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# WHO Global HIV prevention and testing: Guidelines and approved PrEP products

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# Presentation Overview

1. HIV testing in pregnancy and breastfeeding
2. PrEP guidance
3. Examples from Sub-Saharan Africa
4. The future....

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# Guidance on HIV Testing in Pregnancy and Breastfeeding

# Initial Testing and Catch-Up Testing

*All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg) at least once and as early as possible, ideally at the first ANC visit (1).*

*Dual HIV/syphilis rapid diagnostic tests (RDTs) can be used as the first test in HIV testing strategies and algorithms in ANC settings (1).*

*Catch-up testing following a missed or delayed first test or retest is needed (1).*

- Focus on achieving high coverage of testing at ANC-1
- Mitigate impact of supply disruptions with catch-up testing: use self-testing to fill gaps
- Use available tests: HIV self-testing (HIVST), single HIV and syphilis tests

# Third Trimester and Postpartum Retesting

*In settings where HIV prevalence is greater than or equal to 5%, WHO recommends retesting all pregnant women with HIV-negative status in late pregnancy, within the third trimester. An additional retest in the postpartum period can be considered, based on resources and HIV risk in a specific region or for high-risk populations (1).*

*In settings where HIV prevalence is less than 5%, WHO does not recommend universal maternal retesting in late pregnancy. Here, retesting should be offered to women at high ongoing risk, including those from key populations and their partners, and additional postpartum testing can be considered based on resource availability (1).*

- Retesting is **only recommended** in high burden setting
- With limited resources, approaches will need to be adapted
- Implement catch-up testing to fill gaps for those who have missed testing early in pregnancy, consider HIVST options
- Use data to target (ex. geographically)
- **Avoid blanket retesting** outside of high prevalence or high incidence settings

# Linkage to ART or PrEP

*ART initiation should be offered immediately and same-day initiation encouraged following a confirmed HIV diagnosis and clinical assessment for people with no clinical contraindication (1).*

*PrEP is safe to use during pregnancy and ideal for those with substantial HIV risk, such as pregnant and postpartum women in high incidence settings and from a high-risk group. All pregnant women who are HIV-negative but at ongoing risk should be linked to prevention services relevant to them (11).*

- Testing should be an entry point for services
- Women with positive test results need to be linked to ART
- In high incidence settings (where available), following a negative test result, pregnant women at high ongoing risk need to be linked to prevention services like PrEP

# Identify Priorities & Adapt to Limited Resources

	Time points		
Setting	Early in pregnancy (first antenatal care visit)	Late in pregnancy (third trimester ANC visit)	1 additional postpartum retest (14 weeks, six-months or nine-months post-partum)
High HIV burden settings	All	All	Can be considered for those at high ongoing risk
Low HIV burden settings	All pregnant women as part of EMTCT	Can be considered for those at high ongoing risk	Can be considered for those at high ongoing risk
Among key population groups and their partners	All settings	All settings	All settings

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# PrEP Guidance

# WHO Recommendations on HIV Pre-exposure Prophylaxis (PrEP)

WHO recommends four products for use as PrEP:

- **Oral PrEP containing tenofovir** (2015)
- **Dapivirine vaginal ring** (2021)
- **Long-acting injectable cabotegravir** (2022)
- **Long-acting injectable lenacapavir** (2025)

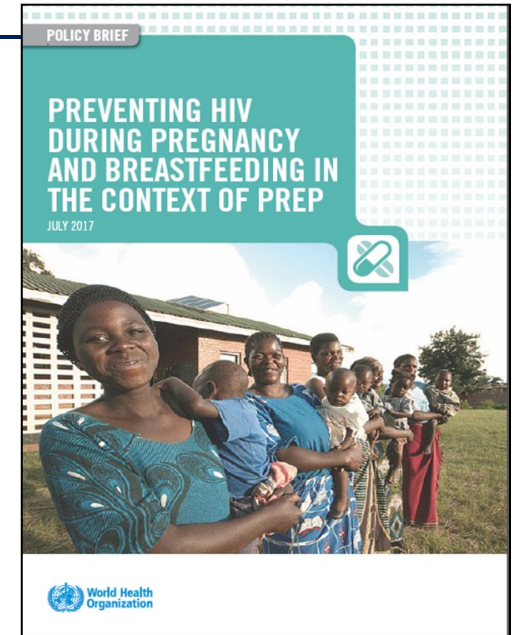
In 2024, 3.9M people used PrEP at least once (<20% of the 21.2M person target for 2025)



# PrEP Use in Pregnancy and Breastfeeding

Based on the available safety data, the WHO recommends that PrEP should **NOT be discontinued** during pregnancy and breastfeeding for women with a risk of exposure to HIV. This is for **all** PrEP options: oral, DVR, CAB and LEN

The choice to **start, continue or discontinue** PrEP when someone becomes pregnant should be **made by the woman**, in discussion of the risks and benefits with a **health care provider**.



**No dose adjustment is required during pregnancy for any PrEP product**

# Oral PrEP Containing Tenofovir

## TDF/FTC or TDF/3TC

Effectiveness: at least 90%

Individuals can start and stop oral PrEP in accordance with their choice



### 1. Dosing regimen for most groups of people with sexual or injecting exposure

- Start with **1 dose per day** for **7 days**
- Continue with **1 dose per day**
- Stop by taking **1 dose per day** for at least **7 days** last potential exposure

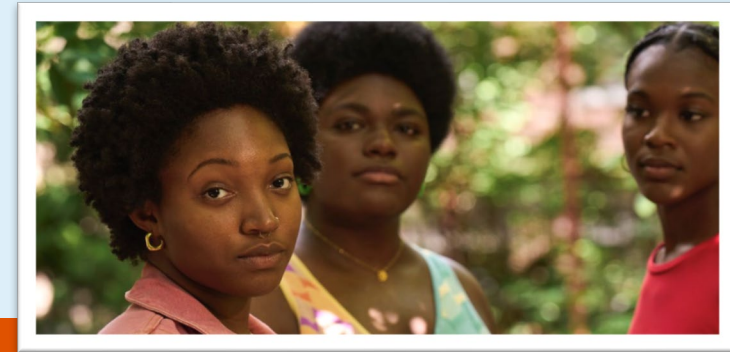
### 2. Dosing regimen for people assigned male at birth a with sexual exposure and who are not taking gender affirming hormones

*Whether for a single event, a short timeframe or a long time.*

- Start with 2 doses 2-24 hours prior to the first exposure
- Continue with 1 dose per day for as long as oral PrEP use is desired
- Stop by taking 1 dose per day for at least 2 days after the last potential exposure

# Dapivirine Vaginal Ring (DVR)

- Effectiveness: 50-75%
- Inserted 24 hours prior to potential exposure
- Worn continuously in the vagina for **1 month** *(including during sex and menstruation)*



# Long-Acting Injectable Cabotegravir (CAB-LA)

## Efficacy

- 88% risk reduction for women / 66% risk reduction for men
- Combined effect size of about 80% relative risk reduction compared with TDF/FTC

Injectable formulation administered as an IM gluteal injection

## Dosing schedule

- First two injections (for initiation) **1 month apart** (+/- 7d)
- Subsequent (follow-up) injections **every 2 months** (+/- 7d)



# Long-Acting Injectable Lenacapavir (LEN)

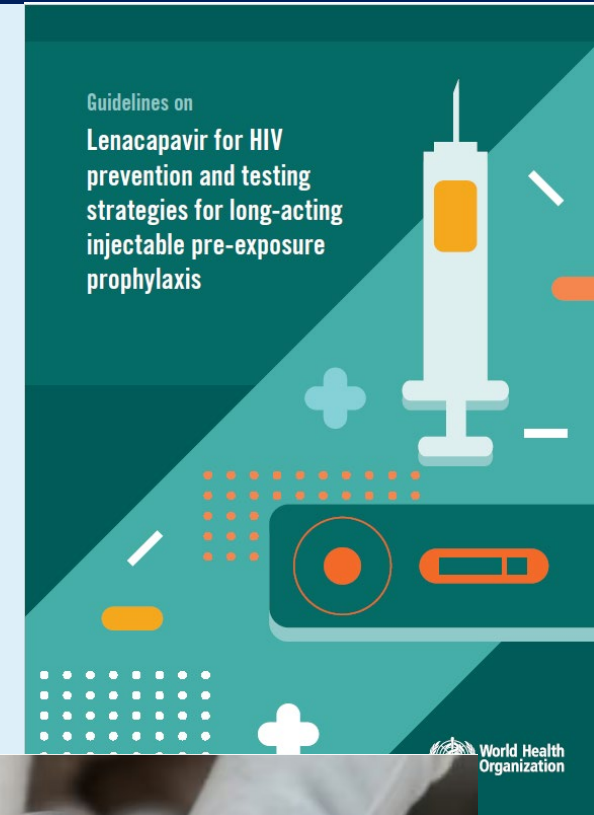
Effectiveness: 96-100%

## Subcutaneous injections every six months

Day 1: 2 subcutaneous injections of 1.5mL each  
Repeat every 26 weeks (+/- 2 weeks)

## Oral loading dose (initiation only)

Day 1: 2 tablets of 300mg each  
Day 2: 2 tablets of 300mg each



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Offering **choice** in prevention and PrEP products can increase uptake, effective use, satisfaction and protection

Prevention and PrEP choice is dynamic

WHO does not support one PrEP product over any other

**The best PrEP product is the one someone wants to use and will use well**



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# Examples from Sub-Saharan Africa

# Early Countries to Roll Out LEN in AFRO

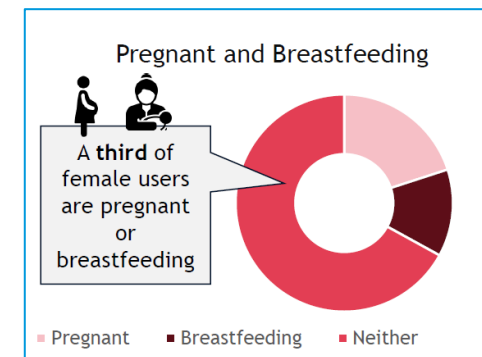
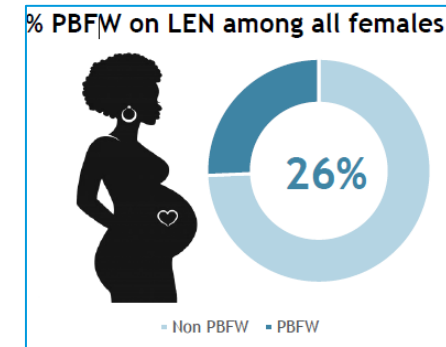
- All early roll-out countries are continuing women on LEN who become pregnant
  - All countries, but one, are also initiating pregnant women on LEN
- Global push
  - Expand LEN to pregnant and breastfeeding women
  - Eliminate mother to child transmission of HIV by the end of 2028



# LEN uptake among PFW in early adopter countries



- **Eswatini** 26% of women on LEN are PFW
- **Kenya** 10 out of 98 clients initiated on LEN are PFW (from 26/2 – 9/3)
- **Zambia** A **third** of all female users are PFW



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# The future....

## Inclusion of PBFW in Clinical Trials

- Oral PrEP ✘
- Dapivirine vaginal ring ✘
- Cabotegravir ✘
- Lenacapavir 😍
- MK 8527 (monthly pill) 😍

**The future of PrEP research will include PBFW participants in trial design**

# Thank you!

## ACKNOWLEDGMENTS

- WHO and MOH colleagues
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**Special thanks to all the women who inspire our work**

