NATIONAL CONSOLIDATED GUIDELINES

For the Prevention and Management of HIV in Adults, Adolescents, Children, Infants and Pregnant & Breastfeeding Women

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National Consolidated Guidelines

For the Management of HIV in Adults, Adolescents, Children and Infants and Prevention of Vertical Transmission

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FOREWORD

South Africa is committed to preventing new HIV infections and attaining the UNAIDS 95-95-95 targets to control the HIV epidemic by providing quality healthcare services, including highly effective antiretroviral medications for both prevention and treatment of HIV.

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, and improve quality of life. To this end, the 2023 ART guideline introduced simplified ART provision, and harmonised the management of children, adolescents and adults, as well as pregnant women living with HIV/AIDS, TB and other common opportunistic infections. The guidelines also introduced the use of Dolutegravir (DTG) dispersible tablets for children from 3kg and 4 weeks old. All pregnant and breastfeeding women must be on DTG-based regimens to ensure that they are virally suppressed as soon as possible to prevent vertical transmission.

These guidelines have been revised with the latest version of the Differentiated Models of Care SOPs to ensure the 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.

Integration of services remains critical in achieving better health outcomes. This guideline provides resources to guide integration, especially with EPI services, maternal contraception, TB services and NCDs to enhance the quality of clinical care, the client's experience of care, support continued engagement in care, and improve health system efficiencies.

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 therefore urge all clinicians at PHC clinics, community health centres and hospitals to use these guidelines diligently to offer quality, comprehensive services to the public, thus contributing to the vision of A LONG AND HEALTHY LIFE FOR ALL.

Dr SSS Buthelezi
Director-General: Health

ABBREVIATIONS

2MMD	2 months dispensing (at once)
3MMD	3 months dispensing (at once)
3TC	Lamivudine
6MMD	6 months dispensing (at once)
ABC	Abacavir
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
BANC plus	Basic Antenatal Care Plus
bd	Twice daily
BMI	Body Mass Index
CBP	Childbearing Potential
CCMDD	Central Chronic Medicines Dispensing and Distribution
CHW	Community Health Worker
CICT	Client-initiated Counseling and Testing
CM	Cryptococcal Meningitis
CNS	Central Nervous System
CPT	Cotrimoxazole Prophylaxis Therapy
CrAg	Cryptococcal Antigen
CS	Congenital Syphilis
CTX	Cotrimoxazole
CVS	Cardiovascular System
DCs	Dispensing Cycles
DHIS	District Health Information System
DILI	Drug-induced Liver Injury
DMOC	Differentiated Models of Care
DMPA	Depo Medroxyprogesterone Acetate
DR	Drug-resistant
DS	Drug-sensitive
DSD	Differentiated Service Delivery
DST	Drug Sensitivity Testing
DT	Dispersible Tablet
DTG	Dolutegravir
EAC	Enhanced Adherence Counselling
EFV	Efavirenz
eGFR	Estimated Glomerular Filtration Rate
EGK	Electronic Gatekeeping
EML	Essential Medicines List
EMTCT	Elimination of Mother to Child Transmission of HIV
EPI	Expanded Programme on Immunization
EX-PUP	External Pick-Up Point
FAC-PUP	Facility Pick-Up Point
FC	Film-coated
FDC	Fixed-dose Combination
FGR	Foetal Growth Restriction
FTC	Emtricitabine
FTIC	Fast Track Initiation Counselling (DMOC SOP 1)
GDM	Gestational Diabetes Mellitus
GIT	Gastrointestinal Tract
Hb	Haemoglobin
HBsAg	Hepatitis B surface Antigen
HBV	Hepatitis B Virus
HCW	Health Care Worker
HEI	HIV-exposed Infant
HEU	HIV-exposed but Uninfected
HIV	Human Immunodeficiency Virus
HIVSS	HIV Self-Screening
HTAs	High Transmission Areas
HTS	HIV Testing Services
IEC	Information, Education and Communication
IM	Intramuscular
IMCI	Integrated Management of Childhood Illnesses
INH	Isoniazid
InSTI	Integrase Strand Transfer Inhibitor
IPT	Isoniazid Preventative Therapy
IPV	Intimate Partner Violence
IRIS	Immune Reconstitution Inflammatory Syndrome
ITSR	Index Testing Services Register
IUCD	Intrauterine Contraceptive Device
IV	Intravenous
KP	Known Positive
LAM	Lipoarabinomannan
LLETZ	Large Loop Excision of the Transformation Zone
LGBTI	Lesbian, Gay, Bisexual, Transgender, Intersex
LP	Lumbar puncture

LPA	Line Probe Assay
LPV/r	Lopinavir/ritonavir
LTBI	Latent TB Infection
MCR	Maternity Case Record
MDO	Missed Diagnostic Opportunity
MIP	Mother-infant Pair
MMD	Multi-month Dispensing
MNCH	Maternal, Neonatal and Child Health
MNCWH&N	Maternal Neonatal Child Women's Health and Nutrition
MSM	Men who have Sex with Men
MUAC	Mid-Upper Arm Circumference
NA	Not Applicable
NCDs	Non-Communicable Diseases
NHLS	National Health Laboratory Service
NNRTI	Non-Nucleoside ReverseTtranscriptase Inhibitor
nocte	at night
NRTI	Nucleoside/nucleotide Reverse Transcriptase Inhibitor
NSA	Non-Suppression Algorithm
NTD	Neural Tube Defect
NVP	Nevirapine
od	Once daily
OGTT	Oral Glucose Tolerance Test
OI	Opportunistic Infection
PBFW	Pregnant and Breastfeeding Women
PCG	Parent/Caregiver
PCR	Polymerase Chain Reaction
PEP	Post-exposure Prophylaxis
PHC	Primary Health Care
PHC EML	Primary Health Care Essential Medicines List
PI	Protease Inhibitor
PICT	Provider-initiated Counselling and Testing
PJP	Pneumocyctis *jerovecii* Pneumonia
PLHIV	People living with HIV
pm	in the evening
PNC	Postnatal Club
PO	Per Os (per mouth)
PrEP	Pre-Exposure Prophylaxis
RfA	Results for Action NHLS Reports
RPCs	Repeat Prescription Collection Strategies
RPR	Rapid Plasma Reagin
RT	Resistance test
RTHB	Road to Health Booklet
Rx	Treatment
SA	South Africa
SC	Subcutaneous
sCR	Serum Creatinine
sd	Single dose
SOP	Standard Operating Procedure
SRH	Sexual and Reproductive Health
std	Standard
STIs	Sexually Transmitted Infections
TAF	Tenofovir Alafenamide
TB	Tuberculosis
TB NAAT	TB Nucleic Acid Amplification Test
TDF	Tenofovir Disoproxil Fumarate
TEE	ART Regimen containing Tenofovir, Emtricitabine, and Efavirenz
TLD	Tenofovir + Lamivudine + Dolutegravir
TLE	Tenofovir + Lamivudine + Efavirenz
TPHA	Treponema Pallidum Haemagglutination Assay
TPT	TB Preventive Therapy
TST	Tuberculin Skin Test
UTI	Urinary Tract Infection
VL	Viral Load
VLS	Viral Load Suppression
VMMC	Voluntary Medical Male Circumcision
VT	Vertical Transmission
VTP	Vertical Transmission Prevention
WASH	Water, Sanitation and Hygiene
WBOT	Ward-based Outreach Team
WHO	World Health Organisation
WLHIV	Woman Living with HIV
WOCP	Women of Childbearing Potential

1 What's new in this Guideline?

HIV Testing Services	3 test algorithm to improve accuracy of results:
	• Removes retesting to cover the window period other than in cases of post sexual violence, occupational exposure or presenting with signs and symptoms of possible acute HIV viral syndrome.
	• Revises frequency for routinely retesting:
	  • Annually for all adults and adolescents 15 years and older or from 12 years if presenting to family planning services or reporting sexually active
	  • Inclusion of screening algorithm for indicating need to test children older than 18 months who missed their 18-month test or who present sick.
	• Expands index testing to:
	  • Not only newly diagnosed clients, but also to all virally unsuppressed ART clients and clients re-engaging in care;
	  • Beyond sexual and drug injecting partners, to offer index testing to:
	  • all biological children under 19 years of age:
	  • the wider social network for key populations and other high prevalence sub-populations to address confidentiality challenges
	• Expands the use of HIV self-testing for PEP follow-up, for PrEP continuation from the second follow-up visit, for PrEP re-engagement (provided testing is conducted at a health facility), within facility-based HTS for triage when insufficient HTS providers are available, and within index and social-network testing.	

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 (28 or 30 days) 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 ≥ 2 kg and ≥ 37 weeks gestational age
		• DTG-containing fixed-dose combination: ALD FDC [Abacavir (ABC) + lamivudine (3TC) + DTG]
		  • ALD 600/300/50 mg - can be prescribed for clients ≥ 25 kg
		  • pALD 60/30/5 mg- can be prescribed for infants and children from ≥ 2 kg, and ≥ 4 weeks of age (and ≥ 37 weeks corrected gestational age)

	Children ≥ 2 kg and ≥ 37 weeks gestational 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) is no longer part of any standard ART regimen. AZT will be reserved only for cases with **both** renal failure **and** ABC hypersensitivity, or for preterm neonates • **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
Advanced HIV Disease	Chapter added on management of advanced HIV disease, including the screening, diagnosis and management of tuberculosis (TB), cryptococcal meningitis (CM), and severe bacterial infections.	

Virological Failure	• **Definition**: two or more VLs ≥ 1000 c/mL after a minimum of 9 months on a DTG-containing regimen (TLD2 or TLD1 with special circumstances).The client must have had at least two adherence assessments and interventions. • Focus on improved adherence: Resistance to DTG is 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. • Resistance testing can be authorised by a medical officer experienced in HIV management, or other expert. Two samples should be collected for both an HIV VL and a drug resistance test. If DTG is detected on drug-level testing (if available), the laboratory will proceed to do an HIV drug-resistance test. • No DTG-containing 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	
Other Updates	• Two 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 two visits per 6-month scripting cycle. • Emphasizes the importance of clinical care including TLD switch and VL management for clients enrolled RPCs with VL 50-1000 c/mL • 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 facility-provided 6MMD specifically for clinically very stable clients meeting eligibility criteria for RPCs plus 12 months on ART and two most recent VLs <50 c/mL (limited to TLD FDC until medicine stock availability is confirmed for other ART regimens and hypertensive/diabetic treatment) • Introduces a differentiated approach to management on re-engagement. • Integrates contraceptive methods and TB preventative therapy into all service delivery models • Aligns ART visit schedules to TB management, infant EPI and family planning schedules to enable integration • Incorporates tools for enhanced adherence counselling and mental health assessment	
HIV-Exposed Infant	Definition of "higher-risk" HIV exposure at birth	• The VL threshold for defining an HIV-exposed infant as "higher-risk" moves from ≥ 1000 c/mL to ≥ 50 c/mL • Dual prophylaxis (AZT twice daily and NVP once daily) will be provided for all HIV-exposed infants at birth until delivery VL result is known
	Cotrimoxazole Prophylaxis (CPT)	• HIV-exposed infants are no longer eligible for CPT • HIV-infected infants remain eligible for CPT
TPT	TPT eligibility in preganncy	• Pregnant women with advanced HIV disease (CD4 ≤ 200, or WHO stage 3 or 4) should receive the complete package of care for a client with AHD, including TPT.

Syphilis	Syphilis testing frequency	• A pregnant woman should be screened and tested for syphilis
		  • At her 1st/booking visit in antenatal care.
		  • If she tests negative, syphilis testing should be repeated at scheduled antenatal visits, at approximately 4-weekly intervals, e.g., for BANC+ clients, this could be at 20, 26, 30, 34, and 38 weeks gestation
		  • During her labour/delivery admission
		  • At the time of diagnosis of an intrauterine death
		  • At any time, if the mother has clinical symptoms or signs suggestive of syphilis
		• Syphilis testing should be aligned with the HIV testing schedule

	Type of syphilis tests	• Rapid syphilis tests (specific/treponemal) are preferred as first-line tests in pregnancy to facilitate immediate treatment.
		  • Dual rapid tests that test for both syphilis and HIV using the same drop of blood should be used for women with unknown HIV status;
		  • Single syphilis rapid tests (syphilis only) should be used for WLHIV
		• All positive rapid tests must be confirmed using an RPR test.

	Notifications	All stillbirths related to syphilis should be **notified**
Other Updates	The following sections have been added/updated/enhanced • Visit Schedule for Integrated Care: Mother living with HIV and her HIV-exposed Infant • Involving fathers in antenatal and postnatal services • PrEP Job Aids • Visit Schedule for Integrated Care: Mother taking PrEP • Three new EGK codes for VLs done in pregnant and breastfeeding women: C#Antenatal; C#Delivery; C#Postnatal	

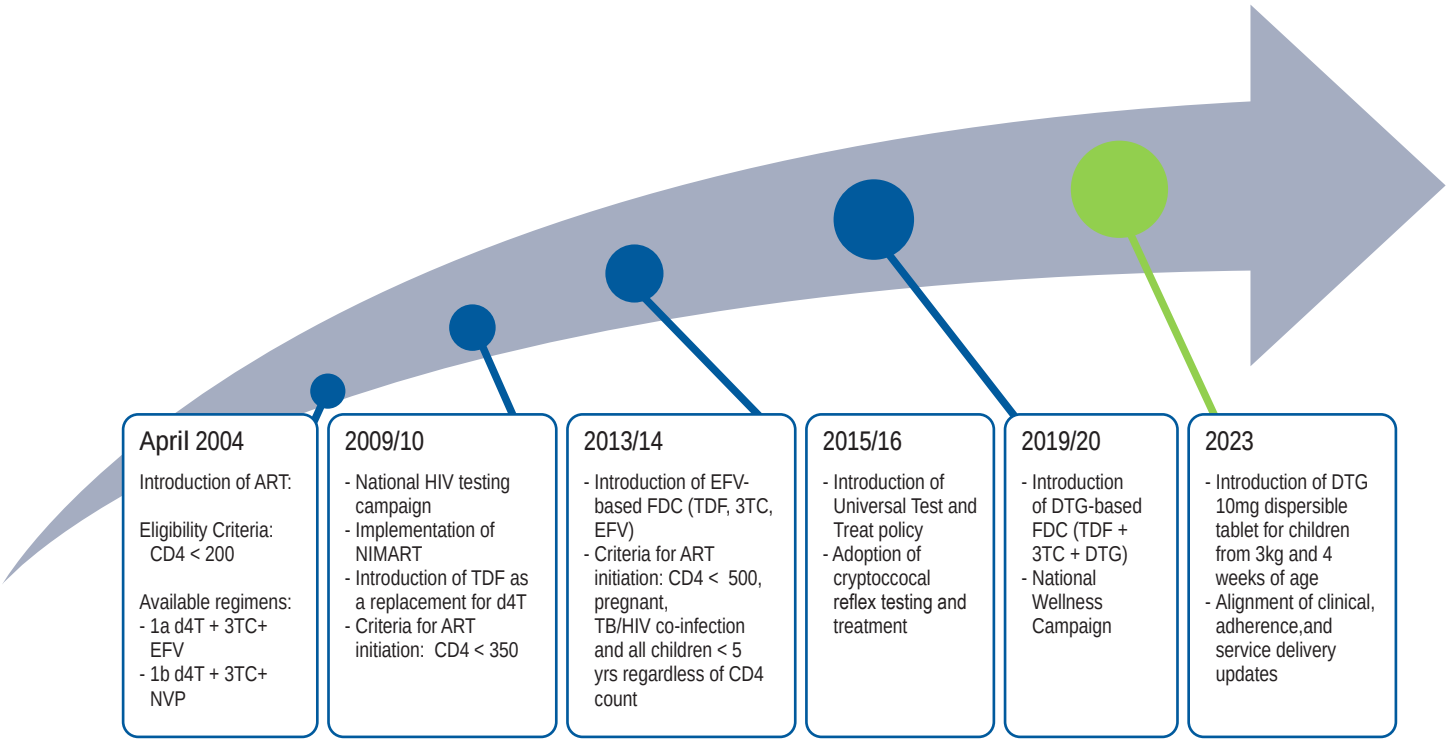


Figure 1: Key Milestones of the National HIV Programme

The national HIV programme has made significant strides in the last 20 years since the introduction of antiretroviral treatment (ART) in 2004, as illustrated in Figure 1. These ART Guidelines replace the 2019 National Consolidated Guidelines for the Prevention of Mother to Child Transmission of HIV and the Management of HIV in Children, Adolescents, and Adults.

Target Audience

The target audience of these guidelines are all categories of healthcare providers, programme managers at national, provincial, district and facility level, and community-based organisations working with PLHIV in South Africa. Of particular note are frontline nurses, doctors, and ancillary healthcare workers that provide the continuum of HIV care, treatment, and support services to people living with HIV (PLHIV).

Scope and Content

These guidelines address clinical and programmatic aspects of HIV prevention and treatment amongst adults, adolescents, children, infants, pregnant and breastfeeding women, and key populations along the continuum of care, including:

Part 1: The minimum package of HIV prevention, care and treatment services to be offered by a health facility

Part 2: HIV prevention, HIV testing services (HTS) and linkage to care

Part 3: ART initiation, optimising ART regimens and management of the client on ART

Part 4: Advanced HIV Disease

Part 5: Vertical Transmission Prevention

Certain aspects of care are covered comprehensively in other guidelines such as the National HIV Testing Services (HTS) Policy (2025), the Differentiated Models of Care SOPs (2025), and the Pre- and post-exposure Prophylaxis Guidelines (PrEP 2021, PEP 2019, and PrEP [Lenacapvir], 2025). While these guidelines provide a summary of the most important clinical aspects, it is recommended that healthcare providers refer to these documents for more detail on these aspects of care. Furthermore, these guidelines do not provide detail for complementary programmes such as sexually transmitted infections (STIs), cervical cancer screening, medical male circumcision, contraception, fertility planning and non-communicable diseases (NCDs), as these are covered comprehensively in other guiding documents. However, using an integrated and person-centred approach, the client's needs should determine the elements within their individualised, comprehensive package of care.

1

The Minimum Package of HIV Prevention, Care and Treatment Services

The Ideal Facility

What package of services do all health facilities need to provide?

1 The Minimum Package of HIV Prevention, Care and Treatment Services

All South African health facilities are expected to provide a minimum package of services for prevention, care, and treatment of HIV for the population they serve. The minimum components of care are outlined in Table 1 below.

Table 1: The minimum package of service to be provided at all facilities

PREVENTION		REFERENCE
Health Education of HIV Prevention	All facilities should provide education on HIV prevention and risk-reduction both during individual client consultations and as part of daily health talks in the facility.	HTS, 2025
Provision of male and female condoms	Condoms should be routinely promoted and be made available in facility waiting areas, toilets, and in every consultation room. Condoms should be routinely offered during every HTS encounter, as part of dual method family planning, and for clients presenting with STIs. Condoms should be promoted and made available in the community using the WBOT CHWs, through outreach activities and mobile services, and other non-governmental organizations. Condoms should be promoted and made available at hotspots and high transmission areas (HTAs), e.g., truck stops, shebeens, and taverns.	HTS, 2025
Screening and treatment of STIs	All facilities should provide screening and syndromic management of STIs and contact tracing according to the National STI guidelines. STI screening should also be incorporated into ART and PrEP clinical reviews.	Sexually Transmitted Infections Management Guidelines, 2018. PrEP Guidelines, 2021' ART Guidelines, 2023
Voluntary Medical Male Circumcision (VMMC)	All facilities should offer VMMC or refer clients for VMMC. VMMC should be included in health talks and other IEC materials.	South African National Guideline for Medical Male Circumcision (2016)
Post Exposure Prophylaxis (PEP)	All facilities should provide PEP for 28 days within 72 hours to healthcare workers who are accidentally exposed to HIV through a needle stick injury (occupational exposure), anyone assessed as having a significant risk of sexual exposure (sexual assault or unprotected consensual intercourse or a burst condom with a known HIV positive person or a person whose HIV status is unknown), or anyone exposed through unintended accidents that lead to contact with blood.	Post Exposure Prophylaxis Guideline, 2019
Pre-exposure Prophylaxis (PrEP)	All facilities, including the antenatal service, should have healthcare workers trained in PrEP and should offer and be able to provide PrEP to those testing HIV negative and who: – request PrEP, even if he/she may not be perceived to be at risk by the provider. – may be at substantial risk of HIV infection. After 1 month of starting PrEP, clients should be provided with 3MMD for PrEP between clinical reviews. For pregnant and postnatal women, PrEP refills are to be aligned with the antenatal, postnatal and EPI schedules to reduce visit burden as per VTP guidelines (pg 49-50).	PrEP Guidelines, 2021' HTS, 2025 VTP, 2023

HIV TESTING SERVICES		REFERENCE
Facilities should provide **routine HIV testing**, including provider-initiated counselling and testing (PICT) and client-initiated counselling and testing (CICT) for all clients attending the facility at all facility service entry points to adults, couples, adolescents, children, infants, pregnant and breastfeeding women and key populations.	HTS services should be provided at, or accessible from, ALL service entry points, including ANC services, TB services, STI services, SRHR/family planning services, outpatient clinics, medical, surgical, and paediatric inpatient wards, emergency units, maternal, newborn and child health (MNCH) services, mental health services and male circumcision services. All facilities should have HIVSS kits accessible for clients to take home to screen themselves or to provide to their partner to screen. HIVSS can also be used to triage clients for further rapid testing where there are insufficient human resources to ensure testing coverage at the service entry point. HIV diagnosis should follow the 3-test algorithm set out in the 2025 HTS guidelines.	HTS, 2025
Facilities should **routinely retest clients** at the specified retesting frequency	Clients should be routinely retested at the frequency set out in the HTS and VTP guidelines. Retesting should be done for any client with HIV symptoms or presenting with a HIV indicator condition (STI, TB or Hepatitis) and at least annually for all adults and for adolescents 15 years or older or from 12 years if presenting to SRHR/family planning or ANC services (or if reporting sexually active at other entry points).	HTS, 2025 – Table 2 VTP, 2023
All clients living with HIV should be provided with **Index case testing** for their partners, biological children or siblings if under 19 years of age	Any HIV positive client is a potential index client, including those (i) newly diagnosed with HIV, (ii) ART clients with an unsuppressed viral load, (iii) ART clients missed by index testing services and (iv) re-engaging ART clients. With the consent of the index client, index testing of their contact list may take place at the facility, in the home (or at a preferred community venue) or if over 18 years of age, by offering HIV self-screening (HIVSS) kits.	HTS, 2025
Focused community-based testing should be provided to under-tested populations	HIV and HTS promotion and awareness campaigns should tailor messages to better reach and create demand among under-tested priority populations less likely to access HTS at facilities specifically focusing on key populations, men and young people. Community-based testing, including distribution of HIVSS kits, should be provided through mobile outreach HTS to hotspots including community venues, workplaces, tertiary institutions and key population specific drop-in-centers with active linkage to confirmatory testing for people screening reactive, treatment services for people diagnosed with HIV and to prevention services for people who will substantially benefit.	HTS, 2025
HIV self-screening should be incorporated as an HIV testing option in facility-based, focused community-based, index/social network HTS and PEP/PrEP follow-up	HIV self-screening kits should be made available and promoted at health facilities and in community HTS for clients who prefer HIV self-screening either on or off-site (primary distribution) and for clients to take for their partners (secondary distribution). Index and social network-based testing should include HIV self-screening as a HIV testing option for identified contacts. HIV self-testing can be used for PEP follow-up and PrEP continuation from 4-months of follow-up or at PrEP re-engagement (provided conducted at a health facility).	HTS, 2025
Social network-based testing should be provided to key populations individuals' social networks	Similar to index testing and also requiring consent, key population individuals who (re)test for HIV should be offered HTS for their social networks, expanding their contact list beyond reported sexual and/or drug-injecting partners.	HTS, 2025
Community Engagement	All facilities should engage with their governance structures (e.g., hospital boards, clinic committees, ward counsellors) and other relevant community-based groups to advocate for the importance of HIV testing and to mobilise clients to attend facility-based and community-based HTS.	HTS, 2025

LINKAGE TO CARE		REFERENCE
Clients who test HIV negative, with a focus on individuals who will benefit substantially, should be actively linked to prevention services (PEP/ PrEP, VMMC and harm reduction services). Clients who test HIV positive should be actively linked to treatment services	All HTS service points should provide post-test counselling that is informative as well as reassuring to facilitate linkage to care. Prevention education, information, and condoms (use, distribution and plan for self-collection) should be addressed with every person during post-test counselling. HTS providers are responsible for making appointments and providing referral slips for people requiring active linkage. Where feasible: • Clients who test HIV positive during community-based testing should be linked to a CHW or community representative • Clients who test HIV positive during facility-based testing should be accompanied to the ART initiation services and introduced to the service provider HTS providers are responsible for linkage. Clear lines of communication and referral pathways should be established between testing sites and relevant service points for follow-up care. Logbooks and appointment systems should be used, and missed appointments should be traced.	HTS, 2025

PROVISION OF ART SERVICES		REFERENCE
ART Initiation	All facilities should provide ART initiation services for adults, adolescents, children, pregnant, and breastfeeding women. Included should be the following: • Baseline clinical assessment and WHO clinical staging • CD4 count/percentage • TB screening, diagnosis, and treatment • TB Preventive Therapy (TPT) • Cotrimoxazole Preventive Therapy (CPT) • Cryptococcal antigen (CrAg) screening and fluconazole prophylaxis • Treatment of Opportunistic Infections (OIs) • Sexual and Reproductive Health Services (SRH) should be integrated into ART services, including screening for pregnancy, family planning assessment and method provision, STI and cervical cancer screening • Mental Health Screening • Screening for non-communicable disease • Pregnant women should be initiated in the Antenatal Care Clinic (ANC) • Breastfeeding women should preferably be initiated within routine maternal and child health services in a “one-stop” approach to improve adherence and retention in care. • At Primary Health Care (PHC) level, children should preferably be initiated within Child Health / IMCI services, using the IMCI six steps	ART Clinical Guideline 2023
ART education and adherence counseling	All facilities should provide the following types of education and adherence support: • Fast track initiation counselling: education and support focused on providing skills and identifying potential barriers to adherence and explaining the treatment pathway ahead, including access to longer ART refill collection at more convenient locations when virally suppressed (DMOC SOP 1) • Enhanced adherence counselling: adherence monitoring and targeted intervention for unstable patients (DMOC SOP 2) • Child and adolescent disclosure for children living with HIV (DMOC SOP 3) • Advanced HIV Disease education and counselling (DMOC SOP 9) All facilities should monitor linkage and retention and ensure tracing of clients missing an appointment by more than 7 days, starting with making telephonic contact and following prioritization order.	2023, ART guidelines – DMOC SOP 1, 2, 3 and 9

<table>
<tr><th></th><th>PROVISION OF ART SERVICES</th><th>REFERENCE</th></tr>
<tr><td>Follow-up for clients on ART</td><td>All clients should have the following assessed at ART follow-up visits, until they are assessed as being stable and can enter either repeat prescription collection strategies (external pick-up points, facility pick-up points and adherence clubs) or facility provided 6MMD. Once in RPCs or facility provided 6MMD, comprehensive clinical assessments will be done annually, unless the clients become ill.
The follow-up of a client should include:
• Clinical assessment and WHO clinical staging
• Monitoring of weight (adults) and growth and neurodevelopment in children
• Screen for medication side effects and potential drug interactions
• Monitoring of renal function using creatinine and eGFR
• VL monitoring and response
• TB screening, TPT eligibility and annual TB NAAT
• CPT eligibility
• Contraception review including pregnancy screening, contraceptive method choice, including offer of LARC and self-care methods prescribed for the same script length with at least the same but preferably longer refill length (oral or self-injectable DMPA-SC*); consider most appropriate RPCs/facility 6MMD depending on method chosen and visit alignment
• STI screening and management
• Cervical cancer screening.
• Mental health screening
• Non-communicable diseases screening
• RPCs/facility 6MMD review, rescript with appropriate refill length (for RPCs minimum of 2 x 3MMD - see DMOC SOP 5)
• At Primary Health Care level, children should preferably be followed up within child health/IMCI services, using the IMCI seven steps</td><td>See Managing the Client on ART on page 41</td></tr>
<tr><td>ART delivery for stable clients
A stable client is defined as a client who:
• Most recent VL < 50 c/mL
• Clinically well
• No OIs, including TB
• No uncontrolled NCD or mental health condition
• Not pregnant or post natal <12 months
• Over 5 years of age</td><td>All facilities should provide a package of differentiated models of care for stable clients on ART, known as RPCs.
Clients should be offered and enrolled in their choice of RPCs immediately on viral suppression with a 6-month script and 3MMD:
• Facility pick-up point (fast track one-stop ART refill collection at facilities)
• Adherence club (group ART refill collection at facilities or in the community)
• External pick-up point (ART refill collection at community venues and private pharmacies)
Once clients on ART* for 12 months and have 2 consecutive suppressed viral loads, they should be offered a choice between RPCs and facility-provided 6MMD.</td><td rowspan="2">ART Guidelines, 2023 – DMOC SOP 4 & 5</td></tr>
<tr><td>A very stable client is defined as a client who meets all of the above plus:
• On ART* for 12 months
• Has 2 consecutive VLs < 50 copies m/L</td><td>Clients may also choose none of the above RPCs or facility 6MMD. They will still be eligible for 3MMD from facilities between clinical consultations. (refer to DMOC SOP 4).
Provided controlled, hypertension and diabetic treatment should be provided through the same RPCs on the same 6-month prescription for the same refill length as ART .
Oral or self-injectable contraception should be provided through the same RPCs/facility 6MMD and scripted on the same 6-month prescription with immediate dispensing of the full 6-months of contraception or at a minimum the same refill length as ART and collection from the same RPCs location.</td></tr>
<tr><td colspan="3">*Limited to ART TLD FDC regimen only until national medicine stock availability is confirmed for other ART regimens and hypertension and diabetic treatment.</td></tr>
</table>

PROVISION OF ART SERVICES		REFERENCE
ART delivery for unstable clients An unstable (or red flag) client is one who: • missed an appointment or attended late for refills • a VL > 50 c/ml • possible signs or symptoms of treatment failure	Facilities should use TIER.Net missed appointment lists (confirmed using client folder or RPCs monitoring tools) and have systems in place to trace clients who have missed their scheduled appointment or last RPCs collection date by more than 7 calendar days, prioritising in the following order: Clients (re)started in the last 6 months with advanced HIV disease (AHD), clients with abnormal results, clients linked but not (re)started on ART or overdue for VL monitoring – See DMOC 7. Facilities should ensure effective VL monitoring and response by: • Using the NHLS reports for action (RfA) to identify clients with a VL more than 1000 and recall them to care for further action. • Having a functional results management process in place, so that VL results are captured in the clinical stationery and into TIER.Net. • Use TIER.net reports to identify those due for a VL, and those who have two VLs more than 1000 c/ml and may require a switch to a second-line regimen. Clinicians should be able to assess a client with a VL > 50 c/ml, implement interventions accordingly, provide enhanced adherence support if indicated, identify clients eligible for a resistance test, and maintain ART as applicable Unstable clients who do not require more frequent clinical management can be provided with 3-month ART refills between clinical consultations to support adherence by reducing health facility attendance burden (refer to DMOC SOP 4.1: Facility 3MMD) Clinicians should be able to assess a re-engaging client (more than 28 days late for a scheduled appointment) and differentiate clinical management and service delivery, including when to repeat a CD4 count/ VL and appropriate ART refill length as set out in the re-engagement algorithm (*Re-engagement Algorithm on page 34*). Clients less than 28 days late are regarded as routine clients and should remain in their RPCs and collect their refill from their RPCs location, or if not enrolled, assessed and offered RPCs.	ART guidelines, 2023 – DMOC SOP 4, 7 and 8 See the Tier.net reports manual v 1.10 See *Data Management on page 167* on how to register for NHLS RfA See *VL Non-Suppression Algorithm on page 144* for the management of an elevated VL

PROVISION OF INTEGRATED TB/HIV SERVICES		
Facilities should provide **integrated TB and HIV services**	All clients testing for HIV should undergo TB screening, and clients who present with one or more symptoms should be referred to a clinician for further management. All clients diagnosed with HIV should be screened for TB at every visit at any facility service, including but not limited to ART services, and have access to: • further investigations if indicated (TB-NAAT, LPA, culture and DST, CXR, and urinary LAM) • DS- or DR-TB treatment as applicable All ART clients, irrespective of TB symptoms, should be annually tested for TB using TB-NAAT. All clients with abnormal results must be urgently recalled by the facility for further management. Clients without TB symptoms should be considered for TPT. All clients with presumptive or diagnosed TB should be tested for HIV. Clients who are TB and HIV coinfected should be able to receive treatment for both conditions from the same consulting room, with script and refill length alignment.	National Guidelines on the Treatment of Tuberculosis Infection, 2023 HTS 2025 ART guidelines, 2023 (see *Visit Schedule for Integrated Care for Clients on ART and Drug-Sensitive TB Treatment on page 48*)

PROVISION OF INTEGRATED SRH/MNCWH&N AND VTP SERVICES		
HIV Testing, Care, Treatment, VTP and SRH services should be integrated into Antenatal Care, at Delivery, during Postnatal Care, and into other routine MNCWH&N services	VTP including HTS, PrEP, ART initiation, VL monitoring, enhanced infant prophylaxis, early infant diagnosis (EID), access for ART (including facility based MMD, RPCs, or facility provided 6MMD if eligible), should be part of routine MNCWH&N services. Wherever possible, different services should be aligned and provided on the same day. The mother and her infant should receive integrated care as a mother-infant pair until at least the end of the breastfeeding period and ideally up to the child being two years of age. Because infant prophylaxis is dependent on the mother's VL, the clinician treating the child should always enquire about the health of the mother, her adherence to ART, her most recent VL, and if she is still breastfeeding. Every woman attending ART services should be screened for pregnancy and breastfeeding, have her family planning needs and method choice reviewed at least annually, and have her contraception method choice aligned and provided with ART refills and where possible, provided through the same RPCs/facility-provided 6MMD. All facilities should be able to provide cervical cancer screening at specified frequency.	VTP guidelines, 2023 (alignment tables on *Visit Schedule for Integrated Care for the Mother living with HIV and her HIV-exposed Infant on page 162*) HTS 2025

PROVISION OF INTEGRATED NCD/HIV SERVICES		
Facilities should provide integrated NCD/HIV services	All PLHIV should be screened for non-communicable diseases, including hypertension, diabetes, and epilepsy, and have their cardiovascular risk assessed as outlined in the PHC EML 2024. All clients on ART should be screened for depression and anxiety at least annually, and at any time if a client presents as unstable/a red flag client (re-engaging, elevated VL, or possible clinical signs of failure). All clients with non-communicable Disease should be screened for HIV.	PHC EML, 2024
NCD treatment delivery for people with stable hypertension or diabetes: • Most recent HbA1c taken in past 12 months ≤8% for Diabetes • 2 consecutive BP <140/90 for Hypertension	Stable hypertensive or diabetic clients, whether or not co-infected with HIV, qualify for RPCs and should be offered and enrolled. If co-infected, these clients should receive their ART and NCD treatment through the same RPCs for the same refill length with integrated clinical reviews.	ART guidelines, 2023 – DMOC SOP 5

PROVISION OF SERVICES FOR KEY POPULATIONS INCLUDING ADOLESCENTS, SEX WORKERS AND PEOPLE FROM LGBTI COMMUNITIES		
Facilities should provide sensitive and appropriate HIV services for adolescents, youth and key populations	All facilities should have HCWs who are trained to provide adolescent and youth-friendly services and key population sensitive and appropriate HIV services in a manner that encourages marginalised populations to access care. Based on their local context, facilities should provide community-based outreach and mobile services to deliver HIV prevention interventions such as HTS, condoms, condom-compatible lubricants, targeted communication, PEP, PrEP and ART to people who face barriers to access mainstream services.	National Adolescent and Youth Health Policy (2017) The South African National LGBTI HIV Framework, 2017-2022

PHARMACY		
Facilities are responsible for ensuring a **constant supply of essential medicines and commodities**	Clinicians should have a constant supply of: • ART, including 84-90-day pack sizes for TLD • PEP and PrEP • Prophylactic medications, e.g., cotrimoxazole preventive therapy (CPT), TB preventive therapy (TPT), and fluconazole • Medications for the treatment of opportunistic infections (OIs) and sexually transmitted infections (STIs) • Nevirapine and AZT syrup for infant prophylaxis • Anti-TB medications • Contraceptive methods, including LARC methods and self-injectable DMPA-SC* • Hypertensive/diabetic medicines • Male (external) and female (internal) condoms All drug stockouts should be reported to Stop Stockouts: (084) 855-7867 (SMS/please call me/WhatsApp)	National Contraception Clinical Guidelines (2019)

LABORATORY		
Facilities are responsible for ensuring a **constant supply of essential diagnostic kits and commodities for side room investigations**	• HIV Rapid Test Kits (screening and confirmatory 1 and 2 in accordance with 3-test algorithm) • HIVSS kits • DBS kits for DNA PCR • Dual HIV/Syphilis Rapid test kits • Pregnancy tests • Syphilis Rapid tests • Haemoglobin Meters and test strips • Glucometers and test strips • Urine dipsticks • Specimen tubes for VL, CD4, FBC, and Biochemistry • Sputum jars • Urine LAM strips	

INFRASTRUCTURE AND EQUIPMENT		
Essential Infrastructure and Equipment	• Running water and electricity • Well-ventilated rooms for infection control purposes • A room that allows for confidential counselling • BP machines Stethoscopes • Torch and otoscope/auroscope Thermometers • Height measuring boards/charts, growth charts for children, MUAC tapes, weighing scales • Examination couches • Speculum, brushes, slides and fixative, and examination lamp for pap smear • Penile and vaginal models for condom demonstration purposes An adequate supply of prescribed clinical stationery	Ideal Clinic policy

MANAGEMENT OF HIV PREVENTION, CARE, AND TREATMENT SERVICES		
Guidelines	Current guidelines, as referenced in this document, should be available (preferably in each consulting room, if resources allow)	
Data Analysis and Reporting	All data should be checked and verified before submission to DHIS. All facilities should practice good documentation and have functional blood results management processes that will allow accurate data to be captured into TIER.Net with effective recall systems in place. Facilities should use TIER.Net reports to track clients missing scheduled appointments and identify clients with elevated viral loads or other abnormal results. Facilities should conduct 3-6 monthly clinical audits to ensure that guidelines are adhered to and that clients are receiving quality comprehensive clinical care (including clients in RPCs). Analysis of facility data should enable continuous quality improvement.	DHIMS policy TIER.Net reports Manual PHC Supervision Manual, and Ideal Clinic Guidelines
Clinic and Community meetings	Facilities should meet with their supervisor/health area manager to review indicator performance relative to targets and the effectivity of actions outlined in their quality improvement plans (in preparation for sub-district/district quarterly review meetings). Facilities should organize regular clinical case discussion meetings to review difficult cases, adverse events, including positive PCRs and maternal or child deaths or near misses. Facilities should meet quarterly with their governance structures and community leaders to increase the demand for HTS, HIV prevention and HIV treatment activities.	PHC Supervision Manual

2

HIV Prevention, HIV Testing Services (HTS) and Linkage to Care

95% of PLHIV should know their status

How do we find and test those living with HIV and link them to care and treatment?

1 HIV Testing Services

HIV testing services (HTS) are the main entry point to the HIV continuum of care.

HTS must focus on people with HIV who (i) remain undiagnosed, (ii) are unlinked to treatment services, (iii) are re-engaging in care and treatment services, and (iv) who would substantially benefit from prevention services. To maximise the impact of HTS, programmes need to consider specific local epidemic contexts and resources available and determine a strategic mix of differentiated HTS approaches for an effective and efficient HTS programme.

The HTS approaches include the following:

- Facility-based HTS by entry service point,
- Community-based HTS,
- HIV self-screening (HIVSS),
- Index testing and
- Social network-based testing

Key guiding principles for HTS

- Apply a **human-rights-based approach** that prioritizes universal health, gender equality and health-rights;
- Use **integrated** approaches:
  - HTS must integrate screening for TB symptoms, STIs, mental health and NCDs into the pre-test information session at health facilities and in community settings
  - Wherever feasible, HTS should be provided together with all SRHR services including family planning.
  - HTS services should be integrated into all service delivery areas and offered to all clients attending at health facilities, ensuring HIV testing coverage of all clients not previously tested or due for retesting.
- Include **high impact testing strategies** in the mix of facility- and community-based HTS approaches such as facility-based PITC, facility- and community-based **index client testing**, focused community-based testing of **high-risk populations**, including female sex workers, men who have sex with men (MSM), transgender individuals (TG) and people who inject drugs (PWID) and under-tested priority populations, including men and young people.
- Implement the 5Cs, namely, **Consent, Confidentiality, Counselling, Correct test results**, and **Connection** along the HTS continuum of care, to ensure clients are not lost to follow-up in the HTS cascade.

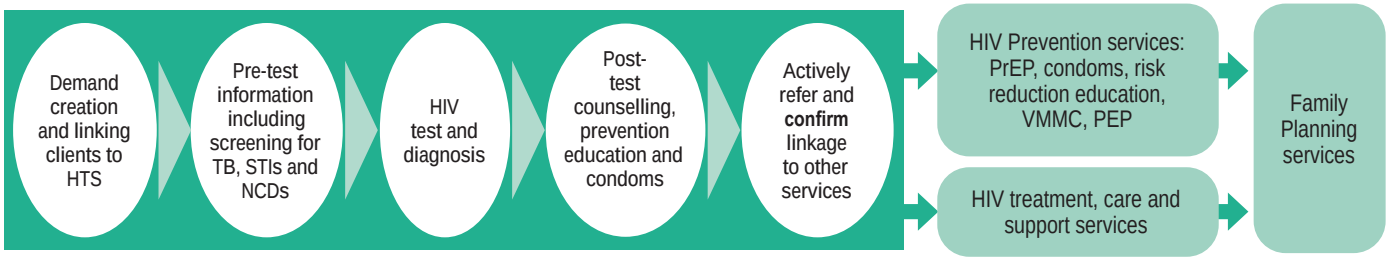


Figure 2: The 5C along the HTS continuum of care

Consent for HTS in children

Children may only be tested for HIV if testing is in their best interest, and lawful consent has been given for the test. Any person aged 12 years and older, and/or with sufficient maturity*, can give consent for HTS in South Africa. Consent for HIV testing for children may be given:

- by a child, if he or she is 12 years or older
- by a child younger than 12 years if he or she has "sufficient maturity*"
- by a parent, caregiver or the provincial head of the Department of Social Development if the child is younger than 12 years and is not sufficiently mature

* A child will be sufficiently mature to provide independent informed consent if he or she is able to:

- understand information about the benefits, risks and social implications of HIV testing; and
- act accordingly (i.e., agree or refuse to test) based on that understanding.

Children under 12 years old who present at ANC/FP/TOP services should be evaluated to determine if they are mature enough to give consent for HIV testing. If the child is not deemed sufficiently mature to provide consent, testing should still be conducted. In such cases, the consent process should involve a caregiver or another designated person, as outlined in the Children's Act.

The Children's Act[1] ensures that a wide range of people may assist a child by consenting for HIV testing on the child's behalf. It facilitates HTS for orphans and vulnerable children. According to the Children's Act, a caregiver is anyone who cares for a child. Caregivers include:

- grannies, aunts and any other person who cares for a child with the implied or express informed consent of a parent or guardian;
- a foster parent;
- someone offering temporary safe care;
- the head of a shelter or child and youth care centre;
- a child and youth care worker supporting children in the community;
- a child (of 16 years and older) heading a child-headed household.

The basic package of HTS services

Where HIV testing is provided by a skilled provider, the package should include:

- Pre-test information and post-test counselling
- HIV-testing according to the national 3-test algorithm
- Risk reduction education and condom provision
- Active referrals to HIV prevention services (PEP, PrEP, VMMC and harm reduction) for those testing negative
- Active referrals to treatment, care, and support services for those who test positive
- Provision of, or referral for, family planning services
- TB, STI, mental health and NCD screening
- Facility and community index testing services for partners and biological children of HIV positive clients over 18 years of age, including those (i) newly diagnosed with HIV, (ii) ART clients with an unsuppressed viral load, (iii) ART clients missed by index testing services and (iv) re-engaging ART clients.

For HIV self-screening (HIVSS), the test kit should include:

- Instructions on how to perform the test, and interpret the results
- Information for how and where to link to other services
- A referral card
- National AIDS Helpline contact details for questions and support (0800 012 322)

HIVSS is a pre-screening test and does not provide a definitive diagnosis. A reactive self-test result must always be followed by additional testing following the national testing algorithm by a trained provider or counsellor.

HTS approaches and settings: when, where, who, and what

A combination of facility- and focused community-based HTS approaches facilitates the early diagnosis of HIV- positive people. Complementary to facility-based HTS, community work increases early diagnosis by reaching first-time testers among people who seldom use clinical services. Men, adolescents, and key populations, for example, visit public health facilities less frequently than women and mothers. Using the principles of differentiated service delivery (DSD), testing services may be adapted to target both high-risk populations and those that are currently hard to reach. Table 2 below provides an overview of differentiated HIV testing approaches, outlined according to the DSD building blocks of when, where, who, and what.

Members of the LGBTI communities often test late due to fear of stigma and discrimination, thus, increasing risks for poor health outcomes.

Table 2: An overview of how HIV testing approaches and settings can be adapted using a DSD approach

	WHEN	WHERE	WHO	WHAT
Facility-based HTS Facility-based **routine HIV testing**, including provider-initiated counselling and testing (PICT) for all clients, including adults, couples, adolescents, children, infants, pregnant and breastfeeding women and key populations.	HTS should be provided within standard operating hours, with PITC available overnight and on weekends for inpatients, casualty, and maternity services.	HTS services should be provided at, or accessible from, ALL service points, including ANC, TB, SRHR/FP, STI, outpatient clinics, medical, surgical, paediatric inpatient wards, emergency units, maternal, newborn and child health (MNCH), mental health, men's health including male circumcision services and dental services.	All healthcare personnel, including but not limited to nurses and counsellors, are trained in HIV testing services.	• Pre-test information • Provider-delivered test or HIVSS with confirmatory testing according to the algorithm • Post-test counselling, including prevention education and condoms • Index contact elicitation if appropriate • Distribution of self-screening kits • Linkage to confirmatory testing, treatment and prevention services
Focused community-based HTS Community-based approach focused on under-tested hard-to-reach populations, including men, young people, and key populations	Community-based services should be offered when the focus population is present and it may be provided during the day, early evening, over weekends, or at night (moonlight testing) to increase access for key populations, men, and young people (<25 years) who are frequently missed during normal working week hours, or school day visits.	Mobile and Outreach HTS to hotspots and venues where under-tested populations congregate Home-based HTS for index testing, social network-based testing and TB contacts HTS in the workplace, schools or tertiary institutions, key population-specific drop-in centres and prisons.	Healthcare personnel, including but not limited to nurses and community health workers, are conducting the outreach service. Clients may perform HIV self-screening (HIVSS). All positive results require confirmation by trained healthcare personnel.	
Index testing Facility and community index testing for partners and biological children of HIV positive clients, including those (i) newly diagnosed with HIV, (ii) ART clients with an unsuppressed viral load, (iii) ART clients missed by index testing services and (iv) re-engaging ART clients.	Index testing consent and partners and biological children elicitation should take place during post-testing counselling of newly diagnosed clients or during ART consultations for ART clients.	Elicitation of contacts for possible testing should happen at the site of testing, whether at the facility or in the community. Alternatively, this should take place at the health facility when attending ART services.	Index testing trained healthcare personnel, including nurses and counsellors.	• Counselling on partner notification • Obtain informed consent • List partners, biological children with unknown HIV status or overdue for retesting • Screen for intimate partner violence (IPV) • Offer and action preferred method (index booklet) • Distribute HIVSS for the partner if this has been selected as the index testing preferred method • HIVSS instructions, including a link to an online demonstration • Linkage-related information • HIVSS distributor contact information for support • National hotline support • All positive results require confirmation by trained healthcare personnel

HIV self-screening HIV self-screening to reach under-tested and test-averse populations, including men (individually or as part of a couple), young people, and key populations. Also, to simplify the retesting of key populations and people using PEP or PrEP.	During facility operational hours and during all times of the day and evening when targeted populations congregate in the community.	• Facilities/community outreach for on-site primary use • Facilities/community outreach for off-site primary use • Facility or communities for secondary distribution to partners or social networks • Online delivery to preferred location • Vending machines • Workplaces • Pharmacies • Home (partner delivered)	Healthcare personnel and community cadres can distribute HIVSS kits to perform assisted or unassisted HIVSS. Clients may perform HIVSS assisted (12-17 years, all clients) or unassisted from 18 years (all positive results require confirmation by a trained HCW).	• HIVSS instructions including link to online demonstration • Linkage related information • HIVSS distributor contact information for support • National hotline support • All reactive/positive results require confirmatory testing according to the algorithm
Social network-based testing Facility and community-based testing of key population individuals and other specifically identified high prevalence sub-population groups (complementing index testing by addressing confidentiality challenges).	At post-testing counselling of clients at facility and community-based testing services (whether HIV positive or negative diagnosis) When attending ART or PrEP services.	At community hotspots or venue-based testing, key population-specific drop-in centres and facility-based services. At the site of testing, whether at the facility or in the community. Offered to key population individuals and any other specifically identified high prevalence sub-population group through recruitment in ART or PrEP service waiting rooms or ART/PrEP clinical reviews.	Trained healthcare personnel, providing HTS services to key populations and other priority populations.	• Recruit clients as peer mobilisers • Brief onboarding • Explain testing options for the person in a social network – home, online or scheduled community-based testing or HIVSS with follow-up • Decide plan for identified social contacts • Distribute coupons/referral slips • Distribute HIVSS kits. • Track coupon/ referral slip distribution

Frequency of testing in different populations

The table below summarizes the frequency at which HIV testing should be conducted in different populations.

Table 3: Frequency of testing in different populations

WHO	WHEN
Pregnant women	As per the most recent VTP guidelines - at confirmation of pregnancy, at every full basic antenatal care (BANC) visit, and at labour (or immediately after delivery)
Breastfeeding women (to detect HIV sero-conversion)	As per the most recent VTP guidelines, at 10-week EPI visit, at 6-month integrated well-baby visit, and then 3 monthly until six weeks post cessation of breastfeeding. Ask about her last testing date at every visit.
HIV-exposed babies	As per the most recent VTP guidelines - at birth, at ten weeks, at the 6-month integrated well-child visit and at 18 months If breastfeeding: At six weeks post-cessation of breastfeeding, even if breastfeeding continues beyond 18 months At any time if the child is clinically unwell.
18 month-old child regardless of exposure	Once as per the most recent VTP guidelines (universal testing at 18 months).
Children (19 months- 14 years)	Once post-18 months old if no documented 18-month HIV test OR sick
12-14 years*	Immediately and annually if presents at FP/ANC/TOP services OR at any other service if sexually active
15-19 years	Annually** or more frequently, based on recent exposure.
Adults	Annually or more frequently, based on recent exposure.
Clients on PrEP	At one month then every three months (as per the PrEP guidelines).
Key populations	Every 6 months.
Known discordant partner (known HIV positive partner)	Annually Positive partner should be on continuous ART and negative partner should be offered PrEP and tested as per the PrEP guidelines
All above individuals presenting with a diagnosis or receiving treatment for sexually transmitted infections or viral hepatitis, a confirmed or presumptive TB diagnosis, outpatients presenting with clinical conditions or symptoms indicative of HIV	Immediately

*Children under 12 years old who present at ANC/FP/TOP services should be evaluated to determine if they are mature enough to give consent for HIV testing. If the child is not deemed sufficiently mature to provide consent, testing should still be conducted. In such cases, the consent process should involve a caregiver or another designated person, as outlined in the Children's Act.
**HIV testing should be offered annually to adolescents, with the assumption that they may be engaging in sexual activity. Healthcare workers should avoid conducting sexual risk assessments, as these are known to exclude adolescents who are sexually active and vulnerable to HIV acquisition. If an adolescent chooses to self-report that they are not sexually active, they are considered to have opted out of testing and do not need to be tested until their situation changes.

Re-testing following the window period

Retesting is not required to rule out the window period except in the following cases.

Table 4: Recommended window period testing

CIRCUMSTANCE	WHEN TO RE-TEST TO RULE OUT THE WINDOW PERIOD
Post sexual violence and rape	At six weeks and 12 weeks, per the relevant guidelines
Occupational exposure & person exposed has been issued with PEP	At six weeks and 12 weeks per guidelines.
Presenting with signs and symptoms of possible acute HIV viral syndrome	At six weeks.

Types of tests to use in different age groups

Table 5 below summarises the types of tests that should be used per age group for screening and confirmation purposes if the screening test is found to be positive.

Table 5: Types of HIV tests to use per age group

Age of the client		HIV screening test	**Confirmatory HIV Test 1**	**Confirmatory HIV Test 2**
Less than 18 months		PCR test	PCR test	
18 months to 2 years		HIV Rapid test	PCR test	
All adults, adolescents and children older than 2 years		HIV Rapid test	HIV Rapid test	HIV Rapid test
Start with HIVSS All adolescents and adults older than 12 years	HIVSS	HIV Rapid test	HIV Rapid test	HIV Rapid test

In a small percentage of babies, maternal antibodies are retained beyond 18 months of age, potentially resulting in false-positive HIV diagnoses and inappropriate initiation of ART.[2] For this reason, HIV PCR testing is done as confirmatory testing in all HIV-positive tests in children under two years of age. At the clinician's discretion, the HIV-PCR may be replaced by a viral load test which has the advantage of both confirming the HIV diagnosis and providing a baseline VL for monitoring the child's response to ART. Any child who tests HIV positive should initiate ART according to the Paediatric ART guideline as a matter of urgency. Do not wait for the confirmatory result before initiating ART but ensure that this result is checked.

The HIV testing algorithm for all adults, adolescents, and children older than 2 years

South Africa has adopted a three-test strategy due to its HIV positivity rate below 5% to ensure the accuracy of results. This testing strategy aims to ensure that at least 99 % of the positive predictive value (PPV) is maintained, thus reducing the chances of a false-positive misdiagnosis. The algorithm is reflected in Figure 4 below and can be summarized as follows:

- Anyone with a non-reactive test result is reported to be HIV negative.
- Individuals whose test results are reactive on both the screening RDT and confirmatory RDT 1 should then be tested using confirmatory RDT 2.
- Report HIV positive if confirmatory RDT 2 is reactive (screening RDT reactive; confirmatory RDT 1 reactive; confirmatory RDT 2 reactive).
- Report as HIV discrepant if confirmatory RDT 2 is non-reactive (screening RDT reactive; confirmatory RDT 1 reactive; confirmatory RDT 2 non-reactive). Request HIV ELISA testing.
- If the screening RDT is reactive and the confirmatory RDT 1 is non-reactive, repeat the screening RDT only. Do not repeat the algorithm. If the repeat screening RDT is non-reactive, report HIV negative (screening RDT reactive; confirmatory RDT 1 non-reactive; repeat screening RDT non-reactive).
- If the repeat screening RDT is reactive, report as HIV discrepant (screening RDT reactive; confirmatory RDT 1 non-reactive; repeat screening RDT reactive). Request HIV ELISA testing. If the HIV ELISA test result is positive, report HIV positive. Individuals whose ELISA test result is inconclusive should be asked to return in 14 days for additional testing.

When implementing HIV rapid diagnostic testing (RDT), a serial testing algorithm should be followed. The selection of rapid test kits used in the testing algorithm should be guided by the National Reference Laboratory and approved by the National Department of Health.

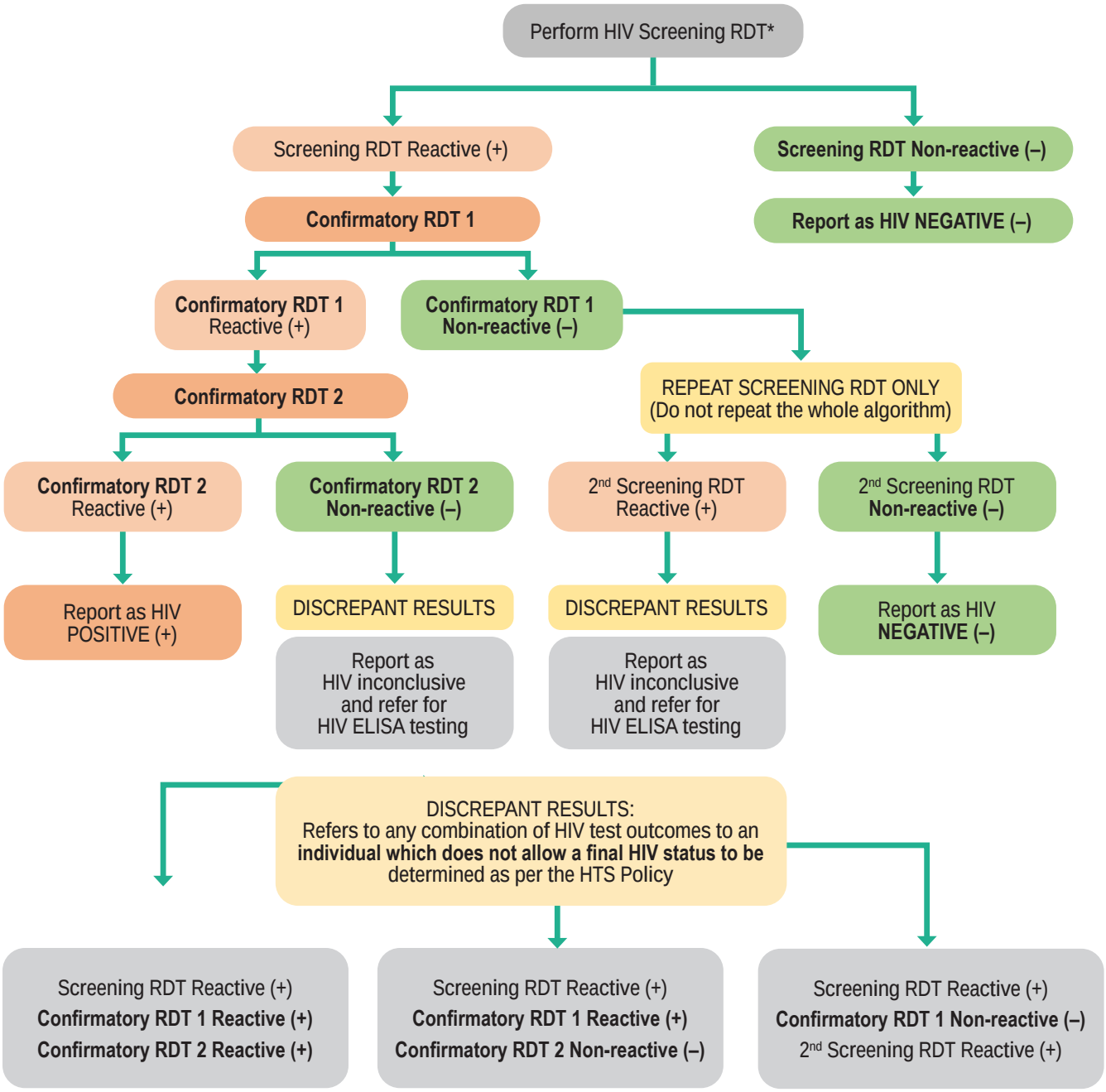


Figure 3: HIV Tesing Algorithm for all adults, adolescents and children over 2 years

* Where a healthcare worker does not have a screening RDT available to perform the first screening test in the algorithm, a healthcare worker can use an HIVSS kit to conduct the first test, replacing the need for a screening RDT. However if the client tests themselves as is intended with HIV self-testing (see section below), then any self-reported reactive test must be followed with a screening RDT and 2 confirmatory RDTs as per the national 3-test algorithm to confirm an HIV positive diagnosis.

HIV self screening algorithm

HIVSS is a pre-screening test and does not provide a definitive HIV-positive diagnosis. It does not replace the first screening rapid diagnostic test (RDT) in the 3-test algorithm except in exceptional circumstances*. All reactive HIVSS results need to be confirmed through the national testing algorithm starting with a screening RDT. Non-reactive HIVSS results should be considered negative, with no need for immediate further testing. HIVSS can also be used for PEP follow-up and PrEP continuation from 4-months follow-up or PrEP re-engagement, and this is only applicable if conducted in healthcare facilities (refer to updated PrEP guidelines).

*Where a healthcare worker does not have a screening RDT available to perform the first screening test in the algorithm, a healthcare worker can use an HIVSS kit to conduct the first test replacing the need for a screening RDT. However if person tests themselves as is intended with HIV self-testing, then any self-reported reactive test must be followed with a screening RDT as per the national 3-test algorithm to confirm an HIV positive diagnosis.

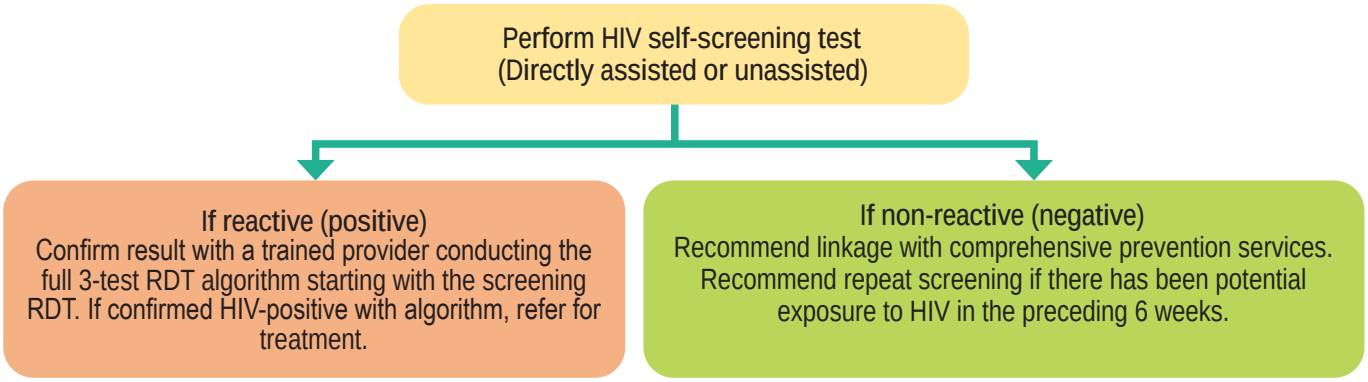


Figure 4: HIV Self Screening Algorithm

HIV index testing

To achieve the 95-95-95 targets and identify PLHIV who remain undiagnosed or not linked or engaged in treatment services, the country is scaling-up index testing for sexual and drug-injecting partners and biological children of PLHIV within all HIV testing and treatment programmes.

Index testing is a voluntary process where trained health care providers ask (i) clients newly diagnosed with HIV, (ii) clients with an unsuppressed viral load, (iii) ART clients missed by index testing services and (iv) re-engaging ART clients about their sexual partners, biological children under 19 years, siblings if the client is child under 19 years or drug injecting partners. Index testing should be offered to all people living with HIV as part of a voluntary comprehensive package of testing, care, and prevention.

All index testing sites should take steps to implement safe and ethical index testing services by:

1. Complying with minimum standards for index testing.
2. Obtaining informed consent prior to the elicitation interview and before contacting partners.
3. Conducting an IPV risk assessment for each named partner and providing appropriate services for clients experiencing or at risk of violence.
4. Utilizing continuous quality improvement to identify and address any gaps in the provision of index testing services; and
5. Implementing a robust mechanism for detecting, monitoring, reporting, and following up on any adverse events associated with index testing services.

There are 10 steps for conducting Index testing services as reflected in *Figure 6: HIV Index Testing Algorithm on page 21*.

HIV Index Testing Algorithm

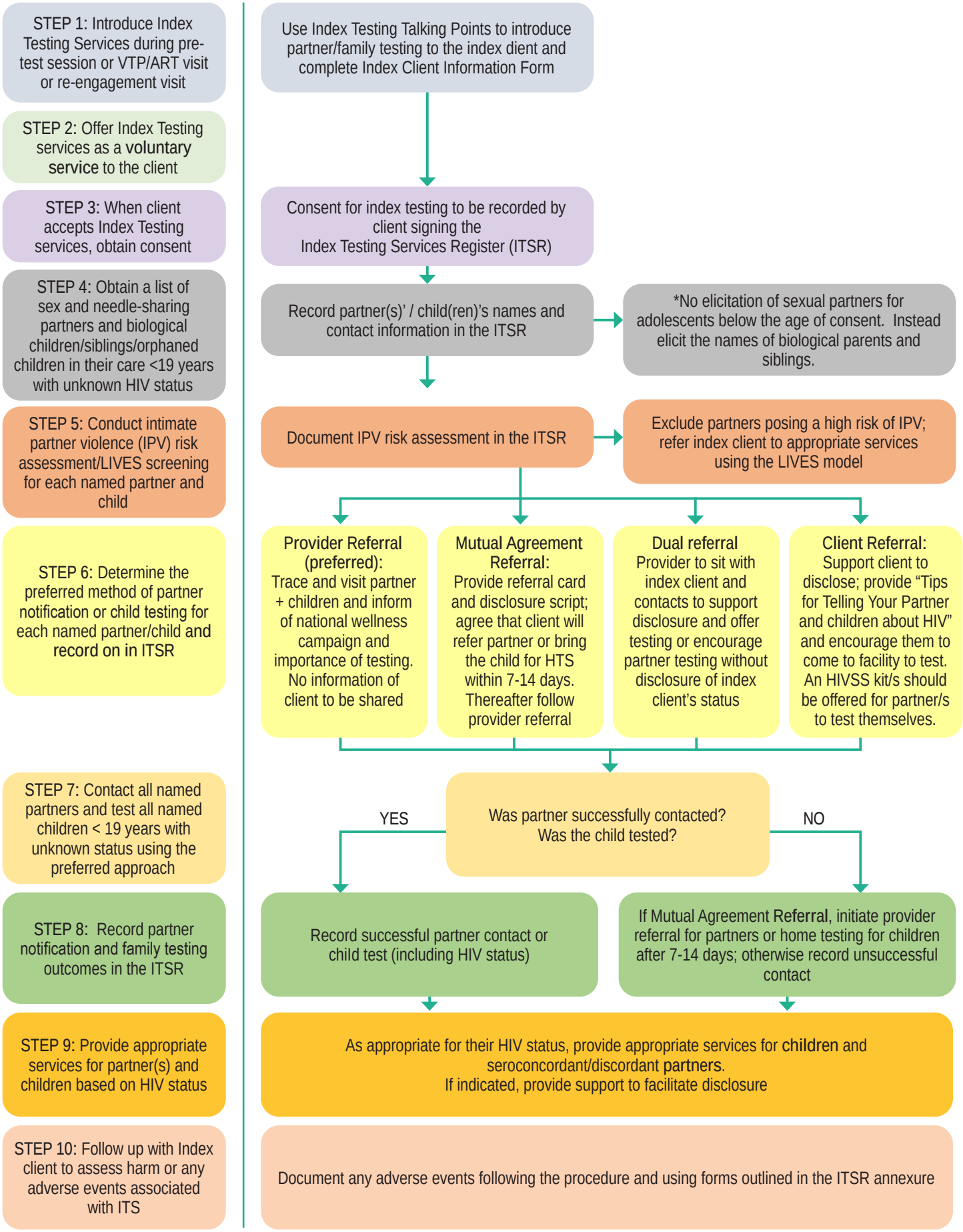


Figure 5: HIV Index Testing Algorithm

2 Linkage to Care

Linkage or "connection" to HIV care is defined as a process of actions and activities that support people testing for HIV and people previously diagnosed with HIV to engage with treatment and prevention services as appropriate for their HIV status and risk of HIV acquisition. It is the responsibility of all HTS providers to ensure that clients are connected to appropriate care.

HTS is of little value if clients that are tested are not linked into prevention and treatment services

For people living with HIV, it refers to the period beginning with HIV diagnosis and ending with enrolment in treatment and other health services, including:

- treatment, care, support and management of the disease
- sexual and reproductive health (i.e., contraception, VTP, STI screening, cervical cancer screening, anal cancer, and screening for men)
- testing for partners and families: this includes partner notification and index case testing

For people who test HIV-negative, it refers to the period beginning with HIV testing and ending with enrolment in preventative health services, including:

- PEP, PrEP, voluntary medical male circumcision (VMMC) and harm reduction services
- Sexual and reproductive health (i.e., contraception, STI screening, cervical cancer screening, anal cancer, and screening for men)

All clients testing for HIV irrespective of their HIV test result should receive appropriate prevention education including on use of condoms, a self-managed plan to collect condoms on an ongoing basis from a convenient location and a distribution of condoms as part of the HTS process.

Table 6: Differentiated linkage to HIV treatment and prevention services

	WHEN	WHERE	WHO	WHAT
Link to treatment	Offer linkage on the same day as a positive HIV test.	Link from testing site to treatment site (ideally same service/ site). Facility-based or Community-based ART initiation.	The healthcare worker performing the HIV test links to treatment.	• Physical escort where appropriate • If in the community and/or where ART services are not provided on site: Make an appointment and use the referral form • On-site same-day TB testing and ART initiation unless excluded by clinician • Provide condoms, lubricants, and refer to SRH or other appropriate services • The person referring should follow up in 7-14 days to ensure they have been linked to treatment services (see detailed section below)
Link to prevention services with a focus on individuals who will benefit substantially	Offer linkage on the same day as a negative HIV test.	Link from testing site to appropriate prevention services site (ideally same service/site). Facility-based or community-based HIV prevention services.	The healthcare provider performing the HIV test links to the appropriate prevention service.	• Physical escort were appropriate • Use a referral form in the community and where services are not provided on site • Where possible provision of streamlined including same day, co-located appropriate HIV prevention service services (PEP, PrEP, VMMC, harm reduction services) and SRH services • Referrer should follow-up with the client in 7-14 days to ensure they have linked to appropriate prevention services

Interventions to improve linkage to care

The minimum package of interventions to be implemented in all health facilities to increase linkage to treatment services

Table 7: Interventions to improve linkage to care

For all clients diagnosed at a community/workplace site
• Provide quality **post-test counseling**, including offering disclosure support and explanation of streamlined services to reduce the burden of starting and continuing treatment. Providing an explanation of a) same day initiation on the scheduled appointment date and b) the treatment pathway ahead - longer ART refills and faster and/or easier collection locations within 4 months of starting treatment if adherent and clinically stable on ART. • Make an **active referral** for a specific time and date. An active referral is one in which the official referring the client makes an appointment for the client and provides a referral letter/form. • Inform clients about the follow-up support, tracing and retention in care system. • Ask the client's consent to **be followed-up** and discuss the best method by which the client would like to be contacted (by phones, SMS, WhatsApp or home visit) • **Obtain accurate contact** details for HIV diagnosed clients and document at the testing site. • Where feasible, the client may be accompanied to the appointment by a community health worker (CHW) or peer (peer navigation to ART initiation service) • **Schedule a follow-up** phone call, text message or visit at a time and date that is convenient to the client • Provide **the list** of names of clients and the date they are expected to come for their appointment to the referral service at the facility. • Systematically **monitor linkage** to ART initiation services through logbooks • **Identify clients who miss their appointments** by more than seven days of set appointment date. • **Trace clients** who have missed scheduled appointments, and re-link them to care • Provide **additional psychosocial support if needed** for clients who return to the facility after tracing. • All tracing and retention in care processes must be **documented**.
For adolescents, key populations, any client who has previously tested but failed to initiate ART, any client who seems reluctant to initiate ART during post-test counseling, and any client tested/initiated on ART as an inpatient
As above, with the following additional enhancements as appropriate • Peer navigation to ART initiation service • Weekly telephonic support and follow-up until ART has been initiated. • Where the client does not have a telephone or is not responding to telephonic follow-up, a home visit may be conducted.
For all clients diagnosed in a health facility:
Client accompaniment to ART initiation services and introduction to the service provider is preferred, where feasible.

3

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

3 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.

Table 8: 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 Vertical 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	

4 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	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 = overweight; ≥ 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 31*	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 sputum TB-NAAT]

- 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 TB-NAAT]

- 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 26*		
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 179*	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	Measure blood pressure (BP), and do 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	Measure blood pressure (BP), and do urine dipstix for proteinuria and glucose. At 1st ANC visit, if BMI ≥35 (or other risk factors present), screen for gestational diabetes mellitus (GDM) using an oral glucose tolerance test (OGTT). If negative, repeat between 24 & 28 weeks gestation.	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.** See also Annexure 17 and Box 11. **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 30*			

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 30*		
	To identify eligibility for cryptococcal antigen (CrAg) screening	A reflex CrAg test will be done automatically by the laboratory on all CD4 counts < 200 cells/µL		N/A
Creatinine and eGFR if TDF used	To assess renal insufficiency	See table titled *Assessing Renal Function on page 30*		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]
TB NAAT	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 < 200 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 < 200 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 37*	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

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

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 37.* 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 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 3 and 4	Discontinue if CD4 count > 200 cells/µL, regardless of clinical stage

TB preventive therapy (TPT)

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 NAAT 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	Pregnant women with Advanced HIV Disease (CD4 ≤ 200, or WHO stage 3 or 4)) 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

For further detail on switching existing stable clients on ART between regimens, see *Switching existing clients to optimised DTG-containing regimens on page 36*

Dolutegravir (DTG) overview

Class of ARV: Integrase Strand Transfer 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 *Antiretroviral Drug Dosing Chart for Children (2025) on page 173*

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 *Antiretroviral Drug Dosing Chart for Children (2025) on page 173* 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 35*

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 35*
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	Metformin initiation: • Initiate metformin at a low dose (500 mg or 1000 mg total daily dose), titrating up as needed. Do not exceed 2 g daily. DTG initiation: • If patient stabilised on metformin dose ≤ 2 g daily, retain metformin dose and monitor for side effects. • If patient stabilised on > 2 g daily, reduce dose of metformin to ≤ 2 g daily and monitor. Patients with renal impairment: • Close monitoring of renal function required. Metformin should be avoided if eGFR <30mL/min.

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 37*

First-line ART regimens in adults, adolescents, pregnant women, children, infants, and neonates

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 and Safe Conception in Women on page 139*

Preterm neonates < 2 kg[1]

2 kg

and ≥ 37 wks gestational age, to < 10 years of age

30 kg

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 *page 172* and ART for Preterm Neonates see *page 173*

Transition does not require a VL before switching

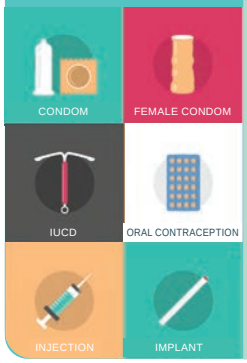
Transition does not require a VL before switching
Ensure adequate renal function[2]

1. For neonates with severe anaemia, obtain advice from an expert or through one of the *Helplines on page 37*
2. Before switching to TDF, ensure adequate renal function by checking eGFR/creatinine as outlined in table *Assessing Renal Function on page 30*

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 and ensure return date alignment (see method choice considerations on *Contraception and Safe Conception on page 130*).
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 (2MMD) of her ART regimen at discharge from labour ward (see VTP guideline *Labour and Delivery on page 134* and 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 long-acting options (implants or intra-uterine contraceptive devices), short-acting options (healthcare worker administered injectables [DMPA-IM or NET-EN IM], self-injectables [DMPA-SC] or oral contraceptives and condoms). 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 *Switching Existing Clients to DTG-containing Regimens in Women on page 139*.
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, by the same provider, for the same refill length.

3. NDoH NEMLC PHC-Adult Medicine review DTG in Pregnancy 17June 2021

Re-initiating ART in non-pregnant clients who have interrupted treatment

Person returning to care after missed scheduled appointment date

- Missed appointment **≤ 28 days** AND self-identifies as well, and not on TB treatment
- Missed appointment > 28 days OR self-identifies as unwell/on TB treatment (with missed appointment of any duration)

Routine care
Presents at:

- RPCs model (EX-PUP, FAC-PUP, Club) → Continue care in RPCs
- Facility → Continue routine care. Assess, offer and enrol in RPCs, if eligible

Re-engagement

Perform clinical assessment + decide if enhanced adherence counselling (EAC) could assist*

EAC session 1 *(see Annexure 3)*

- Presents clinically well
  - Missed appointment 29 - 90 days → Continue ART. Assess for, offer, and enrol/re-enrol in RPCs
  - Missed appointment > 90 days (LTF)
- Presents clinically unwell, or **with a prior VL ≥ 50c/mL before** treatment interruption, or has TB/HIV co-infection
  - Follow the HIV/ART and TB clinical guidelines as relevant

Unless there is a clinical indication to defer ART, restart ART on the same day (switch to TLD**, as outlined on *Switching existing clients to optimised DTG-containing regimens on page 36*
Do a CD4 count to identify AHD

3-month drug refill

Clinical consult frequency as clinically indicated
Align drug refill length

Recall if CD4 ≤ 200 → If CD4 < 200: Provide AHD package

Perform VL monitoring as per *Routine HIV VL Monitoring on ART on page 42* ***

VL assessment **3 months after re-engagement**
If VL suppressed, offer/re-enrol in RPCs

* **Clinician considerations for providing EAC session 1:**
1. Drug side effects impacting adherence? If yes and drug/s switched →no need for EAC
2. Difficulty getting to facility to collect treatment → no need for EAC
3. Challenges with taking/remembering to take treatment → provide EAC (see EAC SOP 2)

** 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)

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

Detailed re-engagement job aid available at:

https://knowledgehub.health.gov.za/elibrary/implementation-streamlined-re-engagement-hiv-treatment-and-care-dmoc-sop-job-aids.

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 26*
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.

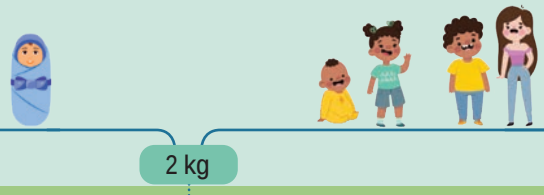
Clients who are already on ART when TB treatment is initiated

- 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 *Visit Schedule for Integrated Care for Clients on ART and Drug-Sensitive TB Treatment on page 48*

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:



	2 kg	30 kg	
ART Regimen	Preterm Neonates AZT + 3TC + NVP	Term Infants and Children ABC + 3TC + DTG	Adolescents and Adults TDF + 3TC + DTG
Significant drug interaction	! Rifampicin + NVP	! Rifampicin + DTG	
Measures to counteract drug interactions with rifampicin	Seek expert advice	Boosting of DTG required 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 *Antiretroviral Drug Dosing Chart for Children (2022) on page 173*	
	Continue boosting the ART regimen until 2 weeks after stopping rifampicin		

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 *Antiretroviral Drug Dosing Chart for Children (2022) on page 173*. 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 37*.

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 *Antiretroviral Drug Dosing Chart for Children (2025) on page 173*. 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 optimised DTG-containing regimens

Switching existing clients to optimised DTG-containing regimens for 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 35*

!

Switching clients in an RPCs model

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 < 1000 c/mL in the last 12 months.

- For clients with a VL <50 c/mL no additional facility visits are required (see DMOC SOP 6).
- For clients with a VL between 50-1000 c/mL:
  - Do an ABCDE assessment and provide enhanced adherence counselling (EAC) if indicated.
  - Schedule an appointment in 3 months time for a repeat VL.
  - If clinically well, they can remain in their RPCs model until the results of the repeat VL can be reviewed.
  - If their VL returns to <50 c/mL they can continue in their RPCs.
  - If their VL returns to 50-1000 c/mL, continue in RPCs, but reassess adherence and the causes of an elevated VL. Intensify efforts to resolve adherence. Repeat VL at the time for the next scheduled clinical review/rescript date. (i.e., in 6 months' time, or at delivery if pregnant).
- If the clients has a VL ≥1000 c/mL at any stage, return to regular care and manage as per the *VL Non-Suppression Algorithm on page 144*.
- If clinically non-stable with possible signs or symptoms of clinical failure, e.g. if the client is acutely unwell, or develops a new OI such as TB, the client should be returned to regular care to ensure appropriate clinical management and more frequent clinical follow-up until they are stable again.

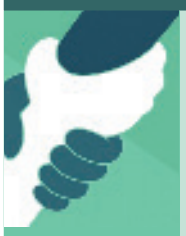
1. If clients are not eligible to use TDF and they had an ABC hypersensitivity reaction, use AZT/3TC/DTG

Switching existing clients to DTG-containing regimens for adults, adolescents or children who have never used a DTG-containing regimen in the past

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			
VL considerations	Current Regimen	Criteria for switch	Regimen if change indicated
VL < 1000 c/mL	Any LPV/r or ATV/r regimen for more than 2 years	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 *VL Monitoring for Clients on TLD or ALD on page 43*	TLD provided no renal dysfunction and age ≥ 10 yrs and weight ≥ 30 kg If clients does not qualify for TDF ABC[1]/3TC/DTG
[2] Two or more consecutive **VLs ≥ 1000 c/mL** taken two or more years after starting PI regimen	Adult or adolescent on any LPV/r or ATV/r regimen and self reported poor adherence	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 *VL Monitoring for Clients on TLD or ALD on page 43*	TLD provided no renal dysfunction and age ≥ 10 yrs and weight ≥ 30 kg If clients does not qualify for TDF ABC[1]/3TC/DTG
	Adult or adolescent on any LPV/r or ATV/r regimen with two adherence assessments[3] and interventions	Clients who meet the definition of confirmed virological failure may need a resistance test. These clients do not qualify for a same-day switch. Discuss with a medical officer experienced in HIV management or a helpline expert who may advise requesting an HIV drug resistance test at the same time as their next scheduled VL. If so, take 2 blood specimens and request both a VL and a drug resistance test. Discuss with an HIV expert to interpret the resistance test. If necessary, provide an individualised regimen as recommended by ADReC committee. Repeat VL 3 months after the regimen change to confirm re-suppression.	
	Child < 10 years, or weight < 30 kg on any LPV/r or ATV/r regimen	These clients do not yet qualify for TLD and may require a resistance test. For advice, approach a HIV Helpline, an infectious disease specialist, or the ARV Drug Resistance committee	

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 consecutive VLs ≥ 1000 c/mL taken two or more years after starting a PI containing regimen, despite two adherence assessments and interventions. 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. Note: Self-reported adherence is not considered a reliable measure of good adherence! For advice from an HIV expert, approach an HIV Hotline, an infectious disease specialist, or the ARV Drug Resistance committee (ADReC)

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

KZN Paediatric Hotline:
0800 006 603

Definitions of first, second and third-line dolutegravir-containing regimens

	Previous ART exposure	Regimen
First-line DTG-containing regimens	• ART-naïve patients who initiated ART on a DTG-containing regimen • Patients who were switched to DTG from a first-line non-DTG-based regimen (e.g., TEE) with a VL < 50 c/mL in the last 12 months	Tenofovir/lamivudine/dolutegravir [TLD 1] Abacavir/lamivudine/dolutegravir [ALD 1]
Second-line DTG-containing regimens	• Patients who were switched to DTG from a first-line ART regimen (NNRTI or PI-based) with a VL ≥ 50 c/mL • Patients who were switched to DTG from a second-line PI-based ART regimen with a VL < 50 c/mL in the last 12 months • Patients who were switched to DTG from a PI-based regimen with a VL ≥ 50 c/mL without a genotypic resistance test	Tenofovir/lamivudine/dolutegravir [TLD 2] Abacavir/lamivudine/dolutegravir [ALD 2]
Third-line DTG-containing regimens	• Patient was switched to a third-line DTG-based regimen based on the results of a genotypic resistance test showing resistance mutations to PI in a previous second-line regimen	Individualised DTG-based regimen
If clients are not eligible to use TDF and they had an ABC hypersensitivity reaction, use AZT/3TC/DTG		

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. At their viral load result review visit a month later, 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 new or uncontrolled chronic or mental health conditions that require clinical review more frequently than 6-monthly, and 4) not being pregnant or delivered in last 12 months.

The diagram *Visit Schedule for Adults, Adolescents and Children 5 Years and Older on ART on page 39* 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 or TB diagnosis. 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 arrives from a different facility, they must be provided with a full supply of treatment on the day of presentation to prevent further interruption and protect viral suppression. Ask the client if they are attending for a once-off visit, or if they plan to transfer in to this facility for their ongoing care.

While referral letters are helpful, a patient must not be required to leave the facility without treatment to obtain one. They should be transferred-in without being short-supplied or sent to collect a transfer letter, which may be unaffordable or create unnecessary barriers to continuity of care. Educate the patient that they should request a transfer letter if they need to transfer out to another facility in the future.

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 *Routine HIV VL Monitoring on ART on page 42* • Integrated services for family planning# and NCDs+ • 2 months ART dispensed (2MMD) - DMOC SOP 4
3	3-month* VL (VL after 3 DCs) sCR and eGFR	• Clinical assessment including VL and any other routine monitoring bloods as outlined on *Routine HIV VL Monitoring on ART on page 42* • 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):
		  • VL < 50 c/mL
		  • Clinically well
		  • No OIs (incl TB) or new/uncontrolled chronic/mental health condition or malnutrition
		  • Not pregnant or delivered in last 12 months

		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 3MMD (DMOC SOP 4.1)
7		• Collect medication from preferred RPCs
10	10-month* VL (VL after 10 DCs) sCR and eGFR CD4 count	• Clinical assessment including VL and any other monitoring bloods as per *Monitoring on ART on page 41* • 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 41* • 12-monthly routine monitoring of VL, sCR and eGFR • Check that chosen RPCs option is still suitable, and consider if eligible for facility-provided 6MMD as per page 40. • 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 34*)
- 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 and VL ≥ 1000 c/mL, 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 facility-provided 3MMD (DMOC SOP 4.1)
- 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)

* 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 (28 or 30 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.

\# See page 40 on how to align contraceptive method choice with ART refills and appropriate script and refill length for oral and self-injectable contraception.

\+ Clients with controlled hypertension and/or diabetes should be scripted for their treatment through the same RPCs model on the same script (see further detail on eligibility and alignment in DMOC SOP 5).

6MMD

Facility-provided 6MMD is now operational.
See DMOC SOP 4.2: Facility-provided 6MMD

Eligibility criteria:

- On ART* for at least 12 months
- 2 most recent VLs < 50 c/mL
- Other RPCs eligibility criteria also met (not pregnant or post-natal < 12 months, above 5 years of age, clinically well with no OIs/ uncontrolled NCD or mental health condition or malnutrition).

* Limited to clients only on TLD until national medicine stock availability is confirmed for other ART regimens and hypertension and diabetic treatment

At any scheduled clinical review, check that the chosen RPCs model is still suitable. If eligible, offer client facility-provided 6MMD as an alternative option to RPCs

Should a client accept 6MMD, renew prescription for next 6 months, with full 6-months supply issued today from the facility.

Consider supplying 2 x 84-90 day pill bottles (now available) rather than 6 x 28-30 day pill bottles to reduce the number of containers.

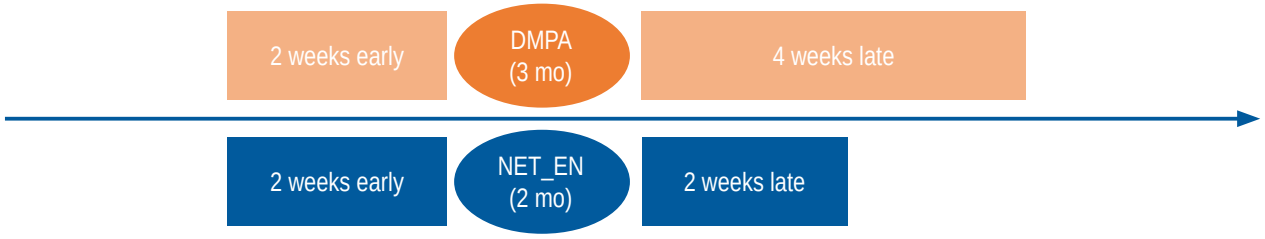
Integrating ART and contraceptive services

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 be scripted and dispensed for 3 or 6 months to align with ART refill length, aligns well with ART and well-baby visit schedules (if applicable), and can be scripted through her preferred RPCs or with facility-provided 6MMD.
- The new DMPA-SC* 3-monthly injection can be dispensed for self-injection at home and enables the provision of 2 units with the first dispense from a 6-month script removing increased visit frequency or alignment concerns.
- The DMPA-IM 3-monthly injection must be administered by a clinician but aligns with ART and well-baby visit schedules
- The NET-EN-IM 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-IM or NET-EN-IM), a facility-based pick-up point (FAC-PUP) or facility-based adherence club may be the preferred option provided visit alignment can be ensured.
- The repeat injection of DMPA (SC and IM) and NET-EN (IM) can be given up to 2 weeks early.
- The repeat NET-EN injection can be given up to 2 weeks late without requiring additional contraceptive protection Remember that:
- The repeat DMPA injection can be given up to 4 weeks late without requiring additional contraceptive protection.

* sub-cutaneous DMPA available in public sector facilities in October 2026. For more information see www.depo2go.co.za

See also *Visit Schedule for Integrated Care for the Mother living with HIV and her HIV-exposed Infant on page 162* and *Visit Schedule for Integrated Care for the Mother-baby Pair Living with HIV on page 46*



Every effort should be made to script contraception and NCD treatment on the same prescription and for the same refill length as ART through the same service delivery model (see DMOC SOP 4 and 5).

6 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 145*

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 27*

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 or ALD on page 43*

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 on ART (aligned with VL).

Thereafter, stop CD4 monitoring unless:
- CD4 still ≤ 200 cells/mm^3: repeat every 6 months until CD4 > 200 cells/mm^3
- 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 re-engaging clients as per the *Re-engagement Algorithm on page 34*)

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 30*

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

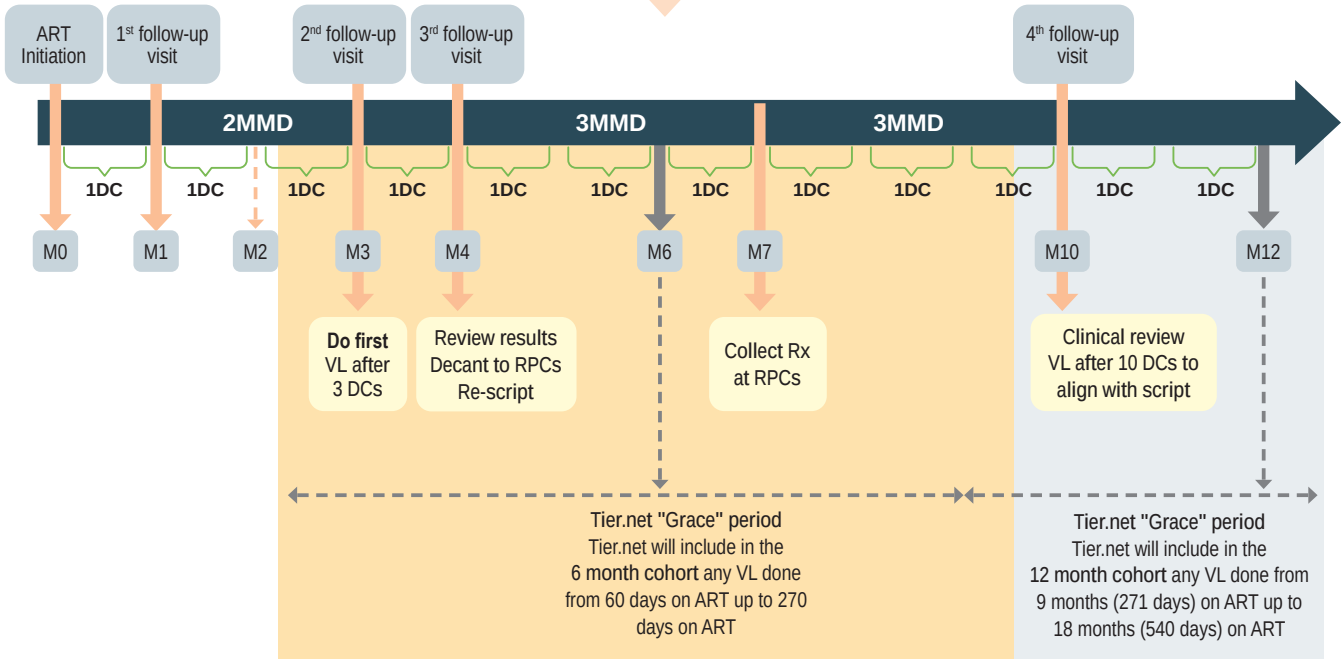
For more information on the package of care for AHD and the management of specific OIs, please refer to *Section 4 - Advanced HIV Disease on page 51*

! 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 28-30 tablets (1DC) or larger pack sizes of 84-90 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 were previously virally suppressed)	This VL can be done from 10 completed 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 • Allows for 6MMD assessment which requires 2 consecutive VLs <50 c/mL and 12 months on ART
Third routine VL after ART initiation (in clients who were previously 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 and management algorithm for clients on TLD or ALD

Routine VL monitoring for virally suppressed clients as outlined in the algorithm *Routine HIV VL Monitoring on ART on page 42.* 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 as per the *Assessing an Elevated Viral Load on page 44*
- Remember to screen for **mental health disorders** e.g., depression or anxiety (*Mental Health Assessment on page 179*)
- **Switch to TLD** if indicated (See *Switching existing clients to optimised DTG-containing regimens on page 36*)
- If breastfeeding, start, re-start, or extend **high-risk infant prophylaxis** (see *Prophylaxis for the HIV-Exposed Infant During Breastfeeding on page 149*), and intensify breastfeeding support.
- Recommend **condom use and contraception** as appropriate, and partner testing.

Implement interventions to re-suppress the VL, including **Enhanced Adherence Support** if indicated (See *Enhanced Adherence Counselling on page 185*)

VL < 50 c/mL

Repeat VL after 3 months (or after 4-6 weeks if pregnant or breastfeeding)

Repeat VL unsuppressed **≥ 50 c/ml)**

Repeat the 'ABCDE' assessment to identify the causes of an elevated VL.[1] Intensify efforts to **resolve adherence.**[2]

Re-assess adherence

Intensify efforts to **resolve adherence issues.**[2]

Re-assess at the time for the next scheduled routine VL (i.e., in 6 months' time, or at delivery if pregnant)

TLD1/ALD1 **without special circumstances**[3]

If on a 2nd **or** 3rd **line** DTG-containing regimen **for at least 9 months** or on TLD1/ALD1 with special circumstances,[3] discuss with a medical officer experienced in HIV management or a helpline expert who may advise requesting an **HIV drug resistance test** at the same time as their scheduled VL. If so, take **2 blood specimens** and request **both** of the following:

1. VL - use a plasma EDTA tube (purple top, or white top with gel)
2. Drug resistance test - use a plasma EDTA tube (purple top, or white top with gel)

VL ≥ 50 c/mL,

and no detectable DTG DLs (if available), provide DRT- informed adherence counseling

If VL < 50 c/mL (No further resistance testing will be done)

VL ≥ 1000 c/mL, and DTG is detected on drug-level testing (if available), the laboratory will proceed to do an HIV drug-resistance test

Discuss with an **HIV expert** to interpret the resistance test.
Provide an **individualised regimen** as recommended by ADReC committee.

Repeat VL 3 months after starting the new regimen to confirm viral re-suppression

ADReC, ARV Drug Resistance Committee (previously TLART Committee); ALD, combination ART regimen consisting of abacavir, lamivudine, DTG; DL, drug level; ART, Antiretroviral therapy; DRT, drug-resistance test; DTG, Dolutegravir; LLV, Low-level viraemia; SOP, Standard operating procedure; TL, Third-line; TLD, fixed-dose combination of tenofovir, lamivudine, DTG; VL, Viral load.

Footnotes to VL monitoring algorithm

1. Repeat ABCDE assessment as outlined below. Remember to ask about treatment side-effects, the potential cost of transport or loss of income related to clinic visits, mental health symptoms, non-disclosure, gender-based violence (GBV), and current or prior drug interactions. Provide EAC if indicated.
2. 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, **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.
3. Special circumstances

- TLD1 patients with persistent virological failure despite good adherence may be discussed with an expert to consider a resistance test on a case-by-case basis:
- Patients with AHD and on a DTG-containing regimen for at least 9 months.
- Current or previous drug interactions with rifampicin, carbamazepine, phenytoin, phenobarbital, or the polyvalent cations that may have resulted in the development of resistance.
- Incorrect classification as TLD1 after prior ART exposure and failing an ART regimen in the past
- Perinatally infected adolescents (perinatally infected adolescents should be classified as TLD2 due to the high likelihood of ART exposure and virological failure in the past).

Additional considerations if VL > 1000 c/mL

- Monitor CD4 count every 6 months see *Monitoring on ART on page 41*
- If CD4 < 200 cells/mm^3, discuss with an HIV expert
- Consider eligibility for cotrimoxazole prophylaxis see *Indications for Starting and Stopping Cotrimoxazole Preventive Therapy on page 30*

Assessing and managing 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 NAAT.
Correct Dose	C	Is the client on the correct dose for their weight? Is the client taking the dose as prescribed? 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 35* If in any doubt, call the HIV Hotline 0800 212 506 or one of the *Helplines on page 37*
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 on the previous page

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 facility-provided 6MMD (if eligible) or providing 3-monthly dispensing (3MMD)	No need for EAC
Drug side effects or unpalatability impacting adherence?	Change to more palatable regimen	No need for EAC
Existing mental health disorders	Complete mental health assessment if not yet done and ensure mental health support/referral provided - see page 177	Consider whether addition of EAC helpful
Challenges with taking/remembering to take treatment	Provide EAC	

Enhanced adherence support

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

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

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

To support the above processes, the following useful tools extracted from the Differentiated Care Models Standard Operating Procedures 2025 included in the annexures:

- SOP 2 Enhanced Adherence Counselling (*page 185*)
- Mental Health Screen (*page 179*)
- Child and adolescent disclosure counseling for children living with HIV (*page 186*)

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 at the same facility
3. Wherever possible, allow the mother and baby to receive ART during the same consultation

Age group	Age of child	Routine visits as per RTHB	Dispensing cycle (DC)	ART Follow-up for baby	ART and Contraception 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 (2MMD) provided at discharge from labour ward which will last mother until 6 week PN visit. Confirm the mother's contraceptive method choice **		x	x						x	x**
	4 weeks			Clinical review and renew script for ABC/3TC/DTG as per paediatric dosing chart. 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 ART for 3 DCs (3MMD) for mother	x	x	x						x	
	10 weeks	10 weeks	3	Clinical review Repeat script for 1DC for baby	If mother received either DMPA-IM (Depo Provera®) or NET-EN (Nur Isterate®) after delivery, give repeat injection at this visit*** If on COCP give 3MMD today	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 ART 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 with EGK code Provide breastfeeding support. Script for and provide treatment for 3DCs at a time (3MMD). Review results of VL and PCR in 1 week using NHLS RfA reports. If VL ≥ 50c/mL recall and manage mother as per the VL Non-Suppression Algorithm on page 141	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. Advise her on the implications of her choice on visit alignment, and amend if necessary as per *Integrating ART and Contraceptive Services on page 40*.

*** 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				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 and contraceptive method review and VL Provide breastfeeding support Assess eligibility and offer RPCs options/facility-provided 6MMD. If ineligible, continue 3MMD.	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 3 DCs at a time (3MMD), unless already on 6MMD or in RPCs 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 6 DCs (facility 6MMD) or offer RPCs options/ rescript for RPCs. If ineligible, continue 3MMD. 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 3 DCs at a time (3MMD), unless already on 6MMD or in RPCs Provide breastfeeding support.		x	x						x	x
	92 -104 weeks		23-26												
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 ART for 3 or 6 DCs at a time (3MMD or 6MMD/RPCs). COCP and DMPA-SC self-injectable units should be prescribed for 6-months with 3-6MMD COCP or 2 units of DMPA-SC dispensed on date of script. 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	3-6 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 NAAT 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

1.

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.

Visit schedule for integrated care for clients already on ART when diagnosed with drug-sensitive TB

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 NAAT 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

1.

* 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.

4

Advanced HIV Disease

A Clinical and Service Delivery Guideline

1 Introduction

As a result of improved access to antiretroviral treatment (ART), the burden of morbidity and mortality associated with Human Immunodeficiency Virus (HIV) infection has decreased over the past decade. However, around one in five persons living with HIV (PLHIV) in South Africa present to care with Advanced HIV Disease (AHD), and a growing number of PLHIV are returning to care with advanced disease following a period of treatment interruption. Persons with AHD are particularly at a higher risk of death, even after initiating ART, with this risk increasing with decreasing CD4 cell count. The most common causes of death are tuberculosis (TB), cryptococcal meningitis (CM), and severe bacterial infections (SBIs).

Definitions

Advanced HIV Disease

- For adults, adolescents, and children aged five years and older, advanced HIV disease (AHD) is defined as
    - a CD4 cell count ≤200 cells /μL or
    - a WHO clinical stage 3 or 4 event
- All children living with HIV younger than five years should be considered as having AHD (regardless of CD4 % or clinical stage) unless they have been receiving ART for longer than one year and are clinically stable on ART[1]

Advanced Clinical Care

The comprehensive management, care and treatment support provided to patients with complex HIV-associated conditions, including AHD and tuberculosis (TB) and other comorbidities (e.g., hepatitis and non-communicable diseases (NCDs).

A seriously ill patient is one with:

- one or more clinical danger signs, or
- a clinical condition severe enough to require immediate hospitalisation for stabilisation or inpatient care

An unstable patient on ART is one who:

- has signs or symptoms of illness or clinical failure, including any opportunistic infections (including TB), malnutrition, or a new or uncontrolled mental health or chronic condition
- has missed a scheduled appointment by more than 28 days, or
- has poor adherence, or
- has an elevated VL ≥ 50c/mL in the last 12 months

A stable patient is defined as follows:

- Most recent VL < 50 c/mL
- Clinically well
- No OIs, including TB
- No uncontrolled NCD, mental health condition or malnutrition
- Not pregnant or post natal <12 months
- Over 5 years of age

Systematic TB Screening

Systematic TB screening intensifies the detection of TB in persons at risk for TB disease. Populations or high-risk groups are assessed not only for symptoms but also using tests, examinations, or other procedures, such as TB nucleic acid amplification test (TB-NAAT), chest X-rays, etc., regardless of whether TB symptoms are present.

Significant TB Exposure

Within the last 12-month period before the patient presents with presumed TB, exposure to a person (adult or adolescent) with pulmonary TB within the same enclosed space for one or more nights (e.g. at home or similar) or for frequent or extended daytime periods (e.g. at a school, crèche or similar) during the three months before the source/index patient started TB treatment.

TB Infection

A state of persistent immune response to stimulation by *Mycobacterium tuberculosis (M.tb)* antigens with no evidence of clinically manifest TB disease is referred to as "TB infection," distinct from "TB disease." Most infected persons have no signs or symptoms of TB but are at risk for TB disease. The term "latent TB infection" has been replaced by the term "TB infection."

[1] *Adapted from: Identifying common opportunistic infections among persons with advanced HIV disease: policy brief. Geneva: WHO; 2023*

TB Disease

Disease caused by M.tb infection. TB disease can either be bacteriologically confirmed or clinically diagnosed.

Presumptive TB

A patient is believed to have presumptive TB when TB is considered a possible cause of illness in those who present with symptoms or signs suggestive of TB.

Clinical diagnosis of TB

A diagnosis made on the grounds of history, clinical findings, radiological features, U-LAM, exposure history, growth trend, or a combination of the above, and where bacteriological tests were either not performed or the results were negative.

Bacteriologically confirmed TB

The diagnosis of TB disease can be confirmed bacteriologically using one of the following tests: genotypic testing, i.e. TB-NAAT, mycobacterial culture, and/or smear microscopy for acid-fast bacilli (AFB).

Pulmonary Tuberculosis

Pulmonary tuberculosis (PTB) refers to TB involving the lung tissue, airways or draining lymph nodes (indicated by mediastinal and/or hilar lymph node enlargement on CXR). PTB is either clinically diagnosed or bacteriologically confirmed.

Extrapulmonary TB (EPTB)

Any bacteriologically confirmed or clinically diagnosed patient with TB involving organs other than the lungs, airways and intrathoracic lymph nodes.

Drug-susceptible (DS) TB

M.tb strains that are susceptible to the first-line agents rifampicin and isoniazid.

Drug-resistant (DR) TB

M.tb strains that are resistant to first-line anti-TB drugs.

Cryptococcal antigenaemia.

All patients with a positive serum cryptococcal antigen (CrAg) are considered to have disseminated cryptococcal disease and will require treatment. A lumbar puncture (LP) and cerebrospinal fluid (CSF) CrAg are required to determine if the extent of the disease dissemination includes the meninges (cryptococcal meningitis), which carries a high mortality rate and requires more intensive hospital treatment. If the CSF CrAg is negative, disseminated cryptococcal disease is diagnosed without cryptococcal meningitis. It commonly involves the lungs or skin.

Cryptococcal meningitis

Cryptococcal meningitis (CM) refers to disseminated cryptococcal disease with meningeal involvement. This will be determined by a positive CrAg test in both serum and CSF. Note that the CrAg remains positive in serum and CSF for months after an episode of cryptococcal meningitis - therefore, a relapse of meningitis cannot be diagnosed using CrAg alone; CSF culture is necessary.

Box 1: **The definition of Advanced HIV Disease (AHD)**

- For adults, adolescents, and children older than five years, advanced HIV disease is defined as
  - ➙a CD4 cell count ≤ 200 cells/μL or
  - ➙a WHO clinical stage 3 or 4 condition
- All children living with HIV younger than five years should be considered as having advanced HIV disease (regardless of CD4% or clinical stage) unless they have been receiving ART for longer than one year and are clinically stable on ART

Source: Adapted from: Identifying common opportunistic infections among persons with advanced HIV disease: policy brief. Geneva: WHO; 2023

Providing appropriate care for AHD at the appropriate level

Throughout the 9 steps to identifying and managing a patient with AHD outlined in *Figure 8*, a patient may need to move between primary health care (PHC) and hospital levels, either for additional investigations, or for admission/re-admission and inpatient treatment, or for ongoing care at clinic level once discharged from the hospital. This cycle is illustrated in Figure 7 below.

Smooth transitions between levels of care are essential to ensure that:

- Unwell patients get appropriate care at the correct level as rapidly as possible
- Clients are not lost from care during the transition process
- Clients get the ongoing care they require for their chronic conditions, whether at PHC or hospital level OPD (outpatient department).

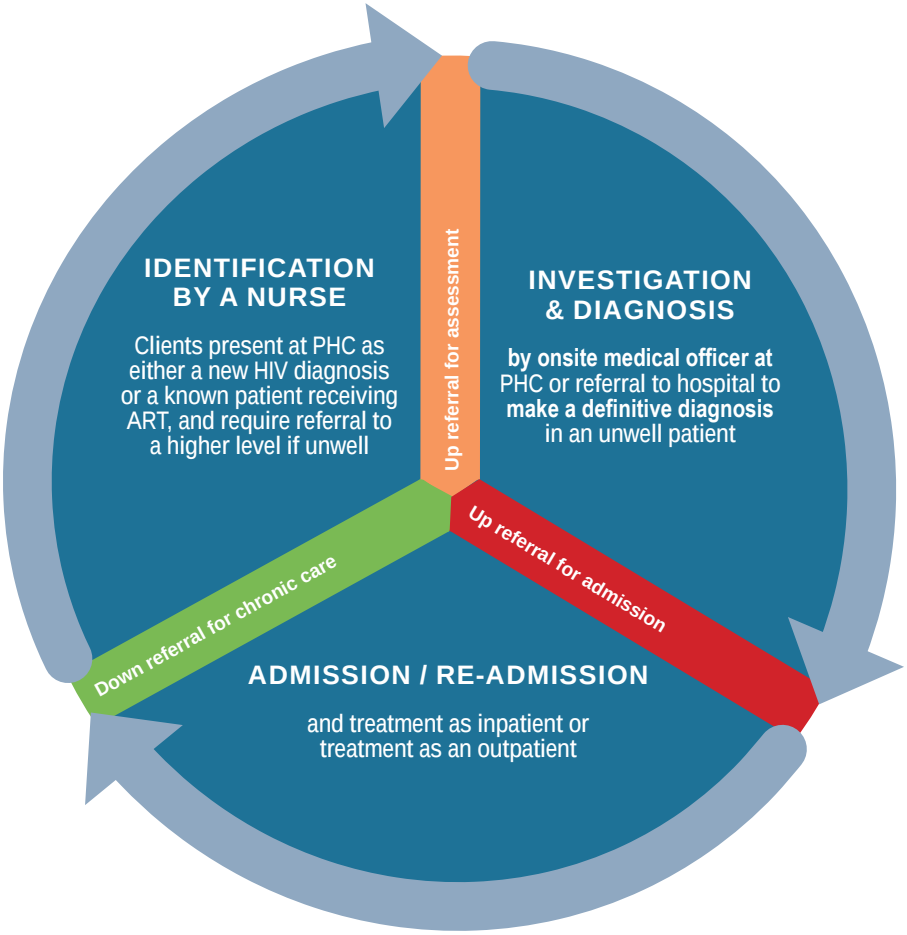


Figure 6: Continuity of care cycle for patients with AHD

Patients with AHD can be broadly grouped into three categories, as per the table below:

Table 9: Broad clinical categories for a patient with AHD

Patient category	Potential risks	Actions
Severely ill with danger signs	Inappropriate pre-referral management or delays in referral to the appropriate level of care may increase mortality.	Assessing a patient should always start with a triage assessment to identify any danger signs to determine if the patient requires immediate referral to hospital. Stabilise and refer to/admit for inpatient care as indicated, detailed in Step 1
Unwell/unstable but not sick enough to warrant immediate referral to hospital	More complex conditions may be missed, or there may be delays in referrals for hospital-level investigations.	If any uncertainty exists, the threshold for a nurse to refer a patient to a higher level of care should be low.
Appearance of being clinically well or asymptomatic	Clients with CD4 counts < 200 may initially appear well but may rapidly deteriorate and remain at a higher risk for death. Such patients are at risk of receiving a less intensive clinical assessment when their CD4 count is taken.	In all patients at risk of AHD, the earliest opportunity to screen for, treat or prevent serious opportunistic infections should be fully utilised to minimise the risk of rapid deterioration and death

- The differential diagnosis of an unwell client living with HIV could include one or more of the following:
    - Opportunistic infections (e.g., TB)
    - Non-infectious HIV-related conditions associated with impaired immune function (e.g., HIV-associated nephropathy [HIVAN])
    - Other infections that share similar transmission routes, e.g. hepatitis B (HBV), hepatitis C (HCV) or congenital syphilis
    - Malnutrition
    - Immune reconstitution inflammatory syndrome (IRIS)
    - Adverse drug reactions such as drug-induced liver injury (DILI)
    - Non-HIV-related, non-communicable diseases (NCDs) such as hypertension, diabetes, or other malignancies

In general, clinicians should follow the Adult Primary Care (APC), Integrated Management of Childhood Illnesses (IMCI), and Essential Medicines List (EML) guidelines that outline elements of care within their scope of practice. However, patients with AHD are often very unwell with multiple and complex conditions. If any uncertainty exists, the threshold for a nurse to refer a patient to a higher level of care should be low. Figure 2 outlines the nine steps for managing a client with AHD. Table 2 outlines the roles and responsibilities of different members of the care team for each step.

3 Overview of the 9 steps to identifying and managing a patient with AHD

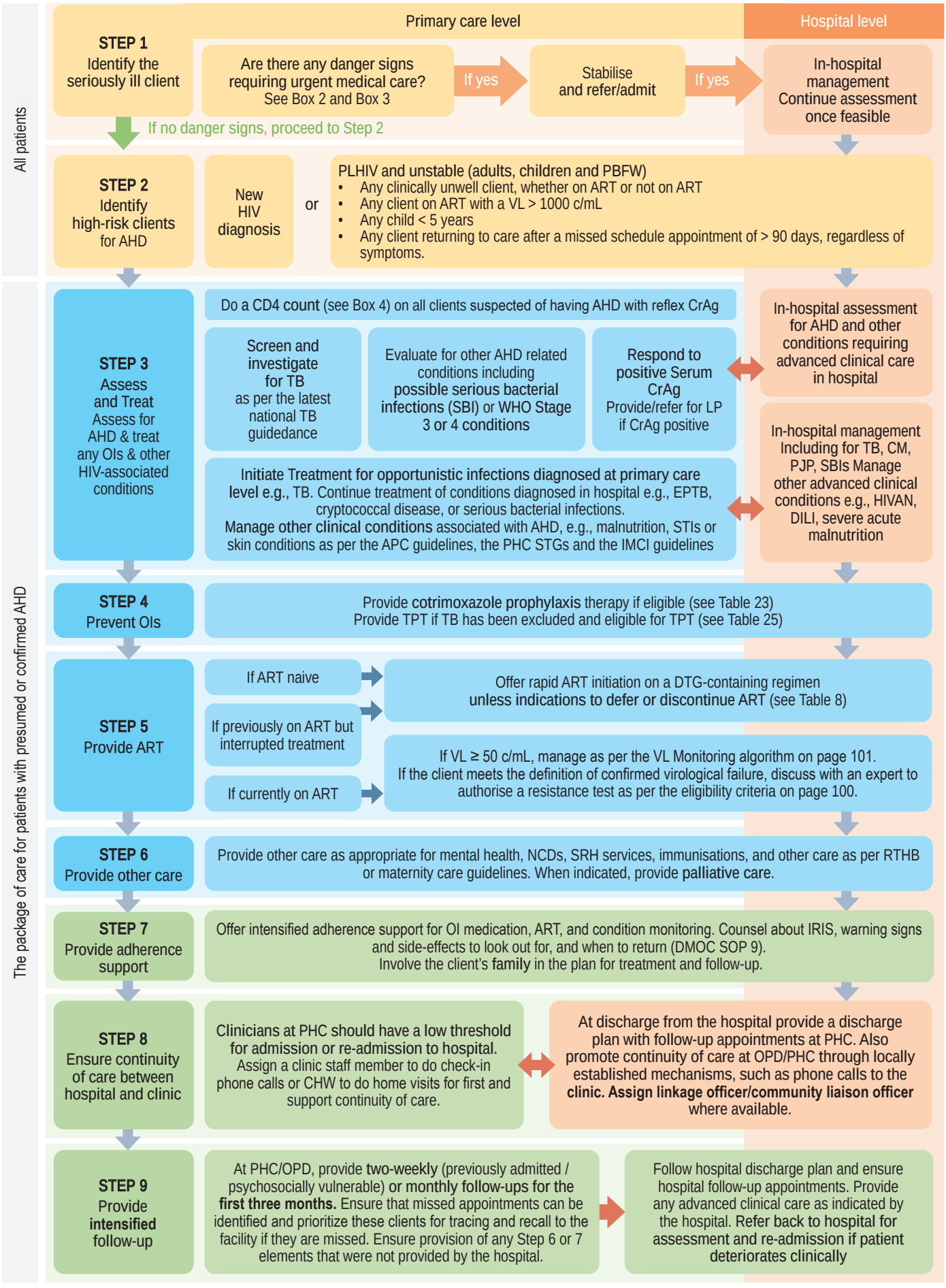


Figure 7: Overview of the approach to identifying and managing a patient with AHD

4 Roles and responsibilities

An important aspect of ensuring prompt identification, screening, and management of AHD is a clear understanding amongst the HIV care team of the roles and responsibilities in delivering the AHD package and where the package's elements are provided.

Table 10: The "who" and "where" of investigating and managing a patient with AHD

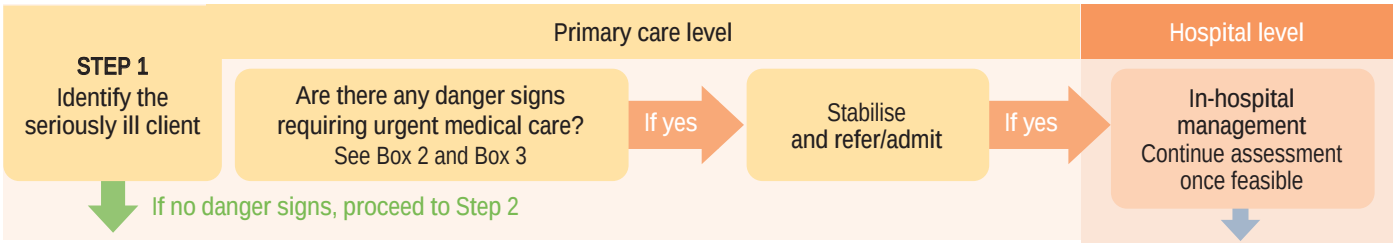
Element of care	Nurse Clinician at PHC	Medical Officer at PHC level	Medical Officer at Hospital Level	
Identification & management of danger signs	✓ Where/when within the scope of practice of a nurse clinician (as per APC and IMCI guidelines). Referral to a higher level of care	✓	✓	Step 1
Identify clients at risk of AHD	✓	✓	✓	Step 2
CD4 count	✓	✓	✓	Step 3
History and clinical examination	✓ Where/when within the scope of practice of a nurse	✓	✓	Step 3
Systematic TB screening, incl. CXRs	✓ Request CXR	✓ Interpret CXR	✓	Step 3
Screening and investigation for CM	A reflex CrAg will be done on CD4 count. Nurse clinicians should identify and respond to abnormal results. If CrAg positive, refer for LP	Do LP and relevant CSF investigations (where feasible)	Do LP and relevant CSF investigations or neuroimaging if LP contraindicated	Step 3
Recall clients with CD4 ≤200 or other abnormal results (CrAg pos, TB-NAAT/culture pos)	✓	✓	✓	Step 2
TB diagnosis	✓ If uncomplicated, bacteriologically confirmed TB. Nurse clinician should refer for further investigations if TB is suspected, but the diagnosis is unclear	✓ Bacteriologically or clinically diagnosed TB	✓ Bacteriologically or clinically diagnosed TB	Step 3
Initiate TB treatment	✓	✓	✓	Step 3
Make a diagnosis of CM or cryptococcal antigenemia and initiate treatment		✓ Initiate outpatient treatment for cryptococcal antigenaemia without CM	✓ Initiate inpatient treatment for CM	Step 3
Diagnosis and management of severe bacterial infections	Nurses clinician should identify unwell patients requiring referral for further assessment and possible admission	✓ Assessment and management as outpatients	✓ Assessment and management as inpatients	Step 3
CPT	✓	✓	✓	Step 4
Initiate TPT	✓	✓	✓	Step 4
ART initiation / re-initiation	✓	✓	✓	Step 5
Provide other care	✓	✓	✓	Step 6

Element of care	Nurse Clinician at PHC	Medical Officer at PHC level	Medical Officer at Hospital Level	
Counsel on adherence to OI medication and ART and identification of warning signs that may require the patient to return to the clinic/hospital urgently.	✓	✓	✓	Step 7
Involve the client's family or another supporter in their follow-up plan. The supporter should be able to monitor for warning signs and know when to respond with urgency.	✓	✓	✓	Step 7
	Check if the doctor did this at hospital level. If not, contact family			
Write a quality comprehensive discharge plan, including hospital follow-up appointments.			✓	Step 8
Determine the frequency of follow-up visits needed for the first 3 months. Follow hospital discharge plan and ensure hospital follow-up appointments are adhered to.	✓	✓		Step 9
Identify missed appointments by clients with AHD.	✓ With support from data capturer			Step 9
Prioritise tracing and recall for clients with AHD.	✓ With support from counsellors, linkage officers and the WBOT team	✓		Step 9

In South Africa, there is a large burden of undiagnosed TB in children of all ages, especially children under five years of age. Difficulties around sample collection from younger children at the primary care level and a lack of confidence to diagnose TB and initiate treatment contribute to this TB treatment gap.

Local referral protocols may mandate that a nurse clinician at PHC first refers to a medical officer at the local CHC. However, certain patients with AHD may be too unwell and may require urgent referral directly to a hospital. If necessary, call the doctor at the CHC to discuss the patient and facilitate referral to hospital to minimise delays in the patient accessing the appropriate care

Step 1 Identify the seriously ill patient



Assessing a patient should always start with a triage assessment and rapid appraisal to identify any danger signs to determine if the patient requires immediate hospitalisation for inpatient care based on the severity of illness. Stabilise and refer to/admit for inpatient care as indicated.

Box 2: Danger signs in adults and adolescents needing urgent attention

Give urgent attention to the adult or adolescent with any of the following danger signs:

- Respiratory rate ≥30 breaths per minute
- Heart rate ≥120 beats per minute
- Unable to walk unaided.
- Breathless at rest or while talking
- Coughs up ≥ 1 tablespoon of fresh blood
- Drowsy/confused/loss of consciousness
- Fitting/seizures
- Aggressive, confused or agitated
- Recent sudden onset weakness, numbness or visual disturbance

Source: Adult APC Guideline 2023

Box 3: Danger signs in children and adolescents needing urgent attention

General danger signs:

- Unable to drink or breastfeed
- Vomiting everything
- Convulsions
- Unconscious or lethargic
- Tachypnoea or tachycardia abnormal for age
- Any signs of shock

Signs of severe respiratory illness:

- Chest indrawing
- Stridor in calm child
- Oxygen saturation < 92% on room air
- Central cyanosis

Signs of severe acute malnutrition:

- Oedema of both feet and/or
- Weight for length/height z-score less than -3, or
- MUAC less than 11.5cm, and
- one or more of the following: any other danger sign, any other red or yellow IMCI classification, weight ≤ 4 kg, or age < six months

Signs of severe dehydration (2 of the following)

- Unconscious or lethargic
- Sunken eyes
- Unable to drink or drinking poorly
- Skin pinch goes back very slowly

Signs of meningitis (any of the following)

- Neck stiffness
- Bulging fontanelle
- Restless, continuously irritable

Signs of severe anaemia (any of the following)

- Severe palmar pallor
- HB < 7 g/dl

Adapted from the SA national 2022 IMCI guidelines & Chapter 15: Respiratory System of the STG and EML for paediatric hospitals in SA, 2023, and the WHO Operational Handbook on TB Module 5

Step 2 Identify adults, adolescents, children and pregnant and breastfeeding women (PBFW) at risk of AHD

STEP 2
Identify high-risk clients for AHD

New HIV diagnosis

or

PLHIV and unstable (adults, children and PBFW)

- Any clinically unwell client, whether on ART or not on ART
- Any client on ART with a VL > 1000 c/mL
- Any child < 5 years
- Any client returning to care after a treatment interruption of > 90 days, regardless of symptoms.

The following patients are at a higher risk of having AHD:

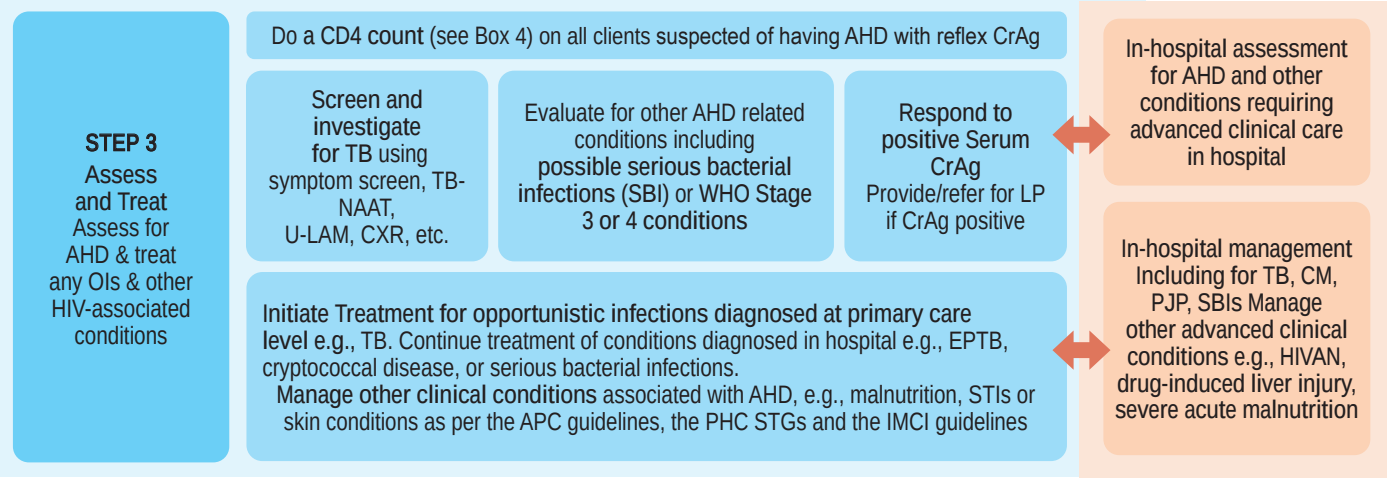
- Any new HIV diagnosis
- Any clinically unwell patient (including those with untreated/uncontrolled mental health disorders) or patient on treatment for an opportunistic infection, whether on ART or not on ART
- Any patient on ART with a **VL ≥ 1000 c/mL**
- Children under five years, unless on ART for > 1 year and virally suppressed
- Any patient returning to care after a treatment interruption of > 90 days, regardless of symptoms.

Persons at higher risk of AHD should be considered to have AHD until proven otherwise through a thorough history, clinical examination and relevant investigations

Although clients who are clinically well and stable on ART are not considered high risk groups for AHD, they may still develop AHD. Therefore, all patients stable on ART should have a comprehensive annual clinical review at the time of their script renewal, including clinical examination, annual HIV viral load (VL), creatinine and estimated glomerular filtration rate (eGFR), TB-NAAT, screening for NCDs and common mental health conditions (depression, anxiety and substance use disorders), an assessment of family planning needs and pap smear if indicated, and an assessment of adherence. CD4 counts should be done per the routine monitoring schedule in Box 4. All patients should be educated on the symptoms of TB and advised to return to the clinic if unwell.

Correct management of stable patients on ART will detect adherence problems early, maintain viral suppression and prevent advanced HIV disease

Step 3 Assess for AHD & treat any OIs & other HIV-associated conditions



Identifying patients with AHD requires:

- A CD4 count to determine the level of immunosuppression (See Box 4)
- A thorough clinical evaluation by means of a history, clinical examination and relevant investigations to identify any WHO Stage 3 or 4 conditions and other co-morbidities
- As part of their comprehensive clinical evaluation, every patient at risk for AHD should be systematically screened for the following major opportunistic infections:
    - Tuberculosis
    - Cryptococcal meningitis
    - Severe bacterial infections

Patients with CD4 counts < 200 may initially appear well but may rapidly deteriorate and remain at a higher risk for death. Such patients are at risk of receiving a less intensive clinical assessment when their CD4 count is taken. In all patients at risk of AHD, the earliest opportunity to screen for, treat or prevent serious opportunistic infections should be fully utilised to minimise the risk of rapid deterioration and death.

Box 4: Indications for CD4 testing

Routine CD4 monitoring should be done for all patients:

- At HIV diagnosis and ART initiation
- After 10-12 months/dispensing cycles (DCs) on ART (aligned with annual VL).

CD4 monitoring is indicated in specific situations:

- If CD4 is ≤ 200 or ≤ 25% (in children under 5 years): repeat every 6 months until CD4 > 200/>25%
- If VL ≥ 1000 c/mL: do a CD4 to identify AHD and repeat CD4 every 6 months until VL < 1000 c/mL
- If a clinical indication arises, such as a new confirmed or presumed WHO Stage 3 or 4 condition in a previously well patient
- If a patient re-engages in care after missing a scheduled appointment, as per the re-egagement algorithm on page 34

Source: SA NDoH 2023 ART Clinical Guidelines

Important considerations when evaluating a patient for AHD:

- **Pregnant women** already on ART at their 1st ANC booking visit should have their previous CD4 count results reviewed, as well as their record of adherence and latest HIV viral load results. If no CD4 is on record, she is returning to care after an interruption, or her last VL was elevated, a CD4 count should be done to assess for AHD at her 1st ANC visit
- AHD will likely **not be identified at a single visit**, and appropriate return dates should be provided based on the patient's clinical condition and the time it takes for results, e.g., TB-NAAT, to become available. Clinicians should schedule a shorter return date (earlier than one month) if a client is at high risk of rapid deterioration and requires closer clinical monitoring and management.
- Clients newly diagnosed with HIV may be **asymptomatic** or have WHO Stage 1 or 2 disease. Therefore, AHD may not be clinically evident initially but will be apparent once their CD4 count result is available in a few days. Facilities cannot rely on the patient's scheduled return date for actioning abnormal results. These return dates could be between 1-3 months later, with a high risk of deterioration in this period.
- **Effective results management processes** are important to ensure that patients with abnormal test results (e.g. positive CrAg, positive TB-NAAT, or CD4 < 200) can be recalled to the facility for prompt action, additional investigations and treatment when indicated.

Laboratory results management

- Every facility should have processes in place to receive, review, document and capture all laboratory investigation results.
- Every facility should act on abnormal results promptly, as outlined in Box 5.
- Table 3 guides the urgency of recalling patients with common abnormal test results.

Box 5: Laboratory results management process

An efficient results management process requires the following steps:

- Inform the patient about the tracing and recall process:
  - ➞This should be discussed as part of their Adherence Support Plan, as detailed in Table 19 under AHD Step 7: Support Adherence
  - ➞Obtain necessary consent from the patient for the tracing and recall process
  - ➞Update the patient's contact details and that of their treatment supporter, if available
- Review results daily in order to identify abnormal results timeously:
  - ➞All lab results must be reviewed and triaged by a clinician on the same day they arrive at the facility.
  - ➞Clinicians should separate abnormal results from normal results to prioritise urgent cases (e.g. CrAg positive, TB positive, Hb < 6g/dL) for immediate action.
- Document results:
  - ➞Results should be recorded in the relevant documents (TB Identification Register, HIV clinical stationery, N4 specimen register), flagging the urgency for abnormal result follow-up
- Recall the patient for action (as per DMOC SOP 7):
  - ➞Patients with abnormal results requiring urgent clinical management (see *Table 11: Recall timelines for abnormal test results at PHC level on page 63*) before their next scheduled appointment must be recalled to the facility via phone calls, SMS, or WhatsApp.
  - ➞If a patient does not return within 7 days of the recall, further attempts should be made using follow-up telephonic recalls and then home visits as per the patient's consent.
  - ➞Document recall efforts in the patient's file.
  - ➞Ensure patient confidentiality throughout the tracing and recall processes.
- Data capture and register management:
  - ➞Data clerks should use the TIER.Net Pending Tests functionality to capture all abnormal and normal lab results that have been signed off by a clinician.
  - ➞After capturing in the relevant register, clerks should mark the results as "captured" in the patient records (clinical stationery) and initial and date them.

Source: NDoH Bulk Capturing of Normal Laboratory Results Guidance, DMOC SOP 7 (Tracking and Recall)

Table 11: Recall timelines for abnormal test results at PHC level

Element of care	
Urgent recall within 1 to 3 days	
First/new CrAg positive	Recall for urgent lumbar puncture (LP) and clinical assessment for meningitis
TB-NAAT positive and not yet on TB treatment	Recall patient for TB treatment initiation
Hb < 6 g/dL	Recall for immediate referral to hospital emergency department for assessment and possible blood transfusion
ALT >200, regardless of symptoms	Recall within 1-3 days
eGFR <30mL/min and on TLD	Recall within 1-3 days to change their ART and investigate underlying causes of renal failure
Recall as soon as possible within the next 7 days	

CD4 count < 200	Review the clinical file:
	• If the patient was symptomatic, ensure that the appropriate tests were done, management provided, and an appropriate return date given as per the APC guideline. If management was appropriate, no recall is needed, and the patient can be seen at their next scheduled appointment within one month.
	• Recall the patient within 7 days if there are any of the following concerns:
	  • the patient does not return for their follow-up visit, or
	  • the timing of the visit was inappropriate based on the client's symptoms or clinical condition, or
	  • there are any concerns that the client did not receive the thorough clinical assessment indicated for a client at risk of AHD

TB-NAAT negative and TB symptoms present	• Confirm that the patient has been given a date to return for their results after two days • If the patient did not receive an appointment date or missed the appointment, recall them for additional TB investigations.
HB between 6-7,9 g/dL	• If anaemia is not already being managed by means of TB treatment or ART, recall the patient for further investigations and management.
ALT >120-199 and no symptoms documented at last visit	• Recall within 7 days.
eGFR 30 - 50mL/min and on TLD	• Recall within 7 days to change their ART and investigate underlying causes of renal failure
No recall required: review results at the next scheduled appointment within 30 days	
TB-NAAT negative and no TB symptoms were present at the last visit.	• Patient can initiate TPT at the next scheduled visit if eligible
ALT 50-120	• Assess at the next scheduled visit
Abnormal Pap smear	• Ensure action if HSIL or infection at the next scheduled appointment.
HBsAg positive	• No recall required if on a TDF-based regimen. ART also treats HBV.
CrAg positive	• No recall if CrAg positive after treatment for CM or previous antigenaemia

Tuberculosis

Introduction

Persons living with HIV have an increased risk of developing TB disease compared to persons who are HIV-negative. TB can occur at any point during the course of HIV infection. Pulmonary TB is the most common manifestation of TB in adults infected with HIV. The clinical pattern of TB correlates with the patient's immune status:

- In the early stages of HIV infection, when immunity is only partially compromised, the features are more typical of post-primary TB (i.e. similar to TB in non-HIV infected persons).
- As immune deficiency worsens, HIV-infected patients present with an atypical pulmonary disease resembling primary TB or with extra-pulmonary TB or disseminated disease.

While the principles of TB diagnosis and treatment are similar for those patients living with HIV and those who are HIV-negative (see the National Tuberculosis Management Guidelines), clinicians should be aware of the following aspects that may delay TB diagnosis or complicate the management of a TB/HIV co-infected patient:

- TB/HIV co-infected patients have increased mortality due to faster TB disease progression
- Clients living with HIV have reduced numbers of alveolar macrophages, are less likely to form cavities, and are more likely to have smear- or TB-NAAT-negative TB
- The clinical presentation of TB is more likely to be atypical or at extra-pulmonary sites.
- Drug interactions and side effects are more prevalent in TB/HIV coinfected patients
- Active TB increases HIV viral replication and accelerates HIV disease progression
- The risk for other opportunistic infections is higher in HIV/TB-co-infected persons than in HIV-positive persons without TB.

Early identification of TB among PLHIV through careful assessment of symptoms and signs, diagnosis using TB-NAAT, and prompt initiation of anti-TB treatment is important to improve survival and quality of life as well as reduce transmission of TB.

TB in pregnant and breastfeeding women is an important cause of maternal and infant mortality. The possibility of TB should be considered at every encounter during antenatal care (ANC), delivery, and in the postnatal period.

In South Africa, there is a large burden of undiagnosed TB in children of all ages, especially **children under five years of age.**

Box 6: TB symptoms

The main symptoms of TB in adults and adolescents are:

- Persistent cough of 2 weeks or more or any duration if HIV positive
- Fever for more than two weeks
- Drenching night sweats
- Unexplained weight loss (more than 1.5 kg in a month), or failure to gain weight in pregnant women

The most common symptoms in children are:

- Cough of two weeks or more
- Persistent fever of more than two weeks
- Documented weight loss/ failure to thrive
- Lethargy (less playful/ always tired)

The most common presentation of pulmonary tuberculosis is a productive cough, often accompanied by systemic symptoms such as fever, night sweats, or loss of weight. However, not all those with TB will have a cough; therefore, a high index of suspicion is required, particularly in PLHIV, who may only have one of the above symptoms. Every patient with a positive symptom screen must be investigated appropriately, as outlined in the National Tuberculosis Management Guidelines.

Source: SA NDoH 2023 ART Clinical Guidelines

Box 7: Clinical indications of extrapulmonary TB

- Clients with AHD are more likely to have atypical and extra-pulmonary TB. They are also often sputum TB-NAAT negative which can result in diagnostic difficulties and treatment delays.
- Although not specific to TB, the following manifestations are highly suggestive of extra-pulmonary/disseminated TB in inpatients with AHD
  - ➞large peripheral lymph nodes
  - ➞lymphocyte-predominant exudative pleural effusion
  - ➞pericardial effusion
  - ➞abdominal lymph nodes/ascites/splenic abscesses on ultrasound
- These clinical findings strongly support a clinical diagnosis of TB in the absence of another clear cause in an AHD patient, and empiric TB treatment should be strongly considered.

Box 8: **Chest X-ray findings suggestive of TB**

- Although not an exhaustive list, the following Chest-X-ray findings are commonly seen in patients with PTB:
  - ➞Cavitations
  - ➞Nodular infiltrates (including and esp. miliary nodules)
  - ➞Large pleural effusions
  - ➞Intrathoracic lymph node TB in children
- Remember that all children with miliary tuberculosis should all be considered to have meningitis, even if no symptoms or neurological signs are present and even if CSF has a normal result

For a detailed approach to CXR interpretation in a child or adolescent with possible TB see the Union's Diagnostic CXR Atlas for Tuberculosis in Children. https://theunion.org/technical-publications/diagnostic-cxr-atlas-for-tuberculosis-in-children

Table 12: TB Investigations: The 'what', 'when' and 'how'

TB investigation		What does this test tell you?	What does this test NOT tell you?	When to do/not to do this test	Type of sample/ other test details
Facility-based tests	Chest X-ray	Typical radiological features can support a clinical diagnosis of TB, even before TB symptoms develop.	A normal CXR does not exclude TB in a symptomatic person. Such results should be interpreted with the clinical history, symptoms and signs, TB-NAAT, U-LAM and TST (if indicated). CXR abnormalities in children with PTB are often non-specific, meaning children with other common forms of lower respiratory tract infections (or pneumonia) can have similar abnormalities.	For diagnostic purposes, do a CXR in any symptomatic person who is presumed to have TB, if available. To rule out TB in an asymptomatic person being considered for TPT, do a CXR if available on site, but the inability to do a CXR should not delay TPT initiation. Do a CXR at the time of any clinical deterioration on treatment.	PA views can be used in older children, adolescents and adults. AP and lateral views are required in children to demonstrate mediastinal lymphadenopathy.

	Urinary LAM	A positive urine LAM provides clinical confirmation of TB disease in persons living with HIV.	A negative U-LAM does not exclude TB.
			A positive U-LAM does not provide any indication of drug susceptibility, and a TB-NAAT should be done on all persons with a positive U-LAM.
			False-positive results are possible, especially if a bag specimen of urine is used.
			Mycobacteria other than Tuberculosis, eg Mycobacterium Avium Intracellulare (MAC) complex, can also cause a positive urine LAM result
				Do a U-LAM test in the following persons being investigated for TB:
				• For all PLHIV admitted to hospital
				• For all symptomatic PLHIV seen in an outpatient setting with either:
				  • CD4 count ≤ 200 or ≤ 25% (if < 5yrs) within the last 6 months, or
				  • advanced HIV disease, or
				  • current serious illness warranting admission
					Use urine sample for a lateral flow side room test.
					A clean-catch urine sample or an in/out urine catheter sample will provide a more reliable test.

	Tuberculin Skin Test (TST) (For children)	A positive TST confirms that a child has been infected with TB, now or in the past	A negative TST does not exclude TB infection or TB disease. A positive TST result does not differentiate between TB infection and TB disease.	A TST provides no additional information on a child who is already known to have TB exposure. It has a role to play in an ill child with vague features that might be due to TB, and in whom TB exposure is unknown. TST requires a functional immune system and sufficient time post-exposure (typically > 2 weeks) to mount an appropriate response. There are multiple reasons for false negatives and false positives.	Done in the facility by a healthcare provider. It can only be read 48 hours after administration.

Abbreviations: ALHIV, adolescents living with HIV; AP, antero-posterior; DR-TB, drug-resistant TB; DST, drug susceptibility testing; MTB, mycobacterium tuberculosis; NTM, non-tuberculous mycobacteria; PA, postero-anterior; PLHIV, person living with HIV; rif, rifampicin; RR, rifampicin resistant; TB, tuberculosis; TPT, TB preventive therapy; U-LAM, urinary lipoarabinomannan assay

TB investigation		What does this test tell you?	What does this test NOT tell you?	When to do/not to do this test	Type of sample/ other test details
Laboratory-based tests	TB Nucleic Acid Amplification Tests (TB-NAAT)	Detects the presence of TB DNA and can detect resistance to rifampicin ± INH. Provides bacteriological confirmation of TB.	A negative NAAT test does not rule out TB, particularly in persons with severe or extra-pulmonary disease. Therefore, a negative result should be viewed in the context of history and clinical and radiological findings, and treatment may be started if the overall picture suggests TB, even with negative NAAT results. TB NAAT cannot differentiate between the DNA of live and dead bacilli and may remain positive for up to 2 years after successful treatment. It should, therefore, not be routinely used as a test to monitor treatment response.	Do a TB-NAAT for diagnostic purposes, to confirm TB, and to detect rifampicin resistance in any symptomatic person being assessed for TB. Always do a TB NAAT in a patient with a positive U-LAM, as a U LAM does not provide information on drug sensitivity. Always attempt to get a respiratory sample before treatment initiation, regardless of the presumed site of TB and even if there is presumed extra-pulmonary TB. TB NAAT should be prioritised over TB culture in a sample with limited volume due to the speed of results.	Potential samples include sputum, induced sputum*, gastric aspirates, nasopharyngeal aspirates and stool. Note: Stool samples cannot be cultured. Tracheal aspirates and broncho-alveolar lavage may be possible in a hospital setting. Also, fine-needle aspirates, aspirates from pleural, pericardial, or joint effusions, and CSF. Aspirated pus/pus swabs from any abscess/site where TB is presumed. Samples may be obtained through spontaneous expectoration, sputum induction, gastric aspirates, nasopharyngeal aspirates, or any other fluid or tissue suitable for culture.
	Culture	The most sensitive indicator for bacteriological confirmation of TB and indicates viable, active bacilli, as well as the type of TB (MTB vs NTM). Culture-positive persons might be smear-negative but are still infectious. Allows for drug susceptibility testing (DST).	Although a TB culture does not directly provide drug susceptibility results, genotypic and phenotypic drug susceptibility testing can be done on the cultured specimen if required. Typically, a treatment decision needs to be made before the culture result is available. TB treatment or TPT initiation should not be delayed while awaiting the culture results if there is sufficient clinical and/or radiological evidence to determine infection or disease. However, results should still be checked at each visit for confirmation and drug susceptibility, even after the treatment decision has been made.	Very helpful if the initial TB-NAAT was negative or inconclusive. If initial TB-NAAT showed rifampicin resistance, genotypic and phenotypic DST should be done automatically as part of DR-TB reflex testing.	
	Smear microscopy	Provides bacteriological confirmation of mycobacterial infection, and if on sputum, is a marker of infectivity. Smear-positivity on sputum in a child suggests cavitatory lung disease and is, therefore, an indication of severe TB disease.	A negative smear does not exclude TB. A positive smear does not indicate the type of TB or drug susceptibility. If negative at baseline in older children, don't repeat smear microscopy to monitor smear conversion (as done in adults) unless clinically deteriorating.	At primary diagnosis of TB, after a positive TB-NAAT result and before treatment initiation. Due to low sputum volume and yield in children, TB-NAAT should be prioritised, followed by culture and DST. Then only do smear microscopy if there is sufficient specimen remaining. It is not a priority investigation in younger children who are rarely infectious.	

*Younger children, particularly those under six, often cannot expectorate adequately. In these patients, induced sputum (induction with nebulised salbutamol followed by nebulised hypertonic saline and nasopharyngeal aspiration) OR gastric aspirate OR nasopharyngeal aspiration (without induction) can be performed.

Who" and "where" and "what" of investigating and managing TB

Table 13: The "who' and 'where" and "what" of investigating and managing TB

Element of care	Nurse at PHC	Doctor at phc level	doctor at hospital level
Systematic TB screening	Screen all clients using the TB symptom screening tool Identify at-risk clients who require investigations, whether TB symptoms are present or not	✓	✓
Investigations	For diagnosis of pulmonary TB: Sputum testing (TB-NAAT ± culture), U-LAM, request CXR as per NTCP and TPT guideline Nurses should refer for further investigations if the client is very unwell or TB is suspected but the diagnosis unclear	For diagnosis of PTB or EPTB: Interpret CXR Lymph node FNA	Any investigations for diagnosis of PTB or EPTB, including ultra-sounds, other imaging and fluid taps
TB diagnosis and treatment initiation	✓ If uncomplicated, bacteriologically confirmed PTB.	✓ Bacteriologically or clinically diagnosed PTB or EPTB	✓ Bacteriologically or clinically diagnosed PTB or EPTB
Monitor on TB treatment	✓	If clinical complications arise or treatment resistance is detected	If clinical complications arise

Abbreviations: CrAg, cryptococcal antigen; CXR, chest X-ray; EPTB, extra-pulmonary TB; FNA, fine needle aspiration; LP, lumbar puncture; NTCP, National TB Control Programme; PTB, pulmonary TB; TB, tuberculosis; TB-NAAT, TB nucleic acid amplification test; TPT, TB preventive therapy; U-LAM, urinary lipoarabinomannan assay

Assessing for TB at clinic level

Systematic TB Screening

Systematic TB screening intensifies the detection of active TB cases in persons at risk for TB disease. Populations or high-risk groups are assessed not only for symptoms, but also using tests, examinations, or other procedures, such as TB-NAAT, chest X-rays, etc.

While all persons should be screened for TB symptoms at every clinical encounter, and all persons with TB symptoms should be investigated for TB, the following high-risk persons should be investigated for TB (as part of systematic TB screening), regardless of whether TB symptoms are present or not:

- Clients at HIV diagnosis/first evaluation for ART, including pregnant and breastfeeding women and girls (PBWG)
- Any patient with confirmed/presumed AHD
- Clients with a new TB exposure
- Clients attending their annual clinical review on ART (aligned with their annual VL)
- Any known HIV-positive woman (whether on ART or not on ART) with a new pregnancy diagnosis

The process of using systematic screening to diagnose or rule out TB is illustrated in the algorithm in *Figure 9: Systematic screening for tuberculosis on page 69*.

Systematic screening for tuberculosis

The following patients LHIV require systematic screening for TB:

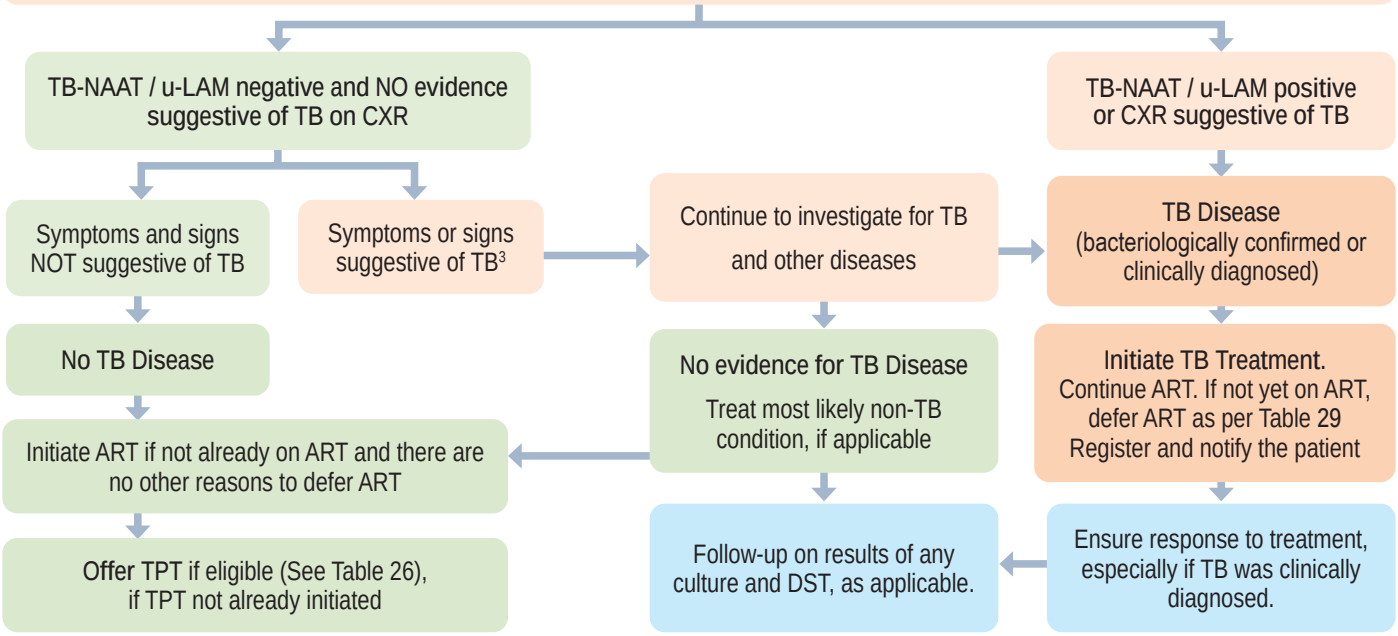
- Clients at HIV diagnosis/first evaluation for ART
- Any patient with confirmed/presumed AHD
- Clients with a new TB exposure
- Clients attending their annual clinical review on ART (aligned with their annual VL)
- Any known HIV positive woman (whether on ART or not on ART) with a new pregnancy diagnosis
- Clients with a past history of TB disease

The following mechanisms can be used to systematically screen a patient for TB:

- Symptom screen: current cough of any duration, fever, unexplained weight loss, night sweats
- Clinical examination
- Sputum testing (TB-NAAT ± culture) if can produce sputum[1].
- Obtain other specimens as clinically relevant, including mycobacterial blood cultures[2].
- Urine LAM if eligible, i.e.
  - for all inpatients LHIV
  - for symptomatic outpatients with AHD (CD4 ≤200 or children <5 years of age, and/or WHO 3 or 4 condition) or other current serious illness
- Chest X-ray[1] and any other imaging as indicated for possible extrapulmonary TB

If a patient is clinically well and has no TB symptoms, there is no need to wait for the test results before 1) initiating/re-initiating ART or 2) initiating TPT if the patient is eligible for TPT. See *Table 25: TB screening and TPT eligibility on page 89*.

ART and TPT can be started on the same day



1. The inability to produce sputum or the unavailability of a CXR should not be a barrier to starting TPT in an asymptomatic patient.
2. Mycobacterial blood cultures are useful in hospitalised patients with AHD and can detect disseminated non-tuberculous mycobacterial disease. This is especially relevant in patients with a CD4<50 and a positive U-LAM.
3. Negative sputum TB-NAAT and CXR in a symptomatic patient with AHD does not exclude TB. Refer for/continue to investigate for extrapulmonary TB.

Figure 8: Systematic screening for tuberculosis

Abbreviations: AHD, advanced HIV disease; ART, antiretroviral therapy; CXR, Chest X-ray; DST, drug susceptibility testing; LHIV, living with HIV; NAAT, nucleic acid amplification test (such as GeneXpert); TB, tuberculosis; TPT, TB preventive therapy; U-LAM, urinary lipoarabinomannan assay; VL, viral load

Figure 9: TB treatment decision algorithm

Source: Clinical Guideline for the Management of Tuberculosis in Children and Adolescents, 2024

TB treatment decision algorithm

Evaluate For TB

Screen

Identify children who may have TB or TB exposure

Screen for TB symptoms and TB exposure
in all children at every healthcare encounter

Identify high-risk children needing a TB assessment regardless of whether TB symptoms or TB exposure are present or not e.g. CLHIV

History and Clinical Examination

Are there symptoms and signs suggestive of pulmonary or extrapulmonary TB? [1]
Cough, especially if persistent and fails to improve, unexplained fever/drenching night sweats, weight loss/faltering growth, lethargy/reduced playfulness, visible neck swelling, blood-stained sputum, headache, persistent vomiting (without diarrhoea)

NO → If asymptomatic, offer TPT if eligible
See the 2023 TPT guideline for details

YES

Are there **danger signs** requiring urgent medical care?
(See Box 1), or do symptoms and signs suggest **TBM**[1] ?

YES → Stabilise and refer to/admit for inpatient care
Once stabilised, continue TB work-up

STABILISED

NO

Is the child
1. aged <2 years, or
2. living with HIV[2], or
3. severely and acutely malnourished?

regardless of symptom duration

NO → Is the child having persisting (>2 weeks), non-remitting features typical of TB

NO → Treat most likely non-TB condition
Follow up in 1-2 weeks [3]

YES

YES

Investigations

If possible, **perform CXR**
±
any other imaging as indicated for possible extrapulmonary TB

and

If possible, **collect a sample for a diagnostic test**[4], **e.g., TB-NAAT ± culture, and/or urine LF-LAM (if the child is LHIV)**
If no clear history of contact with a TB source case, consider doing a TST if any uncertainty remains about a TB diagnosis and the child is < 5 years old

Interpretation

CXR or imaging suggestive of TB and/or Positive result on any diagnostic test

Treat for TB
Determine the starting regimen and duration of treatment based on clinical, radiological, and bacteriological disease severity, and most likely drug susceptibility profile.
Notify even if no microbiological confirmation.

Follow-up on results of any culture and DST, as applicable.
Ensure response to treatment, especially if TB was clinically diagnosed.
Confirm drug susceptibility and response to treatment of any known TB source patient

CXR or imaging not suggestive of TB /unavailable, and diagnostic samples negative/unavailable[5]

YES ← Is there a close or household **TB contact**[3] in the previous year, **or positive TST**

NO

YES ← Do symptoms and signs indicate TB?
If uncertain, use the the **symptom and signs score to the right.**

NO

Consider other diagnoses.
Review in 1-2 weeks until symptom resolution.
Reconsider TB diagnosis or refer if symptoms persist.
Follow-up on any culture and DST results of the child, as applicable
If TB excluded and symptoms resolve offer TPT if eligible.
Refer to the TPT guideline

1. Please see Box 6 and Box 7 for additional details on the clinical features of TB.
2. Ensure HIV status has been established and managed appropriately.
3. If not severely ill, and if diagnosis or persistence (> 2 weeks) of symptoms are uncertain, consider a follow-up evaluation in 1-2 weeks to reassess weight and persistence of, or improvement in, symptoms. This decision will be influenced by other factors, incl. the likelihood of the child returning for reassessment. The child should be encouraged to return earlier if there is any deterioration of the symptoms.
4. Every effort should be made to establish microbiological confirmation of TB and drug susceptibility, even in young children. A range of samples can be collected, as detailed in Table 5. However, it is especially important to obtain samples for children exposed to a RR-TB source case and those with complicated or severe disease.
5. A decision to start TB treatment should not be delayed if the necessary investigations are not available, particularly in children at higher risk of developing severe disease, such as young children, malnourished children or those living with HIV.

Note: The TB Treatment Decision Algorithm does not replace sound clinical judgement.
A clinician could still choose to start TB treatment, even if the symptom score is less than 11, or consider other childhood illnesses to be present, even if the symptom score is ≥ 11

Clinical feature [1]	Score
Cough > 2 weeks	+ 5
Fever > 2 weeks	+ 10
Reduced playfulness/energy	+ 4
Weight loss	+ 5
Haemoptysis	+ 9
Night sweats	+ 6
Enlarged typical lymph nodes	+ 7
Tachycardia	+ 4
Tachypnoea/fast breathing	+ 2
Total score	?

Assign a score to each of the child's symptoms.
If the sum of the scores is **≥ 11**, treat for TB

Always plot weight and document findings in the Road To Health Chart, even if the decision is made NOT to start TB treatment.

Assessing a sick client for TB at the hospital level

An approach to an AHD patient with a respiratory presentation

- Pulmonary presentations (respiratory symptoms and/or pulmonary infiltrate on chest x-ray) are the commonest reason for hospitalisation in persons with AHD.
- The mortality rate is high and early initiation of appropriate therapy is essential.
- Most (80-90%) patients will have TB, bacterial pneumonia, and/or PJP.
- Both TB and PJP can mimic bacterial infections.
- Co-infections occur commonly.

The WHO recommends using the following principles in managing an AHD patient with a respiratory presentation, illustrated in Figure 11 below.

- Treat all seriously ill inpatients with AHD with parenteral broad-spectrum antibiotics (see Adult Hospital EML Chapters 9 and 10).
- Rapid tests for TB should be done in all patients.
- Imaging should guide empiric therapy for TB and/or PJP.
- Patients not responding to antibiotics after about 3 days should be empirically treated for TB.
- Further diagnostic workup should be done in patients not responding to empiric TB therapy.

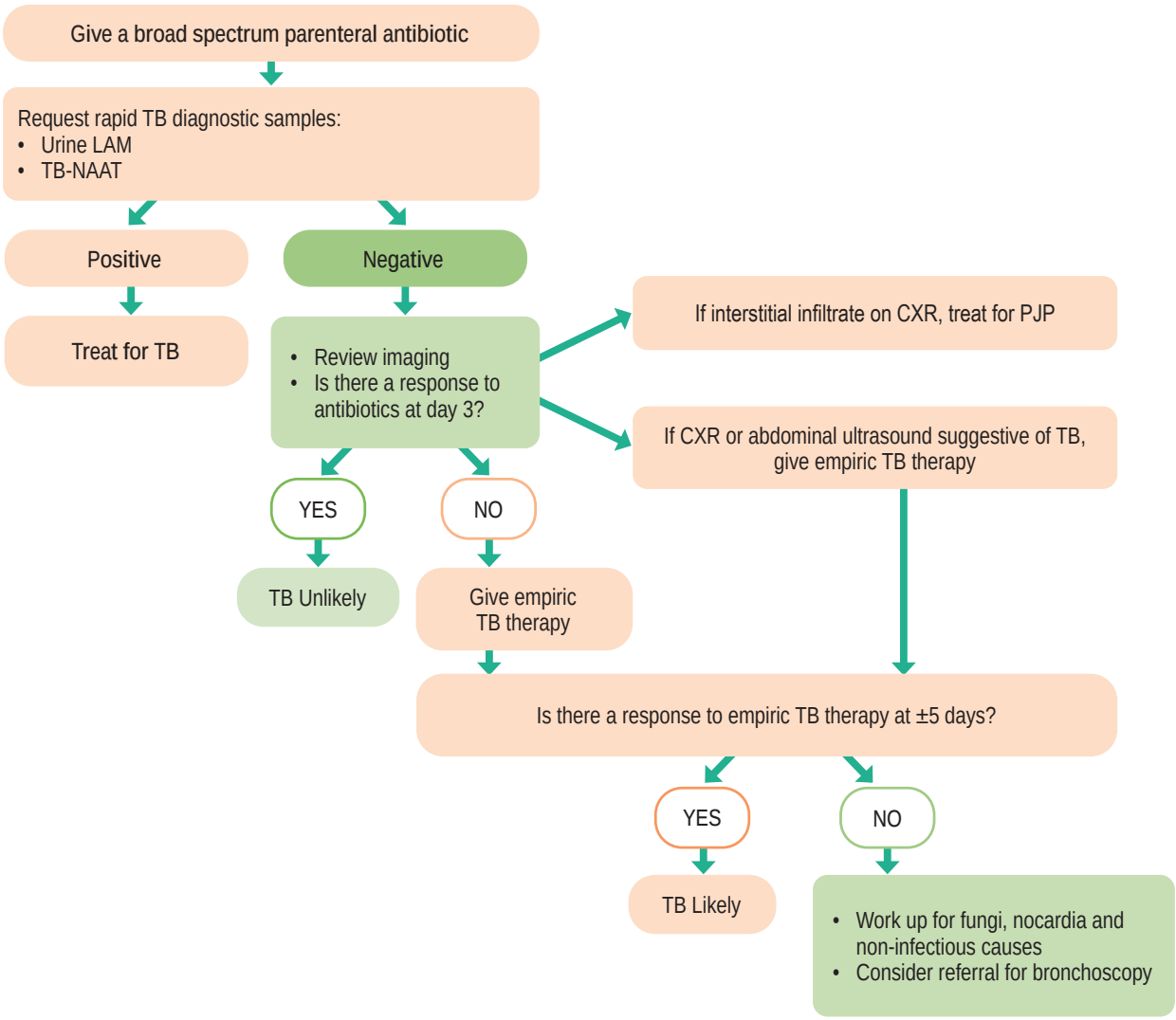


Figure 10: An approach to an inpatient with AHD and a pulmonary presentation

Source: Tom Boyles, Gary Maartens, Jeremy Nel, David Stead Southern African HIV Clinicians Society Clinical Guidelines for Hospitalised Adults With Advanced HIV Disease 2022

Treatment regimens for TB

- For the treatment of DS-TB in adults, please see the latest NTCP Guidelines
- For the treatment of children with TB, please see the 2024 Clinical Guideline for the Management of Tuberculosis in Children and Adolescents
- For Treatment regimens for DR-TB, please see the latest RR-TB Clinical Reference Guide
- For the dual treatment of HIV and active TB in neonates, children, adolescents and adults, including appropriate ART regimens during TB treatment and the management of drug interactions with rifampicin, see *Co-treatment of HIV and Active TB in Neonates, Infants, Children, Adolescents and Adults on page 35*.
- For more information on screening, diagnosing, and managing TB in pregnant women, see *TB screening for pregnant and breastfeeding women on page 152*.

Other helpful resources

- For detailed approach to CXR interpretation in a child or adolescent with possible TB see the Union's Diagnostic CXR Atlas for Tuberculosis in Children. *https://theunion.org/technical-publications/diagnostic-cxr-atlas-for-tuberculosis-in-children*

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.

Cryptococcal disease

Introduction

- Cryptococcal antigenaemia is a common opportunistic infection in persons with AHD
- Cryptococcal meningitis is the most common manifestation of disseminated antigenaemia and a leading cause of death before and after ART is initiated, often due to late presentation and delayed diagnosis.

Prevention of cryptococcal disease

- Early diagnosis of HIV infection and early initiation of ART before immunosuppression is the most important strategy to reduce the incidence of CM and CM-associated mortality.

Screening for cryptococcal disease

- A CrAg assay is used to detect cryptococcal antigenaemia.
- **CrAg screening should occur for all HIV-positive adults and adolescents with a CD4 count ≤200 cells/μL** at ART initiation, at treatment failure, or when re-entering into care after prior disengagement, and whether presenting at clinic or hospital level.
- A serum CrAg is performed as a reflex test on the patient's CD4 sample if it is ≤200 cells/μL.
- CrAg testing of blood should also occur for all adults or adolescents with clinically suspected meningitis if a lumbar puncture cannot be done to make a firm diagnosis immediately.
- Patients with a prior diagnosis of cryptococcal meningitis do not need to be screened using a CrAg, as once positive from an earlier infection, a CrAg remains positive for life. If a patient presents with symptoms suggesting a possible relapse, a CSF cryptococcal culture is required.
- Screening is not currently recommended for children under ten years of age.
- All patients with a new positive serum CrAg test are considered to have cryptococcal antigenaemia and will require treatment.
- A lumbar puncture (LP) and CSF CrAg are required to determine if the extent of the disease dissemination includes the meninges (cryptococcal meningitis), which carries a high mortality rate and requires more intensive hospital treatment.
- An LP should be done regardless of whether symptoms of meningitis are present, since asymptomatic cryptococcal meningitis may be present.
- If the CSF CrAg is negative, cryptococcal antigenaemia is diagnosed without cryptococcal meningitis.
- Disseminated cryptococcal disease without meningitis is commonly diagnosed by positive fungal cultures from the blood or skin. In people with AHD, this is treated in the same way as cryptococcal meningitis.

Patients with a first or new positive serum CrAg test have a high likelihood of developing cryptococcal meningitis within the next three weeks!

"Who" and "where" and "what" of investigating and managing cryptococcal disease

Table 14: The "Who' and 'Where" and "what" of investigating and managing cryptococcal antigenaemia

Element of care	Nurse Clinician at PHC	Medical Officer at PHC Level	Medical Officer at Hospital Level
Screening and investigation for CM	A CrAg will be done as a reflex test on CD4 count ≤200. Nurse clinicians should identify and respond to abnormal CrAg results. ALL patients with a new positive CrAg should be referred for an LP. All patients with symptoms or signs of meningitis should be referred directly to hospital for an LP. Asymptomatic patients with a positive CrAg may be referred for an LP to an onsite doctor at PHC level if available. If no medical officer is available at PHC level, the patient should be referred to hospital for the LP	ALL patients with a new positive CrAg should be referred for an LP. investigations in an asymptomatic patient with a positive CrAg. If CrAg is positive on CSF, refer to hospital for intensive phase of treatment for CM	Do LP or neuroimaging if LP contra-indicated
Make a diagnosis of CM or cryptococcosis and initiate the intensive phase of treatment		✓ Initiate outpatient treatment for cryptococcal antigenaemia without CM	✓ Initiate inpatient treatment for CM
Ongoing management once stabilised and on oral treatment	Support treatment adherence. Switch to consolidation and maintenance phases of treatment when appropriate, as per the hospital discharge plan Check that any hospital follow-up appointments are adhered to. Consult/refer if any concerns or clinical deterioration		

Assessing for cryptococcal disease at the clinic level

- A serum CrAg will be done as a reflex test on CD4 count ≤200. Nurse clinicians should identify and respond to abnormal CrAg results. ALL patients with a positive CrAg should be referred for an LP.

Assessing a symptomatic patient for cryptococcal disease at the hospital level

Cryptococcal meningitis should be included in the differential diagnosis for any patient presenting with symptoms of sub-acute/chronic meningitis.

Table 15: Definitions for meningitis

Definitions	
Acute meningitis	duration of symptoms < 7 days
Sub-acute/chronic meningitis	duration of symptoms ≥ 7 days

An approach to sub-acute/chronic meningitis

- The differential diagnosis is broad and includes bacteria, mycobacteria, fungal, viral, parasitic, and non-infectious causes.
- The most common treatable causes in a patient with HIV in South Africa are:
    - (Myco)bacterial: Tuberculosis, syphilis, listeria
    - Fungal: Cryptococcosis
    - Viral: Herpes Simplex (HSV), Varicella Zoster (VZV), Cytomegalovirus (CMV)
- If no contra-indications, do an LP with the following initial tests:
    - CSF opening pressure
    - Gram stain and bacterial culture
    - Protein, cell count, glucose
    - CrAg
    - Syphilis serology
    - Serum glucose
    - Store up to 10mls of CSF for future tests
- If there is a neurological contra-indication to LP, perform a CT brain.
- **There is no need to start empiric ceftriaxone and specific treatment can wait until the CSF results are received.**
- The following results on CSF are listed in order of usefulness:
    - Gram stain: rarely positive, but if it is, the diagnosis is confirmed
    - CrAg: if positive, confirms cryptococcal meningitis (unless previously treated)
    - VDRL:If positive, confirms neurosyphilis
    - FTA-Abs: a negative result excludes neurosyphilis
    - CSF glucose: if <2.5, suggestive of TBM but a bacterial cause cannot be excluded
    - CSF protein: a value of around 1.5 is suggestive of TBM; if > 5, it is suggestive of bacterial meningitis (but not definitive)
    - Cell counts - not very useful- normal results are suggestive of no meningitis, but up to 5% of cases with TB and bacterial meningitis may have normal results
    - Very high polymorphs suggest bacterial or CMV meningitis
- If the diagnosis remains unclear, consider the following tests on the stored CSF:
    - TB-NAAT (ask the lab to centrifuge the sample first)
    - Mycobacterial culture (for future reference)
    - Viral PCR: HSV, VZV (rash may not be present), CMV, and enterovirus
    - Bacterial PCRs, including Listeria
- Look for other ways to make a diagnosis:
    - Urine lipoarabinomannan (U-LAM) to search for TB
    - Look for rashes suggestive of VZV or HSV
    - Consider malignancy and autoimmune diseases
    - Stop any medications that may be implicated.
- If the TB-NAAT is negative, and there is confirmed meningitis, but other test results are outstanding, consider the following empiric therapies in this order:
    - Consider TBM therapy
    - Treat for HSV
    - Treat for neurosyphilis (unless the fluorescent treponemal antibody absorption (FTA-Abs) test is negative). If VDRL is negative, then syphilis is less likely. It is important to consider suggestive neurological signs.
    - Treat for Listeria using ampicillin if the patient is > 50 years old, on chronic immunosuppressive medication or has brainstem signs and symptoms.

TBM has a very high mortality, and the threshold for initiating treatment for TBM should be low. In a patient with confirmed sub-acute/chronic meningitis, with no evident alternative diagnosis, consider empiric TBM therapy. If an alternative diagnosis becomes evident, stopping TB treatment may be considered.

Treatment of cryptococcocal antigenaemia

- If **cryptococcal meningitis** is confirmed (i.e., serum CrAg positive and CSF CrAg positive), or **disseminated culture-positive cryptococcal disease** without meningitis (i.e. a positive fungal culture from blood, skin, etc.) is confirmed:
    - Depending on the availability of treatment options, patients should be provided with one of the four induction regimens illustrated in *Table 6: Differentiated linkage to HIV treatment and prevention services on page 22*.
    - ART should be deferred for four to six weeks.
    - Therapeutic lumbar punctures may be of value (see Box 10).
- If **cryptococcal antigenaemia without meningitis** is confirmed (i.e., serum CrAg positive and CSF CrAg negative):
    - Clients should receive an oral, fluconazole-only induction regimen for 14 days (See also Table 16)
    - ART can be started immediately.
- The induction phase regimens for both CM, disseminated cryptococcosis without CM, and cryptococcal antigenaemia should be followed by:
    - A consolidation phase of fluconazole 800 mg daily for eight weeks
    - A maintenance phase of fluconazole 200 mg daily. Continue for at least one year, provided the CD4 count increases to >200 cells/μL on ART and virally suppressed. If the CD4 count does not increase, continue treatment indefinitely, or until the CD4 count increases to >200 cells/μL.
- Screening and treatment for CM in adults is summarised in the algorithm in Figure 12. For paediatric doses see Table 17.
- Liver disease: evidence of clinical liver disease warrants careful monitoring because fluconazole may cause liver injury.
- Symptomatic relapses are common and are most often because of inadequate or premature cessation of maintenance fluconazole treatment. Be sure to determine if there is any history of fluconazole use and what their adherence profile was.

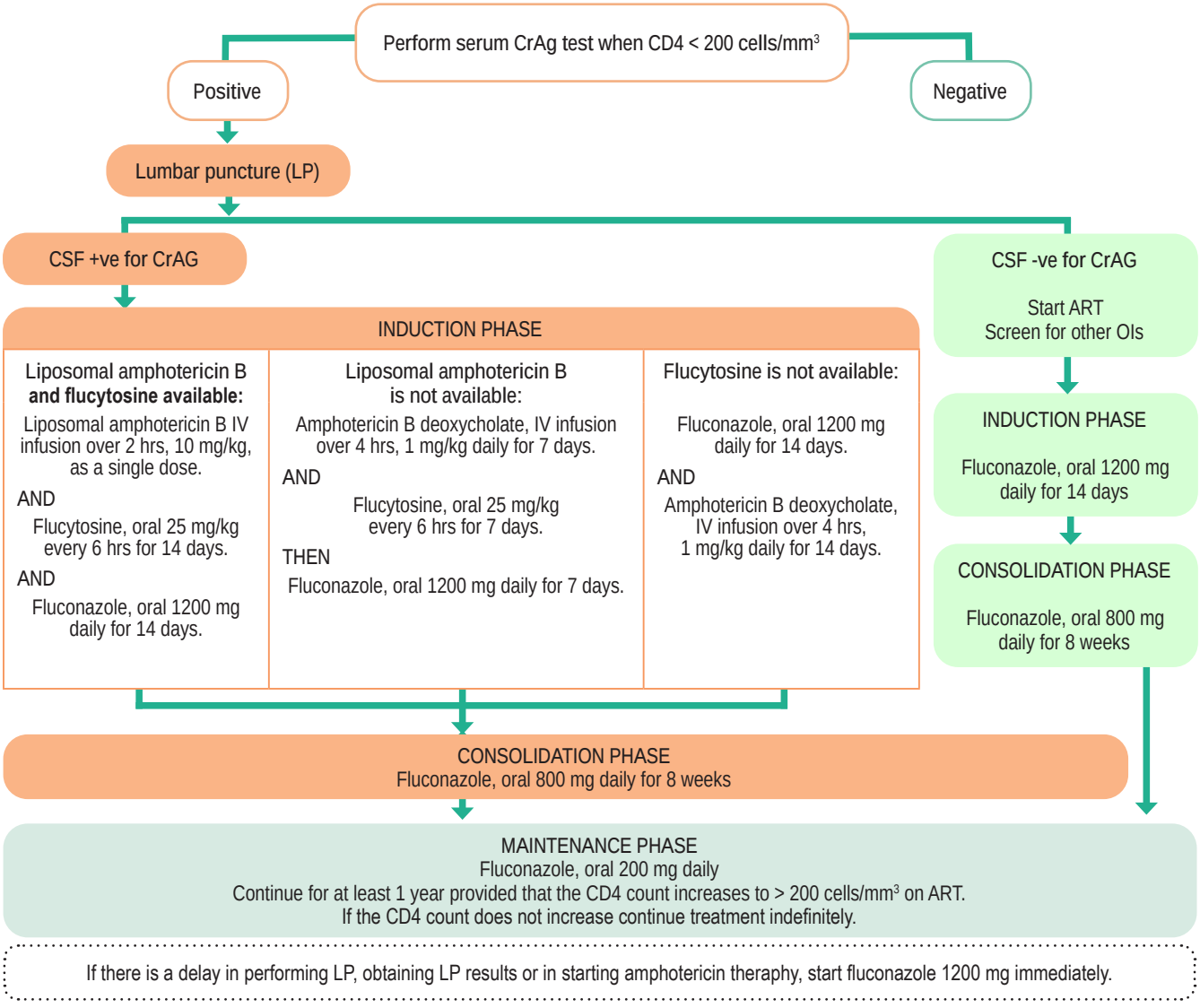


Figure 11: Algorithm for the diagnosis and management of cryptococcal disease in adults

*Source: Govender NP, Meintjes G, Mangena P, et al. Southern African HIV Clinicians Society guideline for the prevention, diagnosis and management of cryptococcal diseases among HIV-infected persons: 2019 update. S Afr J HIV Med. 2019;20(1), a1030. https://doi.org/10.4102/sajhivmed.v20i1.1030, as illustrated in the Hospital level (Adults) Standard Treatment Guidelines and Essential Medicines List to treat **specific pathogens and syndromes. 6th ed. 2024.***

Table 16: Cryptococcosis treatment regimen options in adults

Cryptococcal meningitis OR disseminated culture-positive cryptococcal disease without meningitis IN ADULTS															Cryptococcal antigenaemia without meningitis	
	Regimens	Option 1 (Preferred)			Option 2		Option 3		Option 4							
		If liposomal amphotericin B and flucytosine are available			**If liposomal amphotericin B is not available**			**If flucytosine is not available**			**If neither amphotericin B formulations are available**				
	Medicine	Liposomal amphotericin B	Fluconazole	Flucytosine	Amphotericin B deoxycholate	Fluconazole	Flucytosine	Amphotericin B deoxycholate	Fluconazole	Flucytosine	Fluconazole	Flucytosine			Fluconazole	
	Dose	10 mg/kg in dextrose 5%, slow IV infusion over 2 hours	oral, 1200mg daily	oral, 25 mg/kg 6 hourly	1mg/kg, IV infusion over 4 hours	oral, 1200mg daily	oral, 25 mg/kg 6 hourly	1mg/kg, IV infusion over 4 hours	oral, 1200mg daily	oral, 25 mg/kg 6 hourly	oral, 1200mg daily	oral, 25 mg/kg 6 hourly			oral, 1200mg daily	
Induction phase	Day 1	single dose	x	x	x			x	x	x	x	x			x	
	Day 2		x	x	x			x	x	x	x	x			x	
	Day 3		x	x	x			x	x	x	x	x			x	
	Day 4		x	x	x			x	x	x	x	x			x	
	Day 5		x	x	x			x	x	x	x	x			x	
	Day 6		x	x	x			x	x	x	x	x			x	
	Day 7		x	x	x			x	x	x	x	x			x	
	Day 8		x	x		x			x		x				x	
	Day 9		x	x		x			x		x				x	
	Day 10		x	x		x			x		x				x	
	Day 11		x	x		x			x		x				x	
	Day 12		x	x		x			x		x				x	
	Day 13		x	x		x			x		x				x	
	Day 14		x	x		x			x		x				x	
Consolidation Phase	Week 3 to Week 10	**Fluconazole**, oral, 800 mg daily for 8 weeks														
Maintenance Phase	12 months	**Fluconazole**, oral, 200 mg daily for at least 1 year Continue for at least 1 year provided that the CD4 count increases to >200 cells/mm3 on ART. If the CD4 count does not increase continue treatment indefinitely														

Source: Hospital level (Adults) Standard Treatment Guidelines and Essential Medicines List to treat specific pathogens and syndromes. 6th ed. 2024.

Table 17: Cryptococcosis treatment regimen options in children

Cryptococcal meningitis OR disseminated culture-positive cryptococcal disease without meningitis in children											Cryptococcal antigenaemia without meningitis	
Regimens	Option 1			Option 2			Option 3					
	Preferred option			If flucytosine is not available			If amphotericin B is not available, not tolerated or contraindicated					
Medicine	Amphotericin B deoxycholate	Flucytosine	Fluconazole	Amphotericin B deoxycholate	Fluconazole		Fluconazole	Flucytosine			Fluconazole	
Dose	1mg/kg, IV infusion in dextrose 5% over 4 hours	oral, 25 mg/kg 6 hourly	IV/oral, 12mg/kg/day (max 800mg)	1mg/kg, IV infusion in dextrose 5% over 4 hours	IV/oral, 12 mg/kg/day (max dose: 800 mg/ day)		IV/oral, 12 mg/kg/day (max dose: 800 mg/ day)	oral, 25 mg/kg 6 hourly			IV/oral, 12mg/kg/day (max 800mg)	
Induction phase												
Day 1	x	x		x	x		x	x			x	
Day 2	x	x		x	x		x	x			x	
Day 3	x	x		x	x		x	x			x	
Day 4	x	x		x	x		x	x			x	
Day 5	x	x		x	x		x	x			x	
Day 6	x	x		x	x		x	x			x	
Day 7	x	x		x	x		x	x			x	
Day 8			x				x				x	
Day 9			x				x				x	
Day 10			x				x				x	
Day 11			x				x				x	
Day 12			x				x				x	
Day 13			x				x				x	
Day 14			x				x				x	
Consolidation Phase	Week 3 to Week 10	Fluconazole, oral, 12 mg/kg/day for 8 weeks (max daily dose 800mg)										
Maintenance Phase	12 months	Fluconazole, oral, 6mg/kg/day (max daily dose 400mg) **Discontinue fluconazole:** Children < 6 years of age, on ART: CD4 count > 25% for at least 6 months. Children > 6 years of age, on ART: CD4 count > 200 for at least 6 months. Re-start prophylaxis if CD4 count drops below thresholds above.										

Source: Paediatric Hospital level Standard Treatment Guidelines and Essential Medicines List to treat specific pathogens and syndromes. 5th ed. 2023.

Box 9: Symptoms of cryptococcal disease

Patients with cryptococcal meningitis may present with:

- Signs of raised intracranial pressure (headache, confusion, altered level of consciousness, sixth cranial nerve palsies with diplopia [double vision], and papilloedema)
- Neck stiffness (related to inflamed meninges)
- Memory loss and new-onset psychiatric symptoms (related to encephalitis)

Patients with disseminated cryptococcosis may also present with:

- Pulmonary involvement with cavitation, nodular infiltrates and consolidation (can be confused with TB or Kaposi's sarcoma)
- Skin involvement

Source: The Southern African HIV Clinicians Society guideline for the prevention, diagnosis and management of cryptococcal disease among HIV-infected persons: 2019 update

Box 10: Therapeutic lumbar punctures

Therapeutic lumbar punctures

- Therapeutic lumbar puncture is indicated to lower pressure in symptomatic patients and should be done with pressure monitoring.
- Remove sufficient CSF (maximum 30 mL) to lower pressure to 50% of the opening pressure but not less than 20 cm H_2O.
- Therapeutic lumbar puncture should be done daily until there is clinical improvement.

Source: Adult Hospital Level EML, 2019

CM in pregnant and breastfeeding women

- Fluconazole is potentially teratogenic when used during the 1st trimester, but pregnant women should be counselled that the benefits of fluconazole likely outweigh the risks in the management of cryptococcal antigenaemia.
- All pregnant women <20 weeks gestation exposed to fluconazole should have an ultrasound scan to detect congenital abnormalities.
- Although fluconazole is excreted into breast milk at concentrations similar to maternal plasma concentrations, the dose the infant is exposed to with doses <400 mg is similar to the dose used in systemic treatment in infants. Even for higher doses, the benefits will likely outweigh the risks, though this can be discussed with a specialist

CM in children

- CM is an uncommon childhood meningitis
- Screening is not recommended for children under ten years of age, given the low incidence of cryptococcal meningitis in this age group.
- CM may occur in older HIV-infected children with severe CD4 T-cell depletion.
- Pulmonary and skin involvement can occur.
- For treatment regimens, please see Table 7

Other resources

- The Essential Drugs Programme Hospital level (Adults) Standard Treatment Guidelines Section 10.2.4 Cryptococcosis
- The Southern African HIV Clinicians Society guideline for the prevention, diagnosis and management of cryptococcal disease among HIV-infected persons: 2019 update

Severe bacterial infections

Introduction

Opportunistic infections in patients with AHD can be categorised as follows:

1. Those infections that almost exclusively occur in severely immunocompromised patients with low CD4 cell counts and are rarely seen in the community. Included are infections such as cryptococcal meningitis and pneumocystis jirovecii pneumonia (PJP). These infections are considered 'AIDS-defining'.
2. Those infections that are routinely seen in non-HIV-infected persons but are more frequent in HIV-infected patients (even those with high CD4 cell counts). This second type becomes increasingly common and more severe as CD4 cell counts decrease. While not necessarily considered 'AIDS-defining', they contribute significantly to morbidity and mortality and are now widely considered to be 'opportunistic'. Included are tuberculosis and non-tuberculous severe bacterial infections (SBIs).

Severe bacterial infections cannot be viewed as a homogeneous group because of the range of pathogens and organ systems involved. For persons with HIV and without, the diagnostic tests used and treatment are generally similar. Some examples include:

- Bacterial pneumonia
- Bacterial meningitis, including Listeria meningitis
- Enteric bacterial infections
- Urinary tract infections, including pyelonephritis
- Bacteraemia, including non-typhoidal salmonella bacteraemia
- Sepsis (a clinical syndrome stemming from an overwhelming immune system response to a systemic infection, often bacterial)

Clinical presentation

- The signs of serious bacterial infection in HIV-positive patients can be subtle.
- A high index of suspicion for invasive bacterial disease is appropriate, especially when a patient presents with a new febrile illness.
- Diagnostic evaluation should include (as a minimum):
  - blood cultures in hospitalised patients
  - other relevant clinical specimens, e.g. sputum, urine, or stool, taken before antibiotics are initiated, wherever possible.
  - full blood count and kidney functions

Treatment

- Empiric antimicrobial therapy based on the clinical presentation may be life-saving in patients with invasive bacterial disease complicating HIV infection and should not be delayed while awaiting test results
- When the aetiology has been identified based on reliable microbiological methods, antimicrobial therapy should be modified and directed at the identified pathogen.

- Co-infections in persons with AHD are common, and clinicians should have a low threshold for providing empiric antibiotics.
- Pregnant women with AHD are at a high risk of sepsis, especially post-cesarean section.

"Who" and "where" and "what" of investigating and managing SBIs

Table 18: Investigating and managing SBIs

Element of care	Nurse Clinician at PHC	Medical Officer at PHC Level	Medical Officer at Hospital Level
Identification & management of danger signs	✓ Where/when within the scope of practice of a nurse (as per APC and IMCI guidelines). Referral to a higher level of care	✓	✓
History and clinical examination	✓ Where/when within the scope of practice of a nurse	✓ Initiate outpatient treatment for cryptococcal antigenaemia without CM	✓ Initiate inpatient treatment for CM
Diagnosis and management of severe bacterial infections	Nurses should identify unwell patients requiring referral for further assessment and possible admission (as per APC and IMCI guidelines).	✓ Assessment and management as outpatients	✓ Assessment and management as inpatients

Clinic management

- Patients with severe bacterial infections are frequently very ill and may require urgent referral to hospital.
- The most important function of a nurse clinician at PHC level is to recognise that a patient is unwell and may have a serious bacterial infection.
- At PHC level, a nurse should assess and manage within the scope of practice of a nurse and as per APC and IMCI guidelines, including providing antibiotics before referral to hospital.
- Refer timeously to a higher level of care when indicated.

Hospital assessment and management of patients with possible severe bacterial infections

An approach to a patient with possible acute meningitis

- Meningitis is a common presentation in patients with HIV.
- Meningitis is a possible diagnosis in a patient presenting with any two of fever, headache, neck stiffness, and confusion, but other features may occur, such as a rash, photophobia, and seizures.
- In children, symptoms may include excessive crying, irritability, bulging fontanelle and apnoea in neonates.
- Meningitis is often life-threatening, particularly in patients with HIV, and in general, there should be a low threshold for investigating for meningitis.
- The differential diagnosis of acute meningitis includes a broad range of bacteria, viruses and fungi.
- Patients with more chronic forms of meningitis have an increased likelihood of atypical presentations, and there should be an even lower threshold for investigating such patients.
- Mycobacterium tuberculosis and Cryptococcus neoformans usually cause chronic meningitis, but an acute presentation can sometimes occur.
- The median duration of TB meningitis symptoms is 12 days, and it is rarely less than 4 days.

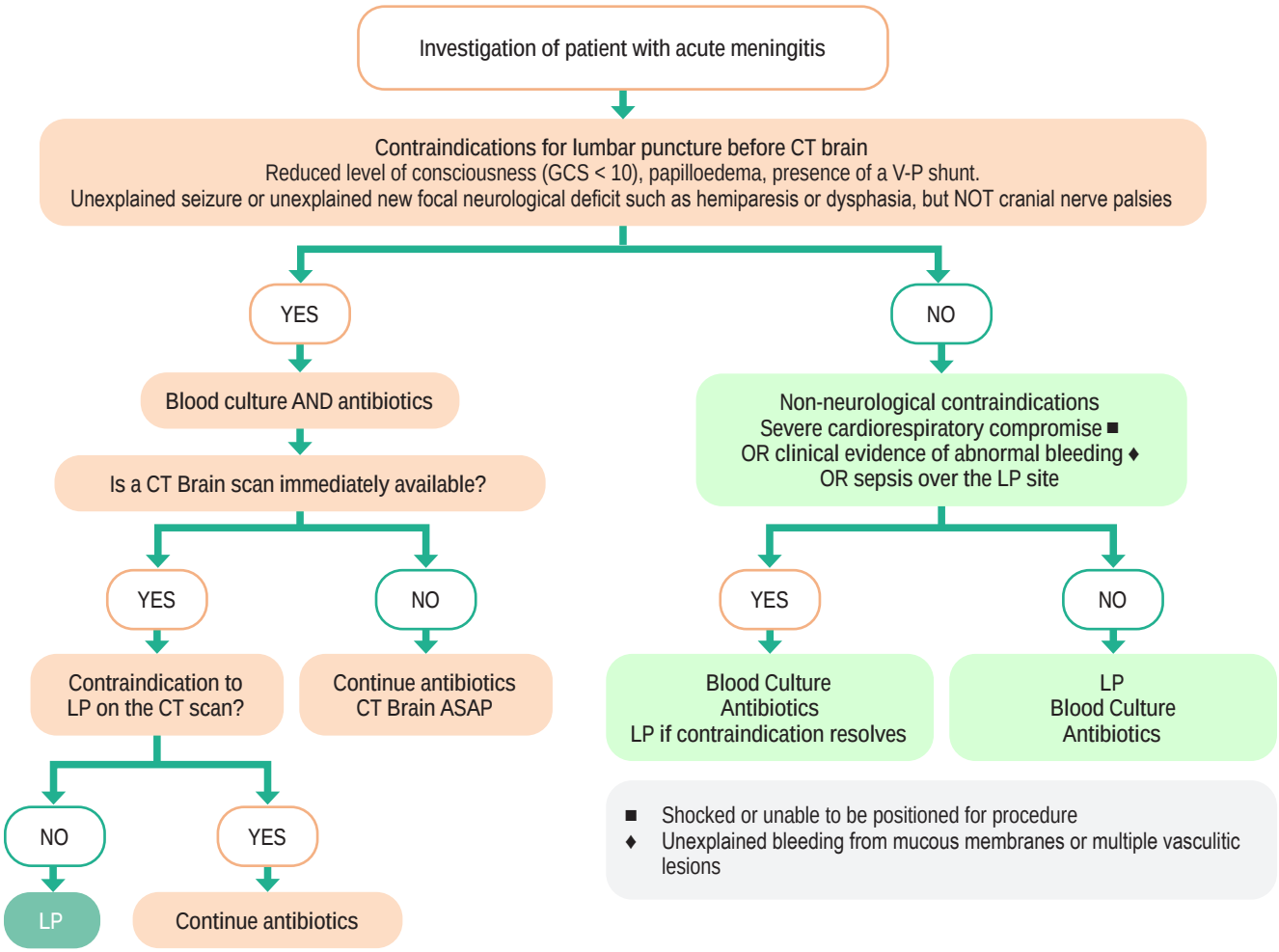


Figure 12: Investigation of a patient with acute meningitis

Source: Tom Boyles, Gary Maartens, Jeremy Nel, David Stead Southern African HIV Clinicians Society Clinical Guidelines for Hospitalised Adults With Advanced HIV Disease 2022

Acute meningitis is a medical emergency and often life-threatening. Antibiotics should not be delayed while waiting for a CT scan.

Initial management of acute meningitis includes the following:

- Administer intravenous ceftriaxone 2 g 12 hourly (or 100 mg/kg once daily in children)
    - Use intramuscular or intraosseous routes if there is no vascular access.
    - Penicillin allergy is not a contraindication to ceftriaxone.
    - Avoid ceftriaxone only if there has been documented cephalosporin anaphylaxis. Instead, give meropenem, IV, 2 g 8 hourly for 7 days.
- If Listeria monocytogenes meningitis is suspected add
    - Ampicillin, IV, 3 g 6 hourly for 21 days.
      AND
    - Gentamicin, IV, 5 mg/kg daily for 7 days (may be prolonged if response is poor).
- In neonates, the addition of ampicillin should also be considered.
- Provide adequate analgesia.
- Corticosteroids are not recommended in a patient with bacterial meningitis.

An approach for making treatment decisions after the first dose of antibiotics, based on the availability of test results over time, is presented in ***Figure 14: Approach to acute meningitis following the first dose of antibiotics on page 83***.

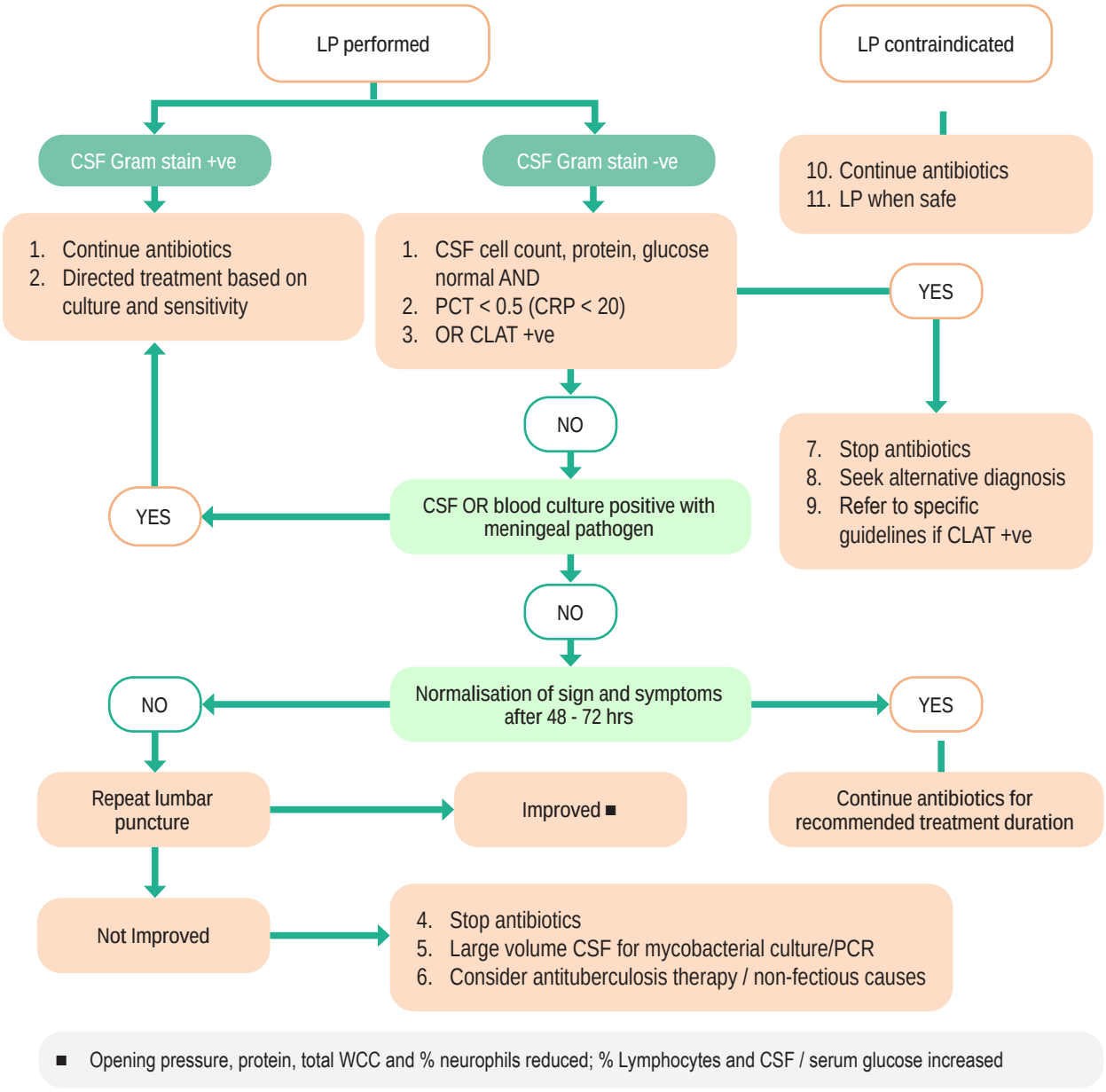


Figure 13: Approach to acute meningitis following the first dose of antibiotics

Source: Tom Boyles, Gary Maartens, Jeremy Nel, David Stead Southern African HIV Clinicians Society Clinical Guidelines for Hospitalised Adults With Advanced HIV Disease 2022

For an approach to a patient with sub-acute/chronic meningitis, see *An approach to sub-acute/chronic meningitis on page 75.*

An approach to a patient with diarrhoea

Diarrhoea is common in AHD, affecting 40-80% of HIV-infected persons not on ART. The resulting dehydration and hypokalaemia is a frequent cause of hospital admission, with significant mortality.

Table 19: Definitions in diarrhoeal disease

Definitions	
Diarrhoea	passing of 3 or more loose/ liquid stools per 24 hours.
Acute diarrhoea	diarrhoea lasting < 2 weeks
Chronic diarrhoea	diarrhoea lasting ≥ 2 weeks.

Table 20: Key features to identify on history & examination of a client with diarrhoea

Key features	
History	Examination
Duration and severity of diarrhoea. Previous episodes.	Hydration status
Stool consistency and presence of mucous or blood.	Blood pressure, pulse
Presence of constitutional symptoms: fever, night sweats, weight loss.	Temperature
Potential drug causes: protease inhibitors, recent antibiotic use.	Signs of TB (adenopathy, chest signs etc.)
Recent travel or possible contaminated water exposure	Abdominal examination: • Tenderness in the left iliac fossa (suggestive of acute colitis) • Other features of generalised tenderness are non-specific
HIV control: if currently taking ARVs, last HIV viral load and CD4	Fundoscopy for features of CMV retinitis (haemorrhages and exudates)

Source: Tom Boyles, Gary Maartens, Jeremy Nel, David Stead, Southern African HIV Clinicians Society Clinical Guidelines for Hospitalised Adults With Advanced HIV Disease, 2022

Table 21: Distinguishing small bowel vs large bowel diarrhoea

	Small bowel diarrhoea (enteritis)	Large bowel diarrhoea (colitis)
History	• Large volume, watery stools • Bland in nature • May have malabsorption • Nausea and vomiting are more common	• Low volume, frequent stools • Red and white cells or mucous • Tenesmus (the feeling of needing to pass stool or urine, even when the bowels or bladder are empty)
Examination	• Often apyrexial	• May be pyrexial • Left iliac fossa tenderness

Treatment doses for children if dysentery is suspected:

Treat initially as Shigella dysentery:

- Ceftriaxone, IV, 100 mg/kg as a single daily dose for 5 days, or
- Ciprofloxacin, oral, 15 mg/kg/dose 12 hourly for 3 days.
- Frequently assess hydration status and be sure to identify signs of severe illness as per Box 2.

If amoebiasis is endemic or demonstrated on stool microscopy:

- Metronidazole, oral, 15 mg/kg/dose 8 hourly for 7 days.
- See also the Paediatric Hospital Level Standard Treatment Guidelines.

Common pitfalls when managing diarrhoea in AHD:

- Mis-diagnosing chronic/intermittent diarrhoea as an acute episode.
- Failing to send stool samples for appropriate stains and therefore missing the opportunity to definitively treat for a specific pathogen e.g., Cystoisospora belli.
- Discharging a severe cryptosporidium case after apparent successful IVI rehydration and potassium replacement to initiate outpatient ART. These patients frequently end up being re-admitted in the same state as before starting their ART. The only treatment for cryptosporidium is immune reconstitution, and hence the urgency for effective and early ART initiation, usually in-hospital, and as soon as contra-indications to immediate ART initiation have been excluded.
- Overuse of loperamide with a protease inhibitor. This can result in severe ileus as the protease inhibitor inhibits loperamide metabolism. A suggested maximum dose is 1 tablet 12 hourly until symptom relief.
- There is no place for antidiarrhoeal medications, i.e. kaolin and pectin, atropine and diphenoxylate, loperamide, or antiemetics in the routine management of acute diarrhoea in children.

The algorithm below provides an approach to the diagnosis and management of chronic diarrhoea:

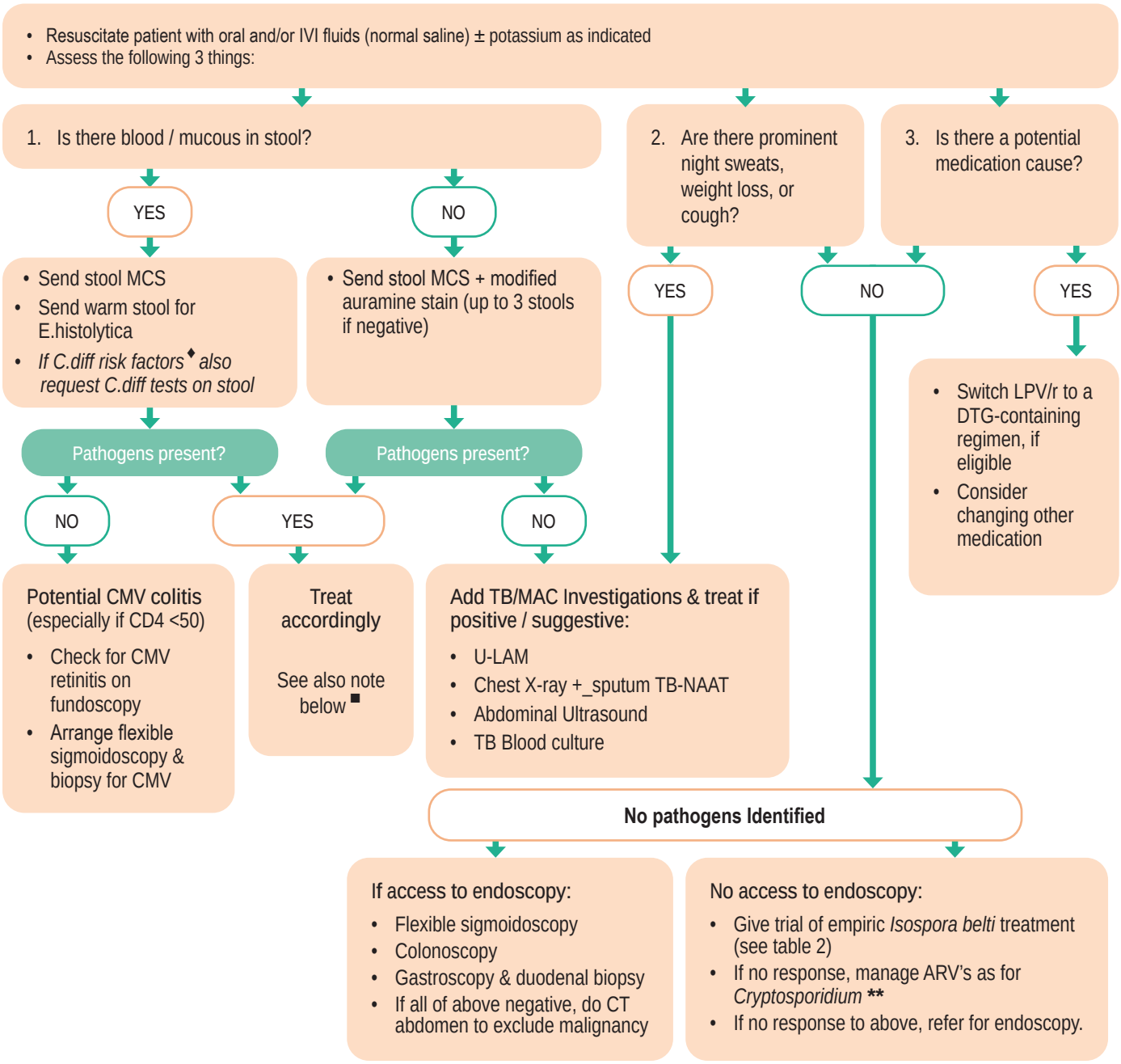


Figure 14: Management of chronic diarrhoea

Source: Tom Boyles, Gary Maartens, Jeremy Nel, David Stead, Southern African HIV Clinicians Society Clinical Guidelines for Hospitalised Adults With Advanced HIV Disease, 2022

An approach to a patient with AHD who is deteriorating despite treatment for an opportunistic infection

A systematic approach is needed for a patient who does not improve on treatment for an opportunistic infection. *Table 22* below outlines the elements to be considered.

Table 22: Elements that may negatively influence improvement on treatment for an opportunistic infection

Problem	Comments	
Drug not getting to 'bug'	Medication not being given appropriately	Check that medications were properly dispensed and administered (to inpatients) or that the patient understood the instructions on how to take the medication correctly.
	Non-adherence	Self-reporting is a poor measure of adherence. Possible reasons for non-adherence, including side effects, non-disclosure, financial stress, or an untreated mental health condition, should be explored.
	Malabsorption	Clients with persistent vomiting and/or diarrhoea may not fully absorb the medications given. Drug levels may occasionally assist in this scenario.
	Drug-drug interactions	Medication effects can be limited by drug-drug interactions, especially with agents such as rifampicin. See also Section xx for more info on drug interactions.
	Difficult	Medications may not always reach adequate levels at the site of infection; for example, anti-tuberculous medications do not always penetrate TB cavities in the lung or abscesses well. In these circumstances, surgery may be indicated.
	Medication being under-dosed for patient weight	Check that the dose is correct for the patient's weight and that it is increased if needed if they gain weight on treatment.
'Bug' resistant to drug	This is less likely if there is confirmed sensitivity (e.g., TB-NAAT with rifampicin sensitivity) and more likely when treatment was either empiric or based on a test that does not identify resistance (e.g., a urine LAM). Seek microbiological confirmation and drug sensitivities.	
Incorrect diagnosis	When empiric therapy has been initiated without microbiological confirmation, always consider if the diagnosis may be incorrect. Examples of common pitfalls include: • Initiating TB treatment based on a positive urine LAM, which may also be indicative of non-tuberculous mycobacterial infections. • Non-infectious conditions such as malignancies (e.g. lymphomas or Kaposi sarcoma) or histoplasmosis mimicking infections in patients with AHD.	
Additional diagnosis	Patients with AHD often have more than one opportunistic infection or concurrent malignancy. Consider the possibility of a second or even third diagnosis.	
Adverse drug reaction	A patient may be responding to appropriate treatment but can appear to have clinical deterioration due to an adverse drug reaction (ADR), e.g., a drug-induced liver injury (DILI). Remember to report ADRs.	
Inappropriate expectations	Some opportunistic infections (OIs) take longer to improve than others and a patient can deteriorate despite appropriate therapy. Severe infections such as TBM and PJP have an approximately 25% mortality rate despite appropriate treatment	
IRIS	• Immune reconstitution inflammatory syndrome (IRIS) is the last consideration. It is common and has been described with multiple antigens, but is a diagnosis of exclusion. • Risk factors for IRIS include a low CD4 count and a shorter duration between initiating treatment for an OI and ART. • Serious forms include TB and cryptococcal meningitis IRIS. • Paradoxical TB IRIS occurs in approximately 18% of patients when initiating ART while taking antituberculous therapy. The most frequent features are pulmonary and lymph node involvement. • There is no specific test for IRIS, but it is rather a diagnosis of exclusion when all of the above have been excluded. • Prednisone 1.5mg/kg given for 2 weeks followed by 0.75mg/kg given for 2 weeks reduces morbidity in patients with non-neurological paradoxical TB IRIS. • There is limited evidence for the use of steroids in other forms of IRIS, and they should, therefore, generally be avoided. • See also ***Immune Reconstitution Inflammatory Syndrome (IRIS) on page 104***	

Source: Tom Boyles, Gary Maartens, Jeremy Nel, David Stead Southern African HIV Clinicians Society Clinical Guidelines for Hospitalised Adults With Advanced HIV Disease 2022

Additional resources

Please see the following additional resources to treat specific pathogens and syndromes in adults, adolescents and children not already covered.

- Hospital level (Adults) Standard Treatment Guidelines and Essential Medicines List 6th ed. 2024
- Paediatric Hospital-level Standard Treatment Guidelines and Essential Medicines List for South Africa. 5th ed. 2023.

Step 4 Prevent OIs

STEP 4 Prevent OIs	Provide **cotrimoxazole prophylaxis** therapy if eligible (see Table 23) Provide TPT if TB has been excluded and eligible for TPT (see Table 25)

Cotrimoxazole Preventive Therapy (CPT)

Co-trimoxazole is a fixed-dose combination of two antimicrobial agents, namely sulfamethoxazole (SMX) and trimethoprim (TMP). CPT is used to treat various bacterial, fungal and protozoal infections, particularly PJP and toxoplasmosis.

The baseline clinical evaluation allows the patient's WHO clinical stage to be determined. The WHO clinical stage and the CD4 count (or CD4 percentage in children under five) will determine the patient's eligibility for cotrimoxazole preventive therapy (CPT). Counsel women that CPT is safe to use during pregnancy.

Cotrimoxazole hypersensitivity is common and usually presents as a maculopapular rash. If there are systemic features or mucosal involvement associated with the use of cotrimoxazole, stop the medicine immediately and permanently, and refer the patient to hospital

Table 22 below provides the indications for starting and stopping CPT in infants, children, adolescents, and adults living with HIV.

Table 23: Indications for starting and stopping Cotrimoxazole Preventive Therapy (CPT)

Age	When to start	When to stop
HIV-positive infant under 1 year	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%, or WHO Stage 3 and 4	Discontinue if CD4% > 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 after that only if CD4 > 200 cells/µL
HIV-positive adults and children older than 5 years, including pregnant and breastfeeding women	CD4 ≤ 200 cells/µL, or WHO Stage 3 or 4	Discontinue if CD4 > 200 cells/µL regardless of clinical stage

CPT at ART initiation

Most patients that initiate CPT will do so around the time of initiating ART, and will continue CPT until their CD4 count done around 10-12 months on ART is more than 200. Certain clients may qualify for CPT based on their clinical stage, even though their CD4 count at CPT initiation was above 200. Such clients may stop CPT after receiving 6-12 months of ART, regardless of clinical stage and provided their viral load is suppressed.

CPT in patients already on ART

Patients on ART who develop AHD with either a CD4 less than 200 or a new WHO Stage 3 or 4 condition while on ART may need to re-initiate CPT. CPT should be continued until their next CD4 count (see Box 4) is more than 200. Certain clients may develop AHD based on their clinical stage (a new WHO Stage 3 or 4 condition), even though their CD4 count at CPT initiation was above 200. Such clients may stop CPT after receiving 6-12 months of ART, regardless of clinical stage and provided their viral load is suppressed.

Box 11: WHO clinical staging before and after ART initiation

Determining a patients WHO clinical stage helps us to understand the severity of a patients condition. It gives an indication of the patients level of immune suppression, and will therefore not improve until the patient initiates ART. The purpose of ART is to restore the patients immune function and it is therefore expected that a patient's clinical condition, and therefore their clinical stage, should improve once ART is initiated. It is therefore helpful to consider a patient's WHO Clinical Stage in two categories:

The pre-ART WHO clinical stage:

- This will not improve until ART is initiated, as their immune function cannot be restored until ART is initiated.

The WHO clinical stage after ART initiation:

- This may fluctuate based on the level of adherence and the effectiveness of the patient's ART regimen.
- It is expected to improve on effective ART. However, a new stage 3 or 4 condition in a previously well patient on ART indicates AHD and requires urgent intervention.

The patient's clinical stage should be determined and documented whenever the patient receives a clinical assessment by a clinician.

Table 24: CPT dosing chart

Recommended daily dose by weight band	Dose of sulfa-methoxazole / trimethoprim	Suspension (200/40 mg per 5 mL)	Single strength tablet (400/80 mg)
3 to 5.9 kg	100/20 mg	2.5 mL	¼ tablet
6 to 13.9 kg	200/40 mg	5 mL	½ tablet
14 to 24.9 kg	400/80 mg	10 mL	1 tablet
≥ 25 kg	800/160 mg	-	2 tablets

TB Preventive Therapy

- PLHIV are more susceptible to TB infection than HIV-uninfected persons at any CD4 count.
- TPT is an effective intervention for reducing the incidence of TB in PLHIV.
- All patients starting ART or already on ART who have not yet received TPT should be considered for TPT.
- Before initiating TPT, active TB should be ruled out through a clinical evaluation and by testing for TB. See *Figure 9: Systematic screening for tuberculosis on page 69.*
- If a patient is clinically well and has no TB symptoms, there is no need to wait for the test results before 1) initiating/re-initiating ART or 2) initiating TPT if the patient is eligible for TPT. See *Table 25: TB screening and TPT eligibility on page 89*.
- ART and TPT can be started on the same day
- 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 required 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.
    - If the patient is asymptomatic, TPT initiation need not be delayed if TB NAAT results are outstanding.
- Other contraindications to TPT include active liver disease, alcohol abuse, painful peripheral neuropathy, previous MDR- or XDR-TB, known hypersensitivity to INH and pregnancy.
- A Tuberculin skin test (TST) is not required before starting TPT.

Table 25: TB screening and TPT eligibility

	TB symptom screen (and tests for TB if symptoms present)	Systematic TB screen (symptom screen and tests for TB regardless of TB symptoms)	Eligible for TPT if TB ruled out (and no other contra-indications to TPT)
All non-pregnant persons LHIV, including adults, adolescents, children, infants > 14 weeks of age, and breastfeeding women			
At HIV diagnosis/ART start		Yes	Yes
New diagnosis of advanced HIV disease		Yes	Yes
Significant TB exposure		Yes*	Yes
Well patient on ART at annual clinical review		Yes	Only if never received TPT in the past or new TB exposure
For all pregnant patients LHIV (see *Box 12: TPT in pregnancy on page 89below).*			
Pregnant at 1st ANC visit		Yes	Yes, if CD4 ≤ 200 cells/mm^3 or WHO stage 3 or 4 If > 200 cells/mm^3 defer TPT till after delivery
Pregnant at follow-up ANC visit	Yes	No (unless also included in one of the above categories)	
Other			
TB-exposed neonate		Yes*	
Health system encounter for any PLHIV (not included in one of the above categories)	Yes	No	Only if never received TPT in the past or new TB exposure

** In a TB-exposed child with no TB signs or symptoms, a CXR and sputum testing are not required to initiate TPT. If available and if it can be interpreted on-site, a CXR can be used to rule out TB. The inability to do a CXR or sputum test should not delay TPT initiation.*

Box 12: TPT in pregnancy

Because pregnant women with AHD are at significant risk of TB and the associated adverse health outcomes, the recommendations for TPT in pregnancy have been aligned with the recommendations for TPT in clients with AHD

- Pregnant women with CD4 counts ≤ 200 cells/mm^3 should receive 12 months of IPT after exclusion of active tuberculosis disease.
- In pregnant women with CD4 counts > 200 cells/mm^3, IPT should be deferred to the post-partum period.
- In the absence of TPT initiation, continued active screening for TB throughout pregnancy must be prioritised

Table 26: TPT dosing chart

Regimen		
Adults and adolescents LHIV, including children ≥ 25kg initiating DTG-containing ART	• 12H • Isoniazid, oral, 300 mg daily for 12 months	• This is the preferred regimen for adults and adolescents initiating a DTG-containing ART regimen • Add Pyridoxine, oral, 25 mg once daily for 12 months
Adults and adolescents LHIV who are: • ≥ 25 kg • virally suppressed on a DTG-based regimen	• 3HP • A weekly combination of isoniazid (900mg if weight >25 kg) plus rifapentine (900mg if weight >25 kg) for three months	• For patients who are already virally suppressed on a DTG-based regimen • 3HP should NOT be used in new patients initiating a DTG-containing regimen • Do not use rifapentine-containing TPT in patients on protease inhibitor (PI) -based ART or in women on oral or injectable contraceptives.

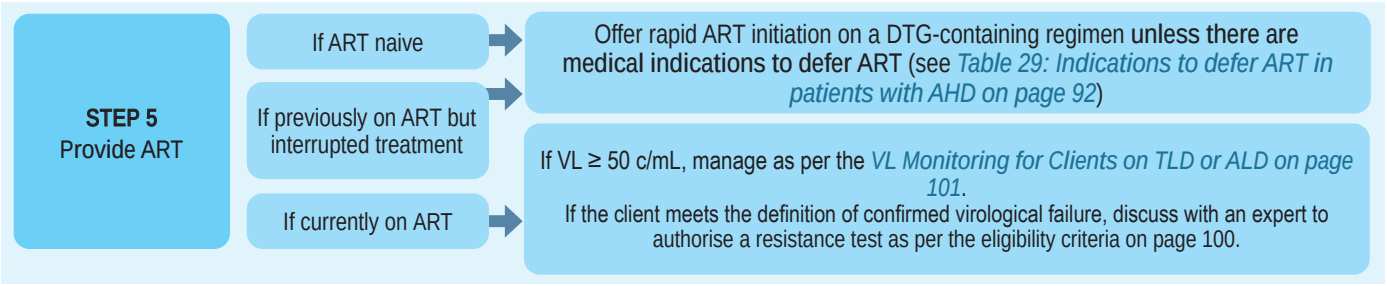
Infants and children LHIV < 25kg	• 6H
	• Isoniazid, oral, daily for 6 months
	• See dosing chart in *Table 27: Recommended daily dosages for 6H amongst children LHIV < 25kg on page 90*
		• Add pyridoxine orally, once daily for 6 months
		  • < 5 years: 12.5 mg daily
		  • ≥ 5 years: 25 mg daily

Table 27: Recommended daily dosages for 6H amongst children LHIV < 25kg

Weight band (kg)	Daily INH 100mg tablet	Duration
2 - 3.4	¼ tablet	6 months
3.5 - 4.9	½ tablet	
5 - 7.4	¾ tablet	
7.5 - 9.9	1 tablet	
10 - 14.9	1½ tablet	
15 - 19.9	2 tablets	
20 - 24.9	3 tablets (or one 300mg tablet)	
≥ 25	Use adult formulations (maximum dose 300 mg per day)	

- Educate patients on the symptoms of hepatotoxicity (nausea, vomiting, yellow eyes, brown urine, and pain in right upper quadrant).
- Instruct the patient to present early if any of these symptoms arise.

Step 5 Provide ART



Clients with AHD should receive a differentiated package of care depending on their profile and individual clinical condition.

Table 28: Differentiated care depending on ART status

ART status	Elements of care
If ART-naive	• Offer rapid ART initiation on a DTG-containing regimen unless there are indications to defer or discontinue ART (See *ART Initiation on page 27*). • Provide all additional care as applicable to any new patient initiating ART, including routine baseline blood tests and Fast Track Initiation Counselling (FTIC) as per DMOC SOP 1.
If previously on ART but interrupted treatment	• Manage as per the *Re-engagement Algorithm on page 34.* • Offer rapid ART initiation on a DTG-containing regimen unless indications to defer or discontinue ART (See *ART Initiation on page 27*). • Do an in-depth assessment of the reasons for interruption, with support and clinical care tailored accordingly.
If currently on ART	• If VL > 50 c/mL, manage as per the *VL Monitoring for Clients on TLD or ALD on page 101*. • If the patient meets the definition of confirmed virological failure, discuss with an expert to authorise a resistance test per the eligibility criteria on page 100. Assess carefully for poor adherence. They are likely to need adherence support tailored to their specific needs.

Abbreviations: ART, antiretroviral therapy; DMOC, differentiated models of care; DTG, dolutegravir; SOP, standard operating procedure

Dolutegravir (DTG) in combination with tenofovir (TDF) and lamivudine (3TC), in the fixed-dose combination known as TLD, is the optimised regimen of choice in adults and adolescents ≥ 10 years of age and weighing ≥ 30 kg, provided the patient has normal renal function.

With few exceptions, DTG-containing regimens are preferred for all patients First-Line ART Regimens in Adults, Adolescents, Pregnant Women, Children, Infants, and Neonates (see *First-Line ART Regimens on page 33*).

- All ART naïve patients and patients re-initiating ART after previously interrupting ART should be initiated on a DTG-containing regimen.
- Patients on ART who have not yet been transitioned to a DTG-containing regimen should be evaluated and transitioned as a matter of urgency. See *Switching Existing Clients to DTG-containing Regimens (Adults, adolescents or children who have never used a DTG-containing regimen in the past) on page 37.*

Important considerations when providing ART to patients with AHD

- Certain opportunistic infections may affect the **timing of ART initiation**. See *Table 29: Indications to defer ART in patients with AHD on page 92*.
- Certain AHD or ACC conditions may affect **drug selection** in patients initiating or established on ART, for example:
    - To provide a once-daily regimen and avoid drug interactions, a patient diagnosed with DS TB may have the option to initiate an efavirenz (EFV)-containing regimen, provided they are ART naïve or already suppressed on an EFV-containing regimen.
        - This will be a temporary regimen that will be used only as long as the risk for **drug-drug interactions** between rifampicin and DTG persist.
        - The client should be transitioned to a DTG-containing regimen 2 weeks after completion of their TB treatment
        - See also Co-treatment of HIV and Active TB in Neonates, Infants, Children, Adolescents and Adults on *Co-treatment of HIV and Active TB in Neonates, Infants, Children, Adolescents and Adults on page 35*.
    - In a patient with an eGFR < 50, TDF should be replaced with abacavir (ABC)
    - In a patient with an eGFR 30-50 and HBV co-infection, TDF should be replaced with tenofovir alafenamide fumarate (TAF), if available. Alternatively, dose-adjust TDF according to *Table 35: ART drug dosage adjustments in renal failure on page 107*.
- Multiple medications to treat HIV and other conditions may result in drug-drug interactions:
    - Rifampicin-containing TB treatment has significant drug interactions with all paediatric ART regimens, as well as with adult/adolescent regimens containing DTG and PIs.
    - Anticonvulsants may decrease DTG concentrations in the blood
    - DTG increases metformin concentrations.
    - See *Drug Interactions with DTG on page 32.*
    - **Side effects** may be exacerbated due to overlapping toxicities, e.g. hepatic or renal toxicity.
- **Adherence** can be affected due to increased pill burden, increased side effects, and the cost of multiple clinic visits. See also *Table 30: Adherence support plan for clients with AHD: Key components on page 94.*

Considerations for RR-TB/HIV co-infected patients

- To improve the chances of RR-TB treatment success, all persons co-infected with RR-TB and HIV should receive ART to suppress their VL.
- The short and longer DR-TB regimens may both be offered to persons with HIV, and HIV status alone does not mandate any changes in the DR-TB regimen composition.
    - Dolutegravir can be used concurrently with all currently recommended RR-TB medications
    - TLD is well tolerated and minimises the additional pill burden due to ART (TLD is one tablet once a day).
    - ABC, 3TC and DTG (ALD) can be used in children 3kg and > 4 weeks of age to < 10 years of age or weighing < 30 kg. Paediatric DTG 10 mg dispersible tablets are available for children weighing < 20 kg.

Table 29: Indications to defer ART in patients with AHD

Indication	Action
Diagnosis of drug-sensitive (DS) TB at a non-neurological site (e.g. pulmonary TB, abdominal TB, or TB lymphadenitis)	Start with TB treatment first, followed by ART initiation according to CD4 count (except TB meningitis – see below): • CD4 <50 cells/μL: initiate ART within two weeks of starting TB treatment. • CD4 ≥50 cells/μL in adults and adolescents: defer ART until 8 weeks after starting TB treatment, which does not increase the risk of mortality and reduces the risk of deterioration due to IRIS • CD4 ≥50 cells/μL in children: ART should be started as soon as TB treatment is tolerated - ideally within two weeks after starting TB treatment unless there is TBM/CNS TB
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 initiating TB treatment.
Cryptococcal meningitis	Defer ART until 4–6 weeks after starting antifungal treatment (earlier initiation has been shown to increase the risk of death).
Positive CrAg and no evidence of meningitis on LP	No need to delay. ART can be started immediately.

Step 6 Provide other care

STEP 6
Provide other care

Provide other care as appropriate for mental health, NCDs, SRH services, immunisations, and other care as per RTHB or maternity care guidelines. When indicated, provide **palliative care**.

Clients with AHD may be pregnant, have known chronic conditions, or have undiagnosed co-morbidities that may impact their AHD management. These conditions should be identified and appropriately managed. The urgency of providing other care will depend on the patient's clinical condition and the clinician's clinical discretion.

The following elements should be screened for and managed as indicated:

- Pregnancy and the need for contraception
- Sexually transmitted infections (STIs)
- Depression, other mental health issues or substance abuse
- Any major chronic non-communicable diseases (NCDs) (diabetes, hypertension, epilepsy, cervical cancer)
- Immunisations, growth monitoring and other care for children as outlined in the RTHB
- Palliative care: some patients may warrant elements of palliative care, including symptom management, pain relief, emotional, psychological and spiritual support, social support, comfort care, end-of-life care, and family and caregiver support leveraged from the hospital, PHC and community level resources.

Remember that several conditions can co-exist in the same patient with AHD!
Other comorbidities may be missed if there is a narrow focus on only one illness.

Step 7 Support adherence

STEP 7 Provide adherence support	Offer intensified adherence support for OI medication, ART, and condition monitoring. Counsel about IRIS, warning signs and side-effects to look out for, and when to return (DMOC SOP 9). Involve the client's family in the plan for treatment and follow-up.

Treatment adherence is crucial to treatment success. However, clients with AHD may experience greater difficulties with adherence for the following reasons:

- Patients with AHD may be clinically unwell and physically weakened, which may make it difficult for them to take their treatment. These clients may require admission or home-based care
- Treating HIV and other opportunistic infections or other AHD conditions at the same time may result in:
    - Increased pill burden
    - Drug side effects or unpalatable medicines.
    - The additional cost of clinic visits to the patient or family, e.g. transport, loss of income, cost of paying another person to take on social responsibilities, especially if care is not provided in an integrated and coordinated manner.
- Patients with AHD may have undiagnosed and untreated mental disorders, especially depressive, anxiety and substance use disorders
- Clients may have developed AHD due to previous challenges with accessing facilities, leading to treatment interruptions.

Developing an adherence support plan

- Each patient identified with AHD requires an individualised adherence plan guided by the components set out in *Table 30: Adherence support plan for clients with AHD: Key components on page 94* and detailed in DMOC SOP 9 (See *Annexure 12 on page 188*)
- A clinician should lead the adherence support, but components such as AHD treatment literacy and counselling can be delegated to a trained counsellor (if available) with oversight from the clinician.
- Always approach your patient with kindness, respect, and a nonjudgmental attitude. Use patient-centred communication (See Box 13) to create a safe, nonjudgmental space for your patient to discuss challenges.
- Document the adherence support plan in the file.

Box 13: Patient-centred care

Patient-centred care is the practice of caring for patients (and their families) in holistic ways that are meaningful and valuable to the individual patient. Patient-centred care is care that:

- Listens to and involves patients/caregivers in their care
- Respects the patient/caregiver's values, preferences, concerns and expressed needs
- Creates a safe and non-judgmental space for patients to discuss their challenges.
- Provides information and education, emotional support and alleviation of fear and anxiety
- Coordinates and integrates care
- Supports access to and continuity of care as well as transition of care if needed

Good communication is essential to providing patient-centred care. It enhances the healthcare worker-patient relationship and improves adherence. Good patient education results in the following:

- An informed patient/caregiver
- An empowered patient/caregiver
- A less fearful patient/caregiver
- Better treatment outcomes

Table 30: Adherence support plan for clients with AHD: Key components

Adherence support plan for clients with AHD	
AHD treatment literacy • Explanation of AHD (WHO stage or low CD4) and increased risk of morbidity and mortality • Importance of intensified clinical management with more regular visits/check-ins to identify any deterioration for 3 months • Importance of monitoring (by the patient and their supporter) for warning signs and returning to the clinic or going to the hospital • Provide information regarding medication side effects and IRIS.	*DMoC SOP 9 on page 188*
Home support network • Identify and document the client's chosen family or friend supporter and their contact details • Ensure the identified supporter also receives information on AHD and how they can support the patient, including monitoring for warning signs and assisting with clinic attendance or hospital admission	
Adherence and disclosure counselling • If newly initiated, provide Fast Track Initiation Counselling (FTIC) as per DMOC SOP 1 • If already on ART but struggling with adherence, provide Enhanced Adherence Counselling (EAC) as per DMOC SOP 2. • For children, provide disclosure counselling when appropriate as per DMOC SOP 3. • Include adherence to OI medication	DMOC SOP 1-3 NDoH adherence plan
Mental health screening and referral • Ensure mental health screening has been done as detailed in Step 6. • Refer for further assessment and treatment if necessary	*Mental Health Assessment on page 179*
Document main adherence barriers and plan • Document the main barriers to adherence • Document a plan to address the main barriers to adherence	
Identify the patients' preferred mechanisms for support • Discuss and document the patient's chosen methods for support, depending on what is available. Potential options include: a family member or friend to check in daily or weekly; WhatsApp communication with clinician/counsellor/linkage officer; WhatsApp or in-person support group; check-in phone calls; CHW home visits; or CBO other community actor check-ins.	Each facility to identify possible support approaches
Psychosocial support referrals • Refer as appropriate for counselling or to a psychologist or social worker for assistance with food parcels, SASSA grants, ID documents, SAPS for safety, etc.	Referral SOPs
Document the agreed follow-up visit schedule and the format of the follow-up interaction e.g. in person or telehealth check-in or home visit • 1st follow-up visit (date and format) • 2nd follow-up visit (date and format) • 3rd follow-up visit (date and format)	Step 9
Tracing and recall • Discuss and get consent to phone the patient and/or visit them at home if they miss an appointment (especially in the first 3 months) or if they need to be recalled to the clinic for management of abnormal test results • Verify and update the client's contact number and residential address	DMOC SOP 7 See further detail in Step 9

Patients who have their family or other support persons involved in their adherence support plan have better retention in care and better treatment outcomes

Additional considerations for patients already on ART

The development of advanced HIV disease in a patient on ART should raise a 'red flag' to alert the clinician to adherence problems. If a patient has developed immunological failure, with or without clinical failure, despite being on ART, the **standard mechanisms for adherence support have been insufficient for this patient**. With additional treatment needed for AHD conditions on top of routine ART, these patients may struggle to adhere and will require intense and individualised support and close follow-up.

Adherence to ART should be assessed by:

- Doing a viral load: a suppressed VL is the most sensitive indicator of good adherence.

If not suppressed:

- The patient requires a thorough ABCDE assessment and management as detailed on *page 44*.
- Identify and understand the factors that negatively influence adherence, as listed in Box 14.
- Remember to ask open-ended questions, e.g. "What makes it difficult for you to collect or take your treatment?"
- Always approach your patient with kindness, respect, and a nonjudgmental attitude. Patients who feel judged, criticised, or misunderstood will unlikely remain engaged in care.
- Provide enhanced adherence counselling (DMOC SOP 2) and Disclosure counselling (DMOC SOP 3), if indicated.

Box 14: **Factors that may negatively influence adherence**

- Direct cost of clinic visits to patients, 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
- Medication side-effects
- Unpalatable medications
- Depression or other mental health conditions
- Alcohol or substance abuse
- Poor social support and/or GBV
- Non-disclosure and/or HIV-associated stigma
- Pregnant women may experience nausea/vomiting, heartburn, and constipation. Assess the need for symptomatic treatment with an anti-emetic, anti-diarrhoea agent or fibre supplement.
- Alternative medical, religious or cultural beliefs

Step 8 Ensure continuity of care between the hospital and clinic

STEP 8
Ensure continuity of care between hospital and clinic

Clinicians at PHC should have a low threshold for admission or re-admission to hospital. Assign a clinic staff member to do check-in phone calls or CHW to do home visits weekly for first month and support continuity of care.

At discharge from the hospital provide a discharge plan with follow-up appointments at PHC. Also promote continuity of care at OPD/PHC through locally established mechanisms, such as phone calls to the **clinic. Assign linkage officer/community liaison officer** where available.

Ensuring continuity of care for patients up-referred from the PHC level

- High-risk patients with AHD have an increased risk of morbidity and mortality. Clinicians should have a high index of suspicion for underlying opportunistic infections, especially in patients with very low CD4 counts (e.g., CD4 < 50). Utilise the APC Clinical Tool and promptly refer to a doctor when needed.
- Maintain a low threshold for admission or re-admission to hospitals.

The following mechanisms should be employed to promote continuity of care at primary care level:

- PHC facilities should have clear referral protocols and lines of communication for any patient needing a higher level of care, including those with AHD or those being referred to specialised care within the same facility, e.g., mental health services.
- PHC facilities should write comprehensive referral letters that include the elements outlined in Box 15.
- Where feasible:
    - Call the receiving clinician to arrange the referral
    - Confirm with the patient or family/friend supporter that the patient reached the referral facility and received the services.

Ensuring continuity of care from the hospital level back to the PHC level

- The treating clinician should write a detailed discharge summary that includes the elements outlined in Box 16.
- Explain the diagnoses and discuss and agree on the management plan with the patient and their family or treatment supporter where appropriate. Patients who have their family or other support persons involved in their discharge plan have better retention in care and better treatment outcomes. The family should be informed about the following:
    - The patient's take-home treatment
    - When and where the patient requires follow-up visits
    - How to recognise danger signs
    - Where to take the patient if they become unwell again
- Ensure that the patient reaches the down referral facility and continues care at the appropriate level by making appointments and/or assigning a linkage officer/community liaison officer, where available, to follow up telephonically with the receiving facility, the patient or both.

Ongoing management of a patient recently discharged from hospital to PHC level

- Clinics must make every effort to follow the discharge plan from the hospital, including checking in with patients that they have attended hospital-scheduled follow-up appointments.
- Continue to supply medication and support adherence to medication.
- Provide any advanced clinical care indicated by the hospital.
- Update or, if not yet done, develop an adherence support plan for the client (step 7).
- Employ a low threshold for referral back to the hospital (see step 8 above).

Box 15: PHC referral letters

PHC referral letter should contain the following information:

- Reason for referral:
    - ➞The presenting complaint, duration, associated signs and symptoms, and
    - ➞The suspected diagnosis
- HIV history:
    - ➞Date of diagnosis,
    - ➞Date of ART initiation
    - ➞Current ART regimen and its start date, previous regimens and dates taken, reasons for switches (treatment failure, poor adherence, side effects)
    - ➞Latest monitoring test results (viral load, CD4 count, and eGFR), and
- The findings of any previous resistance test/s.
- Estimated level of adherence
- Psychosocial circumstances and factors affecting adherence.
- Other known comorbidities and medications, whether they are well controlled or not.
- Pregnancy status, if female
- Other investigations done to date, with laboratory barcodes/references or results if available.
- Management and treatment provided to date, if relevant
- Name and contact number for referring clinician

Box 16: Hospital discharge summaries

Hospital discharge summaries should contain the following information:

- All diagnoses (chronic and acute) and the results of relevant investigations.
- Details of management provided in hospital, including:
    - ➞HIV and ART management. If ART regimens have been changed, note why and whether the change is permanent or when it can change back.
    - ➞Management of opportunistic infections, including treatment regimens and doses
    - ➞Management of any complications or side effects which developed
    - ➞Management of any co-morbidities
- The patient's state on discharge (to allow the nurse to assess whether the patient is improving or deteriorating).
- A detailed plan for care after discharge, including:
    - ➞Medication that needs to be continued after discharge, for how long the medication needs to be taken, and at what dose. Pay particular attention to continuing treatment for opportunistic infections such as Cryptococcal disease and TB, which have different phases.

- For the consolidation and maintenance phases of cryptococcal disease, indicate the dose and duration of fluconazole to be used, as well as the intended start and stop dates for each phase (see a template for inclusion in the discharge summary in Annexure 1 CrAg positive management summary)
- For TB, use the available TB patient card. In children, be sure to provide the disease severity classification and whether or not the child is potentially eligible for treatment shortening

→ The plan for multidisciplinary team involvement, if indicated
→ Clinic- and community/home-based care recommendations,
→ The recommended frequency of follow-ups at the clinic;
→ If relevant, the plan for follow-up appointments at the hospital (where possible, pre-book the follow-up appointments and provide the dates on the discharge summary).

- The expected prognosis
- The signs and symptoms that would require urgent management or referral back to hospital (where possible, give details of which clinician or department to call or go to, should the patient deteriorate).

Step 9 Provide intensified follow-up

STEP 9
Provide intensified follow-up

At PHC/OPD, provide **two-weekly** (previously admitted / psychosocially vulnerable) **or monthly follow-ups for the first three months.** Ensure that missed appointments can be identified and prioritize these clients for tracing and recall to the facility if they are missed. Ensure provision of any Step 6 or 7 elements that were not provided by the hospital.

Follow hospital discharge plan and ensure hospital follow-up appointments. Provide any advanced clinical care as indicated by the hospital. **Refer back to hospital for assessment and re-admission if patient deteriorates clinically**

Why intensified follow-up

- Clients with AHD are at higher risk of clinical deterioration, including the development of IRIS, especially during the initial months after initiating or re-initiating ART.
- Clients with AHD may need to be reviewed more frequently than the standard intervals of "1 dispensing cycle (DC) after ART initiation" and 2 months later at "3 DCs after ART initiation."

Determining the required visit frequency for a client with AHD

- If a patient is being treated for an active OI, additional clinical "check-ins" should be considered to ensure that OI medication and ART are adhered to and that there is no clinical deterioration.
  - These clients should be seen at least **monthly**, whether in person, via phone calls or WhatsApp check-ins, or through community home visits.
  - In cases where the client is particularly vulnerable, interactions may need to be as frequent as **two-weekly**, at least for the first month.
- If a client has been assessed not to have any active OIs or any other indication for more frequent monitoring, telehealth check-ins or community visits may be considered.
- When a clinically well client has an elevated viral load or is re-engaging in care, appointment frequency should be determined based on required clinical management needs. Such patients can be offered three-monthly clinical reviews and aligned ART refills to support retention and viral suppression (DMOC SOP 4.1 3MMD).
- The factors in the table below should be considered to determine an appropriate appointment schedule for the first three months after AHD has been identified:

Table 31: Factors to consider when determining an appointment schedule for clients with AHD

Indications for increased patient interactions
• Recent hospital admission
• Current OIs that require increased clinical management
• Psychosocial vulnerability, e.g., an unstable home environment and/or mental health challenges
• Limited family/social support in the home environment who can monitor and respond to warning signs
• Poor treatment literacy and poor understanding of their AHD condition
• The health facility has limited telehealth/community support systems in place to carry out telehealth check-ins or home visits

Indications for the standard level of interactions or using additional telehealth interactions
• No OIs identified and clinically well
• The patient experiences difficulties in getting to the clinic (cost, work, social responsibilities, mobility)
• Strong family or social support in the home environment who can monitor and respond to warning signs
• The health facility has effective telehealth/community support systems in place to carry out telehealth check-ins or home visits, and the patient has consented to such interactions
• Good treatment literacy and good understanding of their AHD condition

Ensuring continued engagement in care

- Discuss the proposed follow-up schedule with the patient. Agree on the nature of the interactions, i.e., visit to the facility, phove call check-in, or home visit.
- Document the patient's consent to receive a home visit or a telehealth check-in if consent is given.
- Document the agreed appointment schedule in the patient folder. Update the contact details (telephone number and address) of the patient and any identified family member or other support person.
- Ensure that missed appointments, including phone calls or home visits where the patient could not be contacted, can be identified.
- Every effort should be made to trace all patients with missed appointments and/or abnormal results as per DMOC SOP 7. However, if resources are limited, priority should be given to those patients who started or restarted ART in the last six months with AHD and those with abnormal investigation results.

Additional support interventions

Depending on available resources and capacity, facilities may consider the following additional support interventions for clients identified with Advanced HIV Disease (AHD) during the vulnerable first three months:

- Ward-Based PHC Outreach Team (WBPHCOT) Engagement
    - Involve the WBPHCOT in follow-up plans and home visits. This includes monitoring for warning signs, maintaining ongoing communication, and coordinating with the facility if urgent action is needed.
- AHD Emergency Support WhatsApp Line
    - Where possible, establish a WhatsApp number managed by an AHD-trained clinician to provide urgent advice on warning signs to patients and their families and guidance on when to attend the clinic or hospital.
- AHD-Focused Clinics
    - Designate specific days for AHD-focused clinics to ensure the availability of an AHD-trained clinician and provide AHD-focused treatment literacy and psychosocial support. Ensure these clinics do not limit clients' access to services on other days.
- AHD Support Groups
    - Facilitate in-person or virtual support groups to increase AHD treatment literacy, provide peer support, and help clients and their families navigate the challenges of AHD. These could be run on the same day as AHD-focused clinics.
- Enhanced Case Management
    - Designate individuals to act as case managers who support clinicians by enhancing care coordination for vulnerable patients with AHD.
    - Case managers ensure that:
        - virtual check-ins are completed,
        - patients have attended hospital follow-up appointments,
        - WBPHCOT teams are undertaking necessary home visits,
        - missed appointments are identified,
        - tracing and recalls are done,
        - patients and their supporters can reach their clinicians when concerned about warning symptoms.

5 ART-specific conditions that may need advanced clinical care

HIV drug resistance

- Resistance mutations to dolutegravir (DTG) are rare in patients on first-line DTG-containing regimens (TLD 1 and ALD 1)
    - The high genetic barrier to resistance, combined with the other benefits of DTG, including its high potency, minimal side-effect profile, good tolerability, and low pill burden, make it the most likely regimen for patients to achieve and maintain viral suppression in the long term.
    - If other reasons for an unsuppressed VL have been addressed or excluded, e.g., drug interactions and the patient 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. The majority of these patients will re-suppress on TLD if adherent.
- InSTI resistance mutations to second and third-line DTG-containing regimens remain uncommon. However, recent HIV drug resistance surveillance indicates that InSTI resistance mutations can occur sooner than for patients on a PI regimen and before a patient has been on DTG for two years.
- However, there should be no empiric switches from DTG to a PI-containing regimen. Switches off DTG should only be made if DTG is confirmed to be inactive due to InSTI mutations, confirmed by a genotypic resistance test.

Table 32: Definitions of first, second and third-line dolutegravir-containing regimens

	Previous ART exposure	Regimen
First-line DTG-containing regimens	• ART-naïve patients who initiated ART on a DTG-containing regimen • Patients who were **switched** to DTG from a first-line non-DTG-based regimen (e.g., TEE or ABC/3TC/LPV/r) with a VL < 50 c/mL in the 12 months prior to switching	Tenofovir/lamivudine/dolutegravir [TLD 1] Abacavir/lamivudine/dolutegravir [ALD 1]
Second-line DTG-containing regimens	• Patients who were **switched** to DTG from a first-line ART regimen (NNRTI or PI-based) with a **VL ≥ 50 c/mL** • Patients who were **switched** to DTG **from a second-line PI-based ART regimen** with a VL < 50 c/mL in the 12 months prior to switching • Patients who were switched to DTG from a **PI-based regimen** with a **VL ≥ 50 c/mL** without a **genotypic resistance test**	Tenofovir/lamivudine/dolutegravir [TLD 2] Abacavir/lamivudine/dolutegravir [ALD 2]
Third-line DTG-containing regimens	• Patient was switched to a third-line DTG-based regimen based on the results of a genotypic resistance test showing **resistance mutations to PIs** in previous second-line regimen	TLD 3 or ALD 3, or an individualised DTG-based regimen
If clients are not eligible to use TDF and they had an ABC hypersensitivity reaction, use AZT/3TC/DTG		

- HIV drug resistance testing (HIVDRT) is expensive and has the potential for fruitless over-expenditure if requested in a poorly selected patient
- If a resistance test is performed while a patient is non-adherent to their medication, it does not provide any clinically useful information
- Drug-level testing (DLT) before drug resistance testing can objectively assess adherence and act as a gatekeeping mechanism for DRTs
- Before drug resistance testing, DLT will be done as a reflex test by the laboratory on all samples for which a DRT is requested, while the client is taking a DTG-based regimen.
    - A DLT is most helpful where no drug levels are detected. For a DTG DLT, this indicates that the client has not taken any DTG for at least the last 5 days. A resistance test will not be performed under these circumstances, and drug-level informed adherence counselling can be provided.
    - A positive DTG DLT indicates that the client has taken DTG in the last 5 days. However, a DLT cannot distinguish between consistently good adherence and intermittent adherence that coincides with the testing window, e.g., the 'white coat phenomenon,' where patients resume treatment shortly before clinic visits.

Eligibility criteria for a resistance test:

DTG-containing regimens:

- Patients on a 2nd or 3rd line DTG-containing regimen for at least 9 months, or
- Patients on TLD1/ALD1 for at least 9 months with special circumstances (see Box 17), and
- Two or more consecutive VLs > 1000 c/mL, and
- At least two adherence assessments and interventions.

PI-containing regimens:

- Adults, adolescents or children on any LPV/r or ATV/r regimen for at least 2 years, and
- Two or more consecutive VLs ≥ 1000 c/mL taken two or more years after starting the PI regimen, and
- At least two adherence assessments and interventions

If necessary (and if the test is being considered in a nurse-managed patient), discuss these patients with a medical officer experienced in HIV management or a helpline expert who may advise requesting an HIV drug resistance test at the same time as their next scheduled VL. If so advised, take two blood specimens and request both of the following:

1. HIV VL - use a plasma EDTA tube (purple or white top, with gel)
2. Drug resistance test - use a plasma EDTA tube (purple or white top, with gel)

If the VL ≥ 1000 c/mL, and DTG is detected on drug-level testing (if available), the laboratory will proceed to do an HIV drug-resistance test.

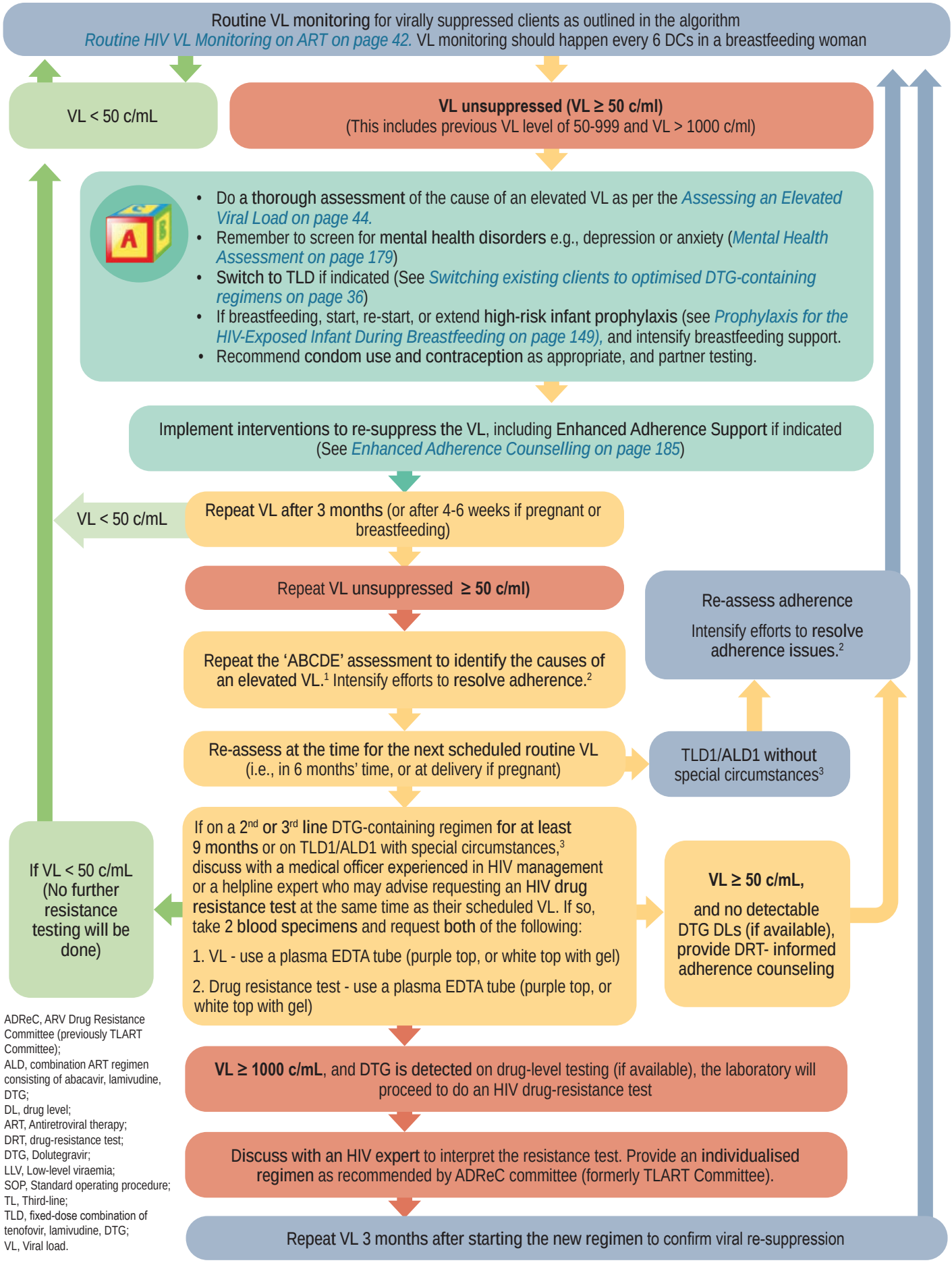
Box 17: Special circumstances that may warrant drug resistance testing on TLD1/ALD1

Patients on TLD1/ALD1 with special circumstances

As a rule, resistance testing is not indicated for clients on TLD1. However, TLD1 patients with persistent virological failure despite apparent good adherence may be discussed with an expert to consider a resistance test on a case-by-case basis:

- Patients with AHD and on a DTG-containing regimen for at least 9 months.
- Current or previous drug interactions with rifampicin, carbamazepine, phenytoin, phenobarbital, or the polyvalent cations that may have resulted in the development of resistance.
- Incorrect classification as TLD1 after prior ART exposure and failing an ART regimen in the past
- Perinatally infected adolescents (perinatally infected adolescents should be classified as TLD2 due to the high likelihood of ART exposure and virological failure in the past).

VL monitoring and management algorithm for clients on TLD or ALD



ADReC, ARV Drug Resistance Committee (previously TLART Committee);
ALD, combination ART regimen consisting of abacavir, lamivudine, DTG;
DL, drug level;
ART, Antiretroviral therapy;
DRT, drug-resistance test;
DTG, Dolutegravir;
LLV, Low-level viraemia;
SOP, Standard operating procedure;
TL, Third-line;
TLD, fixed-dose combination of tenofovir, lamivudine, DTG;
VL, Viral load.

Figure 15: VL monitoring and management for clients on TLD or ALD

Treatment regimens for patients with confirmed DTG resistance

- If DTG or PI resistance is detected, the PLHIV should be referred to the ARV Drug Resistance Committee (ADReC), formerly Third Line ART Committee (TLART).
- The appropriate application form (see *ADReC Third-line Application Form on page 208*) and the results of any resistance tests should be emailed to TLART@HEALTH.GOV.ZA
- The ADReC continuously reviews local resistance patterns and other evidence to inform the best approaches for individual clients and the country as a whole.
- The ADReC will recommend a regimen based on the guidance provided at *https://www.health.gov.za/nhi-edp-stgs-eml/*.

Even if the clinician is aware of the ADReC algorithm, switching should not be done independently. Every client requiring a third-line regimen requires notification to ADReC.

ART side effects

- ARVs can cause a wide range of toxicities, from low-grade intolerance that may be self-limiting to life-threatening side effects.
- It may be difficult to differentiate between complications of HIV disease, ART toxicity, or adverse reactions to other medications.
- ARV toxicity can occur immediately or early, within a few days or weeks of treatment, or late, after months of treatment. It is important to know how long a patient has been on a regimen to understand which toxicities might occur.
- Adverse reactions can vary in severity from mild to severe to life-threatening and may be specific to the drug or generic to the class of drugs in use.
- Side effects are far less common in children than in adults.
- Generally, it is recommended that patients continue ART if the side effects are mild

Surveillance of all adverse drug reactions (ADRs) is fundamental.
Healthcare professionals are urged to report any ADRs and product quality concerns to the SAHPRA pharmacovigilance office using one of the reporting methods provided in *ADR Reporting Form on page 207.*

Increased creatinine due to DTG

- DTG inhibits creatinine secretion directly without affecting renal function. As a result, the creatinine levels of patients starting DTG may increase. Because the equation used to estimate the GFR uses creatinine, it may appear as if their eGFR is falling and their kidney function is deteriorating, but **this does not reflect a true decline in renal function**.
- The estimated rise in creatinine is usually ≤ 30 µmol/L, and occurs within the first few weeks after initiating the medication.
- A rise in serum creatinine of ≥ 30 µmol/L, or a rise that occurs after the first month, should prompt a workup for alternative causes, as indicated in *Figure 17* below.

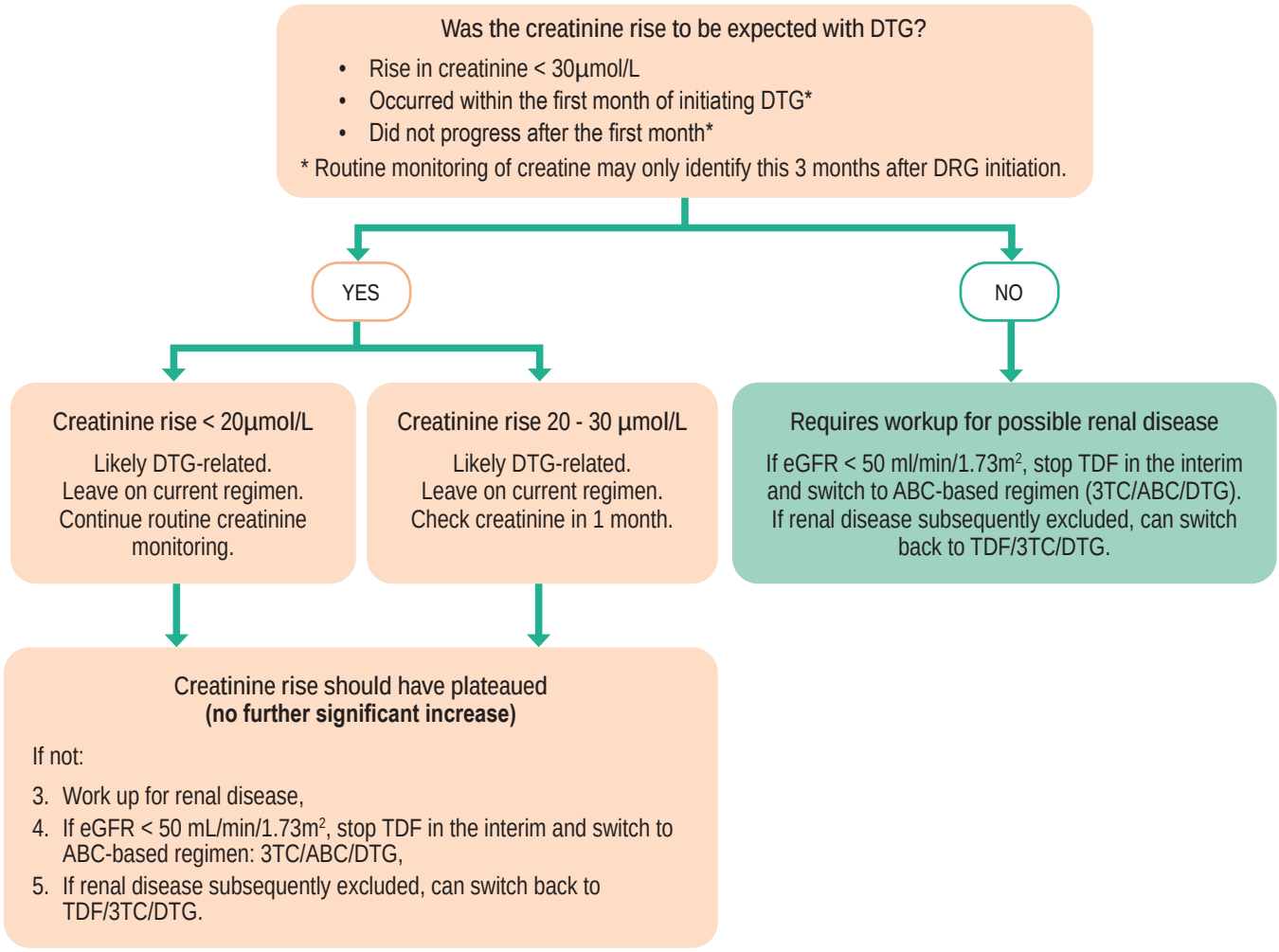


Figure 16: Assessment and management of a rise in creatinine in patients on DTG
Source: Tom Boyles, Gary Maartens, Jeremy Nel, David Stead, Southern African HIV Clinicians Society, Clinical Guidelines for Hospitalised Adults With Advanced HIV Disease 2022

Renal tubular dysfunction due to TDF

- TDF as a cause of acute kidney injury (AKI) or chronic kidney disease (CKD) is uncommon.
- Clinicians should actively exclude other causes of kidney dysfunction (See also *An approach to an AHD patient with renal impairment on page 108*).
- Pre-existing renal disease is a major predictor of TDF toxicity, and baseline testing of renal function is important to identify those in whom TDF should be avoided.
    - If baseline screening eGFR is < 50, abacavir is the preferred alternative option.
    - If the patient also has HBV infection, TAF is the preferred alternative option.
- TDF toxicity can present as AKI or CKD and as a full or partial Fanconi's syndrome characterised by renal tubular dysfunction.
- Because the proximal tubule is responsible for the reabsorption of glucose, uric acid, amino acids, small proteins and phosphate, etc., renal tubular dysfunction may present with proteinuria, glycosuria (with normal urine glucose) and hypophosphataemia.
- The most common risk factors are comorbid hypertension, diabetes, HIV-associated kidney disease, hepatitis B or C co-infection.
    - Management of these comorbid conditions must be prioritised in this group.
- eGFR should be routinely measured at baseline (before ART initiation), at three months on ART, at 10-12 dispensing cycles (28-day month) on ART (aligned with VL), and 12-monthly after that.
- More frequent monitoring may be required in patients with existing risk factors or pre-existing chronic kidney disease.
- eGFR tests must be followed up to ensure results are received as quickly as possible (preferably in 1–4 weeks), and TDF is replaced as needed.
- Whether implicated as the primary cause or not, TDF should be stopped in all cases of AKI, as it may be contributing to the AKI.
    - If the cause of the AKI is not related to TDF, TDF can be reintroduced once renal function normalises.
    - If the patient has had severe renal dysfunction, it is advisable to wait at least 1-3 months after renal function normalises before reintroducing TDF.
- Stopping TDF in a patient who has HBV co-infection may result in life-threatening flares. For this reason, an HBsAg should be done before stopping TDF.
- Tenofovir alafenamide (TAF) is also active against HBV. If TDF has to be discontinued and eGFR is 15-50 ml/min, the alternative regimen is TAF + FTC + DTG. Discuss these patients with a specialist.

Bone density reduction due to TDF

- Renal tubular dysfunction has an impact on vitamin D and phosphate levels which is thought to account for the bone manifestations seen with TDF.
- Any signs of possible osteoporosis (e.g., vertebrae, rib, hip, wrists or other fractures not adequately explained by the degree of trauma fractures) warrant investigation.

Immune Reconstitution Inflammatory Syndrome (IRIS)

- IRIS occurs when improving immune function unmasks a previously occult opportunistic infection, which subsequently presents with an unusually aggressive inflammatory presentation or causes paradoxical deterioration of an existing opportunistic disease.
- Patients with advanced HIV disease, particularly those with a CD4 count < 100 cells/μL, may become ill with IRIS, usually during the first three months of ART.
- Most cases can be managed on an outpatient basis with disease-specific therapies and anti-inflammatories.
- Very ill or complex patients may need to be referred for advice regarding investigation and management.
- TB is the most common IRIS reaction in South Africa.
    - Some patients starting ART when on treatment for TB will experience recurrence or worsening of their TB symptoms/signs or new manifestations.
    - The most common of these presentations is enlarging lymph nodes, often with extensive caseous necrosis.
    - In addition, respiratory symptoms, lung infiltrates, or effusions may worsen.
    - MDR or extensively drug-resistant (XDR) TB needs to be excluded before IRIS is diagnosed. TB culture of sputum, blood, lymph nodes, and other affected tissue is essential.
    - It is important to exclude non-adherence to TB medication.
- Opportunistic infections may also present in atypical ways during this phase of immune reconstitution.
- Rashes (including zoster, herpes, molluscum, and others) and cryptococcal meningitis that occur in the first weeks and months of ART initiation are other manifestations of IRIS.
- IRIS is not indicative of drug failure or drug side effects. It is generally not a reason to stop ART or to change the ARV regimen. However, careful counselling is needed to ensure that the patient understands this.
- Prednisone 1.5mg/kg given for 2 weeks followed by 0.75mg/kg given for 2 weeks reduces morbidity in patients with non-neurological paradoxical TB IRIS.
- There is limited evidence for the use of steroids in other forms of IRIS, and they should, therefore, generally be avoided.
- Prophylaxis for paradoxical TB IRIS in high-risk patients (CD4 ≤100 cells/μL) who have had antituberculosis treatment for <30 days before initiating ART:
    - Prednisone, oral, 40 mg daily for 2 weeks, then 20 mg daily for 2 weeks.

Anaemia

- Patients should have a full clinical history, an examination, a full blood count (FBC), a peripheral blood smear, and a reticulocyte count to characterise the anaemia and determine further investigations that may be needed.
- Anaemia is very common in patients with low CD4 counts. Those who are relatively asymptomatic or who have a serious opportunistic infection (OI) such as TB, which explains the anaemia, should have their ART started right away and monitored carefully. In other patients, an HB < 8 g/dL with no clear cause should trigger additional investigations; often, there is an underlying serious OI, e.g., TB, that requires urgent diagnosis and treatment. A low HB is an independent poor prognostic factor in HIV, and therefore, delays in ART initiation should be avoided as far as possible.
- Where anaemia occurs immediately after ART initiation, confirm that the HB has dropped by comparing previous results. A comprehensive history, examination, and interpretation of an FBC/smear/reticulocyte count are helpful.
- Common causes of anaemia in the first few weeks and months of treatment include IRIS, disseminated TB, and AZT-containing regimens, although many other conditions can cause this. AZT is no longer part of any standard ART regimen and should be replaced by TDF or ABC.
- Anaemia in patients established on ART is unusual and often suggests a serious OI or a condition unrelated to HIV. However, drugs should still be considered as AZT; pure red cell aplasia from 3TC or FTC or cotrimoxazole may also cause FBC abnormalities.

Abacavir-related hypersensitivity reaction (ABC HSR)

- ABC HSR is uncommon in Black African patients but may occur in up to 5% of Caucasian patients.
- It usually occurs within the first six weeks of initiation. It is suspected in the presence of at least two of the following symptoms: fever, rash, constitutional symptoms, gastrointestinal symptoms, and respiratory symptoms.
- The ABC HSR typically gets worse with each dose of ABC. If in doubt about the cause of the symptoms, the patient can be admitted to the hospital and given the next dose of ABC under direct observation.
- If ABC HSR develops, supportive therapy, usually including hospital admission, is required.
- ABC can be switched if the patient is stable.
- However, all ART must be discontinued if the patient is unstable. When the patient has stabilised, ART can be restarted, but ABC must never be included in the regimen as re-exposure is potentially life-threatening.

Hyperlipidaemia

- Protease inhibitors are associated with an increased risk of an abnormal lipid profile.
- Lopinavir causes hypertriglyceridaemia.

Breast enlargement and lipomastia

- Breast enlargement may be due to benign glandular breast tissue proliferation, abnormal fat deposition (lipomastia), or both.
- It occurs in both males (known as gynaecomastia) and females and can occur at any age.
- In currently used regimens, it has most consistently been associated with using EFV.
- The onset occurs several months after ART initiation and may be bilateral or unilateral. The mechanism appears to be related to oestrogen receptor activation in breast tissues by EFV. EFV is no longer the preferred first-line ART regimen; all patients should be transitioned to a DTG-containing regimen.
- In males, it is also important to consider other common causes of gynaecomastia, such as:
    - other medications (including spironolactone, calcium channel blockers, metoclopramide).
    - physiological causes in adolescent males
    - hypogonadism (a serum testosterone level is useful in excluding hypogonadism as a cause. If the serum testosterone is low, other appropriate investigations should be performed to identify the cause and manage accordingly.
- The resolution of gynaecomastia is generally slow, taking months and may be incomplete or may remain. It is, therefore, important to manage the patient's expectations in this regard.

Hepatotoxicity

- Hepatotoxicity is common with ARV drugs
    - NNRTIs and PIs are often associated with hepatotoxicity.
    - InSTIs such as DTG have, on rare occasions, been associated with hepatotoxicity.
    - ATV/r causes indirect hyperbilirubinaemia (clinical jaundice), which can be stigmatising.
    - AZT may cause lactic acidosis or severe hepatomegaly with steatosis.
- All PLHIV should be screened for symptoms of underlying liver disease before ART initiation and at any time they become ill.
- Routine monitoring of ALT at baseline is not recommended unless indicated by the patient's history or clinical examination. See also *Management of drug-induced liver injury in people with HIV treated for tuberculosis on page 109*.

Skin and hypersensitivity reactions

- Skin rashes and hypersensitivity reactions may be seen particularly with the NNRTIs (NVP, EFV).
- In addition, cotrimoxazole, ABC, DTG, DRV/r, and RAL are associated with varying degrees of skin and hypersensitivity reactions (mild to severe).

Table 33: ART dosing and important adverse effects

ART dosing and important adverse effects			
Generic name	Class	Dosages in adults and adolescents *	Important adverse drug reactions (ADRs) and timing
Dolutegravir (DTG)	InSTIs	50 mg once daily	• Hypersensitivity (rare, weeks) • Insomnia (common) • Headache (common) • Other neuropsychiatric symptoms • Nausea, diarrhoea (common) • Hepatitis (uncommon) • Increase in serum creatinine due to inhibition of creatinine secretion by DTG; this is clinically insignificant as the glomerular filtration rate is not reduced but will modestly affect eGFR, which is determined using serum creatinine.
Tenofovir disoproxil fumarate (TDF)	NRTI	300 mg daily	• Acute kidney injury (rare - weeks to months). • Decline in eGFR (months to years) • Fanconi syndrome (rare – months to years) • Reduced bone mineral density (months to years).
Lamivudine (3TC)	NRTI	300 mg daily (or 150 mg 12 hourly)	• Anaemia due to pure red cell aplasia (rare).
Emtricitabine (FTC)	NRTI	200 mg daily	• Palmar hyperpigmentation. • Anaemia due to pure red cell aplasia (rare).
Abacavir (ABC)	NRTI	600 mg daily	• Hypersensitivity reaction (1 to 6 weeks): fever, rash, constitutional symptoms, gastrointestinal symptoms and respiratory symptoms.
Tenofovir alafenamide (TAF)	NRTI	25 mg daily	• Acute kidney injury (rare - weeks to months). • Decline in eGFR (months to years) • Fanconi syndrome (rare – months to years) • Reduced bone mineral density (months to years).
Zidovudine	NRTI	300 mg	• Anaemia, neutropenia (weeks to months). • Gastro-intestinal upset. • Headache. • Myopathy (rare). • Hyperlactataemia / steatohepatitis (medium risk - months). • Lipoatrophy (months to years).
Efavirenz (EFV)	NNRTI	600 mg at night	• Central nervous system symptoms: vivid dreams, problems with concentration, confusion, mood disturbance, psychosis (days to weeks). • Encephalopathy, often with cerebellar features (uncommon – months to years). • Rash (1 to 6 weeks). • Hepatitis (weeks to months) • Gynaecomastia.
Lopinavir / ritonavir (LPV/r)	Boosted PI	400/100 mg 12 hourly OR 800/200 mg daily (only if PI-naïve)	• Gastrointestinal upset. • Dyslipidaemia (weeks). • Rash and/or Hepatitis (1 to 6 weeks).
Atazanavir / ritonavir (ATV/r)	Boosted PI	300 mg with ritonavir 100 mg daily	• Unconjugated hyperbilirubinaemia (common but benign). • Dyslipidaemia (low risk). • Hepatitis (rare - 1 to 6 weeks). • Renal stones (uncommon).
* For ART doses in children, see Annexure 3 Antiretroviral Drug Dosing Chart for Children (2025) * For renal dose adjustment, please see Table 35			

Source: Hospital level (Adults) Standard Treatment Guidelines and Essential Medicines List to treat specific pathogens and syndromes. 6th ed. 2024.

6 Other conditions that may require advanced clinical care

Renal impairment

Patients with AHD commonly have abnormal creatinine levels. The algorithm in *Figure 18: An approach to an AHD patient with renal impairment on page 108* presents a useful approach to a patient with apparent renal impairment.

- While most causes of CKD have small kidneys on ultrasound, some do have normal/large kidneys (e.g. HIVAN, diabetic nephropathy).
- 99% of CKD patients have anaemia. Many patients with AKI also have anaemia from other causes, so anaemia itself isn't helpful – but the absence of anaemia would suggest the renal dysfunction is not chronic.
- It is no longer believed to be strictly necessary to dose adjust lamivudine in renal failure, and thus if eGFR > 30 and it is more convenient (e.g. a fixed-dose combination is available), the full dose may be given.
- TAF is preferred in patients with chronic kidney disease and HBV co-infection. These patients should be discussed with a specialist.

Table 34: ART drug dosage adjustments in renal failure

Drug	eGFR 10-50 ml/min	eGFR < 10
TDF (only if HBV positive and TAF not available)	eGFR 30-50: 300 mg 48-hourly	300 mg once weekly
	eGFR 10-29: 300mg 72-96 hourly	
TAF	25 mg daily If co-formulated with 3TC/FTC, avoid if eGFR <30 ml/min in adults and adolescents, and if eGFR < 50 in children	Avoid[1]
ABC	Unchanged	Unchanged
3TC	eGFR 30-50: 300 mg daily, or 4 mg/kg daily in children eGFR 10-29: 150 mg daily, or 2 mg/kg daily in children	50 mg daily, or 1mg/kg daily in children
AZT	No reduction	50% of dose 12 hourly
NNRTIs	Unchanged	Unchanged
PIs	Unchanged	Unchanged
InSTIs	Unchanged	Unchanged

[1] TAF can be used in patients undergoing dialysis

An approach to an AHD patient with renal impairment

A patient with AHD has an abnormal creatinine level

Confirm if the patient is truly in renal failure (RF),
(defined as an eGFR < 50 ml/min or an absolute creatinine of > 85 in a pregnant woman)

- In non-pregnant patients, creatinine alone can be misleading. Also, look at the estimated glomerular filtration rate (eGFR).
- If the eGFR is confirmed by a nurse to be < 50 in a non-pregnant patient or > 85 in a pregnant patient, refer to a doctor for further assessment
- Exclude benign eGFR decreases due to DTG (see page 65)
- eGFR can be inaccurate in an acute kidney injury (AKI). If AKI is suspected also observe creatinine trends

A patient with AHD has an abnormal creatinine level

Clues that RF may be acute:

- Acutely ill due to the underlying cause (e.g., diarrhoea, pneumonia, dehydration, septicaemia)
- A normal creatinine in the last 3 months
- Normal HB
- Oliguria

Common causes of AKI are:

- Pre-renal AKI – hypoperfusion of the kidney, often from dehydration or sepsis.
- Acute tubular necrosis (ATN) – from either ischaemia because of hypoperfusion or from toxins (usually medications) e.g.,
  - Nonsteroidal anti-inflammatory drugs (NSAIDs)
  - Aminoglycosides
  - Amphotericin B
  - Tenofovir (rarely)
- Acute interstitial nephritis often due to medications such as:
  - Rifampicin
  - Cotrimoxazole (Bactrim)
  - NSAIDs
  - Herbal remedies

Management principles for AKI

- If pre-renal component to the AKI give a trial of fluids
- Stop all commonly nephrotoxic medications, like NSAIDs, tenofovir, and cotrimoxazole
- Dose-adjust any other medications that require dose adjustment in RF, like pyrazinamide and ethambutol
- Attempt to correct any metabolic derangements, especially hyperkalaemia
- Treat the underlying cause (e.g., diarrhoea, pneumonia)
- If there is reason to suspect urinary obstruction, obtain an urgent ultrasound
- Assess for the need for acute dialysis

Clues that RF may be chronic
(i.e., RF lasting at least 3 months)

- Small kidney on ultrasound
- High s-phosphate

Clues suggestive of HIVAN as the cause of chronic kidney disease (CKD):

- AHD with high viral load and low CD4
- Black race
- Large or high to normal-sized kidneys (typical size range is 10.5-15.5 cm)
- Nephrotic or subnephrotic range proteinuria
- Bland urinary sediment (no significant amount of red or white cells in the urine)
- Absence of significant oedema or hypertriglyceridaemia (which often accompanies other forms of nephrotic syndrome)

Common causes of CKD are:

- Diabetes
- Hypertension
- HIVAN

Management principles for CKD

Regardless of the cause of CKD, management should include the following:

- Control relevant risk factors:
  - Blood pressure < 130/80
  - HBA1c < 7.0%
  - HIV viral load undetectable
- Counsel the patient about avoiding nephrotoxic drugs (e.g. NSAIDs)
- Dose-adjust any drugs that need adjustment, including ART (see Table 24)
- Refer to a specialist if the eGFR is < 30

In addition, if HIVAN is suspected:

- Initiate ART urgently with ABC + 3TC + DTG
- Give an ACE-inhibitor if proteinuric (>1g per day)

Figure 17: An approach to an AHD patient with renal impairment

Diagnosis of AT-DILI

Suspect anti-tuberculous drug induced liver injury (AT-DILI) in patients on TB treatment with symptoms of:

1. Hepatitis (visible jaundice/ nausea & vomiting/fatigue/ RUQ pain/LOA/pale stools), OR
2. Systemic hypersensitivity (e.g., a new rash)

DO LFT & INR

Are the criteria for DILI met?

- ALT > 3x ULN WITH symptoms or jaundice or Tot Bili>40 µmol/l
- OR ALT > 5x ULN regardless of symptoms
- OR Patient with liver disease or baseline ALT>120 IU/l and ALT now > 2x baseline

YES

Diagnose PRESUMPTIVE AT-DILI
A definitive diagnosis of AT-DILI can be made if no other diagnosis is found & ALT decreases after interruption of TB treatment

CLASSIFY AT-DILI
Mild: No symptoms and INR <1.5
Moderate: Symptoms and INR <1.5
Severe: INR >1.5 Regardless of symptoms

NO

Consider the following if the criteria for DILI are not met

Tot Bili >2 ULN ALT <3 ULN	Isolated GGT / ALP elevation	ALT < 5xULN and no symptoms
Continue TB Rx Repeat LFT in 1w If > 5x ULN: discuss with an expert	Investigate for TB IRIS / obstruction Consider Abdominal ultrasound	Continue TB Rx Do HBsAg Repeat LFT's in 1 week

Differentiating between likely DILI and TB-IRIS

DILI	TB IRIS
No hepatomegaly Jaundice common ALT/AST predominant	Hepatomegaly Jaundice uncommon ALP/GGT predominant Other IRIS manifestations

Immediate Management

1. Admit the patient
2. Review all medication

3 Stop TB treatment

If patient is in intensive phase: consider using a background regimen EMB, LFX & LZD (if HB >8).
If HB <8g/dl, use CFZ or TRD instead of LZD (See Box XX for dosages)

4 Consider stopping ART:

- If on ART < 6m: consider interruption
- If on DTG based regimen > 6m: consider continuing ART
- If on LPV/r or EFV: switch to DTG
- DRV/r or ATV/r: Cannot give with Rifampicin. Stop ART. When re-challenged use Rifabutin instead of Rifampicin

5 Identify other hepatotoxic medications that may need to be stopped:

- Fluconazole for CM: discontinue only if CD4 > 200 and on maintenance phase for CM. Discuss all other patients with an expert
- Review other potentially hepatotoxic drugs and counsel patient on OTC and herbal medication.

6 Review TB diagnosis

7 Investigate for other causes such as:

1. Hepatitis A in children
2. Hepatitis A, B & E in adults
3. Relevant investigations as per history & examination

Diagnosis of AT-DILI

Monitor ALT
2-3 / week

Expect a downward trend within a few days.

Re-challenge drugs

once ALT < 100 IU/ml and total bili's are on a downward trend

Drugs should be rechallenged in the following order while monitoring ALT closely:

1. Treatment for opportunistic infections e.g., TB treatment
2. ART
3. Prophylaxis e.g., cotrimoxazole /fluzonazole

Schedule for re-challenging TB medication

Day 1:	Start INH 300mg/day (stop LZD) Pt is on INH / EMB/LFX
Day 3:	Check ALT (if raised stop INH)
Day 4:	Add Rifampicin 600mg/day. Pt is on RIF/INH/EMB/LFX
Day 7:	Check ALT (if raised stop RIF)
Day 8:	Decide whether to add PZA (e.g., in TBM patients or INH/ RIF introduction not successful). Stop LFX. Patient is now on either RIF / INH / EMB or RIF / INH / EMB / PZA
Day 10:	Check ALT

Important points in the management of drug-induced liver injury

- Hepatotoxicity usually occurs within 5 - 7 days after reintroduction.
- It takes, on average, eight days (5-13) for ALT to drop <100IU/ml.
- If reintroduction fails at any step, omit that drug, wait for adverse effects to subside and continue to the next drug.
- 20-90% of patients can have TB treatment regimen 1 (incl. PZA) successfully reintroduced.
- After two weeks of stabilising on the new TB regimen, re-challenge ART and, if ALT is unchanged, re-challenge co-trimoxazole. Avoid EFV and LPV/r if possible.
- The start date of TB treatment should be the start date of the final regimen tolerated by the patient.
- Severe DILI, including re-challenge of all drugs, should be managed by an expert (specialist).

Table 35: Alternative TB treatment regimens if certain TB drugs not tolerated

Drug not tolerated	Suggested regimen
PZA	Rif + INH + EMB for 2 months and the Rif and INH for 7 months TBM: Rif +INH + EMB + LFX for 12 months
INH	Rif + EMB + PZA + LFX for 6-9 months Same regimen for TBM
Rif	Provide regimen for rifampicin resistant TB as per RR-TB Clinical Reference Guide TBM: Provide regimen for rifampicin resistant TB in CNS as per RR-TB Clinical Reference Guide

Table 36: Dosages for drugs in alternative TB regimens

Drug	Weight	Dose per day
EMB	< 45 kg	800mg
	> 45 kg	1200mg
LVX	< 45 kg	750mg
	> 45 kg	1000mg
LZD	> 30 kg	600mg
CFZ		100mg
TRD	> 35 kg	750mg

Hepatitis B coinfection

- HIV coinfection has a profound impact on the course of Hepatitis B virus (HBV) infection, including more rapid progression to cirrhosis and hepatocellular carcinoma, higher liver-related mortality, and decreased treatment response compared with HIV-negative persons.
- HBV is transmissible via perinatal, percutaneous or sexual exposure to HBV-infected body fluids, including serum, saliva, semen and vaginal fluids.

HBV is **100 times more infectious** than HIV and 10 times more infectious than HCV.
HBV is **preventable** through immunisation.

Clinical presentation

Acute HBV infection may present with:

- Fever, urticaria, arthralgia and arthritis
- Fatigue, myalgia, loss of appetite, nausea and vomiting, abdominal pain (epigastric or right upper quadrant), with or without hepatosplenomegaly
- Jaundice

Fulminant HBV infection occurs in < 1% of acute HBV infections. It has a very high mortality rate and results in acute liver failure characterised by:

- Jaundice
- Hepatic encephalopathy
- Coagulopathy (INR > 1,5)
- Other complications of acute liver failure, e.g., acute portal hypertension, hepatorenal syndrome, raised intracranial pressure, and metabolic disturbances

Chronic HBV

- Defined as the persistence of HBsAg-positivity for six or more months
- The diagnosis is often missed because:
    - HBV is frequently a clinically silent disease, often identified incidentally
    - HBV may have vague and non-specific signs, and in the absence of jaundice, HBV is not considered part of the differential diagnosis
- May have signs of chronic liver disease such as spider naevi, palmar erythema or signs of portal hypertension

Refer urgently the patient with **jaundice** and any of:

- Temperature ≥ 38°C
- BP < 90/60
- Severe abdominal pain
- Drowsy or confused
- Easy bruising or bleeding
- Pregnant
- Alcohol dependent or recent alcohol binge (≥ 4 drinks1/ session)
- Using any medication or illegal drugs

Diagnosis

- **HBV surface antigen (HBsAg)** is the key marker in diagnosing HBV infection.
- The following persons should be screened for HBV using an HBsAg
    - Adults and adolescents newly diagnosed with HIV, TB or STIs, including pregnant women
    - Any patient with an elevated alanine aminotransferase (ALT) or other clinical indications of liver disease
    - Any patient with an elevated creatinine or other clinical indications of kidney disease
    - Any patient who develops IRIS or a drug-induced liver injury (DILI) should be tested for hepatitis A, B and C.
    - Any patient who may need to discontinue TDF or 3TC/FTC for whatever reason.
    - Sexual partners, children and other family members and close household contacts of those with HBV infection
    - Members of key populations

Management of patients LHIV who test HBsAg positive

- All persons who are HBsAg positive have hepatitis B infection.
- HBV is a notifiable medical condition (NMC) and should be reported to the NICD via one of the **available reporting mechanisms**.
- The recommended NRTI drugs for ART, namely, TDF with 3TC (or FTC), are active against HBV and therefore, all HIV/HBV coinfected patients will automatically be treated for HBV when they initiate TLD 1 or TLD 2
- Life-threatening flares may occur when antiretrovirals that are also active against HBV (TDF, 3TC and FTC) are withdrawn. Always do a HBsAg before stopping any of these agents.
- Tenofovir alafenamide (TAF) is also active against HBV. If TDF has to be discontinued and eGFR is 30-50 ml/min, the alternative regimen is TAF + FTC + DTG. If TAF is not available, adjust the dose of TDF as per Table 24.
- **All HBsAg-positive individuals are infectious**, and all patients with HBV infection should receive education on how to prevent HBV transmission (See Box 19).
- When an asymptomatic patient is found to be HBsAg positive on routine screening, it can be assumed that the patient has chronic HBV infection. Repeating HBsAg after six months is not necessary to confirm chronicity.
- All patients with HBV should be tested for HCV.
- For further details on managing all types of viral hepatitis, please consult the **National Guidelines for the Management of Viral Hepatitis. NDOH. December 2019.**

Box 18: Education for a patient with HBV

Educate a patient with HBV on the following:

- HBV infection is treated by the same medications used to treat HIV.
- Educate that hepatitis B spreads via blood and sexual fluids. Advise patient to:
  - ➝Avoid sharing toothbrushes, razors or needles.
  - ➝Reliably use condoms, especially with a new partner
  - ➝Advise household contact/s and needle-sharing/sexual contact/s to test.
- Advise the patient to return if jaundice develops.

Management of patients who test HBsAg negative

- A patient who tests HBsAg negative does not have hepatitis B infection.
- If they are not known to be immunised , send blood to test for hepatitis B surface antibodies (HBsAbs), which indicates immunity to HBV. Interpret the results as per Figure 13.

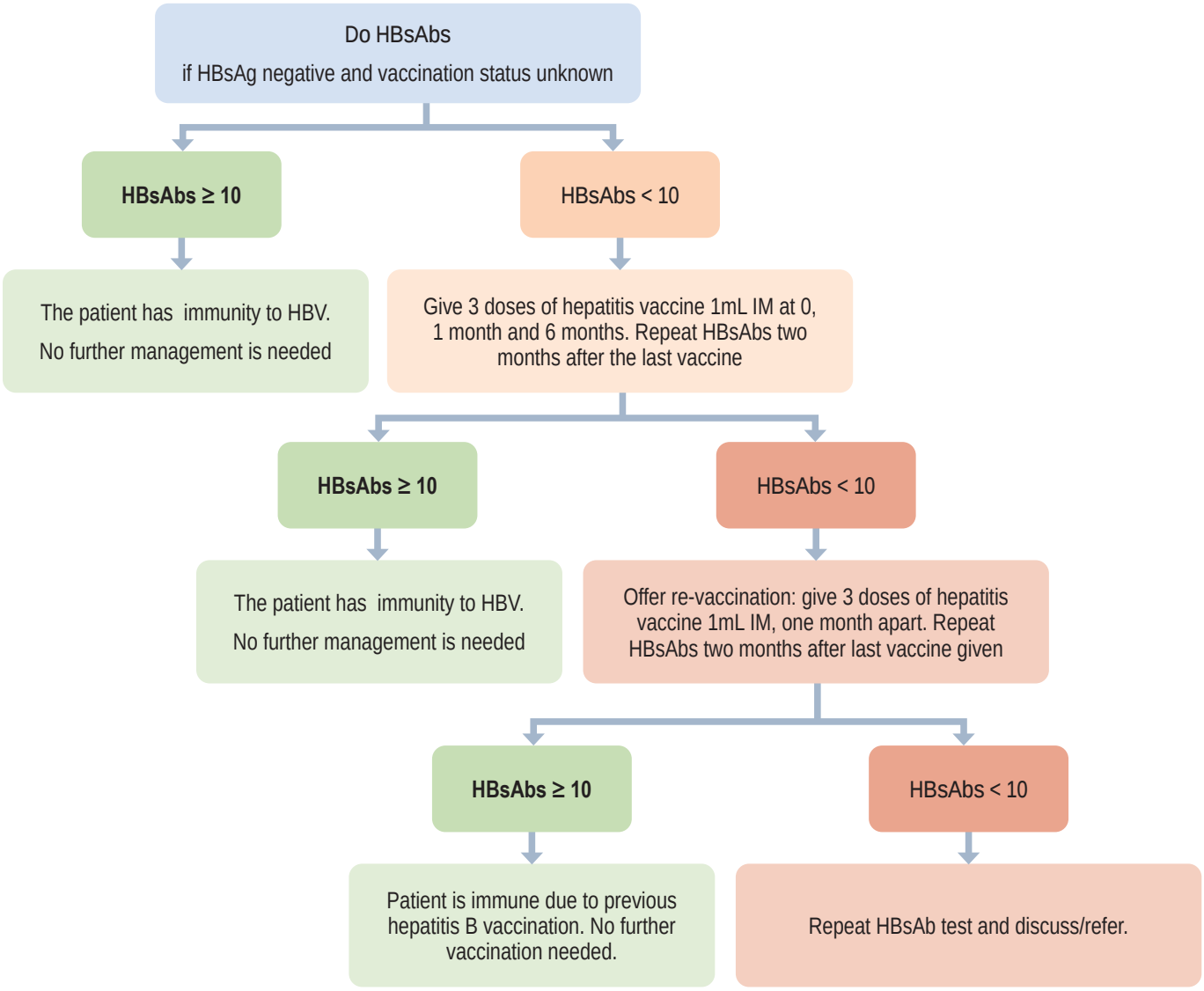


Figure 18: Using the HBsAbs test to determine the need for HBV vaccination

Source: Adult Primary Care (APC) 2023
Abbreviations: HBsAbs, hepatitis B surface antibodies; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; IM, intramuscular

Hepatitis C coinfection

Hepatitis C virus (HCV)-related liver disease progresses more rapidly in persons coinfected with HIV. Treatment of HCV is, therefore, a priority for persons with HIV-HCV coinfection. The decision to initiate treatment for HCV in PLHIV is more complex than in those with HCV mono-infection because response rates are lower, the risk of potential toxicities is higher, and treatment is complicated by a high pill burden, overlapping toxicities, and interactions between drugs used for treating HCV and HIV.

In general, clinical stabilisation of HIV disease with ART is advisable before starting treatment for HCV, especially in persons with advanced immunosuppression (CD4 count below 200 cells/μL).

All-oral direct-acting antiviral (DAA) HCV regimens produce similar rates of sustained virological response regardless of HIV status.

- Careful consideration of drug-drug interactions is important to avoid toxicity and to ensure the efficacy of regimens used to treat both HIV and HCV.
- Pegylated interferon is no longer used. Sustained virological response and cure rates post-DAA treatment are higher than 90%. For complex cases that do not respond to DAAs, refer to experts.
- The newer all-oral DAAs also have fewer drug-drug interactions than earlier interferon-based regimens

The decision to start ART among persons coinfected with HCV should follow the same principles as in HIV mono-infection.

- The potential harmful effects of ARV drugs include their hepatotoxic effects.
- The highest rates of hepatotoxicity have been observed with ARV drugs that are no longer commonly used or recommended, including stavudine, didanosine, and nevirapine.
- For most HIV-HCV coinfected persons, including those with cirrhosis, the benefits of ART outweigh concerns regarding drug-induced liver injury (DILI).

For further details on managing all types of viral hepatitis, please consult the National Guidelines for the Management of Viral Hepatitis. NDOH. December 2019.

Non-communicable diseases

- PLHIV have an increased risk of cardiovascular disease (CVD) compared to HIV-negative persons in the same age range.
- The mechanisms underlying the association between HIV and CVD are multifactorial and include HIV-related chronic immune activation and inflammation, immunodeficiency, and higher burdens of traditional CVD risk factors in PLHIV.
- Exposure to some classes of ARV drugs (e.g., PIs) can cause lipid abnormalities and may increase the risk of premature CVD. Although some ARV medications may increase the risk of CVD, the overall beneficial role of ART on HIV morbidity and mortality has been demonstrated to outweigh potential CVD risks in PLHIV.
- All PLHIV should be screened for non-communicable diseases, including hypertension, diabetes, and epilepsy. Do blood pressure (BP) and urine dipstix for proteinuria and glucose. Identify other risk factors (smoking, increased waist circumference, age) and determine the patient's cardiovascular (CVS) risk.
- Manage NCDs and CVS risk factors, as the PHC EML outlines.
- All patients should be encouraged to maintain an ideal weight, i.e., BMI < 25 kg/m2. Overweight patients with BMIs > 25 kg/m2 should apply the following lifestyle changes to reduce their weight:
    - alcohol intake should be reduced to < 2 standard drinks per day for men and < 1 for women on no more than 5 out of 7 days per week;
    - a prudent eating plan should be followed, i.e. low fat, high fibre, and unrefined carbohydrates, with fresh fruit and vegetables;
    - regular moderate aerobic exercise, e.g., 30 minutes of brisk walking 3-5 times per week (150 minutes/week);
    - the patient should be advised to stop smoking.

Mental health conditions

- Mental health conditions and HIV coexist in a complex relationship. Mental health conditions increase the risk of HIV infection. On the other hand, PLHIV are at high risk of mental, neurological, and substance use disorders.
- Common mental conditions such as depression, anxiety, and substance use disorders are often overlooked and unrecognised by healthcare providers during routine HIV care.
- Lack of care, treatment and rehabilitation for mental health disorders can affect general health, adherence to ART, and retention in care.
- All clients on ART, including older children, adolescents, and pregnant and breastfeeding women, should be screened for common mental health conditions at least annually and at any time if a client presents as unstable or a red flag client (missed appointments, poor adherence, elevated VL, or possible clinical signs of failure).
- Management of mental health and HIV should be aligned with the PHC Standard Treatment Guidelines and Essential Medicines List.
- Be aware of potential drug-drug interactions between ART and psychotropic medications.
- People with comorbid mental health conditions and HIV needing further care, treatment and rehabilitation should be up-referred following the departmental referral policy.
- The mental health screening tool is available in *Mental Health Assessment on page 179*

Sexually transmitted infections (STIs)

- The epidemiological synergy between HIV and STIs is well established, and they frequently coexist.
- Most of these infections are asymptomatic, especially among women. However, even asymptomatic STIs can cause complications, be transmitted to sexual partners, and enhance HIV transmission.
- There is empirical evidence that:
    - Neisseria gonorrhoeae substantially increases the shedding of HIV-1 from the male genital tract in seminal fluid.
    - Herpes simplex virus (HSV) is associated with increased acquisition and transmission of HIV.
- HIV infection may also alter the natural history of STIs.
    - HIV infection changes the natural history of HSV infection, resulting in more frequent recurrences in coinfected individuals, many of which are subclinical.
    - Serious clinical manifestations of HSV, human papillomavirus (HPV), syphilis, and other STIs are seen among persons with advanced HIV disease.
- From a WHO-commissioned systematic review, the prevalence of STI among PLHIV on ART and not on ART was found to be equally high. This suggests that STI coinfection could undermine efforts to use ART for prevention unless STIs are appropriately treated.
    - It is necessary to appropriately screen, diagnose, and treat STIs, especially among the most vulnerable populations and PLHIV.
    - STI services should be an important part of comprehensive HIV care among adults and adolescents.

For further information on the syndromic management of STIs, see the most recent Sexually Transmitted Infections Management Guidelines.

Cervical cancer

- Cervical cancer is a preventable disease and is curable if diagnosed and treated early.
- The most effective strategy available to primarily prevent this infection is by vaccination against the most common oncogenic HPV types, namely types 16 and 18.
    - HPV vaccines are indicated for pre-pubertal girls and offer the most hope to stop the epidemic of cervical cancer in South Africa effectively.
    - Studies have shown sufficient immune response in children LHIV; hence, they, too, can receive the HPV vaccine.
- Women living with HIV (WLHIV) have a higher risk of pre-cancer and invasive cervical cancer. The risk and persistence of HPV infection increase with low CD4 count and high HIV viral load.
- Cervical cancer screening leads to early detection of precancerous and cancerous cervical lesions that will prevent serious morbidity and mortality.
    - All women LHIV should be screened for cervical cancer at diagnosis and subsequently every three years if the screening test is negative.
    - 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 and treatment (e.g. colposcopy and LLETZ procedure) should be determined according to the local referral guidelines.

Refer to the most recent National Cervical Cancer Prevention and Control Policy for more details.

5

Guideline for Vertical Transmission Prevention of Communicable Infections

Overview of the Structure of this section

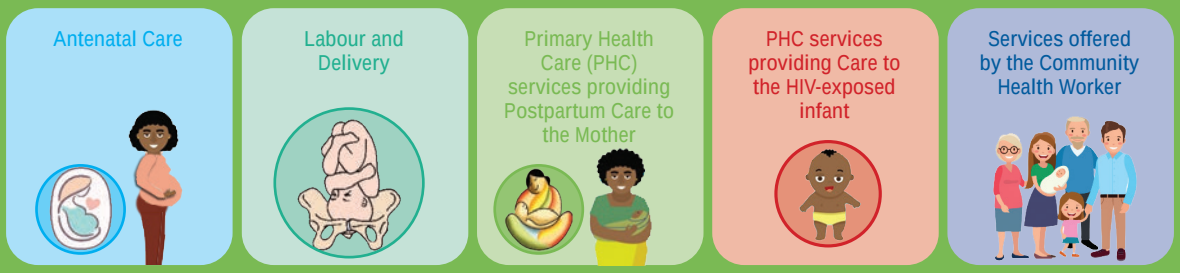
The guideline is divided into four parts:

1 Part One: Introduction provides an introduction and background to this guideline.

2 Part Two: Prevention gives guidance around the universal measures to prevent transmission of infections during pregnancy and breastfeeding, prevent HIV, prevent unintended pregnancies, as well as safe conception.

3 Part Three: Charts per Service Delivery Area is structured by service delivery point across the continuum of care. It deals with the care and treatment of the woman, her partner and children, and preventing vertical transmission to her exposed infant.

START BY SELECTING THE SERVICE POINT AT WHICH SERVICES ARE PROVIDED



For each service delivery point **in the facility** the following components of care are outlined:

1. HIV testing,
2. Antiretroviral therapy (ART) as treatment or prophylaxis,
3. HIV viral load (HIV VL) monitoring and management,
4. Tuberculosis (TB) screening, TB Preventative Therapy (TPT), and opportunistic infection (OI) prophylaxis,
5. Prevention of vertical transmission of syphilis, hepatitis B virus (HBV) and other infections, and
6. Other care required, e.g. basic antenatal care (BANC) services, immunization services (EPI), growth monitoring and nutrition.

For care provided by the **community** health worker (CHW) at home the following components of care are outlined:

7. Care of the non-pregnant woman of childbearing potential (CBP) at home,
8. Home-based care during the antenatal period, and
9. Home-based care after delivery for the mother and infant

Where additional information is needed you will be redirected to the relevant sections in Part Four.

4 Part Four: Algorithms and Decision Tools provides algorithms and decision tools that may apply to any service point, e.g. how to manage an elevated HIV VL, how to screen for TB and initiate TPT, important adherence messages, etc.

1 Introduction

Background

Infections during pregnancy are a major contributing factor to perinatal morbidity and mortality. In utero infections may directly affect the foetus and can lead to intrauterine deaths and stillbirths. The foetus may also be affected indirectly as a consequence of maternal infection leading to premature birth or foetal growth restriction (FGR). Infections that are asymptomatic at birth may present later in life, often within the first five years. In general, primary infections during pregnancy are substantially more damaging than re-infections or reactivations of infection. Likewise, infections acquired at an earlier gestational age tend to lead to more serious infections.[1] HIV, syphilis, TB, HBV, malaria, and more recently, listeriosis, are all infections with significant impact on maternal and child health outcomes in SA. Although all these infections are important, this guideline will focus mainly on preventing vertical transmission of HIV, syphilis and TB.

Overall Guideline Objective

This guideline aims to outline the four pillars for routine care for women of childbearing age and their families relating to:

- the prevention of new HIV cases, TB cases, syphilis cases, and other infections
- the prevention of unintended pregnancies
- the prevention of vertical transmission of HIV, syphilis, and other infections, and
- the care and treatment of the women living with, and their children exposed to HIV, syphilis and other infections

The four pillars embed a family-centered approach, acknowledging the role of partners in primary prevention, pregnancy prevention, and preventing vertical transmission.

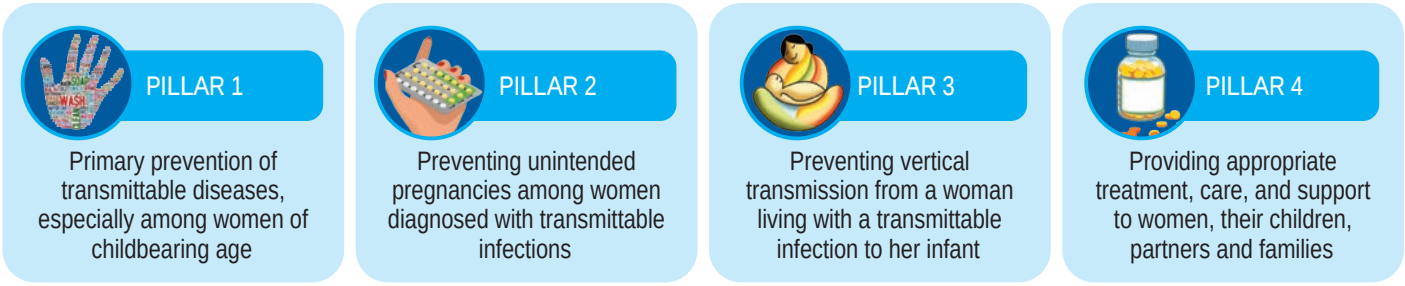


Figure 19: The four pillars of prevention of vertical infections

Overview of Transmittable Infections during Pregnancy

Overview of VTP of HIV

South Africa (SA) is committed to achieving the elimination targets outlined in the Last Mile Plan. Whilst significant progress has been made in preventing HIV infections in children, HIV remains the third leading cause of maternal mortality[2], and a significant contributor to under-five deaths in SA. Therefore, managing the health of women living with HIV and preventing vertical transmission of HIV remains a critical intervention for ensuring that women and children survive and thrive in South Africa. PMTCT Option B Plus entailed initiating ART for life in all pregnant and breastfeeding women regardless of CD4 count or clinical stage and was launched in SA in January 2015. As the programme continues to evolve, it is necessary to reflect on new evidence, both scientific and operational, to ensure that SA's HIV VTP programme remains relevant, practical, and evidence based.

Syphilis in Pregnancy

Syphilis remains a significant cause of preventable perinatal death in SA. According to the 2022 National Antenatal HIV Sentinel Survey, the prevalence of syphilis is estimated at 3.1% at national level. Compared to the prevalence of syphilis in 2015 (2.0%), the current syphilis prevalence represents a 55% increase in prevalence between 2015 and 2022. Maternal syphilis screening coverage at first antenatal visit was 97.5% at national level. However, despite good antenatal attendance and early maternal syphilis testing, there has been a resurgence of congenital syphilis (CS) cases in many provinces in South Africa[3]. Adverse pregnancy outcomes occur in up to 80% of syphilis seropositive, untreated pregnant women. South Africa has committed to dual elimination of both HIV and syphilis, and greater emphasis is therefore needed on the process of screening and effectively treating mothers, their partners, and their infants affected by syphilis.

Tuberculosis in Pregnancy

Non-pregnancy-related infections remain the leading cause of maternal mortality in South Africa. Within this category, respiratory infection remains the most common cause of death, and TB the most common underlying disease. Yet, deaths from TB are likely to be unrecognized, with many deaths due to pulmonary or disseminated TB being attributed to other causes.[4] Furthermore, maternal TB may result in premature birth, low birth weight, and congenital or neonatal TB infection or disease.[5] Preventing, diagnosing and treating women for TB must receive greater emphasis if maternal and child outcomes are to be improved in SA.

Other Infections

Malaria in Pregnancy

Pregnant women, particularly in the second and third trimesters of pregnancy, are more likely to develop severe malaria and have a higher malaria-related mortality rate than other adults. Malaria in pregnancy is more frequently associated with complications such as cerebral malaria, hypoglycaemia, anaemia, and pulmonary oedema/adult respiratory distress syndrome. In addition, maternal malaria increases the risk of spontaneous abortion, stillbirth, premature delivery, low birth weight (a leading cause of child mortality) and rarely, congenital malaria. Foetal distress may occur peripartum. The risk of severe malaria extends into the early postpartum period. Pregnant and breastfeeding women living in malaria-endemic areas should therefore be a focal group for malaria prevention interventions. It is important to follow up pregnant women treated for malaria, and their infants, more closely to promptly diagnose and adequately manage any complications of malaria in pregnancy.[6]

Hepatitis B in Pregnancy

Worsening of liver disease in HBV-infected pregnant women is uncommon, but case reports have suggested that HBV reactivation, hepatic exacerbations and fulminant liver failure may occur. Furthermore, maternal HBV infection may result in higher rates of preterm births, lower APGAR scores, gestational diabetes and antepartum hepatitis. Whilst horizontal transmission during childhood remains the primary mode of HBV transmission, vertical transmission remains an important mechanism of infection in countries with high HBV prevalence.[7] In SA, a large proportion of HBV infected women are also living with HIV and will receive ART during pregnancy. The ART drugs tenofovir and lamivudine treat both HIV and HBV and reduce the risk of vertical transmission by decreasing the viral load of both HIV and Hepatitis B. Health care workers need to be aware of the required management of a HBV-infected mother and her infant as outlined in the National Maternity Care Guidelines.

Listeriosis, Zika and Other Infections

Listeriosis is a disease caused by ingesting food contaminated with the bacterium *Listeria monocytogenes*. Pregnant women, newborn infants and those with weakened immune systems are particularly at risk and the infection may result in sepsis or meningitis with high mortality. Vertical transmission may result in stillbirth, premature delivery or severe infection in the newborn.[1]

Zika virus in transmitted by mosquitos, sexual contact, and contaminated blood products. While the majority of Zika infections are asymptomatic, infected persons may present with a short-lived febrile illness. There is no evidence that pregnant women are more susceptible to Zika virus, or that they are more likely to develop complications of the disease. However, maternal Zika infection may result in congenital brain abnormalities including microcephaly in the infant.[8]

While Zika virus infections may not be an imminent threat in the South African context, the recent outbreak of Listeriosis highlights the importance of universal measures to prevent infections during pregnancy and the breastfeeding period to prevent any form of infection and their consequences during this vulnerable time.

Populations to whom this guideline applies

This guideline covers all settings where routine sexual and reproductive health (SRH) services and HIV care and treatment services are offered to HIV-uninfected and HIV-infected women, their partners and their families. It is to be used in all South African health care facilities, and by doctors, nurses and allied health workers at primary, secondary and tertiary care levels where clients may require uncomplicated VTP care. This guideline does not cover clients with complex care issues who may require individualised client care approaches.

Universal Measures to Prevent Infections during Pregnancy

The table below summarizes the universal preventative measures that all pregnant woman should observe to prevent transmission of infections to her infant during pregnancy or breastfeeding.

Table 37: Universal measures to prevent infections during pregnancy

The Health care provider should advise the pregnant or breastfeeding client about the following practices that may increase or decrease the risks for contracting infections	
Contact with Adults with Respiratory or Flu-Like Symptoms	• Avoid close or intimate contact with adults with communicable respiratory diseases, acute or recent fever or flu like symptoms. To prevent respiratory infections, avoid: - Kissing - Sharing food utensils, drinking from the same container • Wash hands frequently and, if available, use alcohol gel after shaking hands and before eating
Sexual Contact	• Use male latex condoms consistently and correctly. - Carefully handle the condom to avoid damaging. - Put the condom on after the penis is erect and before any genital, oral, or anal contact with the partner - To prevent the condom from slipping off, hold the condom firmly against the base of the penis during withdrawal, and withdraw while the penis is still erect. - Do not use the condom more than once • Use female condoms correctly • Avoid receptive oral sex with a partner with oral herpes or intercourse during the third trimester with men who have genital herpes. • Ensure that all sexual contacts of individuals treated for STIs are linked to care and receive STI treatment.
Blood Contact	• Mastitis or nipple fissures in a woman living with HIV may increase the risk of HIV transmission, especially if bleeding or discharging. Avoid breastfeeding from the affected breast. Express milk from the affected breast. If only one breast is affected, the infant can feed from the unaffected side, and feeding more often and for longer increases milk production. If both breasts are affected, she will not be able to feed from either side. The mother will need to express her milk from both breasts. Breastfeeding can resume when one or both breast/s have recovered. The healthcare worker may need to discuss other feeding options for her to use in the meantime. • Consider the risks if you are thinking about getting a tattoo or body piercing. Infected tools can transmit hepatitis B or other infections • Do not share personal care items that might have blood on them (razors, toothbrushes). • Avoid using drugs. Do not share needles or other equipment related to drug use.
Contact with Children with Respiratory, Flu-Like Symptoms or Skin Rash	• Careful hand washing with soap and running water and, if available at home, use alcohol gel rub after - exposure to a child's bodily fluids and diaper changes, - bathing the child or handling dirty laundry, - touching the child's toys and other objects • Avoid close or intimate contact with the child such as - kissing on the mouth or cheek (kiss them on the head or give them a hug) - sleeping together, - sharing towels and washcloths, • Avoid contact with baby's saliva while feeding - sharing or tasting foods with the same utensils (spoons, forks) - drinking from the same container
Consuming, Handling, and Processing of Food	• Avoid eating raw or undercooked lamb, pork, beef or poultry. Cook all meat until it is no longer pink, and the juices run clear. Reheat any processed meat until steaming • Do not eat food that has passed its expiry date • Do not eat unpasteurized dairy products (including all soft cheeses), • Peel or wash raw fruit and vegetables thoroughly. • Wash hands, knives, and cutting boards after handling uncooked foods or fluids from their packages. • Wash hands thoroughly after handling raw meat
Protection from Insects	• Always use Insecticide-treated bed nets if you live in a malaria endemic area.

Table adapted from 'Perinatal Infections transmitted by the Mother to her Infant', March of Dimes Foundation, Latin American Center for Perinatology / Women and Reproductive Health - Pan American Health Organization / World Health Organization1

Prevention of HIV

All persons of reproductive age need access to comprehensive information, as **well as non-judgemental, confidential, and (as necessary), youth friendly SRH** services.

Contraception and HIV testing services (HTS) should always be provided together. At every FP visit, offer HTS. At every HTS visit, offer FP.

WHO should be offered HIV prevention services?

- All HIV negative women, including adolecent girls, young women, and sex workers
- HIV negative partners and other men
- HIV positive persons

WHAT
HIV prevention options should be offered?

BASIC PREVENTION PACKAGE	BASIC PREVENTION PACKAGE +	TREATMENT AS PREVENTION
HTS services Couples Counselling and partner testing Screen and treat STI's Safe sex education* Post Exposure Prophylaxis (PEP) Pre-Exposure Prophylaxis (PrEP) as applicable & available #	Voluntary Medical Male Circumcision (VMMC) and communication for men	HTS, couples counselling and partner testing, Linkage to Care, ART and HIV VL suppression

Remember, condoms are recommended for all couples regardless of HIV status

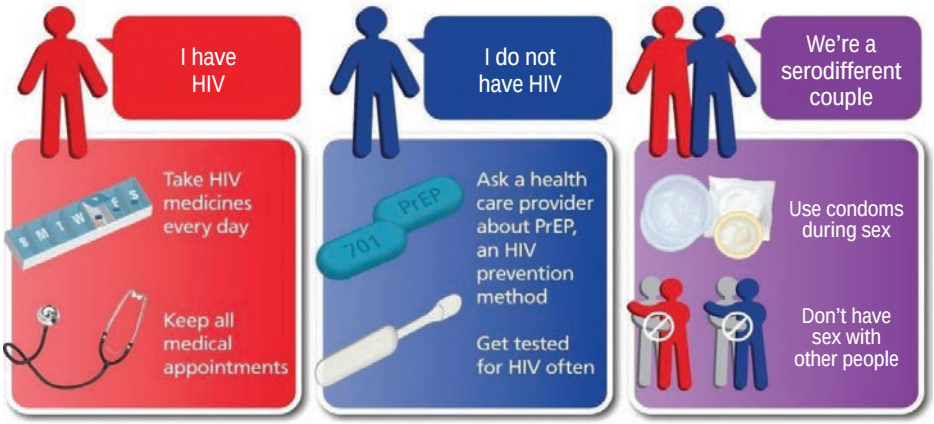
WHERE
should HIV prevention services be offered?

At all contact points with the health system, including PHC, SRH services, MNCWH&N services, Chronic and Acute Care services (including hospitals)

Community-based services, including mobile/outreach services for sex workers and other working persons

School based prevention (in the context of comprehensive sexuality education)

Ways to prevent HIV transmission within a serodifferent couple



*Safe Sex Education:

Counsel the women to avoid the following sexual practices that could put her at risk for contracting HIV and other STI's:

- The woman or her regular partner having new or multiple sexual partners
  Unreliable use of condoms
- Alcohol abuse

#PrEP is now routinely available for all PBFW including adolescent girls, young women and sex workers. It should be a priority prevention intervention offered to all PBFW with a negative HIV test result. *See PrEP Job Aid for Clinicians on page 121* *and the 2021 PrEP guidelines*

Oral PrEP (Pre-Exposure Prophylaxis) Initiation Algorithm

How to start your pregnant clients on PrEP

START WITH AN **HIV TEST**
FOLLOW HTS GUIDELINES

HIV Positive
- POST-TEST COUNSELLING
- IMMEDIATE INITIATION OF ANTIRETROVIRAL THERAPY (HIV TREATMENT GUIDELINES)

HIV Negative

COUNSEL FOR HIV PREVENTION
VMMC | Condoms | PEP | Regular HIV testing | ART for partners living with HIV | STI management

- PROVIDE INFORMATION ON PrEP TO ALL
- PROVIDE COUNSELLING
- IS THE CLIENT INTERESTED IN PrEP?

YES → ASSESS FOR ELIGIBILITY

Assess for PEP eligibility
SCREEN
- ☐ possible exposure to HIV within 72 hours, as per PEP guidelines

Assess for acute HIV infection
SCREEN
- ☐ physical examination

+ **Adolescents and youth**
SCREEN
- ☐ over 15 yrs old or
- ☐ weigh more than 30kg

+ **Creatinine serum**
SCREEN
- ☐ blood test - less than 85µmol/L

START CLIENT ON oral PrEP SAME DAY
PROVIDE 1 MONTH PrEP SUPPLY AND SCHEDULE NEXT APPOINTMENT
OFFER CONDOMS WITH PrEP TO ALL CLIENTS
Month 0: Initiation

Additional note: HepB
Screen for HepB: PrEP is not contraindicated for those with HBV. If the test is positive, start PrEP if eligible then refer to a doctor for liver function monitoring and further management of HepB.

After 1 month: **MONTH 1**
- ☐ HIV Test
- ☐ STI Screening
- ☐ Counselling
  - Importance of taking oral PrEP pills as prescribed
  - Condom use
  - Contraception
  - Importance of attending antenatal visits
  - Encourage clients to return for their next appointment

3 Month prescription for oral PrEP →

Every **3 Months**
- ☐ HIV Test
- ☐ STI Screening
- ☐ Counselling
  - Importance of taking oral PrEP pills as prescribed
  - Condom use
  - Contraception
  - Importance of attending antenatal visits
  - Encourage clients to return for their next appointment

3 Month prescription for oral PrEP →

PrEP ♥ IS CHOICE
#ICHOOSEME

Post-delivery, clinician to report pregnancy outcome on *PrEP Pregnancy Outcome Reporting Form.*

Version: OralPrEP_PBFP_InitiationAlgorithm_Aug2024

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health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Counselling Job Aid for Healthcare Providers

PrEP for pregnant and breastfeeding women

STEP 1:

Offer HIV counselling and testing to determine HIV status.

STEP 2:

For women who test HIV negative, conduct a needs assessment to determine the likelihood of exposure to HIV, by asking the following:

- If they ever have sex without a condom
- If they ever have sex while using alcohol and/or drugs
- If they ever have sex against their will
- Sex without a condom with partner/s living with HIV

be sensitive and non-judgmental

If the response is YES to any, even only one of the above or if the woman requests PrEP, proceed with providing information about PrEP:

- PrEP is an ARV pill used to PREVENT HIV infection.
- PrEP is for HIV-negative people.
- PrEP is taken daily.
- PrEP is safe to take!
- PrEP does not protect you from getting other STIs.
- PrEP does not prevent you from getting pregnant if you are breastfeeding.
- PrEP does not prevent other STIs or pregnancy.
- PrEP can be stopped at any time that you do not need it.

always try to use a condom as well as PrEP

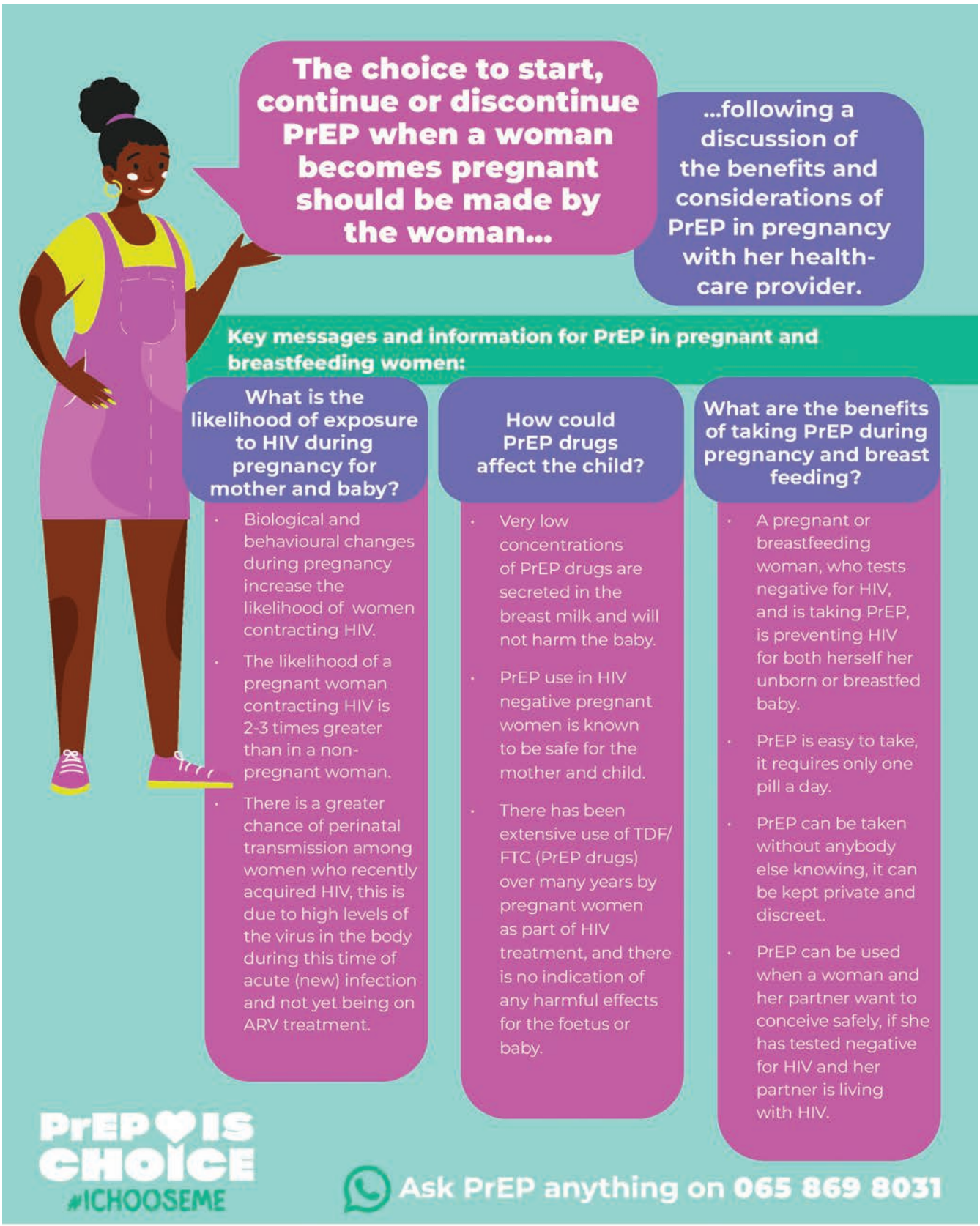
STEP 3:

Counselling on the benefits, and other considerations of PrEP in pregnancy

PrEP is one of several options which should be offered to prevent HIV in pregnant and/or breastfeeding woman who may be affected by HIV. Inform the woman about all the HIV prevention options that are available:

- Condoms
- STI screening and treatment
- Counselling to promote PrEP continuation and for a healthy lifestyle
- HIV counselling and testing for a partner/s and treatment for a partner living with HIV

emphasise the importance of follow up ANC visits



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PrEP

PREGNANT & BREASTFEEDING WOMEN

know the facts

PrEP is a safe HIV prevention method that HIV-negative people can use to prevent HIV:

- The pills need to be taken daily to help prevent HIV.
- Oral PrEP has been shown to reduce the chances of HIV infection by more than 90%.
- You have to take the pills every day, for as long as you need it.
- PrEP is only for people who are HIV-negative.

PrEP during pregnancy:

- If you are pregnant and have sex without a condom, your chances of getting HIV is much higher.
- If you test positive for HIV, you will receive ARV treatment - this prevents your baby from getting HIV.
- Using PrEP before, during and after pregnancy can prevent HIV.

What is the difference between PrEP, PEP, and ART?

All three use antiretrovirals in different combinations for different purposes:

- **PrEP** is when ARVs are taken **before** exposure to HIV, to **prevent** getting HIV.
- **PEP** is when ARVs are taken **after** exposure to HIV, to **prevent** HIV (within 72 hours and taken for 28 days only).
- **ART** is when ARVs are used to treat a person living with HIV, and is taken lifelong.

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PrEP

Pre (before)

Exposure (coming into contact with HIV)

Prophylaxis (a medicine to prevent infection)

Where can I get PrEP...

PrEP is now available in all public primary health care clinics. Visit your nearest clinic if you are interested in using PrEP. For more information about PrEP, please visit **myprep.co.za.**

Find your nearest clinic with this code:

Starting PrEP...

Don't forget your ante-natal care visits

First visit:

- Health check, including screening for HIV and STIs, supported by counselling.
- Get your oral PrEP supply for a month.
- As oral PrEP builds up in your body, use a condom or abstain from sex for the first 7 days of taking oral PrEP.
- After 7 days, you need to continue taking oral PrEP daily for as long as you need it.

Month 1 visit:

- Health check, including screening for HIV and STIs, supported by counselling.
- Get your 3-month supply of oral PrEP pills.

Every 3 months:

- Health check, including screening for HIV and STIs, supported by counselling.
- Every 3 months, you return for an HIV test and a 3-month supply of oral PrEP.

Oral PrEP works best when taken daily and used with a condom.

PrEP is one of many options for HIV prevention. You can also try:

- Condoms
- Other PrEP options which may be available at your clinic, ask your provider
- Counselling
- PEP
- Treatment for STIs
- Male medical circumcision
- ART for partners living with HIV
- Regular HIV testing for you and your partner

Decide if PrEP is for you:

- PrEP is safe for you and your unborn baby and child, while you are pregnant and/or breastfeeding.
- PrEP can protect you from HIV.
- PrEP is easy to take, just one pill a day.
- You can take PrEP without anybody else knowing.
- You can take PrEP if you and your partner who is living with HIV want to have a baby.
- You can continue taking PrEP even when you are breastfeeding.

You can take care of yourself and your baby, choose PrEP!

- Use a condom
- If you test negative for HIV, you can use PrEP!
- Ask your partner to test for HIV
- Start and continue with ARVs if you test positive for HIV
- Encourage your partner living with HIV to take ARVs daily

Oral PrEP (Pre-Exposure Prophylaxis) Counselling Guide

For healthcare providers

Step 1: Pre-test information

Step 2: HIV test

Step 3: Post-test counselling

For clients who test negative for HIV:

Step 4: Assess your client's need for PrEP

be sensitive and non-judgmental

With sensitivity, explore with your client their possible exposure to HIV, this includes:

- If they ever have sex without a condom
- If they ever have sex while using alcohol and/or drugs
- If they ever have sex against their will
- Sex without a condom with partner/s living with HIV

Individuals who answer YES to any of these questions or ask for PrEP should be considered for PrEP.

Step 5: Inform your client that PrEP, a pill that prevents HIV, is available at this clinic.

Step 6: Find out if your client is interested in knowing more about PrEP.

Step 7: Provide information about PrEP - if your client is interested and wants to know more.

- PrEP is an ARV pill used to PREVENT HIV infection.
- PrEP is for people who test negative for HIV.
- PrEP is taken daily.
- PrEP is safe to take!
- PrEP does not prevent other STIs or pregnancy.
- PrEP can be stopped at any time that you do not need it.

always try to use a condom as well as PrEP

PrEP works best when you take it every day!

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Step 8: If your client is interested in PrEP, inform them that the following will need to be checked by the nurse:

Adolescents
- over 15 yrs old or
- weigh more than 30kg

No signs of HIV infection
- physical examination
- HIV test

Kidneys are functioning well
- a blood test will only be done for persons:
  - who have diabetes, or high blood pressure,
  - are over 50 years in age,
  - are pregnant.

If all of these tests are OK, the client could start PrEP immediately. You do not have to wait for the blood results to start PrEP.

Step 9: Starting PrEP

Provide the correct information and education regarding PrEP:
- For the first seven days you need to use additional protection such as condoms, or abstain from sex.
- After this, you will need to take PrEP every day.
- If used correctly, PrEP prevents HIV by more than 90%.
- PrEP works best if you take the pills correctly and consistently, one pill a day, every day!
- You can stop taking PrEP if you feel you no longer need it.
- If you want to stop PrEP, continue to take the pills for 7 days after your last sexual contact.

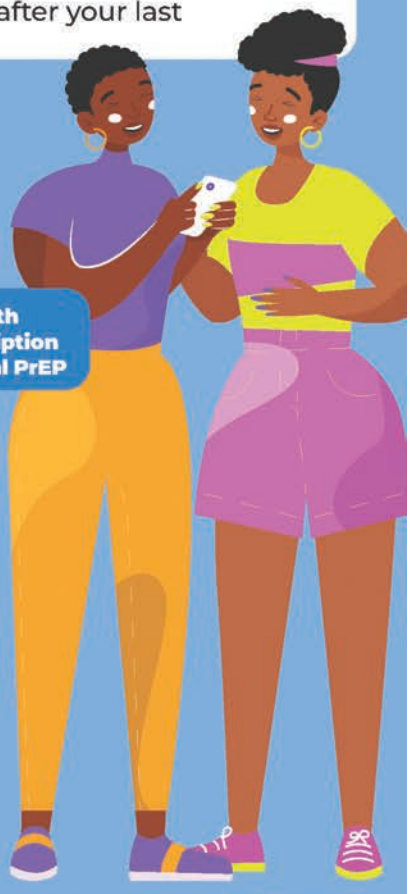
Clinic Visits:

After 1 month:
MONTH 1
- ☐ HIV Test
- ☐ STI Screening
- ☐ Counselling
  - Importance of taking oral PrEP pills as prescribed
  - Condom use
  - Contraception
  - Encourage clients to return for their next appointment

3 Month prescription for oral PrEP

Every
3 Months
- ☐ HIV Test
- ☐ STI Screening
- ☐ Counselling
  - Importance of taking oral PrEP pills as prescribed
  - Condom use
  - Contraception
  - Encourage clients to return for their next appointment

3 Month prescription for oral PrEP



Step 10: Provide support for pill-taking
- Remember to take PrEP every day.
- PrEP tablets can be taken any time of day, with food or without food.
- If you forget to take a tablet, take it as soon as you remember - if more than 2 days have passed, contact your healthcare provider for guidance.
- To help you remember to take your pill, set an alarm or link pill taking to something else that you do every day – like having your morning tea or brushing your teeth before you go to bed.
- PrEP is safe even if you are taking hormonal contraceptives, sex hormones or non-prescription drugs.
- PrEP is safe with alcohol, as long as it does not cause a person to forget to take their daily pill.

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PrEP ♥ IS CHOICE
#ICHOOSEME

VISIT SCHEDULE FOR INTEGRATED CARE: MOTHER TAKING PREP

The principles are as follows:

1. Wherever possible, try to align the mother's PrEP, HIV and STI screening and contraception visits with that of the child's EPI visit schedule so the mother-baby pair need only attend the facility once for all consultations on the same day
2. Wherever possible, allow the mother and baby to receive care at the same service point (ideally PNC/MCH) at the same facility

Age group	Age of child	Routine visits as per RTHB	PrEP Dispensing cycle (DC)	PrEP Follow-up for mother	Immunisations	Feeding advice	Growth monitoring	Development	Head circumference	Vit A	Deworming	Oral Health	TB Screen	Mother's contraception
Delivery			1	• Provide 3 months* of PrEP (3MMD) which will last until 10 week PN visit		x								
Neonate	1st week of life	3-6 days postnatal (PN) visit for mother and baby		• Provide HIV test to mother (if not tested in labour) • Check PrEP supply: The mother should have been provided with 3 months* of PrEP at delivery which will last her until 10 week PN visit • PrEP adherence check-in for mother • Provide breastfeeding support and routine post natal care		x	x						x	x***
2 - 6 months[1]	6 weeks	6 weeks	2*	• Postnatal clinical review • Provide breastfeeding support • PrEP adherence check-in	x	x	x						x	
	10 weeks	10 weeks	3	• Postnatal and PrEP clinical review and PrEP adherence check-in • Provide breastfeeding support. • Provide HIV test and STI screen to mother • Provide PrEP for 3 PrEP DCs (3MMD) for mother** • If mother received either DMPA-IM (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	• Postnatal clinical review • Provide breastfeeding support • PrEP adherence check-in	x	x	x	x	x				x	
	18 weeks	4 months	5			x	x						x	
	22 weeks	5 months	6			x	x						x	
	26 weeks	6 months	7	• PrEP clinical review • Provide breastfeeding support. • HIV test and STI screen for mother • Script for and provide PrEP for 3DCs at a time (3MMD)	x	x	x	x		x			x	x

* Mother may have PrEP supply remaining from her last supply during antenatal care. Provide sufficient PrEP supply to ensure mother has 3 months supply when she leaves the facility after delivery.

** Review and repeat script at 10 weeks (rather than 12 weeks) to align with the RTHB visit schedule. The additional 2 weeks Rx that the mother will have in reserve from delivery will allow for alignment with the 6-month RTHB appointment which usually happens around week 26 (compared to 6 DCs of PrEP which will only provide enough PrEP for 24 weeks).

*** Confirm the mother's FP method choice. Inform her that the DMPA-IM injection or the combined oral contraceptive pill (COCP) can be repeated 3-monthly, and will align well with her PrEP and well-baby visit schedules. If using self-injectable DMPA-SC, 2 units are given at a time skipping every 2nd FP requirement below. Using NET-EN 2-monthly injection will require additional visits by the mother as 2-monhtly repeat injection will not always align with the visit schedule above.

**** As per WHO recommendations[18], the repeat injection of DMPA and NET-EN can be given up to 2 weeks early[1] 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.

Abbreviations:

DC dispensing cycle (PrEP supply 28-days);
3DC three dispensing cycles of PrEP;
DMPA depo medroxyprogesterone acetate (Depo Provera®);
MIP mother-infant-pair;
MMD multi-month dispensing;
3MMD MMD, multi-month dispensing for 3 months;
NET-EN norethisterone enantate (Nur Isterate®);
RTHB road-to-health booklet

Age group	Age of child	Routine visits as per RTHB	PrEP Dispensing cycle (DC)	PrEP Follow-up for mother	Immunisations	Feeding advice	Growth monitoring	Development	Head circumference	Vit A	Deworming	Oral Health	TB Screen	Mother's contraception
7 - 12 months	30 weeks	7 months	8			x	x						x	
	34 weeks	8 months	9			x	x						x	
	38 Weeks	9 months	10	• PrEP clinical review • Provide breastfeeding support. • HIV test and STI screen for mother • Script for and provide PrEP for 3DCs at a time (3MMD)	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	• PrEP clinical review • Provide breastfeeding support. • HIV test and STI screen for mother • Script for and provide PrEP for 3DCs at a time (3MMD)	x	x	x	x	x	x	x	x	x	x
13 - 24 months	56 weeks		14											
	60 weeks		15											
	64 weeks	15 months	16	• PrEP clinical review • Provide breastfeeding support. • HIV test and STI screen for mother • Script for and provide PrEP for 3DCs at a time (3MMD)		X	X	X		X	X		X	X
	68 weeks		17											
	72 weeks		18											
	76 weeks	18 months	19	• PrEP clinical review • Provide breastfeeding support. • HIV test and STI screen for mother • Script for and provide PrEP for 3DCs at a time (3MMD)	X	X	X	X		X	X		X	X
	80 weeks		20											
	84 weeks		21											
	88 weeks	21 months	22	• PrEP clinical review • Provide breastfeeding support. • HIV test and STI screen for mother • Script for and provide PrEP for 3DCs at a time (3MMD)		X	X						X	X
	92 weeks		23											
	96 weeks		24											
2 until < 5 years [1]	24 - 59 months	At 24 months & 6-monthly thereafter		• PrEP clinical review • Provide breastfeeding support. • HIV test and STI screen for mother • PrEP continuation/discontinuation education and counselling • Script for and provide PrEP for 3DCs at a time (3MMD) • 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	3-6 monthly

Abbreviations:

DC dispensing cycle (PrEP supply 28-days);
3DC three dispensing cycles of PrEP;
DMPA depo medroxyprogesterone acetate (Depo Provera®);
MIP mother-infant-pair;
MMD multi-month dispensing;
3MMD MMD, multi-month dispensing for 3 months;
NET-EN norethisterone enantate (Nur Isterate®);
RTHB road-to-health booklet

Prevention of unintended pregnancies and safe conception in women

Contraception should be an integral part of ART services!

Regularly discuss issues of childbearing and contraception to understand current fertility desires and health care needs

! Ideally, engage the woman living with HIV and her current partner in a couples-based approach, as the health and cooperation of both partners are important for safe contraception or conception

Classify client

A. Currently wanting to conceive

Recommend, discuss, and agree on steps before conception

Optimise HIV treatment in the partner living with HIV (serodiscordant couple), or in both partners living with HIV (sero-concordant couple).

- Continue to use condoms
- Document HIV status of both partners
- Identify and manage co-morbidities, including syphilis and other STIs
- Initiate ART and support good adherence
- Maintain an undetectable HIV VL, ideally for 4-6 months before conception
- Start folate supplementation to reduce the risk for neural tube defects. Do an Hb if clinically pale
- Consider PrEP for the uninfected partner

Once viral load suppression is achieved in the partner(s) living with HIV, the following additional options are available should the couple still feel anxious about the risk of HIV transmission

- timed, limited, peri-ovulatory, sex without a condom
- intravaginal insemination
- male circumcision
- intra-uterine insemination
- sperm washing
- surrogate sperm donation

Not readily available in the public sector

If pregnancy is confirmed, counsel the mother to book at ANC before 14 weeks and to continue using condoms consistently during pregnancy and the breastfeeding period

B. Not currently desiring a child, but may do so in the future

Counsel about options for contraception including long-acting reversible contraceptives and short-acting methods, combined with barrier methods

C. No desire for a child now or in the future

Counsel about options for contraception including permanent methods (male and female voluntary sterilisation), long-acting reversible contraceptives (IUCD and implants) combined with barrier methods.
If permanent methods are not appropriate, proceed to an alternative dual method as outlined below

Dual method is always recommended:

Hormonal method (any short acting method or implants/hormonal IUDs) or copper IUD to prevent pregnancy

A barrier method (male/female condoms) to augment the hormonal method, and prevent STIs and HIV

Discuss the different contraceptive options available for use in the women living with HIV (See PC101, and the National Contraceptive Clinical Guideline, 2019)
Available options include:

Long-acting reversible methods
- Implants
- Copper/Hormonal IUDs

Short-acting methods
- HCW administered intra-muscular injectable progestins (DMPA-IM/ NET-EN IM)
- NEW Self-injectable sub-cutaneous injectable progestins (DMPA S/C)*
- Combined oral contraceptive pills
- Emergency contraceptive pill

All hormonal methods including implants (e.g. Implanon NXT®) and the injectables (e.g. Depo Provera®) are effective when used with Dolutegravir.

*A woman's choice of contraceptive method may be influenced by her ART service delivery model to allow for better visit alignment. Certain methods are easier to integrate when collecting longer ART refills outside of a facility, through fast track collection facility pick-up points or adherence clubs. Implants and IUDs don't require any alignment considerations. Subcutaneous self-injectables and oral pills should be prescribed for the same script and refill length as ART. Healthcare worker administered intra-muscular injectables require more frequent facility visits and can negate longer refills and easier collection. See also the *Visit Schedule for Integrated Care for the Mother living with HIV and her HIV-exposed Infant on page 162*.

3 Charts per Service Delivery Area

All Service Areas

All services areas that provide care for women of childbearing potential should include the following in their package of care:

- Ask if she is using reliable contraception, and if not, refer for contraceptive services
- Screen all woman of childbearing potential (CBP) for pregnancy and ask if she is breastfeeding. If she is not on reliable contraception or her period is late, provide/refer her for a pregnancy test.
- Encourage all women and girls to test for HIV if they are sexually active. Offer an HIV test to the woman and her partner if they have not tested in the last year.
- If she is a known to be living with HIV, ask if she is on ART and ask about her last VL.

Antenatal clinic

When caring for a pregnant woman, always be sure to:

- Recognise the pregnant client that requires urgent attention as outlined in BANC Plus and manage/refer as appropriate
- Identify the pregnant client who needs secondary level antenatal care as outlined in BANC Plus and manage/refer as appropriate
- Provide routine antenatal care to the woman not requiring urgent referral.

PRIMARY OBJECTIVES

1. Identify HIV infection and achieve viral suppression
2. Identify and treat syphilis and other infections

TESTING for HIV

HIV Testing: Provider Initiated Counselling and Testing (PICT) should be provided to all women with unknown or HIV-negative status:

- Offer an HIV test at ANC first/booking visit.
  - If she tests negative, HIV testing should be repeated at scheduled antenatal visits, at approximately 4-weekly intervals, e.g., for BANC+ clients, this could be at 20, 26, 30, 34, and 38 weeks gestation
  - During her labour/delivery admission
- Syphilis testing should be aligned with the HIV testing schedule (See *Syphilis on page 157*).
  - If a woman tests positive for HIV, but tests negative for syphilis, repeat syphilis testing should continue at the intervals described above.
  - If a woman tests positive for syphilis but tests negative for HIV, repeat HIV testing should continue at recommended intervals
- Offer couple/partner testing to promote prevention, access to HIV care and treatment, and/or manage serodifferent results (when one partner has HIV and the other partner does not).
- If the woman and/or her partner test HIV-negative, provide HIV prevention information (Go to *Prevention of HIV on page 120*).
- Women who choose not to be tested should be offered 'post-refusal' counselling and offered a re-test at every subsequent visit.
- If a woman tests HIV-positive at any stage, encourage testing of her other children, and linkage to HIV care and treatment as necessary.
- For the HIV testing algorithm, including the management of discrepant HIV test results, refer to the HTS Guideline.

TREATMENT for HIV

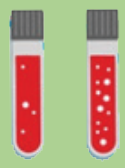
- All pregnant women newly diagnosed with HIV are eligible for lifelong ART regardless of gestation, CD4 count, or clinical stage.
- Creatinine and CD4 count should still be done to determine her renal function and the need for prophylaxis for *pneumocystis jerovecii* pneumonia (PJP) and cryptococcal meningitis (CM).
- TDF, 3TC, and DTG (as the fixed-dose combination TLD) is the preferred regimen for women who are newly initiating, or re-initiating, ART. ART should be initiated on the same day as HIV diagnosis[10], and after contra-indications to ART have been excluded (Go to *ART Initiation Algorithm on page 141*).
- Pregnant women who are already on TLD at entry into antenatal care, should continue their current TLD regimen.
- Pregnant women who are already on ART at entry into antenatal care but not yet on DTG, should be transitioned to a DTG-containing regimen as a matter of urgency (see also *Switching Existing Clients to DTG-containing Regimens in Women on page 139*)
  - Pregnant women on efavirenz-containing ART, or women on AZT, 3TC and DTG (as a second-line regimen), should be switched to TLD at their first antenatal visit. The result of their 1st VL (to be done at entry into antenatal care as outlined below) will not influence the decision to switch, and outstanding VL results should therefore not delay her switch to TLD. If her VL is ≥ 50 c/mL, manage her as per the *VL Non-Suppression Algorithm on page 144*).
  - Pregnant women on a LPV/r-containing regimen should await the results of their 1st VL to be done at entry into antenatal care, and be managed as per the Switching Existing Clients to DTG-containing Regimens table on page 14 of the ART Clinical Guideline.
  - If a woman who is already on ART at entry into antenatal care will now collect her ART from the antenatal service point, ensure that she is documented as a transfer-out from her former ART clinic, and not classified as lost-to-follow-up.
- Known HIV-positive women, who are not currently on ART, but are ART-experienced (e.g. previous VTP, or previous LTFU on ART) should re-initiate TLD*.
- Appropriate ART literacy education should be given to the woman before she leaves the facility. (Go to *Key Adherence Messages on page 142*)
- All women living with HIV should be referred to a CHW to support adherence, breastfeeding and retention in care pre- and post-delivery.

* *Unless previously already on a 3rd line regimen or unsuppressed on a PI-based regimen for over 2 years before interrupting treatment. These clients should be discussed with an expert before re-initiating.*

Remember to put the VTP code: C#Antenatal in the EGK code field of the laboratory form for each VL done to ensure the electronic gatekeeping rules (EGK) do not lead to sample rejection

VL MONITORING and Management

(Go to *Viral Load Monitoring Schedule on page 143*)



Newly diagnosed and initiated ART for the first time:

- Do 1st VL at 3 months on ART.
- If VL < 50 c/mL, repeat VL at delivery.

Known HIV-positive women already on ART:

- VL at first/booking visit in ANC,
- If VL < 50 c/mL, repeat VL at delivery.

Known HIV-positive women, who are not currently on ART, but are ART exposed (e.g. previous VTP, or ART LTFU) and who are initiating a DTG-containing regimen:

- Do 1st VL at 3 months on ART.
- If VL < 50 c/mL, repeat VL at delivery.

If the VL is ≥50 c/mL in any of the above scenarios, go to *VL Non-Suppression Algorithm on page 144.*

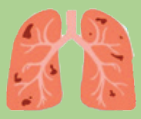
✓ Early referral to community-based services improves adherence to ART, exclusive breastfeeding and retention in care

! Pregnant adolescents are at a higher risk for poor adherence and poor viral suppression and require more intense support.

Go to *Care of the Pregnant Adolescent Living with HIV on page 146*

! Remember to insert the laboratory barcode sticker and record all VL, TB, and syphilis results in the Maternity Case Record/ ANC Card, and the ART Clinical Stationery (if available in that facility)

SCREENING for TB and other OI's



Screen for TB at every visit regardless of HIV status and consider TPT if CD4 < 200 cells/mm^3. Ensure any woman diagnosed with TB is adherent to TB treatment and that she is aware that her newborn may require TB prophylaxis (Go to *TB screening for pregnant and breastfeeding women on page 152*).

Initiate Cotrimoxazole Prophylaxis (CPT) if CD4 count ≤ 200 cells/μL, or WHO clinical stage 3, or 4.

If CD4 ≤200 cells/uL the laboratory will automatically perform a Cryptococcal Antigen test (CrAg). CrAg-positive clients who are pregnant should be offered an LP (regardless of symptoms) and discussed with an expert before a decision is made regarding management.

PREVENTION of transmission of syphilis, HBV and other infections

Syphilis: All pregnant women need to be screened and tested for syphilis

- At her 1st/booking visit in antenatal care.
- If she tests negative, syphilis testing should be repeated:
  - At scheduled antenatal visits, at approximately 4-weekly intervals, e.g., for BANC+ clients, this could be at 20, 26, 30, 34, and 38 weeks gestation
  - During her labour/delivery admission
  - At the time of diagnosis of an intrauterine death
  - At any time, if the mother has clinical symptoms or signs suggestive of syphilis

The frequency of syphilis testing should be aligned with the HIV testing schedule.

- If a woman tests positive for HIV, but tests negative for syphilis, repeat syphilis testing should continue at the intervals described above.
- If a woman tests positive for syphilis but tests negative for HIV, repeat HIV testing should continue at recommended intervals

Rapid syphilis tests are available as a **single** rapid diagnostic test (RDT) that tests only for syphilis, and a **dual** RDT which tests for both syphilis and HIV using the same drop of blood. **Dual syphilis-HIV rapid tests should only be used in clients:**

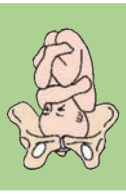
- Whose HIV status is negative or unknown AND
- Who have not had a previous syphilis infection

For more detail on the types of syphilis tests available, their interpretation and the clinical management of syphilis, go to *Syphilis on page 157*

HBV: **All women living with HIV will automatically be treated for HBV when they start routine ART containing TDF and 3TC /FTC.** Any woman who is HIV/HBV coinfected and cannot use TDF due to renal dysfunction should be discussed with an expert. If an HIV-negative pregnant woman is known to have HBV infection, she should be referred to a high-risk clinic for further tests to determine eligibility for treatment. Mothers who are Hepatitis B infected should deliver at a facility where both hepatitis vaccine and anti-Hep B Immunoglobulin can be given to the baby on the day of birth.

Malaria: **Although vertical transmission is rare, malaria in pregnancy poses serious risks for both the mother and the baby.** Malaria presents as a febrile illness and is often unrecognized or misdiagnosed with severe consequences.
The most important aspect of making a diagnosis of malaria is having a high index of suspicion. If a woman presents with a fever during pregnancy, always ask about her travel history. Refer any woman with signs of severe illness or danger signs as outlined in PC101. Comprehensive information on Malaria in Pregnancy is available in the Guideline for Maternity Care in South Africa, and the National Guideline for the Treatment of Malaria SA.

! TB and other non-pregnancy related infections remain an important cause of maternal and neonatal mortality



Labour and delivery

PRIMARY OBJECTIVES

1. Safe delivery for mother and infant
2. Prevent vertical transmission during labour

TESTING for HIV

PICT should be provided to all women presenting in labour ward who are not known to be HIV-positive (including born-before-arrivals [BBAs]):

- Offer couples counselling and partner testing. For the management of the serodifferent couple, go to *the HIV Prevention section on page 120.*
- Women who choose not to be tested should be offered 'post-refusal' counselling and offered a re-test at every subsequent visit.
- If a woman tests positive at any stage, encourage testing of her other children, and linkage to HIV care and treatment as necessary.
- If a woman has indeterminate or discrepant HIV test results, treat the baby as a high-risk HIV-exposed infant until mother's HIV status can be confirmed. Communicate clearly to the mother and document the results and plan of action in the maternal record and RTHB.
- If she tests HIV-negative, offer PrEP at discharge.

Antiretrovirals

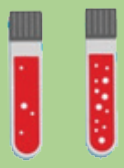
Pregnant women already on ART should continue their current ART regimen at usual dosing times during labour.

Newly diagnosed, or known HIV positive women not on ART:

- Give a stat single fixed dose combination tablet of TDF, 3TC and DTG (TLD) and a stat single dose of NVP.
- Lifelong ART should be initiated the following day after contra-indications to ART have been excluded (Go to *the ART Initiation Algorithm on page 141*). TLD is the preferred regimen. A contraceptive method is recommended. Provide her with a choice of contraceptive options as desired.
- Appropriate ART literacy education should be given to the women before she leaves the facility. (Go to *Key Adherence Messages on page 142*).
- Mothers must understand and anticipate the adherence challenges that may be experienced in the postpartum period.

! An elevated viral load at delivery increases the risk for poor maternal outcomes and vertical transmission during labour and through breastfeeding.

VL MONITORING and Management



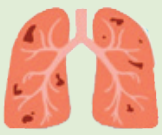
- All women must have a VL test done at the time of delivery.
- Remember to insert the laboratory barcode sticker into the postnatal discharge form and the RTHB.
- The results of the delivery VL will determine the infant's risk-profile. Until the results are known, all infants will receive dual prophylaxis with NVP and AZT.
- The results of the delivery VL must be checked within 3 to 6 days, and the management of the mother-infant pair adjusted accordingly.
- If the mother's delivery HIV VL < 50 c/mL
  - Affirm and encourage good adherence
  - Repeat maternal VL 6 monthly during breastfeeding
  - The infant should be re-classified as low-risk
- If the mother's delivery HIV VL ≥ 50 c/mL
  - The mother should be managed as per *Management of a High Maternal Viral Load after Delivery on page 147*.
  - The infant should be re-classified as higher-risk and managed as per *Prophylaxis for the HIV-Exposed Infant at Birth on page 148*.

Remember to put the correct VTP code in the EGK code field of the laboratory form for each HIV VL done to ensure the electronic gatekeeping rules (EGK) do not lead to sample rejection.

Use the code C#Delivery for all VLs done at the time of delivery.

SCREENING for TB and other OI's

- Screen all women for TB at entry to the labour ward, and initiate TPT for women living with HIV before discharge, if eligible (Go to *TB screening for pregnant and breastfeeding women on page 152*).
- Initiate Cotrimoxazole Prophylaxis before discharge if CD4 count ≤ 200 cells/uL, or WHO clinical stage 3, or 4.



Other Care for the Mother living with HIV at delivery

For **all pregnant women**, including those living with HIV, provide routine, safe and respectful care during labour and delivery according to the Maternity Care Guidelines of SA. This includes:

- avoiding unnecessary episiotomies
- avoiding unnecessary assisted deliveries
- avoiding unnecessary rupture of membranes
- avoiding excessive suctioning of the infant
- If a C/section is required, provide prophylactic antibiotics, unless sepsis in the mother requires the use of therapeutic antibiotics (this is applicable to all women requiring CS, regardless of HIV status).

Within 1 hour of delivery

- Encourage skin-to-skin contact with baby and initiate exclusive breastfeeding. Hospitals and labour wards can support mothers to breastfeed by following the WHO *The Ten Steps to Successful Breastfeeding on page 154*. In addition, counsel mother on *Breastfeeding Plus on page 155*.

At discharge

- Ensure contraception has been administered after appropriate counselling (go to *Contraception and Safe Conception on page 130*).
- Provide the mother with two-months' supply of ART and six-weeks supply of infant prophylaxis.
- Communicate follow-up appointment dates for the six-day post-natal visit at a named facility. Provide necessary referral letters. Provide an ART transfer-out letter, if she will receive her ART at a different facility. However, it is recommended that the mother-baby pair continue to receive integrated care within the maternal and child health stream until the baby is two years old or no longer breastfeeding.

Care of the HIV-exposed Infant at Delivery

- All HIV-exposed Infants should receive **a birth HIV-PCR** to identify HIV transmission that occurred in-utero.
- All HIV-exposed Infants should be initiated on **dual post-exposure prophylaxis with NVP and AZT** until the result of the delivery-VL can be reviewed.
  - If the mother-baby pair have already been discharged, this may be at the 3-6 day postnatal visit at the clinic. Clinicians working in postnatal clinics should therefore review the results of delivery VL.
  - If the baby is still admitted to hospital, ward staff should ensure that the results are reviewed.
- Once the result of the delivery VL is known, prophylaxis should be adjusted accordingly.
- If the mother's delivery HIV VL < 50 c/mL regardless of feeding choice:
  - Re-classify the infant as low-risk
  - Stop AZT
  - Continue NVP daily for six weeks
- If the delivery HIV VL ≥ 50 c/mL in a breastfeeding mother
  - Re-classify as higher-risk
  - Continue AZT twice daily for six weeks
  - Continue NVP daily for a minimum of 12 weeks. NVP should only be stopped when the breastfeeding mother has a HIV VL of less than 50 c/mL, or until four weeks after she has stopped breastfeeding.
  - The mother should be managed as per the *VL Non-Suppression Algorithm on page 144*

All higher-risk infants who are exclusively formula fed should receive AZT for 6 weeks and NVP for 6 weeks. (Go to *Prophylaxis for the HIV-Exposed Infant at Birth on page 148*)

Provide oral polio vaccine, BCG and other routine neonatal care as per the Maternity Care and Neonatal Care Guidelines.

Do not give BCG if baby is TB-exposed, and will be receiving TB prophylaxis (Go to *Management of the Newborn exposed to TB on page 153*).

PREVENTION of transmission of syphilis, HBV and other infections

Syphilis: Examine the newborn of the mother who has confirmed or suspected syphilis (see *Congenital Syphilis on page 161*). All symptomatic newborns will require admission for 10 days of treatment. If unable to admit at the current level of care, refer all babies with suspected congenital syphilis infection to the appropriate level of care for inpatient admission & work-up. The following babies should be treated:

1. **Any symptomatic baby** born to a mother with syphilis, regardless of the mother's treatment status. Admit/refer for admission and 10 days of treatment (see "Congenital Syphilis" on page 41).
2. Asymptomatic babies born to mothers with **inadequately treated or untreated syphilis:**
   a. mother did not complete three doses in full, or
   b. mother received three doses but there was a delay of > 14 days between weekly IM doses, or
   c. the last dose was less than 30 days before delivery, or
   d. the dose that the mother received was incorrect, or
   e. mother did not receive any treatment for syphilis, or
   f. mother was treated for syphilis with an antibiotic that was not penicillin

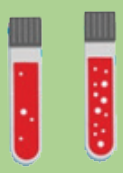
→ Treat with **single dose Benzathine Penicillin G 50 000 units/kg IM**

HBV: All babies born to mothers who are Hepatitis B infected should be delivered at a facility where both hepatitis vaccine and anti-HepB immunoglobulin can be given to the baby on the day of birth. The baby can then continue with the normal hepatitis B vaccination schedule in accordance with the EPI schedule (Go to *Management of the Infant Exposed to Hepatitis B on page 166*).

Care of the mother after birth

PRIMARY OBJECTIVES

1. Prevent vertical transmission through Breastfeeding
2. Retain Mother in Care
3. Achieve and Maintain Viral Suppression

	6 DAYS	6 WEEKS	10 WEEKS	6 MONTHS	18 MONTHS
TESTING for HIV 	Retest the HIV-negative mother if she was not retested in labour		Retest every HIV-negative mother at the 10-week visit (~ three months postpartum), the six-month visit, and every three months whilst breastfeeding Remember to offer partner testing. If no longer breastfeeding, ensure that the mother receives an HIV test at least every year. Offer/continue PrEP as needed		
Antiretrovirals 	Mother to continue ART during the postpartum period and for life. If she is newly diagnosed during the breastfeeding period, initiate ART after contra-indications to ART have been excluded (Go to *ART Initiation Algorithm on page 141*). Provide appropriate fast-track initiation counselling (FTIC) as per DMOC SOP 1. Initiate TDF, 3TC, and DTG (TLD) as the preferred regimen. This is a high-risk period for poor adherence. Ensure that the mother understands the importance of continued viral suppression for her own health and that of her baby. She must also understand and anticipate the adherence challenges that may be experienced in the postpartum period. Link the mother to MomConnect, a CHW, a mentor mother, or a support group/club if available. Whether continued ART care is provided at MNCWH services (preferred) or at PHC/Wellness services, ensure that mother is retained in care, adherent to ART, and maintains a suppressed viral load.				
VL MONITORING and Management 	Check ART adherence Follow-up on result of delivery-VL. (If not yet available, follow-up again in 1 week. If VL not done at delivery, do VL at this visit) If VL ≥ 50 c/mL: • Manage mother as per *VL Non-Suppression Algorithm on page 144*. • Re-classify her infant as higher-risk and manage as per *Prophylaxis for the HIV-Exposed Infant at Birth on page 148*) • If the mother and baby are not receiving integrated care at the same service point, ensure that the delivery VL result is communicated to the clinician caring for her baby	Check ART adherence Repeat VL if delivery-VL was ≥ 50 c/mL. Check mother's ART supply and confirm where she will be receiving her ongoing ART care ! Viral Load suppression is critical for the health of the mother, her baby, her subsequent pregnancies, and her partner!	Check ART adherence Check, record and act on any earlier VL tests Check mother's ART supply and confirm where she will be receiving her ongoing ART care	Check ART adherence at every visit. Check, record and act on results of any earlier VL tests Do a VL for all HIV-positive mothers on ART at six months (use EGK code C#Postnatal) Continue VL monitoring every six months (at 12,18, and 24 months) whilst breastfeeding. Ensure that the results of any VL test done is checked within 1 week. If VL ≥ 50c/mL: • Recall the mother-infant pair to the facility • Manage mother as per *VL Non-Suppression Algorithm on page 144* • Restart/extend infant prophylaxis if mother is still breastfeeding. Go to *Management of a High Maternal Viral Load after Delivery on page 147*.
SCREENING, PREVENTION, and other routine services	• Routine postpartum care as per the Maternity Care Guideline • TB screening, TPT, and CPT according to guidelines • Mental Health: Screen for postpartum depression • Contraception and STI screening • Infant feeding counselling and support according to the Infant and Young Child Feeding Policy • Counselling on safe use of water, sanitation and hygiene (WASH) • A Pap smear can be done from six weeks onwards if she is due for a routine papsmear, or if indicated by an earlier abnormal smear		! Remember to put the correct VTP code in the EGK code field of the laboratory form for each HIV VL done to ensure the electronic gatekeeping rules (EGK) do not lead to sample rejection. Use the code C#Postnatal for all VLs done at 6 months after delivery and any other VL done on a breastfeeding mother. • TB screening, TPT, and CTMX according to guidelines • Mental Health: Screen for postpartum depression • Contraception and STI screening • Infant feeding counselling and support according to the Infant and Young Child Feeding Policy • Counselling on safe use of water, sanitation and hygiene (WASH) • Papsmear (if indicated)	

Care of the HIV-exposed infant after birth

HIV Testing and Early Infant Diagnosis

3-6 DAYS	6 WEEKS	10 WEEKS	6 MONTHS	18 MONTHS	OTHER TESTS (AT ANY TIME)
Follow-up results of **birth** HIV-PCR and manage accordingly. Any HIV positive neonate should be discussed/ referred to a clinician experienced in managing an HIV-positive neonate. ART should be initiated even if the infants weighs less than 2,5 kg.	Ensure that birth HIV-PCR and mother's VL results were checked, recorded and acted upon correctly.	Do HIV-PCR for all HIV-exposed infants who previously tested HIV-PCR negative.	**Known HIV-exposed infants:** • Do HIV-PCR test at 6 months in all HIV-exposed infants, except in those who previously tested positive and are on ART.	**Universal HIV testing at 18 months** (HIV rapid test for <u>all</u> infants regardless of HIV exposure, except in those who previously tested HIV positive and are on ART)	Do an age-appropriate **HIV test 6 weeks post-cessation** of breastfeeding, even if breastfeeding continues beyond 18 months of age. Test a symptomatic child at any age according to IMCI guideline.

! The HIV-exposed but uninfected (HEU) child is at higher risk for poor outcomes and requires careful follow-up. Go to *Care of the HIV-exposed but Uninfected Infant on page 156*

! Use the *NHLS Results for Action (RfA) Reports* to follow up on laboratory results (See *page 167*). Any child with a positive, indeterminate, or not-resulted PCR should be traced to come back to the clinic urgently. A clinical audit can provide insight into reasons for the failed VTP.

Infants not known to be HIV-exposed:

- At six months of age, establish the HIV status of all infants not already known to be HIV-exposed
- Offer an HIV test to the mother. If she tests HIV negative, no infant test is required
- If the mother is not available, or refuses an HIV test, get consent and do an HIV rapid test on the infant
- All positive infant rapid tests need to be confirmed with an HIV-PCR.

Confirmatory test for HIV

Any child under two years with a positive HIV-PCR or a positive HIV rapid test should have their HIV status confirmed with an **HIV-PCR test on a new sample**. At the clinician's discretion, the HIV-PCR may be replaced by a viral load test which has the advantage of both confirming the HIV diagnosis and providing a baseline VL for monitoring the child's response to ART. **Any child who tests HIV positive should initiate ART** according to the Paediatric ART guideline as a matter of urgency. Do not wait for the confirmatory result before initiating ART **but ensure that this result is checked**. For the Management of Indeterminate HIV PCR results, go to *Management of Indeterminate PCR results and the Abandoned Infant on page 151*.

AGE OF CHILD	HIV SCREENING TEST	HIV CONFIRMATORY TEST
Less than 18 months	PCR	PCR
18 months to 2 years	Rapid	PCR
More than 2 years	Rapid	Rapid

Infant Prophylaxis

Check **adherence**/ tolerance to NVP (and AZT, if applicable). Ask the mother to explain how she administers the infant's medication.

Check result of mother's

delivery-VL.

If necessary re-classify infant as higher / low-risk and adjust prophylaxis accordingly.

See *Prophylaxis for the HIV-Exposed Infant at Birth on page 148*)

Low-risk infant:
Stop NVP if mother's VL at delivery was < 50 c/mL.

Higher-risk infants:

- **stop AZT,**
- **continue NVP** for a minimum of 12 weeks until maternal viral load suppression is obtained, or until four weeks after all breastfeeding has stopped.

Higher-risk infants:

Continue NVP prophylaxis.

Review VL result if repeated at 6 weeks and stop/ extend NVP as necessary.

At every visit, check results of mother's most recent VL.
An elevated VL may require higher-risk infant prophylaxis (6 weeks AZT twice daily and 12 weeks NVP daily) to be restarted or existing NVP prophylaxis to be extended. Go to *Management of a High Maternal Viral Load after Delivery on page 147*.

! Remember to adjust NVP dosages according to weight

Stop NVP after 12 weeks only if mother's VL is < 50 c/mL. If the maternal VL is not suppressed by 12 weeks, continued NVP **until mother's VL is <50 c/mL**, or until four weeks after all breastfeeding has stopped.

If a child tests **HIV positive** at any stage, **stop** NVP prophylaxis, **initiate ART**, do a confirmatory HIV PCR, and initiate cotrimoxazole prophylaxis according to guidelines.

! For any child who tests HIV-positive ensure that:

- Confirmatory testing has been done and the child is tracked and linked to care,
- The mother and other significant caregivers are counselled appropriately,
- CHWs are involved,
- The child is registered on Tier.net & retained in care.
- a nutritional assessment is done, and the breastfeeding mother is advised to continue breastfeeding her HIV positive baby

If mother diagnosed with HIV after delivery or during the breastfeeding period go to *Management of a High Maternal Viral Load after Delivery on page 147*

Other Routine Care

Routine growth monitoring, immunisations, nutritional support. Provide advice to support breastfeeding. Go to *Breastfeeding Plus on page 155*

Routine growth monitoring, immunisations, vit A, deworming and nutritional support. Provide advice to support **breastfeeding**. Go to *Breastfeeding Plus on page 155*

The community health worker

Early referral to community-based services improves adherence to ART, exclusive breastfeeding and retention in care

Care of the non-pregnant woman of childbearing potential (CBP) at home

- Ask if she is using reliable contraception, and if not, refer to the clinic. Discuss the advantages of planned parenthood.
- Screen all woman of childbearing potential (CBP) for pregnancy. If she is not on reliable contraception or her period is late, provide/refer her for a pregnancy test.
- Encourage all girls, boys, women, and men to test for HIV if they are sexually active. Offer an HIV test to the woman and her partner if they have not tested in the last year.
- Discuss healthy nutrition with the family.

Encourage pregnant women to attend at the antenatal clinic

- Identify pregnant woman early.
- Encourage booking at the antenatal clinic before 14 weeks.
- Encourage attendance of all 8 antenatal appointments.
- Track and trace any woman who missed their clinic appointments.

Identify the pregnant woman living with HIV

- Check that she has been offered an HIV test during this pregnancy.
- Encourage partner testing.
- Encourage testing of any other children living in the household if she tests positive for HIV.

Counsel all pregnant women on good nutrition and following a healthy lifestyle

- Discuss infant feeding.
- Follow a healthy diet.
- Avoid tobacco, alcohol, drugs and traditional remedies.
- Wash your hands after using the toilet, before and after preparing food, or after changing a baby's diaper/nappy.
- Practice safe sex and continue to use condoms.

Prevent vertical transmission of HIV, syphilis and TB

- Provide education on STI's, HIV, ART and the importance of viral load suppression.
- Encourage adherence to ART and all other treatment provided by the clinic.
- Counsel on the importance of exclusive breastfeeding.
- Screen all woman for TB and STI's.

Promote safety during pregnancy and delivery

- Educate her and her family on danger signs in pregnancy.
- Educate her on the signs of labour.
- Encourage the mother to deliver in a clinic or hospital.
- Encourage her to plan her mode of transport to the delivery site.

Postnatal care for mother and baby

- Check mother for bleeding, infections, mastitis (see *Universal Measures to Prevent Infections during Pregnancy on page 119*), and depression. Screen the mother for TB.
- Refer mother or baby at any stage if ill, including the jaundiced (yellow-skinned) baby.
- Educate mother on universal infection control practices if either mom or baby are ill (Go to *Universal Measures to Prevent Infections during Pregnancy on page 119*).
- Provide support for exclusive breastfeeding and advise on latching and positioning of baby whilst feeding.
- Educate on hygienic cord care and keeping the baby warm (thermal care).
- Continue to support good adherence to ART, cotrimoxazole (if indicated), and other treatment.
- Make sure that the mother is giving infant NVP (and AZT) correctly (NVP once daily and AZT twice daily).
- Make sure mother and baby attend all postnatal check-ups and immunisation appointments.
- Check that baby is growing well. Refer for an assessment by a clinician if there are any growth concerns.
- Educate mother on contents of RTHB, including infant nutrition and danger signs in infants and children.
- Educate mother on child spacing and available contraception methods at the clinic.

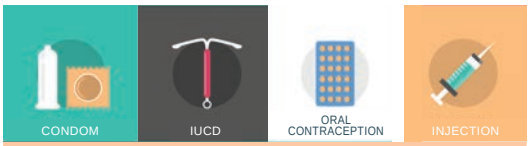
Dolutegravir (DTG) in pregnancy and safe conception in women

BENEFITS OF DOLUTEGRAVIR[16]

- ✓ Superior Efficacy
- ✓ Side-effects are mild and uncommon
- ✓ High genetic barrier to resistance
- ✓ Cost effective
- ✓ Small tablet
- ✓ No interaction with hormonal contraceptives
- ✓ Can be used with TB treatment if boosted

Evolving evidence has found there to be no significant difference in neural tube defect (NTD) prevalence between DTG- and EFV-exposure at conception[17].

TLD is now the preferred first-line regimen in all WOCP, regardless of her intentions to conceive, her pregnancy status, or whether she is using contraception or not.



Concerns regarding neural tube defects (NTDs) on DTG in previous years created an important focus on the **integration of contraception into ART services.**

Contraception 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.

All Adult and Adolescent Females and Males ≥ 30 kg and ≥ 10 years of Age

TDF + 3TC + DTG (TLD)

Switching existing clients to DTG-containing Regimens

Women who have already initiated ART on non-DTG containing regimens should be transitioned to a DTG-containing regimen as a matter of urgency. The table below provides guidance on non-VL dependent switching of existing clients to DTG-containing regimens.

NON VL-DEPENDENT REGIMEN SWITCHES Regimens where the VL result will not influence nor delay the decision to switch to a DTG-containing regimen		
Current Regimen	**Criteria for switch**	**Regimen if change indicated**
TEE ABC/3TC/EFV AZT/3TC/EFV AZT/3TC/DTG On any LPV/r or ATV/r regimen for less than 2 years duration	**Switch all to a DTG-containing regimen, regardless of VL result** Do VL at booking/1st ANC visit as for all pregnant women on ART. If VL at booking visit is not suppressed, continue to switch same day, but do ABCDE assessment and provide enhanced adherence counselling (EAC) if needed.	TLD provided no renal dysfunction and age > 10 yrs and weight > 30 kg If client does not qualify for TDF ABC/3TC/DTG If client does not qualify for TDF and has ABC hypersensitivity AZT/3TC/DTG

VL-dependent switches to DTG

Women who have been on PI-based regimens for more than two years also require a transition to a DTG-containing regimen. However, transitions in these women are VL-dependent: their VL result in the last 12 months will influence the decision of how and when to switch to a DTG-containing regimen. For further guidance, please refer to

Switching existing clients to optimised DTG-containing regimens on page 36

Drug interactions with dolutegravir

INTERACTING DRUG	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
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. 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.

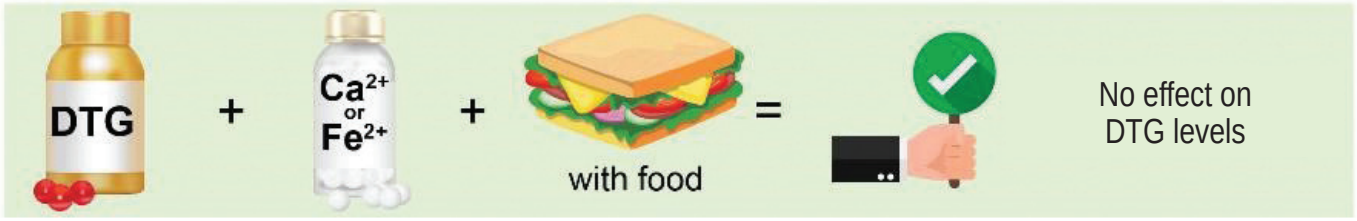
Medications for **diabetes** and **epilepsy** also have important drug interactions.

Pregnant women with co-morbidities, e.g., diabetes or epilepsy are a high risk group who should be discussed with an expert / referred.

See also

https://www.hiv-druginteractions.org/checker as a useful resource to check for drug interactions

or the SA HIV/TB Hotline smart phone application



However, Calcium (Ca^{2+}) and Iron (Fe^{2+}) must be taken 4 hours apart

Any pregnant or breastfeeding women with a new HIV diagnosis, or
any known positive woman (not currently on ART) with a new pregnancy diagnosis

* Known HIV positive women, who are not currently on ART, but are ART-exposed (e.g. previous VTP, or previous LTFU on ART) should initiate TLD.

! Timing of ART initiation in pregnancy is critical. Every week a mother is on ART further decreases her risk of vertical transmission[10]

Take a history and do a clinical examination:

Exclude contra-indications to starting ART on the same day. Ask about TB symptoms, or a history of renal disease. Determine the client's WHO Clinical Stage. Start cotrimoxazole (CPT) if eligible.

Do the following tests on all HIV positive pregnant women, regardless of symptoms or history:
CD4 count, s-Creatinine and eGFR, sputum for TB NAAT, HBsAg, and urine dipstix

TB Symptoms with danger signs:

If TB symptoms with any danger signs*:
- Discuss with doctor/refer
- Delay ART initiation until TB excluded/diagnosed to avoid the risk of IRIS, but if already on ART, do not interrupt ART
- If TBM confirmed, defer ART for 4 - 6 weeks

Ensure a thorough evaluation for TB.
Remember to also consider extra-pulmonary TB

TB NAAT negative, but still TB symptoms

TB NAAT positive

Investigate with CXR, 2nd sputum for culture +/- antibiotics as per National TB Guidelines.
If CD4 ≤200, do a urine LAM.

TB Diagnosis confirmed → Initiate TB Rx

Review in 2 weeks. If stable and tolerating TB Rx, initiate ART (if not already initiated). DTG requires boosting with TB treatment to 50 mg twice daily. If TB symptoms worsen after ART initiation, consider TB IRIS and refer/discuss with the HIV hotline. If TB meningitis, defer ART for 4 to 6 weeks.

TB Symptoms without danger signs

History of renal disease

If no abnormal history

Initiate ART same day: TDF, 3TC/FTC, and DTG preferred*
If TDF contraindicated due to history of/suspected renal disease replace TDF with ABC.
Review results in 3-7 days

TB NAAT negative (or unable to produce sputum), AND no TB symptoms

Continue ART:
TDF, 3TC/FTC, DTG
Initiate TPT if eligible.
See Table 25: TB screening and TPT eligibility on page 89.

CD 4 ≤ 200

Do CrAG

CrAG neg

CrAG pos

Refer Urgently for LP

Creatinine > 85 umol/L

Continue/adjust ART to ABC, 3TC and DTG. Adjust dose of 3TC (and any other drugs) as needed. Discuss with an expert/HIV-hotline re further investigations and management.

No abnormal results and CD4 more than 200

Continue ART
Initiate TPT, if eligible. See *TB screening for pregnant and breastfeeding women on page 152*

1. Give urgent attention to women with any of the following danger signs that may be related to TB:
   - Respiratory rate ≥30 breaths per minute
   - Heart rate ≥120 beats per minute
   - Unable to walk unaided
   - Breathless at rest or while talking
   - Coughs up ≥1 tablespoon of fresh blood
   - Drowsy / confused / agitated / loss of consciousness

For a Summary of 1st Line Art Regimens see *page 33*

KEY ADHERENCE MESSAGES

(DIFFERENTIATED MODELS OF CARE STANDARD OPERATING ROCEDURES, 2025)[11]

Step 1 Education about HIV

- What does HIV do to your body?
- How taking ART can help you?
- The importance of VL suppressions for mother and baby.
- Risks of poor adherence.
- Side-effects of ART.

Step 2 Identify Life Goals

- What are the things that make you want to stay healthy and alive?

Step 3 Identify Support Systems

- Who could support you in taking your treatment?
- Would you agree to have a CHW visit you at home?

Step 4 Coming to your appointments

- What will you do if something prevents you from coming to your appointment (such as no money for transport, raining when you usually walk, taxi strike or a sick child, or any other reason)?
- Go to the clinic as soon as possible if you do miss an appointment or run out of ART
- Always take your medication with you to your clinic appointments to enable the HCW to better assist you

Step 5 Assess readiness to start ART

- Do you feel ready to start treatment as soon as possible?

If not, stay supportive. Invite client to express their beliefs or concerns.Correct misconceptions (avoiding judgments).

! Do not turn away an ART client who reports to have run out of treatment and presents without a transfer letter!

Step 6 Medication schedule

- According to your schedule, what would be the best time for you to take your treatment?

Step 7 Reminders

- What could you use to remind you to take your medication? (e.g. alarm, someone to remind them, when "Generations" is starting on TV, etc.)

Step 8 Missed Doses

- What will you do if you miss a dose?

Advise them to take the treatment as soon as they remember.

Step 9 Storing your medication and extra doses

- Do you worry about people seeing or stealing your treatment?
- Which safe place could you identify to store your treatment? Check that it is outside the reach of children.
- In case you don't have access to your treatment at the time you are supposed to take it, how can you always carry 1 or 2 doses with you?

Step 10 Managing Side-effects

- Side-effects such as dizziness, nausea, headache or diarrhea can happen when starting treatment. Most side-effects go away after a few weeks. If you vomit up to one hour after taking the medication, take your treatment again. Severe side-effects are rare. If you don't feel well, it is important you don't stop your treatment and come to the clinic.

SUMMARY OF ART REGIMENS FOR ADOLESCENT GIRLS (10 – 19 YEARS) AND ADULT WOMAN INITIATING ART

Any WOCP with normal renal function, with or without TB,	Weight ≥ 30 kg	TDF 300 mg, 3TC 300 mg, DTG 50 mg (TLD) as a single fixed dose combination tablet taken once daily
	Weight < 30 kg	Replace TDF with Abacavir 300mg bd (or 600mg once daily)
	DTG requires boosting with TB treatment to 50 mg twice daily. This will require one standard fixed dose combination tablet of TLD to be taken at the normal time, and an additional single tablet of DTG 50 mg to be taken 12 hours later.	
Abnormal renal function	Tenofovir (TDF) is contraindicated	Replace TDF with Abacavir 300mg bd (or 600mg once daily)
Known HIV positive women, who are not currently on ART, but are ART-exposed (e.g. previous VTP, or previous LTFU on ART)	Weight ≥ 30 kg	TDF 300 mg, 3TC 300 mg, DTG 50 mg (TLD) as a single fixed dose combination tablet taken once daily
	Weight < 30 kg	Replace TDF with Abacavir 300mg bd (or 600mg once daily)

These monitoring bloods are in addition to the *Viral Load Monitoring Schedule* *on page 143*

Monitoring Bloods on ART

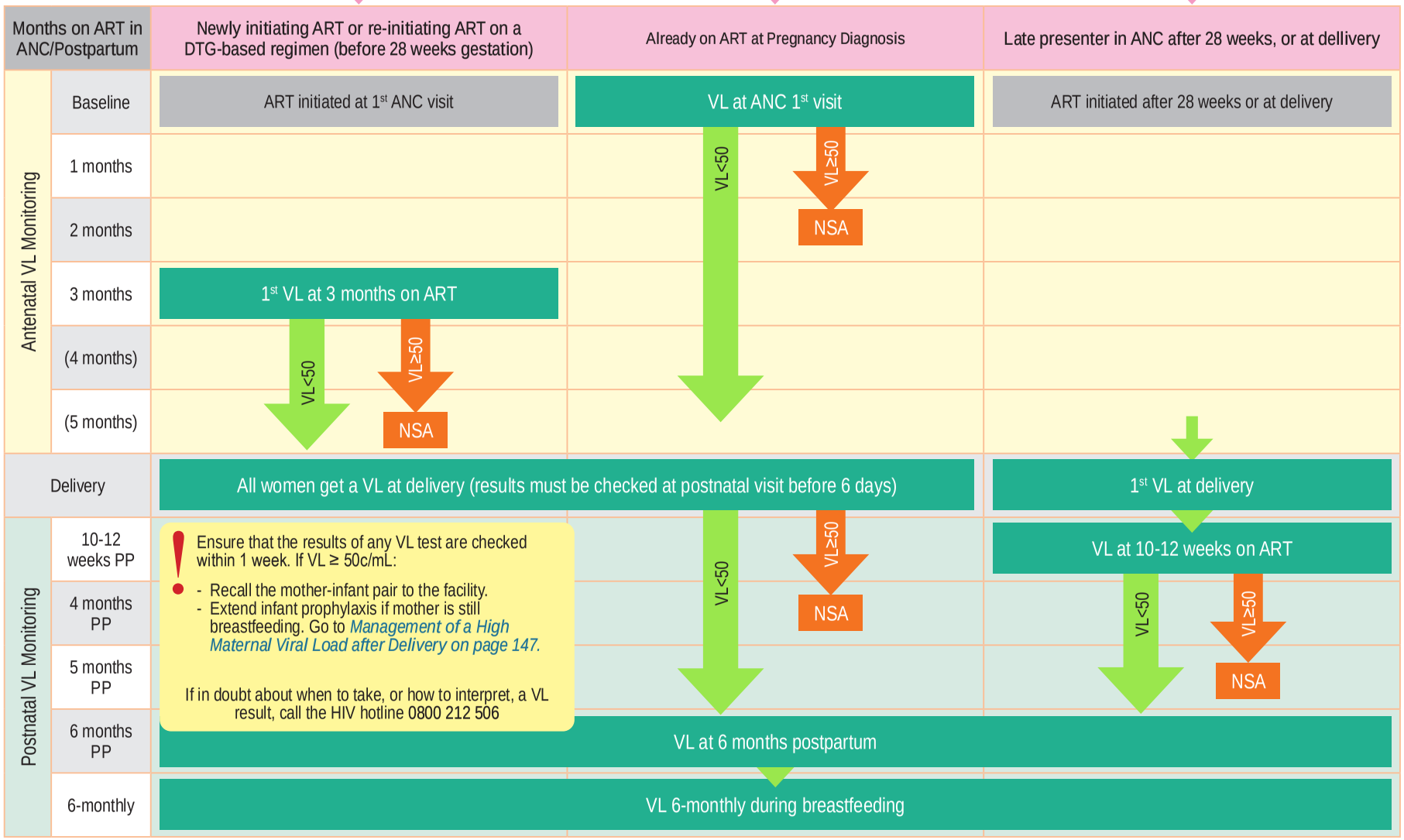
Time on ART	Creatinine (only if on TDF)	CD4
At ART Initiation	✓	✓
Month 3	✓	
At 1 year	✓	✓
Annually	✓ (aligned with annual VL)	If clinically indicated

NSA refers to the *VL Non-Suppression Algorithm on page 144*

Remember to put the correct VTP code in the EGK code field of the laboratory form for each VL done to ensure the electronic gatekeeping rules (EGK) do not lead to sample rejection.
Use the code C#Antenatal for all VLs done during ANC.
Use the code C#Postnatal for all VLs done during the breastfeeding period.
Use the code C#Delivery for all VLs done at the time of delivery.

START HERE

Select a category for the woman starting ART from the pink blocks below:



VL non-suppression algorithm for pregnant and breastfeeding women

HIV VL unsuppressed (VL ≥ 50 c/mL) in a pregnant or breastfeeding woman

Do a thorough assessment of the cause of an elevated VL as per ABCDE Assessment of an Elevated Viral Load on the next page

Implement interventions to re-suppress the VL.
Switch to TLD if indicated (See Switching Existing Clients to DTG-containing Regimens on page 36)
Start, re-start, or extend high-risk infant prophylaxis if breastfeeding, and intensify breastfeeding support.
Recommend condom use and contraception as appropriate, and partner testing

VL < 50 c/mL

Repeat as per the routine Viral Load Monitoring Schedule

Repeat VL after 4-6 weeks [1]

If the repeat VL is unsuppressed [2] **(VL ≥ 50 c/mL)**

Re-assess as per the ABCDE assessment on the next page and resolve adherence issues! [3]
Re-assess at the time for the next scheduled routine VL (i.e., in 6 months' time, or at delivery if pregnant)

If on a 2nd or 3rd line DTG-containing regimen for at least 9 months, or on TLD1 with special circumstances,[4] a medical officer or HIV expert may consider requesting an HIV drug resistance test.

Take 2 blood specimens and request a VL and a DRT. Provide an individualised regimen as recommended by the ADReC committee. Repeat VL 3 months after starting the new regimen to confirm viral re-suppression

On TLD1 with no special circumstances [4] or adherence still suboptimal, or persistent low-level viraemia [5]

Repeat VL in 3 months' time (or at delivery if > 28 weeks gestation) Intensify efforts to resolve adherence issues [6]

1. The shorter 4-week interval between the first VL above 50 and the repeat VL is preferred wherever possible. However, if the first elevated VL is the delivery-VL, the next visit may only occur at the 6-week post-natal visit.
2. 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. Most of these clients will re-suppress on TLD if adherent!
3. Repeat ABCDE assessment as outlined on page the next page. Screen for and manage any vomiting in pregnancy. Check if the patient is crushing/breaking ARV tablets which can affect absorption. Remember to ask about treatment side-effects, the potential cost of transport or loss of income related to clinic visits, mental health conditions, and current or prior drug interactions. Current or previous drug interactions with rifampicin or the polyvalent cations may have resulted in the development of resistance.
4. TLD1 patients with persistent virological failure despite good adherence may be considered for a resistance test in the following special circumstances:
   - Patients with AHD (CD4 < 200 or a WHO Stage 3 or 4 condition) and on a DTG-containing regimen for at least 9 months.
   - Current or previous drug interactions with rifampicin, carbamazepine, phenytoin, phenobarbital, or the polyvalent cations that may have resulted in the development of resistance.
   - Incorrect classification as TLD1 after prior ART exposure and failing an ART regimen in the past
   - Perinatally infected adolescents (perinatally infected adolescents should be classified as TLD2 due to the high likelihood of ART exposure and virological failure in the past)
5. Two or more consecutive VLs between 50 and 999 c/mL
6. Women who fail to suppress on TLD1 despite intensive adherence support or who are failing TLD2 or 3rd line should be discussed with an expert/HIV helpline or referred. These women may be experiencing complex clinical and/or psychosocial challenges beyond the scope of this primary care guideline, and may require a tailored approach to maternal management, infant prophylaxis, and recommendations for breastfeeding.

BREASTFEEDING WITH AN ELEVATED VIRAL LOAD

It is recommended that women with an unsuppressed VL on TLD1 continue to breastfeed. Exclusive breastfeeding is strongly recommended if the baby is less than 6 months old. Infant prophylaxis should be extended/restarted while a concerted effort is made to re-suppress the mother's VL

Although breastfeeding in women with an unsuppressed VL on TLD2 or 3rd line ART is not recommended (particularly if the VL > 1000 c/mL) due to the risk of resistant HIV transmission, exclusively formula feeding may also pose risks to vulnerable children. These mother-baby pairs should be referred or discussed with a team of experts*, and social circumstances considered. If formula feeding is deemed the lesser risk, intensive formula feeding support and close monitoring by the therapeutic nutrition programme are recommended. Infant formula should be supplied by the DoH.

* A team of experts may include an HIV expert, paediatrician, dietician, social worker. If necessary, consult one of the Helplines on the next page.

Abbreviations: ART, Antiretroviral therapy; DRT, drug resistance test, DTG, Dolutegravir; LLV, Low-level viraemia; SOP; TL, Third-line; TLD, fixed-dose combination of tenofovir, lamivudine, DTG; VL, Viral load.

ABCDE assessment of an elevated viral load

A thorough assessment is essential for any client with a viral load measuring ≥ 50 c/mL

> **!** Remember, an elevated VL in a pregnant or breastfeeding mother is a MEDICAL EMERGENCY!
>
> Every week she continues with an elevated VL increases her risk for vertical transmission!

A Adherence	Is adherence to medication poor? Ask about factors that may influence adherence e.g. • Medication side-effects, • Mental health disorders (see mental health screen below), • Alcohol or substance abuse, • Poor social support or • Non-disclosure. Pregnant women may experience nausea, heartburn, and constipation. Assess the need for symptomatic treatment with an anti-emetic, anti-diarrhea agent, or fiber supplement.	Tips Ask open ended questions e.g. "What makes it difficult for you to take your treatment?", and "How many doses have you missed this week?" Be non-judgemental. Statements like "we all miss a dose now and then" can encourage a client to be more open.
B Bugs (Infections)	Check for symptoms and signs of infection. Do a TB and STI screen.	Remember that immune compromised and pregnant clients may not exhibit overt symptoms of TB. If in doubt, do a TB NAAT.
C Correct Dose	Is the client on the correct dose for her weight? This is especially applicable to young or malnourished girls who may have recently gained weight, or clients with previous renal impairment.	
D Drug Interactions	Are there any potential drug interactions? Consider: • Other prescribed treatment e.g. rifampicin, anti-epilepsy drugs • Over the counter treatment e.g. antacids • Supplements and herbal/traditional medications e.g. St John's wort	If in any doubt, call the HIV Hotline 0800 212 506
E RE-sistance	Consider HIV drug resistance if other causes of virological failure have been excluded and the client is adherent to their medication.	Refer to the VL non-suppression algorithm on the previous page

Mental Health Disorders

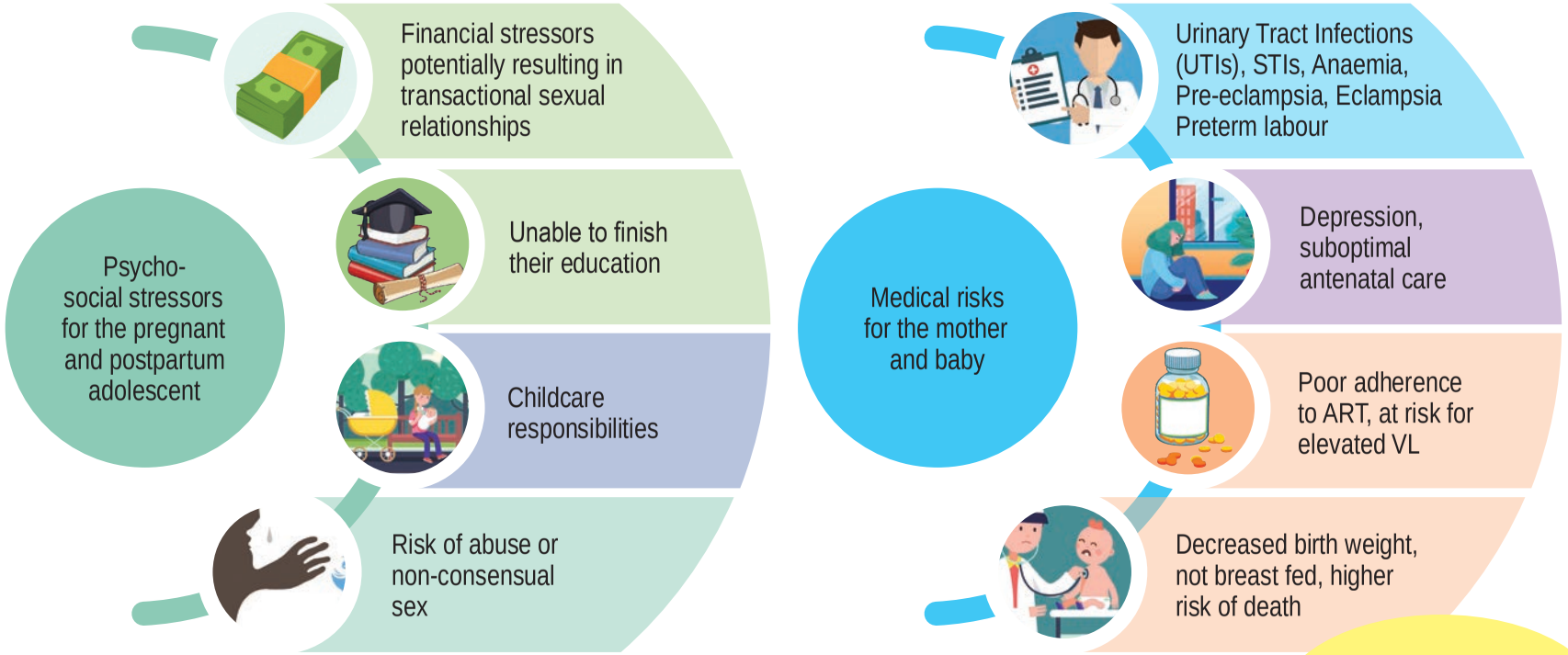
Pregnancy, childbirth and the first year after birth are often stressful times for women. Mental health conditions affect a person's **feelings**, **thoughts**, **behaviours**, and **functioning**. Women with mental disorders may struggle to use health and social services that are available and may struggle to bond with and parent their children.

Mental Health Screen

When to screen	Screen at booking visit in antenatal care, once during each trimester, and once during the postnatal period (from 6 weeks to 3 months). Thereafter, screen at regular intervals for up to one year.
How to screen	**Ask the following 3 screening questions, using a gentle and kind attitude:**
	In the last 2 weeks, have you felt unable to stop worrying or thinking too much? (Yes = 1 point; No = 0)
	In the last 2 weeks, have you felt down, depressed, or hopeless? (Yes = 1 point; No = 0)
	In the last 2 weeks, have you had thoughts and plans to harm yourself or commit suicide? (Yes = 1 point; No = 0)
When to refer	If the Total score across the 3 questions = **2 or 3 points, refer** If a patient answers 'yes' to the **self-harm** question, **refer urgently** for a mental health assessment with a medical officer or mental health professional

Additional Resources: Maternity Care Guidelines: Primary Healthcare and Adult Hospital Standard Treatment Guidelines (STGs); Adult Primary Care (APC); FAMSA 0119757106/7; Lifeline 0861 322 322

Pregnant adolescents are a vulnerable group that have psycho-social stressors and medical risks that may result poor health outcomes[14]



For ART Regimens applicable to adolescents go to *Summary of 1st Line Art Regimens on page 142*

The pregnant adolescent requires non-judgmental, confidential, and quality youth friendly SRH services that are sensitive to the challenges and stressors experienced by adolescents. This care should include:

A determination of whether or not the pregnancy was intended/unintended? wanted/unwanted? Provide counselling about options in terms of proceeding/not proceeding with the pregnancy.

High quality basic antenatal care, considering the additional medical risks in an adolescent.

Intensive ART adherence support during ANC, breastfeeding and there-after. If available, she should attend a peer-led support group.

Education and intensive support for breastfeeding and VTP. Adolescent are more likely not to breastfeed.

Counselling on contraceptives, STIs as well as re-entering the education system. Long-acting reversible contraceptive methods are preferred.

An exploration of the possibility of abuse or non-consensual sex to ensure that she is in a safe environment. If not, the involvement of the police and social services should be facilitated.

Follow ART Initiation Algorithm for mother on page 138, and the VL Monitoring schedule on page 140

A Mother may have a high VL after delivery due to:

A new HIV diagnosis after delivery

or

An elevated VL of ≥ 50 c/mL after previously being suppressed on ART.

Re-suppress the mother's VL as a matter of urgency! Follow the *VL Non-Suppression Algorithm on page 144*

See *Dosing Charts for Prophylaxis for the HIV-Exposed Infant on page 150*

Infant currently breastfeeding, or has breastfed in the last week

Immediate infant HIV-PCR

Provide Dual Infant Prophylaxis: AZT twice daily for 6 weeks, and NVP for a minimum of 12 weeks (until the maternal VL is suppressed), regardless of infant's age. Clearly document the prophylaxis start date.

Infant HIV-PCR negative

Complete 6 weeks of AZT and a minimum of 12 weeks of NVP. If needed, continue NVP for longer until mothers VL < 50 c/mL.

Do HIV-PCR 6 weeks after stopping NVP

Breastfeeding never started or stopped more than 1 week ago.

Immediate Infant HIV-PCR

No prophylaxis needed as baby is no longer being exposed to HIV

Infant HIV-PCR negative

Do all routine HIV tests according to the age and schedule for HIV exposed Infants:

- HIV-PCR at age 10 weeks
- HIV-PCR at age 6 months
- HIV-PCR 6 weeks post-cessation of breastfeeding
- HIV Rapid test at age 18 months
- Test anytime baby is unwell

Enquire as to why breastfeeding was stopped or never started. Ensure that the mother understands the risks of not breastfeeding, and that she has made an informed choice as to whether she will continue breastfeeding or not. See also the Infant and Young Child Feeding Policy.

Women who fail to suppress on TLD1 despite intensive adherence support or who are failing TLD2 or 3rd line should be discussed with an expert/HIV hotline or referred. These women may be experiencing complex clinical and/or psychosocial challenges beyond the scope of this primary care guideline, and may require a tailored approach to maternal management, infant prophylaxis, and recommendations for breastfeeding, including possibly stopping

breastfeeding and the prescription of infant formula to be supplied by the DoH (see *Stopping Breastfeeding on page 156*)

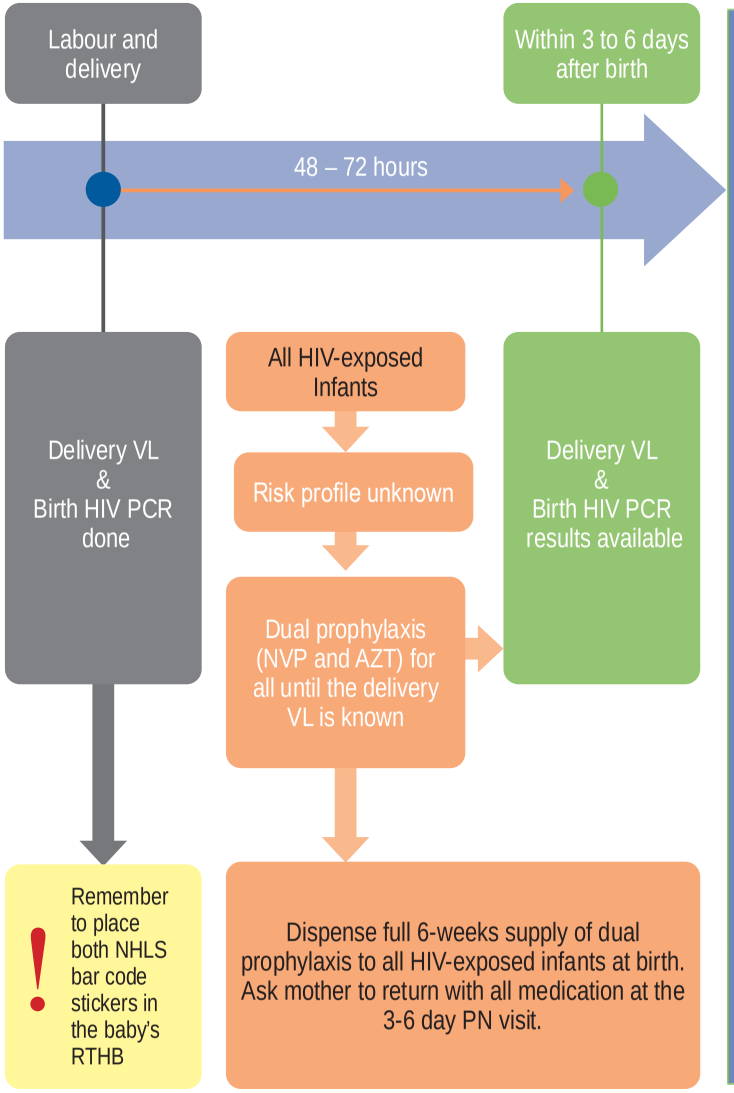
If Infant tests HIV-PCR positive at any stage.

Confirm positive result with a 2nd PCR on a new sample. Stop any HIV prophylaxis. Initiate ART. Start cotrimoxazole (CPT)

! For any child who tests HIV-positive ensure that:

- A confirmatory HIV test was done
- The child is tracked and linked to care
- The mother and other significant caregivers are counselled appropriately
- CHWs are involved
- The child is registered on Tier.net & retained in care
- a nutritional assessment is done, and the breastfeeding mother is advised to continue breastfeeding her HIV positive baby for 2 years or longer

The VTP strategies include timely HIV diagnosis, ART initiation and VL suppression in the mother (either pre- or post-conception) and the provision of HIV post-exposure prophylaxis to the infant. The mother's response to ART by the time of delivery is measured by the delivery VL, which will also determine the risk profile of the infant at birth and, subsequently, the infant's ART prophylaxis regimen. While awaiting the delivery VL result, all infants should, in the meantime, receive dual prophylaxis (NVP & AZT) until the VL result can be reviewed. If the mother-baby pair have already been discharged, this may be at the 3-6 day postnatal visit at the clinic. Clinicians working in postnatal clinics should therefore check the results of delivery VL. If the baby is still admitted to hospital, ward staff should ensure that the results are checked. Once the result of the delivery VL is known, prophylaxis should be adjusted accordingly.



Reclassify risk profile

Maternal Delivery VL *	Classification	Prophylaxis	Comment
Delivery VL< 50 c/mL regardless of feeding choice	Low risk	Change to low-risk prophylaxis • Stop AZT • NVP daily for six weeks.	• Affirm and encourage good adherence. • Repeat maternal VL 6 monthly during breastfeeding. • Do all routine HIV tests for HIV-exposed infants as indicated on *HIV Testing For The HIV-Exposed Infant on page 149.*
Delivery VL ≥ 50 c/mL in a breastfeeding mother**	Higher risk	Continue dual prophylaxis: • AZT twice daily for six weeks. • NVP daily for a minimum of 12 weeks.	• Do an ABCDE assessment and intervention as a matter of urgency to achieve a suppressed VL in the mother as soon as possible. Follow the *VL Non-Suppression Algorithm on page 144*. • Stop infant NVP only after confirmation of maternal VL being less than 50 c/mL, or until four weeks after cessation of all breastfeeding. • Do all routine HIV tests for HIV-exposed infants as indicated on *HIV Testing For The HIV-Exposed Infant on page 149*.
Delivery VL ≥ 50 c/mL in a mother who is exclusively formula-feeding her infant from birth	Higher risk	Continue dual prophylaxis: • AZT twice daily for six weeks. • NVP daily for six weeks.	• Do an ABCDE assessment and intervention as a matter of urgency to achieve a suppressed VL in the mother as soon as possible. Follow the *VL Non-Suppression Algorithm on page 144*. • Do all routine HIV tests for HIV-exposed infants as indicated on *HIV Testing For The HIV-Exposed Infant on page 149*.
Birth PCR positive	HIV infected	Stop any NVP and AZT prophylaxis. Initiate ART. Confirm the positive result with a 2nd PCR on a new sample. Start cotrimoxazole prophylaxis therapy (CPT) at 6 weeks of age.	

* All women known to be living with HIV should have a VL at delivery. This includes women who are newly diagnosed during labour, newly initiating ART, or re-initiating ART

** Breastfeeding includes exclusive breastfeeding or mixed feeding

Prophylaxis for the HIV-exposed infant during breastfeeding

Maternal VL monitoring should happen 6-monthly during breastfeeding.
At every visit, check the results of the mother's most recent VL.
An elevated maternal VL during breastfeeding may require an infant HIV PCR to be done and higher-risk infant prophylaxis to be started, re-started, or extended

The following are situations in which a mother's VL may be elevated. These situations are therefore indications to provide higher-risk infant prophylaxis during breastfeeding: 1. A new HIV diagnosis while breastfeeding 2. A mother on ART with her most recent VL ≥ 50 c/mL 3. A mother who is HIV positive but not on ART Go to *Management of a High Maternal Viral Load after Delivery on page 147*.	Infant prophylaxis to be provided: • AZT twice daily for six weeks. • NVP daily for a minimum of 12 weeks.	Remember to adjust NVP dosages according to weight (See *Dosing Charts for Prophylaxis for the HIV-Exposed Infant on page 150*)

HIV testing for the HIV-Exposed infant

HIV TESTING SCHEDULE
Birth HIV-PCR
HIV-PCR at age 10 weeks
HIV-PCR at 6 months for all HIV-exposed infants • Aligned with 6-month maternal HIV VL
Universal 18 month rapid/ELISA for all children • Whether exposed or un-exposed • Aligned with 18-month maternal HIV VL
Age-appropriate test at 6 weeks post-cessation of BF
Age-appropriate test at any time if the baby is unwell

CONFIRMATORY TESTING
Any child under two years with a positive HIV-PCR or a positive HIV rapid test should have their HIV status confirmed with a HIV-PCR test on a new sample. At the clinician's discretion, the HIV-PCR may be replaced by a viral load test which has the advantage of both confirming the HIV diagnosis and providing a baseline VL for monitoring the child's response to ART. Any child who tests HIV positive should initiate ART according to the Paediatric ART guideline as a matter of urgency. Do not wait for the confirmatory result before initiating ART but ensure that this result is checked. See *Management of Indeterminate PCR results and the Abandoned Infant on page 151*

AGE OF CHILD	HIV SCREENING TEST	HIV CONFIRMATORY TEST
Less than 18 months	PCR	PCR
18 months to 2 years	Rapid	PCR
More than 2 years	Rapid	Rapid

Dosing charts for prophylaxis for the HIV-exposed infant

Summary of infant prophylaxis regimens

	Risk Profile	NVP	AZT
At birth (following maternal delivery VL review)	Low-risk, whether breastfed or formula-fed	6 weeks	Stop AZT
	Higher-risk and breastfed **	minimum of 12 weeks	6 weeks
	Higher-risk and exclusively formula fed	6 weeks	6 weeks
During breastfeeding	Higher-risk during breastfeeding	minimum of 12 weeks	6 weeks

Dosing charts for infant HIV prophylaxis in infants > 2000 g

NVP and AZT dosing table for prophylaxis at birth and during breastfeeding (see also *VL Non-Suppression Algorithm on page 144*)					
	Birth – 6 weeks		6 weeks – 6 months	6 – 9 months	9 – 24 months
	2.0 – 2.49 kg	≥ 2.5 kg			
NVP (Daily)	1 mL (10 mg) daily	1.5 mL (15 mg) daily	2 mL (20 mg) daily	3 mL (30 mg) daily	4 mL (40 mg) daily
AZT (Twice daily)	1 mL (10 mg) twice daily	1.5 mL (15 mg) twice daily	6 mL (60 mg) twice daily	Children > 6 months of age requiring AZT prophylaxis should use treatment doses.	

Dosing charts for infant HIV prophylaxis in preterm infants < 2000 g

Nevirapine, oral, once daily		
Weight	First 2 weeks after birth (mg of NVP)	After first 2 weeks after birth (mg of NVP)
500 to < 625 g	0.1 mL (1 mg)	0.2 mL (2 mg)
625 to < 850 g	0.15 mL (1.5 mg)	0.3 mL (3 mg)
850 to < 1200 g	0.2 mL (2 mg)	0.4 mL (4 mg)
1.2 to < 1.5 kg	0.3mL (3 mg)	0.5 mL (5 mg)
1.5 to < 2.0 kg	0.35 mL (3.5 mg)	0.6 mL (6 mg)
If the infant at the time of discharge is severely underweight-for-age (3 SD or 3 z-scores below the mean), give NVP according to weight (i.e. 4 mg/kg/dose daily) until in the normal weight-for-age range.		

Zidovudine (AZT), oral, twice daily				
Gestational age at birth	First 2 weeks after birth	2 – 4 weeks after birth	4 – 6 weeks after birth	> 6 weeks after birth
30–35 weeks	0.2 mL/kg (2 mg/kg)	0.3 mL/kg (3 mg/kg)	0.4 mL/kg (4 mg/kg)	
<30 weeks	0.2 mL/kg (2 mg/kg)		0.3 mL/kg (3 mg/kg)	0.4 mL/kg (4 mg/kg)

Dosing chart for intravenous (IV) AZT prophylaxis

Gestational Age	Approximate birth weight	AZT IV dosing for the first 14 days (If unable to tolerate oral agents)
≥ 35 weeks	≥ 2.5 kg	3 mg/kg body weight IV every 12 hours
< 35 weeks	< 2.5 kg	1.5 mg/kg body weight IV every12 hours

MANAGEMENT OF INDETERMINATE PCR RESULTS IN INFANTS

Indeterminate HIV-PCR result
(This result is not positive, but not negative either)

Check for prior HIV-PCR and VL results

Prior HIV-PCR is positive or indeterminate
And/or
Prior HIV VL is detectable

Prior HIV-PCR or VL is negative or undetectable, or
No prior HIV-PCR or VL done

Repeat HIV-PCR and HIV VL urgently

Treat infant as HIV infected
Initiate ART

HIV-PCR is positive or indeterminate and/or HIV VL is detectable

HIV-PCR is negative and HIV VL is undetectable #

Further HIV testing as per VTP guidelines

Final HIV status cannot be determined until the infant has stopped all antiretroviral prophylaxis and is at least 6 weeks post-cessation of breastfeeding. In cases where clients have been initiated on ART and diagnosis remains uncertain, clients should be referred for further management by a specialist clinical and laboratory team. ART should never be stopped without specialist supervision.

! If in doubt, discuss with a virologist, or contact the NICD at HIV@nicd.ac.za
Document all test barcodes in the RTHB and referral letters

PCR, polymerase chain reaction; VL, viral load; ART, antiretroviral therapy

THE ABANDONED INFANT

Abandoned infant with unknown HIV exposure
Treat infant as a higher-risk, HIV-exposed infant

Perform an HIV-PCR and HIV rapid test[$].
Provide higher-risk infant prophylaxis.

Start NVP once daily for 6 weeks and AZT twice daily for 6 weeks

HIV-PCR is negative

Do HIV-PCR at 10 weeks of age or 4 weeks after stopping NVP

HIV- PCR is negative

Go to *Care of the HIV-exposed but Uninfected Infant on page 156*

HIV-PCR is positive

HIV-PCR is positive

Stop NVP and AZT

Initiate ART as per guidelines and confirm with a second HIV-PCR or VL

[$] A positive HIV rapid test will confirm HIV exposure and assist clinical management. However, a negative HIV rapid test may be falsely negative. Due to the unavailability of the mother, the HIV-exposure status of an infant with a negative rapid test can therefore not be definitively established. For this reason, all abandoned infants should have an HIV-PCR test performed and be managed as a higher-risk HIV-exposed infant. An HIV rapid test therefore adds value if it is positive but does not change the management of the infant if it should be negative.

TB screening for pregnant and breastfeeding women

All pregnant and breastfeeding women should be evaluated for TB at every visit

Assess for TB symptoms and assess the woman's clinical condition

If very ill or danger signs:
- Discuss with doctor/refer
- Delay ART initiation until TB excluded/diagnosed to avoid the risk of IRIS, but if already on ART, do not interrupt ART
- If TBM confirmed, defer ART for 4-6 weeks

No danger signs present

Categorise the woman

WLHIV At 1st / Booking visit in ANC
All pregnant women with HIV
(newly diagnosed, known on ART or not yet on ART)

WLHIV at any ANC or postnatal follow-up visit

HIV negative women at any visit

Do a TB-NAAT for all, regardless TB symptoms, PLUS other TB investigations as clinically indicated, e.g., urine LAM

Initiate / continue ART (TLD) [2]

Do a TB-NAAT if one or more TB symptoms are present, and any other investigations as clinically indicated

Review results of TB investigations

TB-NAAT negative, but TB symptoms still present

Do further investigations as per TB Guidelines, incl. urine LAM if:
- CD4 < 200 + TB symptoms
- woman admitted for medical condition, regardless of CD4

TB-NAAT positive and/or other tests confirm a TB diagnosis

Initiate TB treatment
Do not interrupt ART

TB-NAAT negative (or unable to produce sputum) AND no TB symptoms

Continue to screen for TB symptoms at every follow-up visit during ANC, at delivery and during breastfeeding. Investigate for TB if symptoms are present.

Review in 2 weeks: If stable and tolerating TB/ART treatment, continue routine follow-up. If unstable/worsening condition, consider possible IRIS and discuss with doctor/refer

The following women are eligible for TPT:
- Pregnant women with advanced HIV disease (CD4 < 200, or WHO stage 3 or 4)
- Women at the 6-week postnatal visit or any subsequent visit while not pregnant:
  - Any woman with significant TB exposure - regardless of HIV status or any prior TPT completion
  - Any woman with HIV who is 6 weeks postpartum and has never completed TPT previously

1. Give urgent attention to women with any of the following danger signs that may be related to TB:
   - Respiratory rate ≥30 breaths per minute
   - Heart rate ≥120 beats per minute
   - Unable to walk unaided
   - Breathless at rest or while talking
   - Coughs up ≥1 tablespoon of fresh blood
   - Drowsy / confused / agitated / loss of consciousness
2. DTG has drug interactions with rifampicin containing TB treatment. See p. 13 of the 2023 ART Clinical Guidelines.

Newborn exposed to TB (born to a mother diagnosed with TB during antenatal or peripartum care, or a newborn with other significant TB exposure[1])

Does the baby have active TB disease?

Do a thorough clinical assessment
Assess for symptoms/signs of TB disease.
Do a CXR if available.
Give BCG at discharge from delivery unit[2]

Clinical assessment suggestive of active TB disease in the newborn

No indications of active TB

Is the mother or close contact still potentially infectious?

Does the mother or close contact have any one of the following that indicates she could still be infectious?

- On TB treatment < 2 months, OR
- Symptoms that are not improving, OR
- Sputum smear or culture has not yet converted to negative, or is unknown at the time of birth

Refer/discuss any mother who is not responding to TB treatment as expected

Telephonic consultation with expert
OR
Undertake appropriate clinical and laboratory investigation in newborn
OR
Refer newborn to hospital

(Hospital-based) TB Evaluation

- Clinical examination incl. general, respiratory and abdominal
- CXR (anteroposterior and lateral where feasible)
- Abdominal ultrasound if any abdominal distension or hepatosplenomegaly
- Respiratory specimens (e.g., gastric aspirate or induced sputum) for *M.tb* microbiology (TB-NAAT, culture, AFB microscopy)
- Lumbar puncture for CSF evaluation if clinically indicated or if CXR suggests miliary TB
- HIV testing, if not yet done

Clinically diagnosed/confirmed TB

- Start appropriate TB treatment (according to mother's or neonate's isolate DST results if available)
- Give ARVs (prophylaxis or ART) if indicated
- Follow up monthly for dose-adjustment and clinical evaluation including adverse effects
- Repeat BCG upon completion of TB treatment, as indicated in Figure 13

No TB disease (exposed only)

NO

YES

Is the baby eligible for TPT?

If eligible, what TPT regimen should the baby receive?

Baby does not require TPT

Baby requires TPT

Refer/discuss any mother diagnosed with drug resistant TB with an expert[3]

Determine if mother has DS or DR TB

Mother has DS TB or drug susceptibility unknown

HIV-exposed/HIV-positive baby on NVP, DTG or LPV/r or on any other drug with rifampicin interaction?

YES

NO

6H[4]

3RH[4]

Support adherence, evaluate for side-effects, monitor weight and adjust doses, evaluate for TB symptoms until TPT completed. Ensure that HIV testing and prophylaxis (or ART treatment) has been provided as appropriate

Repeat BCG [2]

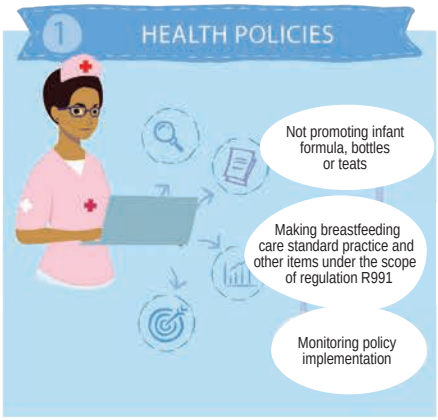
Source: National Clinical Guidelines for the Management of Tuberculosis in Children and Adolescents (2024)
Abbreviations: BCG, Bacillus Calmette-Guérin; CNS, Central nervous system; DS, Drug susceptible; DR, Drug resistant; 6H, 6 months of INH; 3RH, 3 months of rifampicin and INH; TPT, tuberculosis preventive treatment.

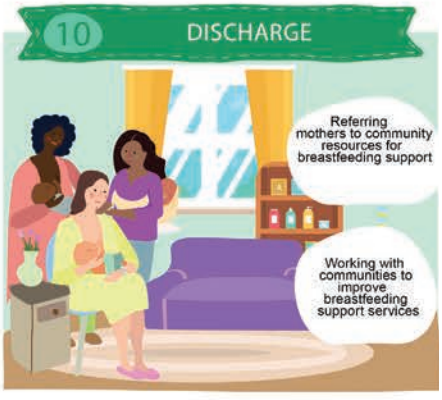
1. Significant exposure is known (documented) exposure to a person (adult or adolescent) with pulmonary TB who shared the same enclosed space for one or more nights (e.g. at home or similar) or for frequent or extended daytime periods (e.g. at a school, crèche or similar) during the three months before the index patient started TB treatment.
2. All infants should receive BCG at discharge from the delivery unit as per the routine EPI schedule. However, BCG is a live attenuated M.bovis vaccine and is killed by TB medications, including those used in TPT or TB treatment. This may affect the effectiveness of the BCG vaccine. For this reason, the BCG vaccine should be repeated immediately on completion of either TPT or TB treatment.
3. For management of DR-TB exposure, refer to the latest National DR-TB Guidelines
4. For TPT Dosing Table see Annexure 3

The ten steps to successful breastfeeding

The TEN STEPS to Successful Breastfeeding

All Health Facilities must support mothers to breastfeed as a standard of care by implementing the following...





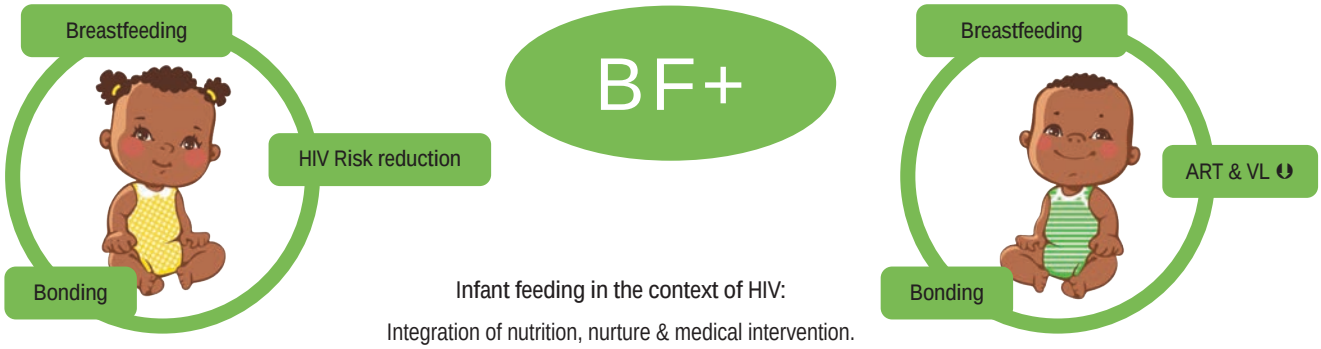
health
Department:
Health
REPUBLIC OF SOUTH AFRICA

World Health Organization

unicef

Poster Adapted for South Africa 2018

Breastfeeding plus



Infant feeding in the context of HIV:

Integration of nutrition, nurture & medical intervention.

HIV Un-exposed Infant

HIV-exposed Infant

HIV Negative Women

1. HIV Risk Reduction
   - Number of sexual partners
   - Condom use
   - Partner testing
   - Partner ART and viral suppression
   - PrEP (as available and applicable)
2. Regular HIV Testing
3. Infant Feeding advice and support

Women living with HIV

1. ART and VL suppression
2. Infant prophylaxis
3. Infant testing
4. HIV Risk reduction (re-infection and risk to partner)
   - Number of sexual partners
   - Condom use
   - Partner testing
   - Partner ART and viral suppression
5. Infant Feeding advice and support

Whether a woman is living with HIV or HIV-uninfected, recommendations for Infant feeding remain the same

! HIV VL suppression in mother is essential to prevent vertical transmission through breastfeeding!

Infant Feeding Advice

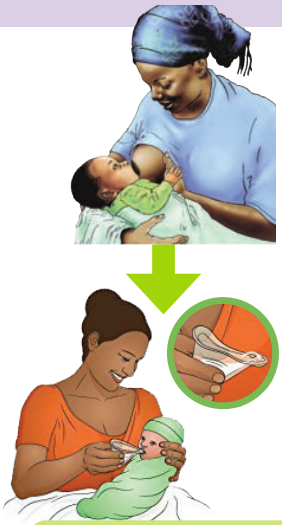
For all women, exclusive breastfeeding (EBF) is recommended for the 1st six months of life. Thereafter, breastfeeding should continue for two years or longer, with the introduction of nutritionally adequate, appropriate and safe complementary feeding. Women living with HIV should be fully supported for ART adherence during the breastfeeding period and thereafter

Antenatal	0 - 6 months	6 - 12 months	12 - 18 months	18 months - 2 years
Counselling on **the benefits of** breastfeeding should start during the antenatal period	Early initiation of BF within 1 hour after birth. EBF for 1st 6 months of life	Continue breastfeeding until 2 years of age or longer		
		Start introducing age appropriate solid foods from 6 months onwards as outlined in the RTHB		

! Introducing solids before 6 months is strongly discouraged! The younger the infant, the higher the risk to the infant's health.

WHO Practice Statements for Women Living with HIV

- Any mother that is mixed feeding in the first 6 months should be encouraged to return to exclusive breastfeeding.
- However, mothers living with HIV and health-care workers can be reassured that ART reduces the risk of postnatal HIV transmission in the context of mixed feeding. Although exclusive breastfeeding is recommended, practicing mixed feeding with formula milk is not a reason to stop breastfeeding in the presence of ARV drugs.
- Mothers living with HIV and health-care workers can be reassured that shorter durations of breastfeeding of less than 12 months are better than never initiating breastfeeding at all.



Stopping breastfeeding

Stopping Breastfeeding

- Mothers living with HIV who decide to stop breastfeeding should do so gradually over a period of a month.
  Abrupt cessation of breastfeeding is not recommended and may increase the VL in breastmilk. If subsequent intermittent breastfeeding should occur, the infant is at increased risk of becoming HIV infected.
- Infants who have been receiving ART prophylaxis should continue prophylaxis for four weeks after all breastfeeding has stopped.
- Children must receive an adequate diet following cessation of breastfeeding as outlined in the Infant and Young Child Feeding Policy.

Indications for Formula Feeding to be provided by the Dept of Health Supplementation Scheme

1. Infants of mothers who are failing TLD2 or third-line ARV treatment (VL ≥1000 c/mL)
   Note: Although breastfeeding in women with an unsuppressed VL on TLD2 or 3rd line ART is not recommended due to the risk of resistant HIV transmission, exclusively formula feeding may also pose risks to vulnerable children. These mother-baby pairs should be referred or discussed with a team of experts, and social circumstances considered. If formula feeding is deemed the lesser risk, intensive formula feeding support and close monitoring by the therapeutic nutrition programme are recommended. See also the *VL Non-Suppression Algorithm on page 144*.
2. The mother has died, or the infant has been abandoned.
3. Other individual circumstances deemed necessary by a multidisciplinary team including certain metabolic conditions in the infant, medical conditions in the mother, or certain maternal medications as outlined in the PHC EML.

Where there are legitimate medical conditions, as diagnosed by a medical practitioner, or when a mother is incapable of caring for her infant or young child, health care personnel should recommend appropriate infant formula feeding as an alternative feeding option for up to 12 months of age. The mother/caregiver should receive appropriate counselling on the safe preparation of formula, the age-appropriate quantities and how to cup feed. Once the child reaches 12 months of age, pasteurised full cream milk (400-600ml/day) should be recommended, as ongoing formula for children older than 12 months is not necessary.

Care of the HIV-exposed but uninfected infant

More than 25% of the total infant population in SA are HIV-exposed and more than 98% of these infants are HIV negative. Yet, having escaped HIV infection, they may still suffer the consequences of being born to a woman living with HIV. HIV-exposed but Uninfected (HEU) children still require:

Routine Child Health Management

- Manage and treat acute problems according to the IMCI guidelines
- Provide feeding counselling and support
- Monitor growth and development
- Provide routine immunizations, Vit A, and deworming
- Screen for TB symptoms and TB index cases and manage accordingly
- Ask about mother's health, ART adherence, and contraception needs
- Provide social support and counselling for age-appropriate parental disclosure

Routine Management for the HIV-Exposed Infant

- Ongoing interventions to prevent vertical transmission through breastfeeding
- All routine HIV tests as indicated in this guideline for HIV-exposed infants

Additional Management for the HEU Infant

HEU infants may experience poorer outcomes despite being HIV uninfected, and may require more regular follow-up.
Identify high-risk HEU infants who may require closer monitoring, including those with:

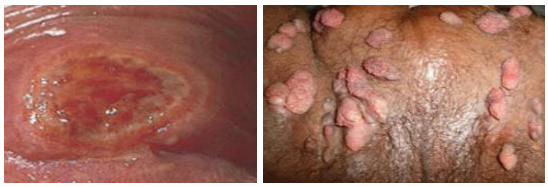
- Poor birth outcomes
- Symptoms of anaemia
- Impaired growth and/or neurodevelopment
- History of hospitalisation
- Maternal illness or death

Ongoing Care for the Mother and her Family

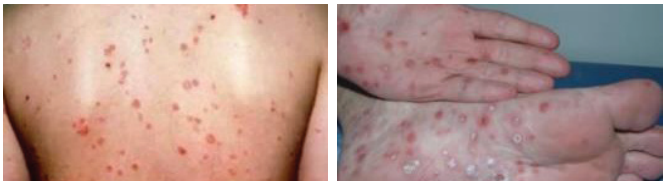
- Remember to provide appropriate ongoing care to the women living with HIV and her family.
- If a breastfeeding mother is sick or hospitalised, consider appropriate ways she can continue breastfeeding. If not, ensure that baby receives appropriate care whilst mother is hospitalised.
- Screen partner and other children for HIV and other infectious disease as indicated (e.g. TB)

Syphilis

Syphilis is a sexually transmitted infection that can have multiple different presentations but also be asymptomatic. The signs of secondary syphilis occur six to eight weeks after the primary ulcer (chancre) and may include a generalized rash (often including palms and soles), flu-like symptoms, flat wart-like genital lesions (condylomata lata), mouth ulcers and patchy hair loss. Tertiary syphilis occurs many years later and affects skin, bone, heart and nervous system.

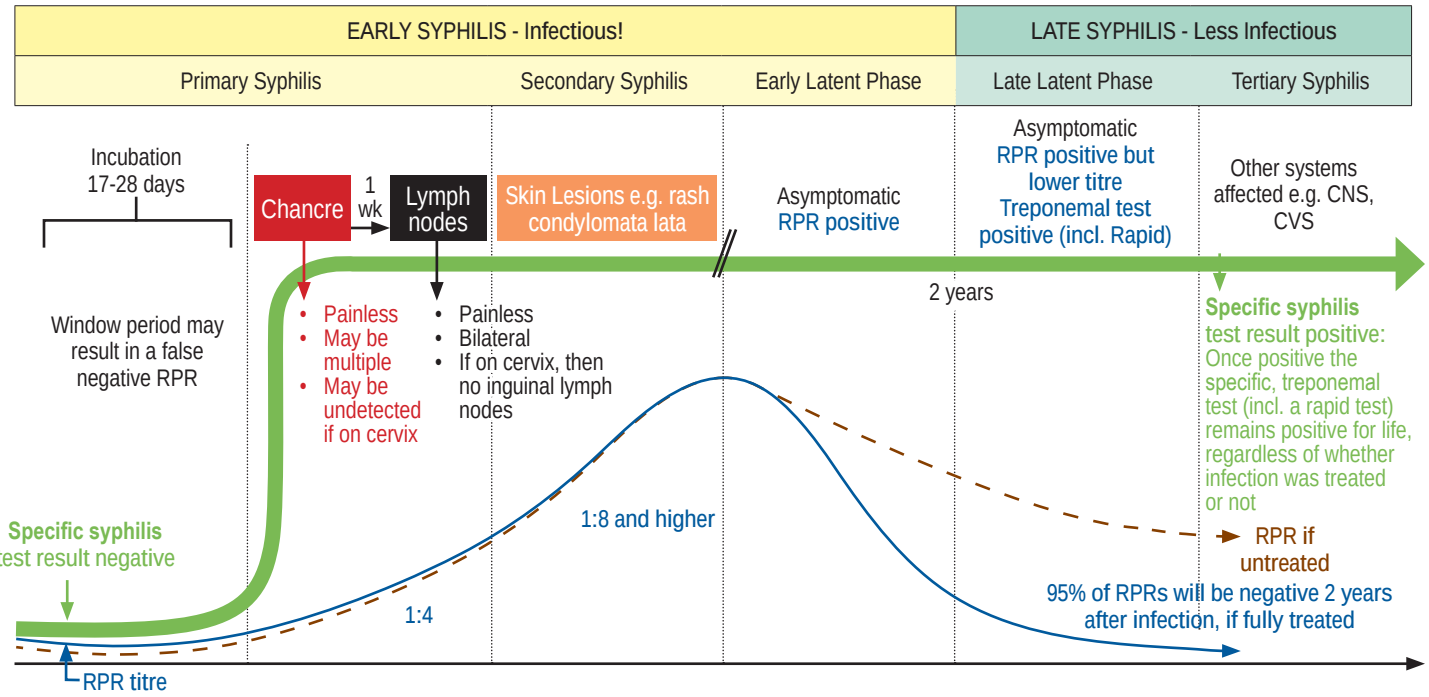


Painless ulcer/chancre and condylomata lata on genitals



Rash involving palms and soles

The stages of disease progression of syphilis are illustrated in the figure below, together with the typical clinical presentation in each stage, and the level of the RPR titre (blue graph) if treated. This timeline is an approximation, and may vary from client to client. Note that a genital ulcer caused by syphilis will resolve spontaneously within four to six weeks without treatment; however, the syphilis infection persists, and the ulcer (or other symptoms) resolving does not represent cure.



Frequency of syphilis testing

A pregnant woman should be screened and tested for syphilis

- at her 1st/booking visit in antenatal care.
- If she tests negative, syphilis testing should be repeated:
  - Scheduled antenatal visits, at approximately 4-weekly intervals, e.g., for BANC+ clients, this could be at 20, 26, 30, 34, and 38 weeks gestation
  - During her labour/delivery admission
  - At the time of diagnosis of an intrauterine death or miscarriage
  - At any time, if the mother has clinical symptoms or signs suggestive of syphilis

Syphilis testing should be aligned with the HIV testing schedule:

- If a woman tests positive for HIV, but tests negative for syphilis, repeat syphilis testing should continue at the intervals described above.
- If a woman tests positive for syphilis but tests negative for HIV, repeat HIV testing should continue at recommended intervals.

NOTE: If a client is CURRENTLY being treated for syphilis during their current pregnancy, they should NOT be re-tested for syphilis apart from the recommended RPR titre test which is performed a minimum of 3 months after concluding syphilis treatment.

Types of syphilis tests and their uses

- **Rapid syphilis tests** use a type of test known as a specific (or treponemal) test for syphilis. Rapid syphilis tests remain positive for life, even if the infection has been treated.
- **RPR type syphilis tests** are known as non-specific (or non-treponemal) tests and are usually done in a laboratory. RPR titres change in response to treatment or disease progression.
- If a rapid test is used as the screening test (preferred), a positive result should be confirmed by requesting syphilis serology tests from the laboratory, which will include an RPR test. The RPR will determine if the positive rapid result indicates a current active infection or an earlier infection, and the baseline titre allows the response to treatment to be monitored
- Once a woman has tested positive using a rapid test, a rapid test should no longer be used for routine screening to identify new infections at subsequent visits. A rapid test cannot differentiate between a new and a previous infection. A RPR should then be used as the screening test to identify new infections

When available and appropriate, **rapid testing is the preferred first-line test in pregnancy**, as it allows for immediate treatment.

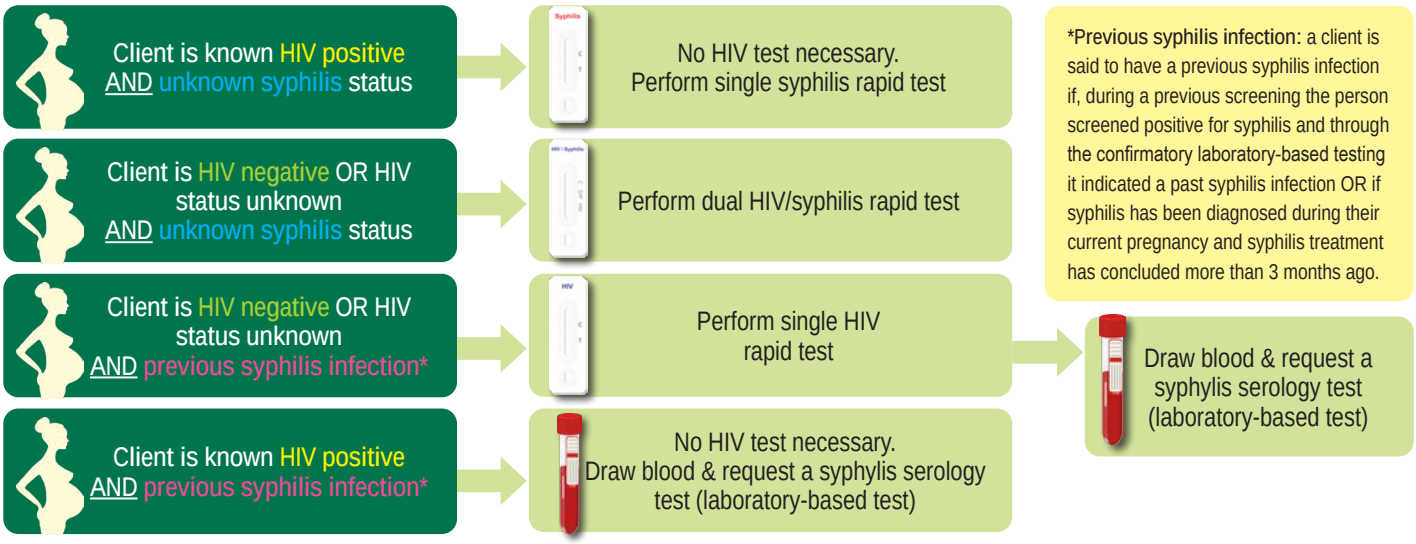
Rapid syphilis tests are available as a **single** rapid diagnostic test (RDT) that tests only for syphilis, and a **dual** RDT which tests for both syphilis and HIV using the same drop of blood.

Dual syphilis and HIV rapid tests should only be used in clients

- Whose HIV status is negative or unknown AND
- Who have not had a previous syphilis infection

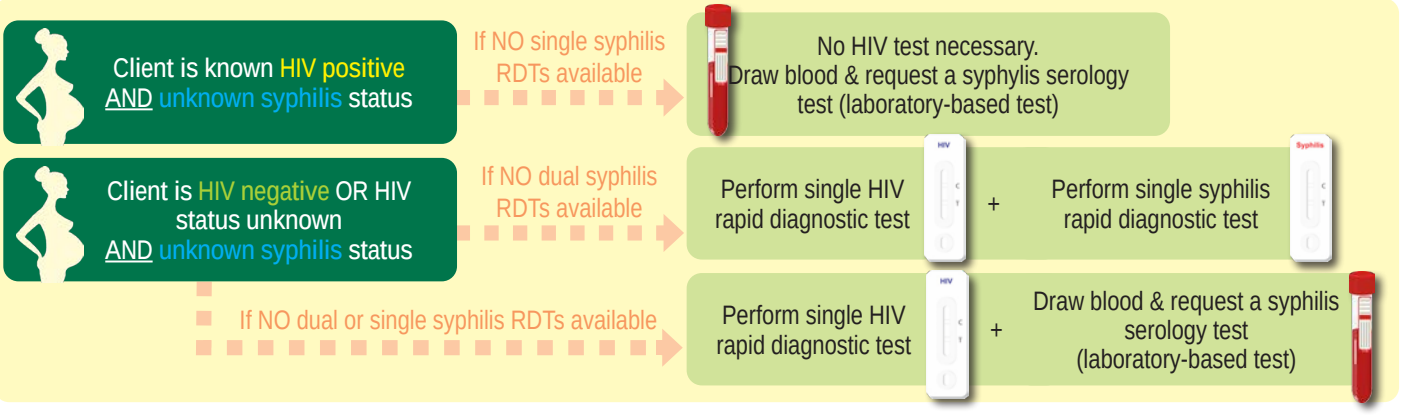
! Clients who are already known to be living with HIV should NOT be re-tested for HIV and should therefore not use a **dual** syphilis and HIV rapid test!

HIV & Syphilis Testing Guide for Pregnancy: Which test should be used when?



*Previous syphilis infection: a client is said to have a previous syphilis infection if, during a previous screening the person screened positive for syphilis and through the confirmatory laboratory-based testing it indicated a past syphilis infection OR if syphilis has been diagnosed during their current pregnancy and syphilis treatment has concluded more than 3 months ago.

What to do when a facility does not have syphilis rapid tests in stock



SYPHILIS RAPID DIAGNOSTIC TESTING

Single syphilis rapid test

Dual HIV syphilis rapid test

Perform **syphilis** rapid test
Assess for clinical signs of syphilis & counsel on condom use.

Interpretation for syphilis component of the dual test

Screening test:
Syphilis REACTIVE

Treat: Penicillin Dose 1*

Confirm the syphilis diagnosis:
Send a single blood sample✦ to the laboratory requesting syphilis serology. Ask the client to return in 1 week for results.

Screening test:
Syphilis NON-REACTIVE

Syphilis Negative

No current & no previous syphilis infection

✦ *If other blood tests are also being requested, e.g. an HIV VL, send the syphilis serology sample with it's own specimen request form to prevent delays in processing of the test.*

RPR REACTIVE

Syphilis Positive

Counsel: that a diagnosis of syphilis is confirmed
Treat: Penicillin dose 2*
Document: RPR titre
Trace & test sexual partners
Schedule: Penicillin 3rd dose in 1 week

Treat: Penicillin dose 3*

Repeat RPR titre 3 months after treatment completion to **confirm response to treatment**◈

RPR NON-REACTIVE

Syphilis Negative

No current active syphilis infection
Positive specific test indicates past infection

Continue routine screening for syphilis using:
syphilis serology samples sent to the laboratory.
Do not use rapid tests as, once positive, it remains positive for life

◈ **Confirm response to syphilis treatment:**
- A 4-fold drop in RPR titre confirms effective treatment (e.g., 1 in 32 goes down to 1 in 8).
- Do not re-check RPR until at least 3 months after treatment is completed.
- If the titre was low to start with (1 in 4 or less), then a drop may not be seen after 3 months.
- A low titre may take years to disappear completely.
- Only be concerned if there is a rise in titre compared to the initial low titre.

✱ Treatment for syphilis
Check for a history of penicillin allergy.
- If no history of penicillin allergy, give 2.4 MU of benzathine penicillin IM x 3 doses, at weekly intervals.

If the mother has a delay of >14 days between weekly IM doses, the mother is considered untreated, and the entire course must be restarted.
If the woman reports a penicillin allergy:
- Take a careful history to confirm the likelihood of true allergy.
- Penicillin is the only known drug that effectively treats syphilis in the fetus.
- Refer to hospital for penicillin desensitization (see EML for details) and syphilis treatment under close observation by a doctor trained to manage anaphylaxis.

Version 3 Feb 2025

Laboratory-based testing when syphilis rapid tests are unavailable or inappropriate

Send a blood sample to the laboratory and request a syphylis serology test.

Assess for clinical signs of syphilis & counsel on condom use.
Ask the client to return in 1 week for results.

Syphilis Positive

Counsel: that a diagnosis of syphilis is confirmed
Treat: Penicillin dose 1*
Document: RPR titre
Trace & test sexual partners
Schedule: Penicillin 2nd dose in 1 week

Treat: **Penicillin dose 2*** / Schedule: Penicillin 3rd dose in 1 week

Treat: **Penicillin dose 3***

Repeat RPR titre 3 months after treatment completion to confirm response to treatment

(See ◈ on the previous page)

Syphilis Negative

No current syphilis infection
Continue routine follow-up screening for syphilis.

✱ Treatment for syphilis
Check for a history of penicillin allergy.

- If no history of penicillin allergy, give 2.4 MU of **benzathine penicillin** IM x 3 doses, at weekly intervals.

If the mother has a delay of > 14 days between weekly IM doses, the mother is considered untreated, and the entire course must be restarted.

If the woman reports a penicillin allergy:

- Take a careful history to confirm the likelihood of true allergy.
- Penicillin is the only known drug that effectively treats syphilis in the fetus.
- Refer to hospital for penicillin desensitization (see EML for details) and syphilis treatment under close observation by a doctor trained to manage anaphylaxis.

TREATING PARTNERS

- Trace and test partners of women with confirmed syphilis
- Test the partner using a rapid syphilis test if available and assess for symptoms and signs of a genital ulcer or secondary syphilis.
- If the rapid test is positive, and symptoms or signs of syphilis are present, treat the partner for early syphilis using one of the following options:
  - A single immediate dose of benzathine penicillin 2.4 MU IM, if stock levels are sufficient
  - If penicillin stock levels are insufficient, give Doxycycline 100mg 12-hourly orally for 14 days
- If the rapid test is positive and there are NO symptoms or signs of syphilis, send a confirmatory blood sample to the laboratory for a syphilis serology test. Do not wait for the results before treating the partner, but be sure to check the results 1 week later. If the confirmatory test is positive, treat the partner for latent syphilis using one of the following options:
  - Benzathine penicillin 2.4 MU IM, once weekly for 3 weeks, if stock levels are sufficient
  - If penicillin stock levels are insufficient, give Doxycycline 100mg 12-hourly orally for 30 days

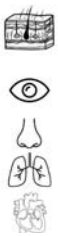
Source: Guideline for vertical transmission prevention of communicable infections (2023).

Congenital syphilis

DIAGNOSIS

Clinical signs depend on gestation at time of transmission, fetal immunological response & maternal syphilis stage & adequacy of treatment.
30-40% of babies who acquire syphilis in-utero, die shortly before or after birth.
Early congenital syphilis presents in first two years of life.
Late congenital syphilis manifests from third year of life onwards.

- Seizures
- Jaundice Hepatomegaly
- Splenomegaly
- Long bone changes
- Pallor Petechiae
- Large, pale, greasy placenta
- Growth restriction



- Peeling Rash, Oedema Nonimmune fetal hydrops
- Loss of eyebrows, chorioretinitis, uveitis, cataract, glaucoma
- Nasal discharge ("snuffles")
- Pneumonia
- Myocarditis

Screening and Diagnosis of Syphilis in Babies
If congenital syphilis is suspected at delivery, perform confirmatory laboratory tests.
Send placenta for histology if possible.
Follow local hospital & laboratory testing protocols for syphilis.

Other investigations that may be considered based only on clinical signs:

- If clinical concerns of thrombocytopaenia (petechiae) & anaemia (pallor):
  - **Full blood count**
- If clinically jaundiced or other signs of liver impairment (bleeding, encephalopathy):
  - **Total serum bilirubin with conjugated fraction and other liver function tests as indicated**
- **Bedside cranial ultrasound scan**, if available, to look for intracranial pathology (bleeds, infarcts).
- In symptomatic babies, long bone x-rays & CSF are not mandatory investigations, as they do not affect treatment duration.
- Ophthalmology assessment for eye abnormalities associated with syphilis (non-urgent assessment).

MANAGEMENT OF SYPHILIS EXPOSED BABIES

ASYMPTOMATIC BABIES BORN TO MOTHERS WITH FULLY TREATED SYPHILIS

Mother treated with benzathine penicillin G
2.4 million IU IM weekly for 3 consecutive weeks with last dose > 30 days before delivery.

No treatment indicated.
Ensure partner traced and tested.

ASYMPTOMATIC BABIES BORN TO MOTHERS WITH INADEQUATELY TREATED* OR UNTREATED SYPHILIS**

Single dose Benzathine Penicillin G

50 000 units/kg IM.
Never give IV.
Ensure partner is traced, tested and treated (as indicated).

* Inadequately treated mother:
- mother did not complete three doses in full, or
- mother received three doses but there was a delay of > 14 days between weekly IM doses, or
- last dose was not more than 30 days before delivery, or
- the dose that the mother received was incorrect was incorrect

** Untreated mother:
- mother did not receive any treatment for syphilis, or
- mother was treated for syphilis with an antibiotic that was not penicillin

SYMPTOMATIC BABIES BORN TO MOTHERS WITH SYPHILIS REGARDLESS OF TREATMENT STATUS

Aqueous crystalline Penicillin G

- 50 000 units/kg 12 hourly IV or IM for the first 7 days of life, then 8 hourly from day 8 of life onwards to complete 10 days of treatment
- **Parenteral penicillin is drug of choice for treatment of congenital syphilis.** Data are insufficient regarding use of other antimicrobial agents (e.g., ampicillin).

Note: If mother was fully treated & baby symptomatic – re-test mother & follow-up on reason for treatment failure; ensure partner tracing done.

If baby misses more than one day of treatment, the entire ten-day course must be restarted.

If unable to admit at current level of care, refer all babies with suspected congenital syphilis infection to appropriate level of care, in accordance with local referral pathways, for inpatient admission & work-up.
Refer all symptomatic babies with complications, e.g., thrombocytopaenia, anaemia, respiratory distress, signs of liver dysfunction, & suspected meningitis to a centre with high care or intensive care unit facilities.

Neurodevelopmental follow-up at 20 weeks corrected gestational age.
Re-test all babies with positive syphilis serology with elevated titres, 3 months after-treatment until titre has decreased 4-fold.
Re-treat if drop in titre less than 4-fold and discuss with specialist.
Follow-up date for re-testing can coincide with 14 week immunisation visit depending on date of discharge from hospital.

MANDATORY NOTIFICATION FOR CONGENITAL SYPHILIS

CS is a Category 2 Notifiable Medical Condition (NMC): Health care workers must notify all cases of congenital syphilis through paper-based or electronic case notification forms (CNF) to the National Institute for Communicable Disease (NICD) within 7 days of diagno-sis. Refer to link: https://www.nicd.ac.za/nmc-overview/notification-forms/
Test or re-test all negative mothers with miscarriages or stillbirths for syphilis at time of presentation.

Visit Schedule for Integrated Care for the Mother living with HIV and her HIV-exposed Infant (HEI)

The principles are as follows:

1. Wherever possible, try to align the mother's ART, VL monitoring, and contraception 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
2. Wherever possible, allow the mother and baby to receive care at the same facility

Age group	Age of child	Routine visits as per RTHB	ART Dispensing cycle (DC)	Follow-up for the HIV-exposed baby	ART Follow-up for mother	Immunisations	Feeding advice	Growth monitoring	Development	Head circumference	Vit A	Deworming	Oral Health	TB Screen	Mother's contraception
Neonate	1st week of life	3-6 days postnatal (PN) visit for mother and baby	1	• Follow-up results of birth PCR# and mother's delivery VL If birth PCR negative, re-classify the risk profile of the HEI: • Delivery VL < 50 c/mL (low-risk) • Stop AZT and continue NVP daily for six weeks • Delivery VL ≥ 50 c/mL (higher-risk) • Continue AZT twice daily for six weeks • Continue NVP daily for minimum of 12 weeks • Check adherence to NVP and AZT	• Follow-up results of mother's delivery VL • Delivery VL ≥ 50 c/mL: manage as per *Viral Load Monitoring Schedule on page 143.* • Check ART supply: The mother should have been provided with 2 months ART at discharge from labour ward which will last her until 6 week PN visit • Adherence check-in for mother • Provide breastfeeding support and routine PN care		x	x						x	x**
2-6 months (monthly follow-up)	6 weeks	6 weeks	2*	• Ensure that birth PCR and mother's VL results were checked, recorded and acted upon correctly • If low-risk, stop NVP • If higher-risk, stop AZT and dispense NVP for additional 6 weeks	• Postnatal clinical review and adherence check-in. If delivery VL ≥ 50 c/mL, repeat VL at this visit • Provide breastfeeding support. • Provide ART for 3 DCs (3MMD) for mother*	x	x	x						x	
	10 weeks	10 weeks	3	• Do 10 week HIV-PCR # • If higher-risk, check result of repeat maternal VL done at 6 weeks visit. • If VL < 50 c/mL, advise to stop NVP after 12 weeks • If VL still ≥ 50 c/mL, dispense and continue NVP until the breastfeeding mother's VL is < 50 c/mL	• If VL repeated at 6 weeks, review results. Manage as per *VL Non-Suppression Algorithm on page 144* • If mother received either DMPA-IM (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	• Check that 10 week HIV-PCR results were checked, recorded and acted upon correctly	• Adherence check-in for mother • Provide breastfeeding support. • Provide ART for 3 DCs (3MMD) for mother*	x	x	x	x	x				x	
	18 weeks	4 months	5				x	x						x	
	22 weeks	5 months	6				x	x						x	
	26 weeks	6 months	7	• Do 6-month HIV-PCR test # • Review results of PCR and VL in 1 week using NHLS RfA reports. If mother's VL ≥ 50c/mL, restart/ extend infant prophylaxis if still breastfeeding. Go to *Management of a High Maternal Viral Load after Delivery on page 147*.	• Clinical review and '6-month' VL. • Provide breastfeeding support and discuss the introduction of complementary feeding at age 6 months • Script for and provide ART for 3DCs at a time (3MMD) • Review results of VL and PCR in 1 week using NHLS RfA reports. If VL ≥ 50c/mL, manage mother as per the *VL Non-Suppression Algorithm on page 144*	x	x	x	x		x			x	x

* Review and repeat script at 6 weeks (even if the mother still has some medication still in hand) to align with the RTHB visit schedule. The additional treatment that the mother will have in reserve will allow for alignment with the RTHB appointments up to 2 years, which use 30 day calendar months, rather than 28 day dispensing cycles.

** 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 her 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[18], 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. If using self-injectable DMPA-SC, 2 units are given at a time skipping every 2nd FP requirement The repeat NET-EN injection can be given up to 2 weeks late without requiring additional contraceptive protection.

HIV testing should only be done in those who previously tested HIV negative. If a child tests HIV positive at any stage, stop NVP prophylaxis, initiate ART, do a confirmatory HIV PCR, and initiate cotrimoxazole prophylaxis.

Age group	Age of child	Routine visits as per RTHB	ART Dispensing cycle (DC)	Follow-up for the HIV-exposed baby	ART Follow-up for mother	Immunisations	Feeding advice	Growth monitoring	Development	Head circumference	Vit A	Deworming	Oral Health	TB Screen	Mother's contraception
6-12 months	30 weeks	7 months	8	• Check that baby's 6-month HIV-PCR results were reviewed • Check that mother's 6-month VL results were reviewed and acted on correctly	• Check that baby's 6-month HIV-PCR results were reviewed • Check that mother's 6-month VL results were reviewed and acted on correctly.		x	x						x	
	34 weeks	8 months	9				x	x						x	
	38 weeks	9 months	10		• Adherence check-in and breastfeeding support • Provide ART for 3DCs at a time (3MMD)	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	• Ensure mother's 6-monthly VL was done. • Review results of VL in 1 week using NHLS RfA reports. • If VL ≥ 50c/mL, re-call MIP to the facility. Do an HIV-PCR on baby and restart/extend infant prophylaxis if still breastfeeding. Go to *VL Non-Suppression Algorithm on page 144*.	• Clinical review and 6-monthly VL • Provide breastfeeding support. • Assess eligibility and offer RPCs options/facility-provided 6MMD. If ineligible, continue 3MMD. • Review results of VL 1 week using NHLS RfA reports • If VL ≥ 50c/mL, manage mother as per *VL Non-Suppression Algorithm on page 144*.	x	x	x	x	x	x	x	x	x	x
13-24 months 3 monthly follow-up	56 weeks		14	• Check that mother's 12-month VL results were reviewed and acted on correctly											
	60 weeks		15												
	64 weeks	15 months	16		• Provide ART for 3DCs at a time (3MMD), unless already using 6MMD/RPCs • Provide breastfeeding support.		x	x	x		x	x		x	x
	68 weeks		17												
	72 weeks		18												
	76 weeks	18 months	19	• Universal HIV rapid testing at 18 months# (HIV rapid test for <u>all</u> infants regardless of HIV exposure, except in those who previously tested HIV positive and are on ART) • Review results mother's VL in 1 week using NHLS RfA reports • If VL ≥ 50c/mL, restart/extend infant prophylaxis if still breastfeeding. Go to *VL Non-Suppression Algorithm on page 144*.	• Renew script and provide treatment for 6 DCs if already on 6MMD or RPCs. If not, assess eligibility and offer these options. If ineligible or decline, continue 3MMD. • Try to align ART for mother and baby with the well-baby visit schedule. • 6-monthly VL if breastfeeding. • Review results of VL 1 week using NHLS RfA reports • If VL ≥ 50c/mL, manage mother as per *VL Non-Suppression Algorithm on page 144*.	x	x	x	x		x	x		x	x
	80 weeks		20												
	84 weeks		21												
	88 weeks	21 months	22		• Provide treatment for 3DCs at a time (3MMD), unless already on facility 6MMD/RPCs • Provide breastfeeding support.		x	x						x	x
	92 weeks		23												
	96 weeks		24												
2 until < 5 years	24 - 59 months	At 24 months and 6-monthly thereafter			• Renew script and provide ART for 3 or 6 DCs at a time (3MMD or 6MMD/RPCs). • Try to align with child's yearly well-baby visit schedule.		Up to 2 yrs	6-monthly	At 3 years		6-monthly	6-monthly	yearly	3-monthly	3-monthly

1. Abbreviations: AZT zidovudine; ART antireroviral ART; DC dispensing cycle (ART supply 28-days); 3DC three dispensing cycles of ART DMPA, depo medroxyprogesterone acetate (Depo Provera®); HEI HIV-exposed infant; MIP mother-infant-pair; MMD multi-month dispensing; 3MMD multi-month dispensing for 3 months; NVP nevirapine; NET-EN norethisterone enantate (Nur Isterate®); PCR polymerase chain reaction (HIV test); RPCs repeat prescription collection strategies (see DMOC SOPs); RTHB road-to-health booklet; VL viral loadDS

Involving fathers* in antenatal and postpartum care

Information for the Health Care Provider

"A FATHER IS NOT A VISITOR…"
Fatherhood campaign, Brazil

Background: Why Should Fathers be Actively Engaged?

- Research shows benefits to the mother, baby, and father if male partners are involved during pregnancy and breastfeeding.
- ANC and PNC services should be family orientated and should welcome fathers to actively participate in clinical consultations and health education.
- During every consultation, screen mothers for intimate partner violence (IPV) and, if safe, invite the male partner to attend the next visit, explaining the benefits of his involvement.
- Men have traditionally been excluded from ante- and postnatal spaces. For this reason, it may take time to build men's trust and for them to feel comfortable in the new male-friendly service environment.
- ANC and PNC services should display male-friendly posters and health information materials.

Involving Fathers: A proposed four visit approach

- Male partners are unlikely to be able to attend every ANC and PNC visit
- A structured, four-visit approach with an outline of helpful content (see below) will help fathers to feel involved, valued, supported, and prepared during the pregnancy and after their baby's birth
- When the father attends, ask his name and call him by his preferred name, not just 'Dad'
- Men may be fearful of HIV testing and may avoid attending visits if they think they may be 'forced' into testing for HIV. For this reason, a status-neutral approach to HIV services, where HIV prevention and HIV treatment are explained, promoted and offered in equal balance may assist with male uptake of HIV testing and services. This means that HIV testing should be offered as one component of a comprehensive package of general healthcare services, and linking to HIV prevention services, e.g. PrEP is an equal priority to linking to HIV treatment.

Visit 1: Early/Mid Pregnancy
(e.g. second antenatal visit)
Inform about pregnancy, good nutrition and general health

- Introduce benefits of involved fatherhood
- Offer HIV testing and HIV prevention or treatment based on couple's needs
- Educate serodifferent couples about Treatment as Prevention, and benefits of PrEP

Visit 2: Late Pregnancy
(e.g. 34-38 weeks)
Provide information on delivery, labour, danger signs

- Advise on what to pack in the mom's bag
- Educate about first days after baby's birth
- Encourage male HIV testing if previously declined
- Use of the HIV self-testing kit can be offered as an alternative

Visit 3: Labour/ Delivery
Allow the father to support the woman during labour

- Encourage skin-to-skin contact with Dad
- Help dad to support early feeding choice
- Engage the father in supporting linkage to post-natal care

Visit 4: With Newborn
(e.g. day 3-6, 6 week or 10 week visit)

- Inform about infant feeding and the importance of immunisations
- Encourage bonding to support early development including skin-to-skin contact
- Educate on mom's postnatal health
- Offer male HIV testing or prevention/ ART services if not yet aware of status or accessing care

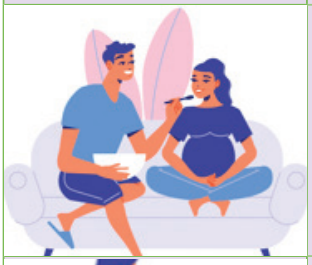
* Father can refer to the biological father or any other supportive male who wishes to be involved including a new partner, grandfather, maternal uncle, cousin, brother, friend

Information for the FATHER

Information for the father during antenatal care

At each antenatal visit, we will:

- Check Mom's blood pressure, weight and urine to make sure she is healthy
- Check for baby's movements and growth
- An ultrasound may be done during the pregnancy to check baby's growth and development
- Answer any questions you may have about the pregnancy or mom or baby's health
- Offer you general health services, including HIV testing and prevention or treatment services because it is important for both Mom and Dad to know their HIV status so that they can be healthy and in control of their health



What you can do to support your partner during pregnancy:

- Help her to eat well and keep active
- Help her to avoid drinking alcohol, smoking or using recreational drugs during pregnancy as these may harm her health and affect the baby's growth and development
- Help her rest enough by helping with cooking, cleaning and looking after older children
- Help her to take any daily medications that have been given without forgetting

What you can do to bond with baby during the pregnancy:

- Did you know your relationship with your baby can start even before your baby is born?
- Place your hand on mom's tummy, baby may play by kicking or punching back
- Baby can hear your voice, and tell it apart from mom's, from four months into the pregnancy. You can sing, read to the baby, tell baby stories or play your favourite tunes through headphones placed against mom's tummy. Baby will recognise these things after he/she is born and will quiet to familiar sounds heard during the pregnancy.

Information for the father during post-natal care

At each post-natal visit, we will:

- Check mom's health and review any chronic medication, including monitoring blood results
- Check on your baby's feeding, growth, and development and provide immunisations
- Answer any questions/concerns you may have about your own, your partner's or baby's health
- Offer you any health services you may need including HIV testing, prevention or treatment so that you can be a healthy member of your family

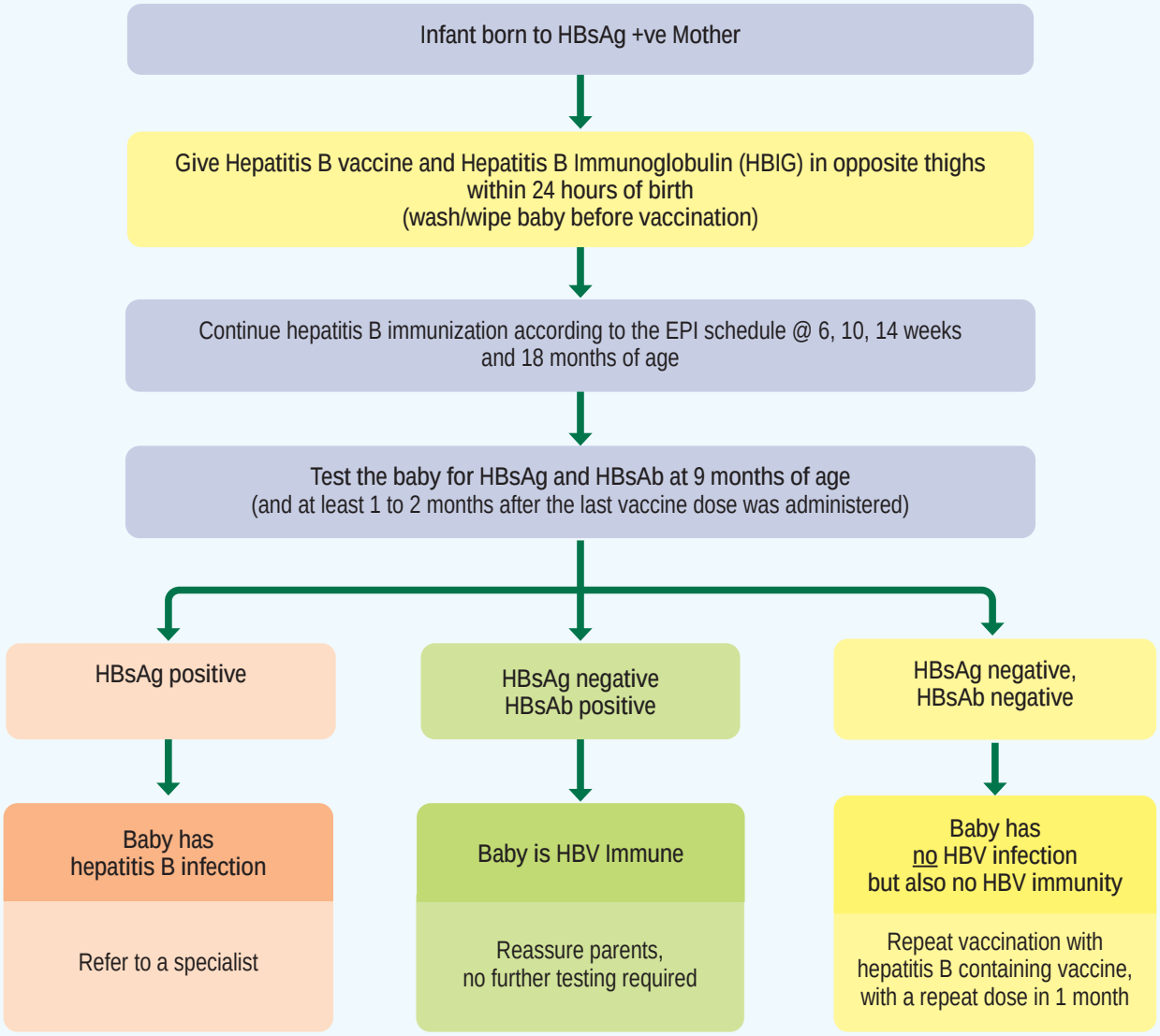
What you can do to support your partner during the time after your baby is born:

- Help your partner to eat well and get enough rest by helping with chores and older children
- If your baby is breastfeeding, you can help by burping/winding baby after a feed or feed baby if mom expresses milk into a cup or bottle
- Having a new baby can be exhausting and busy. Help your partner remember to take daily medications. If she forgets, encourage her to take it as soon as you or she remembers
- If you think you or your partner are getting depressed (low mood) seek help at your local clinic

What you can do to bond with baby during the first few weeks/months:

- The first few weeks can be hard work, take time to hold your baby, and learn how to bathe and change your baby's nappies. Skin-to-skin contact is important for you as a dad too.
- By six weeks your baby will start to smile at you – this is a really special time!
- By three months old baby can play peekaboo and will laugh with you
- Reading, telling stories or listening to music together can help to build a bond
- Take baby out for walks, being outside gives baby plenty to look at to keep them calm

Management of the infant exposed to hepatitis B



Note: Providers should wait until the infant is 9 months of age, and at least one to two months after the last dose of HBV vaccine to perform the Post Vaccination Serologic Tests (PVST). Tests performed before 9 months of age can provide inaccurate anti-HBs results by detecting passive antibodies from HBIG/HBV vaccine administered at birth rather than actual response to the hepatitis B vaccine.

Refer if hepatitis B serology is not available.

EPI	Expanded Programme on Immunisation;	HBsAg	hepatitis B surface antigen;
HBIG	hepatis B immunoglobulin;	HBV	hepatitis B virus;
HBsAb	hepatitis B surface antibody;	PVST	post vaccination serologic tests

Data management

Documentation in the Client Record

Document all clinical findings, results and decisions clearly, and insert the barcode stickers of any blood tests taken in the following client records as applicable:

1. The Maternity Case Record
2. The Adult Clinical Record (ART Stationery) for HIV positive women, if available in that facility
3. The Road to Health Booklet for the HIV-exposed infant

Registering on the self-service portal and requesting reports
STEP 1: Go to www.nicd.ac.za

→ Click on the "M&E Dashboards" and "HIV"
→ Select "Guest User"
→ Click on "Self Service Registration"
→ Self-Service Portal Landing Page

STEP 2: Select "New User Registration" → Complete the registration form, and follow further instructions

Please direct any queries to HIV@nicd.ac.za

Using NHLS reports for quality improvement and client tracking

These reports are compiled from NHLS HIV laboratory data and are e-mailed in different formats depending on the user's requirements. The purpose of these reports is to assist with monitoring of the HIV VTP program, identify HIV-infected pregnant women with high viral loads and link HIV-infected infants to care.

VL Monitoring to facilitate VL suppression

LEVEL	REPORT NAME	REPORT NO.	DESCRIPTION	PURPOSE
Facility / district level	HIV VL RfA Report (all ages)	RPT00001 W/D	• All VL ≥ 50 c/mL (with client identifiers) since the previous weekly (W)/ daily (D) report • **VLs ≥ 50 c/mL done in ANC, at delivery, or during postnatal can be identified in the report if an EGK code was used** • Previous consecutive VL ≥ 1000 c/mL per client are also reported (within limitations of demographic linking)	Facilitates action to regain viral suppression for individual clients at facility level
Facility, district levels	Monthly Maternal EGK (Facility level)		• Facility level use of C#Antenatal, C#Delivery and C#Postnatal codes	Monitors EGK code coverage rates This can be used to monitor the uptake (coverage) of EGK codes used by comparing the number of codes used to the number of women living with HIV who received care: • EGK code uptake during antenatal care= C#Antenatal (Antenatal)/ 'Antenatal on ART at 1st visit' + 'Antenatal start on ART' • EGK code uptake at delivery = C#Delivery/ 'Live births to HIV positive women'
District, province, national levels	Operation Phuthuma report: Monthly EGK code section		Per district, per month, within categories of ANC, delivery, and postnatal: • Total HIV VL tests • Number of tests (< 1000 c/mL and < 50 c/mL) • VL suppression rate (<1000 c/mL and < 50 c/mL)	Monitors VL outcomes Provides an indication of viral suppression rates during ANC, at delivery, and in the postnatal period per district and province

DHIS District Health Information System
MDOs Missed Diagnostic Opportunities = registered HIV PCR tests that are neither positive or negative (includes rejections, invalid and indeterminate results);
RfA Results for Action;

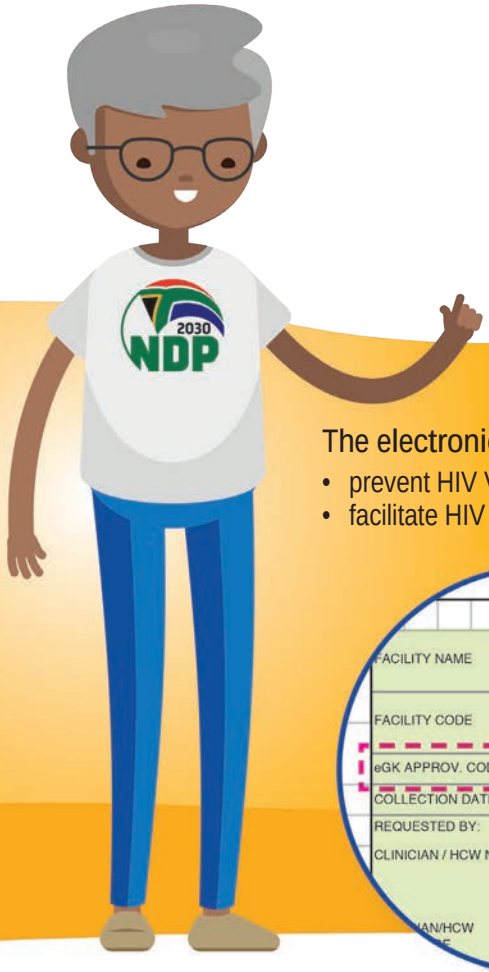
PCR monitoring to identify and link HIV-infected infants to care				
LEVEL	REPORT NAME	REPORT NO.	DESCRIPTION	PURPOSE
Facility / district level	HIV PCR RfA Report weekly (W)/daily (D) report "	RPT01002	• All verified HIV PCR results and rejected samples since the previous weekly (W)/ daily (D) report. Includes client identifiers for intervention at the individual level • All previous HIV PCR results per client are also reported (within limitations of demographic linking)	• To assist with tracing individual HIV-positive infants and linkage to care
District, province, and national levels	Operation Phuthuma report: Monthly EID section		• Reports total number of PCR tests performed and number of positives, disaggregated by age (0 - < 6 weeks, 6 weeks - < 4months, 4 - < 8months, 8 - < 24 months) including EID coverage at around 10 weeks and 6-months of age in comparison to the same month of the previous year. • Number of children with a first PCR positive test are reported (within limitations of demographic linking)	• To monitor EID coverage and number of newly diagnosed children < 24 month of age • Can be used to check accuracy of DHIS data in terms of numbers of PCR tests done per age group, and PCR positivity rates. • Can also be used to monitor trends in transmission rates
Facility, district, provincial and national levels	HIV PCR MDO Report (monthly)	RPT01004/5/6/7	• Facilities with the highest number of MDOs are listed at either National, Provincial, District or Facility level • The 10 facilities with the most MDOs in a region receive a detailed report of their MDOs (e.g. rejection type, rejection reason and test result text) • A laboratory report is also available for laboratorians	• To identify facilities with highest number of MDOs and improve the quality of specimen collection and processing

Facility Guide

EGK authorisation codes for HIV Viral Load testing

in pregnant women and for mothers within two years after delivery

One of the three EGK approval codes must be provided with every maternal HIV viral load done within the 'First 1000 days'*

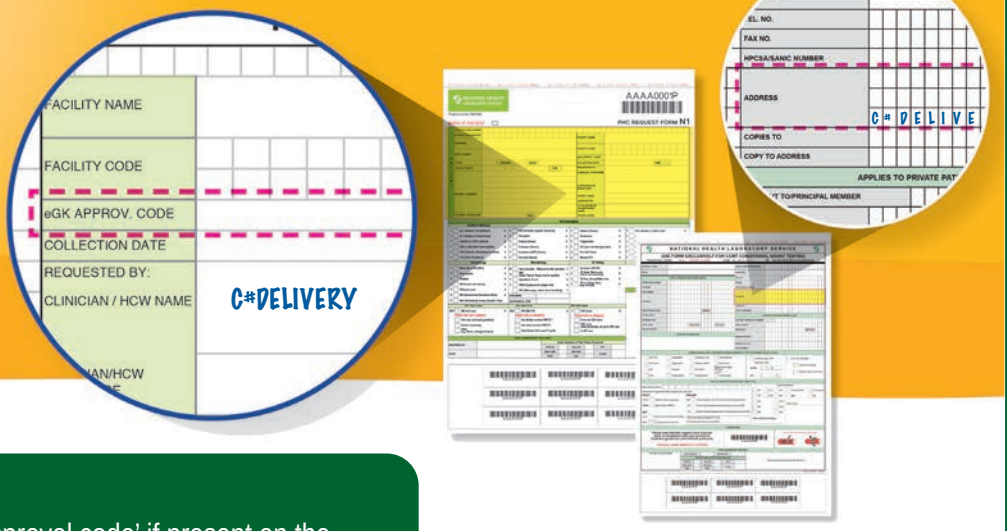


Pregnancy-related EGK approval codes	
C*ANTENATAL	To be used during pregnancy only
C*DELIVERY	To be used around the time of delivery (7 days before or after delivery)
C*POSTNATAL	To be used for any maternal VL until baby is 2 years old **

Please spell the EGK codes correctly

The electronic gatekeeping (EGK) codes will:

- prevent HIV VL tests from being cancelled by gatekeeping at the laboratory
- facilitate HIV VL monitoring of the pregnant and postnatal women



NHLS Requisition Form

Fill in the EGK code in 'EGK approval code' if present on the form or, on forms where this is not provided, clearly state in an available space such as below the 'HPCSA/SANC number' as indicated.

* *The 'First 1000 days' is the time from conception until the child is two years old.*

** *If mother becomes pregnant again before her baby is 2 years old, her HIV VL EGK code will revert to C#Antenatal*

health
Department:
Health
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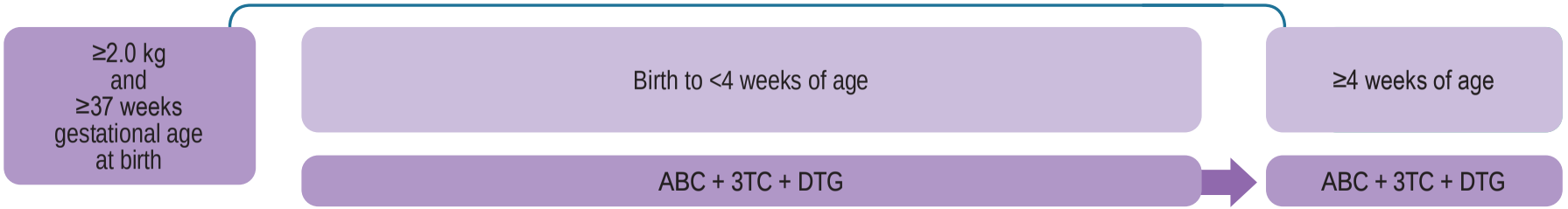
2030 NDP

6

Annexures



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
- 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 Vertical Transmission Prevention of Communicable Infections

Review when 4 weeks of age

- Clinical review and counselling
- Continue ABC + 3TC + DTG - dosing as per ARV dosing chart for children ≥ 28 days
- Continue monitoring as per *Monitoring on ART on page 41*

	Birth - < 2 weeks	2 weeks - < 4 weeks
Available formulation	Dispersible tabs (DT) 120/60 mg (double scored tablet) #	Dispersible tabs (DT) 10 mg
Abacavir + Lamivudine (ABC + 3TC)	¼ of double-scored tab once every 2nd day (alternate days)	¼ of double-scored tab once daily
Dolutegravir (DTG)	½ tab once every 2nd day (alternate days)	½ tab once daily
# *If ABC/3TC **Double scored** dispersible tablet (120/60 mg) is not available, use ABC and 3TC solution with the DTG dispersible tablet.*		
Abacavir (ABC) Solution (20 mg/mL)	1.5 mL Every 2nd day	1.5 mL Once a day
Lamivudine (3TC) Solution (10 mg/mL)	1.5 mL Every 2nd day	1.5 mL Once a day
Dolutegravir (DTG)	½ tab once every 2nd day (alternate days)	½ tab once daily

<2.0 kg
OR
<37 weeks gestational age at birth

Birth to < 4 weeks of age

≥ 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 Vertical Transmission Prevention of Communicable Infections
- Monitor weight gain and adjust ARV doses

Review when ≥4 weeks of age

- Clinical review and counselling
- If <2 kg or <37 weeks corrected gestational age, continue AZT + 3TC + NVP
- If ≥ 2 kg and ≥ 37 weeks corrected gestational age, switch to ABC + 3TC + DTG (refer to ARV dosing chart for children for doses)
- Continue monitoring and evaluations as per *Monitoring on ART on page 41*

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
	≥ 8 weeks - < 10 weeks	12 mg/kg/dose twice daily	4 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		
≥ 35 - < 37 weeks	Birth - < 1 weeks	4 mg/kg/dose twice daily	2 mg/kg/dose twice daily	4 mg/kg/dose twice daily
	≥ 1 - < 4 weeks			6 mg/kg/dose twice daily

When weight is ≥2 kg and ≥37 weeks corrected gestational age, review ARVs and refer to table *ART for the Term Neonate on page 172*

ANNEXURE 3

Antiretroviral Drug Dosing Chart for Children (2025)

	Abacavir + Lamivudine (ABC + 3TC)	Abacavir (ABC)	Lamivudine (3TC)	Zidovudine (AZT)	Dolutegravir (DTG)	Abacavir + Lamivudine + Dolutegravir (ALD)
Target dose	As for individual medicines ONCE 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/m²/dose TWICE daily	By weight band ONCE daily IF PATIENT IS ON RIFAMPICIN TB TREATMENT, ADD ADDITIONAL DTG. SEE NEXT COLUMN	By weight band TWICE daily
Available formulations	Dispersible tablet FDC: ABC/3TC 120/60 mg Tablets FDC: ABC/3TC 600/300 mg ABC/3TC/DTG (ALD)600/300/50 mg	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 FDC: AZT/3TC 300/150 mg	Dispersible tabs (DT) 10 Dispersible tabs (DT) 10 mg, Film coated (FC) tabs 50 mg, FDC: TLD 300/300/50 mg OR ALD 600/300/50 mg DT AND FC TABLETS ARE NOT BIOEQUIVALENT	Dispersible tablets (DT) FDC: pALD 60/30/5 mg ALD 600/300/50 mg
Wt. (kg)	Consult with a clinician experienced in paediatric ARV prescribing for neonates (< 28 days of age) and infants weighing < 2kg					
2 - 2.9	½ x 120/60 mg tab od	-	-	-	½ x 10 mg DT od	1 x pALD DT (60/30/5 mg) od
3 - 5.9		3 ml bd OR 1 x 60 mg tab bd	3 ml bd	6 ml bd		
6 - 9.9	1½ x 120/60 mg tabs od	4 ml bd OR 1½ x 60 mg tab bd	4 ml bd	9 ml bd	1½ x 10 mg DT od	3 x pALD DT (60/30/5 mg) od
10 - 13.9	2 x 120/60 mg tabs od	Once daily dosing > 10 kg 4 x 60 mg tabs od OR 12 ml od	Once daily dosing > 0 kg 12 ml od	12 ml bd OR 1 x 100 mg tabs bd	2 x 10 mg DT od	4 x pALD DT (60/30/5 mg) od
14 - 19.9	2½ x 120/60 mg tabs od	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	2½ x 10 mg DT od	5 x pALD DT (60/30/5 mg) od
20 - 24.9	3 x 120/60 mg tabs od	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	3 x 10 mg DT od OR 1 x 50 mg FC tab od	6 x pALD DT (60/30/5 mg) od
25 - 29.9	1 x 600/300 mg tab od OR ALD (600/300/50 mg) if eligible od	2 x 300 mg tabs od		1 x 300 mg tab bd OR 1 x AZT/3TC 300/150 mg tab bd	1 x 50 mg FC tab od OR ALD (600/300/50 mg) od	ALD (600/300/50 mg) x 1 tab od
30 - 34.9					1 x 50 mg FC tab od OR FDC: TLD, if eligible, 1 tab od OR ALD (600/300/50 mg) x 1 tab od	
≥ 35						

**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.*

d 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.

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

Dolutegravir (DTG) OR Abacavir/Lamivudine/ Dolutegravir (ALD) when on Rifampicin	Lopinavir / ritonavir (LPV/r)	Lopinavir/ritonavir when on rifampicin (and for 2 weeks after stopping rifampicin)		# Atazanavir (ATV) + Ritonavir (RTV)	
By weight band TWICE daily	300/75 mg/m2/dose LPV/r TWICE daily	LPV/r std dose + super-boosting with ritonavir (RTV) powder TWICE daily (≥0.75xLPV dose bd)	OR Double-dose LPV/r tabs ONLY if able to swallow whole LPV/r tabs TWICE daily	By weight band ONCE daily	Target dose
Dispersible tabs (DT) 10 mg, Film coated (FC) tabs 50 mg, FDC: TLD 300/300/50 mg OR ALD DT 60/30/5 OR ALD 600/300/50 mg DT AND FC TABLETS ARE NOT BIOEQUIVALENT	Sol. 80/20 mg/ml Adult tabs 200/50 mg, Paed tabs 100/25 mg TABLETS MUST BE SWALLOWED WHOLE	Oral powder 100 mg/packet	Adult tabs 200/50 mg, Paed tabs 100/25 mg	FDC: ATV/RTV 300/100 mg ATV/r FDC 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 < 2kg					Wt. (kg)
½ x 10 mg DT bd OR [pALD DT (60/30/5) 1 tabs od + ½ x 10 mg DTG DT approx. 12 hours later]	-	-	-	-	
	* 1 ml 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	3 - 5.9
1½ x 10 mg DT bd OR [pALD DT (60/30/5) 3 tabs od + 1½ x 10 mg DTG DT approx. 12 hours later]	* 1.5 ml bd				6 - 9.9
2 x 10 mg DT bd OR [pALD DT (60/30/5) 4 tabs od + 2 x 10 mg DTG DT approx. 12 hours later]	2 ml bd OR [2 x 100/25 mg paed tabs am + 1 x 100/25 mg paed tab pm]	LPV/r std dose (see purple column) + oral RTV powder 200 mg (2 packets) bd	3 x 100/25 mg paed tabs bd		10 - 13.9
2½ x 10 mg DT bd OR [pALD DT (60/30/5) 5 tabs od + 2½ x 10 mg DTG DT approx. 12 hours later]	2.5 ml bd OR 2 x 100/25 mg paed tabs bd OR 1 x 200/50 mg adult tab bd		4 x 100/25 mg paed tabs bd OR 2 x 200/50 mg adult tabs bd		14 - 19.9
3 x 10 mg DT bd OR 1 x 50 mg FC tab bd OR [pALD DT (60/30/5) 6 tabs od + 3 x 10 mg DTG DT 12 hours later] OR [pALD DT (60/30/5) 6 tabs od + 1 x 50 mg DTG FC approx. 12 hours later]	3 ml bd OR 2 x 100/25 mg paed tabs bd OR 1 x 200/50 mg adult tab bd				20 - 24.9
1 x 50 mg FC tab bd OR [ALD (600/300/50 mg) 1 tab od + 50 mg DTG FC tab approx. 12 hours later]	3.5 ml 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]	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 300/100 mg FDC od	25 - 29.9
1 x 50 mg FC tab bd OR FDC: [TLD if eligible od + 50 mg DTG FC tab 12 hours later] OR [ALD (600/300/50 mg) x 1 tab od + 50 mg DTG FC tab approx. 12 hours later]					30 - 34.9
	5 ml bd OR 4 x 100/25 mg paed tabs bd OR 2 x 200/50 mg adult tabs bd		8 x 100/25 mg paed tabs bd OR 4 x 200/50 mg adult tabs bd		**≥ 35**

FC = film coated
DT = dispersible tablet
FDC = fixed dose combination;
TLD = tenofovir/lamivudine/dolutegravir;
ALD = abacavir/lamivudine/dolutegravir;

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

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 600/300 mg; - ALD 600/300/50 mg FDC dispersible tablet: - ABC/3TC 120/60 mg; - pALD 60/30/5 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 - ALD 600/300/50 mg FDC dispersible tablet: - pALD 60/30/5 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 ingested 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, - 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, 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 Tablets: - 200/50 mg, - 100/25 mg	Tablets: NO Must be swallowed whole and not divided, crushed or chewed.	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.#
Ritonavir (RTV)	Oral powder: 100 mg/packet		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)	FDC tablets: ATV/RTV 300/100 mg	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 - ALD 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). pALD DT (60/30/5 mg) can only be dispersed in water, not milk or solid foods. Use approximately 15 mL of water when dispersing 3 tablets or less, and approximately 20 mL water when dispersing 4 tablets or more. Do not chew, crush or cut the tablets.

1.

ALD = abacavir/lamivudine/dolutegravir; FDC = fixed dose combination; eGFR = estimated glomerular filtration rate; GIT = gastrointestinal tract; TLD = Tenofovir/ Lamivudine Dolutegravir; #EML-Antiretroviral interactions table (http://www.mic.uct.ac.za) OR www.hiv-druginteractions.org/checker OR the Liverpool HIV iChart application for smart phones, or any of the helplines: National HIV and TB Health Care Worker Hotline: 0800 212 506 or HIV Expert Helpline: 082 352 6642 or KZN Paediatric Hotline: 0800 006 60TEE

TPT regimens for children weighing less than 25 kilograms

There are two potential regimens for children: 3RH (rifampicin and isoniazid for 3 months), and 6H (isoniazid for 6 months). The choice depends on the child's weight, HIV status or HIV exposure (maternal HIV) status:

- in HIV-negative children < 25kg, the priority regimen is 3RH
- in children living with HIV and on DTG (dolutegravir) containing ART, the preferred regimen is 6H to avoid drug-drug interactions with ART
- in infants born to HIV-positive women (HIV-exposed but HIV-negative infants) on nevirapine, 6H is the priority regimen as rifampicin lowers nevirapine levels below efficacy

All children and breastfeeding infants require pyridoxine (vitamin B6) for the duration of their TPT as follows: Children younger than five years 12.5 mg and children five years or older 25 mg, once daily. Lack of pyridoxine access should not be a barrier to receiving TPT.

For HIV-positive infants who have just had the Bacillus Calmette-Guérin (BCG) vaccine and are not TB-exposed, TPT should be deferred for 14 weeks as Isoniazid (INH) impairs the effect of live BCG (M.bovis BCG) vaccine.

1. Recommended daily dosages for 3RH in HIV-negative children <25kg

Child's Weight (kg)	RH (Daily) fixed dose combinations		Duration
	75 / 50	If dispersed in water	
2 - 2.9	½ tablet	5ml	3 months
3 - 3.9	¾ tablet	7.5ml	
4 - 5.9	1 tablet	10ml	
6 - 7.9	1 ½ tablet	15ml	
8 - 11.9	2 tablets	20ml	
12 - 15.9	3 tablets	30ml	
16 - 24.9	4 tablets	40ml	
≥ 25	Use adult formulations and doses		

2. Recommended daily dosages for 6H amongst children living with HIV < 25kg

Weight band (kg)	Daily INH 100mg tablet	Duration
2 - 3.4	¼ tablet	6 months
3.5 - 4.9	½ tablet	
5 - 7.4	¾ tablet	
7.5 - 9.9	1 tablet	
10 - 14.9	1½ tablet	
15 - 19.9	2 tablets	
20 - 24.9	3 tablets (or one 300mg tablet)	
≥ 25	Use adult formulations (maximum dose 300 mg per day)	

Follow-up Sheet – Management Summary for a Patient with a Positive CrAg

MANAGEMENT SUMMARY FOR A PATIENT WITH A POSITIVE CRAG

Purpose: To communicate the management plan for cryptococcal disease between the hospital and providers at different healthcare levels.
This template can be used as an addendum to the hospital discharge summary

Patient details	*Patient name and surname*				
	Date of birth				
	Hospital name and folder number				
CrAg	*Date of CrAg positive*		*CSF barcode number or barcode sticker*		
	Date of Lumbar Puncture				
Lumbar puncture	*Cryptococcal meningitis* **confirmed**		*or* excluded		
	Other pathology found on LP (explain):				
Intensive phase (IP)	*Intensive phase start date:*				
	Treatment received: *Week 1:*				
	Week 2:				
	Complications/adverse events and their management (e.g. symptoms/ therapeutic taps)				
At discharge from hospital (if hospitalised)	*Discharge date*	*Dr's name*	*Dr's contact number*		
	Discharge plan (e.g. f/u 2 weekly or monthly)				
	Fluconazole dose and supply duration given at discharge:				
	Consolidation phase start date:		Consolidation phase end date:		
	Maintenance phase start date:		Maintenance phase end date:		
	Anticipated ART start date (if not yet on ART)		*Current ART regimen (if already on ART)*		

Mental Health Assessment

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.

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 patient shows signs of intense sadness, risk of harming themselves or others or hears or sees things that others do not see, they should be directly referred for psychiatric support.

Provide the patient with education on mental health and provide them with advice that can help them overcome symptoms, such as:

- 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.

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.

If a patient screens positive for any of the mental health conditions, please do the following:

- Provide a mental health intervention if available and feasible (e.g. interpersonal counselling)
- Refer to clinician and assess for antidepressant prescription if appropriate
- Refer to mental health support specialists' services as needed
- Refer to other organizations for care and support
- Provide access to mental health materials and support services online http://masiviwe.org.za/

Tool to screen for mental health conditions

PART 1 DEPRESSION AND ANXIETY SCREEN							
Question 1: Core features of depression		Score	Question 2: Other features of depression		Score
1	Felt depressed most of the day almost every day?		1	Experienced reduced concentration and attention?	
			2	Experienced reduced self esteem and self **confidence?**	
2	Lost interest or pleasure in activities that are normally pleasureable?		3	Had ideas of guilt and unworthiness?	
			4	Experienced that your view of the future is bleak and negative?	
3	Experienced decreased energy or increased fatigue?		5	Experienced ideas or acts of self harm or suicide?	
			6	Sleep been disturbed?	
			7	Your appetite decreased?	
Total score for Question 1			Total score for Question 2		
A score of 2 or more for Question 1 is a positive screening result Manage as per APC Guidelines			A score of 3 or more for Question 2 is a positive screening result Manage as per APC Guidelines		
Question 3: Anxiety					
1	Is the patient feeling tense/nervous and/or worrying a lot?	Yes		No		A "Yes" answer for Question 3 is a positive result for anxiety. Manage as per the APC Guidelines

PART 2 SUBSTANCE USE DISORDER SCREEN							
Question 1	Score No = 0 Yes = 1	Question 2	Score No = 0 Yes = 1	Question 3 Have you ever experienced any of the following?	Score No = 0 Yes = 1	Question 4	Score No = 0 Yes = 1
Has your taking of drugs or alcohol caused serious problems for yourself, your family or the community		Did you have more than 5 drinks per session in the last week?		Taken a drink to steady your nerves or treat a hangover?		Have you used any elicit drugs or misused prescription drugs?	
		If you are a man: Do you have more than 21 drinks pper week? If you are a woman: Do you have more than 14 drinks per week? (1 drink = 1 tot of spirits or 1 small glass of wine or 1 can of beer)		Felt that you should cut down on drinking?			
				Felt guilty about drinking?			
				Felt annoyed if criticized by anyone about your drinking?			
Total Score		Total Score		Total Score		Total Score	
A score of 1 is a positive screen and needs action		A score of 1 or more is a positive screen and needs action		A score of 2 or more is a positive screen and needs action		A score of 1 is a positive screen and needs action	

Psychosocial Support for Pregnant and Breastfeeding Women

A number medical, mental health and social risk factors may put a mother-infant-pair at risk of poorer outcomes. These factors are identified within currently used clinical records e.g. the maternity case record, the RTHB, and the WBOT household risk assessment form, and are summarised below. These mother-infant-pairs may require closer follow-up and additional support from both clinicians and CHWs.

ANTENATAL RISK FACTORS
Teenage pregnancy
Primigravida
Lives in an informal settlement
Single
Unemployed
Any medical problem (including HIV)
Any obstetric problem
Any psychiatric problem
Use of tobacco, drugs, or alcohol
Any other relevant reason e.g. violence/abuse at home, lack of social support, food insecurity, being a refugee, recent bereavement, etc.

PERINATAL RISK FACTORS
Low birth weight baby (<2500 grams)
Delivery before 37 weeks (premature baby)
Neonatal death or stillbirth
Any neonatal problem: e.g. Low Apgar (<7); breast-feeding problems; suspected hypoxic ischaemic encephalopathy (HIE); congenital problems
Any maternal problem that arose during delivery or post-delivery: e.g. bleeding, tears, infection, re-tained placenta
Any other relevant reason e.g. violence/abuse at home, lack of social support, food insecurity, being a refugee, recent bereavement, etc.

Screening Pregnant Women for Referral to a CHW

Early referral to community-based services improves adherence to ART, retention in care, exclusive breastfeeding and care of the child up to two years of age. Where resources allow, all women should be linked with a CHW during antenatal care. However, in areas with insufficient numbers of CHWs to meet the demand, the factors listed above can be used to screen and prioritise women to be referred. Any woman who has one or more of the listed criteria should be prioritised. Screening should be done antenatally and after the birth of the baby before discharge from labour ward. The screening assessment can be done by a midwife, a BANC nurse, or a lay counsellor in the facility. Each facility should decide which of the above categories of staff are best placed in their facility to conduct the screening and referral.

Screening and referring women for antenatal and postnatal depression and anxiety

The prevalence of depression and anxiety is high in antenatal and postnatal women. It is therefore important to screen women for these conditions and refer as appropriate. The validated screening tool below is able to identify women with potential depression and/or anxiety. Those who answer “yes” to two or more questions, should be referred for a definitive diagnosis and further counselling.

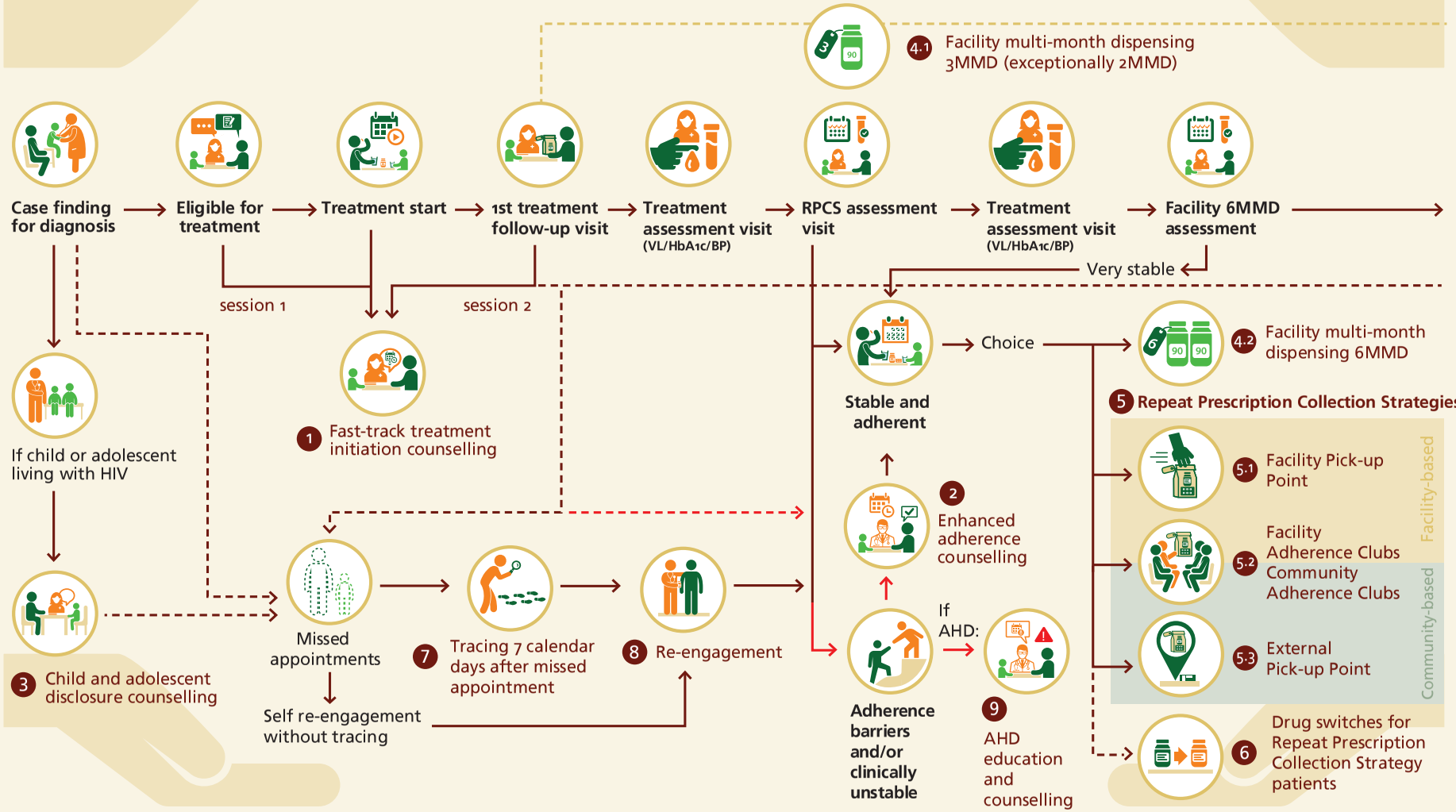
	ANTENATAL RISK FACTORS	YES	NO
1.	In the last 2 weeks, have you on some or on most days felt unable to stop worrying, or thinking too much?		
2.	In the last 2 weeks, have you on some or on most days felt down, depressed or hopeless?		
3.	In the last 2 weeks, have you on some or most days had thoughts and plans to harm yourself or com-mit suicide?*		

1. *the self-harm question will require urgent referral if there are both thoughts AND plans. If there is a history of previous attempt, referral is required even if there are thoughts alone.

Differentiated Models of Care (DMoC) Standard Operating Procedures

Differentiated care aims to strengthen linkage, adherence and retention using a patient-centred approach throughout the treatment cascade. DMoC take into consideration the patient's population group, clinical characteristics and context. It enhances maximum adherence and retention and recognizes the importance of integrated chronic care service provision.

INTEGRATED CARE OF PEOPLE LIVING WITH CHRONIC CONDITIONS



DMOC diagram

DIFFERENTIATED MODELS OF CARE (DMOC)			
Clinically unstable	Not yet stable	Stable	Very stable***
Symptomatic acute/sick <6 months old Pregnant AHD	New on ART OI on treatment 6m to 5yrs old Newly re-engaged Post-natal <12 months Elevated VL	1 x VL<50 c/mL 1 x HbA1c ≤8% 2 x BP <140/90	12 months on ART 2 x VLs <50 c/mL 2 x HbA1c ≤8% 2 x BP <140/90
More intensive service delivery	Standard service delivery	Less-intensive service delivery	
Monthly** clinical reviews and script	3-monthly* clinical reviews + 3 month script (3MMS*)	6-monthly clinical review + 6 month script (6MMS)	
Facility monthly** dispensing	Facility 3MMD*	RPCs: EX-PUP, FAC-PUP or AC 3MMD (or 2+4MMD)	Facility 6MMD***

* 2-monthly if on TB Rx, new on ART at month 1 visit, at delivery (see 2025 VTP guidelines tables) or necessary to align with required follow-up clinical management in 2 months time.

** Monthly can be adjusted: for pregnant women to integrate into BANC Plus visits; for AHD clients 2-weekly or monthly applies in the first 3 months; thereafter, adjust as clinically indicated for AHD and symptomatic/sick clients (can extend to 2- or 3-monthly; do not increase frequency unless clinically required).

*** Limited to ART TLD regimen only until national medicine stock availability is confirmed for other ART regimens and hypertension and diabetic treatment.

DMOC SOP 2 Enhanced Adherence Counselling

Source: Differentiated Care Models Standard Operating Procedures 2025

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).

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

SESSION 1

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

- 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 11

Disclosure Counselling for Children and adolescents Living with HIV

- 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 2025 SOP 3: Child and Adolescent Disclosure Counselling

ADVANCED HIV DISEASE EDUCATION AND COUNSELLING (AHD-EC)

SOP 9

TITLE: SOP FOR ADVANCED HIV DISEASE (AHD) EDUCATION AND COUNSELLING (AHD-EC)	
INSTITUTION: NATIONAL DEPARTMENT OF HEALTH	
REFERENCE NUMBER: AGL: AHD-EC (1)	**EFFECTIVE DATE:** AUGUST 2025

PURPOSE

The purpose of this document is to outline the process for healthcare workers and counsellors to provide Advance HIV Disease (AHD) education and counselling.

PERSONS AFFECTED

- Patient diagnosed with AHD
- Healthcare workers
- Counsellors (includes social worker, psychologist, lay counsellors and dietician/nutritionist providing support to PLWHIV)
- Support system (family member, friend, community health worker and communitybased support organisations)

APPLICABLE POLICY REFERENCE

For HIV: 2025 National consolidated guidelines for the management of HIV in adults, adolescents, children and infants and prevention of vertical transmission For TB: 2023 National guidelines for the management of TB infection; 2017 Community TB Care SOPs

CRITERIA FOR AHD EDUCATION AND COUNSELLING

- Adults and adolescents living with HIV identified with:
  - CD4≤200 cells/mm3 or
  - WHO stage 3 or 4
- Caregivers of children:
  - Under 5 years old who are not on ART or on ART for less than a year or clinically unstable (has signs or symptoms of illness related to HIV or any other disease)
  - Above 5 years old with CD4 ≤200 or WHO stage 3 or 4

GUIDING PRINCIPLES

- This AHD education and counselling session forms part of the AHD guideline adherence support plan to be developed by clinicians together with patients identified with AHD.
- This AHD education and counselling session should be provided along with:
  - the Fast Track Initiation Counselling session two (provided session one already completed on the day of diagnosis otherwise start with session one) (SOP 1: FTIC) for a patient initiating or
  - the Enhanced Adherence Counselling session one (SOP2: EAC) for a patient re-initiating or continuing ART.
- For patient's re-engaging in care, the re-engagement approach detailed in SOP 8 should also be followed.
- The AHD guideline adherence support plan is made up of the following components:
  - providing AHD treatment literacy
  - establishing and informing a home support network
  - appropriate adherence and disclosure counselling
  - mental health assessment and referral
  - documenting adherence barriers and plan (can be updated in existing (Adherence Plan)
  - identifying the patient's preferred mechanisms for support
  - determining and documenting the follow-up visit schedule and format
  - tracing and recall consents and contact detail verification

- The clinician diagnosing a patient with AHD at clinic or hospital-level is responsible for providing this session. It can be delegated to a counsellor who is familiar with AHD (if available) provided the clinician retains responsibility for all components of the adherence support plan, including its documentation in the patient's record and any hospital discharge summary.
- The clinician diagnosing a patient with AHD at clinic or hospital-level is responsible for providing this session. It can be delegated to a counsellor who is familiar with AHD (if available) provided the clinician retains responsibility for all components of the adherence support plan, including its documentation in the patient's record and any hospital discharge summary.
- The session should be provided to patients with AHD without delaying (re)initiation on ART and/or treatment for OIs.
- Use patient-centred communication to create a safe, non-judgmental space for your patient to discuss challenges.
- Where a patient with AHD has been discharged from a hospital to a Primary Health Care (PHC) facility:
  - the clinician at the PHC facility should take over the responsibility for the adherence support plan. Where this has not been fully developed by the hospital clinician or this session on AHD not provided to the patient, this should be done at the patient's first visit.
  - the discharging clinician should ensure the client has a transfer letter and discharge summary with active linkage to a designated primary care facility for continuity of care.

ROLES AND RESPONSIBILITIES FOR AHD SUPPORT, EDUCATION AND COUNSELLING

Clinician's role

- Screen for OIs and provide ART and OI treatment/prophylaxis in accordance with AHD guidelines, explaining indication, duration, timing, side effects and giving written pill schedule if helpful;
- Provide AHD education and counselling session;
- Provide mental health assessment and referral;
- Identify specific adherence barriers, create/update adherence plan (pill burden, side effects, costs of visits to the clinic and the need for support system) and keep it in the patient folder;
- Establish and inform the patient's home support network;
- Identify the patient's preferred mechanisms of support;
- Assess the patient's vulnerability to deterioration and circumstances, discuss and agree on intensity of visit schedule for the next 3 months and agree on next 3 appointment dates;
- Inform the patient about the importance of recall system, e.g. in case of test results requiring urgent action;
- Obtain consent and accurate information for recall for test results and missed appointments;
- Communicate with counsellors and CHW about phone or home check-ins agreed on with patient;
- Ensure continuity of care between hospital and primary care facility.

Counsellor's role*

- Carry out the AHD education and counselling session if delegated by clinician;
- Provide FTIC or EAC counselling as appropriate;
- Create/update the Adherence Plan and keep it in the patient folder;
- Encourage the patient to identify a home support system;
- Carry-out telephonic check-in calls if delegated by clinician;
- Inform the patient about need to have accurate information for recall for test results or missed appointments;
- Check and update patient contact details at every patient interaction.

* Counsellors must have received an orientation on AHD and been designated by the clinician who maintains responsibility to ensure that patients received AHD education and counselling according to their needs.

Patient's role

- Understand AHD, individual diagnosis, treatment, importance of starting/ restarting/continuing ARVs and OI treatment/ prophylaxis, danger signs, side-effects and IRIS;
- Voice concerns and ask questions;
- Take the decision to start/ re-start/ continue/ adapt ART and OI treatment/s (increasing pill burden);
- Elaborate or adapt the Adherence Plan with the clinician/counsellor and be accountable for adherence within the AHD management plan in collaboration with healthcare team;
- Identify a home support network;
- Understand the treatment pathway ahead;
- Consider and provide consent and accurate contact details for recall for test results, missed appointments or check-ins, depending on needs;
- Give input on availability on next proposed appointment schedule and come for next appointment;
- Take treatment to reach goals;
- Choose a facility to continue care (in case of being discharged from a hospital or if moving/travelling to another area) and communicate this choice with the clinician.

Support system's role** (with patient's consent)

- Understand the treatment pathway ahead and accompany the patient on his/her treatment journey;
- Understand how ART and OI treatment must be taken;
- Support the patient in taking treatment daily, as advised by the clinician;
- Understand danger signs, side effects and IRIS. Contact the patient's clinician, counsellor or CHW and facilitate getting the patient back to the clinic or directly to hospital if needed;
- Support the patient in attending clinical visits and remind patient of next appointment;
- Remind the patient of their treatment goals and adherence steps when the patient is experiencing challenges;
- Encourage the patient to urgently re-engage in care or restart treatment in case of treatment interruption;
- Voice concerns and ask questions with the treatment team;
- Inform the treatment team if he/she can no longer be the support system for the patient (or must stop this role for a certain time for whatever reason).

** CBOs can also provide this and other support to the household such as food parcels, documentation support, supporting the family or friend support system

PROCEDURE

BEFORE THE SESSION

- Evaluate patient's ability to receive and understand the session. Check if the patient remembers recent events and if they have experienced any problems remembering, speaking, understanding or concentrating. If the patient shows signs of memory impairment, consider rescheduling the AHD education and counselling session until the patient feels better or when a support person can be present.
- Ensure you have all the tools you need:
  - Patient folder (including CD4 results, viral load, WHO stage, TB screening, TB NAAT and CrAg results;
  - Adherence education flip chart and/or any treatment adherence pamphlet
  - Patient Adherence Plan sheet (stays in the patient's folder for follow-up and further completion);
  - Mental health assessment;
  - Registers, depending on the conditions;
  - List of supporting organisations such as CBOs and FBOs to assist with psychosocial support and home visits;
  - Pen.

DURING THE SESSION

- Build rapport with patient: Introduce yourself, ensure patient is comfortable, establish language preference and explain confidentiality.
- Show your appreciation to the patient for coming (back) to facility.
- Give the patient time to consider the AHD diagnosis and help the patient cope with emotions arising.
- Assess for any memory impairment and provide written information if remembering discussions from session may be an issue.
- Explain that achieving our treatment goals can be challenging and take longer for some of us.
- Explain AHD, any specific infections (including TB, Cryptococcal Meningitis and Serious Bacterial Infections) and treatment.
- Provide guidance regarding danger signs, medication side effects, and information about IRIS.
- Provide this session along with the initiation/continuation of FTIC, or with EAC depending on patients' needs.
- Check understanding, provide clarification as needed and allow time for the patient to ask questions.
- Discuss immediate concerns and help patient to identify a support person.
- Identify any barriers to adherence such as increased pill burden, drug side effects, memory impairment, unpalatable medicines and costs and time to attend clinic appointments and make a plan to address them.
- Make an active referral for a specific time and date to community structures for psychosocial, home visit and other care and support if needed.
- Provide additional referrals for mental health support and other services based on needs.
- Complete/Update the Adherence Plan in the patient's folder (and attach a new plan if extensive revisions), specifically addressing adherence issues related to AHD.

AT THE END OF THE VISIT

- Assess if patient remembers key information from the session (e.g. how to take medication, what to do in case of side effects, etc.). If the patient shows signs of memory impairment, provide written information to take home and consider repeating the AHD education and counselling session when the patient feels better or when a support person can be present.
- Discuss any further questions or concerns that the patient may have.
- Engage with the patient about their follow-up appointment schedule, record next 3 appointment dates, writing it down and setting up a phone reminder.
- Obtain consent and accurate information for recall for test results or missed appointments.
- Leave any IEC materials with the patient after making sure that the patient understands information in IEC material in their language.
- Provide hope and encouragement to the patient.

- Ensure completed/updated Adherence Plan for FTIC, EAC and AHD education and counselling session additions is filed in patient folder and update appropriate facility registers accordingly (if any).

OVERVIEW OF AHD EDUCATION AND COUNSELLING SESSION

- One session of education and counselling on AHD to be provided individually, or with a support person when possible:
  - For ARV naïve patients: Provide Fast Track Initiation Counselling (SOP 1: FTIC) and this session
  - For patients who re-engage in care: Follow the appropriate re-engagement approach (SOP 8: Re-engagement in care). Update Adherence Plan and provide Enhanced Adherence Counselling (SOP 2: EAC) if indicated in addition to this session.
  - For patients on ART: Address the potential reasons for AHD (update the Adherence Plan) and provide EAC if indicated, in addition to this session.
- If the patient is too weak and unable to understand, it is to clinician discretion to consider admission or home care, and delay or select the amount of information to be shared on the day of AHD diagnosis. Involve a support person (if possible), give written information and provide education and counselling on AHD as soon as the patient is well enough (before discharge, for those hospitalised).

AHD EDUCATION AND COUNSELLING SESSION

1. Explain the purpose of your session

- To better understand AHD and any infections diagnosed
- To clarify that ARVs and infection treatment improve health and resolve AHD once the immune system recovers
- To understand tests that will be performed
- To educate on treatment, side effects, danger signs, additional clinical management and support
- To assess and address any reported barriers to adherence and discuss effective strategies to overcome them

2. Explain the AHD diagnosis and why we are concerned

- Use the adherence flipchart to provide explanations related to CD4 and OIs.
- **If AHD is due to low CD4 count (≤200):**
  Your CD4 count is [insert CD4 count]. *Your CD4 cells, which are your immune system's soldiers, are low because they have been attacked and killed by the HIV in your body.*
- If AHD is due to WHO Stage 3 or 4:
  You've been diagnosed with [insert infection/s].
  This infection [name it] *is a common infection of HIV and while you have it, you are at risk of getting other infections that can make you very sick.*

- *While you have this* [infection/low CD4 count]*, it is easier for you to get sick from infections like TB, meningitis (which is a serious infection in the brain), pneumonia (which is a serious infection in the lung), stomach infections, skin rashes, ear infections and viruses, such as flu or COVID. These infections can make you sicker than if your immune system was strong.*
- *We call this stage of HIV, advanced HIV disease. We need to work closely together to get you through this stage.*
- *Will you get better? Yes, I will explain how.*
- Be open and alert to any personal difficulties and struggles with aspects of the information.

3. Educate on how to get better with appropriate treatment

- Use the adherence flipchart to provide explanations related to ARVs.
- *ARVs will stop HIV killing more CD4 cells and over time, your CD4 count will go up, making your immune system stronger. By taking ARVs every day, you'll feel better, recover your health, and live a long life.*
- *If you have an infection, it is important to take the treatment for that too. Sometimes, we need to treat the infection(s) before starting ARVs. We will guide you on when to begin each treatment.*
- *Many people who were very sick with low CD4 counts and other infections like TB have recovered by taking their ARVs and other infection treatment as prescribed. Now, they have healthy CD4 counts and live full, healthy lives.*
- *Once your immune system is strong again and the infection(s) cleared, as long as you keep taking ARVs every day, you won't need extra clinical management or close support. You'll still be living with HIV, but not with advanced HIV disease that requires more frequent care and close monitoring.*

4. Educate on IRIS

- *What is IRIS?*
- *When your immune system begins to recover because you [started/re-started] ARVs, it might start fighting infections already in your body, which could make you feel worse before you get better. It is not the ARVs making you feel sick but your body trying to get rid of those infections. This is called IRIS, and it can be dangerous if not treated quickly.*
- *When should you come back to the clinic?*
- *If you start feeling worse or get any new symptoms—like getting a cough, fever, headache, or losing weight, skin changes or lumps —come to the clinic right away. The sooner we see you, the faster we can help. Don't stop your medications but come to the clinic or hospital immediately, even if it is not your scheduled appointment date.*
- *It is very rare to need to stop any treatments because of IRIS. We can support you through it.*

5. Educate on danger signs

- *Because your body is weak right now, your health can worsen quickly. It is important to recognise danger signs and act fast.*
- *Go to the hospital immediately if you experience any of the following: new seizures, weakness, confusion, headaches, new problems with vision, non-responsive to people around you, strange behaviour, unable to walk, coughing up blood, trouble breathing, shortness of breath, swollen lymph nodes, high fevers, severe diarrhoea or vomiting or any other severe symptoms.*
- *If you've recently been in the hospital and start feeling worse, go back immediately. Do remember to take your hospital records with you.*
- *Ask your support person at home to help you get to hospital if they see any of these danger signs.*

6. Educate on tests performed (or to be performed) and possible results

- *We are doing some tests to check for infections so we can treat them early.*
- CrAg Test:

  If CD4 is below 200:
  - We've already tested for a germ called cryptococcus, which can cause a severe infection in the brain called meningitis. Your result was [insert result].

  If CrAg test is positive:
  - Your CrAg test is positive. This means the cryptococcus germ is in your body and can cause an infection around your brain called cryptococcal meningitis. We need to do a lumbar puncture, which is a procedure where we use a needle to take fluid from the spinal cord to check if the infection has reached the brain. This is a serious infection that need quick treatment to prevent you from getting very sick and dying. Only a doctor can do this lumbar puncture.
  - Schedule appointment for lumbar puncture in consultation with the patient. Confirm place and date and time.
  - The doctor will either ask you to stay for a few hours to get the result or give you a return date. It is important to go back for the results.
  - If the lumbar puncture result is positive, the doctor will give you the treatment needed to treat cryptococcal meningitis. You will need to stay in hospital for a few days.
  - If the lumbar puncture result is negative, you are still at risk of developing cryptococcal meningitis, the doctor will need to give you important medicine to prevent this.

- TB Test:
  - We are also testing for TB. The main symptoms of TB in adults are coughing, fever, night sweats and unplanned weight loss. When your CD4 cell count is very low, you may not have any symptoms but could still have TB, so we need to check thoroughly.
  - We will do a urine test (if available) and a sputum test.

  If patient has TB symptoms but the urine test is negative or only a sputum test is done:
  - You will need to come back in 2 days for your sputum results (include in appointment schedule discussion below). If the test is negative, your clinician will do more tests to find out why you are unwell.

  If patient does not have TB symptoms:
  - If your TB test is positive, we will contact you with the result. You will need to come to the health facility as soon as possible but no later than 3 days to start TB treatment.
- Next CD4 count:
  - You will have another CD4 count after 6 months.

7. Educate on prophylaxis

- *What are the other medicines you're getting?*
- *We'll give you Bactrim (Cotrimoxazole) to help prevent serious infections like pneumonia and diarrhoea. You'll take this until your CD4 count rises above 200, which means your immune system is strong enough to fight infections on its own.*
- *If you don't have TB and are eligible, we'll also give you medicine to prevent TB. This is called TB Preventive Treatment (TPT).*
- Explain which TPT option is being provided:
  - INH taken once daily for twelve months
  - 3HP taken once weekly for 12 weeks
- *You can start Bactrim and TPT at the same time as your ARVs. It is important to take these medicines while your CD4 is low until it improves.*
- *It can feel overwhelming to have so many different medications, but each one is important for your health as your immune system recovers. If you're struggling to take all your pills every day, speak with your clinician so they can help you.*

8. Educate on treatment adherence

- *It's important to start (or restart) your ARVs as soon as soon as we advise and take them every day. This will help your CD4 cells recover and lower your risk of getting sick. Usually this will be on the day that you're diagnosed or return to care, but in a few cases, we will need to delay starting your ARVs to manage your infection first.* Explain if this is the case and when the client will be starting ART.
- Address only relevant co-infection(s):

  If patient has TB:
  - Since you have TB, it's very important to take your TB medicine every day alongside your ARVs. TB can be cured, but only if you take all your tablets daily for the full course prescribed. Missing doses can make TB harder to treat.
  - If patient is required to add ARV dose: TB treatment can interact with your ARVs, making them less effective. You will need to take an extra dose of one of your ARVs until TB treatment is completed.
  - If your symptoms get worse or don't improve with treatment, please come back and don't wait for your next scheduled appointment date.

  If patient has cryptococcal meningitis:
  - Since you have cryptococcal meningitis, it is vital to take the treatment exactly as prescribed. Over the next few weeks, your clinician will adjust the number of tablets you need to take each day. The number will decrease over time, but you'll need to continue the treatment for a year or even longer, even if you start to feel better. Stopping too soon could allow the meningitis to come back. If you notice worsening symptoms, like headaches, a painful or stiff neck, confusion, sensitivity to light, come back to the clinic or hospital immediately.

  If patient has any other co-infection:
  - Explain any other co-infection and treatment adherence

9. Identifying a support person

- *It's important to have someone in your family or friends who knows about your advanced HIV disease and can help monitor your health for any changes. This person can assist you getting to the clinic or hospital and help you take your medicines correctly every day, especially if you are having trouble remembering. Do you have someone who can support you? How can we contact this person?* (review FTIC SOP 1 adherence step 3)
- If a support person cannot be identified, plan for a counsellor or a CHW to provide follow-up calls or home visits to check-in.

10. Identifying barriers

- *We understand, taking ARVs can be challenging, we're here to support you. Please share any difficulties you face in collecting or taking your ARVs so we can help.*
- *Let's talk about any specific challenges you are having and work together to find solutions.*
- Discuss according to patient's specific situation:

  If starting ARVs for the first time:
  - Since you are starting ARVs, we will create an adherence plan together. Taking several different treatments can make it more challenging to adhere, We'll address specific steps in your adherence plan related to increased pill burden, dealing with side effects and the number of clinic appointments. Use FTIC session - SOP 1 and Adherence Plan.

  If missed appointments:
  - It seems you've struggled with collecting or taking your ARVs. We'd like to understand why so we can support you better. Let's review your adherence plan to identify any steps that may be difficult for you and finds way to assist.
  - Focus on the steps identified as problematic and review adherence steps - increased pill burden, dealing with side effects, attending clinic appointments, non-disclosure to people in the household, depression/anxiety/substance use.
  - Use Adherence Plan and the re-engagement approach set out in SOP 8.

If ongoing/new symptoms +/- unsuppressed VL +/- no CD4 count improvement:

- You have been collecting your ARVs, but you are not getting better. We need to work out why your HIV has advanced instead of improving. It is likely you may not have been taking your medication correctly. Can you share what makes it difficult for you to take your medication? Have you received additional adherence counselling after you started ARVs? If not, let's do this together. If you have, we can check and update the information on it.
- Use EAC session - SOP 2 and Adherence Plan.

- Ask open-ended questions, provide support to find solutions and adapt the Adherence Plan accordingly:
  - How do you feel about having to take more pills? When will you take the additional pills and how will you remember? (Review adherence step 6-8)
  - What will you do if you experience side effects? (Review adherence step 10)
  - How will you manage attending your clinic appointments. Do you anticipate needing to travel away from here in the next few months? (Review adherence step 4 and 12)

If patient is using alcohol or substances:

- How will you remember to take your treatments when you are using alcohol or other substances?
- It's important not to tell someone they must stop drinking or using substances, as this could make them feel like they have to choose between their treatment and substance use due to possible negative interactions, leading to stopping treatment out of fear. Instead, work with a patient to find a time that works best for taking their medication, or identify someone who can help support them in taking their treatment(s), even if they use alcohol or other substances. (Review adherence step 13)
- What will you do if you are feeling unwell, stressed or struggling with low mood? Remind of adherence goals and possibility to be referred for mental health support if needed.

11. Inform and plan follow-up appointment schedule

- *We'll need to see you more often for the first 3 months to:* [insert: review test results/perform further test/manage any infections], *continue to check your health and ensure you are getting stronger.*
- *Once you are stronger, it'll get easier with fewer clinic appointments and longer ARV refills. Let's agree on a schedule that works for you.*
- Clinician to consider recent hospital admission, TB result return, any opportunistic infection requiring more frequent follow-up, mental health or lack of social support vulnerability, or treatment literacy concerns to recommend return every second week for the first month, then monthly; or alternatively, monthly for the first 3 months. (For further detail see Table 21: Factors to consider when determining an appointment schedule for clients with AHD in the AHD guidelines)
- *We propose that we set up these follow-up appointments* [insert frequency over the next 3 months]
- *How will attending this number of clinic appointments affect you? How will you manage additional transports costs, time to attend or missing days from work?*
- *If these number of appointments will be difficult for you, we can consider replacing some of these appointments with phone call or WhatsApp check-ins, or home visits. We can also check-in with your identified support person. Let us know how we can reduce the burden for you while managing your health?*
- Adjust proposed schedule as necessary – remember that if it is not feasible, the patient may interrupt treatment with worse outcomes.
- If missing days of work is a problem: explore sick leave availability, check if a sick note will assist.
- Confirm and record in the folder and for the patient the next 3 appointment dates.

12. Explain importance of tracing and recall – obtain consent and valid contact details

- Consent for communicating test results and recall to the facility: *We may need to reach you to inform you of your test results, it is important for us to be able to reach you or someone who supports you in taking your treatment. We will always respect your confidentiality and choice regarding the way you prefer to be contacted: phone call or SMS or WhatsApp message. When calling, we will not disclose your HIV status, and we won't share any other test results without confirming we are speaking to you or your selected support person. In messages, we will never mention your HIV status. We will ask you to return to the clinic for your test results.*
  - Do you consent to us contacting you with your test results?
  - How would you prefer to be contacted: phone call/SMS/WhatsApp?
  - If we cannot reach you, can we contact your support person (without disclosing any result)?
- Record in folder consents given
- Consent for health check-ins and recall to the facility if miss appointment: *If you miss your appointment, we will be worried about you and want to check that you are okay.*
  - Do you consent to us contacting you to check that you are okay?
  - How would you prefer to be contacted: Phone call/SMS/WhatsApp?
  - If we cannot reach you, can we contact your support person to check if you are okay?
  - If we cannot reach you or your support person, can we come to your home to check you are okay and support you back to the clinic? The community health worker won't mention the reason for visiting to anyone else and will come back another time if you are not at home. (Further tracing and recall information: SOP 7).
- Record in folder consents given
- Verify contact details: *Please provide your:*
  - Phone or WhatsApp number
  - Phone or WhatsApp number for your support person
  - Your home address (if consent given)
- Please make sure you let us know if your phone number changes or if you are not reachable on this number anymore
- *If you need to move to another clinic, please visit us first so we can give you a letter to help make the transfer smoother. If you switch clinics without telling us, we might worry about you, and the new clinic may not know your treatment plan. If planning ahead isn't possible, let the new clinic know you were with us and ask them to contact us for your information. It's helpful to keep a note or photo of your medications in case you move unexpectedly. Any clinic must provide you with medication, even without a letter, but having one will make the process easier.*
- Give the clinic phone number to the patient (save on their phone or write on a card).

- *If you ever realise that you will not be able to come on your appointment date, try to come to the clinic before that date to ensure that you don't run out of medication.*

13. Additional Support (adapt to support services available)

- *Would you like a WhatsApp number to contact a clinician for urgent advice?*
- *Would you or your family like to join a support group at our facility or virtually on WhasApp with others going through the same experience and an AHD trained clinician to answer questions?*
- *Offer any other support available (for example a designated case manager if there is such a person at your facility).*

ADAPTATIONS

This AHD education and counselling SOP can be adapted depending on the condition(s) affecting the patient, the treatments or prophylaxis prescribed and according to whether a patient is initiating, re-initiating or continuing ART.

Add for pregnant and breastfeeding women with AHD:

- Add danger sign for return to clinic: *any coughing, repeated vomiting, failure to gain weight*
- Explain that having additional infections whilst pregnant makes the pregnancy high risk so more frequent follow-up will be necessary.
- Ensure Adherence Plan includes managing own medication and prophylaxis for infant
- Actively support continuity of care when patient has to move to different facilities (or departments within facilities) for antenatal care, delivery and post-natal care.
- Prioritise integrated mother-infant pair care (refer to: Visit schedule for Integrated Care for the mother living with HIV and her HIV exposed infant in Guideline for Family-centred Vertical Transmission Prevention of Communicable Infection Guidelines – page 31)
- Where available, enrol in post-natal club for ongoing support during breastfeeding

Add for children:

- If the child is less than 5 years old, provide the session with the caregiver only.
- If the child is over 5 years old, start or continue the child disclosure process using SOP 3 and adapt information on AHD to be provided to the caregiver and the child according to the disclosure status.
- Explain AHD diagnosis:

  For children under 5 years:
  - Your child's is still very young. The CD4 cells, which are like soldiers in their immune system, are being attacked and killed by HIV in their body. This makes it easier for your child to get sick from infections like TB, meningitis (which is a serious infection in the brain), pneumonia (which is a serious infection in the lung), stomach infections, skin rashes, ear infections and viruses, such as flu or COVID. We need to provide extra clinical care and support until their immune system is stronger and can fight off these infections.

  For children over 5 years:
  - Use the same explanation as above.

- Educate on IMCI danger signs: If you notice any of these danger signs, you should bring the child to the clinic immediately:
  - Difficulty drinking, eating, or breastfeeding;
  - Vomiting everything;
  - Convulsions, unconsciousness, or extreme drowsiness;
  - Signs of shock (cold skin, less urine, breathing problems, weakness);
  - Trouble breathing, chest pulling in when breathing, or a whistling sound when breathing; or blue/grey colour around lips, tongue, gums, or fingernails;
  - Swollen feet, poor weight gain or growth;
  - Stiff neck, soft spot on the head that is bulging or sticking out, or constant irritability;
  - Pale palms, swollen tongue, unusual cravings (like dirt), or an enlarged belly (left side).
- Provide education on what constitutes a balanced diet. Provide or refer for nutritional assessment and support.
- Educate on any additional tests to be performed.
- Identify specific barriers to adherence to create or adapt Adherence Plan.

MENTAL HEALTH ASSESSMENT AND SUPPORT

Patients should be assessed for mental health and supported using the Mental Health Assessment tool in Annexure 7 either by a clinician or a delegated trained counsellor with referral back to the clinician for clinical management and any necessary referrals.

TRACING RECALL AND RE-ENGAGEMENT

If patients diagnosed with AHD do not arrive at facility for a scheduled appointment, prioritize for immediate tracing and recall:

- Check consents obtained in the patient folder
- Depending on consents provided:
  - Contact patient/patient's support person by phone, WhatsApp or SMS to check on their current health, any assistance needed and encourage to return to the facility immediately.
  - If unsuccessful, the facility is expected to start patient tracing using WBPHCOT, CHWs, HBCs or other suitable means.
- Where patients diagnosed with AHD return to the facility of their own accord or after tracing within 28 days of their missed scheduled appointment, the patient will be managed as a routine patient but must be seen by a clinician. If more than 28 days late, refer to Re-engagement SOP 8.
- For further details on tracing refer to Tracing and Recall SOP 7.

FACILITY PROVIDED MULTI-MONTH DISPENSING (FACILITY MMD)

SOP 4

TITLE: STANDARD OPERATING PROCEDURE: FACILTY PROVIDED MULTI-MONTH DISPENSING (FACILITY MMD)

INSTITUTION: NATIONAL DEPARTMENT OF HEALTH

REFERENCE NUMBER: FACILITY MMD | **EFFECTIVE DATE: AUGUST 2025**

PURPOSE

The purpose of this document is to outline access to and the process for facility provided multi-month dispensing (Facility MMD) of various treatment supply lengths for utilization by clinicians between patient clinical reviews (for MMD within RPCs care – see SOP 5):

2-month treatment supply = 2MMD
3-month treatment supply = 3MMD — SOP 4.1: 3MMD (exceptionally 2MMD)
6-month treatment supply = 6MMD — SOP 4.2: 6MMD

PERSONS AFFECTED

- Patient living with HIV and/or a NCD and/or on TB treatment
- Healthcare worker
- Pharmacist or pharmacy assistant
- Non-clinicians (could include lay counsellors, CHWs, HBCs, nursing assistants or equivalent)

APPLICABLE POLICY REFERENCE

For HIV: 2025 National consolidated guidelines for the management of HIV in adults, adolescents, children and infants and prevention of vertical transmission
For NCDs: 2023 Adult Primary Care Guide
For TB: 2023 National guidelines for the management of TB infection;
2017 Community TB Care SOPs

FACILITY MMD CRITERIA

- See Facility 3MMD (or 2MMD) criteria in SOP 4.1 and Facility 6MMD criteria in SOP 4.2

GUIDING PRINCIPLES FOR ALL FACILITY MMD

- Requiring monthly clinical consultations can be very costly for patients and can lead to disengagement from care.
- Clinicians should consider appropriate longer scripting (multi-month scripting (MMS)) and treatment supply (multi-month dispensing (MMD)) to offer a patient to support continued engagement in care and associated treatment adherence between necessary clinical reviews.
- MMS and MMD is not only for clinically stable patients or patients enrolled in RPCs (see SOP 5) and should be considered for all patients for whom monthly clinical consultations are not indicated. The clinician should determine an appropriate balance between clinical safety and supporting patient's continued engagement in care and adherence to treatment by reducing clinical review frequency. See DMOC diagram on page 10.
- When a clinician provides Facility MMD outside of RPCs, a return date for the next clinical consultation, the prescription length (MMS) and treatment supply (MMD) must be for the same period. For example, where the clinician gives a return date for a clinical consultation in 3 months time, the prescription period should cover the 3-month period (3MMS) with a 3-month supply of medicine dispensed (3MMD). There should be no repeat medicine collections.
- When a clinician provides Facility MMD outside of RPCs, a return date for the next clinical consultation, the prescription length (MMS) and treatment supply (MMD) must be for the same period. For example, where the clinician gives a return date for a clinical consultation in 3 months time, the prescription period should cover the 3-month period (3MMS) with a 3-month supply of medicine dispensed (3MMD). There should be no repeat medicine collections.

- All patients who opt for a longer treatment supply should be encouraged to come to the facility to see a clinician at any other time should they feel unwell or experience any challenges which require support.
- All processes must be documented.

ROLE AND RESPONSIBILITIES FOR FACILITY MMD

Clinician's role:

a. Consider:
   I. Whether it is clinically safe to only clinically review the patient in 2 or 3 or 6 months time including alignment of investigations or treatment completion visits mandated in clinical guidelines
   2. Whether a patient may benefit from MMD to support treatment adherence

b. Assess eligibility and offer MMD with appropriate patient information.

c. Write a prescription covering the time period until the client's next clinical review with the same treatment supply.

Facility pharmacy/clinicians role: Dispense treatment supply for the entire period of the prescription for one collection only.

TRACING, RECALL AND RE-ENGAGEMENT FOR PATIENTS ON FACILITY MMD

If chronic care patients do not arrive at facility within 7 calendar days from scheduled appointment:

- Contact patients through reminder call or sms to return to the facility for scheduled appointment.
- If unsuccessful, facility initiates patient tracing using WBPHCOT, CHWs, HBCs or other suitable means.

Management of patients who miss a scheduled appointment:

- If the patient returns within 28 days (on their own or after tracing)
  - Manage as a routine patient in the same DMOC.
  - If not already in a less-intensive DMOC, assess eligibility and consider enrolment.
- If the patient is more than 28 days late: Follow the Re-engagement SOP 8.

For further details on tracing refer Tracing and Recall SOP 7.

FACILITY PROVIDED MULTI-MONTH DISPENSING (FACILITY MMD)

SOP 4.1

TITLE: STANDARD OPERATING PROCEDURE: FACILTY PROVIDED MULTI-MONTH DISPENSING (FACILITY MMD)

INSTITUTION: NATIONAL DEPARTMENT OF HEALTH

REFERENCE NUMBER: FACILITY 3MMD | **EFFECTIVE DATE:** AUGUST 2025

PURPOSE

The purpose of this document is to outline access to and the process for facility provided 3-month supply of treatment (3MMD) and exceptionally 2-month supply of treatment (2MMD) for utilization by clinicians between 3-monthly (or 2-monthly) clinical reviews.

PERSONS AFFECTED

- Above 6 months old
- On treatment for at least 3 months
- Patient (or patient caregiver) wants longer treatment supply to support continued engagement in care
- Clinician confirms patient is sufficiently clinically stable not to require clinical follow-up more regularly than in 3 months time.

WHO WOULD BENEFIT FROM FACILITY PROVIDED 3MMD

- Facility 3MMD should be considered to reduce the burden of returning to the facility unnecessarily frequently for all patients who are not acutely unwell requiring more frequent clinical reviews for intensive management.
- It is also appropriate for all patients who are not eligible or do not take up the offer of a RPCs or facility 6MMD (see SOP 4.2) and includes:
  - children 6 months–5 years old on ART
  - after receiving an abnormal assessment result and an enhanced adherence counselling session (if indicated by clinician) to align with their next assessment date (for HIV: VL)
  - re-engaging in care (see SOP 8)
  - travelling
  - post-natal women to align with their next infant EPI visit
  - to facilitate alignment with a guideline mandated clinical review or follow-up assessment (test) or assessment result review date in 3 months time.

CRITERIA FOR FACILITY PROVIDED 2MMD

- Above 6 months old
- On treatment for at least 1 month (TB treatment for at least 2 months)
- Patient (or patient caregiver) wants longer treatment supply to support continued engagement in care.
- Clinician confirms patient is sufficiently clinically stable not to require clinical follow-up more regularly than in 2 months time.
- Not eligible for RPCs

WHO WOULD BENEFIT FROM FACILITY PROVIDED 2MMD

- 2MMD should be considered to reduce the burden to the patient of returning to the facility unnecessarily frequently **in the first few months of treatment.** Thereafter 3MMD is more appropriate.
- It will most commonly be appropriate for a patient:
  - one month after treatment start (at month 1 visit) to supply sufficient treatment to return for the assessment visit (e.g. VL or HBA1c at month 3).
  - completing continuation phase DS-TB treatment
  - at delivery to support adherence while transferring to MCH follow-up services and first infant EPI visit
  - to facilitate alignment with a guideline mandated clinical review or follow-up assessment (test) or assessment result review date in 2 months time.

OVERVIEW OF PROCEDURE FOR 3MMD (AND EXCEPTIONALLY 2MMD)

	Combined clinical consultation + treatment supply
WHEN (service frequency)	3-monthly (or 2MMD)
WHERE (service location)	Health facility
WHO (service provider)	Clinician (dispensed by clinician or facility pharmacy)
WHAT (service package)	Clinical review Adherence check Prescription 3MMS (or 2MMS) Treatment supply 3MMD (or 2MMD)

See Annexure V for Facility 3MMD visit schedule

INFORMATION TO BE PROVIDED TO THE PATIENT

- Where a clinician considers that longer treatment supply may be beneficial to the patient, the clinician should explain:
  - the patient can choose to receive a longer treatment supply to enable less frequent visits to the facility.
  - the patient would need to come back to the facility to see the clinician at their next appointment date. Facility provided MMD (outside of RPCs) does not enable a fast track/one-stop visit only to collect treatment (see RPCs: FAC-PUP).
- If the patient accepts the MMD offer, the clinician should explain:
  - The length of treatment supply provided
  - If this length of treatment supply will continue or may change at the next visit and the reasons for any possible change (for example: if an assessment will be done at the next visit which will require a clinical review of the result the following month). This is important to ensure the patient understands any possible changes to the length of treatment supply ahead.
  - Explain to the patient when the next treatment assessment will take place and that if the result is normal, the patient will be offered simpler treatment collection options at the facility or outside the facility either individually or as part of a support group or longer supply from the facility.
  - Advise the patient that in the case of any health problems or should the patient become pregnant, to come in immediately to see a clinician NOT to wait until the next scheduled appointment date.
- The clinician should clearly prescribe the length of treatment supply (MMD).
- The clinician should prescribe all the patient's other medication for the same length of supply, including but not limited to other chronic, opportunistic infection related or preventative medication (e.g. contraception, TPT, cotrimoxazole) unless scheduling or cold chain prohibits.
- Write the date of the follow-up visit in patient's diary or appointment card.

FACILITY PROVIDED MULTI-MONTH DISPENSING (FACILITY MMD)

SOP 4.2

TITLE: STANDARD OPERATING PROCEDURE: FACILTY PROVIDED MULTI-MONTH DISPENSING (FACILITY MMD)

INSTITUTION: NATIONAL DEPARTMENT OF HEALTH

REFERENCE NUMBER: FACILITY 6MMD | **EFFECTIVE DATE:** AUGUST 2025

PURPOSE

The purpose of this document is to outline access to and the process for facility provided 6-month supply of treatment (6MMD) for very stable patients for utilization by clinicians between 6-monthly clinical reviews.

CRITERIA FOR FACILITY PROVIDED 6MMD

Summary: Same as RPCs (SOP 5) with an additional requirements of 12 months on treatment and two consecutive normal assessments

- Above 5 years of age
- Not pregnant or post-natal within 12 months of delivery
- On treatment* for at least 12 months
- Most recent two assessment results normal:
  - For HIV: Most recent two viral loads, including one in the last 12 months <50 c/mL
  - For Diabetes*: Most recent two HbA1c, including one in the last 12 months ≤8%
  - For Hypertension*: Two consecutive BP <140/90
- Clinically stable with no current TB, other opportunistic infection, malnutrition, new or uncontrolled mental health or chronic condition requiring clinical review more regularly than once every 6 months
- Clinician confirms the patient's eligibility
- Patient voluntarily opts for Facility 6MMD

Children specific additional criteria:

- No regimen or dosage change in the last 3 months
- Caregivers counselled on disclosure process where age appropriate disclosure not yet achieved (see SOP 3).
- Where patient <12 years, caregiver voluntarily opts for Facility 6MMD

Stable family members should be encouraged to join the same DMOC with aligned collection location and date to support adherence. If a caregiver is eligible, Facility 6MMD can still be offered even if the child remains ineligible and on 3MMD, with aligned visits but the caregiver requiring care only every second visit.

*** Limited to ART TLD regimen only until national medicine stock availability is confirmed for other ART regimens and hypertension and diabetic treatment.**

Note for pregnant and post-natal women:

- Pregnant women should receive their ART care aligned and integrated into their BANC plus visits.
- New mothers should continue their ART care aligned with their infant EPI visit schedule (2MMD at birth and 3MMD from 6 week EPI visit) and preferably fully integrated into MNCWH services. At the Month 12 EPI visit, mothers may be assessed, offered and enrolled into RPCs of their choice or Facility 6MMD based on her previous VLs (see integration tables in 2025 VTP guidelines) provided she is seen at her facility every 6 months for her 6-monthly VL until cessation of breastfeeding.

GUIDING PRINCIPLES SPECIFIC TO FACILITY 6MMD (in addition to those on page 49)

- Facility 6MMD is intended for very stable clients only.
- Patient choice of DMOC is key.
  - Where a patient is eligible for RPCs, RPCs options must always also be offered.
  - Where a patient wants to see a clinician more regularly than 6-monthly, they can decide not to take up the offer of RPCs or Facility 6MMD and rather opt for standard service delivery with 3-monthly clinical reviews, 3-month scripts and 3MMD. See DMOC summary table on page 10.

- Facility 6MMD can be considered for clients enrolled in RPCs option who would prefer Facility 6MMD to avoid repeat collections from external or facility pick-up points or adherence club locations (see SOP 5).
- Where treatment prescribed is available in 84-90 day pack sizes, these should be dispensed as preferable for patients and less workload for clinician or clinic pharmacy to dispense.
- Clinicians must record enrolment/disenrolment in Facility 6MMD on clinical stationery, with clerks capturing in TIER.Net. Patients cannot be in Facility 6MMD and an RPCs simultaneously; if opting for Facility 6MMD, they must be disenrolled from RPCs.
- Women with contraceptive needs:
  - Re-explain contraceptive method options, with emphasis on how each impacts return visit frequency.
  - LARC: removes concerns about increased visit frequency or alignment.
  - Oral contraception and new self-injectable**: prescribe for 6 months and dispense full 6-month supply.
  - IM injectable (clinician-administered): explain that 2-4 additional facility visits per year will be required for injections. RPC options (see SOP 5): FAC-PUP or facility adherence club may be preferable.

** Available 1 October 2026 in all facilities - for more information see www.depo2go.co.za

OVERVIEW OF ANNUAL FACILITY 6MMD PROCEDURE

	Combined clinical consultation + treatment supply
WHEN (service frequency)	6-monthly (M6 & M12)
WHERE (service location)	Health facility
WHO (service provider)	Clinician (dispensed by clinician or facility pharmacy)
WHAT (service package)	*Record in clinical stationery* **M6 – Comprehensive clinical consultation visit** Integrated chronic care clinical review (incl. FP review) Routine investigations/exams according to guidelines (for HIV: VL) 6-month treatment script (6MMS) + 6-month treatment supply (6MMD) Add - For children: Dosage check and possible adjustment Disclosure process review and check-in with caregiver Add - For adolescents: Mental health assessment **M12 –Rescripting visit** Brief integrated chronic care clinical check-up 6-month treatment script (6MMS) + 6-month treatment supply (6MMD) Add - For children: Dosage check and possible adjustment For breastfeeding mothers: VL

See Annexure V for Facility 6MMD visit schedule

INFORMATION TO BE PROVIDED TO THE PATIENT

If patient meets criteria for Facility 6MMD, and chooses the Facility 6MMD over RPCs, the patient shall be informed about 6MMD as follows:

- Facility 6MMD requires patients to see a clinician twice a year, once every 6 months. One comprehensive clinical consultation including routine investigations. One rescripting visit for a brief clinical check-up.
- At each visit, the patient will receive a 6-month prescription (6MMS) for their treatment.
- At each visit, the patient will be allowed to collect the full 6 months treatment supply.
- For women using contraception: If the women is using long-acting reversible contraception (LARC), there are no alignment concerns. If the women is using oral contraception or the new self-injectable**, her contraception will be included on the prescription and the full 6-month supply dispensed with treatment. Where a woman chooses to continue clinician administered short-acting intra-muscular (IM) injectable contraception, she will need attend the facility for 2-4 additional visits per year for her injections.
- Advise that medication should be stored in a cool, dry, safe place, away from sunlight and children. Pills should not be transferred out of the original containers into other containers. A few pills can be transferred into a weekly pill box or other small container for the day or week. The small packet inside the original pill container, called the desiccant, should be kept in the container as it absorbs unwanted moisture, keeping the pills dry. The pill bottles lids should be tightly closed after taking out medication.
- It is important for the patient to attend their two clinical consultations on the scheduled appointment dates.

- Patients should be reminded to take treatment every day to remain well and continue to qualify for Facility 6MMD. Patients will return to standard or more intensive DMOC and no longer qualify for Facility 6MMD if the patient requires more frequent clinical care or is more than 28 calendar days late for scheduled collection date.
- Advise the patient that in the case of any health problems or should the patient become pregnant, to come in immediately to see a clinician NOT to wait until the next scheduled appointment date
- A patient collection card with relevant scheduled return dates to the facility shall be issued to patient.

** Available 1 October 2026 in all facilities - for more information see www.depo2go.co.za

ANNUAL VISIT SCHEDULE: FACILITY 6MMD

6 MONTH* TREATMENT (TX) SUPPLY

MONTHS* IN 6MMD	LOCATION 6MMD VISIT	ACTIVITIES	SCRIPT TX SUPPLY NO.	
6MMD M0	Facility – Clinician	Registration and Enrolment visit Facility 6MMD eligibility assessment + offer Facility 6MMD/RPCs options + record Facility 6MMD enrolment in clinical stationery + 6MMS + 6MMD pick-up	1	
6MMD M6	Facility – Clinician	Comprehensive clinical consultation visit Integrated chronic care clinical review (including FP review) + investigations + less intensive DMOC chosen still suitable + 6MMS[a] + record in clinical stationery + 6MMD pick-up	1	2 visits per annum Max 1 visit per 6-month script
6MMD M12	Facility – Clinician	Rescripting visit Brief integrated clinical care check-up + 6MMS + record in clinical stationery + 6MMD pick-up	1	

Cycle repeats from M6

* A month refers to a dispensing cycle (whether 28 or 30 days in length)

a. After Facility 6MMD enrolment, patients should be rescripted at their 6-monthly clinical review dates. Patient should not be required to return for result review prior to rescripting. A small number of Facility 6MMD enrolled patients would receive an abnormal result and need to be recalled to the facility.

See Annexure V for Facility 6MMD annual schedule diagram

CRITERIA FOR RETURN TO STANDARD OR MORE INTENSIVE DMOC

- Patient did not return to the facility within 28 calendar days of their scheduled appointment date.
- Patient is assessed as clinically unstable requiring more frequent clinical management, including diagnosed with TB, other opportunistic infection, malnutrition, new or uncontrolled mental health or chronic condition.
- Other safety lab test results are abnormal:
  - For HIV: VL >1000 (where VL is 50-999 c/mL, the patient must be recalled to the facility to see a clinician for A-E assessment (see ART guidelines), enhanced adherence counselling if indicated (SOP 2) and a follow-up VL 3 months later. A repeat 6MMS/6MMD prescription will only be provided once the second VL result is <50 c/mL. Low level viraemia must be managed).
  - For Diabetes*: HbA1c >8%
  - For Hypertension*: BP >140/90
- Facility 6MMD patient becomes pregnant and is referred to integrated MNCWH services.
- Clinicians determines that the patient is returning to the facility requiring a re-issue of treatment due to lost/stolen treatment supply repeatedly.

All patients returned to standard or more intensive DMOC to ensure more frequent clinical care until they are stable again must be informed to ensure understanding. This is not punitive but supportive. Patients can return to an RPCs option after a single normal assessment result or Facility 6MMD after two consecutive normal assessment results and meeting other RPCs/Facility 6MMD criteria (also see Re-engagement SOP 8).

Annexures:

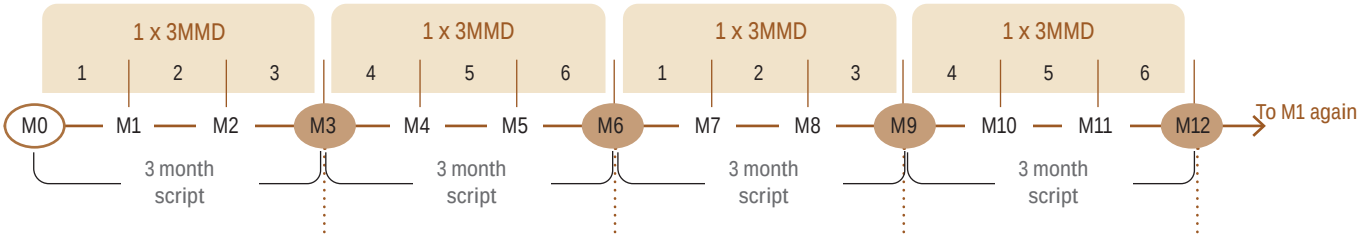
V. Facility MMD eligibility & visit schedules

ANNEXURE V:
FACILITY-BASED MULTI-MONTH DISPENSING SCHEDULES

Facility provided 3MMD

FACILITY PROVIDED 3MMD ELIGIBILITY CRITERIA:

- Not acutely unwell
- On ART for 3 months or more
- Not eligible for RPCs/Facility 6MMD or declines RPCs/Facility 6MMD
- Enables alignment with clinical review dates including: 6 months – 5 years old; re-engaging; abnormal assessment (e.g. elevated VL) after EAC; travelling; post-natal to align with EPI schedule



3MMD Visit 1

Clinical review
Assess for RPCs/6MMD eligibility.
If not eligible or refuse: new script + treatment supply for the full 3-month period from facility

3MMD Visit 2

Clinical review
Assess for RPCs/6MMD eligibility.
If not eligible or refuse: new script + treatment supply for the full 3-month period from facility

3MMD Visit 3

Clinical review
Assess for RPCs/6MMD eligibility.
If not eligible or refuse: new script + treatment supply for the full 3-month period from facility

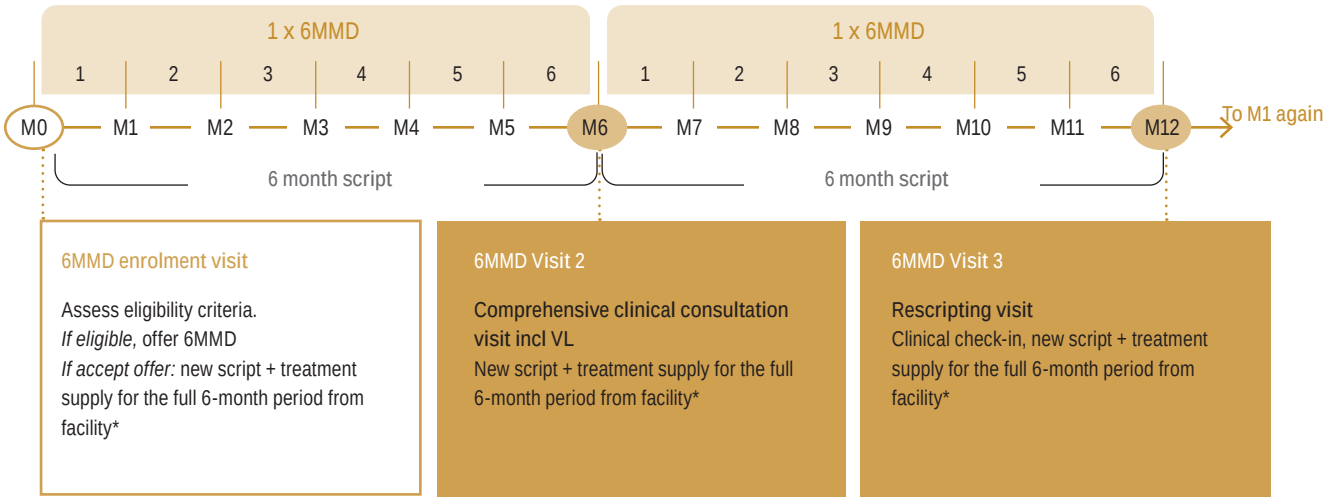
Facility provided 6MMD

FACILITY PROVIDED 6MMD ELIGIBILITY CRITERIA:

- On ART TLD only* for 12 months
- Most recent two VLs <50 c/mL
- Meet **all** other eligibility criteria for RPCs (see SOP 5), including above 5 years old, not pregnant or post-natal within 12 months of delivery and clinically stable with no current TB, other opportunistic infection, malnutrition, new or uncontrolled mental health or chronic condition requiring clinical review more regularly than once every 6 months.
- Clinician confirms eligibility and client voluntarily opts for Facility 6MMD

Children and adolescents additional:

- No regimen/dosage change in last 3 months
- Caregivers counselled on disclosure process



6MMD enrolment visit

Assess eligibility criteria.
If eligible, offer 6MMD
If accept offer: new script + treatment supply for the full 6-month period from facility*

6MMD Visit 2

Comprehensive clinical consultation visit incl VL
New script + treatment supply for the full 6-month period from facility*

6MMD Visit 3

Rescripting visit
Clinical check-in, new script + treatment supply for the full 6-month period from facility*

Consider supplying 84-90 day pack sizes to reduce the number of containers for the client to take home and for dispensing by the clinician/clinic pharmacy.

* Limited to TLD regimen only until national medicine stock availability is confirmed for other ART regimens and hypertension and diabetic treatment.

ANNEXURE 14

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 on page 207*)
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

KZN Paediatric Hotline: 0800 006 603

ANNEXURE 15

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 SAHPRA

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? ☐ Y ☐ N
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
☐ 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)?
☐ Other Intervention (e.g. dialysis): _____	☐ Y ☐ N ☐ Not done ☐ Unknown

Laboratory Results			Additional Laboratory Results		
Lab Test	Test Results	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 33.0 June 2016	

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

Third-line application form

APPLICATION - THIRD LINE ANTIRETROVIRAL THERAPY						
please ensure all fields are completed before submitting						
Patient First Name						
Patient Surname						
Date of Birth day/month/year		*Patient Number*				
Identity number		Age		*Gender*		
Weight		BMI (kg/m^2)		*Height (Child)*		
FACILITY DETAILS						
Facility Name						
Province						
Doctor in Charge Of Patient/Authorised Prescriber						
Doctor's Contact Number						
Doctor and Pharmacist Email Addresses						
		DATE *day/month/year*				

PAST MEDICATION HISTORY				
Timelines *day/month/year*		Past Regimens Only	Reason for discontinuation	Concurrent TB Treatment
Date started				
Date stopped				
Date started				
Date stopped				
Date started				
Date stopped				
Date started				
Date stopped				
Reason for discontinuation codes? SE = Side effect, F = Failure, FC = Formulary change, NC = Non adherent				

CURRENT REGIMEN ONLY			
Date Started *day/month/year*		**Regimen**	

CHILDREN PMTC HISTORY	
Was the mother on therapy during pregnancy or breastfeeding?	
What treatment did the mother take and for how long?	
Was child breastfed?	
Did child receive any ARV at birth/ after birth/ during breastfeeding? State ARV and dura-tion	

WHO Clinical Staging of HIV/Aids for Children, Adolescents and Adults

CLINICAL STAGE	CLINICAL CONDITIONS OR SYMPTOMS (Adolescents and Adults)	CLINICAL CONDITIONS OR SYMPTOMS (Children)
Primary HIV infection	• Asymptomatic • Acute retroviral syndrome	
Clinical stage 1	• Asymptomatic • Persistent generalized lymphadenopathy	• Asymptomatic • Persistent generalized lymphadenopathy
Clinical stage 2	• Moderate unexplained weight loss (<10% of presumed or measured body weight) • Recurrent respiratory infections (sinusitis, tonsillitis, otitis media, and pharyngitis) • Herpes zoster • Angular cheilitis • Recurrent oral ulceration • Papular pruritic eruptions • Seborrheic dermatitis • Fungal nail infections	• Unexplained persistent weight loss • Hepatosplenomegaly • Papular pruritic eruptions • Extensive wart virus infection • Extensive molluscum contagiosum • Fungal nail infections • Recurrent oral ulcerations • Unexplained persistent parotid enlargement • Lineal gingival erythema • Herpes zoster • Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis or tonsillitis)
Clinical stage 3	• Unexplained severe weight loss (>10% of presumed or measured body weight) • Unexplained chronic diarrhoea for >1 month • Unexplained persistent fever for >1 month (>37.6°C, intermittent or constant) • Persistent oral candidiasis (thrush) • Oral hairy leukoplakia • Pulmonary tuberculosis (current) • Severe presumed bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia) • Acute necrotizing ulcerative stomatitis, gingivitis, or periodontitis • Unexplained anaemia • (haemoglobin<8 g/dL) • Neutropenia (neutrophils <500 cells/µL) • Chronic thrombocytopenia (platelets <50,000 cells/µL)	• Unexplained moderate malnutrition not adequately responding to standard therapy • Unexplained persistent diarrhoea (14 days or more) • Unexplained persistent fever (above 37.5°C intermittent or constant for longer than one month) • Persistent oral candidiasis (after first 6-8 weeks of life) • Oral hairy leukoplakia • Acute necrotizing ulcerative gingivitis or periodontitis • Lymph node tuberculosis • Pulmonary tuberculosis • Severe recurrent bacterial pneumonia • Symptomatic lymphoid interstitial pneumonitis • Chronic HIV-associated lung disease including bronchiectasis • Unexplained anaemia (<8 g/dL), neutropenia (< 0.5 × 109 per litre) • And/or chronic thrombocytopenia (<50 × 109 per litre)

CLINICAL STAGE	CLINICAL CONDITIONS OR SYMPTOMS (Adolescents and Adults)	CLINICAL CONDITIONS OR SYMPTOMS (Children)
Clinical stage 4	• HIV wasting syndrome, as defined by the CDC (see Table 1, above) • Pneumocystis pneumonia • Recurrent severe bacterial pneumonia • Chronic herpes simplex infection (orolabial, genital, or anorectal site for >1 month orvisceral herpes at any site) • Oesophageal candidiasis (or candidiasis of trachea, bronchi, or lungs) • Extra pulmonary tuberculosis • Kaposi sarcoma • Cytomegalovirus infection (retinitis or infection of other organs) • Central nervous system toxoplasmosis • HIV encephalopathy • Cryptococcosis, extra pulmonary (including meningitis) • Disseminated non-Tuberculosis mycobacteria infection • Progressive multifocal leukoencephalopathy • Candida of the trachea, bronchi, or lungs • Chronic cryptosporidiosis (with diarrhoea) • Chronic isosporiasis • Disseminated mycosis (e.g., histoplasmosis, coccidioidomycosis, penicilliosis) • Recurrent non-typhoidal Salmonella bacteraemia • Lymphoma (cerebral or B-cell non-Hodgkin) • Invasive cervical carcinoma • Atypical disseminated leishmaniasis • Symptomatic HIV-associated nephropathy • Symptomatic HIV-associated cardiomyopathy • Reactivation of American trypanosomiasis (meningoencephalitis or myocarditis)	• Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy • Pneumocystis pneumonia • Recurrent severe bacterial infections (such as empyema, pyomyositis, bone or joint infection or meningitis but excluding pneumonia) • Chronic herpes simplex infection (orolabial or cutaneous of more than one month's duration or visceral at any site) • Extra pulmonary tuberculosis • Kaposi sarcoma • Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) • Central nervous system toxoplasmosis (after one month of life) • HIV encephalopathy • Cytomegalovirus infection: retinitis or cytomegalovirus infection affecting another organ, with onset at age older than one month • Extra pulmonary cryptococcosis (including meningitis) • Disseminated endemic mycosis (extra pulmonary histoplasmosis, coccidiomycosis) • Chronic cryptosporidiosis • Chronic isosporiasis • Disseminated non-tuberculous mycobacterial infection • Cerebral or B-cell non-Hodgkin lymphoma • Progressive multifocal leukoencephalopathy • Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy • HIV-associated rectovaginal fistula

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World Health Organisation
Right to Care
International AIDS Society
ANOVA
Centres for Disease Control
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