MINISTRY OF HEALTH

GUIDELINES ON USE OF ANTIRETROVIRAL DRUGS FOR TREATING AND PREVENTING HIV INFECTION

RAPID ADVICE

June 2014

This guideline contains all critical updates required by health care providers in the use of Antiretroviral Drugs for treating and preventing HIV infection as of the date of issue. All reasonable precautions have been taken by NASCOP to verify the information in this publication. For clarifications contact National AIDS and STI Control Program (NASCOP) on P.O. Box 19361 00202, Nairobi Kenya, Tel: 254 020 2630867, Email: info@nascop.or.ke, Website: www.nascop.or.ke

Recommended citation for this guideline should be as follows:
"Ministry of Health; National AIDS and STI Control Program (NASCOP). Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: A rapid advice, 2014."

ISBN-13 978-9966-038-05-0

Table of Contents

Foreword

Management of HIV infection is dynamic and fast evolving due to the continuous emerging scientific and programmatic evidence. The World Health Organization (WHO) has been in the forefront in providing generic guidance every 2-3 years for countries to adapt. The Ministry of Health (MOH) has over the years provided national guidelines on HIV infection prevention, care and treatment in line with the WHO recommendations, global and local evidence and country level applicability. The latest editions of guidelines for antiretroviral Therapy and guidelines for Prevention of Mother to Child Transmission of HIV were released in 2011 and 2012 respectively. In June 2013, WHO issued consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection.

In line with the latest guidance issued by WHO, and review of global and local evidence, the MOH has reviewed the guidelines on HIV infection prevention and treatment. This guideline recommends early HIV diagnosis for all populations, earlier initiation of Antiretroviral Therapy for children, adolescents and adults including HIV-infected pregnant and breastfeeding women, HIV-infected spouses and sexual partners in sero-discordant relationships, the use of simplified once-a-day fixed-dose-combination ARV pill to improve adherence, and routine viral load testing for all clients on ART.

This guideline has been developed for all health workers in a health care setup including; medical specialists, medical officers, clinical officers, nurses, pharmacists, pharmaceutical technologists, nutritionists, social workers and laboratory technologists among other service providers who directly or indirectly provide HIV Care services. Additionally this document should guide County health management teams, local NGO's, implementing partners, civil society organization, networks of Persons Living with HIV and other stakeholders on the use of Antiretroviral Drugs for preventing and treating HIV.

I am confident that the recommendations contained herein are timely as counties continue to expand access and enhance the scale up and quality of HIV programmes.

As this guidelines document contains only specific updates which were revised, updated or required special emphasis, reference should be made to other existing guidelines for HIV Prevention, Care and Treatment on other comprehensive components of care that remain unchanged.

Hon. James Macharia
Cabinet Secretary, Ministry of Health

Acknowledgement

The development of this guidelines document was through determined efforts of multiple stakeholders led by the Ministry of Health team who discussed, developed, edited and reviewed the recommendations contained herein.

Sincere appreciation to the National AIDS and STI Control program (NASCOP) team that led the numerous deliberations and eventual development of the guidelines and all stakeholders including bilateral and multilateral donors , implementing partners, academic institutions, other government departments among others.

Special thanks go to members of the ART taskforce and PMTCT technical working group for their tireless efforts in developing the recommendations and guidelines.

The processes of development, review and eventual printing of this document were supported by PEPFAR through the Centre for Disease Control & Prevention, the Health Policy Project (Futures Group) and the World Health Organization.

Dr Francis Kimani
Director of Medical Services, Ministry of Health

Abbreviations

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired immunodeficiency syndrome
ANC	Antenatal clinic
ART	Antiretroviral therapy
ATV	Atazanavir
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine
CD4	T–lymphocyte cell bearing CD4 receptor
DBS	Dried blood spot
DNA	Deoxyribonucleic acid
DOTS	Direct observed treatment supervision
DR	Drug resistance
DRV	Darunavir
DRV/r	Darunavir/ritonavir
DST	Drug sensitivity testing
EFV	Efavirenz
EID	Early infant diagnosis
ELISA	Enzyme-linked immunosorbent assay
FQ	Fluoroquinolones
Hb	Haemoglobin
HIV	Human immunodeficiency virus
ICF	Intensive case finding
INH	Isoniazid
IPT	Isoniazid preventive therapy
LPV	Lopinavir
LPV/r	Lopinavir/ritonavir
MDR TB	Multidrug-resistant TB
NASCOP	National AIDs and STI Control Programme
NLTD-Unit	National TB, Leprosy and lung disease unit
NNRTI	Non-nucleoside reverse-transcriptase inhibitor
NRTI	Nucleoside reverse-transcriptase inhibitor
NVP	Nevirapine
OI	Opportunistic infections
PCR	Polymerase chain reaction
PCP	Pneumocystis pneumonia
PDR	Poly drug resistant
PEP	Post exposure prophylaxis
PI	Protease inhibitor
PLHIV	People living with HIV
PMTCT	Prevention of mother-to-child transmission of HIV
PPI	Proton Pump Inhibitor
PrEP	Pre-exposure prophylaxis of HIV
RNA	Ribonucleic acid
RPR	Rapid plasma reagin
RTV	Ritonavir
SS	Sputum smear
STIs	Sexually transmitted infections
TB	Tuberculosis
TDF	Tenofovir disoproxil fumarate
TWG	Technical working group
US FDA	United States Food and drug administration
WHO	World Health Organization
XDR TB	Extremely drug resistant TB

1. HIV Testing and Counseling

Knowledge of HIV status is the entry point to HIV care, treatment and prevention. Service providers should seek every opportunity to offer HIV testing and prevention messages to all clients irrespective of their reason for visit to the health facility. Reference should be made to the national guidelines for HIV Testing and Counseling (HTC) in Kenya. For those who test HIV negative, re-testing should be done after 3 months. Thereafter all re-testing for HIV negative people should be done annually for the general population and quarterly for key populations.

In addition to provision of facility based HIV testing and counseling, Community-based HIV testing and counseling should target specific population needs including key populations (female sex workers, male sex workers, men having sex with men, and intravenous drug users) with linkage to HIV prevention, care and treatment services. The table below provides a summary of recommendation for HIV testing and counseling for different populations.

Topic and population	Recommendations
HIV testing and counseling of infants and children aged less than 18 months	•HIV exposure status of all infants should be established at the 6-week immunization visit or at first contact thereafter, using maternal medical information •Conduct HIV antibody testing for mother or children less than 18 months of age and of unknown status to establish their HIV exposure status •All HIV-exposed infants should be offered routine DNA PCR testing at the 6-week immunization visit, or at the earliest opportunity for infants seen after 6 weeks of age •Infants with an initial positive HIV DNA PCR results should be presumed to be HIV infected and started on ART in line with national guidelines
HIV testing and counseling of children older than 18 months	•Conduct HIV testing and counseling for all children presenting to the health facility irrespective of reason for their visit to the health facility •Conduct HIV testing and counseling for all children of HIV infected adults as soon as possible, within one month of confirming the HIV positive status of the adult

Topic and population	Recommendations
HIV testing and counseling of adolescents	•Conduct HIV testing and counseling for all adolescents including key populations presenting to the health facility irrespective of reason for their visit to the health facility •All adolescents identified HIV positive should be linked to prevention, care and treatment services •All adolescents should be counseled about the potential benefits and risks of disclosure of their HIV status and empowered and supported to determine if, when, how and to whom to disclose •For sexually active adolescents with partners, HIV testing and counseling should be offered to their partners and children
HIV testing and counseling for pregnant and breastfeeding women	•All pregnant women should be counseled and tested for HIV during their first ANC visit and repeat testing conducted in after 3 months for all women who test HIV negative at the first ANC visit. •All breastfeeding women who tested HIV negative during ANC or whose HIV status is unknown should be offered HIV testing and counseling; if negative, re-testing should be done as per national guidelines •All pregnant and breastfeeding women who opt-out or decline HIV testing during the first clinic visit should be offered HIV counseling and testing in subsequent visit(s) •**HIV testing and counseling should be offered to all spouses/sexual partners of HIV-infected pregnant and breastfeeding women**
HIV testing and counseling of sexual partner/s & children of index case (defined as HIV positive person who is already in HIV care)	•HIV testing and counseling should be offered for all family members of index case including sexual partners and children with linkage to prevention, care and treatment
Disclosure of Status to HIV-infected children and adolescents	Health Service Providers should support and advise caregivers to initiate disclosure of HIV status to the HIV infected child preferably from age of 6 Years Full Disclosure should occur when the child is developmentally ready ideally by age of 10 years (Before adolescence)

2. Use of Antiretroviral Therapy in Children

This section of the guideline recommends earlier antiretroviral treatment initiation for children living with HIV. In addition the guidelines recommend use of the most potent, effective and feasible first-line, second-line and third line ARV treatment regimens for children, and routine viral load testing for treatment monitoring.

2.1. When to Start ART in Children

Population	Recommendations
When to start ART in children less than 15 years	•ART should be initiated in all HIV-infected children **aged 10 years and below**, regardless of WHO stage or CD4 count/%. •ART should be initiated in all HIV infected children **above 10 years of age** with CD4 cell count ≤500 cells/mm3, regardless of WHO stage •All HIV-infected children above 10 years with WHO stage 3 and 4 disease, Hepatitis B Virus/HIV, TB/HIV co-infection should be initiated on ART irrespective of CD4 count •In circumstances where DNA PCR testing is not readily available ART should be initiated in any child younger than 18 months of age who meets criteria for presumptive diagnosis of severe HIV disease, **confirmatory DNA PCR testing should be done as soon as possible**

Age	Preferred regimen	Recommendations
Children less than 3 years	ABC + 3TC + LPV/r*	AZT + 3TC + LPV/r*
****Children ≥3-10 years and adolescents < 35 kg**	ABC + 3TC +EFV	ABC + 3TC +NVP AZT + 3TC + EFV AZT + 3TC +NVP
Adolescents (>10-14 years) and weight ≥ 35 kg	TDF+3TC+ EFV	TDF + 3TC + NVP ABC + 3TC+ EFV ABC +3TC+ NVP AZT + 3TC + EFV AZT + 3TC + NVP

An adolescent is a person aged 10 to 19 years
*Children less than 3 years who are not NVP exposed and are unable to tolerate Lopinavir/ritonavir can be substituted to an NNRTI based regimen
**Consider transitioning from ABC based regimen to a simplified once daily TDF/3TC/EFV based regimen in children if their weight remains consistently above 35kg (at least 2 readings, 1 month apart) for better adherence
A viral load test should be conducted before any single drug substitution to rule out treatment failure.

If First line ART regimen	Then Second line ART regimen
ABC + 3TC + EFV/NVP	AZT + 3TC + LPV/r
AZT/D4T + 3TC + EFV/NVP	ABC + 3TC + LPV/r
ABC + 3TC + LPV/r AZT + 3TC + LPV/r	AZT+ 3TC + DRV/r* ABC + 3TC + DRV/r
TDF + 3TC + EFV	Preferred: AZT+3TC+LPV/r Alternative: AZT+3TC+ATV/r**

* Access to DRV/r for second line ART (for children failing first line PI based ART) will be made available through consultation with regional or NASCOP therapeutic TWG. DRV/r is not approved for use in children less than 3 years of age. For children on LPV/r first line who fail treatment at less than 3 years of age, other treatment options such as Integrase inhibitors (e.g. Raltegravir) should be considered.

** Children above 6 years of age can be given ATV/r but currently child friendly formulations are not available. ATV/r is not approved for use in children below 6 years of age.

Current adult formulation of 300mg/100mg of ATV/r available in Kenya can only be used in children weighing >40 kg

Children, who have had multiple single drug substitution of their NRTI during first line ART and subsequently fail first line, may pose a challenge in selecting an appropriate NRTI for use in second line ART. In such cases, consultation with a senior experienced clinician at regional or national level on second line ART ought to be done.

Children newly diagnosed with TB and HIV (ART naïve)
- Start TB treatment immediately as per the national TB guidelines
- Start appropriate ART after TB treatment is tolerated, preferably within 2-8 weeks

Age	Preferred regimen	Alternative regimen	Comments
0-3 years	ABC + 3TC + LPV/r + RTV (add extra dose of RTV to make the LPV/RTV ratio 1:1 (super boosted LPV)	AZT + 3TC+LPV/r ABC + 3TC + EFV* AZT + 3TC + EFV* ABC + 3TC + AZT**	***Note: US FDA has approved use of EFV in children 3 months old and above and weighing more than 3.5 kg. Currently in Kenya, use of EFV in children aged < 3 years and weighing < 10 kg is recommended ONLY in TB/ HIV co-infection management without prior exposure to NVP for PMTCT** **ABC + 3TC + AZT (triple nucleoside) is an inferior regimen and should only be used if other regimens are not tolerated. After completion of TB treatment, change the triple nucleoside based ART regimen to ABC + 3TC + LPV/r
≥3-10 years	ABC + 3TC + EFV	AZT + 3TC + EFV	
>10-14 years	(<35 kgs) ABC + 3TC + EFV (>35 kgs) TDF + 3TC + EFV	AZT + 3TC + EFV	

Child develops TB while on ART
- Assess for treatment failure if patient has been on ART for a period of more than 6 months change the first line regimen to an appropriate 2nd line regimen if treatment failure is confirmed

Age	Current regimen	Recommended ART substitution while on TB treatment	Comment
0-10 years	If EFV-based ART	Continue EFV-based ART	Conduct viral load to rule out treatment failure and manage as per the national guidelines
	If NVP-based ART	Change NVP to EFV	
	If LPV/r-based ART	Super boost LPV/r (LPV : Ritonavir = 1:1)	Switch back to normal dose of LPV/r after completion of TB treatment Conduct viral load to rule out treatment failure and manage as per the national guidelines

Age	Current regimen	Recommended ART substitution while on TB treatment	Comment
		Alternative: Triple nucleoside of ABC+3TC+AZT	Please note that triple nucleoside is an inferior regimen and should only be used in children not able to tolerate super boosted LPV/r Triple nucleoside should not be used in children who have failed 1st line ART; in such cases clinician should consult/refer to a specialist for management Switch back to LPV/r-based regimen after completion of TB treatment
> 10 yrs	EFV-based ART	Continue EFV-based ART	Conduct viral load to rule out treatment failure and manage as per the national guidelines
	NVP-based ART	Change NVP to EFV	
	If LPV/r-based ART	If < 35 kg weight: Super boost LPV/r (LPV:Ritonavir = 1:1) with rifampicin-based TB treatment	Switch back to normal dose of LPV/r after completion of TB treatment Conduct viral load to rule out treatment failure and manage as per the national guidelines
		If weight is > 35 kg: Continue current regimen and use **Rifabutin (150mg once daily)** instead of rifampicin	Conduct viral load to rule out treatment failure and manage as per the national guidelines
	Note: Rifabutin dosing for TB treatment in TB/HIV patients on PI based ART has been reviewed. Rifabutin should be administered as **ONCE DAILY** dosing of 150 mg instead of 150 mg three times a week alongside other anti-TB drugs.		

2.5. Efavirenz Dosing in Children

Weight (kg)	EFV dose (mg)* Tablets	Quantities
3.5 to 4.9	100	½ of the 200mg double scored tablet
5 to 7.4	150	¾ of 200mg double scored tablet
7.5 to 13.9	200	1 of the 200mg tablet
14 to 19.9	300	1 ½ of the 200mg double scored tablet
20 to 24.9	300	1 ½ tablet of the 200mg double scored tablet
25 to 34.9	400	2 of the 200mg tablets
35 and above	600	1 of the 600mg tablet

Ritonavir dosing for super-boosting LPV/r in children taking rifampicin

Ritonavir super-boosting for TB/HIV co-infection			
Weight Range (kg)	**Lopinavir/ ritonavir (LPV/r)**		**Additional dosing of ritonavir for children taking rifampicin**
	TWICE Daily	**TWICE Daily**	**TWICE Daily**
	80mg Lopinavir/ 20mg ritonavir per ml **solution**	200mg Lopinavir/ 50mg ritonavir **Tablets**	**Ritonavir liquid (80mg/ml, in 90 ml bottle)** Ritonavir dose is adjusted to nearest mark for the ease of measurement
3 - 5.9	**1.5 ml**	-	**1 ml**
6 - 9.9	**1.5 ml**	-	**1 ml**
10 - 13.9	**2 ml**	-	**1.5 ml**
14 - 19.9	**2.5ml**	**1 tab twice daily**	**2ml or 2 of 100mg capsules twice daily**
20 - 24.9	**3 ml**	**1 tab twice daily**	**2.5 ml or 2 of 100mg capsules**
25 - 34.9	**4 ml**	**2 tab in am & 1 tab in pm**	**4 ml in am & 2 ml in pm or 2 of 100mg capsules in morning and 3 of 100mg capsules in evening**

2.7. ARV Prophylaxis for HIV-Exposed Infants

	Scenario	Maternal ARV prophylaxis	Infant ARV prophylaxis	Duration of infant ARV prophylaxis
1	Mother diagnosed with HIV during pregnancy at any gestation, labour, delivery and immediate post-partum irrespective of feeding option	Initiate maternal ART	NVP	•Immediately initiate NVP prophylaxis for 12 weeks •Do HIV PCR test in accordance with national recommendations on early infant diagnosis; •Initiate treatment if the infant is infected
2	Infant identified as HIV exposed after birth (through infant or maternal HIV antibody testing) and is breastfeeding	Initiate maternal ART	NVP	•Immediately initiate NVP prophylaxis •Do HIV PCR test in accordance with national recommendations on early infant diagnosis •If results positive , initiate ART and stop NVP prophylaxis •If results negative, continue NVP prophylaxis up to 12 weeks

	Scenario	Maternal ARV prophylaxis	Infant ARV prophylaxis	Duration of infant ARV prophylaxis
3	Infant identified as HIV exposed after birth (through infant or maternal HIV antibody testing) and is not breastfeeding/on replacement feeding	Refer mother for HIV care and evaluation for treatment	No drug	•Do HIV PCR test in accordance with national recommendations on early infant diagnosis; •No infant ARV prophylaxis; •Initiate treatment if the infant is infected
4	Mother receiving ART but interrupts ART regimen while breastfeeding (such as toxicity, stock-outs or refusal to continue)	Determine an alternative ART regimen or solution; counsel regarding continuing ART without interruption	NVP	Initiate NVP until 12 weeks after maternal ART is restarted or until 1 week after breastfeeding has ended if mother does not restart ART Do HIV PCR test in accordance with national recommendations on early infant diagnosis;

2.8 Nevirapine dosing for HIV Exposed Infants

Age	Nevirapine Dose
0 - 6 weeks	Birth weight < 2500 g - 10 mg (1 ml) once daily Birth weight > 2500 g - 15 mg (1.5 ml) once daily
6 weeks - 14 weeks	20 mg (2 ml) once daily
14 weeks to 6 months	25 mg (2.5 ml) once daily
6 months - 9 months	30 mg (3 ml) once daily
9 months - 12 months	40 mg (4 ml) once daily
> 12 months	50 mg (5 ml) once daily

2.9 Cotrimoxazole dosing for HIV Exposed Infants and HIV-infected children

Weight (kg)	Suspension 240 mg per 5ml	Single strength tablet 480mg (SS)	Double strength tablet 960mg (DS)
1 – 4	2.5 ml	¼ SS tab	–
5 – 8	5 ml	½ SS tab	¼ DS tab
9 – 16	10 ml	1 SS tab	½ DS tab
17 – 30	15 ml	2 SS tabs	1 DS tab
> 30 (Adults and adolescents)	-	2 SS tabs	1 DS tab

Notes: In HIV Exposed Infants, cotrimoxazole prophylaxis should only be discontinued when there is no further exposure to HIV through breastfeeding and the final HIV result following complete cessation of breastfeeding is negative.
For HIV-infected children, cotrimoxazole should be continued for life.

3. Use of ART in Adolescents and Adults

Use of antiretroviral drugs in management of HIV infection has transformed HIV from a debilitating and fatal disease to a manageable chronic disorder. The use of ART has led to reduction in death rates, hospitalization and the incidence of opportunistic infections among HIV-infected people. Accumulating evidence has shown that treatment of the HIV -infected sexual partners in a sero-discordant relationship markedly reduces the risk of HIV transmission to the HIV negative partner.

Further emerging evidence has shown that the use of ART in pregnant and breastfeeding women markedly reduces the transmission of HIV infection from mother to child. Continuing ART for life for the mother provides additional benefit of keeping mothers healthy and alive.

This guideline recommends earlier initiation of ART for adolescents and adults, all HIV-infected pregnant and breastfeeding women, and all HIV-infected spouses and sexual partners in sero-discordant relationships. The guidelines further recommend the use of simplified once-a-day fixed-dose-combination ARV pill, and routine viral load for treatment monitoring.

3.1 When to Start ART in Adolescents and Adults

Population	Recommendations
When to start ART in adolescents ≥15 years and adults	•All HIV-infected adolescents and adults with CD4 count <500 cells/mm3 irrespective of WHO stage •All HIV-infected pregnant women irrespective of CD4 count, WHO stage or gestation age* •All HIV-infected breastfeeding women irrespective of CD4 count, WHO stage* •All HIV-infected spouses and sexual partners in sero-discordant relationships irrespective of their WHO stage or CD4 cell count •All HIV-infected adolescents and adults with WHO stage 3 and 4 disease irrespective of CD4 count •All Hepatitis B Virus/HIV co-infected persons irrespective of CD4 count •All TB/HIV co-infected persons irrespective of CD4 count
***Note for pregnant and breastfeeding women** The use of ART in pregnant and breastfeeding women markedly reduces the transmission of HIV infection from mother to child. Continuing ART for life for the mother provides additional benefit of keeping mothers healthy and alive, and may also offer benefits for preventing sexual transmission of HIV in sero-discordant relationships. **The Ministry of Health recommends immediate initiation of life-long ART in pregnant and breastfeeding women upon HIV diagnosis with continuous adherence support.** Evidence shows that HIV positive women coming late for ANC and initiated on ART have high likelihood of defaulting on HIV treatment. Deliberate and focused patient support and defaulter tracking mechanism need to be put in place to ensure compliance to HIV treatment.	

	Preferred regimen	Alternative regimen
First - line ART regimens for adolescents (≥15 years) and Adults	TDF* + 3TC + EFV	TDF+3TC+NVP AZT + 3TC + EFV AZT + 3TC + NVP
First - line ART regimens for HIV-infected sexual partner in a sero-discordant relationship	TDF* + 3TC + EFV	TDF+3TC+NVP AZT + 3TC + EFV AZT + 3TC + NVP
First - line ART regimens for pregnant women and breastfeeding mothers	TDF* + 3TC + EFV**	TDF+3TC+NVP AZT + 3TC + EFV AZT + 3TC + NVP
First line ART regimen to start in all women with previous exposure to NVP through PMTCT		
Less than 24 months since previous NVP Exposure	TDF* + 3TC + ATV/r***	TDF + 3TC + LPV/r AZT + 3TC + ATV/r AZT + 3TC + LPV/r
More than 24 months since previous NVP exposure	TDF* + 3TC + EFV	TDF+3TC+NVP AZT + 3TC + EFV AZT + 3TC + NVP

* For patients with pre-existing renal disease initiating ART, ABC + 3TC + EFV is preferred. No dose adjustments is required for ABC

**Systematic review and meta-analysis data including ARV pregnancy registry reviews have not found an increase in overall birth defects in pregnant women using Efavirenz compared to other ARV exposure in pregnancy. The World Health Organization (WHO) June 2013 guidelines on use of Antiretroviral drugs recommend use of Efavirenz at any gestation with more heightened surveillance for any birth defects.

*** Hyperacidity and hence use of over the counter antacids are common occurrence in pregnancy. Caution should be exercised in pregnant women initiating ART regimens containing ATV/r who concomitantly use antacids. LPV/r remains an alternative in such cases. Service providers should actively ask about OTC medications. Refer to 3.4 on administration of antacids and ATV/r

If First line ART regimen	Preferred Second line ART	Alternate Second line ART regimen
TDF + 3TC + EFV	AZT + 3TC + ATV/r	AZT + 3TC + LPV/r*
AZT + 3TC + EFV/NVP D4T+ 3TC+ EFV/NVP	TDF + 3TC + ATV/r	TDF + 3TC + LPV/r
TDF + 3TC+ATV/r/LPV/r	AZT + 3TC+DRV/r**	-

- ATV/r is the preferred PI for starting new patient on second line ART. ATV/r can be used as an alternate in patients who do not tolerate LPV/r due to Adverse drug reactions
- Patients currently on LPV/r based ART regimen who have no intolerance, need not be changed to ATV/r based ART

** Access to DRV/r for second line ART (for adults failing first line PI based ART) will be made available through consultation with regional or NASCOP therapeutic TWG

3.4 Dosing and Administration for Atazanavir/ritonavir (ATV/r)

Atazanavir (ATV) is a protease inhibitor in the same class as Lopinavir (LPV) and requires pharmacologic boosting with ritonavir as does Lopinavir. The available ATV/r tablet is a co-formulation of ATV and ritonavir. It is taken once daily.

Recommended Dosage

Adults and children > 40 kg

- 1 fixed dose combination tablet of ATV 300mg/ RTV 100mg given once daily

Children

- ATV/r is not recommended for children aged less than 6 years

Dosing for children aged 6 -18 years

Weight (kg)	Once daily dose
15 to <20 kg	ATV 150 mg plus RTV 100 mg, once daily with food
20 to <40 kg	ATV 200 mg plus RTV 100 mg, once daily with food
≥40 kg	ATV 300 mg plus RTV 100 mg, once daily with food

NB: Formulations for children weighing below 40kgs are currently NOT available in the national program. The ATV 300/ RTV 100mg tablet should NOT be crushed or split.

- Atazanavir/ritonavir must be taken with food to enhance absorption.
- Tablets should be taken whole and should NOT be crushed or split

Co-administration with other medicines

- ATV absorption is dependent on low gastric pH; therefore ATV/r co-administered with proton-pump inhibitors (PPI) eg Omeprazol, or H2-receptor antagonists (eg cimetidine, ranitidine) should be avoided. If given it should be administered with food about 12 hours after the proton-pump inhibitor or H2-receptor antagonists.
- ATV/r should be used with caution in patients taking antacids, ATV/r should be taken 2 hours before or 1 hour after the use of antacids
- Patient with peptic ulcer disease who are likely to continuously use antacids, PPI or H2-receptor antagonist should preferably be started on LPV/r

General information:

- ATV/r is safe to use in pregnancy
- ATV/r co-administered with rifampicin results in reduced blood levels of ATV/r. In TB/HIV co-infected patient on ATV/r, Rifampicin should be replaced with Rifabutin 150mg once daily.

Contra-indications / pre-cautions

- Not recommended for use in children aged less than 6 years

Common Toxicities

Atazanavir/ritonavir is generally well tolerated, it has fewer GI intolerance and less effects on lipid profile compared to LPV/r partly as a result of reduced ritonavir used.

Common toxicities include headache, fever, arthralgia, depression, insomnia, dizziness, nausea, vomiting, and diarrhea. These effects tend to go away with time in the course of treatment.

Patients taking ATV/r may experience asymptomatic elevation of indirect bilirubin (uncobjugated bilirubin) which may result in jaundice or icterus. Jaundice from unconjugated hyperbilirubinemia is largely a cosmetic issue and not related to hepatitis or liver damage. Service providers should exclude other causes of jaundice and advice clients appropriately. Adverse events even when cosmetic may be disturbing to the patients; service providers should offer a substitution to LPV/r to patient who experience significant jaundice.

Kidney stones (nephrolithiasis) has been reported in patient taking ATV/r, although this is a rare occurrence, health service providers should be monitor patients closely.

TB patient newly diagnosed with HIV (ART-naïve)
•Start TB treatment immediately as per the national TB guidelines
•If ART-naïve, start ART after TB treatment is tolerated, within 2-8 weeks

Scenario	ART regimen	Comments
Newly diagnosed HIV in a TB patient (ART naive)	Preferred: TDF + 3TC + EFV Alternative: AZT + 3TC + EFV	Continue same ART regimen after completing TB treatment. ART is not considered to be failing within 6 months of initiation
Patient develops TB while on ART •Carry out a viral load(VL) test if patient has been on ART for a period of more than 6 months and does not have a recent undetectable viral load; change the first line regimen to an appropriate 2nd line regimen if treatment failure is confirmed		
If on NVP-based first line ART regimen	Change NVP to EFV	•Assess for treatment failure •Continue additional adherence counseling and support
If on LPV/r or ATV/r-based regimen	Continue current regimen and use **Rifabutin (150mg given once daily)** instead of rifampicin* for TB treatment *Rifampicin use with LPV/r or ATV/r should be avoided due to drug interactions In circumstances where Rifabutin is not available, alternative options include •Superboost LPV/r with ritonavir to make LPV: Ritonavir ration to 1:1 •Double the dose of LPV/r Note: These two scenarios increases intolerability to LPV/r hence preference for Rifabutin	•Assess for treatment failure •Continue additional adherence counseling and support

4. Third line ART for children, adolescents and adults

Currently there are limited treatment options beyond the drugs recommended for second-line ART. Durable viral suppression on first line ART is the key to treatment success and long life. As such, patients should be made aware that adherence to first line ART is very key for treatment success. Adherence to ART must be supported to the largest extent possible, both at facility and community levels. ARVs for constituting a third line ART regimens are not readily available, however if an ART client is in need of third line, clinical summary form should be sent to the National Therapeutics TWG through 3rdline@nascop.or.ke for guidance on further management. The patient should continue with current 2nd line ART with intensified adherence efforts including adherence counseling, Direct Observed Treatment Supervision (DOTS) and home visits.

- Patients should not be started on third-line drugs unless they are fully prepared and are ready for the treatment.
- Monitoring requirements for patients on third line ART are the same as for other patients. The first visit should be at 2 weeks following 3rd line ART initiation and thereafter monthly till adherence is assured and then less frequently as appropriate.
- Directly observed treatment supervision should be instituted for the first 3 months of treatment. This should involve engaging a treatment supporter including family member or a community health worker
- Adherence assessment must be conducted at each visit (e.g. pill count, self-reports), both with the treatment supporter/CHW/family member and with the patient.

ARV drugs for constituting a third line regimen will include new drugs with minimal risk of cross-resistance to previously used regimens. These include integrase inhibitors, new-generation NNRTIs and PIs. Third line regimen must be based on HIV drug resistance patterns in non-adherent patient.

- Symptom-based TB screening using ICF tool MUST be done for all PLHIV at every visit to rule out active TB
- Infection control measures should be given priority to reduce TB transmission in all settings that provide patient care
- Investigations for TB should be performed in accordance with existing national guidelines
- Chest radiography is not required as part of routine screening; however patients deemed to be TB suspects, should have a chest X ray where sputum is unavailable

5.1. Indications for Isoniazid Preventive Therapy

- HIV-infected children less than 12 months of age who have had recent contact with active TB disease with no evidence of TB
- All PLHIV above 12 months of age who screen negative for TB using the ICF tool
- All children under 5 years irrespective of HIV status who had recent close contact (past 12 months) of smear positive TB case
- Prisoners, irrespective of HIV status

Note:

- Past history of TB and current pregnancy are not contraindications for starting isoniazid preventive therapy. IPT can be started at any time after successful completion of TB treatment.
- IPT has not been shown to increase the risk of developing isoniazid-resistant TB.

5.2 Duration and Dose of INH for IPT

- IPT should be given at a dose of 10 mg/kg/day (maximum 300 mg) for duration of 6 months

Dose of INH for IPT

Weight range (kg)	Dose in mg	Number of 100mg INH tablets	Number of 300mg (Adult) tablet
<5	*50*	*½ tablet*	-
5.1-9.9	*100*	*1 tablet*	-
10-13.9	*150*	*1 ½ tablet*	*½ tablet*
14-19.9	*200*	*2 tablets*	-
20-24.9	*250*	*2 ½ tablets*	-
>25	*300*	*3 tablets*	*1 tablet*
Adults	*300*	-	*1 tablet*

5.3. Dosing of Pyridoxine for All Patients taking Isoniazid

All patients taking INH (whether for IPT or TB treatment) should also receive daily pyridoxine to reduce the risk of developing peripheral neuropathy.

Weight (kg)	Number of tablets of pyridoxine (50mg)
5-7	(1/4) quarter tablet daily
8-14	(1/2) half tablet daily
≥ 15	(1) one full tablet daily

5.4 Follow Up of Patients on IPT

All patients on IPT should be;
Reviewed monthly and adherence messages reinforced

- Screened for active TB during each clinic visit using the intensive case finding (ICF) form
- Should have their ICF cards and IPT register record updated at every visit and outcome documented on completion of therapy
- Monitored for INH adverse events at every visit (co administer with pyridoxine to minimize adverse events)
- The facility should maintain a TB contact register

5.5 Contraindications to IPT

- Active hepatitis (acute or chronic)
- Regular and heavy alcohol consumption
- Symptoms of peripheral neuropathy

IPT should be discontinued in symptomatic patients with ALT/AST more than three times the upper normal limits

5.6. Use of Xpert MTB/Rif (GeneXpert) in Diagnosis of TB for PLHIV

GeneXpert is a molecular diagnostic test for TB disease that can detect Mycobactrium tuberculosis DNA and Rifampicin resistance from sputum specimen in less than 2 hours. This technology is more sensitive than sputum microscopy in detecting TB. In addition, its ability to detect smear negative TB provides added advantage in people living with HIV. GeneXpert is increasingly available in Kenya in the public health sector and is now recommended by Ministry of Health-NLTD-Unit for TB diagnosis in all HIV- infected persons suspected to have TB using the ICF/IPT screening tool.

Note: Refer to the algorithm on "Use of GeneXpert for Diagnosis of Drug Resistance and Surveillance of TB" (Annex 3)

6.1. Use of CD4 Count for Monitoring PLHIV

Indications for CD4 Count

- A CD4 count should be performed for all PLHIV at time of enrollment into care to support eligibility criteria for ART. This will also serve as a baseline for monitoring clinical progress of those not qualifying for ART immediately.
- All PLHIV who are not on ART should be receive CD4 count testing every 6 months to determine their eligibility for ART
- All patients on ART who are on secondary fluconazole prophylaxis should receive CD4 count testing every 6 months to determine when to discontinue their prophylaxis
- Where viral load monitoring is not readily available, 6 monthly CD4 count testing is still recommended for monitoring ART response
- CD4 count may be performed to aid in the differential diagnosis of PLHIV who present with new signs/symptoms of an OI, regardless of ART status. For example in a patient presenting with focal neurological signs with CD4 cell count of less than 100 cells/mm3 toxoplasmosis is likely, while if CD4 cell count is 400 cells/mm3 Toxoplasmosis is unlikely, just as a patient presenting with worsening dyspnea and with a CD4 of 500cells/mm3 is unlikely to have PCP

Note: The following populations do not require CD4 count testing to determine eligibility for ART e.g. children less than 10 years, pregnant women and other clinical conditions mentioned in previous sections (2.1, 3.1) hence CD4 count testing should not delay ART initiation in such populations. However, baseline CD4 cell count is recommended for all PLHIV at enrolment

6.2. Use of Viral Load in ART monitoring

Viral load measurement is gold standard for monitoring ART treatment response. The Ministry of Health now recommends routine viral load testing for all patients on ART. Where routine viral load is not accessible, CD4 count and clinical monitoring should be used to monitor treatment response and identify patients likely to be failing treatment. In such circumstances, suspected treatment failure should be confirmed using viral load testing. Health care providers should be familiar with viral load networks in their region and ensure patients benefits from these services.

It is important for healthcare managers (health facility in-charges, medical superintendent and county health management teams) to establish systems for viral load access in their region if none exist.

Recommendations for Viral Load Testing

- All HIV-infected children, adolescents and adults initiating ART (1st, 2nd or 3rd line ART regimens) should receive a viral load test 6 months following ART initiation, at 12 months and thereafter one viral load test per year.
- All HIV-infected children, adolescents and adults continuing on ART should receive one viral load test per year for monitoring treatment response
- All HIV-infected children, adolescent and adults on ART found to have detectable viral loads (viral RNA > 1,000 copies/ml) on routine viral load testing should receive a repeat viral load test after 3 months following adherence intensification interventions to confirm treatment failure.
- All HIV-infected pregnant women initiating ART should receive a viral load test after 6 months of ART initiation. If viral load is >1,000 copies/ml, adherence should be optimized and repeat viral load testing conducted after 3 months. If a decision to change ART is made, it should be expedited
- All HIV-infected women who become pregnant while on ART and have not had a viral load test in the preceding 6 months, should have a viral load test done as soon as possible upon diagnosis of pregnancy. If viral load is >1,000 copies/ml, adherence should be optimized and repeat viral load testing conducted after 3 months. If a decision to change ART is made, it should be expedited.
- Viral load testing should be performed before making any single-ARV drug substitution if the patient has been on ART for more than 6 months.

Note:
Patients on ART and able to access routine viral load testing as described above should not have routine CD4 cell count measurement while on ART

It is important that a pregnancy intention is assessed routinely as part of enrollment into HIV care and periodically as necessary in women/couples of reproductive age. Women/couples who do not wish to conceive should be offered effective contraception, in addition to condoms. Further, as part of family assessment for HIV care needs, spouses and sexual partners should be tested for HIV as soon as disclosure is done and testing feasible. This will enable discordant couples to be identified and allow proactive support of reproductive desires.

Pre-Conception Care for Concordant Positive or Discordant Couples

- Intensive counseling should be offered to enhance prevention to partners and the baby
- The HIV-infected partner/s should initiate ART regardless of CD4 count or WHO stage if they are planning to conceive (using recommended standard first-line ART)
- Pregnancy should be deferred until the **viral load is undetectable** for the HIV-infected partner/s.
- Unprotected sexual intercourse should be limited to days when ovulation is expected and should deferred until viral load suppression is confirmed
- Use basal temperature monitoring, fertility calendar based on menstrual cycles, and/or an on-line fertility calculator to predict expected ovulation days
- Pre-conception investigations include:

o Hb (manage anemia as early as possible)
o Serum RPR for syphilis screening
o Symptom screening and syndromic management for other STIs
o Cervical cancer screening

- Offer nutritional assessment and counseling and begin the women on folic acid supplementation
- Encourage the couple to seek prenatal care in a facility where they will be able to have continuity of care and the records of the preconception care captured. The male partner should be encouraged to participate in prenatal visits and assist in birth plan

- Virologic suppression should be ensured in the HIV-infected male prior to attempting conception. This minimizes the risk of HIV transmission to the un-infected female partner and subsequently to the baby.
- Where feasible, sperm-washing which reduces the risk of the woman becoming infected followed by artificial insemination may be an option. Couples, who choose this option, may be referred to a center with an obstetrician/gynecologist for specialist management.

Discordant Couples Who Want to Conceive, Female is HIV-infected

- When the female partner is HIV-infected, sperm washing is not beneficial, but artificial insemination can still be used where feasible to minimize the risk of the man from becoming infected

NOTE: Viral suppression for HIV-infected partner(s) on ART should be optimized for clients planning to conceive to minimize risk of HIV transmission to uninfected partner and to the baby.

8. Post-Exposure Prophylaxis (PEP)

ARV prophylaxis is recommended for occupational and non-occupational high risk exposure.

Risk assessment after exposure to body fluids

	Low Risk	High Risk
Type of Exposure	Intact skin	Mucus membrane/ non-intact skin Percutaneous injury
Source	HIV negative	HIV status unknown; clinically well/ unwell
Material	Saliva, tears, sweat, faeces, urine, sputum, vomit	Semen, vaginal secretions, synovial, pleural, pericardial, peritoneal, amniotic fluids Blood and bloody bodily fluids; CSF; viral cultures in labs

Summary of medical management of medical PEP

Considerations	Recommended Action
Eligibility	High risk exposure Exposure within 72 hours Exposed individual is not HIV infected Source individual HIV positive or of unknown HIV status
Counseling and testing the exposed individual	Offer information on risks and benefits Verbal consent adequate Base-line HIV test in HIV exposed person Voluntary testing for both exposed and source individuals
ARV agents for PEP x 1 month	Adult: Preferred : TDF + 3TC + ATV/r
	Children: Preferred : ABC + 3TC + LPV/r
Time of initiation	As soon as possible after exposure, but no later than after 72 hours
Duration of therapy	28 days
Dose of PEP	Same as indicated for ART; use dosing wheel for children

Follow-up	Follow up client at 7 days, 14 days and 28 days Follow-up HIV testing at 3 and 6 months after exposure Pregnancy testing Hb (if AZT-containing regimen used for PEP) Hepatitis B vaccination if not previously immunnized Management of side effects due to PEP
Counseling	Adherence counseling, risk reduction, trauma and mental health counseling, social support and safety
Other services for sexual assault	STI prophylactic treatment to all Emergency contraceptive for non-pregnant women Tetanus Toxoid for any physical injury of skin or mucous membranes Documentation of clinical evidence of assault and collection of forensic evidence **NOTE:** Refer to National Guidelines on management of Sexual Violence in Kenya for comprehensive management

Note: Counseling on behavior change and risk reduction should be offered to clients with repeated exposure risks

9. Pre-Exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis (PrEP) for HIV is the daily use of ARV drugs by HIV uninfected people to prevent the acquisition of HIV.

PrEP is not currently recommended for routine use in Kenya except in research settings.

Weight Range (kg)	Fixed dose combination			Single formulations where FDCs are not available						
	Abacavir (ABC) + Lamivudine (3TC)	Zidovudine (ZDV) + Lamivudine (3TC)	Zidovudine (ZDV) + Lamivudine (3TC) + Nevirapine (NVP)	Efavirenz (EFV)	Nevirapine (NVP) (use weight appropriate formulation)		Lopinavir/ Ritonavir (LPV/r)		Additional dosing for ritonavir for TB/HIV co-infection	
	TWICE Daily	TWICE Daily	TWICE Daily	ONCE Daily	ONCE daily for first 2 weeks then twice daily		TWICE Daily		TWICE Daily	
	60mg ABC + 30mg 3TC tablets	60mg ZDV + 30mg 3TC tabs	60mg ZDV + 30mg 3TC + 50mg NVP tabs	200mg EFV tabs	10 mg/ml suspension	200 mg tabs	LPV/r 80/ 20mg per ml solution	LPV/r 200/ 50 mg tabs	RTV liquid (80mg/ml as 90ml bottle)	RTV capsule 100mg
3 - 5.9	1 tab	1 tab	1 tab	See notes	5 ml	_	1.5 ml	-	1 ml	_
6 - 9.9	1.5 tab	1.5 tab	1.5 tab	See notes	8 ml	_	1.5 ml	-	1 ml	_
10- 13.9	2 tab	2 tab	2 tab	1 tab	10 ml	0.5 tab	2 ml	-	1.5 ml	_
14- 19.9	2.5 tab	2.5 tab	2.5 tab	1.5 tab	15 ml	1 tab in am 0.5 tab in pm	2.5 ml	1 tab twice daily	2 ml	2 cap
20- 24.9	3 tab	3 tab	3 tab	1.5 tab	15 ml	1 tab in am 0.5 tab in pm	3 ml	1 tab twice daily	2.5 ml	2 cap
25- 34.9	300 + 150 mg	300 + 150 mg	300/150/ 200 mg	2 tab	_	1 tab	4 ml	2 tab in am 1 tab in pm	4 ml in am & 2 ml in pm	2 cap in am & 3 cap in pm

Paediatric fixed dose combinations (FDCs) are available as **ABC/3TC, AZT/3TC** and **AZT/3TC/NVP**. All children requiring ART should be put on appropriate FDCs based on their weight.

ABC/3TC tablets - can be chewed or crushed or dispersed in water (5-15 ml) or onto a small amount of food and immediately ingested. Children above 25 kg should be treated as per the adult dose of ABC 300mg+ 3TC 150 mg twice daily.

AZT/3TC and **AZT/3TC/NVP** tablets are water dispersible and should be given in 5-15 ml of water.

For adolescents on ABC based regimen consider transitioning to **TDF/3TC/EFV** if their weight remains consistently > 35kgs (at least 2 readings one month apart) for better adherence. Available Tenofovir/Lamivudine and Tenofovir/Lamivudine/Efavirenz FDCs - can be used in children older than 10 years and above 35 kgs.
Reference should be made to the national guidelines for dosing.

Single formulations

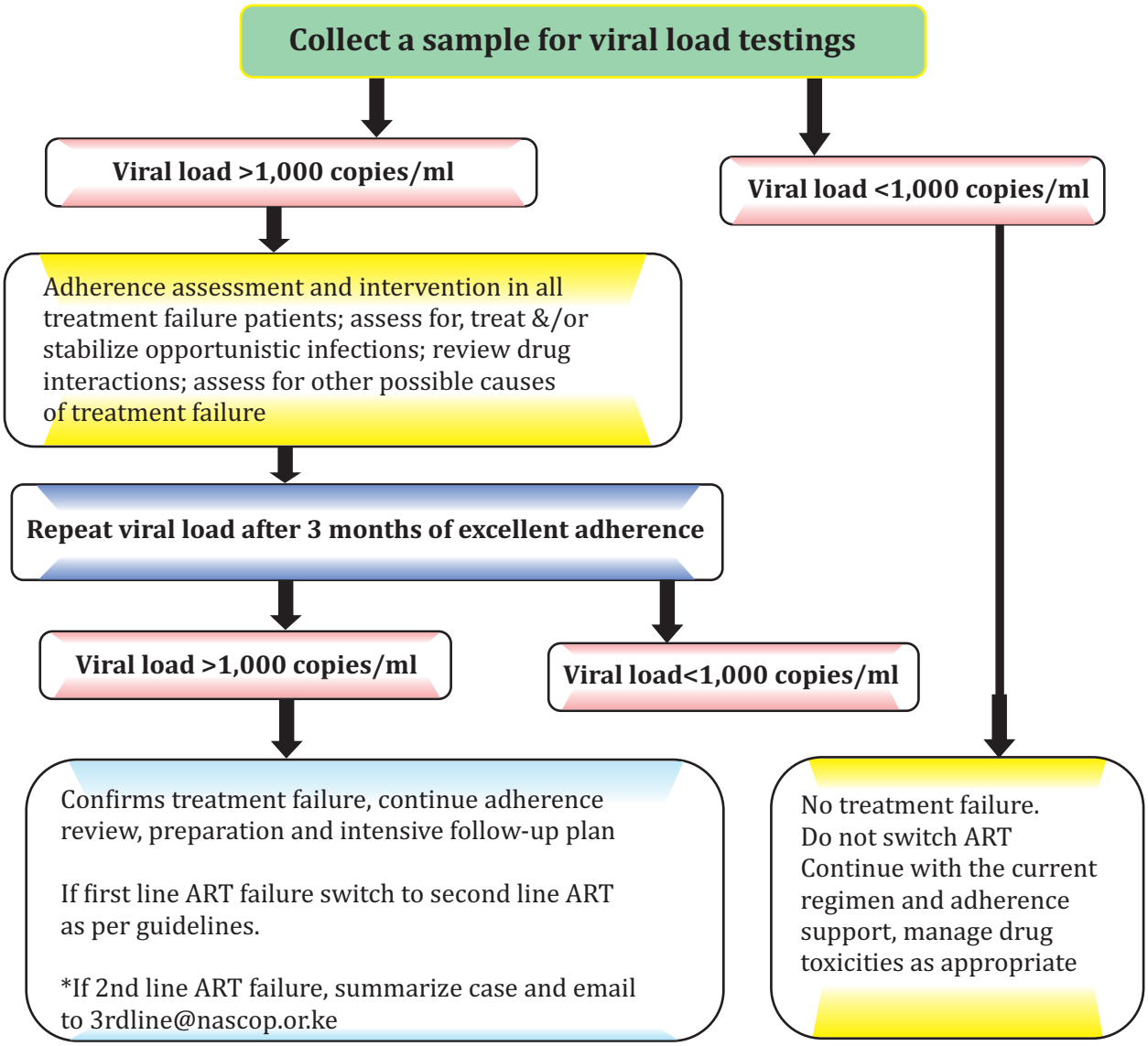
These formulations should only be used where appropriate Paediatric or adult FDCs cannot be used.

Abacavir (ABC) - tablets may be swallowed whole or crushed.
Lamivudine (3TC) - tablets may be swallowed whole or crushed
Efavirenz 200mg - tablet is double scored and may be divided into four or two equal parts. Tablet may be crushed and dispersed in water (5-15 ml) or onto a small amount of food and immediately ingested.
Lopinavir/ritonavir - dose is calculated based on Lopinavir component. Oral solution should be taken with food. Oral solution must be refrigerated until dispensed. After removing from refrigeration oral solution is only stable for 60 days (2 months) at room temperature (up to 25° C). Where temperatures are expected to exceed 25°C, the feasibility of dispensing smaller amounts and giving more frequent refills should be considered (for instance, no more than monthly supplies dispensed at one time). The amount of solution has been rounded up to nearest ½ ml for easier measurement as per the manufacturer's recommendation.
Ritonavir Liquid - Children with TB/HIV co-infection who are on LPV/r based ART, will need additional dosing with Ritonavir to make LPV: RTV as 1:1 (due to reduced concentration of LPV/r when used with Rifampicin) and should be given as indicated. The dosing is rounded off to nearest ml for ease of administration of RTV.

Use of Efavirenz in younger children

The US FDA has approved use of EFV in children 3 months and above and weighing more than 3.5 kg.

Currently in Kenya, use of EFV in children aged <3 years and weighing <10 kg is recommended ONLY in TB/ HIV co-infection management without prior exposure to NVP for PMTCT (for EFV dosing refer to 2.5)



NB: Plasma remains the preferred specimen type for viral load testing. Facilities in close proximity and easy access to a testing laboratory should use plasma samples. Facilities with poor access or in remote areas should use DBS.

Guidance for second line ART failure

- *Patients confirmed to have failed 2nd line ART treatment failure: Summarize case in the clinical summary form provided by NASCOP and submit to 3rdline@nascop.or.ke for approval of Drug Resistance Testing
- NASCOP ART Therapeutics TWG will determine need for DR testing and advise the facility. Results of HIV DR testing should be submitted to this TWG to determine ART regimen
- Meanwhile continue with current regimen

Indications for GeneXpert

TB Diagnosis

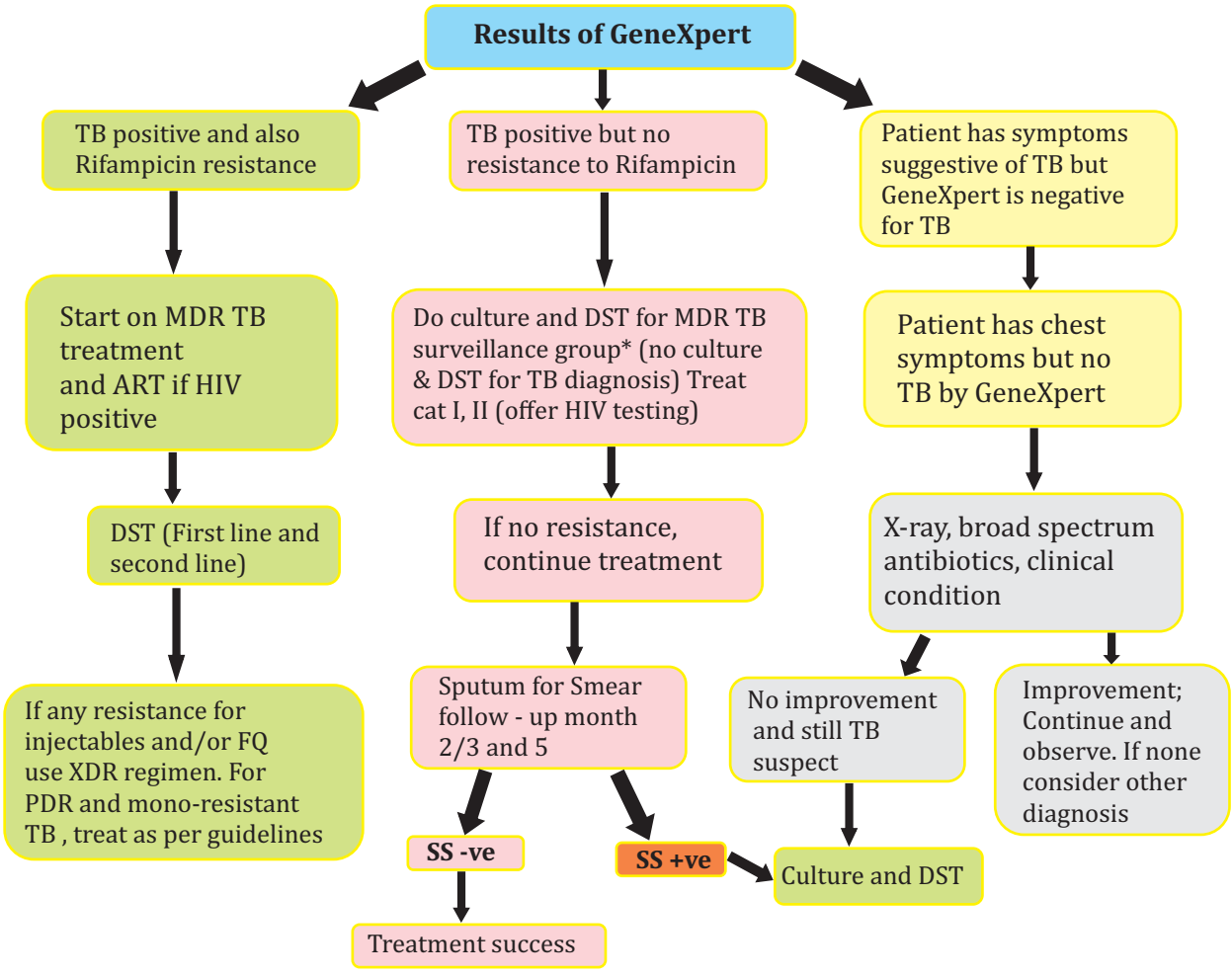
- HIV positive with TB symptoms using screening with TBICF/IPT tool
- Children under 15 years with TB symptoms*

MDR TB surveillance

- All previously treated patients: a. failures; b. relapses; c. treatment after loss to follow up
- DR TB contacts
- Healthcare workers with TB symptoms
- Patients who develop TB on IPT
- Refugees with symptoms of TB
- Smear positive at 2 months

In areas where GeneXpert is available: this should be the first test

Patients diagnosed with GeneXpert should be followed up with microscopy



County Health management teams and Health facility managers should ensure all service providers are updated on the new recommendations through facility level CMEs, on-job trainings and continued mentorship.

HIV testing and counseling and linkage to HIV Care and Treatment

- HIV testing and counseling services should be accompanied by appropriate pre-test information (which can be provided as group pre-test information in some settings) and post-test counseling.
- Quality assurance mechanisms and supportive supervision and mentoring systems should be in place to ensure the provision of quality counseling.
- All Clients identified as HIV positive should be referred and linked to appropriate prevention, care and treatment services upon HIV diagnosis.
- Proper documentation of all referrals including tracking of referrals should be maintained at the points of HIV testing

Early infant Diagnosis (EID) of HIV and HIV exposed Infant follow- up

- All children coming for their 6 weeks immunization visit should be assessed for HIV exposure and DBS samples for DNA PCR testing collected for all HIV-exposed infants (HEI).

- Once infants /children are identified as HIV exposed, a HIV exposed Infant follow up Card should be opened for each infant/child .In addition the child's details should be entered in the HIV exposed infant register which should be updated regularly.

- The follow up of all HIV exposed infants should be integrated in the MCH clinic together with that of the mother until the age of 2 years

- Cohort analysis for HIV exposed infants should be conducted routinely to determine outcomes at 6 weeks, 9 months and 18 months based on the HEI register.

- HIV-infected infants/children identified through EID at the MCH clinics should be followed up and HIV Care services including ART initiated as per guidelines at the MCH preferably up to the age of two years when care for the child and mother should be transitioned to the HIV Comprehensive Care Clinics depending on the health facility set-up.

Children

- To ensure all children aged 10 years and below initiate ART as per guidelines, health facilities should conduct immediate file and register reviews to ensure all such patients currently in care and not on ART are identified, reached and initiated on ART as required with appropriate treatment preparation.

- Facilities should provide care giver education to all parents/guardians of children under their Care on HIV & ART, importance of adherence, retention and treatment support.

- Service providers must take weight measurements on every visit for children on ART and ensure appropriate weight based dose adjustments of their ARVs are made.

Adolescents and Adults

- In view of the recommendation to initiate ART earlier, health facilities should conduct immediate file and register reviews to ensure that all patients in their care who meet the eligibility criteria for ART and are not ART are identified, reached and initiated on ART as required with appropriate treatment preparation.

Services for Pregnant Women for Prevention of Mother to Child Transmission

HIV - infected pregnant women identified during ANC visits

- All pregnant women identified as HIV positive during their ANC visits should have antiretroviral therapy initiated in the same day as that of HIV Diagnosis.

- Treatment preparation sessions , adherence counseling and psychosocial counseling support should be initiated on same day of HIV diagnosis and sustained to support adherence and retention

- Samples for baseline tests including ANC profile, CD4 testing , Biochemistry should be collected on same day of HIV diagnosis and ART initiation

- A supply of ARVs for 1 month should be provided to the mother

- A return appointment of one-two weeks should be scheduled to receive results of baseline tests, adherence assessment and counseling and support and assessment for toxicities

- Subsequent follow –up visits should be scheduled monthly for the first 6 months and three monthly thereafter if stable and should provide ART refills, adherence assessment and support , evaluation for adverse events to ART, OI screening and management, counseled on maternal, infant and young child feeding and other clinical evaluation

- All pregnant HIV-infected women in addition to receiving ART should assessed and m managed for opportunistic infections, receive cotrimoxazole prophylaxis, screened for TB and provided with isoniazid prophylaxis if TB is ruled out, linked to psychosocial support groups and counseled on maternal, infant and young child feeding.

HIV -infected women identified in labour/delivery

- All women identified as HIV positive during labour/delivery should be provided with their first dose of ART upon HIV diagnosis and provided with at least 1 month supply of ART on discharge

- Treatment preparation sessions , adherence counseling and psychosocial counseling support should be initiated in the immediate post-partum period before discharge and continued in the follow up visit at two weeks

- Subsequent follow up visits should be scheduled monthly for the first 6 months and thereafter three monthly if stable

- The follow up visits should include baseline CD4 cell count testing , VL testing as per guidelines, evaluation for adverse events to ART, adherence and supportive counseling , OI screening and management, counseling on maternal, infant and young child feeding and other clinical evaluation and ART refills

Pregnant and Breastfeeding women currently on OPTION A or OPTION B

- All pregnant and breastfeeding currently on short term prophylaxis (option A) should be switched to life-long ART with the necessary adherence counseling and treatment support. Service providers should withdraw remaining stocks of ARVs for prophylaxis (option A) held by the patient following ART initiation.

- All pregnant and breastfeeding currently on short term prophylaxis (option B) should be continued on same regimen for life-long ART with the necessary adherence counseling and treatment support.

- Treatment monitoring using viral load should be in line with the guidelines on monitoring for all new patients on ART (at 6 months and 12 months after ART initiation and thereafter annually). Refer 6.2

MCH clinics will be required to provide ART for pregnant and breastfeeding women who start on ART for PMTCT purposes.

• Facility/ MCH in-charges should determine the readiness of the MCH to provide services including space availability , staffing trained in provision of ART, access to basic laboratory tests (such as CD4, EID , Viral load , Biochemistry), access to ARVs and OI medicines, availability and access to routine M and E tools for HIV care , tools for Logistics management

• Considerations should be made for additional staffing for MCH clinics starting to provide ART for mothers and children to ensure services in those settings are not compromised.

• MCHs starting to provide ART should conduct an immediate file/register review to identify HIV-infected pregnant or breastfeeding women who require immediate initiation of ART

• Patients files should opened for all patients that include the HIV Care Card (MOH 257) , client follow/encounter forms and other relevant clinical forms

• Standard MOH registers should be utilized including pre-ART register (MOH 361A) , ART register (MOH 361 B) , CCC Daily Activity register (MOH 366) and Commodity management tools including Daily activity register (MOH 367A) , Monthly ART Patients register and FCDRR (MOH 730)

• Routine monthly reporting for patient numbers and commodity consumption should be done using routine MOH tools and systems

• Patient flow should be structured to minimize intra-facility referral to different service points

• MCH clinics should ensure they have consistent access to and supply of ARVs, available OI medicines and have access to recommended laboratory tests for diagnosis and monitoring either on-site or off-site by referral

• Facilities should conduct PMTCT cohort analysis to determine retention of mothers started on ART at 3 months, 6 months and 12 months.

• Care for the HIV-infected infants and mothers including ART initiation should be integrated into MCH clinics. Depending on the health facility set –up the mother –baby pair follow-up should be transitioned when the baby reaches 2 years of age. The transition should be contextualized to the facility set-up

• Health care providers should provide ongoing adherence counseling and support to all patients

• Peer counseling support systems such as mentor mother groups and other PLHIV peer support, use of phone reminders , pill boxes are recommended as strategies to improve adherence

• Facilities should use a combination of multiple adherence assessment strategies such as self-reporting, pill counts , treatment buddy /supporter validation

• Formation of support groups that take into consideration that different age categories and populations is recommended to support adherence and retention in care

• Tracking of clients who miss appointments or default from treatment should be conducted using various approaches including phone tracing , physical home visits among others

County and Sub-County health management teams (including county level Implementing Partners) should;

• Conduct capacity site assessments and determine readiness of health facilities that currently provide PMTCT only services to provide HIV Treatment. A site capacity assessment tool is available at NASCOP.

• Support capacity building of sites targeted to offer HIV treatment based on needs and gaps identified , or upgrading of sites targeted to act as referral centers for laboratory , ARV re-supply or other specialized services

• Establish laboratory services networks and commodity supply networks to ensure consistent availability of tests and supplies

• Provide Quality assurance of HIV services including supportive supervision , mentorship, and on-job training and continuous professional development

Facilities should contact their Respective County AIDs and STI Coordinators in case of any queries regarding HIV. In addition facilities should utilize local expertise of senior clinicians and specialists in consultation regarding patient management.

If need be contact of the following NASCOP officers should be used for various issues.

General enquiries on HIV directed to Head NASCOP:
Dr Martin Sirengo; head@nascop.or.ke, info@nascop.or.ke
Telephone; +254 -020 2630867

Antiretroviral Therapy queries
Dr Irene Mukui: Email; imukui@nascop.or.ke
Dr Maureen Kimani: maureen.nyambura@gmail.com

Consultations on the following categories of Patients receiving ART:
- Patients failing second line ART or other treatment experienced patients who require appropriate regimen selection or Drug resistance testing
- Patients with complexities of treatment due to co-existing co-morbidities or co-infections or complex
- Patients experiencing serious Adverse events or drug interactions

Consultations should be sent to;
3rdline@nascop.or.ke

Prevention of Mother to Child Transmission of HIV queries
Dr Rose Wafula; rosewafula@yahoo.com

HIV testing and counseling queries
Dr Joyce Wamicwe: jwamicwe@nascop.or.ke

Strategic Information and M & E
Dr Joyce Wamicwe: jwamicwe@nascop.or.ke
Dr Jacob Odhiambo: drjaqobo@gmail.com
nascop3d@gmail.com

Voluntary Male Medical Circumcision
Dr George Githuka; ggithuka@nascop.or.ke

Services for Key Populations (MARPs)
Helgar Musyoki; helgar@nascop.or.ke
Training queries:
training@nascop.or.ke

HIV Commodity Supply and Security queries
Dr Caroline Olwande: colwande@nascop.or.ke

Nutrition and HIV queries
Gladys Mugambi; gladysmugambi@yahoo.com

Infection Prevention Control & Injection Safety
Japheth Gituku; japhgituku@yahoo.co.uk

National HIV Reference Laboratories
Nancy Bowen: njebungeibowen@gmail.com

World Health Organization

National AIDS and STI Control Programme (NASCOP)
P.O. Box 19361, Nairobi, Kenya
Tel: 254 20 2729502, 2714972
email: info@nascop.or.ke