health

Department:
Health
REPUBLIC OF SOUTH AFRICA

THE SOUTH AFRICAN ANTIRETROVIRAL TREATMENT GUIDELINES 2010

The South African Antiretroviral Treatment Guidelines 2010

Goals of the programme

- Achieve best health outcomes in the most cost-efficient manner
- Implement nurse-initiated treatment
- Decentralise service delivery to PHC facilities
- Integrate services for HIV, TB, MCH, SRH and wellness
- Diagnose HIV earlier
- Prevent HIV disease progression
- Avert AIDS-related deaths
- Retain patients on lifelong therapy
- Prevent new infections among children, adolescents, and adults
- Mitigate the impact of HIV & AIDS

Objectives

- To contribute to strengthening of the public and private health sectors' capacity to deliver high quality integrated health and wellness services
- To ensure timely initiation of ARVs for treatment and prevention according to the Presidential mandates
- To minimize unnecessary drug toxicities

Specific Objectives

- To prioritise ARVs for:
  - ✓ Patients with CD4 counts < 200cells/mm^3 or with severe HIV disease irrespective of CD4
  - ✓ Patients co-infected with TB/HIV
  - ✓ Pregnant women with CD4 $\leq$ 350cells/mm^3 for lifelong ART and CD4 >350cells/mm^3 for prophylaxis
- To test all HIV exposed children under one year and treat all those found to be infected with HIV
- To standardise first and second line therapy for children, adolescents, and adults in the public and private sector
- To reduce the use of stavudine
- To expand the use of fixed-dose and co-packaged formulations
- To enable nurses to initiate ARVs for treatment and prevention
- To enable PHC facilities to initiate, manage, monitor and refer patients

1. Standardised national eligibility criteria for starting ART regimens for Adults and Adolescents

Eligible to start ART
▪ CD4 count ≤200cells/mm3 irrespective of clinical stage **OR** ▪ CD4 count ≤350cells/mm3 ○ In patients with TB/HIV ○ Pregnant women **OR** ▪ WHO stage IV irrespective of CD4 count **OR** ▪ MDR/XDR irrespective of CD4
Require fast track (i.e. ART initiation within 2 weeks of being eligible
▪ Pregnant women eligible for lifelong ART **OR** ▪ Patients with very low CD4 (<100) **OR** ▪ Stage 4, CD4 count not yet available **OR** ▪ MDR/XDR TB
Not yet eligible for ART
▪ Transfer to a wellness programme for regular follow up and repeat CD4 testing 6-monthly. ▪ Advice on how to avoid HIV transmission to sexual partners and children ▪ Initiate INH prophylaxis if asymptomatic for TB ▪ Contraceptives and annual Pap smear

2. Standardised national ART regimens for adults and adolescents

1st Line		
All new patients needing treatment, including pregnant women	TDF + 3TC/FTC + EFV/NVP	For TB co-infection EFV is preferred. For women of child bearing age, not on reliable contraception, NVP is preferred.
Currently on d4T based regimen with no side-effects	d4T + 3TC + EFV	Remain on d4T if well tolerated. Early switch with any toxicity Substitute TDF if at high risk of toxicity (high BMI, low Hb, older female)
Contraindication to TDF: renal disease	AZT+ 3TC +EFV/NVP	
2nd line		
Failing on a d4T or AZT-based 1st line regimen	TDF + 3TC/FTC + LPV/r	
Failing on a TDF-based 1st line regimen	AZT+3TC+ LPV/r	
Salvage		
Failing any 2nd line regimen	Specialist referral	

3. Standardized National Monitoring for Adults and Adolescents with HIV

At initial Diagnosis of HIV	Purpose
Check HIV result	Ensure that national testing algorithm has been followed
Clinical staging if HIV positive	To assess eligibility for ART To assess eligibility for fast-tracking
Ask if pregnant or planning to conceive	To identify women who need ART or ARV for PMTCT (see section 6)
Screen for TB symptoms	To identify TB/HIV co-infected
Do the CD4 count	To identify eligibility for ART or ARVs if pregnant
Hb or FBC if available	To detect anaemia or neutropenia

At Routine Follow-Up Visits	Purpose
Check that CD4 has been done in the last 6 months	To see if they have become eligible for ART
WHO clinical staging	To see if they have become eligible for ART
Screen for TB symptoms	To identify TB/HIV co-infection

If Eligible for ART	Purpose
Serum Creatinine if starting on a TDF based regimen	Refer if estimated creatinine clearance is less than 50
ALT if starting on a NVP-based regimen	If ALT raised, do HepBSAg and avoid NVP
Hb or FBC if available if starting on an AZT-based regimen.	If less than 8g/dl refer to doctor

On ART	Purpose
Clinical stage	To monitor response to ART
CD4 at month 6, 1 year on ART and then every 12 months	To monitor response to ART
VL at month 6, 1 year on ART and then every 12 months	To monitor response to ART To identify problems with adherence
ALT if on NVP and develops rash or symptoms of hepatitis	To identify NVP toxicity
FBC at month 1, 2, 3 and 6 if on AZT	To identify AZT toxicity
Creatinine at month 3 and 6 then every 12 months if on TDF	To identify TDF toxicity
Fasting cholesterol and triglycerides at month 3 if on LPV/r	To identify LPV/r toxicity

Standardised national eligibility criteria for starting ART regimens for infants and children

Eligible to Start ART
▪ All children less than 1 year of age ▪ Children 1 – 5 years with clinical stage 3 or 4 or CD4 ≤ 25 % or absolute CD4 count < 750 cells/µl • Children ≥ 5 years to 15 years with clinical stage 3 or 4 or CD4 ≤ 350 cells/µl
Require Fast-Track (i.e. start ART within 2 weeks of being eligible)
▪ Children less than 1 year of age ▪ Stage 4 ▪ MDR or XDR-TB

4. Standardised national ART regimens for infants and children

1st Line		
All infants and children under 3 years	ABC + 3TC + LPV/r	
Children 3 years or over	ABC + 3TC + EFV	
Currently on d4T-based regimen with no side-effects	Can continue	Substitute – once lipodystrophy suspected
2nd line		
Children above 3 years Failed ABC +3TC + EFV	AZT + ddI +LPV/r	
Failed on AZT or ddI-based regimen	ABC + 3TC + LPV/r	
Failed on LPV-based regimen	Refer	Specialist advice necessary and/or hospital referral
Infants under 3 years failing 1st line	Refer	Specialist advice necessary and/or hospital referral
Salvage		
Failing any 2nd line	Specialist referral	

5. Standardized national monitoring for infants and children with HIV

At initial Diagnosis of HIV	Purpose
Check HIV result	Ensure that national testing algorithm including HIV DNA PCR and HIV viral load (RNA) for infants and children less than 18 months has been followed
Document weight and height	To monitor growth and development + identify eligibility for ART
Screen for TB symptoms	To identify TB/HIV co-infected
Do the CD4 count	To identify eligibility for ART or ARVs
Hb or FBC is available	To detect anaemia or neutropenia

At Routine Follow-Up Visits	Purpose
Document weight and height	To monitor growth and development and to see if they have become eligible for ART
Check that CD4 has been done in the last 6 months	To see if they have become eligible for ART
WHO clinical staging	To see if they have become eligible for ART
Screen for TB symptoms	To identify TB/HIV co-infection

If eligible for ART	Purpose
ALT if starting on a NVP-based regimen	If ALT raised, do HepBSAg and avoid NVP
Hb or FBC if available if starting on an AZT-based regimen	If less than 8g/dl refer

On ART	Purpose
Height + weight + development	To monitor response to ART
Clinical stage	To monitor response to ART
CD4 at month 6, 1 year into ART, and then every 12 months	To monitor response to ART
VL at month 6, 1 year into ART, then every 12 months	To monitor response to ART To identify problems with adherence
ALT if on NVP an develops rash or jaundice	to identify NVP toxicity
FBC at month 1, 2,and 3 if on AZT	To identify AZT toxicity

6. Standardised national ART and ARV regimens for women who are HIV positive and pregnant and their infants

Maternal Regimens		
Eligible for ART (i.e. CD4 ≤ 350 or clinical stage 3 or 4)	TDF + 3TC/FTC + NVP	Start lifelong ART within 2 weeks
Currently on ART	Continue ART	Substitute EFV with NVP if in first 12 weeks of pregnancy
Contraindication to TDF (renal disease)	AZT+ 3TC + NVP	
Not eligible for ART i.e. CD4 > 350	AZT from 14 weeks sdNVP + AZT 3hrly during labour TDF + FTC single dose (stat) after delivery	
Unbooked and presents in labour	sdNVP + AZT 3hrly during labour TDF + FTC single dose after delivery	Assess for ART eligibility before discharge

Infant Regimens		
Mother on lifelong ART	NVP at birth and then daily for 6 weeks irrespective of infant feeding choice	
Mother on AZT for MTCT prophylaxis	NVP at birth and then daily for 6 weeks continued as long as **any** breastfeeding	If formula fed baby can stop NVP at 6 weeks
Mother did not get any ARV before or during delivery	NVP as soon as possible and daily for at least 6 weeks continued as long as **any** breastfeeding	Assess for ART eligibility within 2 weeks
Unknown maternal status, orphaned or abandoned	HIV antibody test Give immediate NVP if baby is HIV antibody positive (i.e. HIV exposed)	Follow up 6 week HIV DNA PCR

Acronym glossary

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine Aminotransferase
ART	Antiretroviral Treatment
ARV	Antiretroviral
AZT	Zidovudine
CD4	Cluster of Differentiation 4
D4T	Stavudine
ddI	Didanosine
DNA PCR	DNA Polymerase Chain Reaction
EFV	Efavirenz
FBC	Full Blood Count
FTC	Emtricitabine
Hb	Haemoglobin
HepBSAg	Hepatitis B Surface Antigen
HIV	Human Immunodeficiency Virus
LPV/r	Lopinavir/ritonavir
MCH	Maternal-Child Health
MDR/XDR TB	Multi-Drug Resistant / Extensively Drug Resistant Tuberculosis
NVP	Nevirapine
PHC	Primary Health Care
SRH	Sexual and Reproductive Health
TB	Tuberculosis
TDF	Tenofovir
WHO	World Health Organization