interactions. It is well tolerated by clients and contributes positively to adherence and retention on ART.

Formulations:
- Fixed-dose combination: tenofovir (TDF) 300 mg + lamivudine (3TC) 300 mg + DTG 50 mg (TLD). TLD can be prescribed for clients ≥ 30 kg and ≥ 10 years of age
- Abacavir (ABC) 600 mg + lamivudine (3TC) 300 mg + DTG 50 mg (ALD). ALD can be prescribed for clients ≥ 25 kg
- DTG 50 mg tablet
- DTG 10 mg dispersible tablet
- Please note that the adult film coated 50 mg tablet and the paediatric dispersible 10 mg tablet are not bioequivalent. The 50mg film coated tablet is the equivalent of 30mg of the dispersible tablets.

Standard Dose: Children ≥ 20 kg; adolescents and adults: DTG 50 mg daily
Children > 4 weeks of age and 3-19 kg: As per ***"Drug Dosing Chart" on page 34***

DTG dose with concomitant rifampicin-containing TB treatment: Increase DTG dose to 50 mg 12-hourly. If on TLD or ALD FDC, add DTG 50 mg 12 hours after TLD or ALD dose. If on paediatric DTG, follow ***"Drug Dosing Chart" on page 34*** for DTG and concomitant rifampicin-containing TB treatment

Side-effects: Usually mild and self-limiting. Side-effects include insomnia, headache, central nervous system (CNS) effects, and gastrointestinal effects. DTG can be taken in the evening or the morning as per the client's preference. However, if the client develops insomnia, TLD should be taken in the morning.

Contrary to initial speculation that the integrase inhibitor class may be causing **weight gain**, the association now appears not to be causal. Instead, the association may be the result of comparatively less metabolic toxicity than alternative older ART regimens (that mitigate weight gain through toxicity) combined with an initial return-to-health phenomenon, and an obesogenic environment. Dolutegravir-based ART regimens have numerous advantages over comparators and are still recommended first-line agents for people living with HIV. There is no role for switching from dolutegravir-containing regimens in patients gaining weight.

Drug Interactions with Dolutegravir

Drug interactions can result in suboptimal drug concentrations which can cause
- an elevated HIV viral load
- drug resistance, due to replicating virus in the presence of subtherapeutic drug concentrations
- For interactions with paediatric regimens see ***"Drug Interactions with DTG and Rifampicin-containing TB Treatment" on page 13***

Interacting Drug[1]	Effect of Co-Administration	Recommendation
Rifampicin	↓ Dolutegravir	Increase DTG dose to 50 mg 12-hourly. If on TLD FDC, add DTG 50 mg 12 hours after TLD dose. For interactions with paediatric regimens see ***"Drug Interactions with DTG and Rifampicin-containing TB Treatment" on page 13***
Polyvalent cations (Mg^{2+}, Fe^{2+}, Ca^{2+}, Al^{3+}, Zn^{2+}) e.g. antacids, sucralfate, multivitamin and nutritional supplements*	↓ Dolutegravir	Calcium supplements decrease DTG concentrations if taken together on an empty stomach. To prevent this, DTG and calcium supplements can be taken at the same time if taken with food. It is safe to dissolve the DTG dispersible tablets in breast milk. Iron supplements decrease DTG concentrations if taken together on an empty stomach. To prevent this, DTG and iron supplements can be taken at the same time if taken with food. However, calcium and iron supplements must be taken at least 4 hours apart. Magnesium/aluminium containing antacids decrease DTG concentrations regardless of food intake and should be taken a minimum of 2 hours after or 6 hours before DTG
	* Many over the counter (OTC) medications contain polyvalent cations. Clinicians should regularly ask clients about OTC medication use and advise about possible interactions	
Anticonvulsants: • Carbamazepine • Phenobarbital • Phenytoin	↓ Dolutegravir	Avoid coadministration if possible. Alternative agents that do not interact with DTG include valproate, lamotrigine, levetiracetam, and topiramate. Remember that valproate is contra-indicated during pregnancy. Double DTG dose to 50 mg 12-hourly for carbamazepine, phenytoin, or phenobarbital if an alternative anticonvulsant cannot be used
Metformin/DTG	↑ Metformin	DTG increases metformin concentrations. Maximum metformin dose 500 mg 12-hourly

[1] This table includes some of the most important drug interactions with DTG. For more information, please refer to the following resources: *www.hiv-druginteractions.org/checker*, the Liverpool HIV iChart application for smart phones, or any of the ***"Helplines" on page 23***

All Adult and Adolescent Males and Females, including Pregnant Women ≥ 30 kg and ≥ 10 years of Age

TDF + 3TC + DTG (TLD)

Neonates, Infants and Children 0 to < 10 years of Age

For further detail on transitioning between regimens, see ***"Switching existing clients to DTG-containing regimens" on page 14***

2.0 kg	3 kg	30 kg
Birth to < 4 weeks of age[1]	and ≥ 4 wks of age, to < 10 years of age	and ≥ 10 years of age
Neonates AZT + 3TC + NVP	Infants and Children ABC + 3TC + DTG	Adults and Adolescents TDF + 3TC + DTG (TLD)
For further details on initiating ART for Neonates see ***"ART for the Term Neonate" on page 28*** and ***"ART for the Preterm Neonate" on page 29***	Transition does not require a VL before switching	Transition does not require a VL before switching Ensure adequate renal function[2]

1 For neonates with severe anaemia, obtain advice from an expert or through one of the ***"Helplines" on page 23***

2 Before switching to TDF, ensure adequate renal function by checking eGFR/creatinine as outlined in table ***"Assessing Renal Function" on page 8***

ART Initiation in Women and Adolescent Girls Diagnosed with HIV during Labour

During labour, give a stat single fixed-dose combination tablet of TLD and a stat single dose of nevirapine (NVP).

Lifelong ART should be initiated the following day. TLD and a contraceptive method is recommended. Provide information on different contraceptive methods available. Provide her with a choice of contraceptive options as desired.

Appropriate ART literacy education should be given to the woman before she leaves the facility. Also provide her with information on infant feeding, infant HIV prophylaxis, and follow-up infant HIV testing. Provide a 2-month supply of her ART regimen at discharge from labour ward (see DMOC SOP 4).

FEMALE CONTRACEPTIVE METHODS

Concerns regarding neural tubes defects (NTDs) on DTG in previous years created an important focus on the integration of family planning into ART services. Although evidence has shown that there is no increased risk for NTDs on DTG-containing regimens[3], family planning services should continue to be offered with ART and child health services in an integrated and patient-centred manner. This is especially urgent if the women's VL is not suppressed.

Women should be **provided a choice of contraceptive options**, which includes condoms, oral contraceptives, implants, injectables, and intra-uterine contraceptive devices (IUCDs). Dual methods are recommended, and consist of a hormonal method or IUCD to prevent pregnancy, and a barrier method (male/female condoms) to prevent STIs and HIV transmission.

Contraceptive choices need to respect and fulfill human rights and enable clients to make informed choices for themselves. Client contraceptive choices, however, are often influenced directly or indirectly by social, economic and cultural factors. It is in this context that clients should be given comprehensive, scientifically accurate information in order to assist them to make an informed, voluntary choice of a contraceptive method. A woman's choice of contraceptive method may be influenced by her ART service delivery model to allow for better visit alignment. See also the ***"Visit Schedule for Integrated Care for Clients on ART and Drug-Sensitive TB Treatment" on page 26***

Should a woman desire pregnancy, counsel her regarding optimal timing for a healthy pregnancy. Recommend that ART is established, viral suppression is attained, and that she has no current OIs before she tries to become pregnant.

Issues of family planning and contraception should be discussed at every clinical interaction.
Where feasible, every attempt should be made to provide ART and family planning from the same service delivery point

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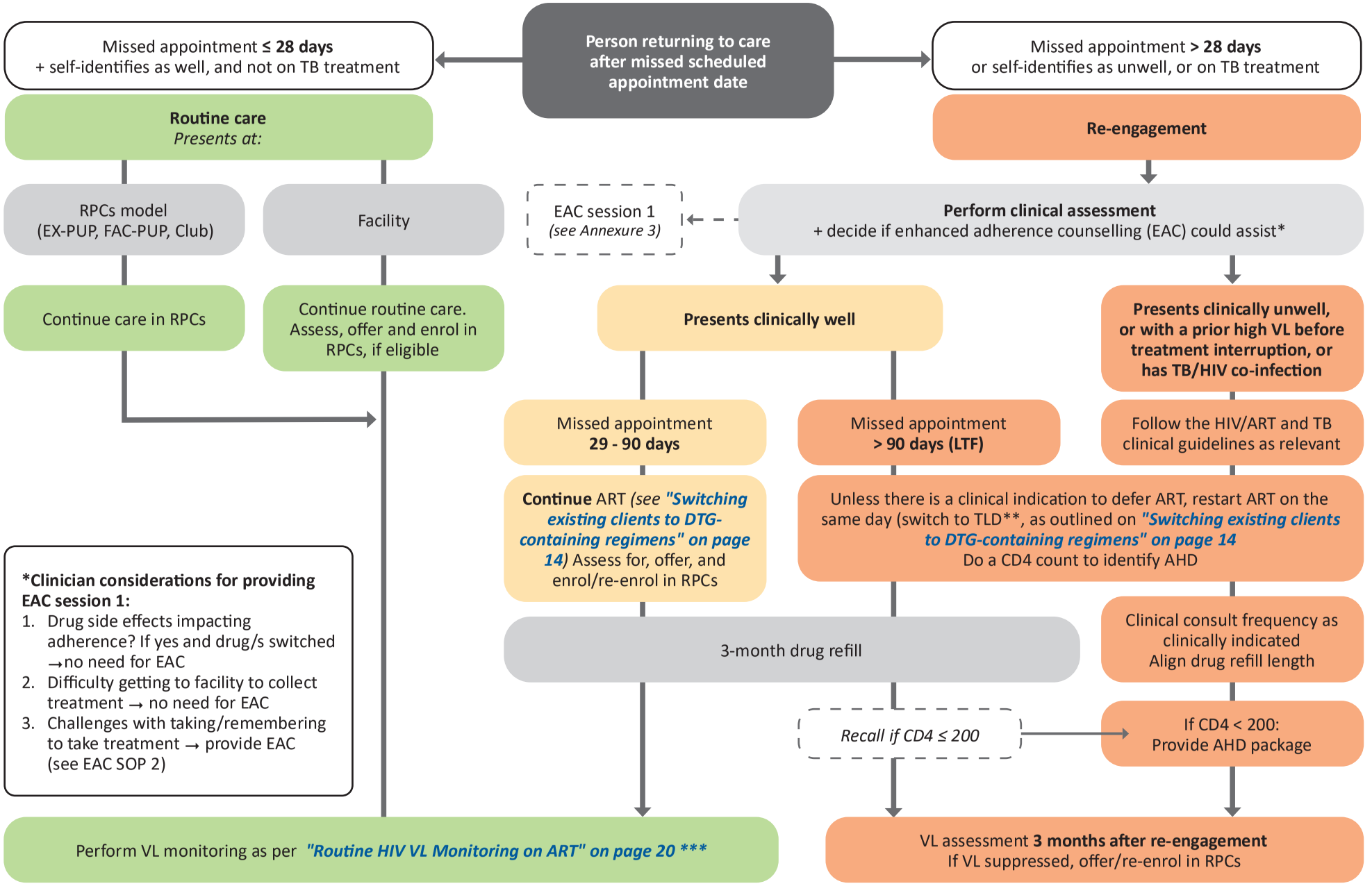
Re-initiating ART in Non-pregnant Clients who have Interrupted Treatment



AHD	= Advanced HIV Disease	FAC-PUP	= Facility pick-up point
EX-PUP	= External pick-up point	RPCs	= Repeat Prescription Collection Strategies

** All clients returning to care after > 90 days, and who were previously on TEE, TLD, or a PI-based regimen, should re-initiate a DTG-containing regimen. Clients who became LTFU on third-line should re-initiate their third-line regimen

*** Where the patient is overdue for their routine assessment at return, only perform the assessment once the patient has taken treatment for 3 months (or if in RPCs, the closest clinical review date thereafter).

Co-treatment of HIV and Active TB in Neonates, Infants, Children, Adolescents and Adults

TB/HIV co-infection impacts on ART in a number of ways. It affects:

1. **The timing of ART initiation** *see"Medical Indications to Defer ART" on page 4*
2. **Drug selection** in clients who are not yet on ART when TB treatment is initiated
3. Drug levels, due to significant **drug interactions** that reduce ART concentrations in the blood
4. **Adherence**, due to increased pill burden
5. **Side-effects** due to overlapping toxicities, e.g. hepatic toxicity

Clients who are not yet on ART when TB treatment is initiated

- Children and adolescents should initiate ART with a DTG-containing regimen, with boosting of DTG as explained below.
- Adults should initiate ART with either:
  i. a DTG-containing regimen, with boosting of DTG as explained below, or
  ii. an EFV-containing regimen, provided the client is ART treatment-naive. EFV has no significant drug interaction with rifampicin and has the benefit of being a once-daily regimen which supports adherence.

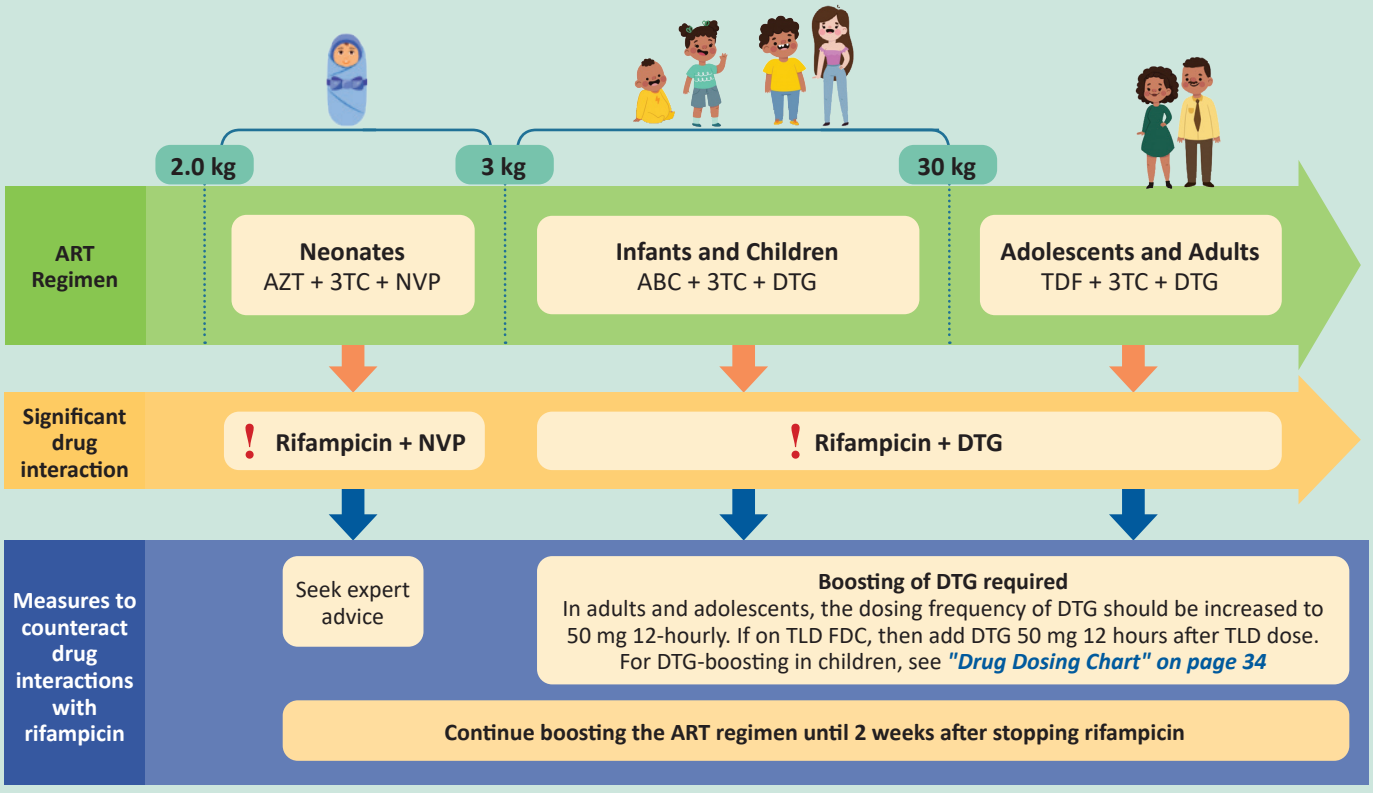
Clients who are already on ART when TB treatment is initiated

- All clients who are already on a DTG-containing regimen when TB treatment is initiated should continue the DTG-containing regimen whilst also taking TB treatment, with boosting of DTG as explained below.
- Clients who are already virally suppressed on an EFV-containing regimen when TB treatment is initiated should continue the EFV-containing regimen whilst also taking TB treatment. The EFV-containing regimen should be continued until two weeks after TB treatment is completed. Thereafter, EFV can be switched to DTG.

! Clinicians should provide integrated TB and ART management at clinical consultation visits. Failure to combine care leads to increased visits and significantly increases the risk of disengagement. See also *"Integrated Visit Schedule for Clients on ART and Drug-Sensitive TB Treatment" on page 26*

Drug Interactions with DTG and Rifampicin-containing TB Treatment

Rifampicin-containing TB treatment has significant drug interactions with all paediatric ART regimens, as well as with adult/adolescent regimens containing DTG:



Drug Interactions with Protease Inhibitors, e.g., Lopinavir/ritonavir

Every effort should be made to switch clients to DTG-containing regimens. However, during the transition process, some clients may still be on PI-containing regimens and may also require TB treatment. Rifampicin cannot be given with ATV/r or DRV/r. Significant drug interactions between LPV/r and rifampicin should be managed as follows:

LPV/r tablets: Double-dose LPV/r tablets in adults, adolescents and children able to swallow whole LPV/r tablets. See *"Drug Dosing Chart" on page 34*. Tablet must not be crushed, broken or chewed. If the client is unable to tolerate LPV/r at double doses, consult one of the *"Helplines" on page 23*.

LPV/r solution or pellets or 4 in 1 (ABC/3TC/LPV/r): Super-boosting with additional ritonavir powder: maintain standard LPV/r dose but add additional ritonavir twice daily as per *"Drug Dosing Chart" on page 34*. If no powder is available, consult an expert for a suitable alternative. Ritonavir powder has a shelf-life of 36 months. Note that ritonavir 100 mg tablets must not be crushed, broken or chewed.

Switching Existing Clients to DTG-containing Regimens

(Adults, adolescents or children)

Non VL-dependent regimen switches Regimens where the VL result will not influence nor delay the decision to switch to a DTG-containing regimen			
VL considerations	**Current Regimen**	**Criteria for switch**	**Regimen if change indicated**
Switching regardless of VL result	**TEE** ABC/3TC/EFV (or NVP*) AZT/3TC/EFV (or NVP*) AZT/3TC/DTG Any LPV/r or ATV/r regimen for **less than 2 years**	**Switch all to a DTG-containing regimen, regardless of VL result** Review VL in last 12 months. If VL in last 12 months was not suppressed, continue to switch same day, but do ABCDE assessment and provide enhanced adherence counseling (EAC) if needed. If VL was not done in last 12 months, do it at this visit, but do not wait for the result to switch	**TLD** provided no renal dysfunction and age ≥ 10 yrs and weight ≥ 30 kg If client does not qualify for TDF **ABC[1]/3TC/DTG** If client does not qualify for TDF and has ABC hypersensitivity **AZT/3TC/DTG**

! * There should no longer be any client (older than one month and > 3 kg) using a NVP-containing treatment regimen. Clients who previously used NVP as an alternative to EFV for psychiatric reasons, should be switched to DTG as a matter of urgency

Be sure to check for possible drug interactions when switching to DTG and manage as per ***"Drug Interactions with DTG and Rifampicin-containing TB Treatment" on page 13***

! Clients on TEE and receiving treatment through an RPCs can be switched to TLD at their next re-scripting visit and can remain in their RPCs, provided they have a VL < 50 c/mL in the last 12 months. No additional facility visits are required (see DMOC SOP 6).

! Any client in an RPCs with a VL ≥ 50 c/mL in the last 12 months, should be recalled to the facility for further clinical management. If the client is on TEE, continue to switch same day to TLD, but do an ABCDE assessment and provide enhanced adherence counselling (EAC) if indicated. If clinically well, 3MMD can be provided by the facility until the repeat VL assessment (see DMOC SOP 4) in 3 months, as per ***"VL Monitoring for Clients on TLD" on page 21***. Review the repeat VL result. If suppressed again, re-enrol in RPCs. If the VL remains unsuppressed, manage as per the ***"VL Monitoring for Clients on TLD" on page 21***. Clients with clinician confirmed low-level viraemia can be re-enrolled in RPCs.

1. If clients are not eligible to use TDF and they had an ABC hypersensitivity reaction, use AZT/3TC/DTG

Switching Existing Clients to DTG-containing Regimens

(Adults, adolescents or children who have never used a DTG-containing regimen in the past)

<table>
<tr><th colspan="4">VL-dependent regimen switches
Relevant to all clients who have been on PI-based regimens for more than two years: their VL result in the last 12 months will influence the decision of how and when to switch to a DTG-containing regimen</th></tr>
<tr><th>VL considerations</th><th>Current Regimen</th><th>Criteria for switch</th><th>Regimen if change indicated</th></tr>
<tr><td>VL < 1000 c/mL</td><td>Any LPV/r or ATV/r regimen for more than 2 years</td><td>Switch all to a DTG-containing regimen
If VL in last 12 months was ≥ 50 c/mL, continue to switch same day, but do ABCDE assessment, provide EAC if needed, and repeat the VL after 3 months as per "The VL non-suppression algorithm" on page 21</td><td>TLD
provided no renal dysfunction and age ≥ 10 yrs and weight ≥ 30 kg

If clients does not qualify for TDF
ABC[1]/3TC/DTG</td></tr>
<tr><td rowspan="3">[2] Two or more consecutive VLs ≥ 1000 c/mL taken two or more years after starting PI regimen</td><td>Adult or adolescent on any LPV/r or ATV/r regimen and adherence less than 80%[3]</td><td>Switch all to a DTG-containing regimen
Do not do a resistance test
These clients are unlikely to have PI resistance mutations. Rather switch to a more tolerable once daily FDC regimen which is likely to support adherence. Manage as per "The VL non-suppression algorithm" on page 21</td><td>TLD
provided no renal dysfunction and age ≥ 10 yrs and weight ≥ 30 kg

If clients does not qualify for TDF
ABC[1]/3TC/DTG</td></tr>
<tr><td>Adult or adolescent on any LPV/r or ATV/r regimen and adherence more than 80%[3]</td><td colspan="2">Clients who meet the definition of confirmed virological failure and have confirmed adherence more than 80% may need a resistance test.
These clients do not qualify for a same-day switch.
Discuss with an HIV expert[4] to authorise and interpret a resistance test.

Provide individualised regimen as recommended by HIV expert.
Repeat VL 3 months after the regimen change to confirm re-suppression, as per the "Management of Confirmed Virological Failure on TLD" on page 23</td></tr>
<tr><td>Child < 10 years, or weight < 30 kg on any LPV/r or ATV/r regimen</td><td colspan="2">These clients do not yet qualify for TLD and may require a resistance test.
Refer to algorithm "Switching children on PI-containing regimens to DTG-containing regimens" on page 16</td></tr>
</table>

1. If clients are not eligible to use TDF and they have ABC hypersensitivity, use AZT/3TC/DTG
2. Confirmed virological failure is defined as two or more VLs ≥ 1000 c/mL taken two or more years after starting a DTG or PI containing regimen, despite adherence > 80% by objective measurement. A patient who has only 1 VL > 1000 after 2 years on a PI-based regimen should have an ABCDE assessment, EAC if applicable, and their VL repeated in 3 months. The result of the repeat VL will allow the patient to be grouped into one of the categories in the table above and will inform the further course of action
3. 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 [e.g. TFV urine lateral flow assay (LFA) for presence of TDF in urine, TFV diphosphate (detects TDF on dried blood spot samples), DTG plasma levels]

   Note: Self-reported adherence is not considered a reliable measure of good adherence!
4. For advice from an HIV expert, approach an HIV Hotline, an infectious disease specialist, or the Third Line ART committee

Switching Children on PI-containing Regimens to DTG-containing Regimens

Child (< 10 years, or weight < 30 kg) on a **PI-containing regimen**
(who have never used a DTG-containing regimen in the past)

On **PI** for at least **2 years**

On PI for **less than** 2 years, irrespective of VL

Two or more **VLs ≥ 1000** c/mL
taken two or more years after starting PI regimen

VL < 1000 c/mL

Adherence > 80% [1]

Adherence < 80% [1]

For children on LPV/r solution or pellets, consider switch to **4-in-1 ABC/3TC/LPV/r** capsules to improve [2] tolerance/ adherence & **repeat VL** after 2-3 months

Children on LPV/r tablets

VL ≥ 1000 c/mL

VL < 1000 c/mL

Discuss with an HIV expert [3] to authorise and interpret **a resistance test**

Individualised regimen as recommended by HIV expert

ABC + 3TC + DTG

If the most recent VL before their regimen change was ≥ 50 c/mL,
repeat VL 3 months after starting the new regimen to confirm viral re-suppression

1. Although objective measures of poor adherence include pharmacy refills or attendance of scheduled clinic visits in the previous 6-12 months of <80%, 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 out or vomit the medicine, and whether the caregiver has been able to overcome this. Considering these limitations, objective measures of good adherence could include one of the following:
   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
2. If a switch to the 4-in1 capsules does not improve adherence, or is not available, continue to switch to ABC + 3TC + DTG as for non-adherent children on LPV/r tablets
3. The following would qualify as HIV experts: the HIV Helplines, a paediatric infectious disease specialist or the paediatric Third line ART committee

Summary of the Care Continuum for Clients 5 years of age and older on ART

Clients on ART can be differentiated into those who are 1) clinically well and adherent on ART and 2) those who are clinically non-stable and/or struggling with adherence. Clients that are clinically well at their first clinical review one month after starting ART, only need to be seen again 2 months later for clinical review and their first viral load and serum creatinine. After that, taking treatment and clinical follow-up should be made as convenient as possible for the client. Therefore, they may continue to receive ART using a differentiated care approach, provided they meet the eligibility criteria of 1) having a suppressed VL, 2) being clinically well with no opportunistic infections (OIs), 3) not having any other uncontrolled chronic conditions that require clinical review more frequently than 6-monthly, and 4) not being pregnant.

The diagram ***"Visit Schedule for Adults, Adolescents and Children 5 Years and Older on ART" on page 18*** provides a summary of the components of care at different visits for clinically well and adherent clients during the first year on ART. Clients who are enrolled in repeat prescription collection strategies (RPCs) should be rescripted for RPCs at their comprehensive clinical review at which a further VL will be taken. Clients should not be required to come back the following month for VL result review prior to rescript. Rather, recall to the facility only those clients with elevated VL. For more detail on repeat prescription strategies (RPCs), see the DMOC standard operating procedure (SOP) 5 (facility-pick-up points, adherence clubs and external pick-up points).

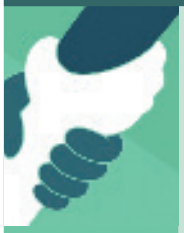
! If a patient comes from a different facility, it is critical that the patient be provided with treatment on the day of presentation to limit any further treatment interruption and its impact on viral suppression. While referral letters are helpful, a patient cannot be required to leave the facility without treatment to first obtain a referral/transfer letter.

Women with contraceptive needs should have contraceptive method options explained, specifically how each method impacts all required return visits' location (facility or outside of the facility) and visit frequency:

- Long-acting reversible contraception (LARC) removes any increased visit frequency or alignment concerns.
- The combined oral contraceptive pill (COCP) can be repeated 3-monthly, aligns well with ART and well-baby visit schedules (if applicable), and can be scripted through her preferred RPCs.
- The DMPA 3-monthly injection must be administered by a clinician but aligns with ART and well-baby visit schedules
- The NET-EN 2-monthly injection also needs to be administered by a clinician, but will require additional visits by the mother.
- Where a woman chooses to continue clinician administered short-acting injectable contraception (e.g., DMPA or NET-EN), a facility-based pick-up point (FAC-PUP) or facility-based adherence club may be the preferred option provided visit alignment can be ensured.

See also ***"Visit Schedule for Integrated Care for Clients on ART and Drug-Sensitive TB Treatment" on page 26*** and ***"Visit Schedule for Integrated Care for the Mother-baby Pair Living with HIV" on page 24***

HELPLINES



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**

Visit Schedule for Adults, Adolescents and Children 5 Years and Older on ART

DC/ Months* on ART	Routine monitoring tests	Overview of Management
0	**Baseline clinical and lab assessment as outlined on pages 4 to 6 ART initiation and session 1 of fast track initiation counselling**	
1	**Review test results**	• Session 2 of fast track initiation counselling including planning for travel and VL education • Clinical assessment and routine monitoring as outlined on page 19 • Integrated services for family planning and NCDs • **2 months ART dispensed (2MMD) - DMOC SOP 4**
3	**3-month* VL sCR and eGFR**	• Clinical assessment including VL and any other routine monitoring bloods as outlined on page 19 • Integrated services for family planning and NCDs

4	**Review test results**	• Clinical assessment and review of VL and any other monitoring results
		• Integrated services for family planning and NCDs
		• Assess eligibility for Repeat Prescription Collection strategies (RPCs) (South Africa's differentiated models of care for stable patients)
		  • VL < 50 c/mL
		  • Clinically well
		  • No OIs, including TB
		  • Not pregnant

		Repeat Prescription Collection strategies (DMOC for stable patients) Facility Pick-up Point (FAC-PUP) (DMOC SOP 5.1) | Adherence Clubs (AC) Facility or community-based support groups (DMOC SOP 5.2) | External Pick-up point (EX-PUP) (DMOC SOP 5.3)
		• Renew prescription for next 6 months, with first 3 month's supply issued today from the facility • If not eligible for RPCs or refused RPCs: Assess eligibility for facility provided multi-month dispensing (MMD) – DMOC SOP 4
7		• Collect medication from preferred RPCs
10	**10-month* VL sCR and eGFR CD4 count**	• Clinical assessment including VL and any other monitoring bloods as per *"Monitoring on ART" on page 19* • Integrated services for family planning and NCDs • Check TPT eligibility • Renew prescription for next 6 months • Do not require clients to return to the facility in 1 month to review the VL results, unless other clinical indications exist that require review. Rather, recall to the facility only those clients with elevated VLs
11+		• 12-monthly clinical assessment and family planning review as per *"Monitoring on ART" on page 19* • 12-monthly routine monitoring of VL, sCR and eGFR • Check that chosen RPCs option is still suitable • Collect medication from preferred RPCs

Non-stable clients

If at any stage the client becomes clinically non-stable and /or non-adherent i.e. a client who has:

- missed a scheduled appointment by more than 28 days (including in an RPCs) (see also *"Re-engagement algorithm" on page 12*)
- a VL ≥ 50 c/ml
- possible signs or symptoms of clinical failure, e.g. if the client is acutely unwell, or develops a new OI such as TB

A clinician should:

- If in an RPCs, return the client to regular care to ensure more frequent clinical follow-up until they are stable again.
- Provide appropriate clinical management
- If clinically well and struggling with visit frequency: provide multi-month dispensing (DMOC SOP 4)
- If experiencing side effects or the child cannot tolerate their medication: switch drugs/formulation
- If struggling to take ART as prescribed: enhanced adherence counselling (See Annexure 3)

! Clients on TEE and receiving treatment through RPCs can be switched to TLD and remain in their RPCs if they have a VL < 50 c/mL in the last 12 months.

* The term dispensing cycle (DC) is defined as the number of days for which a client would have treatment if a single standard "monthly" quantity of tablets was dispensed (usually 28 days). Although it is understood that the time frame for a month and a DC are not necessarily the same, for ease of reading, the term 'DC' and 'month' are used interchangeably in this table, and should be considered synonymous.

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

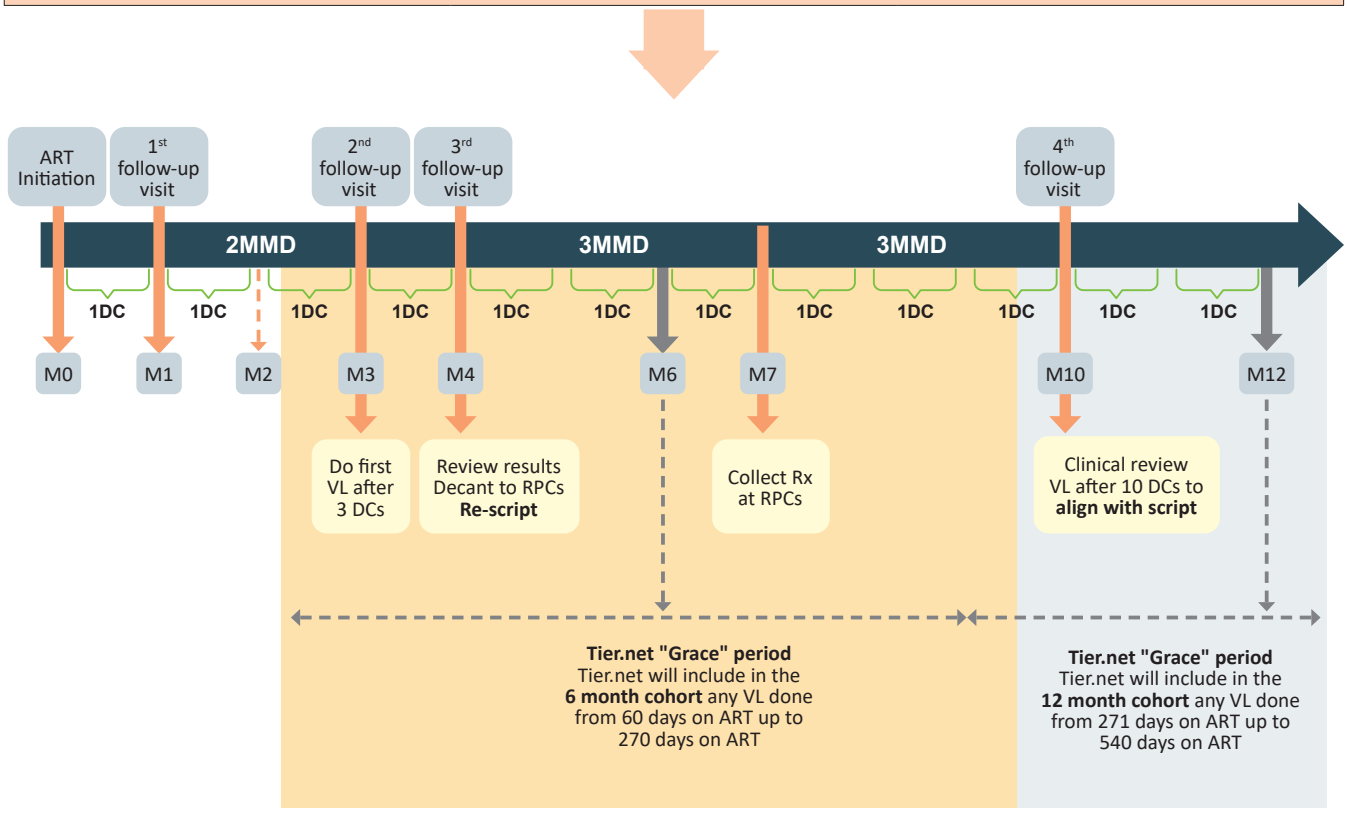
For more information on the package of care for AHD and the management of specific OIs, please refer to the ***Consolidated ART guideline***

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.

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 > 1000 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 ≥ 1000 c/mL**
taken two or more years after starting TLD regimen
or at least one VL ≥ 1000 c/mL and either
CD4 < 200 cells/mm3 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

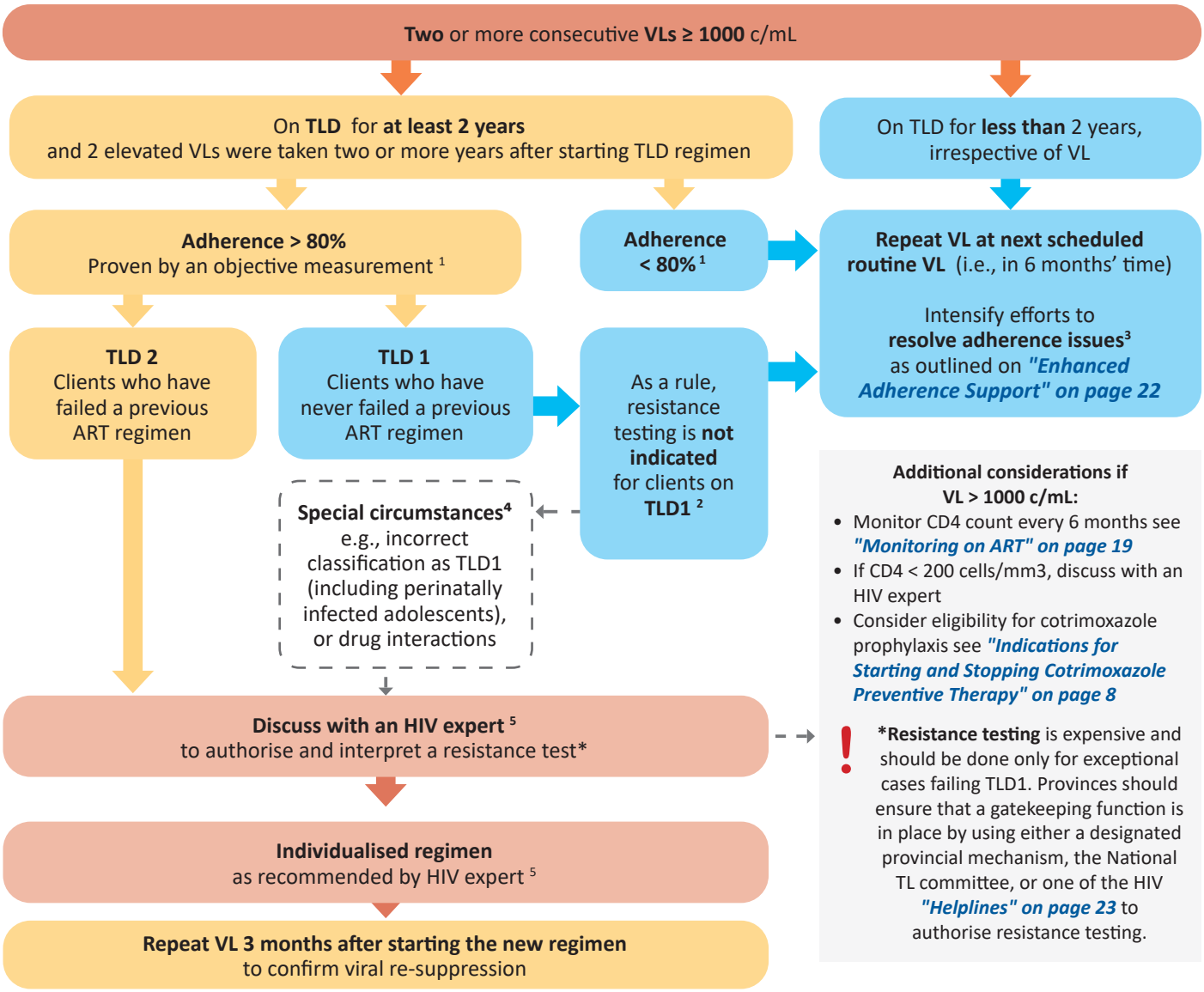
'better late than never': clients should be counselled they can take their ARVs up to several hours late if they miss their chosen time

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 counseling for children living with HIV (Annexure 7)

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.

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

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	2 months ART provided at discharge from labour ward which will last mother until 6 week PN visit		x	x						x	x**
	4 weeks			**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											
2-6 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

* 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

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.

≥2.0 kg and ≥35 weeks gestational age at birth

Birth to <4 weeks of age

≥3.0 kg AND ≥4 weeks of age

AZT + 3TC + NVP → **ABC + 3TC + DTG**

Baseline Assessment

- Clinical review
- Bloods: confirmatory HIV PCR (or HIV VL), CD4 count, FBC +/- HIV drug resistance test if mother failing treatment on TLD2 or a protease inhibitor regimen
- Counsel parent / caregiver
- Ensure the mother is on ART, and advise that breastfeeding is recommended for all infants living with HIV.

Review after 1 week then 1-2 weekly

- Clinical review and counselling
- Check baseline blood results
- If indeterminate / negative confirmatory HIV PCR test result, refer to Guideline for Family-Centered Transmission Prevention of Communicable Infections

Review when 4 weeks of age

- Clinical review and counselling
- If <3 kg, assess reasons for poor weight gain & manage appropriately, continue ART with AZT (12 mg/kg/dose twice daily) + 3TC (4 mg/kg/dose twice daily) + NVP (6 mg/kg/dose twice daily) until ≥3.0 kg
- If >3 kg, switch ART to ABC + 3TC + DTG (refer to ARV dosing chart for doses)
- Continue monitoring as per ***"Monitoring on ART" on page 19***

	Zidovudine (AZT)		Lamivudine (3TC)		Nevirapine (NVP)	
Available formulation	Solution 10 mg/mL		Solution 10 mg/mL		Solution 10 mg/mL	
Weight (kg) at birth	Dose		Dose		Dose	
	AM	PM	**AM**	**PM**	AM	PM
≥2.0 – <3.0	10 mg (1 mL)	10 mg (1 mL)	5 mg (0.5 mL)	5 mg (0.5 mL)	15 mg (1.5 mL)	15 mg (1.5 mL)
≥3.0 – <4.0	15 mg (1.5 mL)	15 mg (1.5 mL)	8 mg (0.8 mL)	8 mg (0.8 mL)	20 mg (2 mL)	20 mg (2 mL)
≥4.0 – <5.0	20 mg (2 mL)	20 mg (2 mL)	10 mg (1 mL)	10 mg (1 mL)	30 mg (3 mL)	30 mg (3 mL)

<2.0 kg
OR
<35 weeks
gestational age
at birth

Birth to < 4 weeks of age
OR < 3 kg

≥ 4 weeks of age
AND
≥ 3 kg

AZT + 3TC + NVP → **ABC + 3TC + DTG**

Baseline Assessment

- Clinical review
- Bloods: confirmatory HIV PCR (or HIV VL), CD4 count, FBC +/- HIV drug resistance test if mother failing treatment on TLD2 or a protease inhibitor regimen
- Counsel parent / caregiver
- Ensure the mother is on ART, and advise that breastfeeding is recommended for all infants living with HIV

Review after 1 week then 1-2 weekly

- Clinical review and counselling
- Check baseline blood results
- If indeterminate / negative confirmatory HIV PCR test result, refer to Guideline for Family-Centered Transmission Prevention of Communicable Infections
- Monitor weight gain and adjust ARV doses

Review when ≥4 weeks of age

- Clinical review and counselling
- If <3 kg, continue AZT + 3TC + NVP
- If >3 kg, switch to ABC + 3TC + DTG (refer to ARV dosing chart for doses)
- Continue monitoring and evaluations as per ***"Monitoring on ART" on page 19***

Gestational age at birth	Chronological age	Zidovudine (AZT)	Lamivudine (3TC)	Nevirapine (NVP)
		Solution 10 mg/mL	Solution 10 mg/mL	Solution 10 mg/mL
< 30 weeks	Birth - < 4 weeks	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily
	≥ 4 weeks - < 8 weeks	3 mg/kg/dose twice daily	4 mg/kg/dose twice daily	4 mg/kg/dose twice daily
	≥ 8 weeks - < 10 weeks	12 mg/kg/dose twice daily		6 mg/kg/dose twice daily
≥ 30 - < 35 weeks	Birth - < 2 weeks	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily
	≥ 2 - < 4 weeks	3 mg/kg/dose twice daily		4 mg/kg/dose twice daily
	≥ 4 - < 6 weeks		4 mg/kg/dose twice daily	6 mg/kg/dose twice daily
	≥ 6 - < 8 weeks	12 mg/kg/dose twice daily		

When weight is ≥2 kg and ≥35 weeks corrected gestational age, review ARVs and refer to table ***"ART for the Term Neonate" on page 28***

Annexure 3 *Enhanced Adherence Counselling*

Source: Differentiated Care Models Standard Operating Procedures 2023

ENHANCED ADHERENCE COUNSELLING SESSIONS

There are two sessions:
Session 1: Initial enhanced adherence counselling for patients struggling with adherence.
Session 2: Enhanced adherence counselling for persistent non-adherent patients (covered in DMOC SOP 2).

SESSION 1

Benefits of Viral Suppression:

- Undetectable VL means the virus is untransmittable to HIV negative partners
- CD4/immune function recovery
- Less chance of illness
- Reduced visits to clinic through access to MMD/RPC

1. Explain the purpose of your session, define terms:

- Determine possible reasons for abnormal assessment results.
- Assess and address any reported barriers to adherence and discuss effective strategies to overcome.
- Update or develop an adherence plan with the patient.

2. Education on the assessment result

- Assess patient for mental health using the Mental Health Assessment tool in Annexure II.
- Find out what treatment education the patient has received. Recap the benefits of VL suppression as outlined in the box above.
- Find out what the patient knows about the treatment they are taking and check the treatment regimen has been understood correctly i.e. when each medicine is taken.
- Explain in a supportive way that the most common reason for such result is a problem with taking medication correctly.
- Find out if the patient received education on the assessment to check adherence and effective treatment(VL/BP/HbA1c) and its meaning. If not, provide this information (see SOP 1: FTIC session 2).

3. Flexibility on treatment

- Clear any myths and misconceptions around taking treatment and explain that there is some flexibility.
- Emphasize the importance of patients choosing their own suitable time for taking medication as prescribed.
- Explain what to do with late or missed doses depending on the treatment.
- Explain what to do in case of alcohol use while on treatment. If patient cannot control their use of alcohol, they should make sure that they take their treatment anyway.
- Explain to patient that it is better not to use traditional medicines that could interfere with the treatment. If they take traditional medicine, they should make a plan with the clinician to still take their treatment.

4. Patient's experiences

Ask: What makes it difficult for you to take the treatment sometimes? Encourage the patient to be honest about personal issues that may affect their adherence and help them to address issues such as alcohol or other substance intake as they can lead to forgetting medication.

- Explain that medication should be taken even without food and what they can do if food insecurity is an issue. Inform and assist patient on how to access government support programmes, if necessary.
- Consider patient's religious and traditional beliefs that may contribute to non-adherence to treatment.

5. Identify strategies to ensure good adherence

Ask: What could help you to remember to take the treatment?

Discuss treatment reminders and adherence options including the advantages and disadvantages of each for the specific patient:

- Treatment buddy to remind the patient to take treatment
- Setting phone alarm
- Support by a family member
- Pill counts
- Marking a calendar or using a pill box
- Linking medication to meals times or other daily routine such a brushing teeth
- Storing medication somewhere accessible if unable to disclose to others in the home
- Carrying/keeping spare medication to take at work in case dosing at home was forgotten or client late returning home
- Modified Direct Observed Therapy such as treatment supporter (this is also applicable to children)

Ask: Who could support you to take the treatment every day?

Discuss sources of social support for the client. Emphasise the importance of support structures in coping and adherence such as family, friends, peer support groups, faith-based group and work-based support.

- Encourage sharing of feelings and emotions regarding the illness.
- Empower the patient in making a plan that is adapted to the barriers expressed. Be aware not to create dependency, but to find their own solutions, with the help of the healthcare worker or lay counsellor.

6. Inform the patient about pathway ahead

- Explain further assessments (tests) to check adherence and effective treatment as per disease specific guidelines (for HIV: a further viral load will be taken in 3 months, for hypertension: a BP will be taken at every visit for the next 3 months, for diabetes: a further HbA1c test will be done in 3 months)
- Explain that if the next assessment is normal, it will become easier to collect treatment. The patient can ask and the clinician should offer and enroll the patient into a simpler treatment supply collection system of their choice with longer treatment supply based on what is available at the facility (FAC-PUP/Adherence Club/EX-PUP).

Annexure 4 *Mental Health Assessment*

Source: Differentiated Care Models Standard Operating Procedures 2023

As mental health disorders can impact adherence negatively, it is recommended that screening is provided for mental health disorders while treating HIV, TB and NCDs.

Basic screening should assess:

1. What is the patient's appearance?

- Is he/she clean and looking after him or herself
- Does the person look worried or sad?
- Does the person seem agitated?
- Does he/she seem suspicious, nervous or hostile?

2. Assess the patient's mood, asking:

- How have you been feeling over the last week?
- Have you been feeling mostly normal, or sad or happy, or worried?
- How do you feel today?
- What are your feelings about the future?

3. Assess the patient's thoughts:

- Are you having negative thoughts?
- Are you having strange thoughts?
- Any unusual fears (such as being followed, spied on)?
- Have you had any strange experiences (such as hearing voices/seeing visions other people cannot hear or see) or special abilities?

Negative thoughts can suggest depression, other strange thoughts or experiences could raise suspicion of psychosis.

4. Assess patient's cognition:

- Does thinking seem slow?
- Is the person able to concentrate?
- Does the memory seem impaired?

If you suspect a mental health disorder while asking the previous questions, try to answer the following questions:

- What is the main problem?
- How long has it been present?
- Does it affect the patient's daily functioning?
- Can this be managed at this clinic?

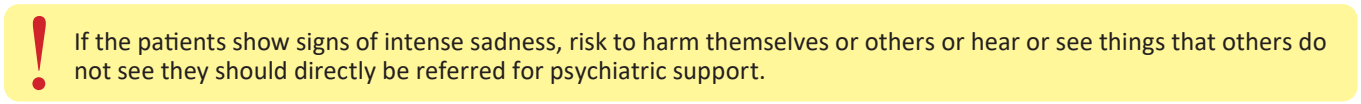
If further assessment and treatment cannot be provided at the clinic, refer to a psychiatric nurse or service. Tools such as SRQ 20 recommended by the WHO can help to identify mental health disorder.

Provide the patient with education on mental health and provide them with advice that can help them overcome symptoms. Explain to the patient that the following signs could mean that they may need support to improve their mental health condition:

If they feel:

- constantly angry or very worried
- very sad for a very long time
- they are losing interest in things they used to enjoy doing
- they can not cope with work or daily activities
- their mind is controlled (such as by voices) or out of control
- they need to use alcohol or drugs
- Obsessively do things such as repeat washing hands, non-stop sport activity, eating too much, obsessive diet or other obsessive behaviours.
- Hurt themselves or other people or destroy things.
- Do irresponsible things that could harm them or others.
- Having problems sleeping or feeling tired and not having energy.
- Feeling anxious, looking or feeling 'jumpy' or upset, having panic attacks.
- Not wanting to spend time with people; spending too much time in bed.
- Hearing and seeing things that others do not see.

Other differences in the way the person sees what is happening around them, for example believing that someone is trying to harm you, or laughing at you.



If the patients experience some of the other symptoms, explain to them that they can identify some ways to help them cope with their situation by telling them that it might help to:

- Share your feelings and spend time with other people you trust.
- Get back to daily routine as much as possible (such as work, school, housework).
- Participate in religious or spiritual activities.
- Play sports or get regular exercise.
- Eat regular meals.
- Get adequate rest.
- Take a break and relax.
- Participate in enjoyable activities (such as singing, dancing, reading), even if at the moment it may be hard for you to enjoy them.
- Help other people talk about how they feel, but also respect if they choose not to talk about it.

Recommend that they avoid:

- Using alcohol or drugs to cope with the symptoms
- Withdrawing from family and friends
- Withdrawing from daily activities
- Overworking
- Blaming yourself or others
- Neglecting your health or self-care (such as sleep, hygiene, diet)

Explain that the patient, may need to seek help from a psychiatric nurse, social worker, psychologist or counsellor if they want to talk with someone outside of their family or circle of friends or if their symptoms do not improve with coping strategies.

ARV Drug	Formulations (as used in dosing chart)	Can tablets/capsules be split/crushed/ opened if unable to swallow?	Comment
Abacavir (ABC)	Oral solution: 20 mg/ml Tablets: 60 mg, 300 mg FDC tablets: ABC/3TC 120/60 mg; ABC/3TC 600/300 mg; ABC/3TC/DTG 600/300/50 mg FDC capsules: ABC/3TC/LPV/r 30/15/40/10 mg	Tablets: **YES** FDC 120/60 mg tablet is a dispersible tablet. May be split/crushed. FDC capsules should be opened and contents added to a small amount of food or dispersed in a liquid.	Hypersensitivity reaction (fever, rash, GIT & respiratory symptoms) may occur during first 6 weeks of therapy, very uncommon in black African patients. Symptoms typically worsen in the hours immediately after the dose and after each subsequent dose. Caregivers or patients should discuss symptoms early with the clinician rather than stopping therapy. Stop ABC permanently if hypersensitivity reaction has occurred.
Lamivudine (3TC)	Oral solution: 10 mg/ml Tablets: 150 mg; FDC tablets: ABC/3TC 120/60 mg; ABC/3TC 600/300 mg, TLD 300/300/50 mg ABC/3TC/DTG 600/300/50 mg FDC capsules: ABC/3TC/LPV/r 30/15/40/10 mg		Well tolerated, adverse-effects uncommon. Pure red cell aplasia causing anaemia can occur but is very rare.
Zidovudine (AZT)	Oral solution: 10 mg/ml Tablets: 100 mg, 300 mg Capsules: 100 mg FDC tablet: AZT/3TC 300/150 mg	Tablets and FDC: **YES** Capsules: Can be opened and added to a small amount of soft food/liquid and ingest immediately.	Avoid or use with caution in neonates or children with anaemia (Hb <8 g/dl) due to potential to cause bone marrow suppression.
Tenofovir (TDF)	Tablets: 300 mg FDC tablets: TDF/FTC 300/200 mg, TEE 300/200/600 mg, TLD 300/300/50 mg	Tablet and FDC tablets: **YES**	TDF may be prescribed for adolescents ≥ 10 years of age AND ≥ 30 kg body weight after ensuring adequate renal function by checking eGFR/creatinine using the appropriate formula (refer to HIV guidelines). TDF is usually prescribed as part of an FDC tablet: TDF/FTC, TDF/FTC/EFV or TDF/3TC/DTG. To assess for TDF-induced nephrotoxicity, do creatinine and eGFR at months 3 and 10 and thereafter repeat every 12 months.
Lopinavir/ ritonavir (LPV/r)	Oral solution: 80/20 mg/ml Capsules: Pellets 40/10 mg per capsule Tablets: 200/50 mg, 100/25 mg FDC capsules: ABC/3TC/LPV/r 30/15/40/10 mg	Tablets: **NO** **Must be swallowed whole and not divided, crushed or chewed.** Capsules: Can be opened and added to a small amount of soft food/liquid and ingest immediately.	Oral solution should be refrigerated/stored at room temperature (if <25°C) for up to 6 weeks. Preferably administer oral solution with food as increases absorption. Strategies to improve tolerance and palatability of oral solution: coat mouth with peanut butter, dull taste buds with ice, follow dose with sweet foods. Many drug-drug interactions.# LPV/r 40/10 mg capsules should be opened, and contents (pellets) of each capsule poured onto a spoon of soft food and fed to child. Don't try and dissolve pellets in food or water as they will develop a bad taste. ABC/3TC/LPV/r capsules should be opened and contents (granules) of each capsule poured onto a spoon of soft food or dissolved in water and fed to child. Capsules should never be swallowed whole. Discard capsule casing after contents have been emptied from it.
Ritonavir (RTV)	Oral powder: 100 mg/packet Tablets: 100 mg		Each 100 mg packet of RTV powder should be mixed with a small amount of water or soft food and immediately ingested. Many drug-drug interactions.#
Atazanavir (ATV)	Capsules: 150 mg, 200 mg FDC tablets: ATV/RTV 300/100 mg	Capsules: Can be opened and added to a small amount of soft/food/liquid and ingested immediately. FDC tablets: **NO** **Must be swallowed whole and not divided, crushed or chewed.**	ATV is used in combination with RTV. May cause unconjugated hyperbilirubinaemia resulting in jaundice but this does not indicate hepatic toxicity and not a reason to discontinue the drug unless it is worrying the patient. Consider drug-drug interactions.#
Dolutegravir (DTG)	Dispersible tablet (DT): 10 mg Film coated (FC) tablets: 50 mg FDC tablets: TLD 300/300/50 mg FDC tablets: ABC/3TC/DTG 600/300/50 mg	Dispersible tablets: **YES** Film coated tablets (including FDCs): **YES**	Iron supplements decrease DTG concentrations if taken together on an empty stomach. To prevent this, DTG and iron supplements can be taken at the same time if taken with food. May be helpful to administer as a morning dose rather than an evening dose if insomnia occurs with evening dosing. May raise creatinine levels by up to 15% without affecting renal function. Consider drug-drug interactions. # DTG DT and DTG FC tablets are not bioequivalent; 30 mg of DTG DT corresponds to 50 mg DTG FC tablets. DTG 50 mg FC tablets are preferred for children who have reached 20 kg (unless they cannot swallow tablets).
Efavirenz (EFV)	Capsules: 50 mg, 200 mg Tablets: 50 mg, 200 mg, 600 mg FDC tablets: TEE 300/200/600 mg	Tablets: **NO** **Must be swallowed whole and not divided, crushed or chewed.** Capsules: **YES**. Open and add to small amount of soft food and ingest immediately	Best given at bedtime to reduce CNS side-effects, especially during first 2 weeks. Consider drug-drug interactions.#

FDC = fixed dose combination;
eGFR = estimated glomerular filtration rate;
GIT = gastrointestinal tract;
TEE = Tenofovir/Emtricitabine/Efavirenz;
TLD = Tenofovir/Lamivudine/Dolutegravir;

Annexure 6 *Antiretroviral Drug Dosing Chart for Children (2022)*

Compiled by Child and Adolescent Committee of SA HIV Clinicians Society in collaboration with the Department of Health

	Abacavir + Lamivudine (ABC + 3TC)	**Dolutegravir (DTG)**	**Dolutegravir when on Rifampicin**	**Abacavir (ABC)**	**Lamivudine (3TC)**	**Zidovudine (AZT)**
Target dose	As for individual medicines **ONCE daily**	By weight band **ONCE daily**	By weight band **TWICE DAILY**	8 mg/kg/dose **TWICE daily** OR **If ≥ 10 kg:** 16 mg/kg/dose **ONCE daily**	4 mg/kg/dose **TWICE daily** OR **If ≥ 10 kg:** 8 mg/kg/dose **ONCE daily**	180 - 240 mg/m^2/dose **TWICE daily**
Available formulations	Dispersible tablet FDC: ABC/3TC 120/60 mg Tablets FDC: ABC/3TC 600/300 mg ABC/3TC/DTG 600/300/50 mg	Dispersible tabs (DT) 10 mg, Film coated (FC) tabs 50 mg, FDC: TLD 300/300/50 mg OR ABC/3TC/DTG 600/300/50 mg **DT AND FC TABLETS ARE NOT BIOEQUIVALENT**	Dispersible tabs (DT) 10 mg, Film coated (FC) tabs 50 mg, FDC: TLD 300/300/50 mg OR ABC/3TC/DTG 600/300/50 mg **DT AND FC TABLETS ARE NOT BIOEQUIVALENT**	Sol. 20 mg/ml Tabs 60 mg (scored, dispersible), 300 mg (not scored)	Sol. 10 mg/ml Tabs 150 mg (scored)	Sol. 10 mg/ml Tabs 100 mg, 300 mg (not scored), FDC: AZT/3TC 300/150 mg
Wt. (kg)	Consult with a clinician experienced in paediatric ARV prescribing for neonates (< 28 days of age) and infants weighing < 3kg					
3 - 5.9	1 x 120/60 mg tab od	0.5 x 10 mg DT od	0.5 x 10 mg DT bd	3 ml bd **OR** 1 x 60 mg tab bd	3 ml bd	6 ml bd
6 - 9.9	1.5 x 120/60 mg tabs od	1.5 x 10 mg DT od	1.5 x 10 mg DT bd	4 ml bd **OR** 1.5 x 60 mg tab bd	4 ml bd	9 ml bd
10 - 13.9	2 x 120/60 mg tabs od	2 x 10 mg DT od	2 x 10 mg DT bd	**Once daily dosing > 10 kg**	**Once daily dosing > 10 kg**	12 ml bd **OR** 1 x 100 mg tabs bd
				4 x 60 mg tabs od **OR** 12 ml od	12 ml od	
14 - 19.9	2.5 x 120/60 mg tabs od	2.5 x 10 mg DT od	2.5 x 10 mg DT bd	5 x 60 mg tabs od **OR** 1 x 300 mg tab od	1 x 150 mg tab od	2 x 100 mg tabs am + 1 x 100 mg tab pm **OR** 15 ml bd
20 - 24.9	3 x 120/60 mg tabs od	3 x 10 mg DT od **OR** 1 x 50 mg FC tab od	3 x 10 mg DT bd **OR** 1 x 50 mg FC tab bd	1 x 300 mg tab + 1 x 60 mg tab od **OR** 6 x 60 mg tabs od	2 x 150 mg tabs od	2 x 100 mg tabs bd **OR** 20 ml bd
25 - 29.9	1 x 600/300 mg tab od **OR** ABC/3TC/DTG FDC (600/300/50 mg) if eligible od	1 x 50 mg FC tab od **OR** FDC: ABC/3TC/DTG if eligible od	1 x 50 mg FC tab bd OR FDC: ABC/3TC/ DTG if eligible od + 50 mg DTG FC tab 12 hours later	2 x 300 mg tabs od		1 x 300 mg tab bd **OR** 1 x AZT/3TC 300/150 mg tab bd
30 - 39.9		1 x 50 mg FC tab od **OR** FDC: TLD if eligible od **OR** FDC: ABC/3TC/DTG if eligible od	1 x 50 mg FC tab bd **OR** FDC: TLD if eligible od + 50 mg DTG FC tab 12 hours later **OR** FDC: ABC/3TC/ DTG if eligible od + 50 mg DTG FC tab 12 hours later			
≥ 40						

* Avoid LPV/r solution in any full-term infant <14 days of age and any premature infant <42 weeks post conceptual age (corrected gestational age) or obtain expert advice.

✦ Children weighing 25-29.9 kg may also be dosed with LPV/r 200/50 mg adult tabs: 2 tabs am + 1 tab pm.

Atazanavir + ritonavir should not be used in children/adolescents on treatment with Rifampicin, obtain expert advice.

No dosage adjustments are required for children receiving treatment with Efavirenz and Rifampicin.

od = once a day;
nocte = at night;
bd = twice a day;
am = in the morning;
pm = in the evening;
std = standard;

Lopinavir / ritonavir (LPV/r)	Abacavir + Lamivudine + Lopinavir/ ritonavir	Lopinavir/ritonavir when on rifampicin (and for 2 weeks after stopping rifampicin)		# Atazanavir (ATV) + Ritonavir (RTV)	Efavirenz (EFV)	
300/75 mg/m²/dose LPV/r **TWICE daily**	**By weight band TWICE daily**	LPV/r std dose + super-boosting with ritonavir (RTV) powder **TWICE daily** (≥ 0,75 x LPV dose bd)	Double-dose LPV/r tabs ONLY if able to swallow whole LPV/r tabs **TWICE daily**	By weight band **ONCE daily**	By weight band **ONCE daily**	**Target dose**
Sol. 80/20 mg/ml Adult tabs 200/50 mg, Paed tabs 100/25 mg **TABLETS MUST BE SWALLOWED WHOLE** Pellets 40/10 mg per capsule **ONLY FOR USE IF NOT TOLERATING LPV/r SOLUTION. CAPSULES ARE NOT RECOMMENDED < 6 MONTHS OF AGE**	Caps 30/15/40/10 mg **IF PATIENT IS ON RIFAMPICIN TB TREATMENT, ADD RTV POWDER** (next column)	Oral powder 100 mg/packet	Adult tabs 200/50 mg, **Paed tabs** 100/25 mg	ATV caps 150, 200 mg; RTV tabs 100 mg; FDC: ATV/RTV 300/100 mg RTV TABLETS AND ATV/r FDC TABLETS MUST BE SWALLOWED WHOLE	Caps/tabs 50, 200, 600 mg; FDC: TEE 300/200/600 mg; TABLETS MUST BE SWALLOWED WHOLE	**Available formulations**
Consult with a clinician experienced in paediatric ARV prescribing for neonates (< 28 days of age) and infants weighing < 3kg						**Wt. (kg)**
* 1 ml bd **OR** 2 capsules bd	2 capsules bd	LPV/r std dose (see purple column) + oral RTV powder 100 mg (1 packet) bd	Do not use double-dose LPV/r tabs	Not recommended	Not recommended	**3 - 5.9**
* 1.5 ml bd **OR** 3 capsules bd	3 capsules bd					**6 - 9.9**
2 ml bd OR 4 capsules bd **OR** 2 x 100/25 mg paed tabs am + 1 x 100/25 mg paed tab pm	4 capsules bd	LPV/r std dose (see purple column) + oral RTV powder 200 mg (2 packets) bd	3 x 100/25 mg **paed tabs** bd	ATV 1 x 200 mg cap od + RTV 1 x 100 mg tab or 100 mg oral powder (1 packet) od	1 x 200 mg cap/tab nocte	**10 - 13.9**
2.5 ml bd OR 5 capsules bd **OR** 2 x 100/25 mg paed tabs bd **OR** 1 x 200/50 mg adult tab bd	5 capsules bd		4 x 100/25 mg **paed tabs** bd **OR** 2 x 200/50 mg **adult tabs** bd		1 x 200 mg cap/tab + 2 x 50 mg caps/ tabs nocte	**14 - 19.9**
3 ml bd OR 6 capsules bd **OR** 2 x 100/25 mg paed tabs bd **OR** 1 x 200/50 mg adult tab bd	6 capsules bd					**20 - 24.9**
3.5 ml bd OR 7 capsules bd **OR** 3 x 100/25 mg paed tabs bd **OR** 1 x 200/50 mg adult tab bd + 1 x 100/25 mg paed tab bd	Not recommended	LPV/r std dose (see purple column) + oral RTV powder 300 mg (3 packets) bd	6 x 100/25 mg **paed tabs** bd **OR** 3 x 200/50 mg **adult tabs** bd	1 x ATV/RTV 300/100mg FDC od **OR** ATV 2 x 150 mg caps od + RTV 1 x 100 mg tab or 100 mg oral powder (1 packet) od	2 x 200 mg caps/ tabs nocte	**25 - 29.9**
5 ml bd OR 10 capsules bd **OR** 4x100/25 mg paed tabs bd **OR** 2x200/50 mg adult tabs b			8 x 100/25 mg **paed tabs** bd **OR** 4 x 200/50 mg **adult tabs** bd			**30 - 39.9**
					2 x 200 mg caps/ tabs nocte **OR** FDC: TEE if eligible od	**≥ 40**

FC = film coated
DT = dispersible tablet
FDC = fixed dose combination;
TLD = tenofovir/lamivudine/dolutegravir;
TEE = tenofovir/emtricitabine/efavir

Weight (kg)	3 - 5.9	6 - 13.9	14 - 24.9	≥ 25
Cotrimoxazole Dose	2.5 ml od	5 ml or ½ tab od	10 ml or 1 tab od	2 tabs od
Multivitamin Dose	2.5 ml od	2.5 ml od	5 ml od	10 ml od

- Disclosure should ideally be a gradual process over many years, advancing from partial disclosure to full disclosure, post-disclosure, and ongoing support.
- Ideally full disclosure should take place between 10 and 14 years old if the child is of normal cognition and maturity, making sure that it is done before sexual debut.
- The parent or caregiver (PCG) should be prepared for disclosure and supported through each step by the healthcare worker (HCW). PCGs should decide what role the HCW should play.
- The HCW/PCG should make sure to use age-appropriate language, pictures where possible, excellent counselling skills, be aware of emotions, use a private space, and refer to psychologists and social workers when necessary.

Failure of full disclosure by early teenage years can lead to:

- Poor adherence
- Emotional difficulties
- Poor school performance
- HIV transmission if sexually active
- The adolescent finding out their HIV status through other mechanisms
- Psychological issues if disclosure is not sensitively done

No disclosure yet (0 — 4 Years)

- Conduct the consultation with the child present (but do not mention the word HIV if the child can understand the conversation)
- The child is too young for direct information about HIV but explanations to the caregiver about how HIV can affect the child remain important.
- Provide ideas to help the caregiver support the child taking medicine. Congratulate the child on taking their medicines well.
- Address the caregiver's anxieties and inform them that in time you will support them through the partial and full disclosure process as outlined below.
- Provide a safe and welcoming clinic and build a relationship with the child through play/singing.
- Warn the PCG that when the child starts asking questions about why they must take medicine, they should give the information described under partial disclosure below. They should try not to lie and name other illnesses as the reason for needing medication.

Partial Disclosure (5-9 years)

- The child needs to learn about illness and why they must take medicine but not HIV by name yet.
- Introduce the concepts of good and bad health. Talk about how good health can be promoted by eating healthy food, keeping clean, exercising, looking after teeth etc. Explain that medicines help to keep a body healthy and strong.
- Introduce infections as 'germs' that can damage the body/make you sick and (white) blood cells as the part of the body that look for and kill germs.
- Explain that some germs hide, and you need to take medicines to help fight the germs or explain that they were born without enough white blood cells so they need to take medicine every day to make their white blood cells increase so that they can stay healthy and are able to fight the germs
- Advise PCG that they can start teaching their child about HIV and other illnesses without telling them that they have HIV, so that the child learns correct information about HIV and not the negative myths (see the 5 points in the red box below)

Before Full Disclosure:

- Assess the adolescent's cognitive and emotional maturity (if they are passing school at the appropriate level for their age, they can be assumed to be of normal cognitive maturity)
- Prepare the PCG for full disclosure
- Get consent to disclose the adolescent's (and PCG's) HIV status. It is preferable to disclose the PCG's status as well, but not essential if the PCG requests not to.
- Find out what the adolescent knows about HIV already before disclosing to them.
- Educate them about HIV and dispel the negative myths:

Children and adolescents living with HIV (C/ALWH) often learn negative myths about HIV from their community, their friends and school, such as "HIV kills", "people with HIV are promiscuous or bad" and "people with HIV can't live a normal life". It is therefore extremely important to educate C/ALWH and dispel all of these myths before you tell them they have HIV. Different ways of educating them include teaching them about a few different illnesses, holding education sessions in the clinic or telling their parents to teach them about HIV at home from a young age. Five important things for them to understand include:

1. These days we have very good treatment for HIV, so people living with HIV (PLHIV) can remain perfectly healthy and never get AIDS.
2. PLHIV can live as long as people without HIV if they take their treatment every day.
3. Anyone can have HIV and it does not make them different/bad. Many people around you have HIV and you do not know because they are just as healthy as those without HIV.
4. PLHIV can have relationships and have children, and if they are taking their treatment and have a suppressed viral load, they will not transmit HIV to their sexual partner or children.
5. Living with HIV does not prevent people from living a completely normal life and following any career they want.

Full disclosure:
Ensure they first understand points 1- 5 in the box above before you explain that:

- They were born with a germ/virus called HIV, which can kill their white blood cells so they can't protect their body from other germs.
- The medicine they receive works very well at making the HIV virus sleep so that it can't kill white blood cells. That way the body is well protected from other germs and you won't get sick.
- If you don't take your medicines every day the HIV virus can get stronger and prevent the medicines from working
- They need to understand their responsibility for not transmitting HIV e.g. safer sex, and family planning

Once the adolescent has been disclosed to it is very important to offer for them to join a support club, answer any questions they have, let them express their emotions, and make sure they understand the following things:

- Repeat the 5 points mentioned in the red box above, now relating to the adolescent themselves.
- It is not their mother's fault that the adolescent got HIV. When their mother was pregnant we did not have such good medicine, so many babies got HIV from their mothers, but nowadays we have very good medicine so if an adolescent wants to have a baby one day the medicine will be able to prevent their baby from getting HIV.
- It is not their parents' fault they have HIV: millions and millions of people in the world have HIV and they did nothing wrong and they are no different to anyone else. You can't tell who has HIV by looking at them because they will be healthy when they are taking their medication.
- They are allowed to keep their HIV status a secret, and are allowed to lie about it if their friends or strangers ask, because some people don't know enough about HIV and might treat them differently or think that it means they are going to be very sick. It is up to them and their PCG to decide who they think deserves to know.
- When they are ready to have a boyfriend/girlfriend or become sexually active they can come to the clinic to discuss how or when they would like to tell their partner about their HIV status.
- They should know how much their PCG loves them and be grateful for all the effort they put in over the years to make sure that they took their treatment every day to keep them healthy. This is a good opportunity for the child to thank the PCG and for them to tell each other how much they love them and give each other a hug.
- They must feel free to come into the clinic any time to ask any questions they have or discuss anything they are struggling with.

Post Disclosure (10-19 years)

- During follow up visits after full disclosure the information mentioned under "Full Disclosure" will need to be repeat many times as the C/ALHIV will not remember everything, might be in denial, might have since heard conflicting information, and will develop a deeper understanding of the information as they get older.
- They must feel free to ask any questions they might have.
- It is very important to assess their mental health and how they are coping with the information and with adolescence in general.
- Discuss whether they have or would like to disclose their status to friends or partners.
- Ask (privately) if they are sexually active or are thinking of becoming sexually active. Educate about safe sex, condom use, and family planning.
- Repeat information about the importance of taking medication every day to stay healthy and avoid development of drug-resistant HIV.

For more details on disclosure, please refer to the Differentiated Care Models Standard Operating Procedures 2023 SOP 3: Child and Adolescent Disclosure Counselling or contact the Right to Care Helpline on 082 352 6642

Other Resources and Important Information

Adverse Drug Reactions

Surveillance of all adverse drug reactions (ADRs) is fundamental. Healthcare professionals and consumers are urged to report any ADRs, adverse events following immunisation (AEFI), and product quality concerns to the SAHPRA pharmacovigilance office using one of the following reporting methods:

1. Form requests and submissions via e-mail: adr@sahpra.org.za (For the ***ADR reporting form, see page 39***)
2. Online e-reporting portal: https://primaryreporting.who-umc.org/ZA
3. Med Safety smartphone application: search for "Medsafety" on apple store or google play store and install the app on your mobile device. Select South Africa and you are ready to go. Information on the Med Safety App: https://medsafety.sahpra.org.za/

More information available from:
- The SAHPRA pharmacovigilance office - Tel: 012 501 0311
- SAHPRA's Health Products Vigilance link: https://www.sahpra.org.za/health-products-vigilance/
- Information on AEFIs, including COVID-19 vaccines: https://aefi-reporting.sahpra.org.za/

Drug Stock-outs

To report drug stock-outs, or for assistance with drug stock-outs, please contact Stop Stockouts:
SMS/please call me/WhatsApp (084) 855-7867
Email: reports@stockouts.org

Resources for Clinical Management and Drug Interactions

National HIV & TB Health Care Worker Hotline: 0800 212506
Email pha-mic@uct.ac.za
SMS/please call me/WhatsApp (071) 840-1572

Right to Care Paediatric, Adolescent and Adult HIV Helpline (082) 352-6642
Right to Care Helpline can be contacted vial call/SMS/please call me/WhatsApp/missed call

KZN Paediatric Hotline: 0800 006 603

ADR Reporting Form

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NDoH Pharmacovigilance Centre for Public Health Programmes (NPC)
Adverse Drug Reaction (ADR) / Product Quality Problem Report Form
This report will be shared with the
South African Health Products Authority (SAHPRA)
adr@sahpra.org.za or call 012501031

Reporting Health Care Facility/Practice				
Tel: 012 395 9506 (NPC) **Fax:** 086 241 2473 **Email:** npc@health.gov.za	Facility/Practice			
	District		Tel	
	Province		Fax	

Patient Details									
Patient Initials		File/Reference Number			Date of Birth/Age				
Sex	□M □F □Unk	Race		Weight (kg)		Height (cm)		Pregnant?	□N □Y
Allergies				Estimated Gestational Age at time of reaction					

Suspect Medicine(s) **[Medicines suspected to have caused the ADR]**

Trade Name [Generic Name if Trade Name is unknown]	Name of Manufacturer	Route	Dose (mg) and Interval	Date Started	Date Stopped	Reason for use	Batch Number / Expiry Date

All other Medicines Patient was taking at time of reaction **[Including over-the-counter and herbal products]**

Trade Name [Generic Name if Trade Name is unknown]	Name of Manufacturer	Route	Dose (mg) and Interval	Date Started	Date Stopped	Reason for use	Batch Number / Expiry Date

Adverse Drug Reaction/Product Quality Problem			
Date and time of onset of reaction		Date reaction resolved/duration	

Please describe Adverse Reaction/Product Quality Problem: (kindly add as much clinical information as possible)

Intervention **[tick all that apply]**	**Patient Outcomes** **[tick all that apply]**
□ No intervention	□ Patient recovered □ Patient recovering
□ Intervention unknown	□ Patient not recovering □ Outcome unknown
□ Patient counselled/non-medical treatment	□ Patient died; Date of death:_____
□ Discontinued Suspect Drug; **Replaced with**:_____	□ Impairment/Disability □ Congenital Anomaly
□ Decreased Suspect Drug Dosage; **New Dose**:_____	□ Patient hospitalised or hospitalisation prolonged
□ Treated ADR with:_____	□ Life threatening □ Other:_____
□ Referred to hospital; **Hospital Name**_____	□ ADR reappeared after restarting suspect drug/similar drug (rechallenge)?: □ N □ Y □ Not done □ Unknown
□ Other Intervention (e.g. dialysis): _____	

Laboratory Results

Lab Test	Test Result	Test Date	Lab Test	Test Result	Test Date

Co-morbidities/Other Medical Condition(s) **[tick all that apply]**

□ Hypertension □ Diabetes □ Asthma □ Tuberculosis □ HIV/AIDS □ Other:

Reported by

Name		E-mail	
Designation	□ Nurse □ Pharmacist □ Doctor □ Other:	Date Reported	
Telephone		Signature	**VERSION 35.0 May 2021**

THIS ADR REPORT IS NOT A CONFIRMATION THAT THE REPORTER OR THE SUSPECT MEDICINE(S) CAUSED THE ADR

Abbreviations

3TC	Lamivudine
ABC	Abacavir
AGL	Adherence Guideline
AHD	Advanced HIV disease
ALT	Alanine transaminase
am	In the morning
ANC	Antenatal Care
APC	Adult Primary Care
ART	Antiretroviral therapy
ARV	Antiretroviral
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine
bd	Twice daily
BMI	Body mass index
CM	Cryptococcal meningitis
CNS	Central nervous system
CPT	Cotrimoxazole preventive therapy
CrAg	Cryptococcal Antigen
CVS	Cardiovascular
DILI	Drug-induced liver injury
DMOC	Differentiated Models of Care
DR	Drug-resistant
DS	Drug-sensitive
DT	Dispersible tablet
DTG	Dolutegravir
EAC	Enhanced Adherence Counselling
eGFR	Estimated glomerular filtration rate
EFV	Efavirenz
EX-PUP	External pick-up point
FAC-PUP	Facility pick-up point
FC	Film coated
FDC	Fixed-dose combination
GIT	Gastrointestinal tract;
Hb	Haemoglobin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
InSTI	Integrase strand transfer inhibitor
IRIS	Immune reconstitution inflammatory syndrome
IUCD	Intrauterine contraceptive device
LP	Lumbar puncture
LPV/r	Lopinavir/ritonavir
MMD	Multi-month Dispensing
MUAC	Mid-upper arm circumference
NA	Not applicable
NCDs	Non-communicable diseases
nocte	at night
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NTDs	Neural tube defects
NVP	Nevirapine
od	Once daily
OI	Opportunistic infection
PBFW	Pregnant and breastfeeding women
PCR	Polymerase chain reaction test for HIV
PHC EML	Primary Health Care Essential Medicines List
PI	Protease inhibitor
PJP	Pneumocyctis jerovecii pneumonia
PLHIV	People living with HIV
pm	in the evening
RPCs	Repeat prescription collection strategies
RT	Resistance test
sCR	Serum creatinine

std	Standard
STIs	Sexually transmitted infections
TB	Tuberculosis
TDF	Tenofovir disoproxil fumarate
TEE	Tenofovir + emtricitabine + efavirenz
TLD	Tenofovir + lamivudine + dolutegravir
TPT	TB preventive treatment
VL	Viral load
VT	Vertical transmission
WHO	World Health Organisation

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SUPPORTING ORGANISATION

World Health Organisation
Right to Care
International AIDS Society
CDC
ANOVA
Medicines Information Centre

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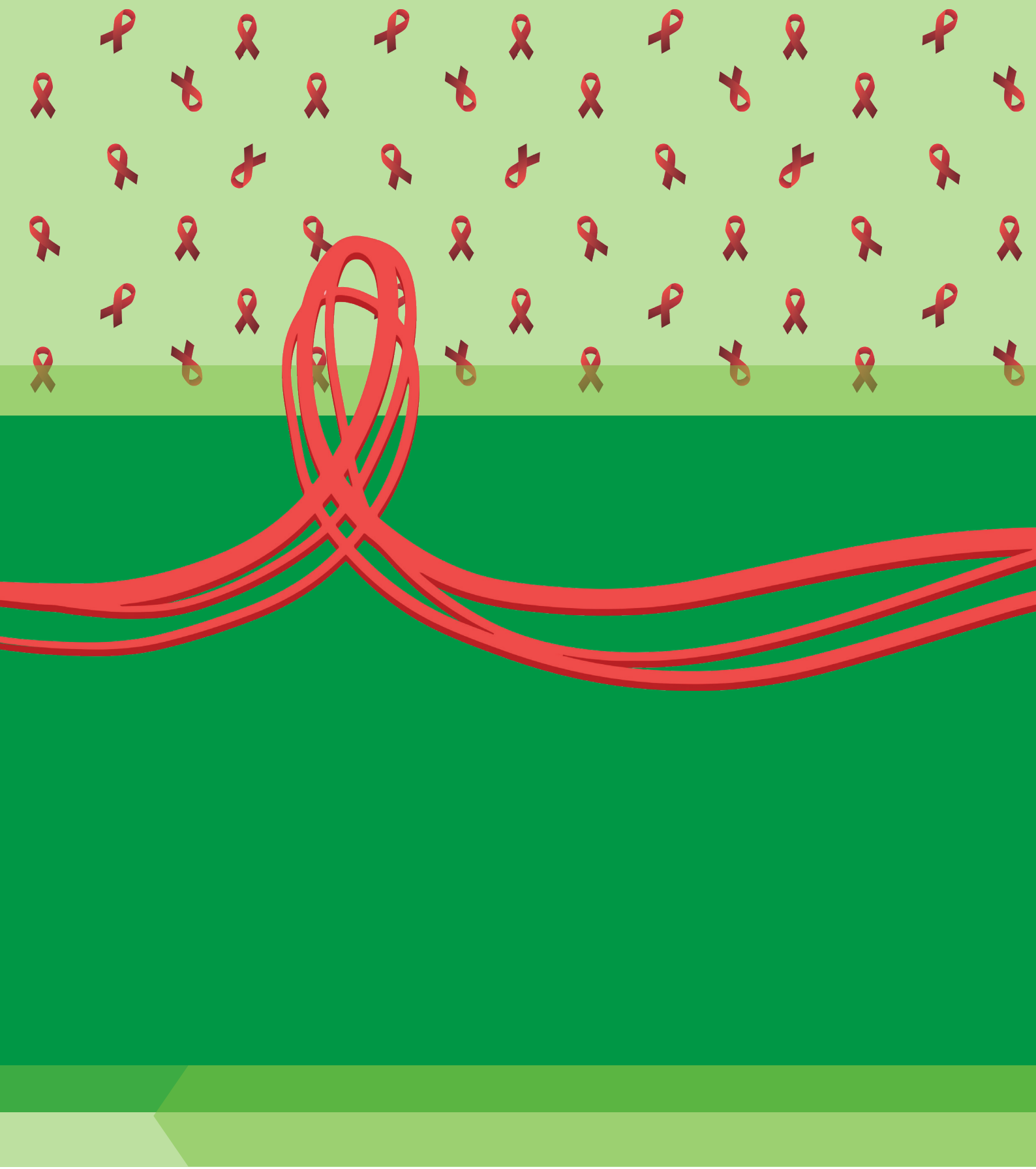

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