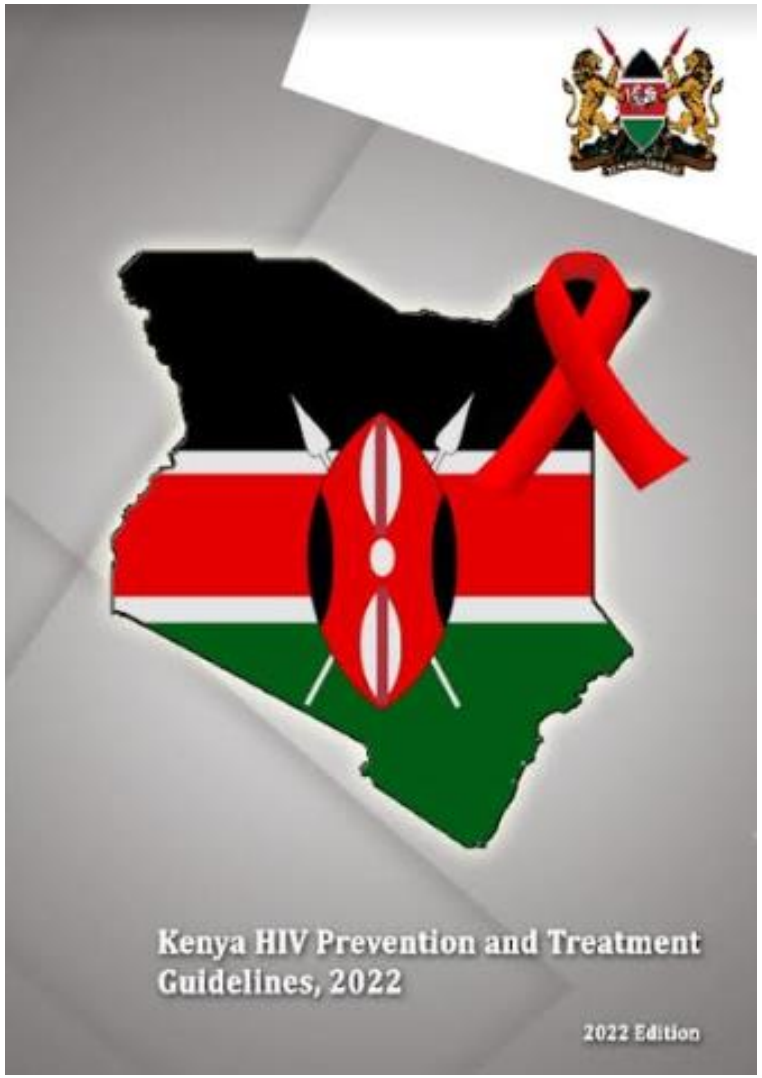
Updated Kenya HIV Prevention & Treatment Guidelines, 2022

Overview of Recommendations/What's New?

August 2022



This is an OVERVIEW of the 2022 guidelines; the details will be discussed within the cases in the Orientation Package

Outline of the Guidelines

1. Summary of Key Recommendations
2. HIV Testing Services and Linkage
3. Initial Evaluation and Follow-up
4. Standard Package of Care
5. Adherence Preparation, Monitoring and Support
6. Antiretroviral Therapy
7. Prevention of Mother to Child Transmission of HIV
8. TB/HIV Co-infection
9. HBV/HIV and HCV/HIV
10. Post-exposure Prophylaxis
11. Pre-exposure Prophylaxis
12. People Who Inject Drugs (PWID) and HIV
13. Annexes

2 - HIV Testing Services

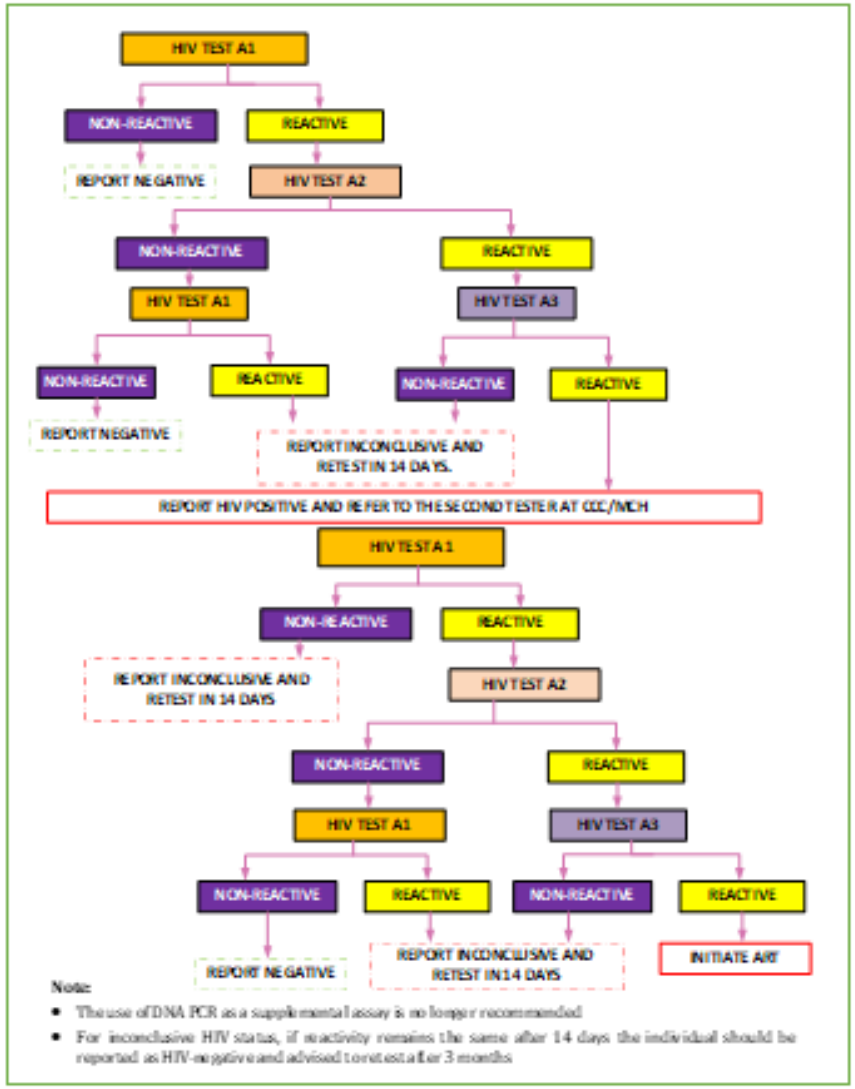
- **6Cs : C**onsent, **C**onfidentiality, **C**ounselling, **C**orrect Results, **C**onnection to Treatment & Prevention, **Creating an Enabling Environment**
- **Testing Strategies:**
  - Facility based
  - Community
- **Targeted HIV testing:** is recommended:
  - Includes **index client listing of contacts, HIV self-testing, Social Network Strategy (SNS)** and use of **HTS eligibility screening tool** to identify people at risk of HIV infection as eligible for testing

2 - HIV Testing Services

HTS Service Package

- There are five primary components of HTS service package which include;
  - Pre-test counselling
  - HIV testing
  - Post-test counselling
  - Assessment of other health related conditions
  - Referral and linkage to other appropriate health services

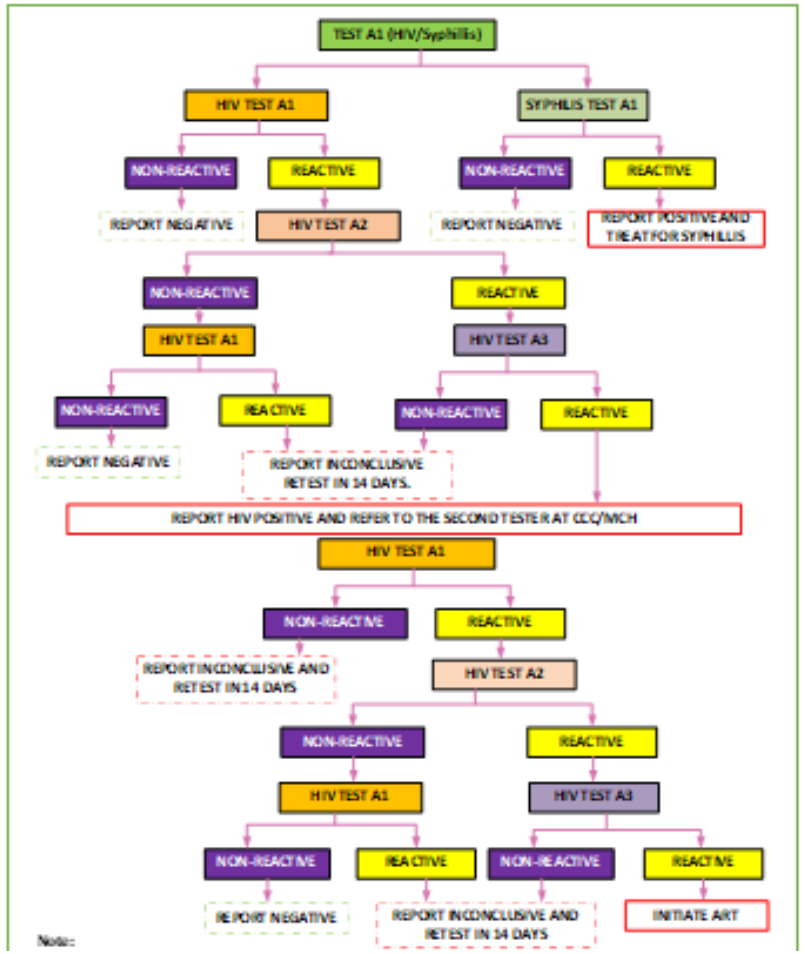
2 - HIV Testing Services



HIV Testing Algorithm (New)

- Shift from **2 to a 3-test algorithm** to increase the positive predictive value (PPV)
- Minimises risk of false positive with decrease in HIV Prevalence (<5%)

2 - HIV Testing Services



Dual HIV/Syphilis Testing Algorithm - PMTCT (New)

- All pregnant women, unless known positive, should be counseled and tested for HIV, Syphilis
  - HIV-Syphilis dual test) and HBV - 1st ANC visit
  - If negative a repeat HIV-Syphilis dual test (3rd test)

2 - HIV Testing Services

- **Early Infant Diagnosis (EID)**
  - All HEIs should be tested with:
    - DNA PCR at 6 weeks or first contact thereafter
    - If negative, DNA PCR at 6 months
    - If negative, DNA PCR at 12 months
    - Rapid antibody test at 18 months, then 6 weeks after complete cessation of breastfeeding

3 - Initial Follow Up & Evaluation of PLHIV

- **Advanced HIV Disease** (AHD) is defined as:
  - Adults, adolescents, and children five years and older as having a CD4 cell count of less than 200 cells/mm3 or
  - WHO clinical stage 3 or 4 disease
  - All children younger than five years
- Screening for **AHD** uses both WHO Staging & CD4 Testing
- **Criteria for CD4 Testing:**
    - Baseline test for ALL PLHIV
    - PLHIV ≥5 years of age and who had previously initiated ART and are reinitiating after >3 months)
    - Individuals who have documented persistent unsuppressed viral load
- All patients with AHD should be offered a package of care that includes **OI Screening, prophylaxis, diagnosis and treatment**

3 - Initial Follow Up & Evaluation of PLHIV

- **Differentiated Service Delivery** (DSD)
  - PLHIV should receive differentiated care based on initial evaluation (advanced vs. well) and follow up (established vs not established on ART)

- **Criteria for Categorization** of Clients as **established on ART** (must have achieved ALL the following); **(NEW)**
  - On their current ART regimen for ≥ 6 months
  - No active Illness (including TB) in the previous 6 months (patients with well controlled chronic conditions should not be excluded)
  - Adherent to scheduled clinic visits for the previous 6 months
  - VL < 200 copies/ml (LDL) within the last 6 months

4 - Standard Package of Care for PLHIV

8 Components

- Antiretroviral therapy
- Positive Health, Dignity and Prevention, GBV/IPV & HIV Education and Counseling
- Screening for and prevention of specific OIs
- Reproductive heath services
- Screening for and Management of Non-communicable Diseases
- Mental health Screening and Management
- Nutrition services
- Prevention of other infections

4 - Standard Package of Care for PLHIV

- **ART**
  - Immediate ART should be initiated in all PLHIV (delay inpatients with Cryptococcal disease and TB)
- **Positive Health, Dignity & Prevention**
  - Counselling and support for disclosure of HIV status; index testing; condom use; family planning; sexually transmitted infections screening; treatment adherence; and pre-exposure prophylaxis for HIV-negative sexual partners
  - Screen and support for GBV/IPV
  - HIV Education and Counseling

4 - Standard Package of Care for PLHIV

Screening and Prevention of OI

- Cotrimoxazole Preventive Therapy (CPT) is **no longer recommended as life-long** prophylaxis **(NEW)**
- Recommended in the following sub populations:
  - All HIV Exposed Infants
  - HIV infected children < 15 years of age
  - All PLHIV > 15 years of age:
    - Living in malaria-endemic zones
    - Presenting with WHO stage 3 or 4 event, or meeting the AHD criteria
    - Suspected treatment failure
  - All Pregnant and Breast-feeding women

4 - Standard Package of Care for PLHIV

Screening and Prevention of OI

- All PLHIV should be **screened for TB at every visit** using the Intensified Case Finding (ICF) tool and assessed for TB Preventive Therapy (TPT) if screened negative for TB
- All adolescent and adult PLHIV with a baseline CD4 count of ≤ 200 cells/mm3 should be **screened for cryptococcal infection** using the serum CrAg test

5 - Standard Package of Care for PLHIV

Reproductive Health Services

- All PLHIV should be **screened for STI** at every clinic visit
- Pregnancy status should be determined for all women of reproductive age at every visit and their **contraception** need determined and met
- All HIV positive women between the ages of 18 - 65 years should be **screened for cervical cancer** (HPV testing conducted every 2 years or Annually if using VIA-VILI)

5 - Standard Package of Care for PLHIV

NCDs/Mental Health Screening and Management

- **Integration of Screening of NCDs/HIV:**
  - hypertension, diabetes mellitus, dyslipidemia, and renal disease annually)
  - Routine screening should be provided for early detection of cervical cancer, breast cancer, bowel cancer, and prostate cancer

- **Integration of mental health screening and management in PLHIV and all caregivers:**
  - Depression
  - Anxiety using Generalized Anxiety Disorder Assessment (GAD-7**)** **(New)**
  - Alcohol and drug use

5 - Standard Package of Care for PLHIV

- **Nutritional Services**
  - Nutritional assessment, counseling and support for all PLHIV
  - All infants should be exclusively breastfed for the first 6 months of life, with the introduction of appropriate complementary feeding at 6 months while breastfeeding continues
- **Prevention of other Infections**
  - All PLHIV should receive vaccinations as recommended MoH
  - Vaccination for COVID-19 following national guidelines for age and dosing **(New)**

5 - Adherence Preparation, Monitoring & Support

Adherence Preparation

- Begins at the post-test counseling session and continues at every visit until ART initiation
- ART treatment preparation involves:
  - HIV education and counselling
  - Identifying likely barriers to adherence
  - Developing an individualized adherence plan
- Patient's readiness to begin ART should be assessed using ART readiness assessment forms

5 - Adherence Preparation, Monitoring & Support

Adherence Monitoring

- Adherence monitoring requires a combination of interventions
  - At every clinical visit, the MMAS-4 should be administered as well as pill counts
  - MMAS-8 should be administered any time a healthcare worker suspects adherence problem

5 - Adherence Preparation, Monitoring & Support

Adherence Support

- Adherence counselling and support for patients from the time of ART initiation until the 3-month viral load results are available is important
- Clients with inadequate or poor adherence barriers should be assessed and addressed
- Adherence monitoring, counselling and support should continue despite viral suppression, but at a lower intensity and frequency unless concerns are identified
- All PLHIV with durable undetectable Viral Load should be offered messaging on Undetectable=Untransmittable, U=U **(NEW)**

5 - Adherence Preparation, Monitoring & Support

Enhanced Adherence Counselling (EAC)

- EAC should begin as soon as a detectable viral load (≥ 200 copies/ml) is received, preferably within 2 weeks **(New)**
- The goal of EAC is to assess possible barriers to adherence in a non-judgmental way and to help the patient construct an adherence plan with concrete objectives.
- At least three sessions of EAC spaced 2-4 weeks apart, are recommended
- Patient with confirmed 1st line or 2nd line treatment failure requires targeted counselling and education to prepare them for the new regimen and to support ongoing adherence

6 - ART in Infants, Children, Adolescents, and Adults

- 1st Line ART

Age	Weight	Preferred Regimen (1st Line ART)	Dosing (Correct weight-based dosing must be confirmed at every visit)
Birth to 4 weeks	Any	AZT + 3TC + NVP[3]	Weight-based dosing
> 4 weeks to < 15 years	< 30 kg	ABC + 3TC + DTG **(NEW)**	Weight-based dosing
	≥ 30 kg	TDF + 3TC + DTG	TDF/3TC/DTG (300/300/50mg): 1 tab once daily
≥ 15 years	Any	TDF + 3TC + DTG	TDF/3TC/DTG (300/300/50mg): 1 tab once daily

(Tenofovir Alafenamide/TAF) to be adopted as preferred NRTI once FDC is available)

6 - ART in Infants, Children, Adolescents, and Adults

- 2nd Line ART

Weight/Scenario	First-line ART	Second-line ART
< 30 kg	• ABC (or AZT) + 3TC + DTG	• DRT-based second-line • PI/r
	• ABC + 3TC + LPV/r	• Take sample for DRT and change to AZT + 3TC + DTG
	• AZT + 3TC + LPV/r	• Take sample for DRT and change to ABC + 3TC + DTG (DRT based
	• ABC + 3TC + EFV	• AZT + 3TC + DTG
	• AZT + 3TC + EFV	• ABC + 3TC + DTG
≥ 30 kg or ≥ 15 years old	• TDF (or ABC) + 3TC + DTG (or PI/r)	• DRT-based second-line
	• TDF (or ABC) + 3TC + EFV	• TDF + 3TC + DTG
	• AZT + 3TC + EFV	• TDF + 3TC + DTG

DRT Based 2nd Line Switch from 1st Line DTG Based Regimens (NEW)

6 - ART in Infants, Children, Adolescents, and Adults

- **Viral Load Monitoring Intervals**

Population	First VL	Follow Up
0 - 24 Years (New)	3 Months after ART Initiation	6 Monthly
25 Years and Older (New)	3 Months after ART Initiation	At 12 months, then Annually
Pregnant & BF Women (New Pos)	3 Months after ART Initiation	6 Monthly
Pregnant & BF Women (On ART)	At Baseline (Pg Diagnosis)	6 Monthly
Regimen Switch	N/A	3 Months after Switch

6 - ART in Infants, Children, Adolescents, and Adults

- **Viral Load Cut-Offs & Recommended Management (NEW)**

Clinical Definition	Category	Lab Value	Interpretation	Guidance
Suppressed	• LDL	• <50 Copies/mL	• Treatment Goal	• Continue management
	• Low Risk LLV	• 50 – 199 Copies/mL	• Suppressed, Untransmissible	• Continue management, Enrol in DSD
Unsuppressed	• High Risk LLV	• 200-999 Copies/ML	• Increased risk of progression to treatment failure	• Institute is EAC, repeat VL after 3 months
	• Suspected Treatment Failure	• ≥1000 copies/mL	• Client at increased risk of morbidity and mortality	Conduct EAC, Repeat VL after 3 months, 2nd Line if 2nd Line VL is >1,000 copies

7 - Prevention of Mother to Child Transmission of HIV/Syphilis/HBV

- Prevention of mother-to-child transmission (PMTCT) of HIV, Syphilis and Hepatitis B (triple elimination) - should be offered as part of a comprehensive package of fully integrated, routine antenatal care interventions
- All pregnant women, unless known positive;
  - Counsel and test for HIV, Syphilis (using the HIV-Syphilis dual test) and HBV during their first ANC visit
  - if negative a repeat HIV-Syphilis dual test should be performed in the 3rd trimester
- ART should be started as soon as possible, ideally on the same day HIV diagnosis is made, with ongoing enhanced adherence support
- The preferred first line ART regimen: TDF + 3TC + DTG

7 - Prevention of Mother to Child Transmission of HIV/Syphilis/HBV

- **Infant prophylaxis;**
  - AZT+NVP for 6 weeks, NVP + cotrimoxazole should be continued until 6 weeks after complete cessation of breastfeeding
  - Infant prophylaxis can be discontinued after a minimum of 12 weeks on NVP if the child is not breastfeeding
  - The infant prophylaxis regimen applies to all infants irrespective of age when HEI identified
- Exclusive breastfeeding, complementary foods after 6 months, and continued breastfeeding up to 24 months or beyond

8 - TB/HIV Co-infection Prevention and Management

TB screening and prevention services should be offered at every clinical visit

Symptom-based TB screening using the ICF tool should be performed at every clinic visit to rule out active TB disease

Patients who screen positive (presumptive TB cases) must complete definitive diagnostic pathways and patients who screen negative should be evaluated for (TPT)

Note: All patients who have HIV should be screened and tested for TB and all patient who have TB should be tested for HIV

8 - TB/HIV Co-infection Prevention and Management

- **TB Preventive Therapy (TPT)**

Target Populations	TPT Regimen
• Adult PLHIV excluding patients on PI/r-based ARV regimens	• Rifapentine and Isoniazid (3HP) : Once weekly for three months *(12 doses)* *(NEW)*
• Adult PLHIV on PI/r-based ARV regimens • All CALHIV aged below 15 years • Any patient with intolerance or contraindication to 3HP • Pregnant women	• Isoniazid (6H) : Once daily for 6 months

8 - TB/HIV Co-infection Prevention and Management

- **TB Diagnosis in PLHIV**

GeneXpert is the recommended initial test for TB diagnosis

Where a facility has no GeneXpert, smear microscopy SHOULD BE USED as another sample is collected & referred for GeneXpert

TB LAM should be used where indicated among PLHIV as per guidelines

TB LAM SHOULD NOT be used as an alternative to GeneXpert testing

Chest Xray can be obtained to augment and aid deferential diagnosis

8 - TB/HIV Co-infection Prevention and Management

- **Use of ART in PLHIV with TB Co-infection**

Age	Weight	1st Line ART if TB/HIV Co-infection
Birth to 4 weeks	Any	• Start anti-TB treatment immediately • Start ART after 4 weeks of age, once tolerating anti-TB drugs
> 4 weeks to < 15 years	< 30 kg	• ABC + 3TC + DTG • Increase DTG dosing frequency to twice daily for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment
	≥ 30 kg	• Give TDF/3TC/DTG FDC morning + DTG 50mg evening for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB Treatment
≥ 15 years	Any	• Give TDF/3TC/DTG FDC morning + DTG 50mg evening for duration of rifampicin-containing TB treatment and for an additional 2 weeks after TB treatment

9 - HBV/HIV and HCV/HIV Co-infection Prevention and Management

- Screening for HBV (using HBsAg):
  - All adolescents and adults living with HIV at baseline
  - Children Living with HIV who did not complete routine childhood immunizations
- PLHIV without evidence of hepatitis B infection (HBsAg negative) should be vaccinated against hepatitis B
- Recommended 1st-line ART for adults with HIV/HBV co-infection: TDF+ 3TC + DTG

10 - ARVs for Post-Exposure Prophylaxis (PEP)

- PEP should be offered as soon as possible (< 72 hours) after high-risk exposure
- Recommended ARV agents for PEP (administered for 28 days):
  - **<15 years old**
    - < 30 kg: ABC + 3TC + DTG (NEW)
    - ≥ 30 kg: TDF + 3TC + DTG
  - **≥ 15 years old**
    - TDF + 3TC + DTG

11 - Pre-Exposure Prophylaxis (PrEP)

- PrEP is the use of ARVs to prevent HIV acquisition by someone who is HIV **negative but at substantial risk of acquiring HIV**

PrEP Dosing Strategies	Preferred	Alternative
(1) Daily Oral PrEP	TDF/FTC (300 mg/200 mg) as FDC once daily	TDF/3TC 300 mg/300 mg as FDC once daily
(2) Event Driven Oral PrEP (2:1;1) **(NEW)** • Appropriate for all people assigned **male** at birth not taking exogenous estradiol-based gender affirming hormones • Transgender women and non-binary individuals assigned male at birth & not taking gender affirming hormones	TDF/FTC (300 mg/200 mg) as FDC: ○ 2 pills taken between 2 and 24 hours in advance of anticipated sex ○ 1 pill taken 24 hours after the first 2 pills and ○ 1 pill 48 hours after the first 2 pills	TDF/3TC (300 mg/300 mg) as FDC (2:1:1)
(3) Dapivirine Vaginal Ring (NEW)	Dapivirine ring, 25mg, inserted vaginally and used for 28 days continuously without removal	

Lab Monitoring for Clients on PrEP

Laboratory Test	Guidelines for clients initiating PrEP	Guidelines for clients on follow up
HIV Rapid Test	Before initiating PrEP as per the National HTS algorithm	At Month 1, Month 3, thereafter every 3months
Creatine Test (UECs)	Test within 1-3 months of PrEP Initiation	>50years – Screen every 6-12months
	Clients of any age with renal comorbidity: test BEFORE of initiating PrEP	Screen every 6-12months
Hepatitis B Surface Antigen (HBsAg)	Test once within 3 months of initiating PrEP. If negative, offer/refer for immunization	
Hepatitis C Virus Serology	Test once within 3months of PrEP initiation	Every 12 months for persons at high risk of Hepatitis C infection

12 - People Who Inject Drugs (PWID) & HIV

- Regular HIV testing and counselling and be linked to comprehensive HIV treatment and prevention services including harm reduction counselling and support
- The recommended 1st ART for adult PWID: TDF + 3TC + DTG
- Key Services for PWID:
  - Screening, diagnosis, treatment and prevention of STIs
  - Access to TB prevention, screening and treatment services
  - Screening for HBV (by HBsAg) and HCV (by HCV serology) at first contact
  - Linkage to Needle and Syringe Programs (NSP) to access sterile injecting equipment
  - Linkage to Medically Assisted Therapy (MAT)

13 - Annexes


THANK YOU :)