NATIONAL GUIDELINES FOR COMPREHENSIVE HIV PREVENTION, CARE AND TREATMENT

February 2022

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Foreword

Antiretroviral treatment (ART) began in 2003 and free ART was launched in Ethiopia in 2005. According to the 2020 spectrum estimate, 622,326 Ethiopians are living with human immunodeficiency virus (HIV) and all of them require ART. However, only 80.5 % of adults and 40% of children and adolescents are currently taking antiretroviral (ARV) drugs.

Recognizing the need for antiretroviral treatment, the Government of Ethiopia (GOE) issued the first ARV guidelines in 2003, which were revised in 2005, 2008, 2014 and 2018 for provision of quality prevention, care and treatment services at all levels. With continued evidence based updates, the Ministry of Health has revised the national guideline to scale up and improve the quality of service at all levels.

Expansion and strengthening HIV prevention, care and treatment activities at regional, zonal, woreda and community levels through targeted social mobilization emphasizing Key and Priority Populations and active community participation are expected to enhance the HIV epidemic control.

These consolidated guidelines on preventing and treating HIV infection bring together a series of recommendations to promote the highest quality, person-centered delivery of care for people living with and affected by HIV. Amid COVID 19 pandemic, program adaptations are required to ensure continuity of the services including service delivery approaches put forward with the aim to promote self-management.

The Ministry of Health believes that these guidelines, along with other national guidelines and training manuals, provide the much needed framework and impetus to move towards universal access for HIV services and the agenda for ending AIDS by 2030 as a key national health strategic objective.

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Acknowledgement

The Ministry of Health expresses its appreciation for the institutions participated in the revision of these consolidated HIV prevention care and treatment guidelines and partners, which supported the revision workshops expense. Special thanks goes to UNICEF for design, printing and ICAP-Ethiopia for printing of the documents. The ministry also recognizes the following experts for their contribution in the revision of the guidelines.

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Acronyms and Abbreviations

3TC	Lamivudine
ABC	Abacavir
AFB	Acid fast bacilli
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ARV	Antiretroviral
ART	Antiretroviral Therapy
AZT/ZDV	Zidovudine
CBC	Complete Blood Count
CD4 cells	Type of T-lymphocyte, white blood cells
CMV	Cytomegalovirus
CPT	Cotrimoxazole Preventive Therapy
CrAg	Cryptococcal antigen
DBS	Dried Blood Spot
DTG	Dolutegravir
DRV	Darunavir
DHS	Demographic and Health Survey
DNA	Deoxyribonucleic acid
DPV-VR	Dapivirine vaginal ring
DOTS	Directly Observed Therapy Short Course
EFV	Efavirenz, also abbreviated as EFZ
FBO	Faith-based organization
FDC	Fixed dose combination
FHAPCO	Federal HIV/AIDS Prevention and Control Office
MOH	Ministry of Health
HAART	Highly active antiretroviral therapy
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
IP	Infection Prevention
IPT	INH Preventive Therapy
IPLS	Integrated Pharmaceuticals Logistics System
IRIS or IRS	Immune Reconstitution Inflammatory Syndrome also called Immune Reconstitution Syndrome (IRS)

INSTI	Integrase strand transfer inhibitor (also known as integrase inhibitor)
LFT	Liver Function Test
LPV	Lopinavir
MTCT	Mother-To-Child Transmission (of HIV)
MD	Medical Doctor
NFV	Nelfinavir
NGO	Non-governmental Organization
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside Analogue Reverse Transcriptase Inhibitor
NVP	Nevirapine
OIs	Opportunistic Infections
PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis
PI	Protease Inhibitor
PITC	Provider Initiative Testing and Counselling
PLHIV	People living with HIV
PMTCT	Prevention of mother-to-child transmission (of HIV)
PrEP	Pre-exposure prophylaxis using ARVs before HIV exposure
RMU	Rational medicine use
RNA	Ribonucleic acid
RTV, r	Ritonavir
PI/r	Ritonavir boosted Protease Inhibitor
RAL	Raltegravir
RFT	Renal function test
RT	Reverse transcriptase
STI	Sexually Transmitted Illnesses
TB	Tuberculosis
TDF	Tenofovir
U/A	Urine analysis
UNAIDS	The Joint United Nations Program on HIV/AIDS
UP	Universal Precautions
WHO	World Health Organization
ZDV	Zidovudine (also abbreviated as AZT)

Summary of the changes made in these guidelines

The following list of recommendations consists of either introducing new initiatives or/and modifications of previous recommendations, as adopted from the updated WHO 2021 guidelines, and other relevant working documents.

HIV Prevention

- For adults and adolescents TDF + 3TC are recommended as the preferred backbone regimen for HIV PEP and Dolutegravir (DTG) is recommended as the preferred third drug for HIV PEP and when available, ATV/r, DRV/r and LPV/r may be considered as an alternative third drug options for PEP.
- In ten years and younger, AZT + 3TC is recommended as the preferred backbone regimen for HIV PEP and ABC + 3TC or TDF + 3TC can be considered as alternative regimens and DTG is recommended as the preferred third drug for HIV PEP with approved DTG dosing and when available.
- Undetectable=Untransmittable (U=U) is contextualized in Ethiopia setting by naming **"የማይታይ መጠን = የተገታ መተላለፍ (የ=የ)** ("Yemaytay Meten = Yetegeta Metelalef") focusing on demand creation for viral load testing, improving adherence to ART that result in durable undetectable viral load resulted preventing sexual transmission of HIV.
- All HIV Exposed Infants will undergo through DNA-PCR antigen test at 4-6 weeks and repeat DNA-PCR test at 9 months for those who tested negative.

HIV Case Finding

- HIV Risk Screening Tool (HRST) should be implemented for all individuals (children, adolescents and adults) at service delivery units to improve HIV case detection and yield of provider initiated testing.
- Universal HIV testing will be implemented for all pregnant women at the first ANC visit, however retesting will be done based on their risk.
- Retesting for unknown or HIV-negative post-partum women, can be considered for key populations or for those who have virally unsuppressed HIV positive partners.
- The age limit of biological children of PLHIV for ICT service increased from 15 to 19.
- The window period has been changed from 12 weeks to 6 weeks since third generation kit can detect infection of 4 to 6 weeks.
- Recency testing is implemented to detect recent HIV infection less than one year.

- Provider Initiated Testing and Counseling workflow has been modified to follow those who decline testing

- The HIV testing algorithm is revised considering the current implementation challenges and the available recommendations.

HIV care and treatment

- 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.

- 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 and/or weight ≥ 3kg and the preferred first-line regimen for all adults and adolescents and children >30kg is TDF+3TC+DTG as a once-daily dose. Accordingly the optimized treatment regimen sequencing is modified.

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

Revised treatment monitoring with viral load testing

1. Viral suppression: is a viral load that is undetectable, equal to or less than 50 copies/ml.

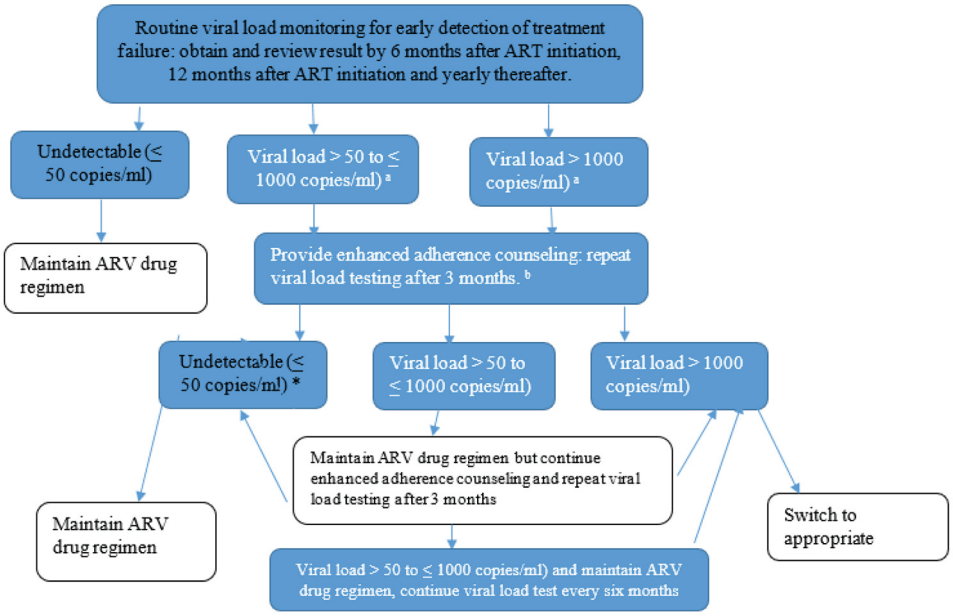
2. Low-level viraemia: is one or more viral load results that are detectable (more than 50 copies/ml) but equal to or less than 1000 copies/ml.

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. The treatment monitoring algorithm is revised based on these new recommendations.
- Whenever possible, use same-day point-of-care testing (POC) 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.
- The viral load testing schedule is revised for pregnant and breast feeding women.

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).



TB/HIV

- LF-LAM is included for active TB diagnosis in PLHIV with TB symptoms, serious illness and/or Advanced HIV Disease

- TB Preventive Therapy (TPT) is the use of Isoniazid, rifapentine or other medications to sterilize latent TB infection. The preferred regimen for adult PLHIV is a combination of INH and refapentine to be taken once per week for three months (3HP).

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.

Service Delivery

- Differentiated service delivery for HIV treatment is based on four building blocks. 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.

- The diversity of models and eligibility criteria are modified based on the new recommendations. 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.