Republic of the Sudan

Federal Ministry of Health

GUIDELINES FOR THE USE OF ANTIRETROVIRAL DRUGS FOR HIV PREVENTION AND TREATMENT

2014

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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
d4T	Stavudine
DNA PCR	DNA Polymerase Chain Reaction
EFV	Efavirenz
FBC	Full Blood Count
FTC	Emtricitabine
Hb	Haemoglobin
HBSAg	Hepatitis B Surface Antigen
HIV	Human Immunodeficiency Virus
IPT	Isoniazid Preventive Therapy
LPV/r	Lopinavir/ritonavir
MCH	Maternal and Child Health
MDR/XDR-TB	Multi-Drug Resistant / Extensively Drug Resistant Tuberculosis
NVP	Nevirapine
PHC	Primary Health Care
SRH	Sexual and Reproductive Health
STI	Sexually transmitted infection(s)
TB	Tuberculosis
TDF	Tenofovir
WHO	World Health Organization

Foreword

Sudan is currently experiencing a low level HIV/AIDS epidemic characterized by low HIV prevalence among the general population and higher prevalence in key populations at higher risk. The goal of its national response is reduction of HIV related morbidity and mortality with the ultimate aim of eliminating HIV/AIDS as a public health threat. This necessitates a well-coordinated effort to prevent new infections and treat those who are already infected.

We have adopted the public health approach in providing HIV prevention, care and treatment services to our population; and, based on that approach, we have produced several guidelines since the early days of the epidemic. Those guidelines have undergone a series of revisions based on state of the ART knowledge and relevant recommendations for resource limited settings.

In 2013, WHO updated its guidelines on the use of ARVs for HIV prevention and treatment. In addition, it adopted a consolidated approach in which all the areas where ARVs are used are treated in one document. Instead of separate guidelines for adult treatment, pediatric treatment and PMTCT, we now have one consolidated guidance for these interventions. We in Sudan find this a very practical approach and have decided to adapt the 2013 recommendations and issue consolidated guidance.

The guideline provides a summary of the key clinical recommendations for

- Adult and adolescent treatment
- Treatment of infants and children
- Management of pregnant and breastfeeding mothers and their infants

It also contains important annexes dealing with key issues of HIV prevention and treatment. Therefore, it is hoped that the guideline will serve as a quick source of information for clinical practitioners and program coordinators.

The guideline will be regularly reviewed and updated when new scientific evidence becomes available. In this respect, we would like to encourage colleagues to forward queries and comments to the FMOH at the following address:

Sudan National HIV/AIDS Prevention and Control Program (SNAP)
Website:

Dr Tarig Abdalla Abdallrahim
Director, CD, NCD &SNAP

Acknowledgements

The MOH would like to express its appreciation for colleagues who participated in the development and finalization of this guideline. The following individuals and institutions deserve special mention:

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- All participants and facilitators of the two workshops conducted to adapt the WHO recommendations and finalize the adaptation process

In addition, we would like to express our deepest gratitude to the WHO Country, Regional and HQ for covering the cost of the development of this guideline.

1. Goals of the programme

The national response to HIV/AIDS in Sudan aims at reducing HIV-related morbidity and mortality ultimately aiming at eliminating HIV/AIDS as a public health threat. Provision of reliable information, HIV testing and counseling, care and treatment as well as robust monitoring and evaluation will lead to the achievement of the goals.

2. Purpose of the guideline

This document is a summary of recommendations related to the use of ARVs for HIV prevention and treatment. It is intended to serve as a quick reference for clinical practitioners and program coordinators at all levels.

Strict implementation of the recommendations will ensure optimal outcomes for patients and efficient use of resources to achieve these outcomes. By standardizing clinical practice throughout the country, the guideline makes it easier to prepare plans at national, state, locality and facility level.

3. How to use the guideline

A copy of this document should be kept in each facility providing HIV prevention and treatment services. Use the table of contents to go to the specific page containing the topic you would like to check. If further information is required on any specific topic, the reader is advised to refer to the WHO 2013 consolidated guidelines at the following link:

http://www.who.int/hiv/pub/guidelines/arv2013/en/

Please also visit the SNAP website for latest guidelines, manuals and SOPs.

If you need additional information on the annexes, refer to the detailed documents published by SNAP.

4. Adults and Adolescents

4.1. Standardised national eligibility criteria for starting ART regimens for adults and adolescents

Eligible to start lifelong ART
• CD4 count <500 cells/mm^3 irrespective of WHO clinical stage • All types of TB irrespective of CD4 count (TB drug resistant or sensitive, including extra pulmonary TB) • WHO stage 3 or 4 irrespective of CD4 count • HIV positive women who are pregnant or breastfeeding • HIV Positive partner in a serodiscordant couple • Patients with HBV co-infection with severe chronic HBV liver disease
Patients not yet eligible for ART
• Enroll in care, regular follow-up and repeat CD4 testing 6-monthly. • Advise on how to avoid HIV transmission to sexual partners and children • Provide counselling on nutrition and contraception

4.2 Standardised National ART Regimens for Adults and Adolescents

First-Line		
Patient Group	**Regimen**	**Comments**
All new patients needing treatment, including pregnant women	TDF + 3TC + EFV (FDC preferred)	• Replace EFV with NVP in patients with significant psychiatric co-morbidity or intolerance to EFV and where the neuro-psychiatric toxicity of EFV may impair daily functioning, e.g. shift workers. • Replace TDF with AZT in patients with renal disease or the use of other nephrotoxic drugs e.g. aminoglycosides. • If patient has contraindication to TDF or AZT, use ABC. • In case of contraindication to all of the above drugs, use d4T.
Currently on d4T-based regimen	TDF + 3TC + EFV (FDC preferred)	• Mandatory if patients experience toxicity and for patients who are at high risk of toxicity (high BMI or pregnant). • Switch to TDF if virally suppressed and the patient has normal creatinine clearance, even if well tolerated.
Second-Line		
Failing regimen	**Switch to**	**Comments**
TDF-based 1st line	AZT + 3TC + LPV/r	For patients with anaemia and renal failure, switch to ABC
d4T–based 1st line	TDF + 3TC + LPV/r	
Dyslipidaemia or intractable diarrhea associated with LPV/r	Switch LPV/r to ATV/r	
Third-Line		
• Refer! Decision will be made by experts based on genotype resistance testing • The drugs will be managed centrally by CMS • Most likely regimens will be RAL + DRV + ETV		

4.3 *Standardized National Monitoring for Adults & Adolescents with HIV*

At initial Diagnosis of HIV	Purpose
Confirm HIV result with rapid test	To ensure that national testing algorithm has been followed
If HIV positive, do CD4 count and WHO clinical staging	To assess eligibility for ART
Screen for TB symptoms	To identify TB/HIV co-infected
Do Hb or FBC if patient requires AZT	To detect anaemia or neutropenia
Creatinine if patient requires TDF	To detect renal insufficiency
For patients initiated on NVP-based regimen, do ALT	To exclude liver disease

On ART	Purpose
CD4 at 6 months on ART, then yearly	To monitor immune response to ART
VL at month 6, 1 year on ART and then every 12 months[1]	To identify treatment failures and problems with adherence
ALT only if on NVP and develops rash or symptoms of hepatitis	To identify NVP toxicity
FBC at month 3 and 6 if on AZT	To identify AZT toxicity
Creatinine at month 3 and 6, 1 year 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

At Routine Follow-Up Visits for those not yet eligible for ART	Purpose
Repeat CD4 count at 6 months	To see if they have become eligible for ART
WHO clinical staging at every visit	To see if they have become eligible for ART
Screen for TB symptoms to identify TB suspects	To identify TB/HIV co-infection
Offer prevention for HIV positives	To prevent HIV transmission and re-infection To prevent STIs

See annex for list of recommended and desirable laboratory tests.

It is to be noted that, apart from HIV serology, all other lab tests are not mandatory. The MOH will exert every effort to make the recommended and desirable lab tests available to all ART centers. Therefore, you should not defer services because these tests are not available

[1] Initially, we will use VL only for patients with suspected treatment failure. Later (2015 onwards), we will introduce routine VL for all patients.

5. Infants and Children

5.1 Standardised national eligibility criteria for starting ART regimens for Infants and Children

Eligible to Start ART
▪ All children less than 5 years of age, irrespective of CD4 ▪ Children 5 years to 15 years with WHO clinical stage 3 or 4 or CD4 ≤500 cells/mm^3

5.2 Standardised national ART regimens for Infants and Children

First Line Regimen	
All infants and children under 3 years (or < 10kg)	ABC + 3TC + NVP[2] AZT+3TC+NVP; alternative: d4T+3TC+NVP (special cons.)
All infants and children <3 years exposed to NVP as prophylaxis	AZT + 3TC + LPV/r
Children 3-9 years (and ≥ 10kg)	ABC + 3TC + EFV (preferred) AZT+3TC+ EFV/NVP or TDF+3TC+EFV/NVP
Adolescents (10-19 years, >35kg)	Adult regimens TDF+3TC+EFV
Second-Line Regimens	
Failed first line NNRTI-based regimen	**Recommended second line regimen**
ABC + 3TC + EFV (or NVP)	AZT + 3TC + LPV/r
d4T + 3TC + EFV (or NVP)	AZT + ABC + LPV/r
Third line Regimens	
Failing any 2nd line regimen	▪ Refer! Decision will be made by experts based on genotype resistance testing ▪ The drugs will be managed centrally by CMS

5.3 Standardized national monitoring for Infants and Children with HIV

At initial Diagnosis of HIV	Purpose
Verify HIV status	Ensure that national testing algorithm has been followed
Weight, height, head circumference (<2 yrs) and development	To monitor Growth and Development + identify eligibility for ART
Screen for TB symptoms	To identify TB/HIV co-infected
WHO Clinical Staging	To determine if patient is eligible for ART (>5 years)
Do the CD4 count	Children <5 years – Baseline, DO NOT wait for CD4 count to start ART
	Children ≥ 5 years – To determine eligibility for ART and start CPT
Hb or FBC if available	To detect anaemia or neutropenia

[2] If LPV/r sprinkles become available in Sudan, the preferred 1st line regimen for infants <3 years will be changed to AZT + 3TC + LPV/r

At Routine Follow-Up Visits (patients not yet on ART)	Purpose
Document weight, height, head circumference (<2 years) and development	To monitor growth and development and to see if patient has become eligible for ART
Check that a CD4 count has been done in the last 6 months	To determine if patient has become eligible for ART
WHO Clinical Staging	To determine if patient has become eligible for ART
Screen for TB symptoms	To identify TB/HIV co-infection

At Initiation of ART (Baseline)	Purpose
Hb or FBC	If less than 8g/dl start ART and refer for specialist opinion
CD4 count (if not performed in last 6 months)	Baseline assessment
HIV Viral Load (VL)	Baseline assessment
Creatinine + urine dipstix if on TDF regimen	If abnormal, refer for specialist opinion
ALT (if jaundiced or on TB treatment)	To assess for liver dysfunction

On ART	Purpose
Document weight, height, head circumference (<2 years) and development	To monitor growth and developmental stage
Clinical assessment	To monitor response to ART and exclude adverse effects
CD4 at 12 months into ART, and then every 12 months	To monitor response to ART,
If on AZT: Hb or FBC at month 1, 2, 3 into ART and then annually	To identify AZT-related anaemia
Clinical drug-related adverse events	To identify drug-related adverse events If develops jaundice or rash on EFV or NVP, do Liver function test and refer to specialist

See annex for list of recommended and desirable laboratory tests.

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It is to be noted that, apart from HIV serology, all other lab tests are not mandatory. The MOH will exert every effort to make the recommended and desirable lab tests available to all ART centers. Therefore, you should not defer services because these tests are not available

6. HIV-positive pregnant and breastfeeding Women and HIV-exposed Infants

6.1 Standardised national ART and ARV regimens for women who are HIV positive and pregnant, breastfeeding and their HIV-exposed Infants

Maternal Regimens		
Woman	**Regimen**	**Comment**
At antenatal visit		
All women diagnosed with HIV during pregnancy, labor or breastfeeding	▪ Active referral to ART center; FDC (TDF+3TC+EFV) initiated immediately at ART center	If there is a contraindication to the FDC: Start AZT-based regimen immediately and review within a week.
Currently on lifelong ART	Continue the ART regimen If on a compatible regimen (EFV, 3TC, TDF) change to FDC	Check VL when pregnancy diagnosed, if available
All women diagnosed with HIV during labor or immediately postpartum and plan replacement feeding	▪ Active referral to ART center ▪ Assess eligibility for ART (at ART center)	

Infant Regimens		
Infant	**Regimen**	**Comment**
Mother on lifelong ART	***For breastfed infant***: NVP at birth and then daily for 6 weeks ***For infant on replacement feeding***: AZT at birth and then daily for 6 weeks	
Mother did not get any ART before or during delivery and tests HIV positive post delivery	***For breastfed infant***: NVP at birth and then daily for 6 weeks ***For infant on replacement feeding***: AZT at birth and then daily for 6 weeks	Actively refer mother for care and to be evaluated for ART eligibility
Unknown maternal status because orphaned or abandoned	Test infant with rapid HIV test. If positive give AZT for 6 weeks.	Follow up at 6 weeks with HIV PCR

ARV Adult Dosing Guide

Drug	Acronym	Dosage	Comments
Tenofovir	TDF	300mg daily	Check RFT if available
Stavudine	d4T	30mg 12 hourly	
3TC	Lamivudine	300mg daily	
FTC	Emtricitabine	200mg daily	
NVP	Nevirapine	200mg daily for 2 weeks, then 200mg 12 hourly	Avoid if CD4 >250 cells/mm^3
EFV	Efavirenz	600mg (at night)	Avoid if active psychiatric illness
LPV/r	Lopinavir 200mg, ritonavir 50mg	2 tabs 12 hourly (LPV 400mg/r 100mg)	
AZT (ZDV)	Zidovudine	300mg 12 hourly	

NVP Infant Dosing Guide

For NVP syrup with strength of 10mg/ml, and dispersible tablets 50mg, use the following table to estimate the quantity for morning and evening doses. (Use syrup or tablets based on availability)

Weight Band (kg)	Morning Dose		Evening Dose	
	Syrup (ml)	Tab (no.)	Syrup (ml)	Tab (no.)
3--5.9	5	1	5	1
6--9.9	8	1.5	8	1.5
10--13.9	10	2	10	2
14--19.9	-	2.5	-	2.5
20--24.9	-	3	-	3

7. Special Considerations

7.1 TB Patients

Suspect TB if patient has one of the following:

- Current Cough
- Fever
- Weight loss or
- Night sweats

The patient that presents with TB before commencing ART:

HIV positive TB patients qualify for lifelong ART regardless of CD4 cell count.

Complete 2 to a maximum of 4 weeks of TB therapy before commencing ART (**and as soon as possible if CD4 count is less than 50 cells cells/mm^3**)

In general, ART should be initiated as soon as the patient is tolerating their TB therapy; this is usually within 2-4 weeks.

EFV-based regimens are generally preferred in patients with active TB; however, other regimens are also effective. Dose adjustment of PI may be required. Patients on LPV/r should have their dose doubled slowly over two weeks (to 800/200 mg twice a day).

Patient developed tuberculosis while on ART:

ART should be continued throughout TB treatment.

Patients on LPV/r should have their dose doubled slowly over two weeks (to 800/200 mg twice a day); all other regimens can be continued unmodified. Monitor and investigate appropriately for hepatotoxicity symptoms.

Continue these changes to LPV/r until two weeks after completion of TB treatment.

Antiretroviral Treatment for Adults with Concomitant TB	
TB develops while on ART	**TB diagnosed before starting ART**
Continue ARV therapy throughout TB treatment. **First-line regimen**. Patient can remain on the regimen they are taking.	Introduce ART between 2-8 weeks ***First line ART regimen***: 1. Tenofovir 300mg daily 2. Lamivudine 300mg daily 3. Efavirenz 600mg at night

Second-line regimen:

- The LPV/r dose should be doubled (from 2 tablets 12 hourly to 4 tablets 12 hourly) while the patient is on rifampicin-based TB treatment.
- Monitor ALT monthly.
- Reduce LPV/r to standard dose 2 weeks after TB treatment is completed.

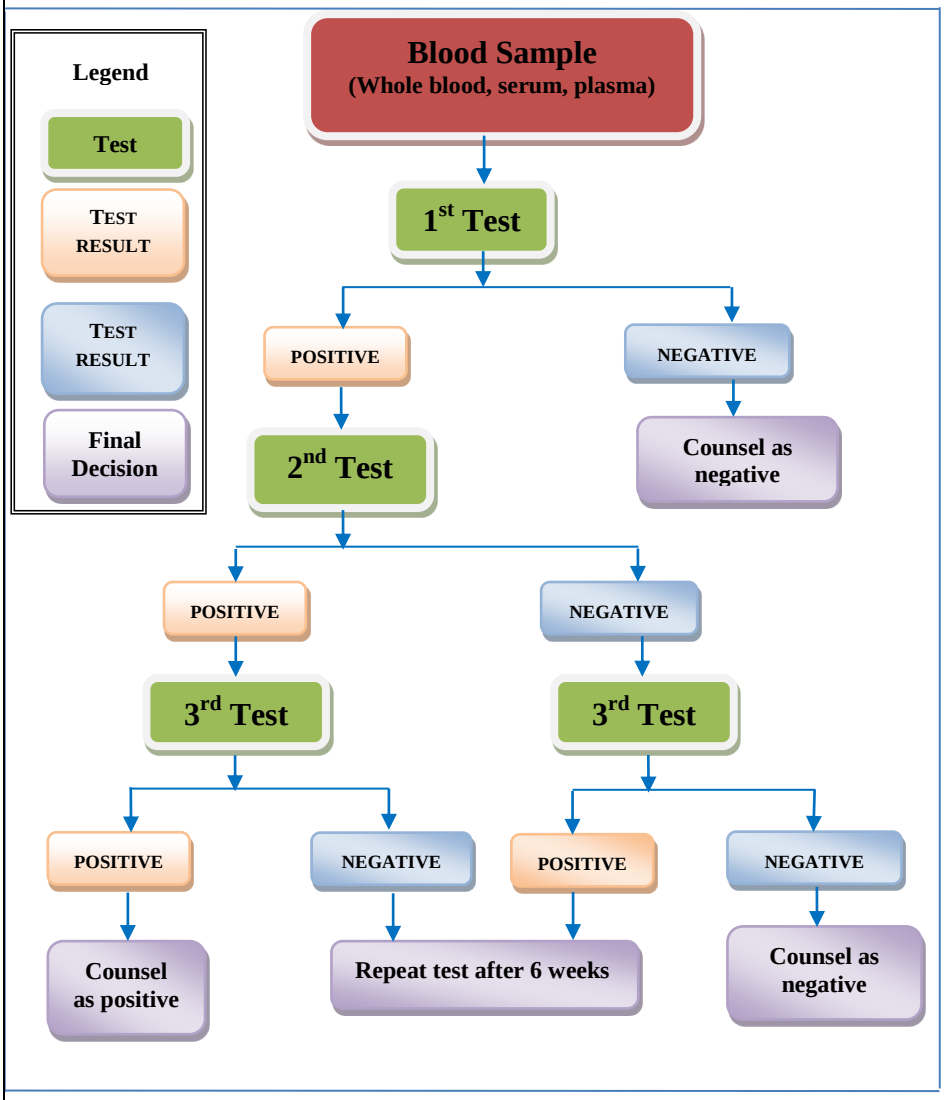
Annex 1: WHO Clinical Staging for Adults and Adolescents[3]

In a patient with a confirmed HIV+ test

Clinical stage 1		**Eligibility for ART**
• Asymptomatic	• Persistent generalized lymphadenopathy	If CD4 < 500
Clinical stage 2		
• Moderate unexplained weight loss (under 10% of body weight) • Recurrent upper respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis) • Herpes zoster • Angular cheilitis	• Recurrent oral ulcerations • Papular pruritic eruptions • Seborrhoeic dermatitis • Fungal nail infections	If CD4 < 500
Clinical stage 3		
• Unexplained severe weight loss (over 10% of body weight) • Unexplained chronic diarrhoea for longer than 1 month • Unexplained persistent fever (intermittent or constant for longer than 1 month) • Persistent oral candidiasis • Oral hairy leukoplakia	• Pulmonary tuberculosis • Severe bacterial infections (e.g. pneumonia, empyema, meningitis, pyomyositis, bone or joint infection, bacteraemia, severe pelvic inflammatory disease) • Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis • Unexplained anaemia (below 8 g/dl), neutropenia (below 0.5 x 109/l) and/or chronic thrombocytopenia (below 50 x 10^9/l)	Eligible
Clinical stage 4		
• HIV wasting syndrome • *Pneumocystis jiroveci* pneumonia • Recurrent severe bacterial pneumonia • Chronic herpes simplex infection (orolabial, genital or anorectal of more than 1 month's duration or visceral at any site) • Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) • Extrapulmonary tuberculosis • Visceral Leishmaniasis • Kaposi sarcoma • Cytomegalovirus disease (retinitis or infection of other organs, excluding liver, spleen and lymph nodes) • Central nervous system toxoplasmosis	• HIV encephalopathy • Extrapulmonary cryptococcosis including meningitis • Disseminated nontuberculous mycobacteria infection • Progressive multifocal leukoencephalopathy • Chronic cryptosporidiosis • Chronic isosporiasis • Disseminated mycosis (histoplasmosis, coccidiomycosis) • Recurrent septicaemia (including nontyphoidal *Salmonella*) • Lymphoma (cerebral or B cell non-Hodgkin) • Invasive cervical carcinoma • Atypical disseminated leishmaniasis • Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy	Eligible

[3] *We use this table for staging adults and adolescents who are 15 years or older. For younger adolescents, we use the pediatric staging.*

Annex 2: Rapid HIV Testing Algorithm



The national rapid test algorithm is the backbone of the system established to ensure quality of HIV testing. Reliability of HIV test results is a key issue for the success of HIV prevention and treatment.

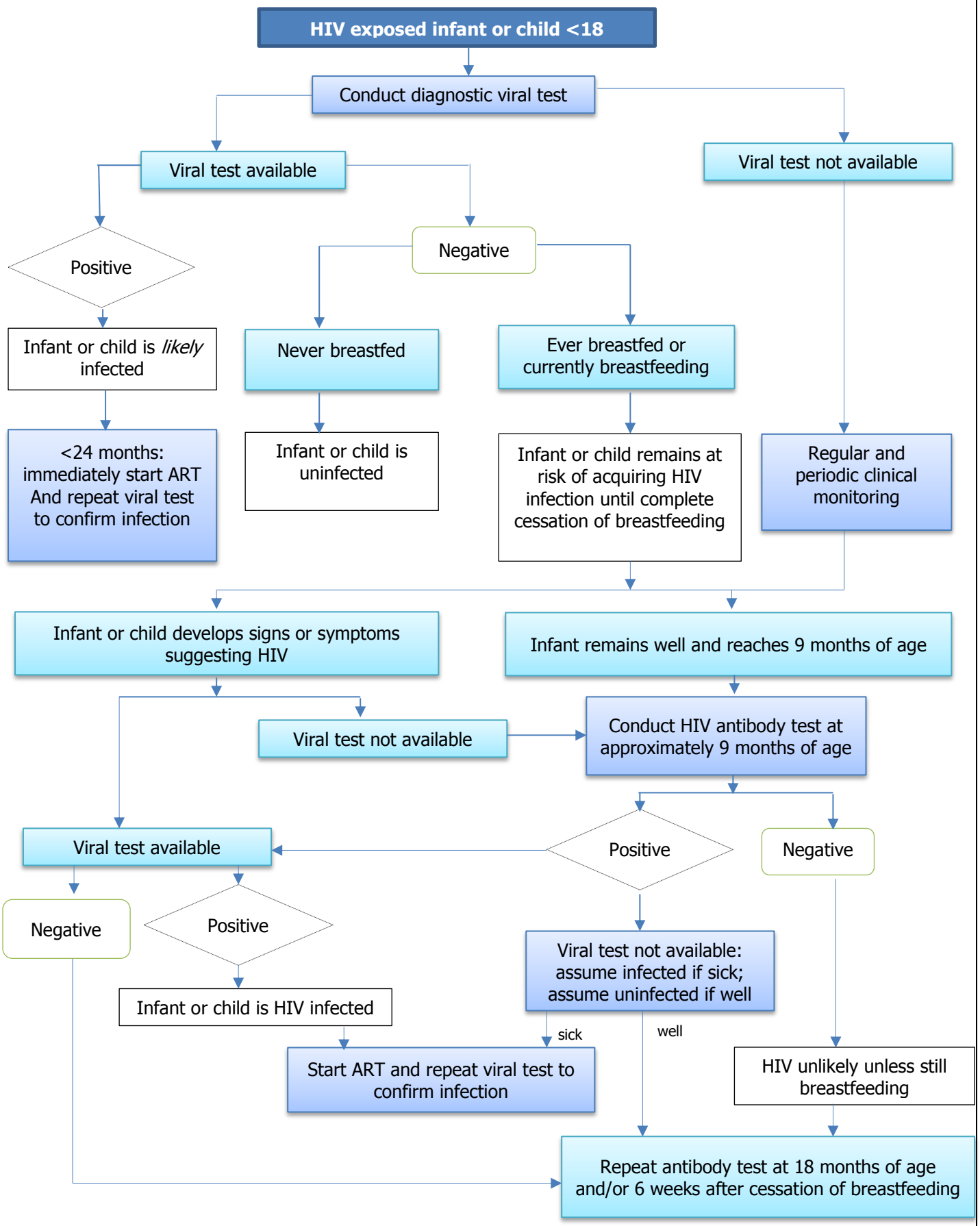
Rapid tests selected by NPHL and currently in use in Sudan

1. SD bioline and determine for 1st test
2. UniGold for 2nd test
3. Colloidal gold for 3rd test

The NPHL/MOH will regularly update this list based on scientific evidence and the specific context of Sudan.

Please note that the algorithm is currently under revision.
The updated algorithm will be distributed to health facilities as soon as it is available

Annex 3: Algorithm for Early Infant Diagnosis



Annex 4: Recommended and Desirable Tests at HIV diagnosis and Monitoring on ART

Phase of HIV Management	Recommended	Desirable
HIV diagnosis	HIV serology, CD4 cell count TB screening (if symptomatic)	HBV (HbsAg) serology HCV serology Cryptococcal antigen if CD4 ≤100 cells/mm^3 Screening for STI Assessment of major non-communicable chronic diseases and comorbidities
Follow-up before ART	CD4 cell count (first after 6 months, then annually)	
ART initiation	CD4 cell count	Hb test for AZT Pregnancy test BP measurement Urine for glycosuria, eGFR, serum creatinine for TDF Alanine aminotransferase (ALT) for NVP
Receiving ART	CD4 cell count (every 12 months) HIV viral load (at 6 months after initiating ART and every 12 months thereafter)	Urine dipstick for glycosuria and serum creatinine for TDF
Treatment failure	CD4 cell count HIV viral load	HBV (HbsAg) serology (before switching ART regimen if this test was not done or if the result was negative at baseline)

NB

- *It is to be noted that, apart from HIV serology, all other lab tests are not mandatory. Therefore, you should not defer services because these tests are not available.*
- *The MOH will exert every effort to make the recommended and desirable lab tests available to all ART centers.*

Annex 5: Summary Information on Provider-Initiated HIV Testing and Counseling (PITC)

Enabling people to know their HIV status is one key strategy in the national response to HIV/AIDS. HIV testing and counseling (HTC) is a key entry point for prevention, care and treatment. It can be delivered through client-initiated or provider-initiated approaches in fixed, outreach or mobile sites. [4]

Whatever the approach, HIV testing has to be based on the "5 Cs"

- Informed **consent**
- **Confidentiality** of information and test results
- Adequate pre-test information and post-test **counseling**
- High quality testing for **correct** results
- **Connection** to prevention, care and treatment services

PITC is recommended in the following settings:

- Presumptive or diagnosed TB patients
- STI patients
- Leishmaniasis patients
- Outreach testing for key populations
- Pregnant mothers (as an integral part of ANC)
- Any patient presenting with symptoms suggestive of HIV infection

Implementation of PITC in our settings

- Group information can be provided in the waiting area if this is an established practice. For ANC, this has to be established.
- The clinician (doctor or medical assistant or midwife or nurse) will ask the patient/client if they have attended the session (if group session is practiced), or will explain the importance of knowing HIV status and the right of the patient to decline the test.
- The clinician will order the test unless the patient/client declines.
- The test result is brought to the clinician by lab staff, (never by the patient!)
- The clinician will disclose the test result to the patient.
- The clinician provides post-test counseling if the result is negative
- If the result is positive, the clinician ensures that post-test counseling is provided by a trained counselor and that the patient is actively referred for care and treatment (see Annex...)

[4] For details, see national PITC guideline

Annex 6: Active Referral

The FMOH has made a policy decision that all newly diagnosed HIV positive patients should be **actively referred** to a facility where HIV care and treatment is provided. This differs from routine referral in that a **staff member** of the referring facility has to **accompany the patient** to the receiving facility. Such an approach will ensure that most, if not all, of our newly detected HIV+ patients will be linked to HIV care and benefit from the available services.

Note the following when you refer

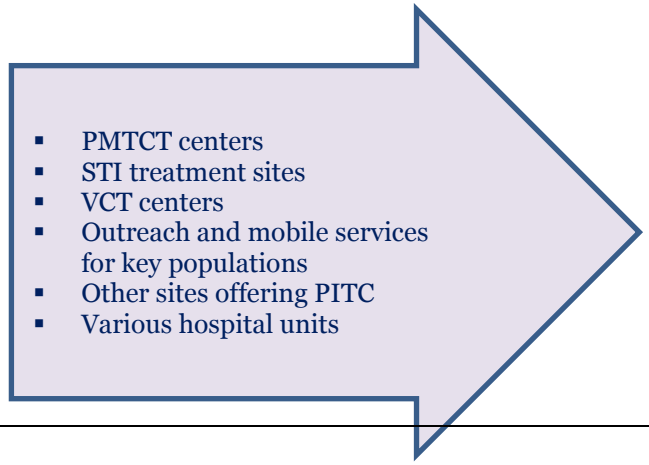
- ***Give the patient a choice of facilities***; the nearest facility might not be the most convenient for them (fear of recognition might force some patients to seek treatment in a facility far from home).
- ***Respect the patient's decision*** if they refuse to be accompanied to the receiving facility.
- In any case, ***fill the referral form***; take it with you if you are accompanying the patient, give it to the patient if they refuse to be accompanied.
- ***Maintain regular contact*** with facilities that receive your referred patients.

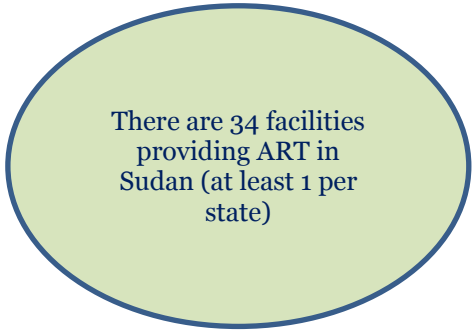
Operational Considerations

- If available, use a ***vehicle provided by your facility.***
- Use ***public transport*** if facility vehicle is not available; the receiving facility will reimburse you the transport cost.
- Submit the ***referral form*** and get the feedback form filled by the receiving facility. Take that back with you to your facility.
- If the patient refused to be accompanied, ***follow up by telephone***. Your telephone expenses will be covered by the facility.

Referral and Feedback

- Both incoming and outgoing referrals have to be correctly documented. For this purpose, use the standard tools provided by SNAP/FMOH. Adequate documentation will help in improving the reach and quality of our services.
- In addition to written documentation, you can follow up your referrals and provide feedback on received patients by telephone.





Annex 7: Hospitals Providing ART in Sudan

Facility	Phone No.	Facility	Phone No.
Omdurman	0123390526	Port Sudan Teaching	0123390542
Bahri	0123390525	Port Sudan FP	0123390543
Bashaier	0123390520	Sinja	0123390527
Khartoum Teaching	0123390521	Sinnar	0123390528
Military	0123390524	Damazin	0123390529
Police (Ribat)	0123390523	Kosti	0123390531
Al-Banjadeed	0123390522	Dweim	0123390530
Medani Teaching	0123390545	El-Obeid	0123390539
Medani Military	0123390544	Umrwaba	0123390537
Gedarif Teaching	0123390547	Kadugli	0123390536
Gedarif Military	0123390546	Delenj	0123390535
Doka		Al-Nuhud	0123390538
Kassala Teaching	0123390549	Nyala	0123390533
Halfa	0123390548	El-Fashir	0123390534
Wad-Sherifey		Jeneina	0123390532
Atbara	0123390541	Eddaen	
Dungula	0123390540	Zalinji	

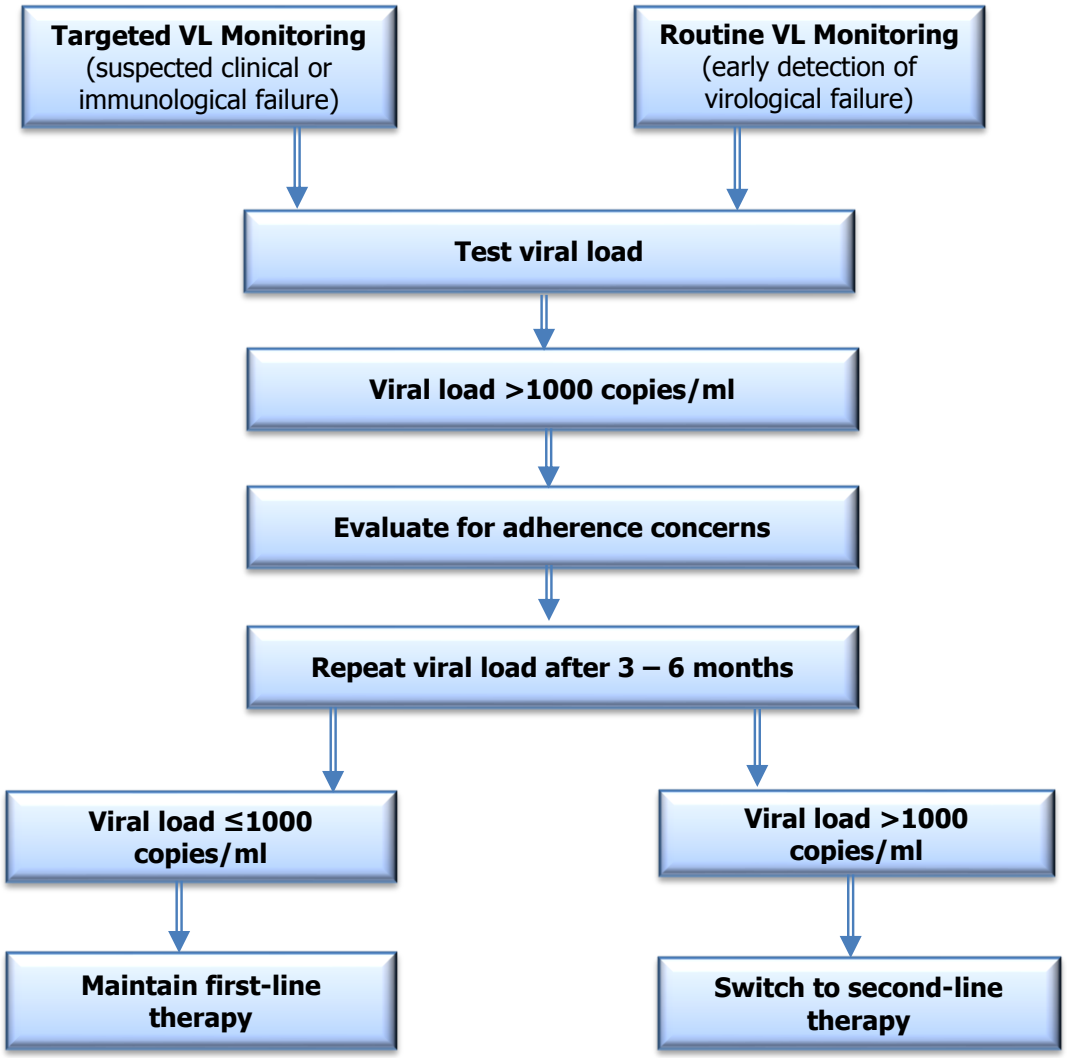
- Use these numbers for follow up of referral and feedback
- Calls between the facilities using these numbers are free
- You can also consult a senior clinician at Omdurman Hospital using the number provided

Annex 8: ARV Side Effects

ARV drug	Major types of toxicity	Risk factors	Suggested management
AZT	Anemia, neutropenia, myopathy, lipoatrophy or lipodystrophy	Baseline anemia or neutropenia CD4 count ≤200 cells/mm^3	If AZT is being used in 1st line ART, substitute with TDF or ABC If AZT is being used in 2nd line ART, substitute with d4T
	Lactic acidosis or severe hepatomegaly with steatosis	BMI >25 (or body weight >75 kg) Prolonged exposure to nucleoside analogues	
TDF	Tubular renal dysfunction, Fanconi syndrome	Underlying renal disease Age >40 years BMI <18.5 (or body weight <50 kg) Untreated diabetes mellitus Untreated hypertension Concomitant use of a boosted PI or nephrotoxic drugs	If TDF is being used in 1st line ART, substitute with AZT or d4T or ABC If TDF is being used in 2nd line ART (after d4T + AZT use in 1st line ART), substitute with ABC or ddI
	Decreases in bone mineral density	History of osteomalacia and pathological fracture Risk factors for osteoporosis or bone loss	
	Lactic acidosis or severe hepatomegaly with steatosis		
	Exacerbation of hepatitis B (hepatic flares)	Discontinuation of TDF due to toxicity	Use alternative drug for hepatitis B treatment (such as entecavir)
d4T	Peripheral neuropathy, lipoatrophy or lipodystrophy	Older age CD4 count ≤200 cells/mm^3 Concomitant use with INH or ddI	If d4T is being used in 1st line ART, substitute with TDF or AZT or ABC If d4T is being used in 2nd line ART (after TDF or ABC are used in 1st line ART), substitute with AZT
	Lactic acidosis or severe hepatomegaly with steatosis, acute pancreatitis	BMI >25 (or body weight >75kg) Prolonged exposure to nucleoside analogues	
EFV	Persistent CNS toxicity (such as abnormal dreams, depression or mental confusion)	Depression or other mental disorder (previous or at baseline) Daytime dosing	NVP. If the person cannot tolerate either NNRTI, use boosted PIs
	Hepatotoxicity	Underlying hepatic disease – HBV and HCV coinfection Concomitant use of hepatotoxic drug	
	Convulsions	History of seizure	
	Hypersensitivity reaction, Stevens-Johnson syndrome Potential risk of neural tube birth defects (*Very low risk in humans*) Male gynecomastia	Risk factors unknown	
NVP	Hepatotoxicity	Underlying hepatic disease HCV and HBV co infection Concomitant use of hepatotoxic drugs CD4 >250 cells/mm^3 in women CD4 >400 cells/mm^3 for men First month of therapy (if lead-in dose is not used)	EFV. If the person cannot tolerate either NNRTI, use boosted PIs
	Severe skin rush and hypersensitivity reaction (Stevens-Johnson syndrome)	Risk factors unknown	
ABC	Hypersensitivity	Presence of HLA-B*5701 gene	If ABC is being used in 1st line ART, substitute with TDF or AZT or d4T If ABC is being used in 2nd line ART, substitute with TDF

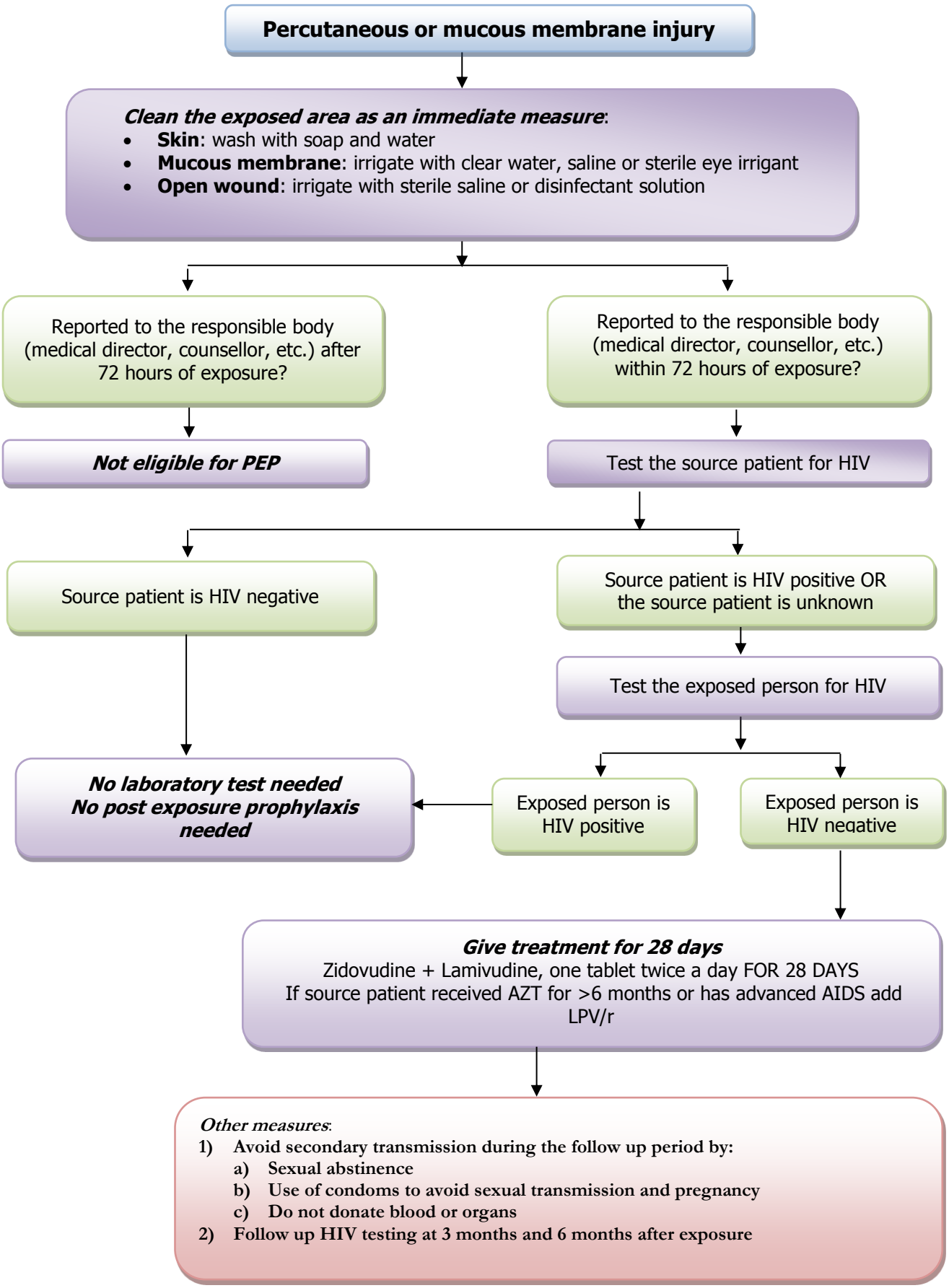
ARV drug	Major types of toxicity	Risk factors	Suggested management
LPV/r	ECG abnormalities (PR and QT interval prolongation, torsades de pointes)	People with pre-existing conduction system disease Concomitant use of drugs that may prolong the PR interval	If LPV/r is used in 1st line ART for children, use an age-appropriate NNRTI (NVP for children <3 years, and EFV for children ≥3 years) If LPV/r is used in 2nd line ART for adults, use ATV/r or DRV/r. If boosted PIs are contraindicated and NNRTIs have failed in 1st line ART, consider integrase inhibitors.
	QT interval prolongation	Congenital long QT syndrome Hypokalemia Concomitant use of drugs that may prolong the QT interval	
	Hepatotoxicity	Underlying hepatic disease HBV and HCV coinfection Concomitant use of hepatotoxic drugs	
	Pancreatitis	Advanced HIV disease	
	Risk of prematurity, lipoatrophy or metabolic syndrome, dyslipidemia or severe diarrhea	Risk factors unknown	
ATV/r	ECG abnormalities (PR interval prolongation)	People with pre-existing conduction system disease Concomitant use of drugs that may prolong the PR interval	LPV/r or DRV/r. If boosted PIs are contraindicated and NNRTIs have failed in 1st line ART, consider integrase inhibitors
	Indirect hyperbilirubinemia (clinical jaundice)	Underlying hepatic disease HBV and HCV coinfection Concomitant use of hepatotoxic drugs	
	Nephrolithiasis and risk of prematurity	Risk factors unknown	
DRV/r	Hepatotoxicity	Underlying hepatic disease HBV and HCV coinfection Concomitant use of hepatotoxic drugs	If DRV/r is being used in 2nd line ART, substituting with ATV/r or LPV/r can be considered. When it is used in 3rd line ART, limited options are available.
	Severe skin and hypersensitivity reaction	Sulfonamide allergy	

Annex 9: Viral Load testing strategies to detect or confirm treatment failure and switch ART regimen

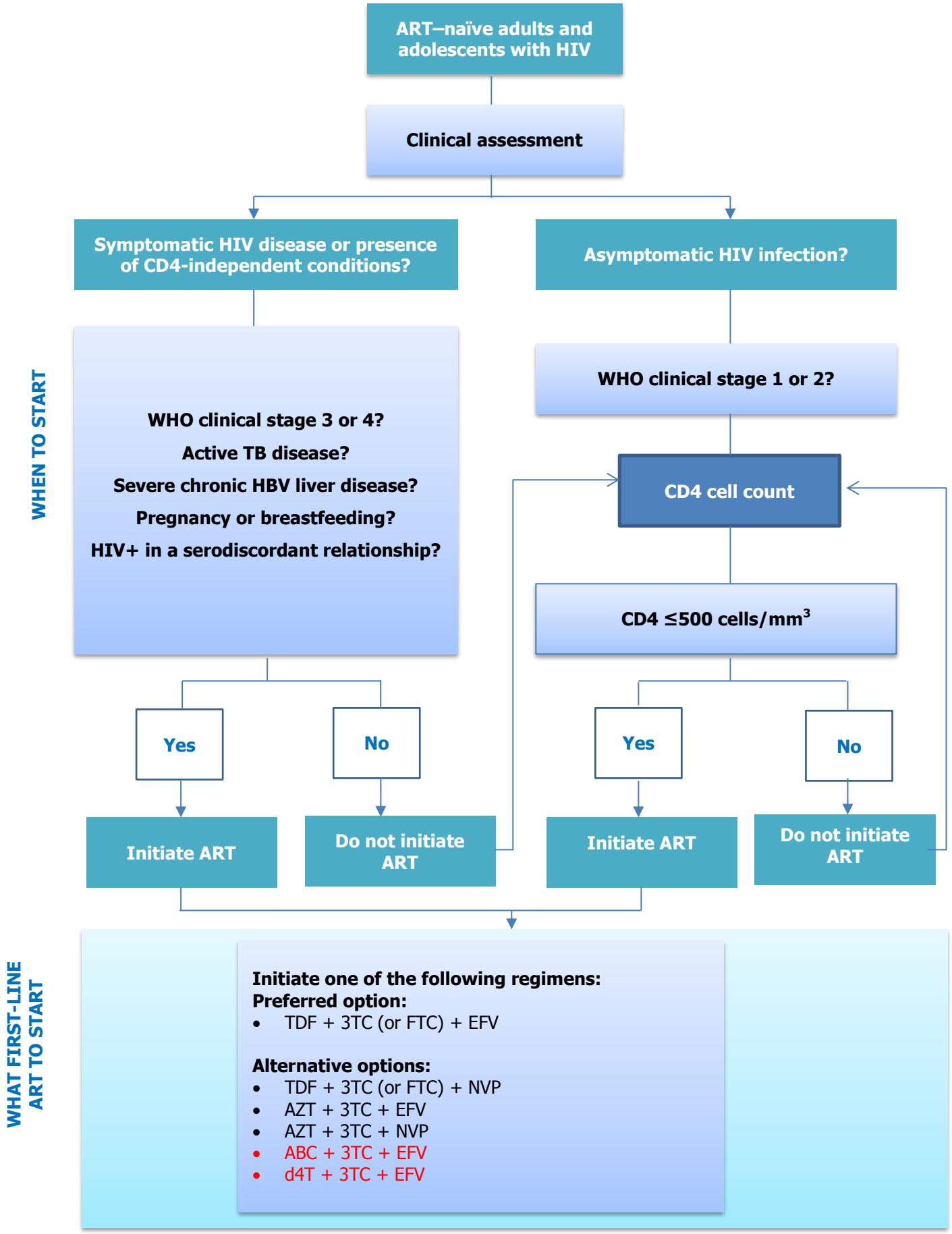


If we suspect treatment failure, the principle is to assess adherence before deciding to switch to second-line therapy.

Annex 10: PEP Flowchart

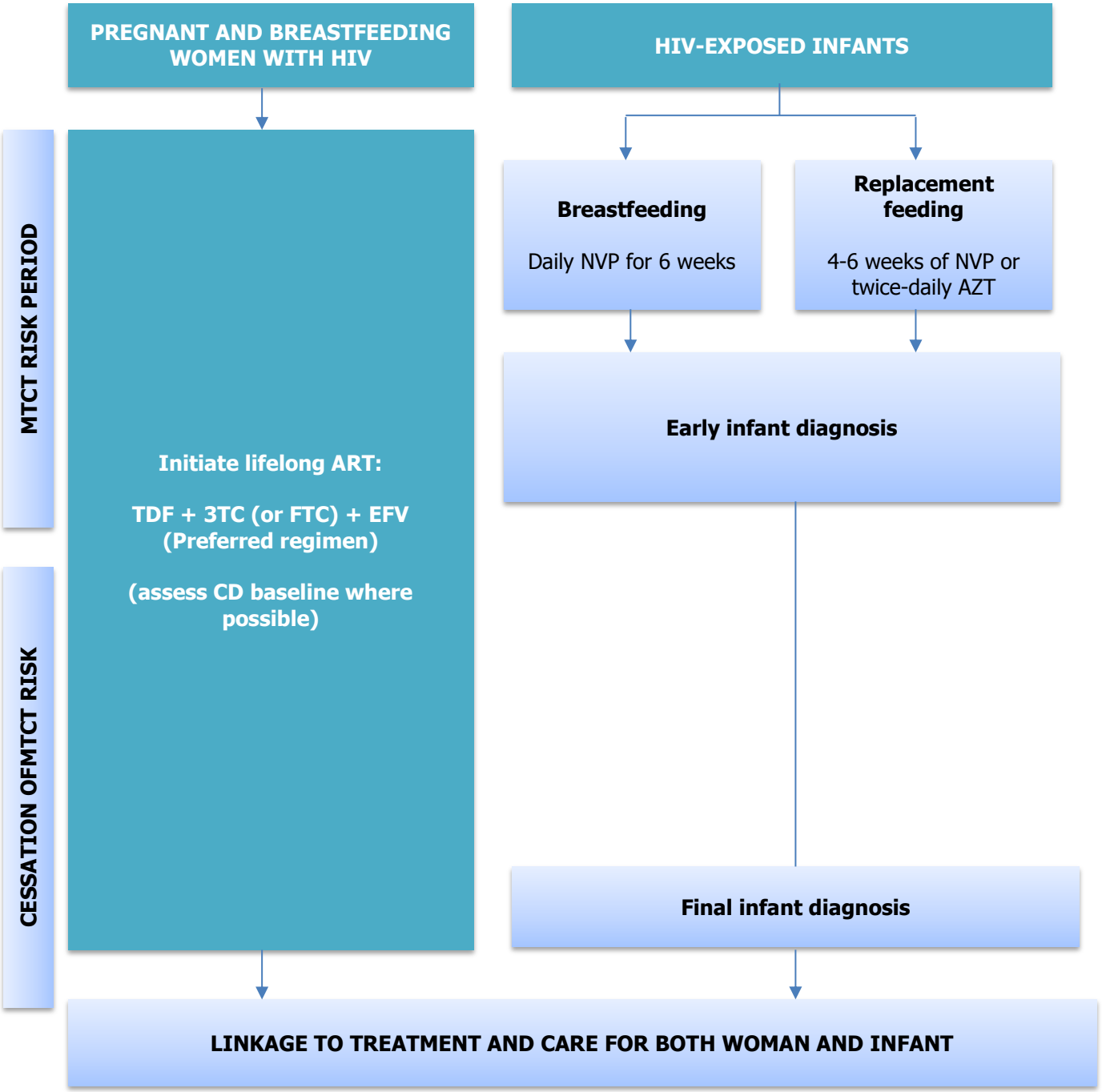


Annex 11: Algorithm for Adult and Adolescent Recommendations[5]

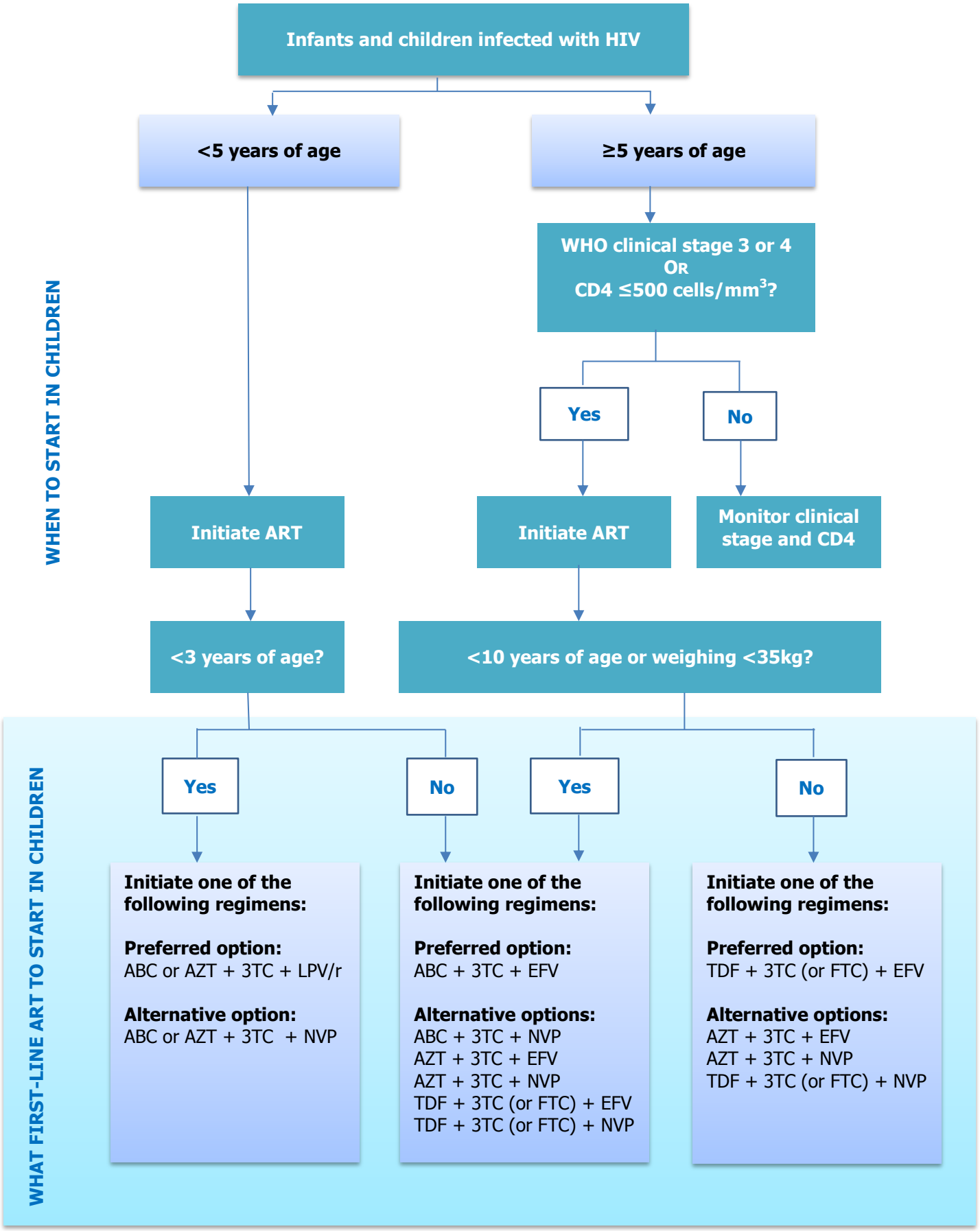


[5] Modified from WHO 2013 Guidelines

Annex 12: Algorithms for Recommendations for Pregnant and Breastfeeding Women



Annex 13: Algorithm for Recommendations for Children[6]



[6] WHO 2013 consolidated guidelines

Annex 14: Summary of Chronic Care SOPs

1. CLINIC ORGANIZATION

Clinical Team

- The HIV clinic is part of the hospital. Therefore, it must maintain good communication with the hospital management.
- Staff assigned at the clinic should work as a team.
- Minimum staffing
  - 1 doctor responsible for assessing eligibility, prescribing medications including ARVs
  - 1 counselor responsible for pre/posttest counseling, adherence counseling, patient tracking, rapid HIV testing
  - 1 nurse/sister responsible for registration and preparing reports, can also refill ARVs for stable patients
- Depending on workload, additional professionals can be assigned
  - More doctors and counselors
  - Full time lab person
  - Full time pharmacy professional
  - Adherence supporters (PLHIV)
  - Support staff

Clinic days

- Based on patient load, the clinic can work daily or on some days of the week,
- The clinic can be open during the working hours or a few hours on the working days

Recording and reporting

- There should be one person responsible for recording and preparing reports
- The standard forms distributed by SNAP must be used for recording and reporting
- All reports from the clinic should be signed by the team leader (Doctor) and countersigned by the hospital manager
- Contact details of the patients should be checked and updated on every visit (this makes it easier to trace them if they fail to come on appointment.)

2. FOR ALL PATIENTS, AT EVERY VISIT

- Assess TB status; if symptoms are suggestive, proceed according to national TB guidelines
- Assess pregnancy status; if pregnant, tell the mother she is eligible for ART and refer her to ART site
- Order CD4 if needed (baseline or yearly monitoring)
- Prescribe CTX, enough until next appointment
- Assess adherence to safer sex practices
- Promote and provide condoms

3. SERVICES FOR NEW PATIENTS

- Assess eligibility for ART by clinical staging
- If not stage 3 or 4, order CD4 count
- If eligible for ART, send to counselor for adherence preparation

4. FOLLOW UP VISITS

Assess adherence to CTX
Manage any new complaints
For a patient who completed adherence preparation, check their preparation.

- If not well prepared, send back to counselor with a note.
- If well prepared, prescribe ARVs for 1 month (TDF-3TC-EFV preferred)
- For all, prescribe CTX for 1 month

For a patient on ART:

- Adherence to ART
- Manage any new complaints
- Prescribe ARVs enough until next appointment. (If the patient is stable after 6 months, you can prescribe 2 or 3 months' ARVs.)

5. REFERRAL

- Record all referrals (incoming or outgoing) using the form provided by SNAP.
- The receiving facility has to provide feedback by telephone

6. REDUCING LOSS TO FOLLOW UP

- Create partnership with the patient
- Assess adherence at every visit
- Link to adherence supporters
- Reduce frequency of appointments in the pre-ART period

7. PATIENT TRACKING

- If a patient fails to come on the day of appointment, we will try to reach them using the telephone number they gave us.
- As a last resort, we can do home visits to the address provided by the patient.
- We have to ensure confidentiality in the process.
- The counselor is responsible for patient tracking.
- The tracking register has to be used for this activity.

Annex 15: Summary of PMTCT SOPs

The following table summarizes the sequence of activities and persons responsible for them[7]

Service	Where	By Whom	Main Activities
Pretest information	ANC waiting area	Person responsible for health talk	• Explain benefits of ANC for mother and her fetus • Explain what services are provided as part of the ANC package • Explain that HIV is part of the package
ANC examination	ANC room	Clinician	• Assess pregnancy (gestational age, fetal movement, etc.) • Check whether mother has attended health talk; if not, explain benefits of HIV test for her and her child • Offer HIV test, explain her right to refuse (this is the opt-out approach) • Order routine lab tests, include HIV test if mother doesn't refuse
Rapid HIV test	Lab doing routine tests for ANC	Lab technician	• Perform rapid test according to national algorithm • Record results in lab register and request/reporting form • Ensure confidentiality of the HIV test result
Announcing HIV test result (negative)	ANC room	Clinician	• Tell her the result • Remind her that the test cannot detect recent infection, and that she has to return in 3 months if she had a recent high risk encounter • Remind her that she has to take necessary care to remain negative
Announcing HIV test result (positive)	ANC room	Clinician	• Tell her that the test result is positive • Allow enough time for the news to sink in • If there is a counselor in your facility, refer her for posttest counseling. • Explain the benefits of ART and that she is eligible for ART • Refer her immediately to the nearest ART center; use the standard referral form for this.
Delivery (mother known HIV+)	Delivery room	Midwife, Dr	• Avoid AROM • Avoid instrumental delivery
Neonatal care	Delivery room	Midwife, Dr	• Measure and record weight, height, head circumference • Perform other routine tasks (e.g. to prevent ophthalmia neonatorum) • Administer 1st dose of AZT • Tell mother to come after 6 weeks for infant testing
Infant testing			See algorithm (Annex 3)
Managing HIV exposed infant			• Prescribe CTX
Managing HIV+ infant			• Refer to pediatrician

[7] For more details, refer to the PMTCT SOPs issued by the FMOH.