



National Guidelines for Comprehensive HIV Prevention, Care and Treatment

POCKET GUIDE

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MINISTRY OF HEALTH-ETHIOPIA
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Chapter One

Introduction

HIV infection is one of the global public health issues. In 2020, more than 37.7 million [30.2 million–45.1 million] people were living with HIV, and 1.5 million [1.0 million–2.0 million] people acquired HIV. Nearly 45% of the people newly infected with HIV live in sub-Saharan Africa (UNAIDS; 2021).

The HIV epidemic in Ethiopia is characterized as mixed, with wide regional variations and concentrations in urban areas, including some distinct hotspot areas driven by key and priority populations. According to the EDHS done in 2016, the national adult (15–49) HIV prevalence is 0.96 %; the urban prevalence was 2.9%, which is seven times higher than that of the rural (0.4%). National HIV Related Estimates and Projections (2020), also shows that the HIV prevalence varies from region to region ranging from less than 0.15% in Ethiopia Somali to 4.13% in Gambella.

In 2020, around 465,457 adults and 17,670 children under the age of 15 are taking ARV, with ART need of 578,188 for adults and 42,971 for children under 15 years of age. Free ARV service was launched in January 2005 and public hospitals start providing free ART in March 2005. Recently ART service is being available in more than 1,474 health facilities Based on the new spectrum estimate for 2020, ART coverage for adults (age >15) has reached 80.5 % but the coverage remains low (40.03%) for children (age <15) living with HIV. According to EPHI 2020/21 VL Dashboard report, the national VL coverage was 74.5%, with a suppression rate of 95%.

The National Guidelines for Comprehensive HIV Prevention, Care and Treatment was last revised in 2018. Since then, new information as well as evidence-based best practices has become available to make HIV prevention, testing and treatment more effective and accessible, ensuring the continuity of HIV prevention, treatment and care specially focusing on KPPs amid COVID-19 pandemic which create a need to revise the existing guidelines. Hence, this guideline is revised taking into consideration of the current recommendations released by WHO in 2021.

Chapter Two

HIV Prevention

HIV prevention approach based solely on one element does not work and can hinder the HIV response and hence use of a mix of behavioral, biomedical, and structural HIV prevention actions and tactics which suit with our country's epidemic has greater impact in preventing HIV.

Core programmatic components of the combination approach include three types of mutually reinforcing interventions:

- 1. Behavioral interventions** include a range of social behavior change communication and demand creation programs and condom promotion and skill building for correct and consistent use.
- 2. Biomedical interventions** are those that directly influence the biological system through which the virus infects a new host and these include condoms, PrEP, PEP, VMMC, STIs, HTS and ART.
- 3. Structural interventions** address the critical social, legal, political, and environmental enablers that contribute to the national HIV response.

To address gaps in condom programming for KPP and general populations coordination, supply chain management and access to quality condoms, four major strategic objectives have been identified and is being implemented:

- Enhance supportive environment and leadership for the implementation of coordinated and sustainable condom programming.
- Ensure the availability and accessibility of quality condoms in sustainable manner.
- Increase demand and enhance correct and consistent use of condoms for different segments of population; and
- Generate strategic information and ensure an integrated, effective monitoring and evaluation system for condom programming.

Pre-exposure prophylaxis (PrEP) of HIV is the use of ARV drugs by people who are not infected with HIV but at a substantial risk to block the acquisition of HIV.

The target beneficiaries for PrEP service in Ethiopia are HIV Negative FSWs and HIV negative partners of sero- discordant couples. PrEP should also be offered for HIV negative pregnant and breast feeding women who have HIV positive partners. The nationally recommended PrEP drug is a fixed dose combination of TDF 300mg + 3TC 300mg once daily dose.

Starting PrEP does not mean staying on PrEP for life. At every follow up visit, review patient reported risk behavior and evaluate the need to continue PrEP as a component of HIV prevention. Any person who wishes to resume taking PrEP medications after having stopped should undergo all the same pre-prescription evaluation as a person being newly prescribed PrEP,

The span and scope of addressing gender inequalities and gender-based violence requires multi-sectoral responses and investments and should include gender responsive programming and gender responsive budgeting in the HIV response. Some of the interventions include strengthening the capacity of health care providers to provide comprehensive services for survivors of GBV, strengthening school and community based literacy on GBV, availing and utilizing referral systems and strengthening youth friendly clinics at facility level to provide comprehensive GBV services.

Management of Occupational Exposure to HIV

- Compliance with infection prevention recommendations is the backbone in prevention of occupational HIV infection.
- Risk of HIV infection after a needle stick or cut exposure to HIV-infected blood is estimated to be 0.3% (3 in 1000). The risk of HIV infection after exposure of mucous membranes to HIV-infected blood is estimated to be 0.1% (1 in 1000).
- ARV treatment immediately after exposure to HIV can reduce the risk by about 80%.

To be effective, PEP should commence as soon as possible (within 1-2 hours). The maximum delay for initiation of treatment which would prevent infection is not known in humans. Do not consider PEP beyond 72 hours post exposure. Prophylaxis is to be given for 28 days.

Testing and monitoring after occupational exposure:

- **Testing source:** rapid HIV test is done after counseling and consent has been secured. If the source patient is negative, there is no need of further assessment of the exposed health care worker. If the result is positive the health care worker needs to be tested.
- **Testing of HCW:** HIV serology should be performed immediately after exposure. If result is positive there is no need for PEP, but if negative you should administer PEP as soon as possible as outlined above and then repeat serology at 6 weeks.

Prevention of HIV Transmission after Sexual Assault

- Any person presenting to a health facility after potential exposure to HIV during sexual assault should be strictly counseled and examined by trained health care provider about the potential risk of HIV infection and ensure there is no misuse of PEP.
- Parents/guardian of traumatized children should be counseled and informed on the risk of HIV infection after sexual assault
- It is strongly recommended that the implementation of PEP should be carefully monitored and evaluated for other services and occurrences (pregnancy test, emergency contraceptives, psychosocial and legal support, STI screening and management, drug side effects and Sero-conversion)

- DTG is also recommended as the preferred third drug for HIV PEP and when available, ATV/r, DRV/r, LPV/r and RAL may be considered as alternative third drug options for PEP.
- The HIV exposed client should be reassessed within 3-5 days for medication tolerability and toxicity.
- When a person living with HIV is taking HIV drugs regularly as prescribed by healthcare provider and their viral load has reached undetectable levels (<50 copies/ml) and maintained at least for 6 months, that person prevents passing of HIV through sex. Globally, this concept is called Undetectable = Un-transmittable (U=U) and Ethiopia has contextualized its naming in to “የማይታይ መጠን = የተገታ መተላለፍ (P=P)” (“Yemaytay Meten = Yetegeta Metelalef”).
- Active screening and treatment of STIs using syndrome approach will be provided to KPPs particularly FSWs and high risk adolescent girls and young women and their partners integrated through community and health facility level service delivery outlets.
- VMMC services should be offered as part of a combination HIV prevention effort to reduce the incidence of HIV in high HIV and low Male Circumcision prevalence settings, targeting males aged between 10-49 years with a special focus on 15-29 years.
- A minimum package of services, including targeted information and education on safer sex, condom promotion and distribution, offering HIV testing service and management of STIs, must be delivered along with the male circumcision procedure.
- Infants born to HIV positive pregnant women by definition are HIV exposed and these infants can be infected with HIV during pregnancy, labor or after birth through breast feeding. All HEI will undergo through DNA-PCR antigen test at six weeks and repeat DNA-PCR test at 9 months for those who tested negative. While the child with HIV infection can often be identified during the two months of life, HIV infection often cannot be excluded until after 18 months of age particularly in breast feeding babies.

- Enhanced postnatal prophylaxis (ePNP) is recommended for all HEI by providing NVP+AZT prophylaxis for the first 6 weeks and continuing only NVP prophylaxis for an additional 6 weeks. Infant prophylaxis should begin within 1 hour at birth or as soon as HIV exposure is recognized postpartum.
- For HEI on breastfeeding, initiate ART for the mother Provide NVP+AZT for 6 weeks and continue only NVP for additional 6 weeks. Collect specimen for DNA PCR testing at 6 weeks of age and repeat at 9 months of age for those who tested negative at 6 weeks of age
- For HEI not breast feeding, initiate ART for the mother If infants are receiving replacement feeding, they should be given 6 weeks of infant prophylaxis with daily NVP & AZT Collect specimen for DNA PCR testing.
- If the infant is brought within 72 hours of birth provide AZT+NVP prophylaxis for 6 weeks, whereas if the infant is identified as HIV exposed after 72 hours after birth (through infant or maternal HIV antibody testing) and is NOT Breastfeeding, initiate maternal ART, no prophylaxis needed and do DNA PCR testing and initiate treatment if the infant is infected.

Table 2.1. Dosage of AZT and NVP syrup for infant prophylaxis for different age groups

Infant age	NVP daily dosing (10mg/ml)		AZT daily dose (10mg/ml)	
	Dose in mg	Dose in ml	Dose in mg	Dose in ml
Birth to 6 weeks:				
Birth weight <2000g	2mg/kg, once daily	0.2ml/kg, once daily	4mg/kg per dose, twice daily	0.4ml/kg per dose, twice daily
Birth weight 2000-2499g	10mg, once daily	1 ml, once daily	10mg, twice daily	1ml, twice daily
Birth weight >2500 g	15mg, once daily	1.5 ml, once daily	15 mg twice daily	1.5ml twice daily
> 6 weeks to 12 weeks				
	20mg, once daily	2 ml, once daily or half a 50 mg tablet, once daily	No dose established for prophylaxis for this age group.	

Table 2.2. Dosage of CTX for prevention of PCP in infants and children

Age	Suspension Per 5ml (200/40mg)	Pediatric tablet (100/20mg)	Single Strength adult tablet (400/80mg)	Double Strength adult tablet (800/160mg)
< 6mo	2.5ml	1 tablet	1/4 tablet	--
6 mo-5yrs	5 ml	2 tablets	1/2 tablet	--
6-14 yrs	10 ml	4 tablets	1 tablet	1/2tablet
>14 yrs	--	--	2 tablets	1 tablet

Chapter Three

HIV Case Finding

Targeted HTS

Ethiopia is getting closer to HIV epidemic control, hence targeted HIV testing where a high-risk individuals or specific groups of population who are at risk of acquiring of HIV and eligible are tested for HIV. Proper utilization of HIV risk screening tool will be useful to achieve the first 95.

Targeted HIV testing and counseling services can be provided in facility and community-based settings. Community based settings include workplace, mobile outreach, and home-based HTS.

As for any HTS, linkage to appropriate services after community-based testing is critical.

Approaches of HTS

The following HTS approaches are recommended:

- *Client Initiated: Voluntary Counseling and Testing (VCT)*
- *Provider Initiated Testing and Counseling (PITC)*
- *Index Case Testing (ICT)*
- *Social Network based HIV testing (SNS)*
- *Mandatory HIV Testing*
- *HIV self-testing (HIVST)*

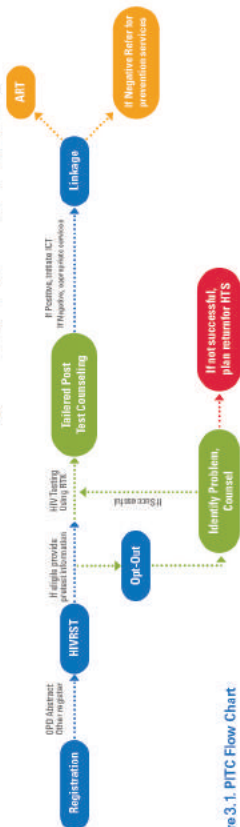


Figure 3.1. PITC Flow Chart

VCT is initiated by clients seeking to know their HIV status. The VCT intervention is “client- focused” to the extent that you focus on the client’s unique issues and circumstances related to HIV risk.

PITC refers to HIV testing, and counselling recommended by a provider during a visit to a health care facility. The health care provider should use HIV risk screening tool to determine whether the client is eligible for the HIV testing or not. A brief counselling or pretest information should always accompany testing even for diagnostic purposes. PITC is an “Opt-out” approach, hence individuals may decline HIV test.

If a client declines HIV testing service, a provider should try to understand the reasons for the refusal. If a client is convinced, HTS can be provided. But if not, the client will be advised to reconsider his decision and return to get HTS at another time.

Use of HIV Risk Screening Tool (HRST) to Enhance PITC

HRST helps to determine a client’s HIV risk and whether the client is or not eligible for HIV testing based on the below category:

- Client’s HIV status (is the client a known HIV positive case or not?),
- *HIV risk behavior (unprotected sex, having concurrent multiple sexual partners, etc.)*
- Clinical symptoms or signs of HIV, etc.

Benefits of Using HIV Risk Screening Tool: HRST reduces over testing, improves case finding and subsequently increase yield.

Eligible clients for HIV Testing and counseling while providing PITC includes:

- All pregnant at first ANC visit, laboring, and postpartum women with unknown HIV status.
- Partners of HIV positive pregnant/postpartum women
- Sexual partners of adult index case, biological children of index cases including siblings of CLHIV under the age of 19 years.
- Female sex workers with unknown HIV status.
- All TB patients and presumptive TB cases with unknown HIV status

- All sexually transmitted infections (STI) patients with unknown HIV status.
- Children orphaned by AIDS.
- Patients with clinical signs or symptoms of HIV/AIDS visiting health facilities

Index case Testing

When counsellors identify index cases whose sexual partners or eligible biological children are not tested for HIV, they should immediately provide partner services. Index case testing is a high yield testing approach for identifying a new HIV infected individual. It should be utilized for case detection optimally to break HIV transmission cycle.

Approaches of ICT Services

1. Client Referral: Index clients tell partners about infection and encourage him or her to come to testing center for testing.

2. Contract referral: The index client enters a “contract” with the health care provider whereby he or she agrees to disclose their HIV status to all partner(s) and or to refer them for HTS within two weeks. If partner(s) do not access HTS within this period, health care providers contact the partner(s) directly to notify them that they may have been exposed to HIV without any disclosure of the index client after getting permission from the index client.

3. Dual Referral: Index clients and service provider will notify his/her partner together. The provider offers voluntary HIV testing to the index client and partner(s) for the potential exposure to HIV and encourage them to seek HIV testing together without any disclosure of the index client HIV status.

4. Provider Referral (Optional): Health care provider will call or send text message to his/ her partner of potential exposure of HIV without disclosing the index client name and HIV status to visit community testing center without telling them the client’s name (this will be done anonymously). In this approach, the index client has no role and involvement in the process.

Index Case Testing (ICT) minimum standards

- Providers trained on index testing procedures including IPV screening, adverse event monitoring, 5Cs, and ethics (respect for the rig of clients, informed consent and 'do no harm')
- Adherence to 5C's (consent, confidentiality, counseling, correct test results, and connection to prevention/treatment)
- IPV risk assessment and provision of first line response, including safety check and referrals to clinical and non-clinical services (if not provided on site)

- Secure environment to store patient information, and
- A site level adverse event monitoring and reporting system.

Social network strategy (SNS) is a case-finding strategy that uses social network connections to locate individuals engaging sexual partner/s and it can also be applied for FSWs, drug injecting partners and social contacts of key population members with HIV and of those who are HIV-negative and at ongoing risk.

Mandatory HIV testing can only be performed for:

- Individuals when requested by the court, and
- Blood or tissue for HIV before transfusion, transplantation or grafting.

HIV self-testing (HIVST) refers to a process in which a person collects his or her own specimen and then performs an HIV test and interprets the result. To create awareness and increase uptake of HIVST, tailored demand creation activities need to be conducted among targets groups that are at high risk for HIV infection

Directly assisted HIVST refers to trained/oriented providers, or peers giving individuals an in-person demonstration before or during HIVST on how to perform the test and interpret the test result.

Unassisted HIVST refers to when individuals self-test for HIV and only use an HIVST kit with manufacturer-provided instructions for use.

Recency Testing

Probable recent infection case is a confirmed newly diagnosed HIV positive individual who tested positive for recent infection. A detailed information is available in the main HIV CBS (Case based surveillance) response guideline

Confirmed recent infection is a confirmed newly diagnosed HIV positive individual who tested positive for recent infection and has high viral load.

Purposes of Recency Testing

The identification of newly infected individuals and the presence of recent infection will support the national HIV program to rapidly respond to sub-populations and sites where high levels of HIV transmissions are detected. As we are getting closer to epidemic control it is recommend conducting recency testing for all newly diagnosed HIV cases. Identification of recent infections should be followed by enhanced individual/site level response and analysis of clusters based on CBS data, while other clusters may require enhanced response activities.

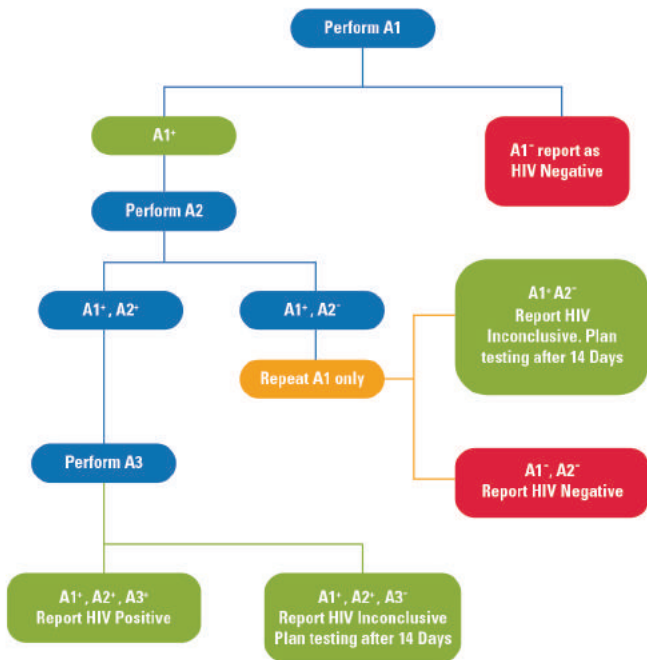


Figure 3.2 Recommended HIV testing strategy for Ethiopia.

HIV Testing for Infants and Children

Mortality is very high among untreated infants infected with HIV in the first year of life, making early HIV testing, prompt return of results and rapid initiation of treatment is essential. Definitive diagnosis at the end of the risk period of mother-to-child transmission (breast feeding period) should be ensured. For children 18 months of age and older (who are not being breastfed or who stopped breastfeeding for at least six weeks), standard HIV serological tests such as rapid diagnostic tests can be used to reliably determine HIV infection status.

Retesting: Refers to a situation where additional testing is performed for an individual after a defined period for explicit reasons, such as a specific incident of possible HIV exposure within the past six weeks, or ongoing risk of HIV exposure such as risky sexual exposure. Retesting is always performed on a new specimen and may or may not use the same assays (tests) as the one at the initial test visit. It is important to accurately identify persons who require retesting including:

- *For newly diagnosed clients before ART initiation*
- *Those whose initial test results were indeterminate,*
- *Those who tested negative but are at ongoing risk for acquiring HIV (e.g., due to high-risk behaviors), and*
- *Those who may be in the early stages of infection and have not yet developed a sufficient level of antibodies that can be detected by rapid antibody ('window period').*

Retesting for individuals with ongoing risk

1. Occupational exposure or sexually assaulted client who started post exposure prophylaxis (PEP): retest at 6 weeks, 3 months, and 6 months.
2. A pregnant during the third trimester, laboring, or postpartum period will be eligible for re-testing if:
 - She has unknown or HIV-negative status and in sero-discordant relationships
 - Pregnant women whose partner has an updated but unsuppressed viral load result
 - She has ongoing HIV risk in late pregnancy (unprotected sex, STI, etc.)
 - People with STI, viral hepatitis, presumptive TB, clinical manifestations of HIV: retest at 6 weeks
 - Female sex workers and PWID consider retesting every six months

- Have specific incidents of known HIV exposure at 6weeks
- Discordant couple: retest after 6-12month or even earlier based on risk of infection to a discordant partner such as HVL
- Individuals receiving PrEP every quarter

Repeat testing: The same specimen is tested again on the same assay when the initial result is reactive, or test results are discordant. The assay is repeated to rule out biological false reactivity. For assays that utilize capillary whole blood, another prick may be needed to collect adequate specimen volume, but it must be in the same testing event.

Quality assurance and Quality Improvement for HTS

Quality can be defined as accessible services that meet the need of clients and providers, in an equitable and acceptable manner, within the available resources and in line with national guidelines. Quality assurance (QA) for HIV counseling and testing refers to periodic assessments of factors that affect the quality of HIV testing while **Quality control (QC)** is a procedure or set of procedures intended to ensure that a performed service adheres to a defined set of quality criteria or meets the requirements of the client.

Linking People Diagnosed with HIV Infection

Linkage is defined as a process of actions and activities that support people testing for HIV and people diagnosed with HIV to engage with prevention, treatment, and care services as appropriate for their HIV status. For people with HIV, it refers to the period beginning with HIV diagnosis and ending with enrolment in care or treatment. It is critical for people living with HIV to enroll in care as early as possible.

ART should be initiated for all individuals (children, adolescents, and adults) living with HIV rapidly, preferably same day, (within an hour for laboring mother) after confirming HIV diagnosis, regardless of WHO clinical stage and CD4 cell count except for TB and cryptococcal meningitis.

Start ART in all TB patients living with HIV as soon as possible within 2 weeks following initiation of anti-TB treatment regardless of their CD4 count except when there is TB meningitis. If a patient has TB meningitis, delay ART for at least 4 weeks and initiate within 8weeks after treatment of TB meningitis is initiated.

Chapter Four

HIV Care and Treatment

ART should be delayed by 4-6 weeks of ART following initiation of treatment for cryptococcal meningitis. Earlier ART is associated with more severe adverse event and increased mortality with cryptococcal meningitis.

DTG containing regimens is the preferred first line regimens for all children age >4weeks; weight and appropriate dosing guidance is available for those \geq 3kg.

The preferred first-line regimen for adults and adolescents and children >30kg is TDF+3TC+DTG as a once-daily dose.

Diagnosis of advanced HIV disease is done through CD4 testing of clients at base line for those initiating treatment, (re-engaging with care after a period of interruption for >28 days) and targeting those who have interrupted ART treatment and with persistently unsuppressed VL (>1000 copies per ml).

In addition to CD4 testing and when CD4 testing is unavailable, a clinical diagnosis of WHO stage 3 or 4 can also be used to diagnose advanced HIV disease.

For adults and adolescents, and children older than five years, advanced HIV disease is defined as CD4 cell count <200cells/mm³ or WHO stage 3 or 4 event. All children younger than five years old with HIV are considered as having advanced HIV disease.



All children **younger than five years** old with HIV are considered as having advanced HIV disease

All people living with HIV with a positive cryptococcal antigen result on screening should be carefully evaluated for signs and symptoms of meningitis and undergo a lumbar puncture, if feasible, with CSF examination and India ink or CSF cryptococcal antigen assay to exclude active cryptococcal disease. India ink has low sensitivity, and a negative result on India ink should be confirmed by CSF cryptococcal antigen testing. A short-course (one-week) induction regimen with amphotericin B deoxycholate and flucytosine is the preferred option for treating cryptococcal meningitis among PLHIV.

Figure 4.1. Decision making guide for Cryptococcal screening

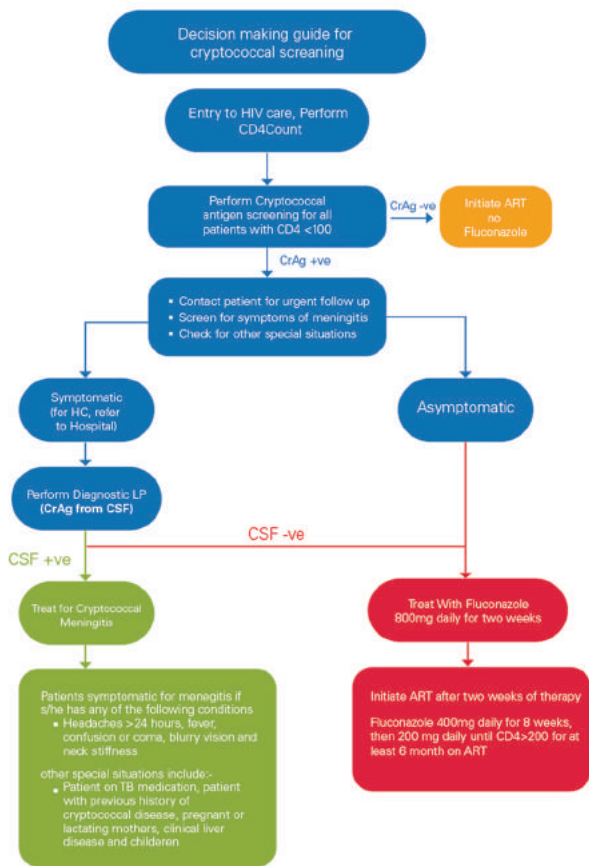


Table 4.1. Revised preferred first line regimen

Population	Preferred first-line Regimens	Alternative first-line regimens	Special circumstances ^a
Adolescents(10 to 19 years OR weight \geq 30 kg), adults, pregnant, childbearing and breast feeding women including those with TB/ HIV- co infection	TDF+ 3TC+DTG ^b (FDC)	TDF + 3TC + EFV AZT + 3TC + DTG AZT + 3TC + EFV	AZT+ 3TC + ATV/r ^c TDF+ 3TC+ ATV/r ABC ^c +3TC+DTG
Children > 4weeks and \geq 3kg but less than 10 years	ABC + 3TC + DTG ^{b*}	ABC+ 3TC+LPV/r AZT+3TC+DTG	ABC+3TC+EFV ^d AZT+3TC+EFV AZT+3TC+LPV/ra

^a ABC or boosted PIs (ATV/r, LPV/r) can be used in special circumstances for those clients who could take neither DTG nor EFV due to contraindication and/or side effects.

^b In case of TB-HIV co-infection, the dose of DTG should be 50mg BID.

^{b*} In case of TB-HIV co-infection, the dose of DTG should be doubled depending on body weight of the child.

^c For PLHIV with renal insufficiency and anemia

^d EFV is for children 3 years and older.

Revised treatment monitoring algorithm

- 1. Viral suppression:** is a viral load that is undetectable, equal to or less than 50 copies/ml.
- 2. Low-level viraemia:** is one or more viral load results that are detectable (more than 50 copies/ml) but equal to or less than 1000 copies/ml.
- 3. Virological failure:** Viral load above 1000 copies/ml based on two consecutive viral load measurements in 3 months, apart with enhanced adherence support following the first viral load test.

Treatment failure threshold should remain at 1000 copies/ml. Those with low-level viraemia at the first viral load test (50–1000 copies/ml) need to be provided with enhanced adherence support (EAS) and repeat viral load test after 3 months to promote viral suppression. If viral load is still 50–1000 copies/ml, maintain ARV drug regimen and continue viral load test every six months. In addition, continue the routine follow up support and link to community-based adherence support services.

Implementation considerations for treatment monitoring of pregnant and breastfeeding women

Whenever possible, use same-day point-of-care testing for viral load testing of pregnant and breastfeeding women to expedite the return of results and clinical decision-making. If this is not available, viral load specimens and results for pregnant and breastfeeding women should be given priority across the laboratory referral process (including specimen collection, testing and return of results).

a) For pregnant women receiving ART before conception:

- For women already on ART, conduct VL testing at 1st contact at ANC (VL result conducted in the last 3 months before 1st contact can also be used), at 34–36 weeks of GA or delivery at the latest, followed by three months after delivery and then every 6 months.
- For those who are already on ART with previous VL test conducted more than three months back repeat VL test at 1st ANC contact /PMTCT visit, at 34–36 weeks of gestational age (or at the latest at delivery) and 3 months after delivery and every six months thereafter until MTCT risk ends.

b) For pregnant women starting ART during pregnancy:

Conduct a viral load test by three months after ART initiation to ensure that there has been rapid viral suppression followed by VL testing at 34-36 weeks of GA or delivery at the latest, three months after delivery and then every 6 months.

For all breastfeeding women, regardless of when ART was initiated:

Conduct viral load test three months after delivery and every six months thereafter to detect viremic episodes during the postnatal period.



Figure 4.2. Revised treatment algorithm

^a Unsuppressed viral load results should be immediately communicated

^b Conduct same-day testing using point-of-care viral load testing for a repeat viral load test, where available, to expedite the return of results. If not available, viral load specimens and results for a repeat viral load should be given priority across the laboratory referral process (including specimen collection, testing and return of results).

Table 4.2. Summary of preferred sequencing of 1st, 2nd and 3rd line ART

Population	1st line regimens		2nd line regimens	3rd line regimens a,b
Adults and adolescents 10 years & older	Preferred	TDF + 3TC + DTG	AZT+3TC+ATV/r or LPV/r	DRV/ r ^C +TDF+3TC+E DRV/ r+TDF+3TC+DTGe
		TDF+3TC+EFV	AZT+3TC+DTG or ATV/r or LPV/r	DRV/r+TDF+3TC +DTGf
	Alternative	AZT+3TC+ EFV	TDF+3TC+DTG or ATV/r or LPV/r	DRV/ r+AZT+3TC+DTG
		AZT+3TC+DTG	TDF+3TC+ ATV/r or LPV/r	DRV/r+AZT+3TC +EFV
	Special Circumstances	ABC+3TC+EFV	AZT+3TC+ DTG or ATV/r or LPV/r	DRV/r+TDF+3TC +DTG
		ABC+3TC+DTG	AZT+3TC+ATV/r or LPV/r	DRV/r+TDF+3TC +EFV
		TDF+3TC+ATVr or LPV/r	AZT+3TC+DTG	DRV/r+TDF+3TC +EFV
		AZT+3TC+ATVr or LPV/r	TDF+3TC+DTG	DRV/r+AZT+3TC +EFV
Children 4weeks to 10 years and >3kg	Preferred	ABC+3TC+DTG	AZT+3TC+LPV/r	For those <3 years, maintain second line regimens till they become 3years. For children 3-10 Years, switch to DRV/ rd+DTGg+ABC+3T C
		ABC+3TC+LPV/r	AZT+3TC +DTG	For those <3 years, maintain second line regimens till they become 3years. For children 3-10 Years, switch to DRV/r +ABC+3TC+ EFV

Population	1st line regimens	2nd line regimens	3rd line regimens ^{a,b}
Children 4weeks to 10 years and >3kg	Alternative AZT+3TC+DTG	ABC+3TC+LPV/r	For those <3 years, maintain second line regimens till they become 3years. For children 3-10 Years, switch to DRV/r +AZT+3TC+EFV or DRV/ r+DTG+AZT+3TC
	ABC+3TC+EFV	AZT+3TC+DTG	For those <3 years, maintain second line regimens till they become 3years. For children 3-10 Years, switch to DRV/r +ABC+3TC+EFV
	Special circumstances AZT+3TC+EFV	ABC+3TC+DTG or LPV/r	For those <3 years, maintain second line regimens till they become 3years. For children 3-10 Years, switch to DRV/r +AZT+3TC+EFV or DRV/ r+DTG+AZT+3TC
	AZT+3TC+LPV/r	ABC+3TC+DTG or EFV	For those <3 years, maintain second line regimens till they become 3years. For children 3-10 Years, switch to DRV/ r+AZT+3TC+EFV or DRV/ r+DTG+AZT+3TC

^a Consider genotyping before constructing a third line regimen when accessible, however switching to third line should not be delayed while waiting for the result, if the TAT is prolonged.

^b When constructing third line regimens for special circumstances in the absence of genotyping please consult senior experts on HIV

^c In PI-experienced patients, the recommended DRV/r dose should be 600mg/100 mg twice daily; refer the weight band for pediatrics

^d DRV/r should not be used in children younger than three years of age.

^e DTG based 3rd line following use of INSTI must be administered with DTG BD.

TB/HIV

Diagnosis of TB in HIV infected people

Lack of quality sputum production and the pauci-bacillary nature of TB in HIV positive individuals are additional factors that make the use of sputum-based testing more difficult. LAM test could decrease mortality through quicker diagnosis and early treatment commencement among PLHIV and severely sick. In this guideline LF_LAM is included for active TB diagnosis in Advanced HIV Disease.

Eligible PLHIV for LF_LAM Test In inpatient settings

- With signs and symptoms of TB (pulmonary and/or extra pulmonary)
- With advanced HIV disease^b or who are seriously ill^a
- Irrespective of signs and symptoms of TB, with a CD4 cell count of less than 200 cells/ mm³

a. "Seriously ill" is defined based on four danger signs: respiratory rate of more than 30/ minute, temperature of more than 39°C heart rate of more than 120/minute and unable to walk unaided.

b. For adults, adolescents, and children aged 5 years or more, "advanced HIV disease" is defined as a CD4 cell count of less than 200 cells/mm³ or a WHO clinical stage 3 or 4 event at presentation for care. All children with HIV who are aged under 5 years should be considered as having advanced disease.

In outpatient settings

- With signs and symptoms of TB (pulmonary and/or extrapulmonary) or seriously ill
- Irrespective of signs and symptoms of TB and with a CD4 cell count of less than 100 cells/mm³

TB prevention therapy

Treatment of LTBI to prevent progression to active disease is one of the global key strategies to ending the TB epidemic. Increasingly, eligible targets and treatment options are expanding, with significant implications in the programmatic management of LTBI. TPT is the use of Isoniazid, rifapentine or other medications to sterilize latent TB infection. Screening for exclusion of active TB in HIV infected persons is the single most important step that should precede the decision to initiate TPT. Concerns regarding the development of INH resistance should not be a barrier to providing TPT.

Figure 4.3. Algorithm for initiating TPT in adults and adolescents ≥ 15 years living with HIV

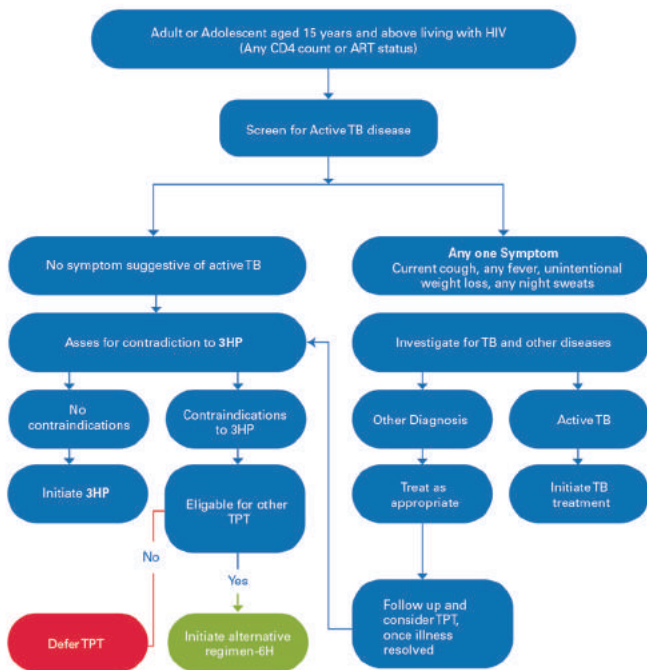


Table 4.3. Regimen and dosage for treatment of LTBI

Population group	Age group and ART regimen	Selection of TPT regimen	
		Preferred regimen regimen	Alternative
Persons living with HIV	Adults, adolescents, children, and infants of all ages taking a PI-based ART regimen	Daily isoniazid preventive treatment for 6 months (6H)	
	Children and adolescents aged <15 years taking a DTG-based ART regimen	Daily isoniazid preventive treatment for 6 months (6H)	
	Children and adolescents aged <15 years taking EFV-based ART regimen	Weekly isoniazid Plus rifapentine for 3 months (3HP*).	<ul style="list-style-type: none"> • Daily isoniazid preventive treatment for 6 months (6H) • Daily rifampicin Plus isoniazid for 3 months (3RH).
	Adolescents and adults living with HIV (≥ 15 years of age) taking non-PI based ART regimen	Weekly isoniazid Plus rifapentine for 3 months (3HP).	<ul style="list-style-type: none"> • Daily isoniazid preventive treatment for 6 months (6H)
HIV-negative persons	Infants and children <2 years of age)	Daily rifampicin Plus isoniazid for 3 months (3RH).	<ul style="list-style-type: none"> • Daily isoniazid preventive treatment for 6 months (6H)
	Eligible adolescents and children aged between ≥2 -14 years (refer to eligibility criteria specified above)	Weekly isoniazid Plus rifapentine for 3 months (3HP).	<ul style="list-style-type: none"> • Daily isoniazid preventive treatment for 6 months (6H) • 3RH will be used as alternative to 3HP

*3HP: should be taken with food to prevent GI upset; If patients are unable to swallow tablets (due to age or illness), the tablets can be crushed and added to a small amount of semi-solid food

Cervical cancer Screening

Cervical cancer screening is an important test in women living with HIV to prevent significant morbidity and mortality associated with HPV. Cervical cancer is a preventable disease and is curable if diagnosed and treated early. Women living with HIV have a higher risk of pre-cancer and invasive cervical cancer. WLHIV should be screened every two years as part of routine care for HIV-positive women, regardless of whether they are on antiretroviral. Following abnormal results and/or treatment, repeat screening in one year. If follow-up screening is normal, return to screening every two years.

Cervical ca Screening methods:

Depending on the availability of resources, the following types of screening methods can be applied:

1. Visual inspection: with acetic acid (VIA) or Lugol's iodine (VILI)
2. HPV DNA test
3. Cytology: conventional (Pap smear) and

liquid-based Treatment of Precancerous Lesions:

- a. Cryotherapy
- b. Thermal ablation
- c. Loop Electrosurgical Excision Procedure (LEEP)
- d. Conization (Cone Biopsy)

HCV HIV co-infection management

HIV/HBV co-infected persons demonstrate more rapid HIV disease progression compared to those who are HIV-infected alone, and have an impaired recovery of CD4 cells. HIV clients are among the high risk groups for HBV and should be given priority for screening of HBV and evaluated for chronic infection as per the national viral hepatitis prevention and control guideline.

Treatment options for patients with HIV/HBV co-infection:

- ART should be started rapidly
- If treatment is indicated for HBV, TDF+3TC + DTG as a preferred regimen
- When switching treatment in patients with HIV on ART failure, the second line regimen should contain TDF + 3TC to continue the treatment against HBV
- If tenofovir-associated renal toxicity occurs, the dose of tenofovir should be adjusted according to the renal clearance
- Note: treatment of HIV without the use of TDF in the regimen may lead to flares of hepatitis B due to ART-associated immune reconstitution. Similarly, treatment discontinuation, especially of 3TC, has been associated with HBV reactivation, ALT flares and, in rare cases, hepatic decompensation

HCV HIV co-infection management

HIV patients are among high risk groups for HCV. Therefore, all HIV patients should be screened and confirmation VL test should be done for HCV screened positives. Anti-HCV rapid diagnostic test (RDT) or immunoassay (IA) can be used for screening and HCV RNA viral load test using either quantitative or qualitative PCR should be used to confirm chronic HCV infection.

All chronic HCV infected individuals should be treated to eradicate the virus and achieve cure so that complications can be avoided. Follow up quantitative or qualitative HCV RNA viral load is required to confirm if the patient has achieved Sustained Virologic Response (SVR).

The HCV treatment for children is differed until 12 year of age and treatment with interferon-based regimens should no longer be used.

For adolescents (12–17 years), the treatment at this time still requires genotyping to identify the appropriate regimen. This include:

- Sofosbuvir/ledipasvir 12 weeks in genotypes 1, 4, 5 and 6
- Sofosbuvir/ribavirin 12 weeks in genotype 2
- Sofosbuvir/ribavirin 24 weeks in genotype 3

For adults without cirrhosis, the following pan-genotypic regimens is recommended for use in adults 18 years of age or older can be used:

- Sofosbuvir/velpatasvir for 12 weeks
- Sofosbuvir/daclatasvir for 12 weeks
- Glecaprevir/pibrentasvir 8 weeks 3

For adults with compensated cirrhosis, the following pan-genotypic regimens can be used:

- Sofosbuvir/velpatasvir for 12 weeks
- Glecaprevir/pibrentasvir for 12 weeks
- Sofosbuvir/daclatasvir for 24 weeks

Priority mental health disorders (WHO)

1. **Psychosis:** this is the collective name for a group of serious disorders characterized by changes in behavior (for example poor self-care, restlessness), strange thoughts or beliefs (for example believing that others wish to do the individual harm) and related dispositions.
2. **Mania:** a form of severe mental illness in which a person is excessively happy or irritable (experiences extreme mood swings), appears over-active and sleeps poorly. People with mania have poor reasoning skills (they have difficulty understanding what is good and what is bad), and display excessive self-confidence.
3. **Depression:** this is the most common priority disorder and is characterized by excessive sadness, loss of interest, lack of energy and related symptoms.
4. **Suicide:** refers to the intentional ending of one's own life.
5. **Abuse of alcohol and other substances:** this is the excessive use of these substances to the detriment of one's health.
6. **Childhood mental disorders:** these are different types of mental disorders related to childhood developments.

7. Dementia: is characterized by memory problems and broader problems with thinking and understanding.

8. Epilepsy: this is a chronic or longstanding condition caused by abnormal electrical conductions in the brain. In its most obvious form, it is characterized by episodic loss of consciousness and repetitive jerky movements of the body.

Chapter Five

Service Delivery

Differentiated care is a client-centered approach that simplifies and adapts HIV services across the cascade to reflect the preference and expectations of various groups of people living with HIV (PLHIV) while reducing unnecessary burdens on the health system. The central driver to adapting service provision is the client's needs.

Differentiated care applies across the HIV continuum to all three of the 95-95-95 targets. Differentiated care includes models of testing people unaware of their HIV status to treatment and care to viral suppression of HIV clients enrolled in care. Based on the level of stability of the clients, DSD models can be based in the facility or outside in the community.

Differentiated service delivery for HIV treatment is based on four building blocks (When, Where, Who and What). In any given differentiated service delivery model for HIV treatment, the building blocks need to be defined separately for clinical consultations, ART refills and psychosocial support.

Being established on ART (stability) should be applied to all populations, including those receiving second- and third-line regimens, those with controlled comorbidities, children, adolescents, pregnant and breastfeeding women and key populations. It also suggest, considering people's clinical needs, differentiated service delivery for HIV treatment should also consider the specific populations and contextual settings.

There is also increasing experience of how such models have been adapted in settings with lower HIV prevalence, acute conflict or other emergency responses.

Eligibility criteria to be considered as Established on ART (Stable) are those clients which are above 5 years old of age, on ART for >6 month, evidence of Treatment of success, Adherence of the client should be >95% and No current illness(well controlled chronic illness and also Opportunistic Infections should be ruled out).

Ethiopia has adopted appointment spacing model of HIV care as the first model of differentiated HIV service delivery in 2017. Then scaled up other models such as Fast Track ART Refill, 3MMD in the context of COVID 19, Health Extension Professional managed Community ART groups (CAGs), Peer Led Community ART Group/ Distribution (PCAG/D), Adolescent ART group, Advanced HIV Disease (AHD), MCH and Key Population.

Chapter Six

Guidance For Program Managers And Leaders

Policy development and review is a dynamic process. Policies change and/or revision like strategic shifts, evolution of new initiatives as well as evidence and knowledge change over time at national, regional and global level are happening according to the lessons learnt during the implementation of the HIV program.

The following guiding principles are expected to lead the implementation of the national HIV program and services provision (each principle described in the main document):

- Ownership and commitment
- Multi-sectoral
- Gender Responsiveness
- Inclusiveness
- Equity
- Resource mobilization and proper utilization
- Service Integration and Linkage
- Evidence Based Response

The 2021-2025 HIV/AIDS National Strategic plan was developed being informed by situation and response analysis and investment case analysis based on Goals Modeling using existing national data for geographic, population and intervention prioritization. This strategic plan aims to attain HIV epidemic control nationally by 2025, by reducing new HIV infections and AIDS mortality to less than 1 per 10,000 population.

The Strategic Plan has six strategic objectives, and ten social and programmatic enablers are identified to maximize the reach and impact and achieve the set goal (refer the main guideline document for details). Program managers and leaders must understand the scope of NSP and its strategic approaches for the standardization of program approach across the country.

Program Performance and Response Analysis

In the planning process, programmers, managers, leaders, and policy makers are recommended to follow inclusiveness of the planning process, identify modes of transmission and the most affected populations, ensure the availability and utilization of the appropriate tools and identify and understand structural barriers that might fuel HIV. Data on case finding yield, linkage to care, adherence, retention, and viral load suppression are keys to assess the quality of the services provided. Surveillance of transmitted and acquired HIV drug resistance can also be instrumental in informing decisions on optimal regimen choices for ART program. A review of epidemiological and programmatic data is incomplete without a deeper understanding of what drives HIV vulnerability and how various political, social, economic, and legal factors affect the ability and willingness of various groups to seek and access health services.

HIV response in the context of COVID 19

Individuals living with HIV, especially those with co-morbid condition and/or advanced HIV disease experience more severe outcomes and have higher comorbidities from COVID-19 than people not living with HIV. Hence, to ensure the health of PLHIV as well as maintaining the continuity of HIV services in the era of COVID-19 pandemic, program managers need to monitor the implementation of the national standard response guideline to be updated to prevent the HCPs and PLHIV from COVID-19 which includes COVID-19 testing, vaccine and treatment must be accessible for PLHIV.

