



Amplifying  
Community Voices  
for Prevention

Strategic  
Community HIV  
Prevention  
Empowerment

## E-MEETING SUMMARY REPORT

Developments in the HIV Biomedical  
Prevention Pipeline & PrEP Implementation  
Issues – An Update for Community  
Educators and Advocates

May 18, 2022



# Contents

<b>What’s New &amp; Next in HIV Prevention? HIV Prevention Research, Development and Implementation Pipeline in 2022 and Beyond</b> .....	<b>4</b>
Overview of the current ARV-based prevention options.....	4
<b>Implementation Challenges for Novel PrEP Modalities: What Can We Learn from Oral PrEP?</b> .....	<b>6</b>
Three Main Challenges and Lessons Learnt.....	6
<b>Access to HIV Prevention: Communities’ Perspectives</b> .....	<b>7</b>
Sex Workers’ access to PrEP.....	7
HIV Care & Prevention Intervention in Community Setting for Migrants and Asylum Seekers in the Mid-West of Ireland (Limerick, Clare, Tipperary) .....	7
Enhancing PrEP Information and Uptake in the EECA region .....	8
<b>Summary of Discussion and Key Take-Aways for Community Advocacy</b> .....	<b>9</b>



## Background

This report summarises highlights from the e-meeting on the HIV Biomedical Prevention Pipeline & PrEP Implementation Issues for Community Educators and Advocates on 18 May with EATG (European AIDS Treatment Group), PrEPster, AIDS Action Europe, AVAC and ECOM. The meeting was opened by Harriet Langanke, Chair of the EATG Combination Prevention Programme, and moderated by Will Nutland Co-Director of the Love Tank.

*Link to the recording:* <https://www.youtube.com/watch?v=AQbJsYuOpVA>

This e-meeting was part of the [Strategic Community HIV Prevention Empowerment \(SCOPE\) Project](#), which has been developed by the EATG and was made possible through a grant from ViiV Healthcare Europe Ltd. The donors have not had any control or input into the structure or content of the event.



# What's New & Next in HIV Prevention? HIV Prevention Research, Development and Implementation Pipeline in 2022 and Beyond

Cindra Feuer, AVAC Senior Programme Manager: Partnerships & Capacity Strengthening. To access the slides (EN & RU), click [here](#).

## Overview of the current ARV-based prevention options.

- **Dapivirine vaginal ring**: the first long-acting HIV prevention product that was approved in 2020 by WHO (World Health Organization) and EMA (European Medicine Agency) for distribution in the African countries where clinical trials were conducted. A discrete silicone vaginal ring that is self-inserted monthly, which does not interfere with penetrative vaginal sex. Although clinical trials resulted in a relatively low efficacy rate (35-60%), this remains a worthwhile option in regions with high HIV-incidence. However, due to its low efficacy shown in previous trials and the harmful narrative on women's non-adherence, this HIV prevention option will not be introduced in most regions outside of Africa. More targeted advocacy efforts should therefore be channelled towards increasing resources and access to rings, while refocusing the narrative around the options, choices, needs and desires of women.
- **Long-acting Injectables:**
  - Bimonthly injectable **Cabotegravir for PrEP** (CAB-LA/CAB-PrEP/ CAB for PrEP): its efficacy was proved in early 2021 and was approved by FDA in the U.S. in December 2021. Additionally, CAB-LA has been filed with other regulatory authorities (including in CAB trial countries - decisions expected in 2022) and EMA filing is planned for summer 2022. WHO has published [new prevention guidelines](#), which include CAB-LA. Additional sub-studies are currently underway for women, pregnant women, breastfeeding women and younger people.
  - Two points require community advocacy, namely **registration** and **affordability** (price must be comparable to generic oral PrEP to be considered cost-effective), and access to better **testing options** for HIV and viral load and
  - **Bi-annual injectable Lenacapavir**: In December 2021, efficacy trials were placed on clinical hold due to emerging concerns about the compatibility of the borosilicate glass with the drug solution, which could have potentially led to the formation of sub-visible glass particles in the solution.<sup>i</sup> On May 16, 2022, the U.S. Food and Drug Administration (FDA) removed the clinical hold and all activity can resume.<sup>ii</sup>
- **Monthly oral Islatravir**: In December 2021, efficacy trials among [MSM, trans women](#), and [cisgender women](#) evaluating Islatravir for HIV treatment and prevention were placed on hold due to reported decreases in total lymphocyte and CD4+ T-cell counts in some participants.<sup>iii</sup>
- **Daily dual prevention pill for women (TDF/FTC/COC)**: A single co-formulated tablet containing TDF/FTC and combined oral contraceptive. Regulatory approval and early introduction might take place in late 2022.



- **Ad26 preventive vaccine (MOSAICO):** Currently in a late-stage efficacy trial among MSM and trans people and the only ongoing clinical trial in Europe (Spain, Italy, Poland).
- **Broadly neutralising antibodies (bNAbs):** bNAbs were proven to be effective for prevention. While not intended for licensure or market due to the fact that they cannot be scaled up, bNAbs might play a pivotal role for new prevention interventions and vaccine development.



# Implementation Challenges for Novel PrEP Modalities: What Can We Learn from Oral PrEP?

Thijs Reyniers, Social Health Science Researcher at the Institute of Tropical Medicine (Antwerp).

To access the slides (EN & RU), click [here](#).

## Three Main Challenges and Lessons Learnt

### Potential PrEP Users

PrEP risk-based eligibility criteria may exclude potential users preferring injectable PrEP. Furthermore, it excludes those anticipating an increased risk. Additionally, criteria targeting specific populations can increase PrEP stigma and thus hinder uptake. Therefore, PrEP should be presented as a prevention option for all individuals wanting to proactively take precautions and not just as a product for certain profiles.

However, considering the anticipated cost of injectable PrEP, a more cost-effective approach will be needed. Targeting specific populations has proved to maximise the impact of novel interventions on the HIV epidemic<sup>iv</sup> and cost-effectiveness. It may encourage national health systems to reimburse injectable PrEP. Furthermore, eligibility criteria help establish a profile that potential users can identify with, which could increase PrEP uptake.

### PrEP Delivery

Differentiated delivery models (e.g. community/peer-led, telemedicine/eHealth, inclusion of family physicians) could meet the growing demand for PrEP, improve uptake, and retention in care.

However, LAI-PrEP may require specialised clinical service delivery as it may require more sensitive HIV testing and regular medical follow-up (to avoid potential drug resistance).

### Monitoring and Evaluation of PrEP Rollout

Assessing adherence to oral PrEP has been burdensome for both PrEP providers and users, making surveillance of PrEP use challenging. Therefore, simplified monitoring and evaluation methods should be developed to assess impact of novel HIV prevention tools as they are required to help optimisation of their implementation.



## Access to HIV Prevention: Communities' Perspectives

### Sex Workers' access to PrEP

Luca Stevenson, Operations Officer at the European Sex Workers Alliance (ESWA).

The persistent lack of data and information on HIV and access to PrEP for sex workers remains a central issue, which jeopardises the possibility of drawing a global, clear picture of the situation. In 2016, the Global Network of Sex Work Projects (NSWP) conducted sub-regional consultations regarding sex workers' access to PrEP. Data were collected from a total of 379 sex workers in 10 countries and showed that the main issue reported by sex workers was the lack of information on PrEP, coupled with fears and concerns about it. Although the current situation might have slightly changed and more sex workers advocate for access to PrEP, in many countries the product is still either unavailable or made inaccessible by structural barriers and bureaucratic ostracism. It is the case of many sex workers in the European region who are undocumented migrants and cannot access PrEP in traditional healthcare systems.

Partnership with sex worker-led organisations and communities for projects on the implementation and access to PrEP should be scaled up.

Between 2016 and 2017, a large study on female sex workers and PrEP was conducted in India with two collectives of sex workers: the [Durbar Mahila Samanwaya Committee](#) and [Ashodaya](#) ("Dawn of Hope"). Trial results reported high level adherence and no seroconversion. The success of this study is attributed to close collaboration and participation of two sex workers collectives.

In Europe, a number of trends hinders participatory approaches and PrEP access, namely the criminalisation of sex work and clients, the lack of funding accessible to sex worker-led organisations and the active exclusion of sex workers from decision and policy-making processes. Moreover, PrEP is targeted to MSM thus limiting access for female sex workers who might want to use PrEP.

The focus on biomedical interventions overshadows other HIV vulnerability factors for sex workers such as poverty and housing. Moving forward, a holistic approach is critical.

### HIV Care & Prevention Intervention in Community Setting for Migrants and Asylum Seekers in the Mid-West of Ireland (Limerick, Clare, Tipperary)

Ann Piercy, Personal Support Worker at GOSHH (Limerick, Ireland).

To access the slides (EN & RU), click [here](#).

In Ireland, the pandemic disrupted linkage to support groups and to treatment, follow-up and PrEP referrals. Many migrants and asylum seekers living with HIV, faced reduced accessibility to HIV care services being housed in the outskirts and the lack of public transportation. As a consequence, appointments were frequently missed.

Housing and privacy are central issues for asylum seekers. Sharing accommodations exposes a person living with HIV by way of their medication being visible and exacerbates HIV-related stigma. Several African women expressed their discomfort with taking HIV medication in front of their roommates, not having disclosed their status. An eloquent example was a cabinet where HIV medication was disguised in make-up containers or chewing-gum boxes



and the risk of COVID-19 contamination was used as a point to prevent other people from touching the boxes.

Different solutions were implemented to foster treatment continuity: integrated support for mental health (peer support and counselling), fundraising and monitoring initiatives, and new advocacy and communication strategies that aimed to involve relevant stakeholders in policy formulation. GOSHH's activities included community self-testing ([sh24.ie](https://sh24.ie)), testing stations and promotion through different channels (window display, social media, podcast), innovative delivery solutions through community leaders or influencers, workshops or talks, dedicated events ("The Hub Parade", "LIT Valentines Week" and "The outing festival").

## Enhancing PrEP Information and Uptake in the EECA region

Nikolay Lunchenkov, LGBTQI+ Health Coordinator at Eurasian Coalition on Health, Rights, Gender and Sexual Diversity (ECOM).

To access the slides (EN & RU), click [here](#).

Currently, most EECA countries have developed and implemented PrEP programmes, with Ukraine being the most successful within the region, and although prospects point towards an increase of PrEP users, some limitations persist. PrEP remains a privilege of cisgender gay men and other MSM, while access for other key populations is still limited. A lack of knowledge exchange between countries is observed and best practices are not easily passed among organisations. In addition, PrEP stigma levels are still high, among both medical professionals and members of the LGBTQI+ community. Finally, most PrEP programmes rely entirely on funding from external donors. Therefore, ECOM works to foster close cooperation within local governmental authorities and community-based organisations:

- **Establishment of a resource centre for PrEP in Central Asia (CA):** a platform for knowledge exchange and the transfer of best practices between organisations within the region. The centre coordinates sub-regional joint advocacy plans and community engagement into national PrEP programmes. In April, a first exchange of experience from Kyrgyzstan to Kazakhstan took place.
- **Educational platform for community-based organisations:** [the platform](#) provides several courses, including the use of [online technologies for effective PrEP counselling](#). An accompanying technical guide was developed.
- **Studies on health-related needs of PrEP users.** In 2021, a study titled "Sex, Love and PrEP during the COVID-19" was conducted in Ukraine, in collaboration with the Alliance for Public Health, Alliance Global and the Technical University of Munich (6 weeks, 1,303 participants) assessed PrEP use behaviours, mental health changes and, for the first time, intimate partner violence (IPV). Preliminary findings show that many participants remained on PrEP regimen during the pandemic and that, in addition to mental health symptoms (depression, anxiety, stress), a high prevalence of IPV was reported among MSM. Results suggest that research on PrEP adherence might be a useful instrument to further investigate psychosocial variables within key populations.





## Summary of Discussion and Key Take-Aways for Community Advocacy

Moderator: Will Nutland, Director of *The Love Tank* and co-founder of PrEPster.

- Interprofessional collaboration among health professionals (e.g. general practitioners, sexual health specialists, community health workers, mobile nurses and inclusion of general practitioners,<sup>v</sup> etc.) to improve decentralised implementation and rollout of current and future biomedical interventions to populations who can benefit most.
- Improved monitoring and evaluation methods to better assess the impact of HIV prevention tools. These cannot be burdensome to PrEP-users or providers.
- Increase digitalisation and use of technology for PrEP services to support adherence and community awareness, while enabling community level PrEP delivery.
- Registration and affordability of PrEP options to offer choices according to community needs and preferences.
- Focus advocacy on technologies that are already in phase two and three and gaining access to more sensitive HIV and viral load tests.
- Enable participatory research.
- Address broader implementation barriers of HIV prevention with a holistic and human-rights based approach:
  - Stigma as barrier in accessing HIV care and prevention for sex workers, LGBTQIA+ persons and migrants.
  - Sex work remains criminalised in many countries, and sex workers are frequently still denied HIV prevention services. HIV or public health organisations must work closely with sex worker- and trans led organisations and support their self-organisation in countries where spaces are lacking for sex workers.
  - Provide updated information on HIV prevention throughout the entire migration route to increase migrant access to health services.
  - Address social determinants of health (discrimination, housing, social protection), as they influence HIV vulnerability.



## Endnotes

- i [Press Release: Gilead Announces Clinical Hold on Studies Evaluating Injectable Lenacapavir for HIV Treatment and Prevention Due to Vial Quality Concerns \(Dec. 21, 2021\).](#)
- ii [Press Release: FDA Lifts Clinical Hold on Investigational Lenacapavir for the Treatment and Prevention of HIV \(May 16, 2022\).](#)
- iii [News Release: Merck Announces Clinical Holds on Studies Evaluating Islatravir for the Treatment and Prevention of HIV-1 Infection \(Dec. 13, 2021\).](#)
- iv Holt et al. Community-level changes in condom use and uptake of HIV pre-exposure prophylaxis by gay and bisexual men in Melbourne and Sydney, Australia. *Lancet HIV* (2018).
- v [News Release: Clinics will need new systems to administer injectable HIV therapies, says Canadian early adopter \(November 5, 2021\).](#)



European  
AIDS Treatment  
Group

### **About the European AIDS Treatment Group:**

The European AIDS Treatment Group (EATG) is a patient-led NGO that advocates for the rights and interests of people living with or affected by HIV/AIDS and related co-infections within the WHO Europe region. Founded in 1992, the EATG is a network of more than 150 members from 45 countries in Europe. Our members are people living with HIV and representatives of different communities affected by HIV/AIDS and co-infections. EATG represents the diversity of more than 2.3 million people living with HIV (PLHIV) in Europe as well as those affected by HIV/AIDS and co-infections.

For more information, please visit [www.eatg.org](http://www.eatg.org)