VTP FOR HIV-POSITIVE MOTHERS 2023

July 2024, Version 3 (Updated January 2025)

MONITORING FOR ALL PATIENTS AT FIRST ANC VISIT

Routine clinical evaluation	Recognise the client with respiratory, neurological, or abdominal danger signs. Screen for meningitis, active depression, other mental health issues or substance abuse. Screen for chronic diseases and treat according to relevant guidelines. Determine WHO clinical stage. Routine antenatal care according to BANC Plus guide
CD4 *If newly diagnosed with HIV or a known HIV-positive client who missed an appointment for more than 90 days or a known HIV-client with a VL > 1000 or if a clinical indication arises*	If **CD4 < 100**, a reflex CrAg screening will be done automatically. If **CD4 is 100—199** a serum CrAg test must be ordered separately **If CrAg-positive**: refer for urgent LP and patient should be discussed with an expert. Fluconazole is teratogenic. Defer ART if ART-naïve depending on LP result, but don't stop ART if already on ART; **If CrAg-negative:** start or continue ART
TB clinical screen and TB-NAAT[$] (e.g. GXP) *To identify TB suspects*	Regardless of symptoms, do TB-NAAT on enrolment in antenatal care. **Symptomatic patients:** Do TB-NAAT. In addition do U-LAM if patient admitted to hospital, or in the outpatient setting if CD4 < 200 within the last 6 months, or patient has advanced HIV disease or current serious illness. Consider other investigations for extra-pulmonary TB if clinically indicated
Nutritional assessment *To detect deficiency and provide necessary nutritional support*	All pregnant women should receive calcium, folate and iron. **Be aware that DTG interacts with some medicines, including calcium and iron[##]** Women with BMI < 23: refer to dietician
Family planning	Provide counselling for safer sex, post-natal contraception and partner testing
STI and syphilis screening (rapid syphilis test—specific/treponemal[#]) *To identify and treat STIs*	Negative: syphilis testing should be repeated at scheduled antenatal visits, at approximately 4-weekly intervals, at labour/delivery, at time of diagnosis of intrauterine death or miscarriage, or at any time if clinically indicated. All positive rapid tests must be confirmed using a RPR test
Viral load, if on ART *To identify treatment failure and eligibility for switch to DTG-containing regimen*	See algorithm on centre spread **Be sure to check results and respond quickly!**
Hb or FBC *To detect anaemia and/or neutropaenia*	If Hb < 10 g/dL: treat with ferrous sulphate tds. Refer if Hb < 8 g/dL with symptoms of anaemia, or anaemic and ≥ 36 weeks pregnant, or no response to iron[##]
HBsAg[**] *(if unknown)* *To assess HBV status*	If HBsAg-positive: include TDF in regimen (if sCr < 85µmol/L) . Provide post-exposure hepatitis B prophylaxis for infant, as per relevant guidelines

[$] If the client has recently had TB, the TB-NAAT may give a false-positive. Please call an expert or the hotline to discuss; [##]See interaction checker on the hotline app—scan QR code;[#]Rapid syphilis tests remain positive for life, even if the infection has been treated. 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 RPR should be used; [**]If HBsAg negative and not immune, provide Hep B Vaccination, as per National Viral Hepatitis guidelines. Hep B vaccination is not contraindicated in pregnancy. If high-risk and status unknown at delivery, test.

MONITORING AT MONTHLY ANC VISITS: PATIENTS ON ART

Viral load *To confirm viral suppression or detect virological failure timeously*	Refer to VL monitoring on centre spread
CD4 count *To assess immunological status, risk of OIs and need for prophylaxis*	Repeat at month/DC 10 on ART. Thereafter, only repeat 6-monthly if CD4 < 200 or VL > 1000. Repeat CD4 if a clinical indication arises
TB symptom screening *To identify TB suspects*	Every clinic visit
FBC, if on AZT *To detect anaemia and/or neutropenia*	At initiation, month/DC 1, month/DC 3. Repeat if clinically indicated
sCr[ϖ], if on TDF *To assess renal function and eligibility for TDF*	At initiation, month/DC 3, month/DC 10 and then annually. **If sCr[ϖ] > 85 µmol/L:** do not use TDF. See front page

[ϖ] Please note: use serum creatinine and **not** eGFR during pregnancy

BREASTFEEDING

- Breastfeeding should be initiated within one hour of delivery
- Any mother that is mixed feeding in the first 6 months should be encouraged to return to exclusive breastfeeding
- Exclusive breastfeeding is strongly recommended for the first 6 months of life
- Mixed feeding is not a reason to stop breastfeeding
- Introduction of age-appropriate solids from 6 months onwards
- Continue breastfeeding until 2 years of age or older
- Ensure mother is on ART, adherent and VL is suppressed
- It is recommended that women with a VL ≥ 50 c/mL on TLD1 continue to breastfeed. Infant prophylaxis should be extended/restarted while a concerted effort is made to re-suppress the mother's VL
- Stopping breastfeeding should be done **slowly**, over a month
- Breastfeeding is not recommended in mothers who are failing TLD2 or third-line ART. Discuss with an expert

WHAT DOES EXCLUSIVE BREASTFEEDING MEAN?
For the first six months of life, the baby only gets mother's milk and medication. This means no water, formula, other foods or fluids

3TC = lamivudine; **ABC =** abacavir; **ANC** = antenatal clinic; **ART =** antiretroviral treatment; **ATV/**r = atazanavir/ritonavir; **AZT** = zidovudine; **BANC** = Basic Antenatal Care; **CPT** = cotrimoxazole preventive therapy; **CrAg** = cryptococcal antigen; **CXR =** chest Xray; **DC =** dispensing cycle, number of days for which a client would have treatment if a single standard "monthly" quantity of tablets was dispensed; **DTG =** dolutegravir; **EAC =** enhanced adherence counselling; **EFV =** efavirenz; **EGK** = electronic gate keeping; **FBC** = full blood count; **FTC** = emtricitabine; **GXP** = Gene Expert TB test; **Hb** = haemoglobin; **HBsAg** = Hepatitis B surface antigen; **HIV** = human immunodeficiency virus; **IRIS** = immune reconstitution syndrome; **LP** = lumbar puncture; **LPV/**r = lopinavir/ritonavir; **LTFU =** lost to follow up; **NVP =** nevirapine; **OI** = opportunistic infections; **RPR** = Rapid plasma reagin; **Rx =** treatment; **sCr** = serum creatinine; **STI =** sexually transmitted infections; **TB-NAAT** = tuberculosis nucleic acid amplification test; **TDF** = tenofovir; **TEE** = tenofovir + emtricitabine + efavirenz; **TLD** = tenofovir + lamivudine + dolutegravir; **TLD1 =** Clients on a DTG-containing regimen, who have never failed a previous regimen; **TLD2 =** Clients on a DTG-containing regimen, who have failed a previous regimen; **TST =** tuberculin skin testing; **VL** = viral load; **VTP** = vertical transmission prevention

RECOMMENDED REGIMENS

Keeping the mom's VL suppressed is the best way to protect her infant

UNBOOKED/PRESENTS IN LABOUR

Women not on ART, who test HIV-positive in labour	Stat dose of TLD + NVP. Start lifelong ART the next day	Check sCr[ϖ] and CD4. Review results at 3-6 day visit and adapt ART accordingly

[ϖ] Please note: use serum creatinine and **not** eGFR during pregnancy

ART FOR PREGNANT AND BREASTFEEDING WOMEN

Current regimen		Criteria for switching	Preferred regimen
New ART initiation (ART-naïve)		Not applicable	**TLD** (no renal dysfunction: sCr <85 µmol/L, ≥ 10 years of age and weight ≥ 30 kg) If client does not qualify for TDF: **ABC + 3TC + DTG** If client doesn't qualify for TDF and has ABC hypersensitivity: **AZT + 3TC + DTG**
Currently on TEE, or (AZT or ABC) + 3TC + (DTG or NVP or EFV)		Switch all to a DTG-containing regimen, regardless of VL. Do VL at booking/1st ANC visit. If VL at booking visit is not suppressed, continue to switch same day, but do ABCDE assessment and provide enhanced adherence counselling, if needed.	
Not currently on ART and previously on TEE			
Any LPV/r or ATV/r regimen for < 2 years			
Any LPV/r or ATV/r regimen for > 2 years	VL < 1000	Switch all to a DTG-containing regimen. If VL in last 12 months 50-999: switch, but do ABCDE assessment and provide EAC if needed. Repeat VL in 4-6 weeks as per VL non-suppression algorithm (NSA)	
	Two or more consecutive VLs ≥ 1000 taken ≥ 2 years after starting LPV/r or ATV/r regimen	Adherence < 80 %: switch but do ABCDE and provide EAC. Repeat VL in 4-6 weeks as per VL NSA	
		Adherence > 80 %	**These clients do not qualify for a same day switch.** Discuss with an HIV expert or the hotline (0800 212 506) to authorise and interpret a resistance test. Provide individualised regimen as recommended by HIV expert
	Only 1 VL > 1000 after 2 years on a LPV/r or ATV/r based regimen	Do ABCDE assessment, EAC if applicable, repeat VL in 4-6 weeks as per VL NSA. This result will group the client into one of the above categories	

HOW TO OBJECTIVELY MEASURE ADHERENCE

For adherence to be > 80 %, patient must meet one of the following criteria:

- Pharmacy refills > 80 % in the last 6-12 months
- Attendance of > 80 % of scheduled clinic visits in the last 6-12 months
- Detection of current antiretroviral drugs in the client's blood or urine

To calculate adherence % in the past 6-12 months:

$$\frac{\text{Amount of scheduled visits actually attended by client}}{\text{Amount of scheduled visits}} \times 100$$

NEED HELP?

Contact the TOLL-FREE National HIV & TB Health Care Worker Hotline

0800 212 506 / 021 406 6782

Alternatively "WhatsApp" or send an SMS or "Please Call Me" to 071 840 1572

www.mic.uct.ac.za

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REPUBLIC OF SOUTH AFRICA

MEDICINES INFORMATION CENTRE

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ART INITIATION ALGORITHM

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

Take a history and do a clinical examination (see table on Monitoring for All Patients at First ANC Visit)**:**
Exclude contraindications to starting ART on the same day (refer to 2023 ART Guideline). 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, sputum for TB NAAT, urine dipstix, syphilis, Hb and HBsAg (if unknown)

TB Symptoms with danger signs:
If the woman appears very ill with any of the following signs, **discuss with a doctor or refer for further assessment. Do not start ART until TB is excluded/diagnosed, as these women may be at a higher risk of developing IRIS:** difficulty breathing, respiratory rate > 30/min, temperature > 38°C, pulse > 100/min, BP < 90/60, coughing up blood, signs of meningitis (neck stiffness, visual disturbances), confusion, agitation, or unable to walk unaided

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

TB-NAAT-negative, but still TB symptoms

Investigate with CXR, 2nd sputum for culture +/- antibiotics as per National TB Guidelines. Do urine LAM

TB diagnosis confirmed

Initiate TB Rx

Review in 2 weeks. If stable and tolerating TB Rx, initiate or continue ART. DTG requires boosting (50 mg twice daily) with rifampicin-based TB treatment. 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

No abnormal history

Initiate ART same day: TLD preferred[#], see first page
If TDF contraindicated due to history of/suspected renal disease replace TDF with ABC.
Review results in 3-7 days

TB-NAAT-positive

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

Continue ART

CD4 < 200

If **CD4 < 100**, a reflex CrAg screening will be done automatically

If **CD4 is 100—199** a serum CrAg test must be ordered separately

CrAG Negative

CrAG Positive

Refer urgently for LP

sCr > 85 µmol/L

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

No abnormal results and CD4 > 100

Continue ART

WOMEN ON ART

Pregnant or breastfeeding

See front page for how to switch to DTG-regimen. Do VL. See VL monitoring below

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

Use the following EGK codes for VL monitoring:

C#PMTCT
for VLs done during ANC or breastfeeding

C#DELIVERY
for VLs done at delivery

[#]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 on TLD, 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

VL MONITORING

	When to do VL
Established on ART	At first ANC visit **If VL < 50 c/mL, repeat at delivery**
Newly initiated	At 3 months on ART **If VL < 50 c/mL, repeat at delivery**
Previous ART history	At 3 months after restart on DTG-regimen **If VL < 50 c/mL, repeat at delivery**
During breast-feeding	Every 6 months or when clinically indicated

VIRAL LOAD NON-SUPPRESSION ALGORITHM (NSA)[Φ] - VL ≥ 50

Do a thorough assessment of the cause of the elevated VL (**A**dherence; **B**ugs; Infections; **C**orrect Dose; **D**rug Interactions; R**E**sistance). Implement interventions to re-suppress the VL. If patient not on TLD, consider switch. Start, restart or extend infant higher-risk prophylaxis (AZT and NVP)

Repeat VL in 4-6 weeks

VL < 50

Repeat VL at delivery or at next scheduled VL

VL ≥ 50

Re-assess and resolve adherence issues

On TLD **less than** 2 years **or** adherence still suboptimal, **or** persistent low-level viraemia

Repeat VL in 3 months' time (or at delivery if > 28 weeks gestation). Intensify efforts to **resolve adherence issues**

On TLD for **at least 2 years**, and **two** or more **VLs ≥ 1000 c/mL** (taken two or more years after starting TLD regimen) and **Adherence > 80%**

Go to the algorithm for **"Management of confirmed virological failure on TLD"** of the ART Clinical Guideline

[Φ]For clients on PI-based treatment, see criteria for switching on front page or phone the hotline (0800 212 506)