ANTIRETROVIRAL THERAPY

The Wellness Program (Pre-ART)

PATIENTS with CD4 > 500, Not yet eligible for ART:

- Repeat CD4 and clinical staging 6 monthly
 * CD4 count 500-550 cells/mm³: Do not wait 6 months; bring back in 3 months
- · TB screening with every visit and initiate IPT if eligible
- Screening and management of sexually transmitted infections
- Counselling on risk-reduction and combination HIV prevention approaches
- Support for disclosure and partner notification
- Counselling related to planning for conception or contraception
- · Counselling on nutrition and healthy lifestyle
- Screening and management of co-morbidities and noncommunicable diseases
- Annual cervical cancer screening (pap smear) for all HIVpositive women
- Advise patients to come back whenever they have health problems

Source: National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults, December 2014.

ANTIRETROVIRAL THERAPY Pregnant and Breastfeeding Women

Initiation of ART for HIV-positive Women (ART Naive): Antenatal Visit

HIV-positive not on ART (known and newly diagnosed) History and clinical assessment including for STI and TB screening, and WHO staging Blood specimens sent for creatinine and CD4 cell count. Counsel on safer sex, postnatal contraception, partner testing, routine cervical cancer screening. Perform nutritional assessment. If no active psychiatric illness or history If history of renal disease or active of renal disease: psychiatric illness: Start FDC on the same day The woman has a high risk Return in 1 week to review results pregnancy and needs urgent referral. If Hb ≥7g/dl, start AZT 300mg bd. Refer for high risk pregnancy 1 week later: Review results of CD4 cell count, serum creatinine If serum creatinine >85µmol/L: Stop FDC (TDF contraindicated), initiate AZT 300mg bd if Hb≥7g/dl. If serum creatinine ≤85 µmol/L: Continue FDC lifelong and refer to See 1st Line ART for Pregnant and HIV/ART services if appropriate. Breastfeeding Women and Emphasise exclusive breastfeeding refer for high risks pregnancy. for the first 6 months, with The woman has a high risk complementary feeding from 6 pregnancy and needs urgent months in addition to breastfeeding referral. If Hb ≥7g/dl, start AZT until 12 months 300mg bd and stop the FDC (will require individual agents for ART and investigation for renal compromise) Check CD4 count

Source: National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults, December 2014.

If CD4 < 200 or WHO stage 3 or 4, start cotrimoxazole

If CD4 < 100, send cryptococcal Ag test

Initiation of Maternal ART during Labour or Post-Partum Visit

- Unbooked woman presents in labour and tests HIV-positive: sd NVP + sd Truvada and AZT 3-hourly in labour. Start FDC next day (BEFORE discharge) if no psychiatric illness or renal disease.
- Emergency caesarean section in an unbooked woman not on ART: sd NVP + sd Truvada + antibiotics prior to C/S. Start FDC next day (BEFORE discharge) if no psychiatric illness or renal disease.
- Mother diagnosed with HIV within 1 year post-partum or still breastfeeding beyond 1 year: start FDC same day if no psychiatric illness or renal disease.

For all cases, perform history and clinical assessment, TB and STI screening, WHO staging. Send bloods for CD4, creatinine and review in 1 week. Provide 8 week's supply of ART on discharge.

Counsel all HIV-positive mothers on EXCLUSIVE breastfeeding for 6 months up to 12 months.

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1 week later: Review results of maternal CD4, serum creatinine and infant PCR

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If serum creatinine > 85 umol/L: see 1st Line ART for Pregnant and Breastfeeding Women.
If infant PCR positive: Initiate ART:
Infants, Children, and Early Adolescents) and confirm diagnosis with 2nd PCR. If infant PCR negative: see Initiation of Infant ART Prophylaxis in HIV-Exposed Infants

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Continue FDC as lifelong treatment

Infants: Check HIV status in all infants born to HIV-positive women (PCR at birth or <18 months; rapid test > 18 months).

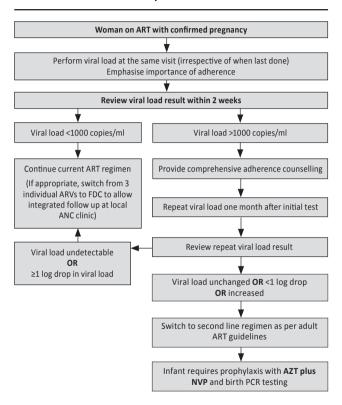
Birth PCR for high risk infants:

- low birth weight < 2.5kg
- premature infants
- infants born to mothers with VL > 1000 copies/mL
- infants of mothers who were on ART <4 weeks prior to delivery
- infants of mothers who were unbooked or diagnosed HIV+ in labour or shortly after delivery
- infants of mothers with TB/HIV co-infection at any point during pregnancy
- infants who are symptomatic at birth

Give BCG to all infants unless mother has active TB or <2 months on TB treatment; follow EPI schedule. Start infant ART prophylaxis (see Infant Regimen) and give 6 week's supply on discharge.

Source: National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults. December 2014.

Algorithm for Management of Pregnant Women Already on ART >3 Months



Source: National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults, December 2014.

1st Line ART for Pregnant and Breastfeeding Women

All pregnant and breastfeeding women not yet on ART	FDC initiated immediately	If FDC ontraindicated, start AZT immediately and review within 1 week
Currently on lifelong ART	Continue the ART regimen; if the woman is on individual ARVS (EFV, 3TC, TDF) and virally suppressed, change to FDC	Check a VL when pregnancy diagnosed regardless of when last VL was done Patients with confirmed 2nd or 3rd line regimen failure should NOT breastfeed their infants
	2nd antenatal visit or 1 week later	veek later
Creatinine ≤ 85µmol/l	Continue FDC	
Creatinine > 85μmol/l	AZT + 3TC + EFV	Refer for high risk-pregnancy and start alternate triple therapy within 2 weeks; investigate renal disease. If $Hb < 7g/dl$ use ABC instead of AZT
EFV contraindicated (active psychiatric illness)	TDF + FDC + NVP or LPV/r	Refer urgently for alternate triple therapy within 2 weeks. Substitute LPV/r for NVP in women with CD4 counts > 250 but < 350
Unbooked or Newly diagnosed HIV-positive in labour	sdNVP + sd TDF / FTC (Truvada) + AZT 3 hourly in labour sd NVP + sd Truvada for C/S	Begin FDC prior to leaving hospital

Source: National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults, December 2014.

Recommended 2nd Line ART for Pregnant and Breastfeeding Women

Failing on a TDF-based 1st line regimen AZT + 3TC + LPV/r AZT + TDF + 3TC + LPV/r (4 drugs if HBV coinfected) Failing on a d4T or AZT-based 1st line regimen TDF + 3TC (or FTC) + LPV/r Dyslipidaemia or diarrhoea associated with LPV/r Switch LPV/r to ATV/r	Second-Lir	Second-Line Regimen
v/r	Failing on a TDF-based 1st line regimen	AZT + 3TC + LPV/r AZT + TDF + 3TC + LPV/r (4 drugs if HBV coinfected)
	Failing on a d4T or AZT-based 1st line regimen	TDF + 3TC (or FTC) + LPV/r
	Dyslipidaemia or diarrhoea associated with LPV/r	Switch LPV/r to ATV/r

Source: National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults, December 2014.

Baseline and Routine Monitoring for Pregnant and Breastfeeding Women

HIV diagnosis (First ANC visit)	Purpose
Confirm HIV result with rapid antibody test if no test results are available	To confirm HIV-positive status in patients who present without documented proof of positive HIV status
WHO clinical staging if HIV-positive	To assess risk of developing advanced disease and opportunistic infections
CD4 count	To identify eligibility for Cotrimoxazole (CD4<200) To identify eligibility for CrAg or CLAT (CD4<100) Not used to determine eligibility if pregnant/breastfeeding or has TB or HIV/Hep B co-infected or has WHO stage IV
VL (Women becoming pregnant while on ART)	Assessment of effectiveness of treatment and to detect treatment failure Do VL for all pregnant and breastfeeding women at first visit regardless of when the last VL was done
Screen for chronic diseases (hypertension, diabetes, proteinuria, previous renal disease)	To identify high-risk pregnancy
Nutritional assessment	To detect any nutritional deficiencies and provide appropriate nutrition care and support
Ask about family planning	To provide counselling on safer sex, family planning, postnatal contraception, partner testing and routine cervical cancer screening.
Screen for TB symptoms using the TB screening tool	To identify TB suspects for investigation and to assess eligibility for INH/IPT
Screening for STIs and syphilis	To identify and treat those with STI

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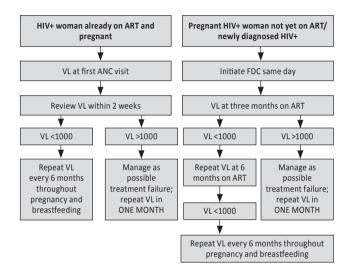
Baseline and Routine Monitoring for Pregnant and Breastfeeding Women

continued

HIV Diagnosis (First ANC visit)	Purpose
Cryptococcal Antigen (CrAg) test if CD4<100	To identify and provide prophylaxis for disseminated cryptococcal infection
Do Hb or FBC Do Creatinine ALT only if requires NVP	To detect anaemia or neutropenia To detect renal insufficiency To exclude liver dysfunction
On ART	Purpose
CD4 at initiation and then 1 year on ART, then yearly	To monitor immune response to ART
Do VL at confirmation of pregnancy if already on ART >3 months VL at months 3, 6, 12, 18, 24 throughout pregnancy and breastfeeding	To identify treatment failures and problems with adherence To ensure women who conceive on ART are fully suppressed to minimise risk of MTCT To more actively monitor VL throughout pregnancy and breastfeeding to inform urgent response to detectable VL as this increases risk of MTCT
Alanine transaminase (ALT) if on NVP and develops rash or symptoms of hepatitis	To identify NVP toxicity
FBC at month 3 and 6 if on AZT and then every 12 months	To identify AZT toxicity
Creatinine at month 3 and 6, month 12, then every 12 months if on TDF	To identify TDF toxicity

Source: National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults. December 2014.

Viral Load Monitoring and Treatment Failure for Pregnant or Breastfeeding Women



Viral Load Monitoring and Treatment Failure for Pregnant and Breastfeeding Women

Viral Load (VL)	Response
Note: Always check hepatitis B status (HBsAg) before stopping TDF. If patient has chronic hepatitis B, stopping TDF may lead to a fatal hepatitis flare. If hepatitis B positive, TDF should be continued as a 4th drug in the 2nd line regimen	
<50* copies/mL	Routine 6 monthly VL monitoring throughout pregnancy and breastfeeding Routine adherence support
50*-1000 copies/mL	Assess and manage adherence carefully Repeat VL in 6 months If VL still 50*-1000 copies, begin intensive adherence support (step-up adherence) and repeat VL in 6 months
>1000 copies/mL	Adherence assessment and intensive adherence support (step-up adherence package) Repeat VL in 1 month If VL<50* copies/mL or ≥1 log drop in VL, switch from individual ARVs to FDC if appropriate and perform routine VL monitoring every 6 months If VL unchanged/increased OR < 1 log drop, switch to 2nd line as per adult ART guidelines Infant requires prophylaxis with AZT plus NVP and birth PCT testing Mothers failing 2nd or 3rd line regimens should be instructed to AVOID breastfeeding

^{*}If laboratory does not test down to 50 copies/mL, use 400 copies/mL

Source: National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults, December 2014.