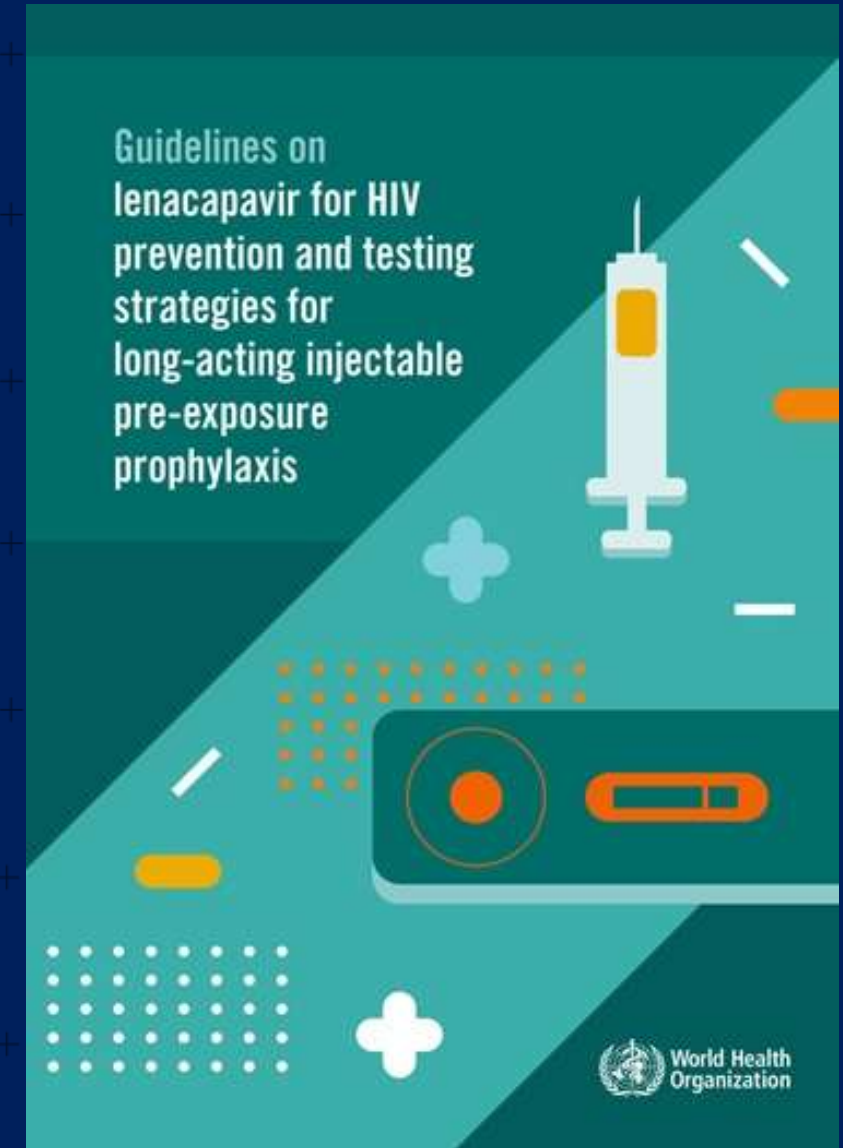


WHO Global PrEP Network:

*New WHO guidance on
lenacapavir for prevention
& HIV testing for long-
acting injectable PrEP*



Housekeeping



Questions:

Please type any questions or comments in the **Q&A box**.

We'll respond during the Q&A session with the Panelists at the end of the webinar or, if we can, in the chat.

Please tell us who you would like to answer your questions.



Recording:

This webinar is being recorded and will be published on the WHO Global PrEP Network website (<https://www.who.int/groups/global-prep-network>)



Slides:

Where we have received permission, slides from the presentations will be distributed to attendees who registered for the webinar.

Speakers

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Love Yourself
The Philippines



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UNAIDS and WHO,
Switzerland



**Carlotta Baptista
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WHO, Switzerland



Taiwo Olakunle
MoH, Nigeria



Lloyd Mulenga
MoH, Zambia



Webinar Agenda:

Welcome and overview (13.00)	Michelle Rodolph (WHO, Switzerland)
Overview of new guidance (13.05-13.30)	
Lenacapavir for PrEP	Heather-Marie Schmidt (WHO and UNAIDS, Switzerland)
Testing for LA PrEP	Carlota da Silva Baptista (WHO, Switzerland)
Panel discussion (13.30-14.00)	Danvic Rosadiño (Guideline co-chair, The Philippines) Hasina Subedar (Guideline co-chair, South Africa) Taiwo Olakunle (MoH, Nigeria) Lloyd Mulenga (MoH, Zambia) Heather-Marie Schmidt (WHO and UNAIDS, Switzerland) Carlota da Silva Baptista (WHO, Switzerland)
Q+A	
	Moderator: Michelle Rodolph (WHO, Switzerland)

Lenacapavir for HIV prevention: new guidance

Heather-Marie Schmidt (UNAIDS and WHO)

schmidt@unaids.org

On behalf of the WHO PrEP and PEP team: Michelle Rodolph, Mateo Prochazka,
Heather Ingold and Heather-Marie Schmidt



World Health
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WHO recommendations on HIV pre-exposure prophylaxis (PrEP)

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

As part of comprehensive HIV prevention approaches, based on evidence for effectiveness, safety, community values and preferences, likely cost effectiveness etc.



Lenacapavir (LEN) for HIV prevention

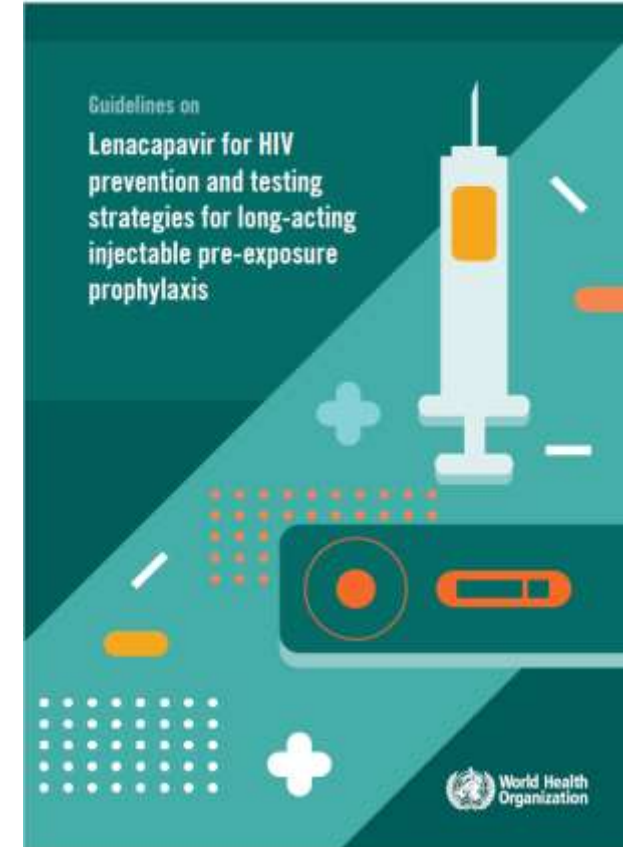
WHO Recommendation 2025



Recommendation [NEW]

Long-acting injectable lenacapavir should be offered as an additional prevention choice for people at risk of HIV, as part of combination prevention approaches. (*strong recommendation, moderate to high certainty of evidence*)

- **Lenacapavir (LEN)** is a first in class HIV-1 capsid inhibitor
 - Sub-cutaneous injectable formulation administered every 6 months, accompanied by an oral loading dose
 - Approved by US FDA in 2022 for treatment of multidrug resistant HIV in highly treatment experienced PLHIV, and **in June 2025 for HIV prevention**



Dosing for lenacapavir

- **Subcutaneous injections every six month**
 - Day 1: 2 subcutaneous injections of 1.5mL each
 - Every 26 weeks (+/- 2 weeks)
- **Oral loading dose**
 - Day 1: 2 tablets of 300mg each
 - Day 2: 2 tablets of 300mg each
- **Oral loading dose is needed to reach target PK levels within first 3-24 hours of taking first 2 pills**
 - Without the oral loading dose, protection levels from the injection are reached after weeks 3-4
 - No oral loading needed for follow-up injections if they are on time (28 weeks maximum)



Efficacy and safety for LEN for prevention

- PURPOSE 1 and 2 trials demonstrated **high efficacy**, showing a significant reduction in HIV acquisition compared with background incidence and daily oral PrEP (TDF/FTC)
 - **PURPOSE 1: 100% efficacy** (0 HIV infections) compared to background HIV incidence
 - **PURPOSE 2: 96% efficacy** (2 HIV infections among 2180 participants) compared background HIV incidence rates
- Rates of most **adverse events were similar between LEN and oral PrEP** (TDF/FTC), and most were mild or moderate
 - Injection site reactions (ISRs) to LEN were common, but typically mild, decreased over time and did not lead to high rates of discontinuation
- No difference in safety or efficacy for adolescents aged 16-17 years
- Data remain limited for some key populations, such as PWID (explored in PURPOSE 4)



Lenacapavir use in pregnancy

- **LEN showed no increase in adverse pregnancy or birth outcomes** in pregnancies with outcome data available in PURPOSE 1. There were a total of 193 pregnancies in PURPOSE 1 among 184 women.
- **No dose adjustment is likely to be required during pregnancy**, with pharmacokinetic data indicating standard dosing remains effective.
- **WHO-recommended PrEP products, including LEN, can be continued** during pregnancy and breastfeeding.
- When someone becomes pregnant, the choice to start, continue, stop, or switch PrEP, should be made by the individual, following discussion of the risks and benefits with a health care provider.



Impact of LEN on HIV prevention

- **Two breakthrough infections in PURPOSE 2 showed capsid inhibitor resistance (N74D)**
 - As LEN is first in class ARV, current public health impact is limited
 - Ongoing surveillance is needed
- Mathematical modelling suggests that LEN could substantially reduce new HIV infections
 - Increased coverage, higher efficacy and/or better persistence contributed to higher impacts compared with other forms of PrEP in some models

Values, preferences and feasibility for LEN

- **Injectable PrEP was highly acceptable to individuals**, with users citing convenience, potential for discreet use and effectiveness
 - Interim analysis of PURPOSE 1, suggested 2/3 of participants preferred LEN
 - Clear preference for less frequent dosing (e.g. ≥ 6 months), due to reduced user burden
 - **Concerns varied by setting**, including injection-related pain, potential side effects, scheduling challenges for follow-up doses and costs
- Evidence suggests **providers find injectable PrEP acceptable and feasible**, although concerns remain about costs and logistics
- **LEN is likely to be feasible for implementation in national PrEP programs**
 - Clinical trial sites across multiple countries successfully delivered LEN, suggesting integration into existing services is achievable
 - Indirect evidence from CAB-LA implementation into broader programmes supports the feasibility of implementing LEN



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

- WHO does not support one PrEP product over any other
- Providers should explain the advantages, disadvantages and features of different options
- Different attributes may be more or less important for different people
- Choice is dynamic

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



Implications for implementation

- **LEN** should be delivered as an **additional prevention choice** alongside other HIV PrEP and prevention options.
- Considerations for introduction should include:
 - population-specific needs e.g. adolescents, KPs, PBF
 - **differentiated service delivery** models
 - **integration** of services to maximize acceptability and access
 - **awareness raising** and **demand generation** activities
 - **provider training**
- Monitoring and surveillance systems should include:
 - routine PrEP data collection AND
 - adverse event monitoring during **pregnancy and breastfeeding**
 - **seroconversions** and **drug resistance (LEN specific)**
- Successful introduction of LEN depends on the full participation of **communities** in designing, implementing and monitoring programmes.



The WHO and Jhpiego Provider Training Toolkit on Use of Oral and Long-Acting HIV Pre-Exposure Prophylaxis (PrEP)

This toolkit is designed to help clinicians develop knowledge and skills to provide multiple HIV PrEP methods. The toolkit includes resources for oral PrEP, long-acting cabotegravir (CAB-LA), dapivirine vaginal ring (DVR), and long-acting lenacapavir (LEN).

Research Gaps



- Implementation science can provide answers to outstanding questions on:
 - Product choice and switching in the real world
 - Optimal service delivery approaches, including differentiated service delivery models, for access, uptake and persistence (on-time injections)
 - Adolescents, key populations (including PWID) and other vulnerable populations
 - Costs and impact country-specific modelling
 - Drug resistance
- **Further research should not delay programmatic implementation in countries**

Next steps

- LEN has received US-FDA approval for prevention, EU market authorization (and EMA positive opinion for EU-M4all), under consideration in additional regulatory agencies
- LEN is being considered for WHO pre-qualification
- Collaborative registration procedure (CRP) through WHO: Gilead submission expected October 2025
- 9 early adopter countries are expected to begin programmatic LEN implementation by early 2026
- Countries are getting ready for LEN e.g. updating their guidelines, creating implementation plans, undertaking modelling/estimating demand



Thank you!

Guideline Development Group (GDG), with a special thank you to the co-chairs: **Hasina Subedar and Danvic Rosadiño**

External Reviewers

Systematic reviewers: **Ginny Fonner and Jason Ong** and their teams

Methodologist: **Nandi Siegfried**

External contributors: **Britta Jewell, Michael Jordan, Lynne Mofenson, Robert Shafer and Gert Van Zyl**

The Gates Foundation, Unitaid and CIFF for supporting this work

WHO colleagues

Michelle Rodolph, Mateo Prochazka, Heather-Marie Schmidt, Cheryl Johnson, Carlota Baptista da Silva, Maggie Barr-DiChiara, Heather Ingold, Françoise Renaud, Meg Doherty

Anita Sands and Petrus Steyn

WHO HQ, country and regional colleague

And all the other important people who have helped make this happen

WHO recommended testing strategies for long-acting injectable PrEP

Carlota Baptista da Silva

World Health Organization

Global Programme on HIV, Hepatitis and STIs

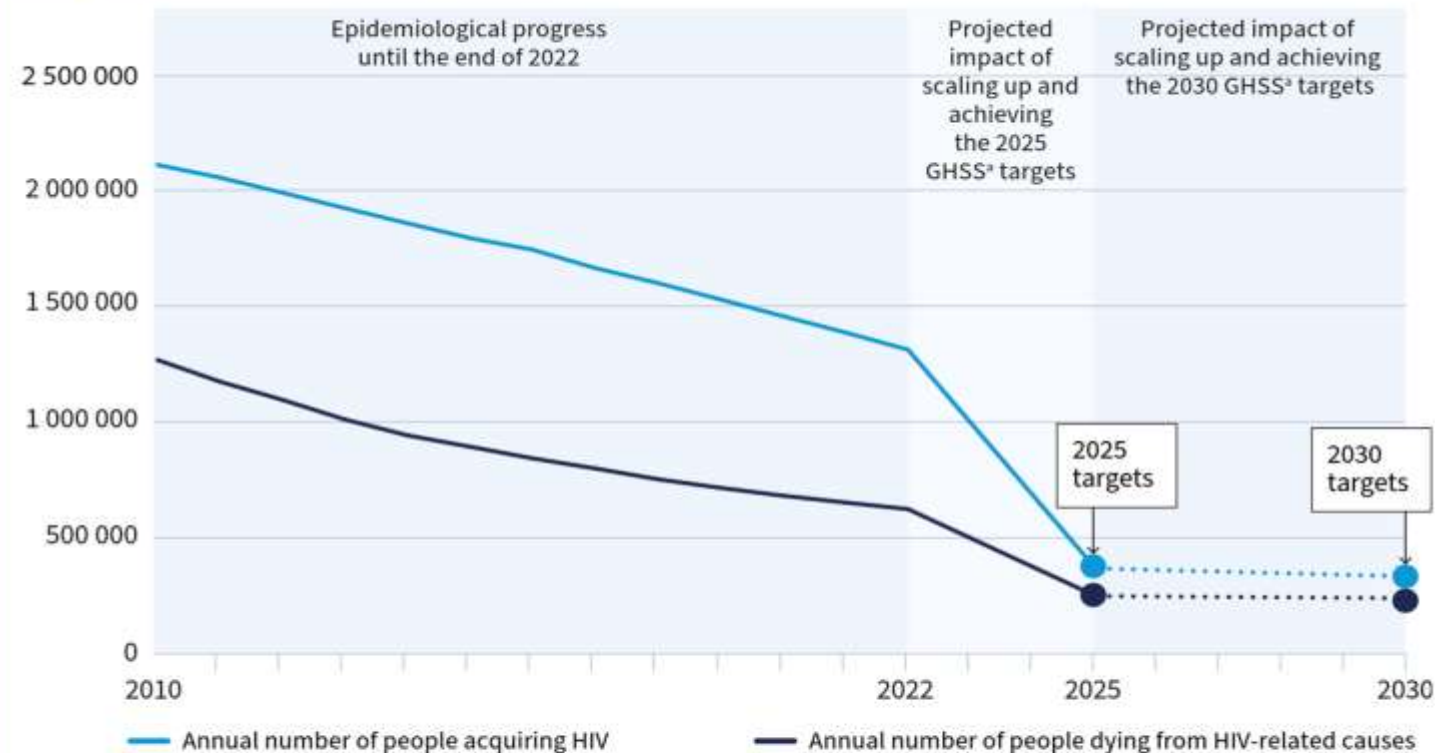
28th August 2025



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Where are we with HIV prevention?

Global trends in people acquiring HIV and people dying from HIV-related causes, 2010–2022 and projections to 2030



Note: The United Nations global targets for 2025 are twofold: reducing the number of people acquiring HIV to less than 370 000 and reducing the number of HIV-related deaths to less than 250 000. To end AIDS as a public health threat by 2030, the targets are a 90% reduction of the number of people acquiring HIV and dying from HIV using 2010 as the baseline.

Sources: Avenir Health using 2025 targets and UNAIDS/WHO epidemiological estimates, 2023.

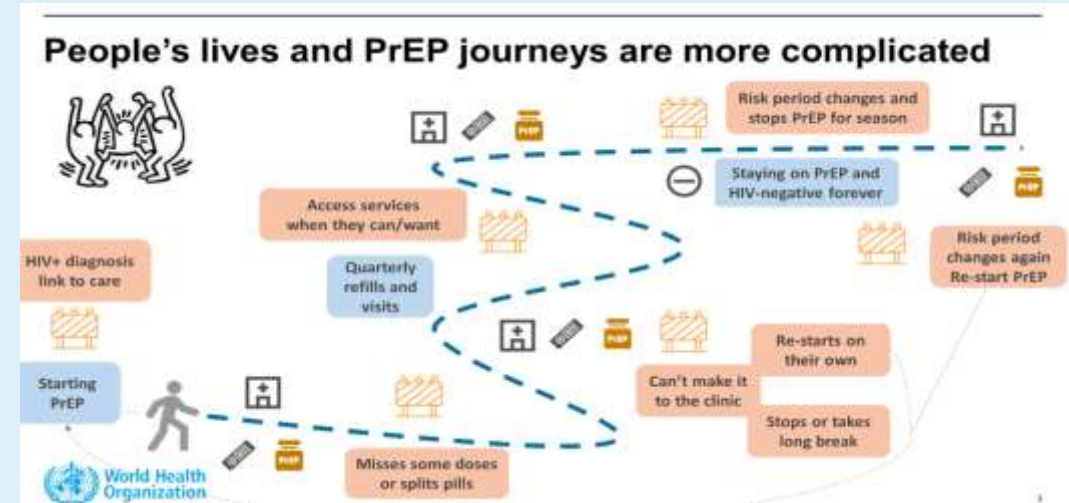
* Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022–2030. Geneva: World Health Organization; 2022 (<https://apps.who.int/iris/handle/10665/360348>, accessed 7 July 2023).

- ~1.3 million new HIV infections annually
- 2030 goal: < 335,000 new infections
- Simplifying HIV testing not prioritized to date

Key strategies for scaling-up PrEP

Provide **increasing range of PrEP options** - more choices and including innovations like new long-acting tools (e.g. LEN, CAB-LA)

Simplify PrEP delivery - lighter touch, differentiated services, low cost and streamlined client management (including testing)



Differentiated PrEP delivery

Mobile
PrEP
services,
South Africa



Tele-health
for PrEP,
Brazil



Home PrEP
delivery,
Thailand



Simplified rapid or self-testing can facilitate these differentiated service delivery models

Photo credit: Mplus Foundation, Chiang Mai

Photo credit: Washington University in St. Louis

Is HIV testing being a gateway for PrEP?



Generally, not using public health approach to testing, especially for LA-PrEP

- Not always relying on routine HIV testing algorithm
- Uses costly and complex approaches (e.g. RNA/NAT, laboratory-based Ag/Ab EIA and/or Ag/Ab RDT)
- Cumbersome and frequent testing at facilities (e.g. initiation, 4-weeks, 2-month and 3-6-month follow-ups)
- Often restricts rapid testing, self-sampling or self-testing

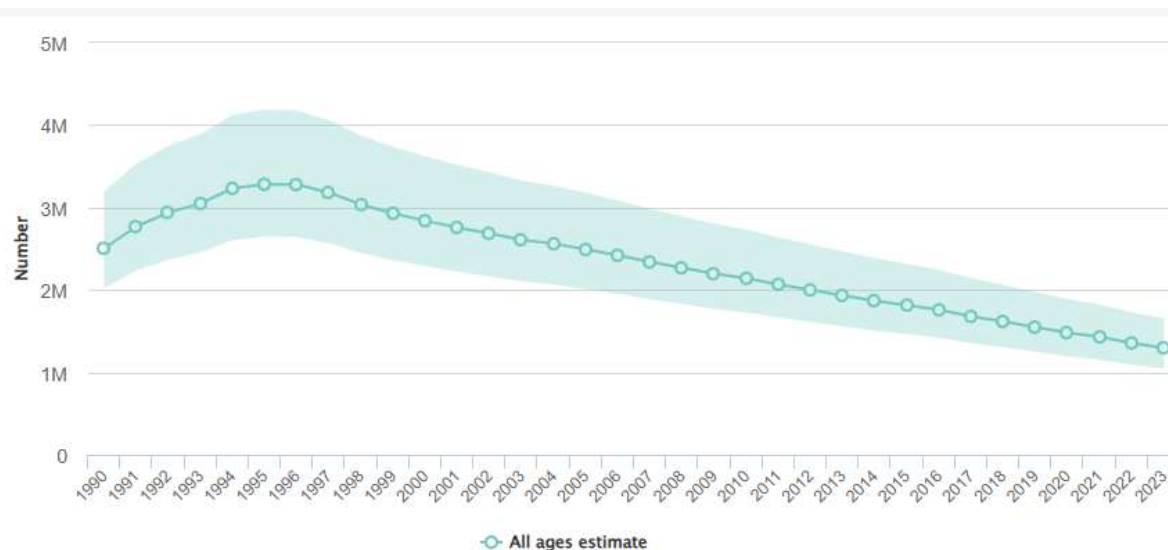
Evidence has shown these approaches are often infeasible, too expensive and have limited value

- Even in high-income settings

Time to rethink the focus on acute HIV infection

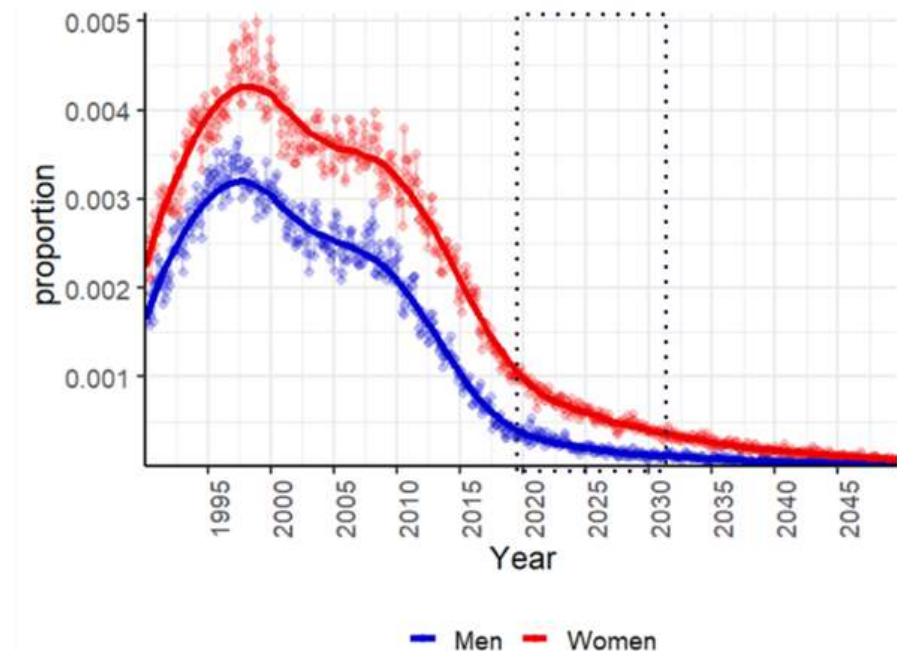
Changing HIV epidemiology

HIV incidence 1990-2023, UNAIDS estimates



As HIV incidence has declined the risk of missing acute infection also has also declined

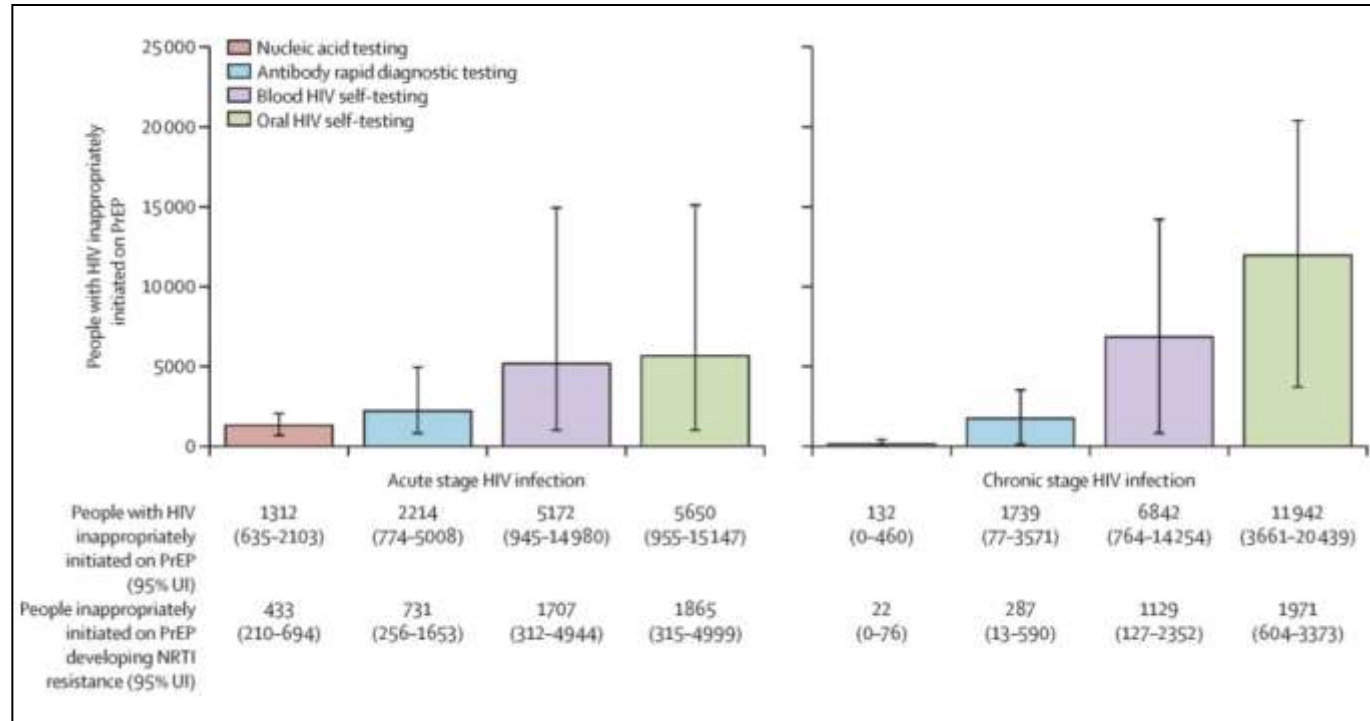
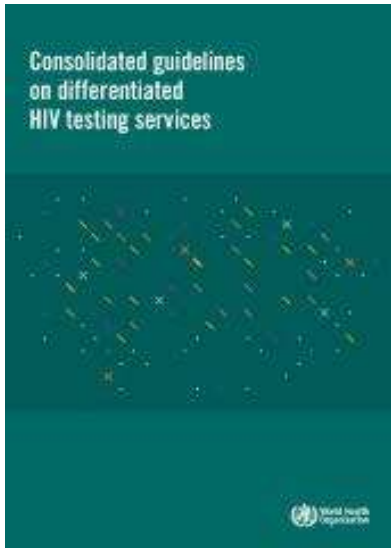
Modeled acute infection as proportion of the population (15-34 year olds)



Across 4 African cohorts with high HIV risk – 0.26% (122/46,000) acute HIV cases detected

Across 6 large PrEP trials acute HIV prevalence was 0.1-0.4%

HIV rapid tests and self-tests are safe for oral PrEP



- No substantial difference in drug resistance at population-level
- No difference on HIV-deaths or infections averted

WHO recommends HIVST for PrEP initiation, reinitiation, and continuation

Current guidance covers HIVST for all oral PrEP, dapivirine vaginal ring (DVR) and PEP

Implementation of WHO recommendations for HIVST-supported PrEP is growing

HIVST for PrEP demand creation



Nepal: Gyani, a 28-year-old woman from Nepal's Rautahat district, is a PrEP champion. Gyani has inspired more than 40 of her peers, at substantial HIV risk to self-test, enroll in and take PrEP.

HIVST for PrEP initiation



Thailand: Pangpond, a 26-year-old man, was attracted to the convenience of self-testing for PrEP. "It was so simple. The clinic sent me the HIVST kit. I had to ask the clinic for advice online when I first used it, then I sent them the result, and they sent me PrEP to initiate. This was incredibly convenient, and I quickly regained control, feeling ready to enjoy life again."

HIVST for PrEP re-initiation



Brazil: João Luis, a TelePrEP user, reported that, "Self-testing is simple and quick, with clear instructions and results available in less than 20 minutes. This convenience ensures that tests are regular, protecting me against HIV. With a significant reduction in the time spent at health facilities."

HIVST for PrEP continuation



Eswatini: Sandra, a 29-year-old woman, explains her experience self-testing for PrEP. "This is a perfect arrangement. After self-testing negative, the nurse provided me with PrEP right away. I felt confident and took 2 tests kits for my partners so they could test themselves".

WHO guideline process

- Systematic review of clinical, diagnostic, values and preferences and resource-use outcomes of different HIV testing strategies for the delivery of injectable long-acting pre-exposure prophylaxis (LA-PrEP).
- Directly compared use of HIV rapid diagnostic tests (RDTs) and HIV self-tests (HIVST) to use of laboratory-based immunoassays, RNA testing and/or nucleic acid testing (NAT)
- Expert GDG: January 2025



Source: WHO 2025, [Tieosapjaroen et al](#) 2025



New WHO recommendation



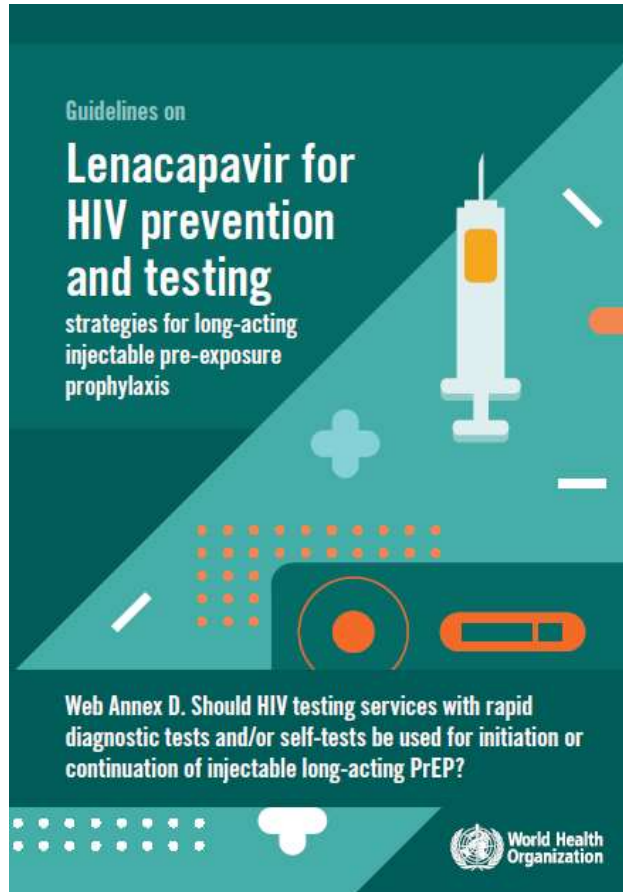
Rapid diagnostic tests may be used for HIV testing for initiation, continuation and discontinuation of long-acting PrEP

(strong recommendation, very low certainty of evidence)



- HIVST may be an important implementation consideration in some contexts, increasing programme flexibility and testing frequency
- Implementation research remains important in this area
- WHO will review emerging evidence as soon as it is available and update guidance

Evidence* on HIV RDTs for injectable LA-PrEP



HIV RDT supported injectable LA-PrEP compared to NAT and/or laboratory-based testing algorithms resulted in:

- Faster turnaround time and more rapid ART initiation
- Fewer delayed or missed injection visits
- Similar negative predictive value and positive predictive value
- No difference in absolute number of missed or delayed HIV infections detected or the detection of breakthrough infections
- No difference in the prevention of INSTI resistance associated mutations
- No difference in frequency of testing
- No difference in clinical or social harm
- High acceptability and feasibility
- **Substantial cost-savings** ----->

To detect 1 additional HIV case, missed by a rapid test, using NAT requires testing 5,305 people with estimated cost of \$46,684 - \$451,456 per test*

Source: WHO 2025, [Tieosapjaroen et al 2025](#); [see annex for more details](#)

*Systematic review included 22 studies (CAB-LA: 20 studies, LEN: 2 studies) involving 15 594 participants and spanning Africa, Asia, Europe and the Americas. Evidence included non-randomized comparator studies (n=7) and observational studies without a comparator group (n=15). There was limited information on continued HIV testing among those who discontinued injectable LA-PrEP.

Evidence on HIVST for injectable LA-PrEP



Several studies actively evaluating the use of HIVST as part of LA-PrEP

Direct evidence on HIVST for delivery of injectable LA-PrEP was limited

Limited evidence identified did suggest HIVST could potentially have ability to

- Improve flexibility, increasing or decreasing testing frequency when beneficial
- Be affordable, feasible and acceptable
- Achieve sufficient accuracy

Data among adolescents receiving injectable LA-PrEP in Brazil highlights HIVST achieved good accuracy compared to NAT

- Both oral HIVST and HIV RDT demonstrated sensitivity, specificity, PPV, and NPV exceeding 99.9% ($p = 0.006$; kappa = 1).
- IAS oral presentation *Oliveira Leite et al IAS 2025*

Managing HIV test results for LA-PrEP



Suspected breakthrough infections are rare and should be managed case by case with PrEP continued, with condom use, until diagnosis clarified.

HIV negative test result

- Initiate or continue PrEP, including LA-PrEP option that is available and desired by client

HIV reactive test result

- Ensure confirmation with full national algorithm
- Start ART promptly
- Drug resistance testing if available (for clients already in PrEP*)

HIV inconclusive test result (repeated discrepant results)

- Retest with standard algorithm in 14 days (provide condoms; PEP for clients not on PrEP)
 - If not on LA-PrEP, upon negative retest, initiate
 - If on LA-PrEP, upon negative retest, continue
 - If HIV positive, start ART immediately + drug resistance testing if available*
 - NAT not advised for resolving discrepant results

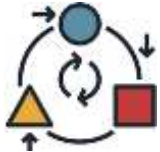
Implementation considerations and priorities

How to adopt public health approach for HIV testing for LA-PrEP?



Follow WHO recommended testing strategies and align with national algorithms

- Remove complex and costly testing requirements
- Opt for simple low-cost quality RDTs is priority
- No added benefit of Ag/Ab RDTs (**50% sensitivity in acute infection; 25% in PrEP users**)



Adapt testing to support LA-PrEP access

- Aligning testing with refill/injection visit can often be pragmatic
- Flexibility is key to enabling person-centred approach
- Simplified low-cost service delivery (task sharing, multi-month dispensing, virtual- and AI-driven, self-care, pharmacy, private sector)
- Self-testing when appropriate - **more implementation research needed**



Strengthen and redirect systems for quality management and monitoring

- Programmes and labs embrace simplified testing and shift focus to QMS, training, support and supervision, routine M&E, and enabling highly targeted monitoring for drug resistance
- WHO QMS tool kit + drug resistance testing resources via [WHOResNet](#) + [New DHIS-2 module](#) for routine monitoring

Obrigada, thank you, asante, merci, khanimambo, gracias, grazie, danke schön for your attention

WHO colleagues

Cheryl Johnson

Maggie Barr-DiChiara

Mateo Prochazka

Heather-Marie Schmidt

Heather Ingold

Michelle Rodolph

Also.....

The Gates Foundation, Unitaid and CIFF for supporting this work

Jason Ong and their teams for the systematic reviews
And all the numerous people who have supported us for the last year to make this happen



WEBINAR SERIES

TEST, ADAPT, DELIVER: HIV Testing Services in a Shifting Landscape

A webinar series on navigating change, driving innovation, and delivering impact in HIV testing services.



Supporting PrEP access with simplified and person-centred testing approaches

SEPTEMBER 4, 2025 | 2:00 PM - 3:30 PM CAT/CEST

As global efforts to end HIV continue, simplifying access to and delivery of pre-exposure prophylaxis (PrEP) has become an urgent priority. With both oral and long-acting PrEP options expanding, innovative testing strategies are essential to ensure that individuals can initiate and continue PrEP in ways that are convenient, client-centered, and scalable.

This session will bring together key stakeholders, country implementers, and global experts to explore the latest evidence, strategies, and innovations in simplifying HIV testing, which is a critical gateway to PrEP delivery.

Organizers: WHO and Population Services International

[REGISTER HERE](#)

Panel discussion

&

Q&A



Rollout plan for Lenacapavir Pre-Exposure Prophylaxis (PrEP)

*Mr Olakunle Taiwo, PrEP focal point, National AIDS, Viral hepatitis and STI Control Programme, (NASCP)
Federal Ministry of Health Nigeria
August 2025*

HIV Prevention in Nigeria – PrEP Landscape



- ❑ **2016:** Nigeria adopted Oral PrEP as an additional HIV prevention tool.
- ❑ Oral PrEP was initially prioritized for **sero-discordant couples** and later expanded to **key populations, vulnerable groups, and GBV survivors**.
- ❑ **2019:** Revised National HIV/AIDS Strategic Framework (2019–2021) published to fast-track the national AIDS response based on NAHS findings.
- ❑ **2020: Oral PrEP scale-up began**, mainly through donor-funded projects.
- ❑ **2022:** Several **guidelines and policies** were developed, including:
 - ❑ National HIV Self-Testing and Pre-Exposure Prophylaxis Communication Strategy
 - ❑ National Oral PrEP Implementation Plan
 - ❑ National Oral PrEP Training materials
 - ❑ The first harmonized national job aids and standard operating procedures for oral PrEP service delivery
- ❑ **2024:** Nigeria adopted **long-acting injectables (CAB-LA)** following WHO guidance.

PrEP Implementation Footprint following USG Aid Pause

Intervention	Target Population	# of States
Oral PrEP Implementation	All priority population	4 GF States
Oral PrEP Implementation	High-risk pregnant and breastfeeding women	33 PEPFAR States
CAB PrEP Implementation	SDC, KPs, emancipated minors	4 GF States, Lagos

- ❑ **Current:** Both Oral PrEP and CAB-LA approved in national guidelines; plans are underway to introduce **Lenacapavir (LEN)** to expand choice.
- ❑ **Challenge:** External disruptions (e.g., USG Stop-Work Order) have interrupted critical PrEP programs, suspended CAB-LA rollout, reduced workforce, and strained fragile delivery systems.

Nigeria's National Rollout Plan for Lenacapavir PrEP



Rollout Plan, Scale and Target Populations

Lenacapavir (LEN) PrEP will be introduced in eight states (Akwa Ibom, Anambra, Benue, Cross River, Ebonyi, FCT, Gombe, Kwara) in 2026.

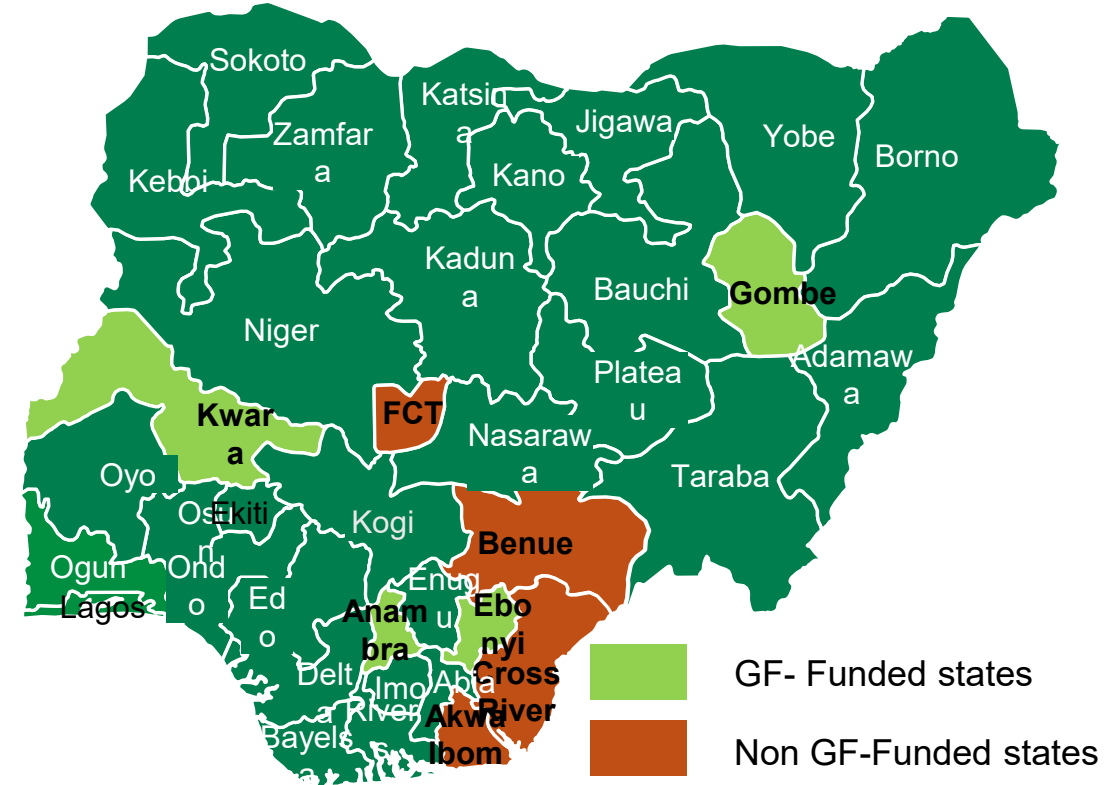
National Targets: The program aims to reach **21,000 high-risk individuals** by 2026, with a **30% annual increase** in targets through 2028. The **PrEP-it tool** was used to determine these targets.

The target population (in line with the 2024 HIV guidelines) includes:

- Key populations (MSM, FSW, PWID, TG).
- Sero-discordant couples.
- Sexually exposed adolescents and young people.
- HIV-negative individuals at high risk of HIV acquisition who are eligible for PrEP.

Implementation Strategy:

- Leverage existing **ART/PrEP service delivery platforms**.
- Utilize **differentiated service delivery models** (Facility, CBOs and OSS)
- Implement robust **awareness, advocacy, and demand generation** strategies.



State selection was guided by; high prevalence of HIV, current GF support/presence, availability of existing infrastructure for prompt rollout, state willingness and operational feasibility

Nigeria's National Rollout Plan for Lenacapavir PrEP



Timeline and Key Milestones

The three phased approach includes;

- **Planning (July–September 2025)**
- Preparatory Activities (October–December 2025)
- Implementation Phase I (January–December 2026)

Key milestones include:

- National Regulatory Approval
- National guideline updates
- **Site readiness assessment**
- Supply chain dry-runs
- Launch events
- Mid-line evaluations.

Risks, Mitigation Strategies and Sustainability

- ❑ **Risks include** regulatory delays, low demand, and weak logistics.
- ❑ **Mitigation strategies involve stakeholder engagement, cascade training, rapid guideline updates, and demand generation.**
- ❑ **Sustainability will be ensured through** government ownership, policy integration, community engagement, and operational research.
- ❑ Lessons from CAB-LA roll-out and **strong stakeholder coordination will inform scale-up**

Demand Generation

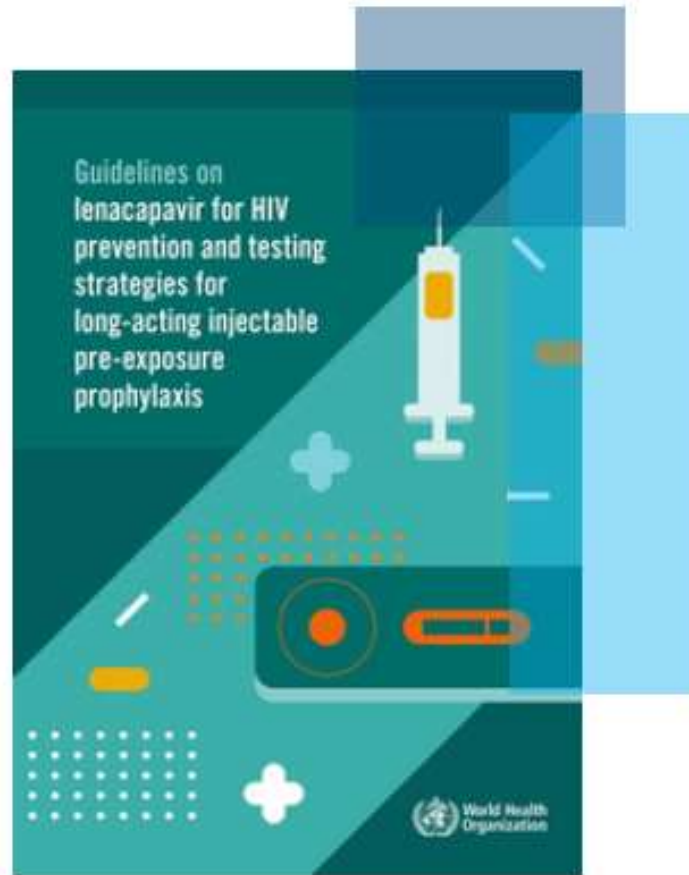
- ❑ Demand generation strategies will be used to raise awareness about PrEP options among the target population, service providers, policymakers, and the general public.
- ❑ **The goal is to ensure equitable access, stigma-free services, and improved adherence for long-term HIV prevention.**
- ❑ This will be achieved through the following strategies in line with the [*National HIV Self-Testing and PrEP Communication Strategy*](#)
 - Targeted IEC materials
 - Community mobilization and engagement
 - Digital and social media engagement
 - Strategic events and launch activities
 - Stakeholder and policy advocacy messaging



Before we go...



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WEBINAR SERIES

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HIV Testing Services in a Shifting Landscape

A webinar series on navigating change, driving innovation, and delivering impact in HIV testing services.



World Health
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Supporting PrEP access with simplified and person-centred testing approaches

SEPTEMBER 4, 2025 | 2:00 PM - 3:30 PM CAT/CEST

A WHO Global PrEP Network & Jhpiego Webinar

From Oral PrEP to LEN: Leveling Up Prevention with the WHO–Jhpiego PrEP Provider Training Toolkit

1pm CET 8 October 2025

