

Welcome to our webinar on

PrEP implementation:

What's worked, and what are we learning?



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AGENDA

PrEP implementation:

What's worked, and what are we learning?

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	Session	Speakers
	1 Opening and Welcome	Prof. Mulenga, MoH Zambia
	2 Background and Objectives of the Meeting	Chair: Wawira Nyagah
	Key Insights from the AVAC Report: Getting PrEP Rollout Right This Time: Lessons from the Field	Catherine Verde Hashim, AVAC
	Country Insights and Experiences on Introducing New and Emerging PrEP Products	Hasina Subedar, NDoH, SA Patriciah Jeckonia, LVCT, Kenya
	Making HIV Prevention work: What Works to support PrEP use in Sub- Saharan Africa	Natasha Okpara and Kamo Nunu, SSLN-i2i
	6 Discussion & Q&A	Chair: Wawira Nyagah
	7 Closing remarks and next steps	Lucy Maikweki



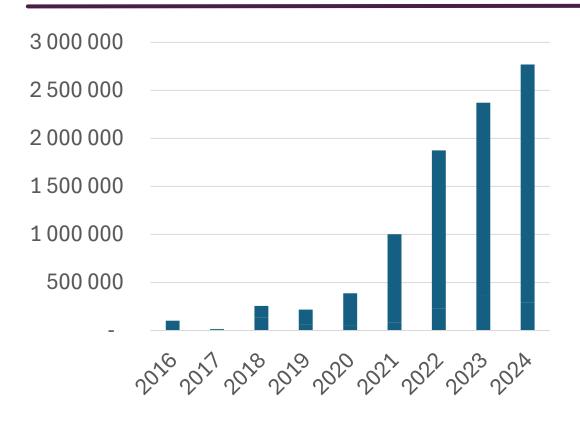


Background and Objectives of the Meeting

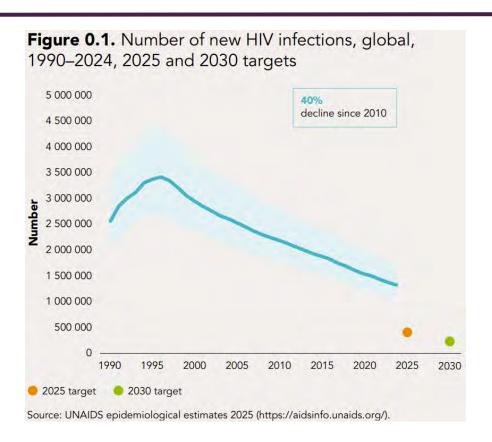




PrEP Rollout vs HIV Incidence



Over 8 million PrEP initiations to end of 2024, with significant scale-up from 2021 onwards...



But still far off UNAIDS' 2025 target for reduction in incidence

Growing Prevention Toolbox





Daily oral PrEP



Combo oral PrEP/OC

Possible dual pill to market by 2025 2



Newly Approved and Recommended



Dapivirine vaginal ring



Injectable cabotegravir



Injectable lenacapavir

And in implementation science projects:

www.prepwatch.org/resources/ implementation-study-tracker/

Currently available



HIV treatment for people living with HIV/U=U



Male & female condoms



Voluntary medical male circumcision



Syringe exchange programs



Daily oral PrEP

PEP

Event-driven for some populations

Today's Objectives

- Disseminate **key findings** from AVAC's report, *Getting PrEP Rollout Right This Time*, with a focus on country experiences thematically analysed across the key stages of the Product Introduction Pathway.
- Share country-level evidence and insights on the introduction of new PrEP products, such as injectable Cabotegravir (CAB) and the Dapivirine Vaginal Ring (DVR) and preparations for the rollout of Lenacapavir.
- Introduce an SOP to guide the adaptation of national PrEP policies for the inclusion of Lenacapavir, supporting evidence-informed decision-making and implementation planning
- Highlight effective interventions that support PrEP adherence and uptake, drawing on evidence products developed by the i2i programme.



Key Insights from the AVAC Report: Getting PrEP Rollout Right This Time: Lessons from the Field





Background

- PrEP is scaling up, but still not at the level it needs to be
- PrEP choice is here- CAB for PrEP and the DVR are available in limited settings, LEN introduction is about to start, and the DPP and MK-8527 will, hopefully, soon follow
- To support countries with scaling up PrEP and introducing new products, we wanted to identify actionable lessons and recommendations by answering these questions:
 - What are some of our biggest successes and challenges with daily oral PrEP introduction and scale-up and what can be done differently for new PrEP products?
 - How can public health systems prepare for the introduction and scale-up of new PrEP products?
 - What are **key considerations for improving and accelerating** PrEP regulatory approval, normative guidance, demand generation, stakeholder engagement, and health systems strengthening?

Methodology

Rapid Desk Review

59 scholarly articles, meting reports, consultation summaries, Country Operational Plans, media resources, online sources, etc

Key Informant Interviews

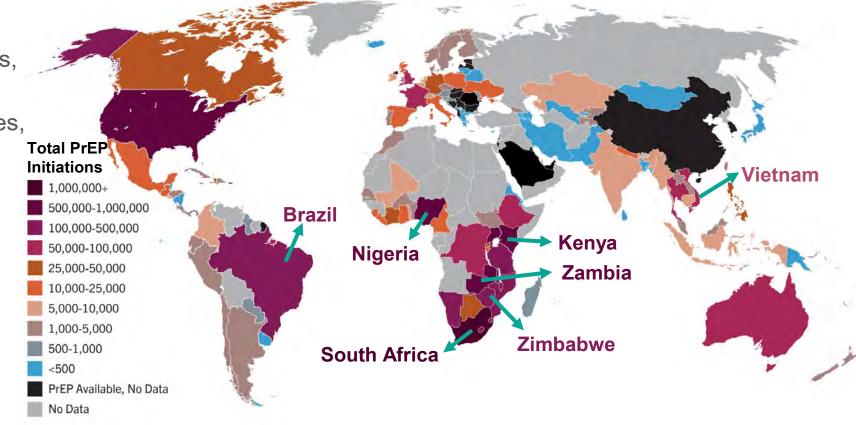
26 interviews with MoH officials, implementing partners, and civil society leaders

Time Period

November 2024- January 2025

Prior to PEPFAR stop work orders

Qualitative Analysis



Seven countries were chosen for key informant interviewsbased on size and duration of PrEP programme, with diverse geographic representation

- Early engagement with MoH, regulators, and other stakeholders creates awareness of new products prior to regulatory review
- Approvals from other regulatory bodies, such as from the US FDA or EMA, and WHO pre qualification can help expedite national approvals
- WHO guidelines can form the basis of national guidelines for new products- advocates can help ensure guidelines are inclusive as possible for all populations

- Begin engaging stakeholders now!
- Leverage <u>approvals by the US FDA</u> and <u>positive opinion from the EMA</u> to support and expedite the regulatory review process, and look out for WHO pre-qualification decision in September 2025
- Begin forming PrEP Technical Working Groups to adapt <u>WHO's LEN guidelines</u> (released July 2025) into national guidelines
- Ensure guidelines are as inclusive as possible- <u>latest data from LEN trials shared at IAS shows</u> LEN is safe and effective for adolescents and pregnant and lactating people- guidelines must reflect this

- Important considerations in deciding which PrEP products to introduce:
 - Effectiveness, as seen in clinical trials
 - Price and cost-effectiveness, including knowing what a price will be without donor subsidy and when generics will become available
 - Sustainability of supply, and confidence a product will be available long term
- Budgeting should include costs for awareness campaigns, demand generation, updated M&E systems,
 preparing the public health system, and provider training

- Advocate for pricing transparency to allow MoH to plan accordingly, with the expectation generics will become available in 2027
- Consider what choice means in your local context- does this include multiple injectables?
- Consult the latest <u>evidence on preference for injectables</u>, <u>data on product switching</u>, <u>PURPOSE results</u>
 and <u>KP need estimations</u> to help with demand forecasting
- Plan how to fund procurement post donor funding- such as taxpayer levies, national health insurance schemes, and exploring private sector (including pharmacy) models that include user cost-sharing

- Communities are not being kept up to date on pressing issues around new products, leading to low levels of awareness and engagement, particularly amongst youth
- Constant and early active engagement with CSOs is essential, as is direct engagement with young people and KPs
- The private sector must also be engaged early to ensure buy-in to PrEP delivery
- Stakeholder engagement requires budget allocation

- Start engaging communities and CSOs now on LEN for PrEP- including youth and KPs
- Start engaging the private sector, including pharmacies, to explain and promote the value proposition of LEN for PrEP, and ensure providers are ready and motivated to offer it once it becomes available.
- <u>The Coalition to Accelerate Access to Long-Acting PrEP</u> is fostering coordination amongst a wide range of stakeholders including through a community of practice with early LEN adopter countries.

- Collaborating with CSOs on demand generation materials and campaigns can ensure these are non stigmatising
- National campaigns with status-neutral messaging are perceived as the most successful
- Campaigns must be properly funded, and have consistent, up-to-date, aligned messaging
- Demand generation partially takes place through healthcare workers, who should be trained to lead literacy and awareness sessions in health facilities

- MoH should begin developing status-neutral LEN messaging and campaigns now, alongside information, education, and communication (IEC) materials – ensuring to co-create content with communities
- Consider using innovative approaches, such as digital platforms, peer-led models, and integrating messaging into popular media
- Train providers to deliver key messages on LEN awareness
- Ensure sufficient budget for demand generation



- Leverage existing ARV supply chains when introducing new products
- Urban areas are often prioritised for new product introduction, but this widens health disparities with rural areas- a more equitable approach is inclusive of underserved areas
- Sites should be assessed for readiness prior to site selection for new product introduction
- To manage the risk of stock-outs impacting continuity of care, some countries have adopted measures such as adjusting testing algorithms (during testing stock-outs) or allowing multi-month PrEP dispensation

- Plan to integrate LEN procurement into existing supply chains
- Prioritize equitable LEN access, including rural and underserved areas via community distribution
- Begin infrastructure assessments of sites selected to offer LEN for PrEP now to ensure facilities meet requirements

- Lack of counselling in many facilities is leading to early discontinuation
- PrEP uptake is higher when integrated into other sexual health services (e.g. STIs, family planning)
- Innovative and de-medicalised approaches can improve access
- Early sensitisation and training with providers, including private providers, is key to ensure enthusiasm and readiness
- Task shifting can free up provider time for more complex services and improve PrEP access

- Explore differentiated and de-medicalised delivery models (e.g. pharmacies, mobile sites, community-based), and review what policy changes may be needed to facilitate this
- Begin sensitising and training providers- explore training of trainer (ToT) and virtual models and consider
 a phased approach starting with providers already delivering PrEP- use <u>WHO and Jhpiego's new</u>
 Provider Training Toolkit to support this process
- Develop and adapt tools for choice counselling to include LEN as an additional PrEP option
- WHO guidelines released in July 2025 recommend RDT for initiation and continuation- this should be taken into account when countries design their own delivery models



Research, Monitoring, and Evaluation

Key Insights

- Look at data when deciding where to rollout new products- such as geographically (e.g., based on population density and/or HIV incidence data), by population (e.g., focusing on KPs), or impact-driven (e.g., rollout in facilities with current high numbers of PrEP users)
- Review indicators to assess readiness for new product rollout
- Robust, centralised health data systems support accurate measurement of PrEP products and other commodities in the supply chain

- Leverage existing data in deciding where to roll out LEN
- MoH should begin updating monitoring and evaluation (M&E) systems to include LEN, and consider including the following indicators:
 - PrEP uptake by product, age, and population
 - Amount of PrEP dispensed by method
 - Reasons for switching and/or discontinuation
 - Number of people with an HIV positive test results while on PrEP, by method
- LEN should be included as part of any "minimum prevention package" being defined by MoH.

Key Takeaways

Keys to Successes

- Address gaps in your health system to prepare for efficient product introduction
- Plan and discuss financial sustainability
- Proactively educate yourself and other stakeholders about the benefits of PrEP, including new products
- Collaborate with CSOs to actively reduce stigma associated with PrEP and package messaging and counselling based on end-user preferences
- Make healthcare provider needs, including comprehensive training, a top priority
- Use data to drive PrEP rollout
- Leverage existing product procurement and distribution systems and update your M&E systems/EMRs

Challenges to Address

- Regulatory approval processes mired in inefficiencies and policymakers' personal value systems
- Lack of transparency from manufacturers, delays in the product supply chain, and a potential lack of donor support
- Insufficient engagement with the private sector and youth, and budget allocations for engagement not prioritized
- Insufficient funds for demand generation, limited provider capacitation on counselling, and inadequate product supply
- Unequal societal distribution of PrEP and infrastructure challenges hindering holistic, population-level service delivery
- Existing human resource and commodity constraints





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Country Insights and Experiences on Introducing New and Emerging PrEP Products

Lessons from South Africa Reflections on oral PrEP, CAB-LA, DVR, and Looking Ahead to Lenacapavir

Presented by Hasina Subedar, NDoH SA









Introducing New and Emerging PrEP Products:

Lessons from South Africa

Reflections on oral PrEP, CAB-LA, DVR, and Looking

Ahead to Lenacapavir

14 August 2025

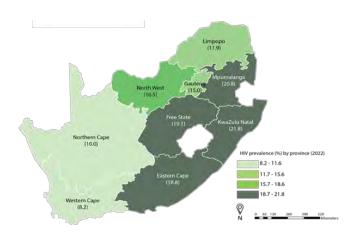
Presenter: Hasina Subedar





South Africa: HIV Epidemic

HIV Prevalence 2022



HIV Incidence 2023 Incidence rate 15-49 (per 1000) December 2023 8.0 6.0 4.0 2.0 0.0

HIV incidence rate among adults 15-49 years by district, 2023 L. F. Johnson and R. E. Dorrington (2024) Modelling the impact of HIV in South Africa's provinces: 2024 update

South Africa remains the epicentre of the HIV epidemic:

7.6 million people are living with HIV (2022)160,000 new infections that same year, more than 400 each day45,000 AIDS-related deaths

Adult prevalence (15–49 years):

17.8%

Prevalence key populations:

62% among sex workers, 58% among transgender people, and nearly 48% among gay and bisexual men.

These figures remind us that HIV prevention is not optional, it is urgent. Every infection we prevent today saves a lifetime of treatment and preserves a life.

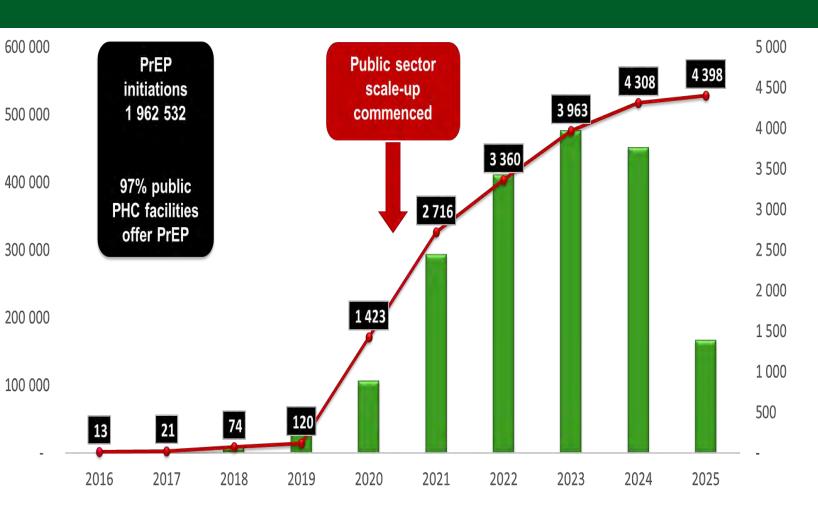
Status of South Africa's Oral PrEP Programme (June 2016-June 2025)

Since the launch of oral PrEP in 2016, South Africa:

- **1.9 million** people have started using oral PrEP.
- 97% of public primary healthcare facilities now provide PrEP services.
- 4,350 service delivery locations actively provide oral PrEP throughout the country.

In 2024 alone, over **450,000** new users were introduced to PrEP.

The key to South Africa's success is that PrEP is embedded within an integrated primary healthcare service.







Data Driven Target Setting for PrEP

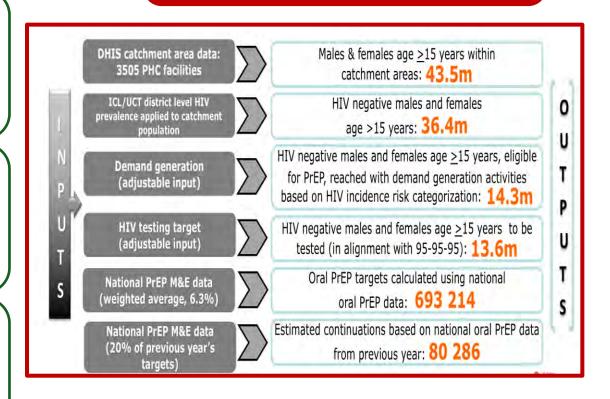
South Africa precision strategy for oral PrEP targeting

This strategy uses data on HIV prevalence, service coverage, and programme performance to allocate PrEP resources where they're most needed, ensuring alignment with local demand, capacity, and HIV risk.

PrEP targets are based on the needs of the population, facility capacity, and epidemic trends. This helps to optimise demand generation, HIV testing, and supply chain planning.

The approach also provides a scalable framework to guide the rollout of long-acting PrEP by improving targeting, forecasting, and service delivery systems.

Oral PrEP Targets
April 2025- March 2026



Implications of lenacapavir

- **Prioritise high-burden districts** using district-level HIV incidence data to guide early LEN rollout.
- **Maximise impact and cost-effectiveness** by focusing limited initial supplies where need is greatest.
- Apply spatial targeting to avoid diluting stock and training in low-priority areas.
- Concentrate efforts in high-incidence districts to boost demand creation and uptake before scaling nationally.
- **Use disaggregated targets** (by population group, age, gender) to align services with epidemiological risk profiles.
- Ensure equity by giving those at highest risk earlier access to LEN.
- Tailor demand creation messaging for specific audiences.
- **Implement differentiated models** such as youth-friendly clinics, integrated SRH services, and mobile outreach for remote communities.
- Monitor and track uptake by district, age, gender, and population group to guide programme adjustments.





Early insights from implementation science studies

- PrEP uptake was notably higher at sites where all three PrEP options (oral PrEP, Ring, and CAB-LA) were available compared to sites with only one or two options.
- National guidelines, job aids, social mobilization efforts, and reporting tools ensured standardized delivery, messaging, and reporting.
- Uptake of injectable PrEP was high highest amongst age groups 20-34 years and females.
- CAB-LA injections are practical in pubic PHC clinics and mobiles, with no major logistical challenges related to transportation or storage.
- Persistence rates for CAB-LA across sites were higher than oral PrEP (75-77% vs. 39% at month one; 62% -41% vs. 33% at month three).





Availability of commodities is critical for successful implementation

- In country availability of commodities after regulatory approval delayed timeous implementation
- Dapivirine Vaginal Ring 16 months Cabotegravir 14 months







Key Recommendations for Scale-up of Injectable PrEP

- Training of health care providers should cover all available PrEP and HIV prevention products
- Additional support and guidance required for:
 - Injection techniques, injection pain, and managing injection site reactions
 - Support for clients to return on time for follow-up visits
 - Simplified choice counselling
 - Transitioning to other PrEP and HIV prevention methods
 - Bridging doses and injection scheduling for mobile populations
 - Stopping injectable PrEP and monitoring HIV status during the tail period requires close monitoring
 - Drug-drug interactions
- HIV testing schedules, especially testing requirements and frequency of testing, especially for longacting injectables.
 - Generating evidence for use of self-screening tests with long-acting injectables is required





THANK YOU







Country Insights and Experiences on Introducing New and Emerging PrEP Products

The Kenyan Experience

Presented by Patriciah Jeckonia, LVCT Health

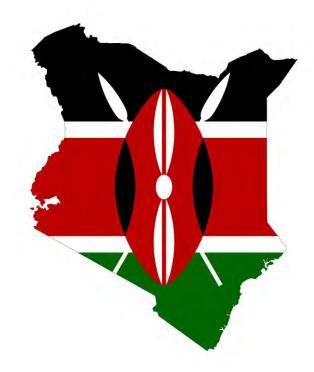




Kenya's PrEP performance



- Oral PrEP was rolled out nationally in May 2017 with government (NASCOP) leadership. National PrEP TWG in place.
- To date, Kenya has initiated 747,876 in more than 2,527 facilities across 47 counties
- Kenya is off-track in preventing new infections (16,752 estimates 2024)
- Majority of users are categorized as general populations –data tools to capture sub-populations include PBFP
- Persistent challenge of initiation and effective use among AGYW on oral PrEP
- Very low continuation rates among users of oral PrEP
- PrEP offered at comprehensive care clinics for HIV+ clients and suboptimal integration in MCH
- Little to no demand generation especially after stop work order.
- HIV stigma is still high
- Dapivirine Vaginal Ring (PrEP Ring) and CAB-LA introduced through studies but not rolled out programmatically
- PrEP program heavily donor funded



© Vemaps.com

Key learnings



Regulatory approval and budget:

- Need for early engagement of Pharmacy and Poisons Board (PPB) even before submission of approval application package
- Government to allocate budget for HIV prevention technologies

Provider training:

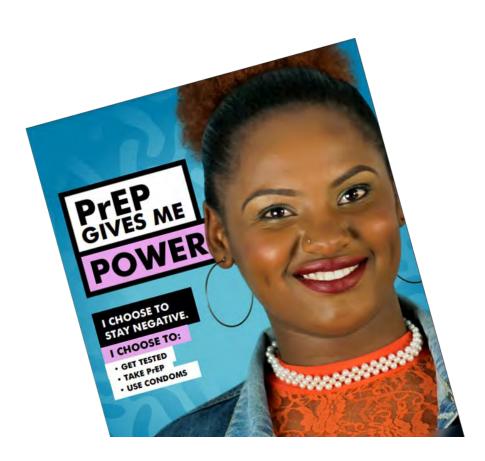
- Hybrid approach (online and offline)
- Ongoing mentorship
- Job aids

Sustainable demand generation:

- Sustain and grow interest for PrEP through SBC approach
- PrEP for anyone with high likelihood of HIV infection
- Use appropriate channels go beyond posters in facilities to peer-led, community spaces and digital media

Supply Chain:

- Elaborate plan for management of limited long-acting PrEP commodities
- Ensure enough HIV test kits and consumables



Key learnings





Service delivery:

- Optimise integration of PrEP into SRH (ANC, FP, post-abortal care clinics)
- PrEP choice counselling will be key
- Take PrEP to community spaces
- Delivery in private sector e.g. pharmacies



Stakeholder engagement

- Rigorous and early engagement of key gate keepers especially on injectables
- Put AGYW at the front and centre in introduction of long-acting PrEP
- Address myths and misconceptions
- Private sector engagement as part of total market approach



Monitoring, evaluation and learning

- Inclusion of indicators that will capture all PrEP methods and key indicators for decision making
- Scale-up of EMR (electronic medical records)
- Define national implementation research agenda







MAKING HIV PREVENTION WORK:

What works to support Pre-Exposure
Prophylaxis (PrEP) use in Sub-Saharan Africa
An evidence summary by Insight 2 Implementation

Presented by Natasha Okpara and Kamo Nunu









MAKING HIV PREVENTION WORK:

What works to support Pre-Exposure Prophylaxis (PrEP) use in Sub-Saharan Africa



















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CONTEXT MATTERS RECOMENDATIONS

Programme Recommendations
Policy Recommendations
Evidence Generation

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INTRODUCTION

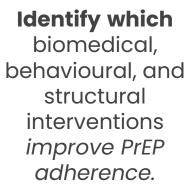
Despite increased availability of PrEP options, limited uptake and high PrEP discontinuation rates threaten the overall effectiveness of HIV prevention efforts.

- Multiple PrEP options are already available or are entering the market to meet user needs. Oral PrEP is the most widely approved and used PrEP option, with DVR and injectables reach expanding.
- Yet, PrEP uptake falls short of the PrEP need.
- Effective use and adherence remain a challenge.
 PrEP's potential is undermined when individuals disengage or do not use it during periods of increased risk.
- Emerging questions about what strategies have been effective in supporting effective use of PrEP, and what are the lessons for the way forward.



Our scoping review aimed to identify effective interventions and implementation strategies to support effective use of PrEP in Sub-Saharan Africa.







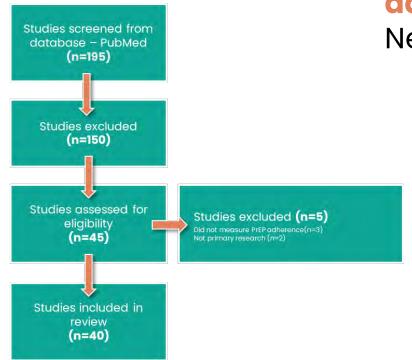
interventions are implemented to address barriers to PrEP access and adherence, with a focus on practical strategies across intervention levels



influences the
effectiveness of
adherence
interventions,
including who is being
reached and where
the gaps remain

METHODS

We conducted a scoping review of 40 peer-reviewed articles from PubMed (2019-2025) focusing on PrEP adherence and support in 15 South-to-South Learning Network (SSLN) countries.

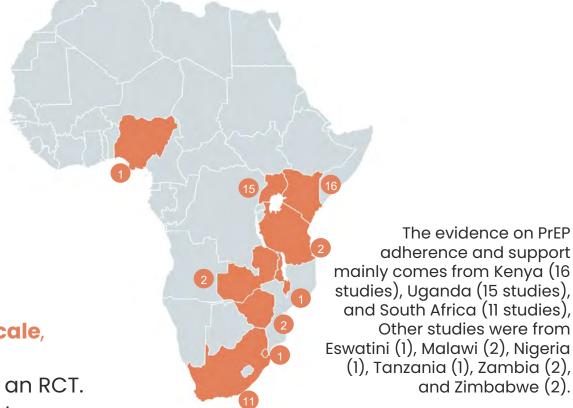


The majority of the studies focus on oral PrEP.

 The majority of these studies were implemented at pilot scale, followed by large-scale implementation.

14 of the studies used a rigorous research design, such as an RCT.

 PrEP adherence measures varied, including drug/pill counts, biomarkers, and self-reported adherence.







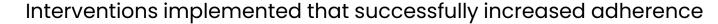


WHAT INTERVENTIONS IMPROVE ADHERENCE?

How interventions address adherence barriers:

- Individual Level
- Healthcare Provider & System Levels and,
- Community Level.

Individual level interventions, often combined with healthcare interventions, were most successful in improving PrEP adherence





- Interventions with individual PrEP users were the most tested (14); followed by multi-level interventions (11); individual-level interventions combined with health care interventions (8); and others
- Over half the studies (22 out of 40) reported an improvement in PrEP adherence.
 - Of these, 10 used objective measures (e.g., drug-level testing) of adherence.
 - Using the more objective measures, the combination of individual-level and healthcare interventions seem to yield the best PrEP adherence outcomes.

PrEP adherence interventions vary significantly

across SSLN countries, highlighting disparities in tested implementation strategies.



Dominant Research Hubs

Kenya, South Africa, and Uganda had the widest diversity and highest number of interventions with an improvement in PrEP adherence across all categories of interventions (i.e., individual, healthcare, and community), indicating a multifaceted approach to HIV prevention.

Varied Implementation:

- South Africa and Uganda are particularly strong in individual interventions
- Eswatini, Malawi, Zambia, and Zimbabwe show minimal but existing efforts, each implementing one or two types of interventions that resulted in an improvement in PrEP adherence
- There is a general underutilisation of community interventions across most countries, with only Kenya, South Africa, and Uganda showing notable use
- Most countries (i.e., Botswana, Côte d'Ivoire, Ghana, Mozambique, Nigeria, Republic of Congo, South Sudan, Tanzania) showed zero implementation across all categories, suggesting limited or no documented interventions of these types







Individual Level

Successful individual interventions address education on effective use of the PrEP method, personalised counselling, risk assessment, and personal readiness.











Level

In the IPAD study, effective education, counselling, support tools and incentives were facilitators of PrEP adherence among high risk **AGYW** in Uganda

Examples of individual-level intervention that improved PrEP adherence

Study Overview

- Led by MRC/UVRI & LSHTM Uganda Research Unit.
- AGYW reporting transactional sex were recruited from sex work venues, bars, lodges, and urban slums in southern Kampala.
- Enrolled in the IPAD study at an existing women's clinic and offered oral PrEP.
- Adherence was measured by one time blood samples, pill counts, and self reports.

Intervention components

- Group education that covered what PrEP was and its purpose
- Adherence counselling from healthcare workers
- Support tools / devices such as phones, alarm clocks, watches and adherence assessment cards helped to keep participants on track
- Incentives such as transport, free sanitary pads, free reproductive health services and treatment for common illnesses, continuous HIV testing, and education

Kayesu, I., Mayanja, Y., Nakirijja, C. *et al.* Uptake of and adherence to oral pre-exposure prophylaxis among adolescent girls and young women at high risk of HIV-infection in Kampala, Uganda: A qualitative study of experiences, facilitators and barriers. *BMC Women's Health* 22, 440 (2022). https://doi.org/10.1186/s12905-022-02018-z







Healthcare Level

interventions address healthcare provider knowledge & biases, include non-traditional providers in PrEP delivery, and improve access by providing targeted services and integrating PrEP into existing health services.

Effective HCP interventions*

- Inclusion of non-traditional healthcare providers (e.g., pharmacists, CHWs) on PrEP delivery (PrEP info + motivational interviewing + adherence counselling)
- Training on PrEP eligibility and clinical management
- Increased provider knowledge of PrEP options
- Stigma reduction activities with healthcare providers



Effective Health System interventions*

- KP & Youth-friendly clinics
- Integration of PrEP into existing SRH services or other routine care (e.g., family planning, MCH clinics, STI clinics)
- Increased number or diversity of access points for PrEP (e.g., mobile clinics, telehealth, pharmacy)









Level

In the Partners Scale Up Project in Kenya, training providers & delivering PrEP services within public HIV clinics improved adherence.

Study Overview

- Led by KEMRI in Kenya
- Women and men aged 18+ years were offered daily oral PrEP at public health facilities.
- PrEP was integrated into 25 high volume public HIV care clinics.
- Health care providers attended a two-day training on PrEP delivery.
- Adherence was measured by dried blood spots and pharmacy refill

Service Integration Strategies:

- PrEP-related topics added to routine health talks,
- Follow-up calls to clients for missed appointments
- Regular clinic staff meetings included discussions on PrEP delivery & service challenges
- Fast-tracked PrEP clients
- Dispensed PrEP in clinic rooms rather than at clinic-based pharmacies.









Successful community
level interventions
address PrEP-related
stigma, negative social
norms around sexual
practices, and foster
supportive environments
for PrEP use.

Examples of effective community interventions

- Community leader engagement and mobilisation
- Community-wide PrEP education campaigns
- Peer-led outreach and support
- Stigma reduction campaigns

Example of Community Engagement Strategies in DREAMS Programming, Kenya

- Meetings at communal centres with local chiefs and parents to build PrEP support
- Male change agents led sensitisation events for male partners
- "Buddy Days" engaged couples in safe spaces
- Routine health services offered to reduce stigma

However, community-level efforts alone were <u>not</u> sufficient. Studies with improved adherence consistently **combined community interventions with individual-level support**.

POPULATION & CONTEXT-SPECIFIC CONSIDERATIONS

CONTEXT MATTERS

A "one-size-fits-all" approach to PrEP adherence is insufficient; interventions must be tailored to the unique needs, behaviours, and social realities of specific populations.





CONTEXT MATTERS



AGYW

- Dynamic HIV risk perception
- High mobility & unpredictable schedules
- Anticipated PrEP-related stigma
- Anticipated social stigma re: sexual activity

Counselling that addresses fluctuating risk perceptions, guide AGYW on 'rational PrEP use' and PrEP choice to fit lifestyle, and supplement with community-level support for PrEP use.



MSM & LGBTQI+

- Persistent societal stigma
- Judgemental and nondiscreet health services
- Adherence challenges & preference for non-daily PrEP formulations

Choice-based delivery models incorporating long-acting forms of PrEP, alternative delivery methods, and discreet, affirming care supported by peer-led models to enhance access.



ABM

- Low perceived HIV risk
- Transient lifestyle
- Concerns about PrEP side effects & impact on daily life
- Negative perceptions about PrEP

Tailored multi-level support addressing mobility, substance use, multiple prevention needs. Tech tools for awareness & adherence. Sensitisation of healthcare providers.



FSWs

- Multiple prevention needs (contraception, STIs, HIV)
- Substance abuse
- Low community awareness on PrEP
- Restrictive health facility policies
- Judgemental health services & inconvenient hours

Targeted PrEP
education, mobile (nonfacility based) delivery,
long-acting PrEP
options, and partner
support for improved
uptake & adherence.



PWIDs

[Very limited evidence & insights]

- Multiple health & support needs
- Restrictive access to health facilities and services
- Social stigma
- Legal barriers

Discreet and confidential care in community-based settings.

CONTEXT MATTERS

Effective use of PrEP depends on the social, structural, and policy contexts within which HIV prevention/PrEP are offered



Socio-Cultural & Socio-Economic Contexts

Fear of being labelled as sexually promiscuous.

Fear of being seen as HIV positive

Negative attitudes towards PrEP.

Experience of intimate partner violence.

Proximity to health facilities & loss of link to facility due to high mobility.

Competing needs health/prevention vs. economic survival.



Health System Characteristics

Product availability and stock-out.

Lack of private spaces to counsel clients.

Lack of trained provider for PrEP services.

Provider attitudes toward PrEP options and clients.

Lack of infrastructure for monitoring effective use.



Policy & Programme Environments

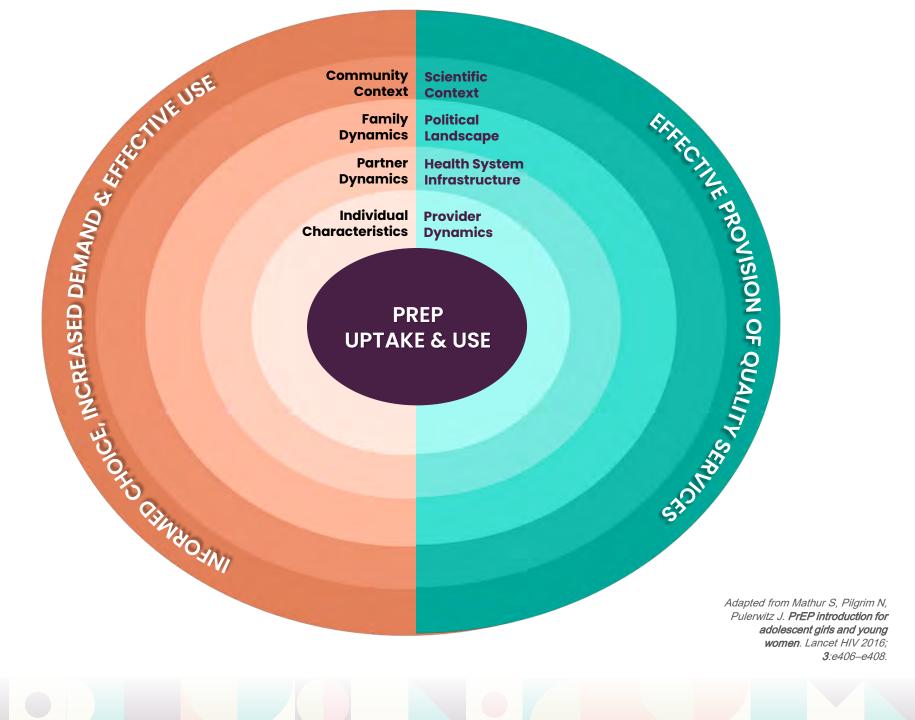
Guidelines prioritize PrEP for certain populations.

Guidelines limit the number and type of providers/facilities that are eligible for PrEP. administration & counselling.

Inflexibility in provider's ability of health providers to make innovative adaptations to PrEP delivery to reduce barriers for clients and staff.

Restrictive health facility policies.

Our review confirms the need to focus on both individual and service delivery factors, as well as relevant socioecological factors for effective PrEP uptake & use



RECOMMENDATIONS FOR PREP POLICIES, PROGRAMMES & EVIDENCE GENERATION





Prioritise user-centred design and choice-based counselling, strengthened provider support, and basic digital tools

- ▶ **Empower choice.** Offer choice-based counselling that supports personal agency and addresses product-specific concerns and fears.
- ▶ Offer tailored adherence support. Train providers for brief, repeat counselling sessions to address evolving adherence challenges and PrEP needs.
- ▶ **Reduce logistical burdens.** Use mobile delivery, multi-month dispensing, and community dispensing to make it easier for users to stay engaged with PrEP.
- ▶ Normalise Prep. Embed in routine (non-HIV) care interactions to improve user experience and reduce stigma.
- ▶ **Use simple technology.** Leverage SMS reminders or phone calls, or other tech that is accessible and practical and tailored to local infrastructure.

POLICY RECOMMENDATIONS









- ► Leverage existing platforms and infrastructure. Integrate PrEP services and adherence support into national HIV/SRH services (ART, MCH, FP) rather than stand-alone services.
- ▶ **Decentralised Prep Delivery.** Expand Prep access & use support through community-based sites, drop-in centres and CHW-led outreach to reach marginalised groups effectively.
- ▶ Standardise support. Adopt a "minimum adherence support package" in national guidelines (e.g., brief counselling, optional SMS reminders, quarterly check-ins).
- ► Expand PrEP delivery. Engage existing cadres of healthcare providers (e.g., Pharmacists, CHWs) to reduce the need for specialised staff or major new investments.
- ▶ **Promote regional learning.** Use the SSLN or other regional networks to develop technical guidance and share tools and lessons across countries that are further ahead (e.g. Kenya, Uganda) and those with few documented adherence interventions (e.g. Tanzania, Nigeria), reducing duplication and costs.







Fill gaps in **knowledge** and **evaluate** new service delivery models

- ▶ Build in monitoring and evaluation into PrEP programmes: Assess the effectiveness of PrEP programmes across diverse contexts to fill knowledge gaps.
- ▶ Evaluate Long-Acting PrEP options: Study uptake, effective use, and acceptability across different populations.
- ▶ **Strengthen qualitative insights:** Explore enablers and barriers like personal agency, stigma, and provider attitudes to unpack mechanisms of success or failure.
- ▶ Assess task-shifting models: Compare cost-effectiveness and outcomes for non-traditional provider-led programmes.
- ▶ **Standardise adherence measurement:** Inconsistencies in adherence measurement (self-report versus biomarkers) limit comparability. Adopt standardised, validated adherence metrics.



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Learn more about Insight 2 Implementation and the South-to-South HIV Prevention Learning Network (SSLN): https://www.hivinterchange.com/

















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Lenacapavir Pre-Exposure Prophylaxis: SOP Resource for Countries



- The release of <u>WHO's recommendations on Lenacapavir</u>
 <u>PrEP</u> is a great step towards enhancing the global response for HIV prevention
- In response, SSLN & i2i, in collaboration with The Global Fund, CHAI and Wits RHI have developed a Standard Operating Procedure (SOP) for LEN PrEP to make it easier for countries to adapt the WHO recommendations.
- The SOP is designed as a template to support the quick development and adoption of national SOPs that align with WHO recommendations and guidance on injectable LEN PrEP.
- The SOP can also be adapted for national guidelines on LEN PrEP or as a policy addendum

LEN PrEP SOP Highlight on Content

Product Information

- Formulation, effectiveness, potential side effects, drug interactions, contraindications and LEN use
- Switching between PrEP methods
- Prep Initiation
 HIV Testing & counselling, Assessments, Prep Counseling, Prep Prescription
- PrEP Follow-up visits
 HIV testing and counseling, assessments, PrEP counseling, prescription refill
- Management of Clients in Specific Situations

 Management of seroconversion, management of side effects and adverse drug reactions, pregnancy an breastfeeding
 - Who can deliver PrEP and where

The content for the SOP was sourced from various documents including <u>Guidelines on Lenacapavir for HIV Prevention and Testing Strategies for Long-acting Injectable PrEP</u> from WHO (July 2025); <u>The WHO and Jhpiego Provider Training Toolkit on Use of Oral and Long-Acting HIV Pre-Exposure Prophylaxis (PrEP)</u> (July 2025); <u>United States Food and Drug Administration Yeztugo Label</u> (June 2025) – among other documents.

How to use the LEN PrEP SOP Template

The document includes prompts for national-level consideration during the SOP adaptation process which countries can discuss and update to suit their country situations.

1.

Areas in red font - these require national updates

OVERVIEW OF PRE-EXPOSURE PROPHYLAXIS

Pre-exposure prophylaxis (PrEP) is the preemptive use of antiretroviral (ARV) drugs by people who do not have HIV to reduce the probability of HIV acquisition. The level of effectiveness provided by PrEP is strongly correlated with effective use, meaning it is important for clients to use PrEP methods as prescribed during periods when they may be at increased likelihood of acquiring HIV. Current PrEP methods recommended by the World Health Organization (WHO) do not prevent pregnancy or sexually transmitted infections (STIs) other than HIV. WHO does not make any statements on minimum age, and PrEP can be used by adolescents, although additional support may be needed for adolescents to effectively use PrEP, and there is a minimum weight requirement for safety indicated on product labels.

This document focuses on long-acting injectable lenacapavir (hereafter referred to as "LEN") as the newest PrEP method currently recommended by WHO and approved for use in [country].

2.

COMPONENT 1: HIV Testing and Counseling

HIV testing and counseling should be conducted per national guidelines using rapid diagnostic tests. Sameday HIV testing is strongly suggested. If the test result is negative, a client can continue through the initiation visit and may be able to start PrEP. If their result is positive, the client must not be initiated on PrEP but should receive further testing per the national algorithm and, if the result is confirmed positive, the client should be immediately initiated on or referred for ART. If the test result is inconclusive, defer PrEP and follow the national algorithm/guidelines until a definitive HIV test result has been obtained. Further implementation research is needed to fully determine the role of HIV self-testing (HIVST) in delivering long-acting injectable PrEP such as LEN.

As part of HIV testing and counseling, clients should be counseled on combination HIV prevention and provided with condoms and condom-compatible lubricant.

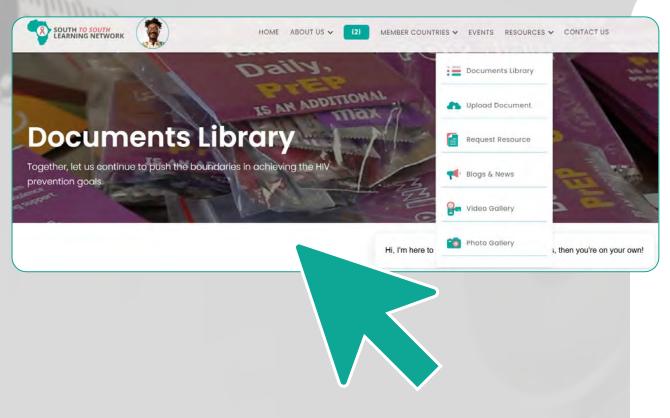
For consideration:

may be difficult to offer a client PrEP on the same day when they test negative for HIV. Some programs accept the results of tests conducted within the last three to seven days if a client has had no potential exposure to HIV since their test.

Green boxes – these highlight areas for additional consideration by policymakers - informed by regulatory bodies, available product information, and country-level insights.

 These boxes can be updated with text or removed once a decision has been made about the proposed considerations

Where to access the LEN PrEP SOP



- The SOP will be available on the <u>SSLN i2i</u> <u>website</u> as a Microsoft Word document for ease of adaptation
- Any queries / comments or feedback related to the SOP can also be sent via email info.i2i@genesis-analytics.com
- Other resources you can find on our website include the recently launched WHO online health provider <u>e-training course</u> for PrEP that includes LEN. This resource supports providers with knowledge on how to offer multiple HIV PrEP methods

