

Global PrEP Learning Network: What's next for CAB PrEP?

24 FEBRUARY 2022



Please introduce yourself in the chat!



- Name
- Organization
- Country

Feel free to ask questions and add comments to the chat box at any point during today's session. At the end of each presentation, we will dedicate time to Q&A.

Don't forget to select "Everyone"

The screenshot shows a video conference interface with a teal 'To:' dropdown menu. The menu lists three participants: 'Hosts and panelists' (with a checked checkbox), 'Everyone' (which is highlighted with a blue background and has an arrow pointing to it from the top text), and two individuals: 'Aubrey Weber (Co-host)' and 'Kristine Torjesen (Panelist)'. Below the menu, there is a text input field with placeholder text 'Type message here...' and a small toolbar with icons for file, smiley face, and more options.

To: Hosts and panelists ▾

Everyone

Aubrey Weber (Co-host)

Kristine Torjesen (Panelist)

Type message here...

Agenda

- Welcome and introductions
- Studies and introduction projects
 - Q&A
- Regulatory and introduction pathway
 - Q&A
- Panel discussion
- Closing

MOSAIC Project Overview

VALUES

- Country-led
- Women-focused with emphasis on AGYW
- Informed choice
- Equitable co-leadership
- Intentionality

- 5-year global project funded by PEPFAR through USAID (2021-2026)
- Focus on research/research translation to support introduction and access for new biomedical prevention products to prevent HIV for women in sub-Saharan Africa
- Work across multiple countries to support evidence-informed and user-centered product introduction, research, research utilization, and capacity development
- Support a multi-product market with informed choice for HIV prevention as new products enter the market
- Collaborate closely with ministries of health, missions, implementing partners, civil society, end users, providers, other local and global stakeholders, and product developers

Today's speakers and panelists



Sinead Delany-Moretlwe (she/her)

Professor and Director: Research, Wits RHI and University of the Witwatersrand

Sinead Delany-Moretlwe, MBBCh PhD DTM&H is a Research Professor and Director: Research, Wits RHI at the University of the Witwatersrand, Johannesburg. Her research interests span the intersections between infectious diseases and sexual and reproductive health. She has worked on several phase III trials of new HIV prevention technologies, including oral, topical and most recently long-acting injectable PrEP, and has led several oral PrEP implementation projects. She serves on the South African National Department of Health PrEP technical working group, and the WHO HIV, Hepatitis and STIs Scientific and Technical Advisory Group (STAC).



Michelle Rodolph

Technical Officer, HIV, Hepatitis and STI Department, World Health Organization

Michelle Rodolph is a technical officer with the Testing, Prevention, and Populations team of the WHO HIV, Hepatitis, and STI Department. She works on pre-exposure prophylaxis (PrEP) for HIV prevention with a particular focus on PrEP delivery for women, future prevention products and integration of HIV prevention into SRH programs. Prior to her work on PrEP and SRH integration, Michelle was involved with harm reduction and HIV prevention programs for key populations.



Nittaya Phanuphak (she/her)

Executive Director, Institute of HIV Research and Innovation (IHRI)

Nittaya Phanuphak is Executive Director at the Institute of HIV Research and Innovation in Bangkok, Thailand. Nittaya has deep interest in Key Population-Led Health Services (KPLHS) which empower key population lay providers who are members of key population communities to design and co-deliver HIV and STI services to their peers. She currently works towards the establishment of national accreditation and domestic financing systems for lay providers to ensure KPLHS sustainability.



Stephen Mills (he/his)

Asia Regional Director, FHI 360, EpiC Project, Thailand, Laos, Burma

Steve is with FHI 360's Asia-Pacific regional office in Bangkok, Thailand and has worked in HIV for over 25 years. He is a member of the Global Fund Technical Review Panel and was a co-editor of the HIV bio-behavioral surveillance guidelines for key population published by UNAIDS, WHO, and FHI 360.



Beatriz Grinsztejn

Instituto Nacional de Infectologia Evandro Chagas-Fiocruz

Dr. Beatriz Grinsztejn is an Infectious Disease physician with a PhD in Infectious Diseases. She has been working on HIV/AIDS patient care and research on prevention and treatment for the last three decades. She is the Head of the STD/AIDS Clinical Research Laboratory at IPEC/FIOCRUZ and the Principal Investigator of the Fiocruz NIH funded Clinical Trials Unit (FioTrials), which is affiliated to the HIV Prevention Trials Network, the AIDS Clinical Trials Group and implements Prevention and Therapeutic Clinical Trials and cohort studies.



Omar Sued (he/him/his)

Advisor, HIV Care and Treatment, Pan American Health Organization/World Health Organization

Omar Sued is an infectious diseases doctor trained in Buenos Aires, Argentina who has been caring for HIV patients since 1995. As Research Director at the Fundación Huésped between 2012-2021, he implemented several large HIV prevention and treatment trials in Buenos Aires, where he was also involved in multidisciplinary and implementation research for vulnerable populations. He was Chair of the XVI and XX Argentinean Congress of Infectious Disease, former President of the Argentinean Infectious Disease Society, LAC representative at the International AIDS Society Governing Council and member of the HPTN Sexual and Gender Minority Scientific Committee. Dr. Sued has co-authored more than 120 articles and many other publications. In 2021, he was appointed as International Advisor for HIV Treatment and Care for the Pan American Health Organization, in Washington DC.



Hasina Subedar (she/her)

Senior Technical Advisor, South Africa National Department of Health

Hasina Subedar is a Senior Technical Advisor supporting the South African National Department of Health in South Africa since 2015. She has supported the implementation of Pre-Exposure Prophylaxis and the She Conquers Campaign focusing on HIV prevention amongst youth.



Prof. Saiqa Mullick (she/her)

Reader/Associate Professor and Director of Implementation Science, Wits RHI

Prof Saiqa Mullick (MBBCh MSc MPH PhD) is a medical doctor with a PhD in Infectious Disease Epidemiology from the London School of Hygiene and Tropical Medicine. She currently oversees a large portfolio of projects addressing introduction of innovative approaches and technologies for HIV prevention and Sexual and Reproductive Health. Her experience is primarily in sexual and reproductive health and HIV prevention research with a focus on adolescent girls and young women. She has supported oral PrEP introduction in South Africa and currently serves as principal investigator on a number of trials evaluating integrated service delivery approaches for young women. Over the past five years she served as Deputy Director of the OPTIONS consortium and is currently a member of the Strategic Leadership Committee for the MOSAIC consortium.

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Injectable Cabotegravir for PrEP: Studies and Introduction Projects

SINEAD DELANY-MORETLWE, WITS RHI

CAB-LA is generally safe and effective as PrEP

HPTN 083



- Cisgender men and transgender women who have sex with men
- 4,566 participants
- Argentina, Brazil, Peru, US, South Africa, Thailand, Vietnam (43 sites)

Results: **66% reduction in HIV infections** in CAB-LA arm compared to TDF/FTC.

HPTN 084



- Cisgender women 18 to 45 years
- 3,224 participants
- Uganda, Kenya, Malawi, Zimbabwe, Eswatini, South Africa, Botswana (20 sites)

Results: **88% reduction in HIV infections** in CAB-LA arm compared to TDF/FTC.

Both trials were unblinded early in 2020 as CAB-LA demonstrated to be effective in preventing HIV compared to daily oral PrEP. CAB-LA likely confers an adherence advantage

Emerging evidence

- Protective effect of CAB-LA appears to be sustained
 - 66% risk reduction for CAB-LA vs. TDF/FTC in unblinded Year 1 phase
 - HR=0.34 95% CI 0.17-0.67
 - Majority of CAB infections d/t injection delays or ≥ 6 months off-CAB-LA
 - No new safety concerns
- CAB-LA delayed detection of HIV with conventional diagnostics
 - CAB-LA suppresses viral replication and delays antibody production
 - Prolonged monotherapy may lead to INSTI resistance in rare cases
 - Resistance can be overcome by other (non-INSTI) HAART regimens
 - Use of a sensitive HIV RNA assay may detect early infection and prevent INSTI resistance
- In pregnant women who received CAB-LA up until pregnancy diagnosis
 - No congenital anomalies
 - Residual CAB-LA generally well tolerated during pregnancy
 - Drug concentrations comparable in pregnant vs non-pregnant women

HIV Prevention Trials Network (HPTN) – ongoing clinical trials with injectable cabotegravir for PrEP

Study name	Description	Location	Population	Sample Size	Status
HPTN 083 Give PrEP a Shot	Now in open-label extension of the phase IIb/III trial	Argentina, Brazil, India, Peru, South Africa, Thailand, United States, and Vietnam	MSM and TGW	4570	In follow up through Dec 2024 (estimated)
HPTN 083-01 Inject to Protect	Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Males – A sub-study of HPTN 083	United States	Adolescents assigned male at birth	55	In follow up through May 2023 (estimated)
HPTN 083-02	Factors Influencing Adherence to Injectable PrEP and Retention in an Injectable PrEP Research Study	Brazil, South Africa, Thailand, United States	MSM and TGW	300	In follow-up through November 2022 (estimated)

HIV Prevention Trials Network (HPTN) – ongoing clinical trials with injectable cabotegravir for PrEP

Study name	Description	Location	Population	Sample Size	Status
HPTN 084 LIFE Trial	Now in open label extension of the phase III trial, includes active dosing for CAB PrEP during pregnancy Includes qualitative data collection	Botswana, Eswatini, Kenya, Malawi, South Africa, Uganda, Zimbabwe	Women	3224	In follow-up through February 2023 (estimated)
HPTN 084-01 LIFT Trial	Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Females – A Sub-study of HPTN 084	Uganda, Zimbabwe, South Africa	Adolescents assigned female at birth	55	In follow-up through July 2023 (estimated)

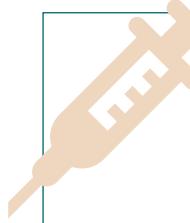
Under consideration for the future:
MPT concept, HPTN studies on integrative strategies that include CAB PrEP

Additional analyses in progress



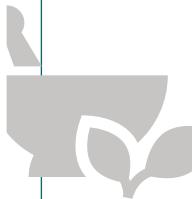
Ongoing safety and effectiveness

- Safety and effectiveness during unblinded Y1 of HPTN 084
- Correlates of protection HPTN 083/084



Extended interval dosing

- 8 vs. 12 weeks



Drug-drug interactions with hormones

- DMPA, NET-EN, etonorgestrel in HPTN 084
- Gender-affirming hormone therapy in HPTN 083



Acceptability and product preferences



Costs, cost-effectiveness, population impact

Funded PrEP introduction studies that will include injectable cabotegravir for PrEP

Donor/project	Description	Location	Population	Sample Size	Status
USAID/MOSAIC	Assess uptake, continuation, switching, HIV testing strategies, feasibility and cost for oral PREP, PrEP ring and injectable CAB for PrEP	Lesotho, Kenya, South Africa, Uganda, Zimbabwe	AGYW, FSW, PBFP, TG, other women at USAID PEPFAR service delivery sites with PrEP targets	Anticipate up to 4225 clients on injectable CAB for PrEP across five countries	Stakeholder consultations to inform protocol development; injectable CAB for PrEP will be included after national regulatory approvals
Unitaid/ ImPrEP	Assess uptake, continuation, switching, HIV testing algorithm, and feasibility of injectable CAB for PrEP	Brazil (6 sites)	MSM and TGW ages 18-30 yrs seeking PrEP at public health delivery clinics	Anticipate 1200 participants on injectable CAB for PrEP	Protocol development

Funded PrEP introduction studies that will include injectable cabotegravir for PrEP

Donor/project	Description	Location	Population	Sample Size	Status
Unitaid/ PrEP1519	Evaluate the effectiveness, adoption, acceptability and feasibility of injectable CAB and ED-PrEP	Brazil (3 sites)	MSM and TGW ages 15-19 yrs	Anticipate 340 adolescents on injectable CAB for PrEP at the end of the study (3 years)	Protocol development
Unitaid/ Project PrEP	Increase the uptake and coverage of PrEP through the introduction and integration of new PrEP products (injectable CAB, ring and oral PrEP) into comprehensive SRH services for AGYW	South Africa (8 sites in 4 clusters)	AGYW 18-24 yrs and older women (will also consider inclusion of women ages 15-18 yrs)	Initiate 2609 AGYW and older women on injectable CAB for PrEP followed up for a minimum of 6 and a maximum of 21 months	Protocol development; stakeholder consultations; awaiting in-country SAHPRA approval.
BMGF	In the planning stages for introduction studies that will include injectable CAB for PrEP in Kenya and South Africa with a focus on private pharmacy delivery				

MOSAIC planned CAB PrEP work along the introduction pathway

Policy, Plans, & Costing	Supply Chain & Market Development	Service Delivery	Uptake & Effective Use	Monitoring & Evaluation	Cross-Cutting Contributions
Global guidance & national guidelines Contributing updates to WHO PrEP Implementation tool, providing technical assistance on testing algorithms, developing template guidelines for CAB PrEP, supporting adoption of national guidelines for CAB PrEP	Market shaping Incorporating CAB PrEP in market shaping efforts to address supply-side barriers and global demand Demand forecasting Conducting analyses for demand forecasting Private sector Assessing feasibility and barriers and opportunities for CAB PrEP in the private sector Bottlenecks Identifying potential bottlenecks in the supply chain and testing possible solutions	Research collaborations Collaborating with EpiC, RISE, CASPR on systematic reviews and formative research Implementation research Conducting studies to assess feasibility, acceptability, choice, testing, uptake, continuation, switching, service delivery models, and cost Differentiated service delivery (DSD) Assessing opportunities for DSD and how to leverage technology to introduce DSD models, including models that blend virtual and in-person service delivery Provider training Developing and integrating CAB PrEP provider trainings and job aids into national PrEP curricula	End-user engagement Building structures to meaningfully engage potential end-users Demand generation strategies & tools Providing technical guidance on integration of CAB PrEP into demand creation national strategies and integrating CAB PrEP into demand creation tools, including the HIV Prevention Ambassador Training Continuous quality improvement (CQI) Assessing and strengthening CQI processes to support providers and CAB PrEP users in providing and receiving quality services	Resistance surveillance Supporting inclusion of CAB PrEP in HIV drug resistance surveillance platforms Routine M&E Assessing feasibility and acceptability of novel PrEP indicators for multi-product M&E, supporting system improvements/integration Data informed approaches Strengthening data use to inform CAB PrEP activities across the Introduction Pathway	Evidence & Resources Synthesizing and sharing CAB PrEP evidence and resources Global collaborations Building and strengthening global collaborations with programs, networks, product developers, and funders Situation analyses Conducting value chain situation analyses to build on lessons learned from oral PrEP to inform rollout of CAB PrEP Capacity strengthening Strengthening local partner capacity to design and implement biomedical prevention product introduction activities and research Civil society engagement Developing and strengthening civil society partnerships, engagement, and advocacy
Implementation plans & national strategies Developing implementation plans and integrating CAB PrEP into national strategies, including support for target setting and forecasting					
Costing Conducting costing studies to inform implementation planning and budgeting					

Biomedical Prevention Implementation Collaborative (BioPIC) to Accelerate PrEP Access

- Established to help coordinate product introduction efforts in the HIV prevention field
- Convenes product developers, civil society, donors, researchers, policy makers, normative agencies, and implementers to develop strategies for introduction of emerging and future prevention products

Resources

- [BioPIC CAB Introduction Strategy Brief and CAB Priority Product Introduction Activities: Narrative Synthesis](#) outline critical activities for ensuring global and national bodies have sufficient evidence on safety, resource needs and the impact of CAB, enabling programs to quickly scale and identify interventions to support uptake and continued use.
- [Biomedical Prevention Adaptable Product Introduction Framework](#) an overarching framework for product introduction that can be adapted to specific products.
- [Advocates' Primer on Injectable Cabotegravir for PrEP: Trials, Approvals, Rollout and More](#)

The screenshot shows the BioPIC website with the following sections:

- Header:** Biomedical Prevention Implementation Collaborative | HIV Prevention & Planning for Success. Subtext: The HIV prevention product pipeline offers exciting potential to curb incidence—but we know from previous products, that achieving impact will be challenging without advanced planning and coordination.
- Oral PrEP Product Introduction Experience:** Without advanced planning and coordination, the introduction and impact of an effective biomedical prevention tool was delayed in low- and middle-income countries (LMICs). Key components of product introduction were not well-timed, causing delays in introduction and scale up.
- Ideal Scenario for Future HIV Prevention Products:** To support rapid, successful introduction of HIV prevention products, BioPIC aims to forge a new path forward for future products.
- The BioPIC Approach:** Using CAB-LA as a focal product and example, BioPIC takes an innovative, collaborative approach to product introduction to ensure activities are well-designed, well-timed, and well-funded to meet the needs of global and country decision-makers.
- Objectives:**
 - Using CAB-LA as an initial example, develop an adaptable HIV prevention product introduction framework.
 - In parallel to clinical trials, develop a shared introduction and access strategy for CAB-LA.
- Members:** BioPIC has engaged diverse stakeholders including civil society, donors, researchers, policy makers, normative agencies, and implementers. Statistics: 100+ HIV Prevention Experts, 80+ Organizations, 20+ Countries.
- Focal Product: Cabotegravir Long-Acting:** BioPIC efforts have focused on planning for evaluated in two large-scale Phase III efficacy for HIV prevention in men who have sex with men and transgender women. This would be one of the first long-acting additional HIV prevention option with the.
- Regulatory Approval & Normative Guidance:** Ensure global and national bodies have sufficient evidence and safety assurance:
 - Plan in advance to obtain safety data for pregnant and breastfeeding women
 - Plan in advance and bolster systems to monitor resistance
 - Conduct research for additional populations not included in clinical trials
 - Support efficient regulatory review and development of normative guidance
- Planning & Budgeting:** Establish evidence to understand resource needs and the impact of CAB-LA:
 - Model impact on multiple end-points and in different country contexts
 - Build consensus and align methods on indicators, monitoring, and target-setting
 - Conduct cost and payer analyses to inform budgeting
 - Coordinate and align procurement
- Delivery & Supply Chain:** Enable programs to quickly move from small projects to scale:
 - Conduct delivery channel analyses to identify operational opportunities and barriers prior to early implementation projects
 - Support development of guidance and tools during early implementation
 - Consolidate implementation questions in fewer, larger-scale projects
- Individual Uptake & Continued Use:** Identify methods to support high uptake and continued use:
 - Engage and build community mechanisms to refine program design and implementation
 - Conduct human-centered design research to understand barriers and enablers for providers, communities, and priority populations
- Next Steps for BioPIC: CAB-LA Introduction and Future Products:** BioPIC aims to leverage the shared product introduction strategy for CAB-LA to forge a new path forward for HIV prevention and catalyze more rapid LMIC access to a growing portfolio of products.
 - BioPIC will continue to serve as a coordination structure, tracking progress against the strategy and disseminating learnings for CAB-LA and HIV prevention more broadly.
 - BioPIC will still learn from the CAB-LA strategy into an adaptable product introduction framework, which will support planning for future products.

BioPIC is made possible through the generous support of the Bill & Melinda Gates Foundation. Please contact the BioPIC Implementation Strategy Committee (AVAC, BMGF, Chai, ViiV Healthcare) for further information. ISG@InfectingCAB.org

For more information, visit PrEPWatch.org

PrEPWatch An initiative of AVAC

Search

About PrEP | PrEP Planning A-Z | In Practice | Resources | Next-Gen

Populations Spotlight

Home - About PrEP - About Cabotegravir (CAB-LA)

About Cabotegravir (CAB-LA)

What is CAB-LA?

CAB-LA, or long-acting injectable cabotegravir, is an antiretroviral drug developed by ViiV Healthcare and formulated to be administered once every two months as an injectable form of PrEP. Cabotegravir previously was approved in the US and Canada for treatment, in combination with another injectable ARV, rilpivirine. As of December 2021, CAB-LA was additionally approved by the US for use as a prevention option.

CAB-LA inhibits HIV viral DNA from integrating with human DNA. Blocking this integration plays a role in both treatment and prevention. In treatment, CAB-LA, in combination with injectable rilpivirine, is used as a long-acting agent to maintain virologic suppression and has been approved for use among those who have already demonstrated virologic suppression using oral ARVs.



Q & A

2

Injectable Cabotegravir for PrEP: Regulatory and Introduction Pathway

MICHELLE RODOLPH, WORLD HEALTH ORGANIZATION

LA CAB as PrEP: Regulatory Timeline



2022

U.S. FDA regulatory approval (Dec 2021)	National registration dossiers submitted in Australia, Botswana, Brazil, Kenya, Malawi, South Africa, Uganda, Zimbabwe (as of 08 Feb 2022)	WHO guidance meeting (March 2022)	Application for WHO PQ (pending WHO recommendation) (April/May 2022)	Application for inclusion in USAID procurement catalog (mid-2022)	WHO guidance released (pending WHO recommendation) (mid-2022)	Additional country regulatory review decisions expected (mid-to-late-2022)
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LA cabotegravir as PrEP: Product Overview



USER REQUIREMENT

Gluteal injections every two months

EFFICACY

High individual efficacy and opportunity for epidemic impact if widely available, accessible, and used

PREVENTION RANGE

Sexual exposures to HIV

SIDE EFFECT PROFILE

Typically, mild or moderate, treatable without stopping product use. Injection site reactions (ISRs) common, clients may need support mitigating potential impacts. ISRs shown to become less frequent and less severe over time

POTENTIAL VISIT SCHEDULE

Every two months after two initiation visits one month apart

TESTING GUIDANCE*

4th generation/RNA assays for HIV testing are to be conducted at initiation and continuation visits (additional tests recommended per standard of care)

CADRE OF PROVIDER

Training will be needed to support provision by lower cadre healthcare workers, or it will have to be confined to clinical settings

SHELF LIFE

3 years

STORAGE REQUIREMENTS

2°C to 25°C (36°F to 77°F); exposure up to 30°C (86°F) permitted (length unknown)

ADDITIONAL COMMODITIES NEEDED

Non-sterile gloves, alcohol wipes, gauze pads, sharps container, potentially longer needles for injection for clients BMI > 30kg/m²

WASTE DISPOSAL CONSIDERATIONS

Sharps disposal necessary

POTENTIAL FOR HIV DRUG RESISTANCE

Clinical trials suggest the potential for resistance if client begins or continues use after HIV acquisition

CONTRAINdications

Concurrent use with rifampin and rifapentine (used for tuberculosis treatment) and carbamazepine, oxcarbazepine, phenobarbital, phenytoin (anticonvulsants)

USE DIRECTLY LEADING UP TO OR DURING PREGNANCY / BREASTFEEDING*

Data not available

PRODUCT DISPENSATION

Likely to take place in a clinic, client privacy will be needed to provide injections

*From U.S. FDA Label

WHO review process and considerations for LA CAB

Systematic review of the evidence



Exciting new results from long-acting PrEP study show it to be effective in preventing HIV acquisition in men who have sex with men and transgender women



The image shows a screenshot of a WHO news article. At the top, there is a navigation bar with links for Home, Health Topics, Countries, Newsroom, Emergencies, Data, and About Us. Below the navigation bar, a breadcrumb trail reads "Home / Trial results reveal that long-acting injectable cabotegravir as PrEP is highly effective in preventing HIV acquisition in women". The main content features a large photograph of a diverse group of women smiling together. Below the photo, the headline reads: "Trial results reveal that long-acting injectable cabotegravir as PrEP is highly effective in preventing HIV acquisition in women". A timestamp indicates the article was published on 9 November 2020. To the right of the headline, there are five small circular icons for sharing on various platforms. Further down, a "Related" section is visible.

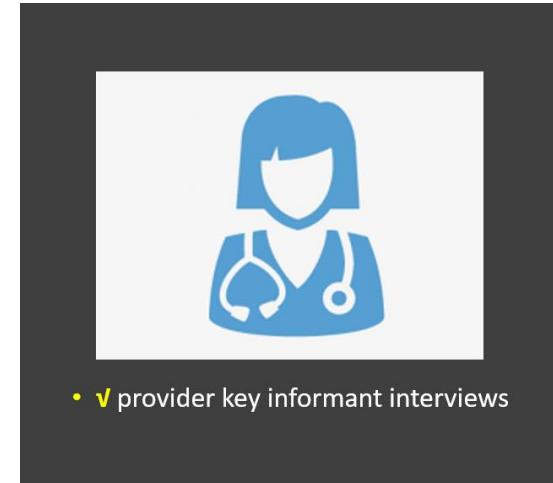
Values and preference

Users & communities

- AGYW in ESA
 - ✓ South Africa with Unitaid partners
- Higher risk men in ESA
- Key populations
 - ✓ Global KP networks Q1 2021
- MSM
 - ✓ Asia – APCOM, IHRI
 - ✓ Latin America – with Unitaid partners
- Transgender populations
 - ✓ Latin America – with Unitaid partners
- Sex workers
 - ✓ Zimbabwe - CeSHHAR
 - ✓ India - Ashodaya Samithi /DSMSC
- People who inject (use) drugs



ಅಶೋದಯ ಸಮಿತಿ (ನ್ಯೂ)
Ashodaya Samithi (R)



- ✓ provider key informant interviews





Values and preference Providers

- ✓ provider key informant interviews
- 

General implementation issues

Populations and approaches

- How to deliver for specific focus populations
- Models of delivery
 - Within current PrEP programmes?
 - Within key populations services?
 - Within SRH services (ANC, PNC, FP, STI)
 - KP services
 - others?
- Alongside other prevention – options and choices

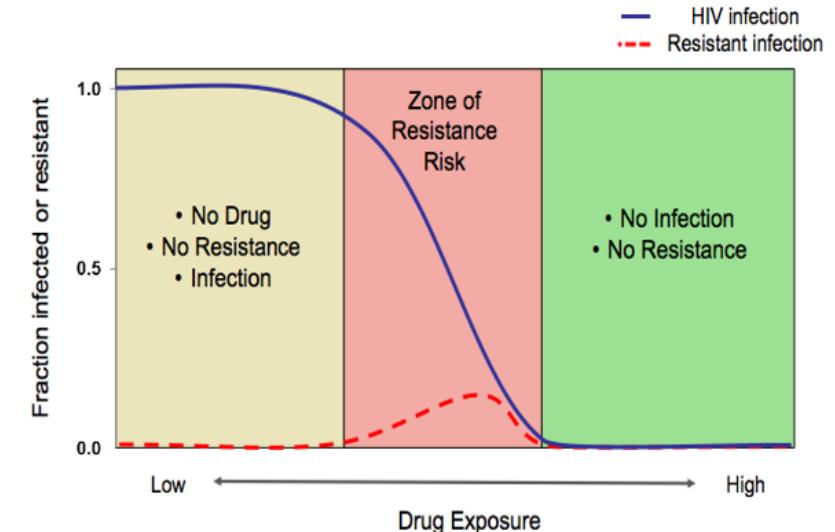
Need to plan an implementation science agenda



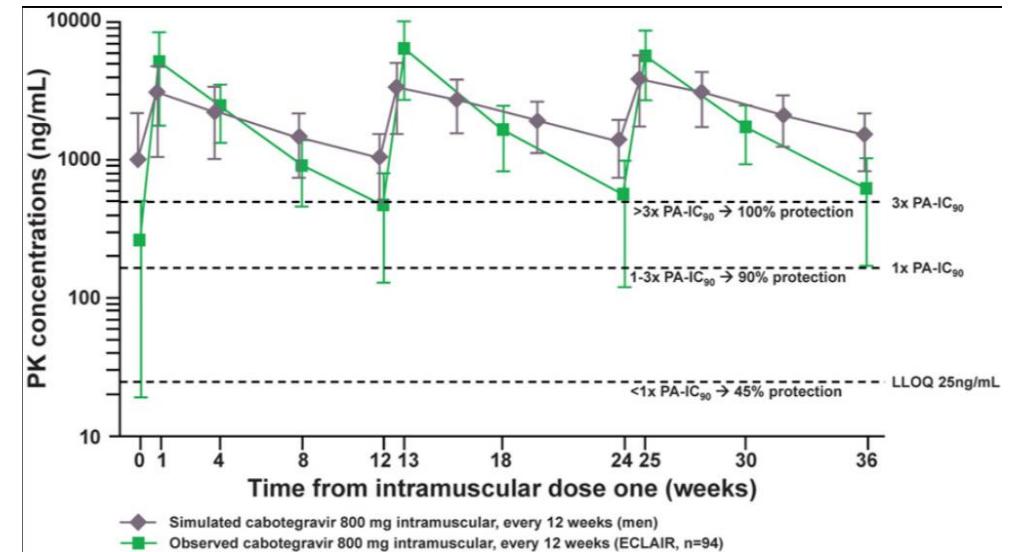
World Health Organization

Specific implementation issues

- Oral lead in – ‘direct to inject’ can we do without lead in
- Covering the tail to avoid potential seroconversions and DR
 - Covering the tail with TDF/FTC
 - How long
 - Other options
- Restarting after missed appointments
 - What is the wiggle room?



Markowitz et al, Lancet HIV 2017;4:e331-40



Specific implementation issues

HIV testing

- Challenge - initiation in acute phase
- Delayed diagnosis for seroconversion detection in tail seroconverters

Will NATT be the only option?



Frequently asked questions – Testing for HIV, including HIV self-testing, in the context of pre-exposure prophylaxis (PrEP)

This document is intended for testing providers, and for HTS clients.

With regard to the concept of antiretroviral pills for people to become negative:

1. Although not recommended, individuals with known HIV-positive status or unknown HIV status (24%) may seek HIV testing services to "clarify" their HIV status.
2. Individuals without HIV-negative determine HIV (i.e. oral pre-exposure prophylaxis (PrEP) increases HIV risk) see no recommended to HIV testing.

Role of frequently administered test will be as on the revised situation:

WHO recommends certain strategy for individuals at HIV-negative individuals who are high risk of HIV acquisition (WHO 2012 PEP):

- Testing is required to start PrEP in Africa prior to initiating PrEP since an individual has been invited to PrEP. HIV testing is suggested every three months and immediately beginning PrEP after cessation of oral PrEP (but not PrEP in the form).
- Individuals on PrEP with an HIV-inconclusive status should be retested in 7-14 days. Individuals on PrEP with an HIV-positive diagnosis will need to be placed on fully suppressive antiretroviral therapy (ART).
- Olfine testing by recommended in the context of PrEP initiation and monitoring in terms. Children to check immune function, number of organs for subsequent vaccination for masking, incomplete response to drugs, and drug side effects (mostly to transmitted infections such as respiratory, genitourinary and diarrhoeal diseases indicated).

WHO 2012 PEP

Public health approach to quality HIV testing in the context of antiretroviral drugs

Meeting report

12-13 December 2017 | Centre for the AIDS Programme of Research in South Africa, Durban, South Africa



Specific population issues

Key Populations

More experience needed delivering CAB to key populations groups

Transgender women

People with buttock implants/fillers excluded from trials due to concern for altered pharmacokinetics

- Current experience is only with buttock region (gluteus medius or maximus).
- Alternative muscle injection sites (e.g. rectus femoris)?



World Health Organization

THANK YOU

Thanks to the Testing, Prevention, and Populations team of the WHO Global HIV, Hepatitis and STIs Programmes for contributions to this presentation.

Special thanks to Rachel Baggaley, Robin Schaefer and Heather-Marie Schmidt.

For more information:

WHO Global HIV, Hepatitis and STIs Programmes:

<https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/overview>

WHO work on PrEP

<https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/prevention/pre-exposure-prophylaxis>



The background of the slide features a repeating pattern of orange and yellow triangles, creating a low-poly geometric effect.

Q & A



3

Panel discussion

Panelists



Nittaya Phanuphak

Institute of HIV Research
and Innovation, Thailand



Beatriz Grinsztejn

Instituto Nacional de Infectologia
Evandro Chagas-Fiocruz, Brazil



Saiqa Mullick

Wits Reproductive
Health Institute, South Africa



Stephen Mills

FHI 360/EpiC, Thailand



Omar Sued

Pan American Health
Organization, Argentina



Hasina Subedar

South Africa National
Department of Health

- 1 What are you hearing from potential users, providers and communities about their desire and interest in injectable cabotegravir for PrEP?
- 2 What do you see as the greatest opportunities and challenges for implementation of injectable cabotegravir for PrEP?
- 3 What do you see as the benefits of expanding the HIV prevention method mix and offering informed choice across multiple products?

Visit PrEPWatch

All webinars are **recorded** and will be accessible on PrEPWatch within a week.

Complementary resources including relevant articles and tools plus **registration for upcoming webinars** can also be found on PrEPWatch.

Virtual Learning Network

The PrEP Learning Network, hosted by [MOSAIC](#), provides national and sub-national ministries, implementing partners, community-based organizations (CBOs), and others working with PrEP around the world with the tools and resources, best practices, and opportunities to learn from others to help to advance PrEP scale-up. Prior to February 2022, the PrEP Learning Network was hosted by CHOICE, OPTIONS, EpiC and RISE.

Its webinar series features presentations from experts in specific content areas, lessons learned and insights from implementing partners and government ministries, and new tools or research on specific topics related to PrEP scale-up, ranging from demand creation to continuation.

The following pages include links to register for upcoming PrEP Learning Network webinars, watch previously recorded webinars and access complementary resources, research and tools on webinar topics. See the [WHO website](#) for information on additional PrEP webinars hosted by the World Health Organization.

Upcoming Webinars

- MOSAIC PrEP Learning Network Kick-off: an Exploration of CAB PrEP

Thursday, February 24, 2022 at 8:00 EDT | 15:00 SAST | 16:00 EAT

In this webinar, we will introduce our audience to the newly launched MOSAIC project and orient attendees to the scope of this webinar series. We will then explore ongoing and completed research on CAB PrEP, learn more about the recently released FDA guidance, and hear from a panel of implementers and policymakers on what's needed to advance introduction of this new HIV prevention product. This webinar is part of the global PrEP Learning Network webinar series, now hosted by the USAID/PEPFAR-supported MOSAIC project.

[Register here.](#)

Visit www.prepwatch.org/virtual-learning-network for more.

Upcoming sessions

The MOSAIC PrEP Learning Network will take place quarterly.

Upcoming sessions are planned for May, August, and November 2022.



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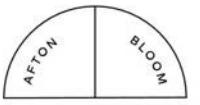


<https://www.mosaicproject.blog/>



<https://mailchi.mp/prepnetwork/prep-learning-network>

THANK YOU!



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