

# Global PrEP Learning Network

## The Future of PrEP: Implementation Studies to Guide the Rollout of New PrEP Products

13 JUNE 2023





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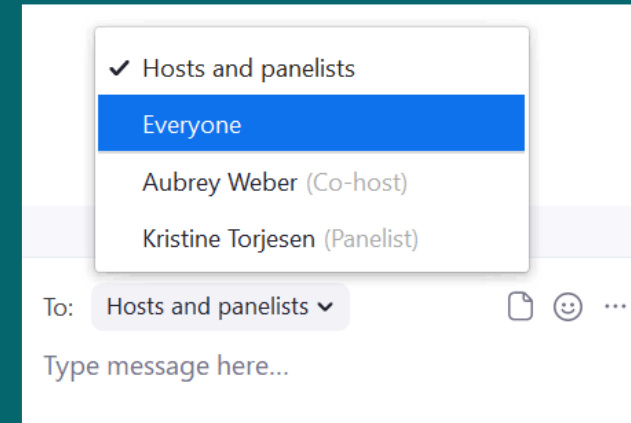
Please introduce yourself in the chat!



- Name
- Organization
- Country

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

Don't forget to select "Everyone"





# Global PLN Agenda

- Welcome and introductions
- Overview of PrEP studies
- PrEP Studies
  - SEARCH Study
  - CATALYST Study
  - Malawi Injectable PrEP Path to Scale Study
  - PrEP1519 Study
- Question & Answer

# Today's moderators



**Kristine Torjesen, she/her**

MOSAIC Project Director, FHI 360

Kristine Torjesen, MD, MPH is a paediatrician and global health expert who currently serves as the Project Director for the USAID-funded Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC) project. As the Project Director for MOSAIC, Dr. Torjesen leads a consortium of international and country-based organizations working to accelerate market introduction of new biomedical HIV prevention products in sub-Saharan Africa.

 [@MOSAICproj](https://twitter.com/MOSAICproj)



**Sanele Ngulube, she/her**

MOSAIC NextGen Squad member, Pangaea Zimbabwe AIDS Trust

Sanele Ngulube is a qualified social worker serving as a NextGen Squad representative under the MOSAIC project at Pangaea Zimbabwe Aids Trust (PZAT). Sanele is a sexual reproductive health and rights (SRHR) defender who served as a national representative of youth in faith-based organizations under the Young People's Network on Sexual Reproductive Health, HIV, and AIDS. She was also an adolescent advocate for the SRHR of adolescent girls and young women under the Social Norms project of PLAN International, Norway.

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 [@Nele\\_Mabuya](https://twitter.com/Nele_Mabuya)

 [@pangaea\\_zimbabwe](https://www.instagram.com/pangaea_zimbabwe)



# Today's presenters



**Catherine Koss, she/her**

Assistant Professor, University of California, San Francisco

Dr. Catherine Koss is an infectious disease physician and Assistant Professor of Medicine at UCSF. Dr. Koss conducts research on biomedical HIV prevention strategies, with a focus in Eastern Africa and the United States. She is co-principal investigator of the SeroPrEP, ACTION, and Peers for PrEP studies and a co-investigator in the SEARCH Collaboration, in which she has helped to lead the Dynamic Choice Prevention Trials with Dr. Ayieko.



**James Ayieko, he/him/his**

Research Scientist, Kenya Medical Research Institute

James Ayieko is a research scientist at the Kenya Medical Research Institute. He has participated in designing, implementation and evaluation of various interventions aimed at optimizing delivery of prevention options such as PEP and PrEP in rural Uganda and Kenya. Currently he is an investigator in the SAPPHIRE trial and the SEARCH Youth trial among other studies.



**Elizabeth M. Irungu, she/her**

Regional Technical Advisor, Jhpiego

Elizabeth Irungu, MBChB, MPH, PhD, is Regional Technical Advisor for Implementation Science and PrEP service delivery at Jhpiego and protocol co-chair for CATALYST Study under Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC).



**Sara M. Allinder, she/her**

Deputy Director, Center for Innovation in Global Health, & Program Director, Blantyre Prevention Strategy, Georgetown University

Sara M. Allinder, MPP, is Deputy Director, Center for Innovation in Global Health and Program Director of the Blantyre Prevention Strategy—an innovative systems-focused, HIV prevention project. She is a member of Malawi's Ministry of Health Cabotegravir Expert Committee, is a co-investigator for Malawi's Injectable PrEP implementation science study, and serves on MOSAIC's Product Access Advisory Committee.



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**Friday Saidi, he/his**

Specialist OBGYN/Research Investigator, University of North Carolina Project Malawi

Dr. Friday Saidi, MBBS, MMed (OBGYN) serves as the Pregnancy and Infant Sub-study Advisor in the landmark HPTN 084 Open Label Extension (OLE) study and is an Adjunct Assistant Professor at University of North Carolina at Chapel Hill. He is a member of the Malawi's Ministry of Health Cabotegravir Expert Committee where he is one of the leading investigators for Pathway to Scale for Injectable PrEP in Malawi study.



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**Ines Dourado, she/her**

Professor, Federal University of Bahia, Brazil

Dr. Ines Dourado is a full professor at the Federal University of Bahia, Brazil. She has extensive experience in leading research in public health. Her main research area is in the field of HIV/AIDS. She is the PI of a recent study on PrEP implementation and effectiveness among sexual minorities in Brazil between the ages of 15 and 19.



# **PrEP Studies Overview**

Kristine Torjesen, FHI 360

Sanele Ngulube, Pangaea Zimbabwe AIDS Trust, NGS



# Globally, there is still a high unmet need for HIV prevention... ...new prevention products may help fill that gap



## Oral PrEP

### ADVANTAGES

- High efficacy
- Affordable
- Readily available
- Safe in pregnancy

### CHALLENGES

- Daily adherence
- Side effects
- Stigma



## PrEP Ring

### ADVANTAGES

- Monthly
- Non-systemic with minimal side effects
- Safe in pregnancy
- Discreet

### CHALLENGES

- Moderate efficacy
- Unfamiliar formulation
- Cost



## CAB PrEP

### ADVANTAGES

- High efficacy
- Bi-monthly
- Discreet
- Familiar formulation

### CHALLENGES

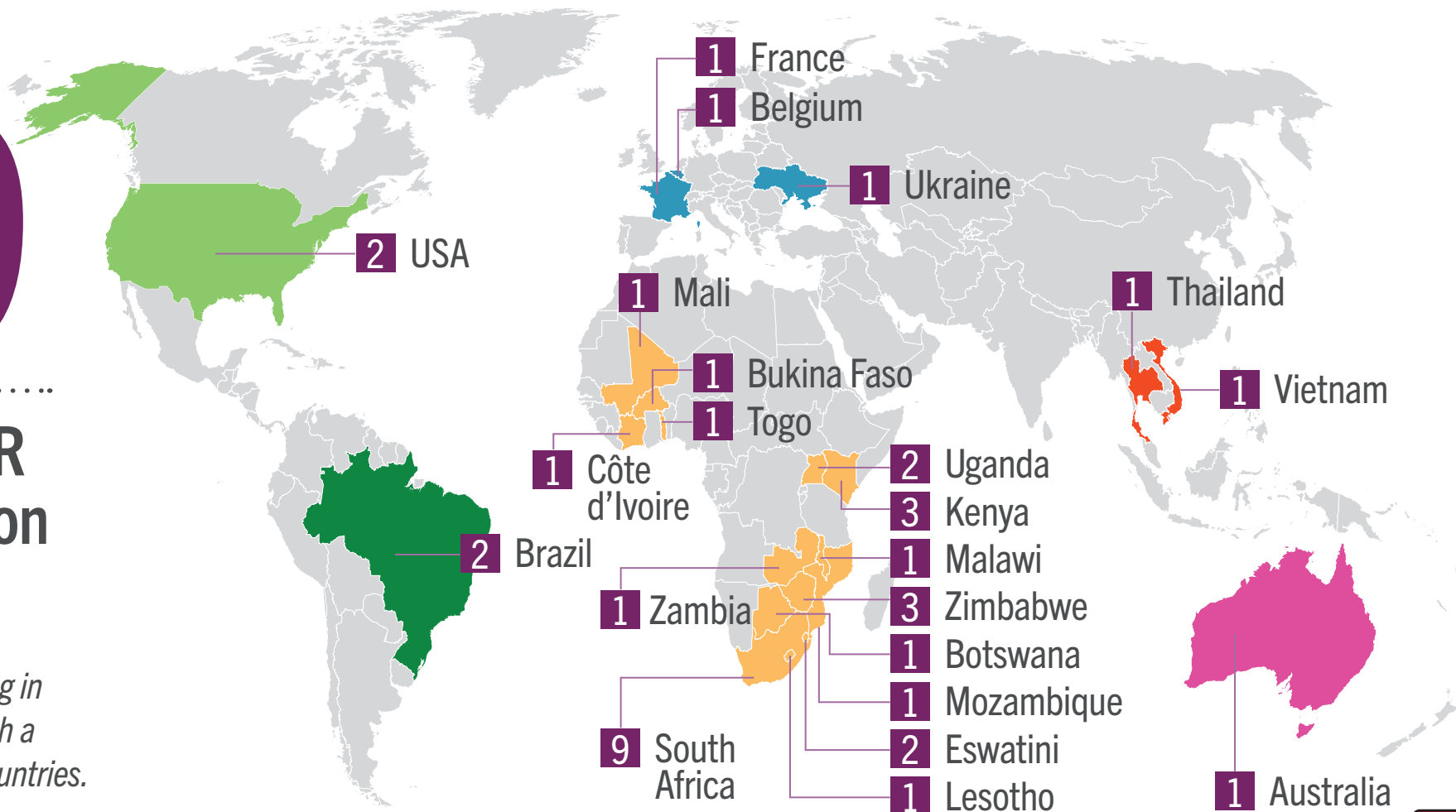
- HIV testing
- Long drug tail
- Pregnancy data pending
- Cost

# PrEParing for New Products – Geographically

# 29

## CAB and DVR Implementation Studies

*Some studies are happening in more than one country, with a total of 29 studies in 22 countries.*



# PrEP Ring Implementation



## IMPLEMENTATION STUDIES

Country	No. of Studies	Organizations	Donors
<b>South Africa</b>	7	Wits RHI, DTHF, AHRI, MRC, NACOSA, AFSA, HSRC	USAID, UNITAID, Global Fund
<b>Lesotho</b>	1	JHPIEGO	USAID
<b>Eswatini</b>	1	FHI 360	USAID
<b>Zimbabwe</b>	2	PSH PZAT	USAID
<b>Uganda</b>	2	FHI 360 UCSF	USAID NIH
<b>Kenya</b>	2	LVCT Health TBA	USAID CIFF
<b>Ethiopia</b>	1	PSI	USAID

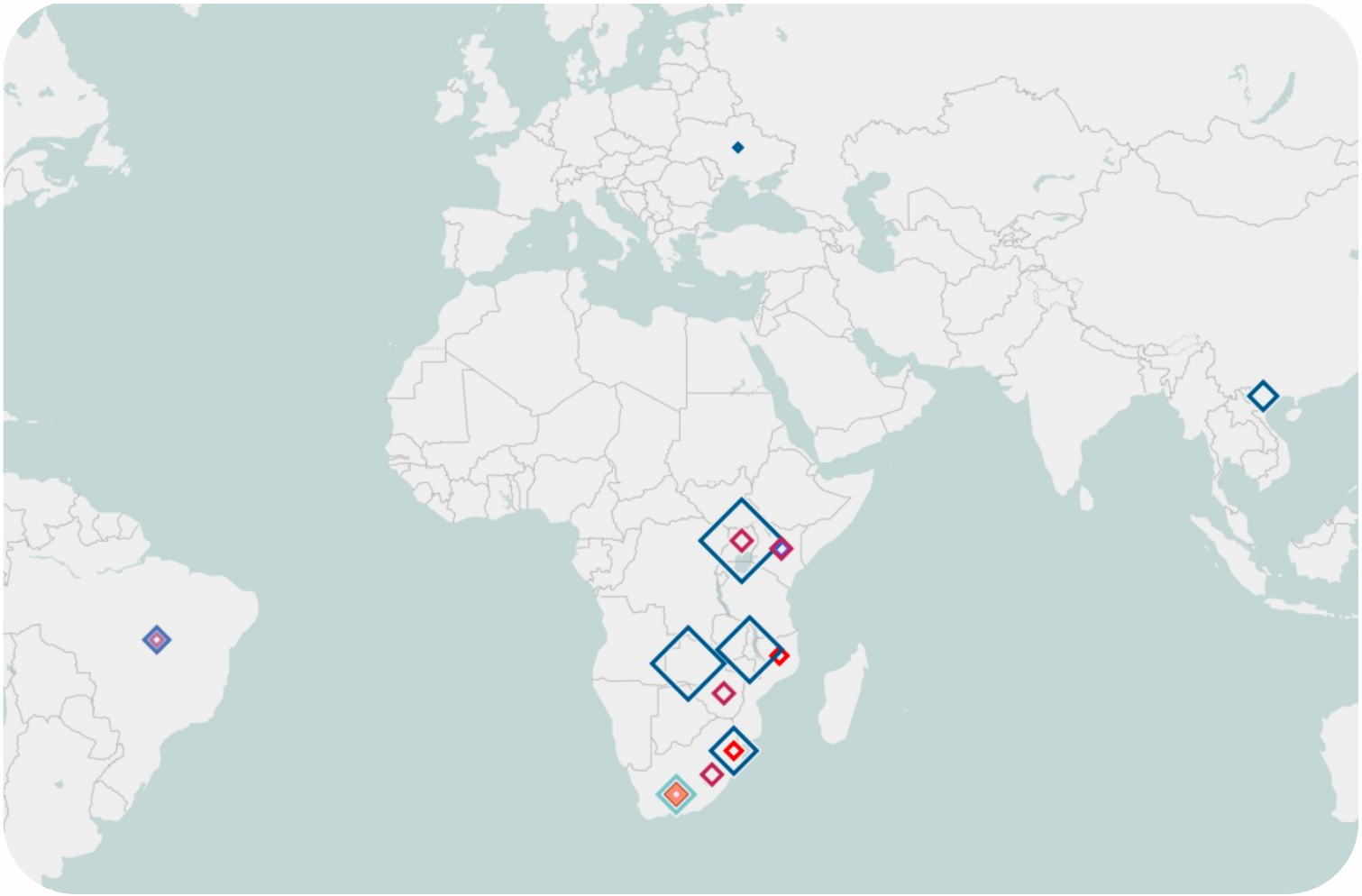
**AFRICA:** 16 implementation pilot/integration studies across the region

**OTHER REGIONS:** Planned UNAIDS feasibility study in Asia Pacific (Cambodia, Philippines, Papua New Guinea, Indonesia)



# Projects Introducing CAB PrEP in the coming year (as of June '23)

Location of CAB introduction projects



Vials per project/donor

PEPFAR	366,000
MOSAIC/CATALYST	38,750
Project PrEP	26,000
ImPrEP/CAB-Brasil	12,000
SEARCH	5,000
LAPIS	5,000
FastPrEP/PrEPared to Choose	5,000
PrEP 1519	3,400
Axis	3,000





# **SEARCH Study**

Catherine Koss, University of California, San Francisco

James Ayieko, Kenya Medical Research Institute

# Dynamic Choice HIV Prevention

in the SEARCH study

James Ayieko MBChB, MPH, PhD

Kenya Medical Research Institute-Kenya

Catherine Koss, MD

University of California, San Francisco-USA

On Behalf of **the SEARCH Collaboration**

## Principal Investigators:

Diane Havlir, MD - University of California, San Francisco-USA

Moses Kamya, MBChB, MMed, MPH, PhD - Makerere University-Uganda

Maya Petersen MD, PhD - University of California, Berkeley-USA

## Study Leadership:

Jane Kabami, MPH, PhD(c) - Infectious Diseases Research Collaboration-Uganda

Elijah Kakande, MBChB, MPH - Infectious Diseases Research Collaboration-Uganda

Gabriel Chamie, MD - University of California, San Francisco-USA

Laura Balzer, PhD - University of California, Berkeley-USA



# Sustainable East Africa Research in Community Health (SEARCH)

- Multinational, multidisciplinary research collaboration examining population-level approaches to **reduce HIV incidence** and **improve community health** in rural Kenya and Uganda
- We design and evaluate multi-disease (HIV and non-HIV) interventions that consider different contexts and health priorities for persons of all ages and genders (>100 publications)
- Prior work over past decade in SEARCH has informed our current HIV prevention interventions
  - **Universal test and treat using multi-disease, patient-centered care model**
    - UNAIDS **90-90-90 targets** rapidly exceeded; increases in **population-level viral suppression**; reductions in mortality, perinatal HIV transmission, TB, hypertension<sup>1-8</sup>
    - Reduction in **HIV incidence** in intervention arm – but incidence above targets
  - **Population-level PrEP intervention**
    - Reduced HIV incidence on top of test+treat among persons who initiated PrEP<sup>9-12</sup>
    - Gaps in prevention coverage – new option needed for persons with unanticipated, periodic sexual exposures
  - **Post-exposure prophylaxis (PEP) pilot**
    - High levels of completion, gateway to PrEP<sup>13,14</sup>

## SEARCH Sapphire: Dynamic choices in HIV prevention

- With expanding HIV prevention options – PrEP, PEP – and additional long-acting products in the prevention pipeline – how do we offer and deliver choices?
- Prior studies have provided important data on *theoretical* choices of HIV prevention products, but data limited on actual product choices made by clients and the impact of choice-based delivery models on prevention coverage
- We hypothesized that a **dynamic choice** HIV prevention service delivery model – that offers *choices* in prevention products and services, and the option to *change* preferences over time – would increase HIV prevention coverage

# Methods

## SEARCH Sapphire Phase A study (NCT04810650)

We developed a **Dynamic Choice HIV Prevention (DCP)** intervention<sup>1</sup> based on PRECEDE framework

### PRODUCT CHOICE

- Oral PrEP (TDF/XTC)
- PEP<sup>2</sup> (pill in pocket option<sup>3</sup>)
- (+ option to switch products over time)*

### HIV TESTING CHOICE

- Rapid test
- HIV self-test option

### SERVICE LOCATION CHOICE

- Clinic
- Community site/home

### PATIENT-CENTERED CARE

- **Phone access to clinician** for PEP or PrEP starts, advice/questions (24hrs/7 days/week)
- **Longer PrEP supply for start/refills** (up to 3 months)
- **Structured assessment of barriers** to PrEP/PEP start/adherence, with **personalized plans** in response
- **Psychological support** – referrals to counseling for trauma/gender-based violence

### PROVIDER TRAINING in patient-centered care and patient education

- Emphasis on **patient agency in selecting choices**

### 3 Randomized Trials of Dynamic Choice Prevention

DCP intervention<sup>1</sup> vs. standard of care (SOC) referral to HIV clinic for prevention services in 3 settings:

#### 1) Antenatal/postnatal clinics<sup>2</sup> –

- Pregnancy and postpartum time of increased risk of HIV acquisition, potential perinatal infection
- Frequent engagement in care ante/postnatal – opportunity to offer biomedical prevention

#### 2) Outpatient departments<sup>3</sup>

- Provide routine primary and urgent care services to men and women
- Diagnose a substantial proportion of new HIV infections, understudied entry point to prevention

#### 3) Delivery by **community health workers (CHW)**<sup>4</sup>

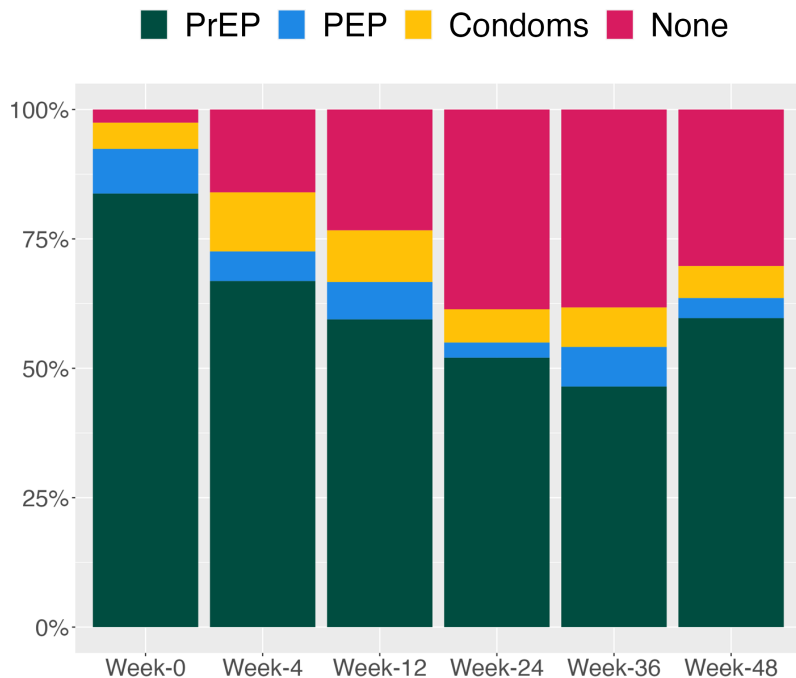
- CHWs provide a range of primary health care and health promotion services
  - Community-based entry point for HIV prevention - extend reach beyond health facilities
- **Design:** ANC and OPD – individually randomized; CHW – cluster RCT
  - **Population:** women and men ≥15 years reporting current or anticipated risk of HIV exposure
  - **Primary outcome** over 48 weeks: proportion of follow-up time covered by PrEP/PEP, assessed via self-report



## Example: Outpatient Department Trial

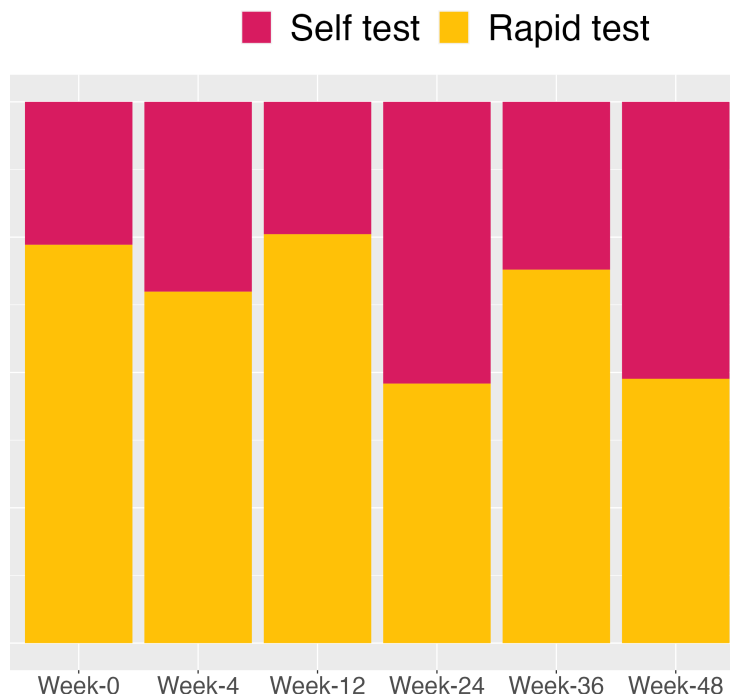
### DCP Intervention arm: Choice of product, HIV testing, visit location

#### Product Choice



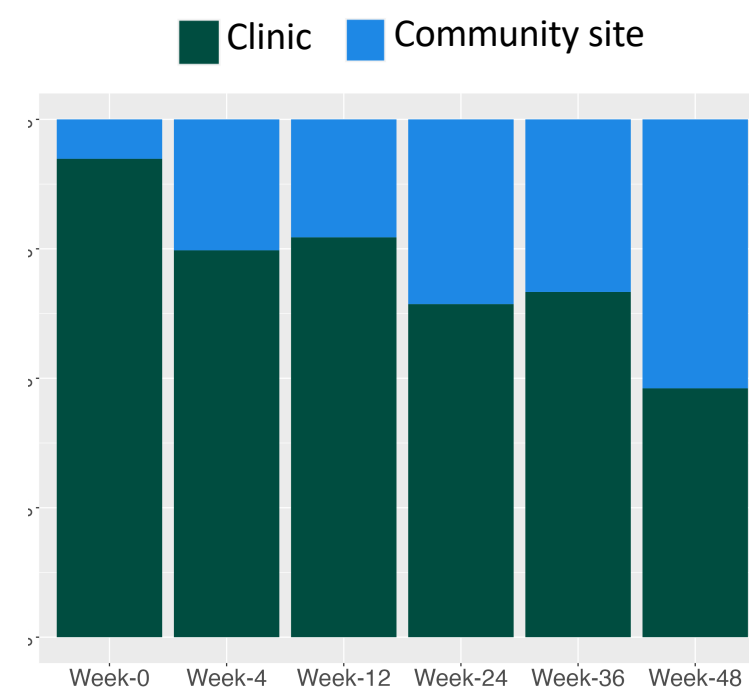
Most chose PrEP at each visit  
15% ever chose PEP

#### HIV Testing Choice



Choice of HIV self-testing  
increased from 26% to 51%

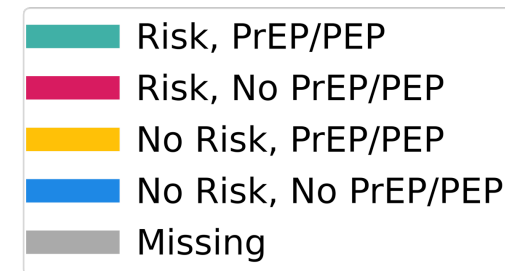
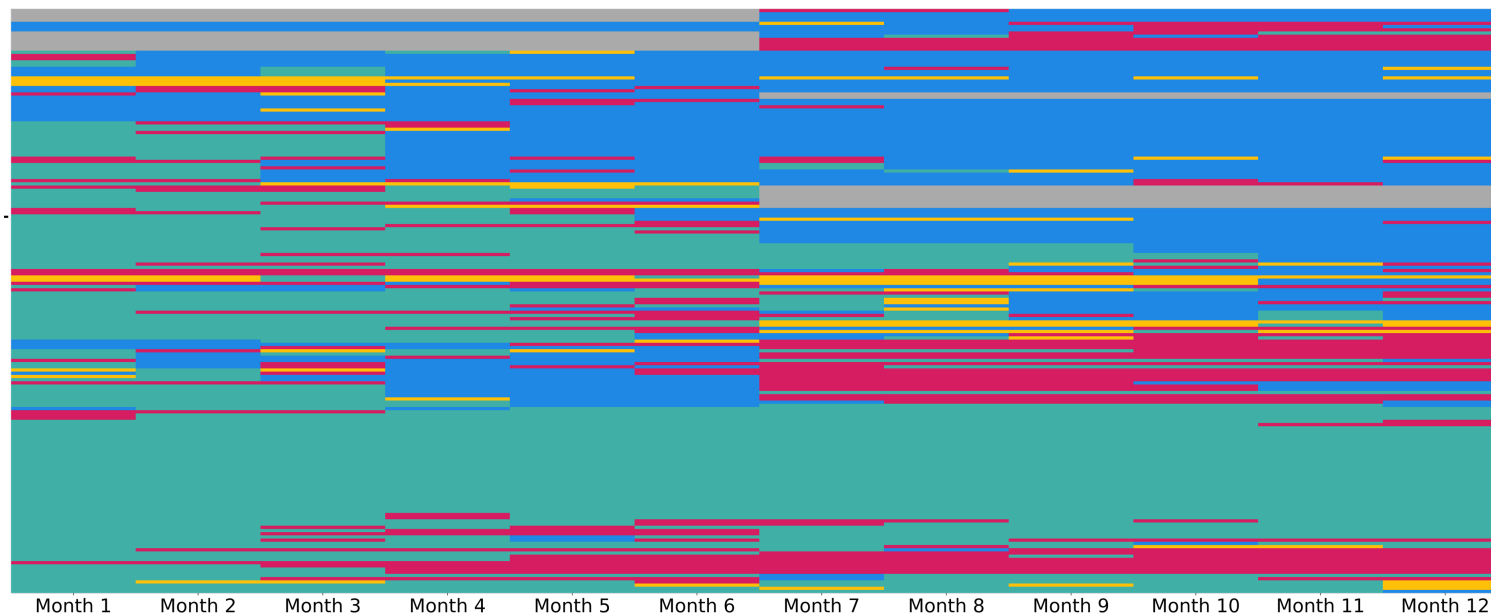
#### Location Choice



Choice of out-of-facility community  
visits increased from 8% to 52%

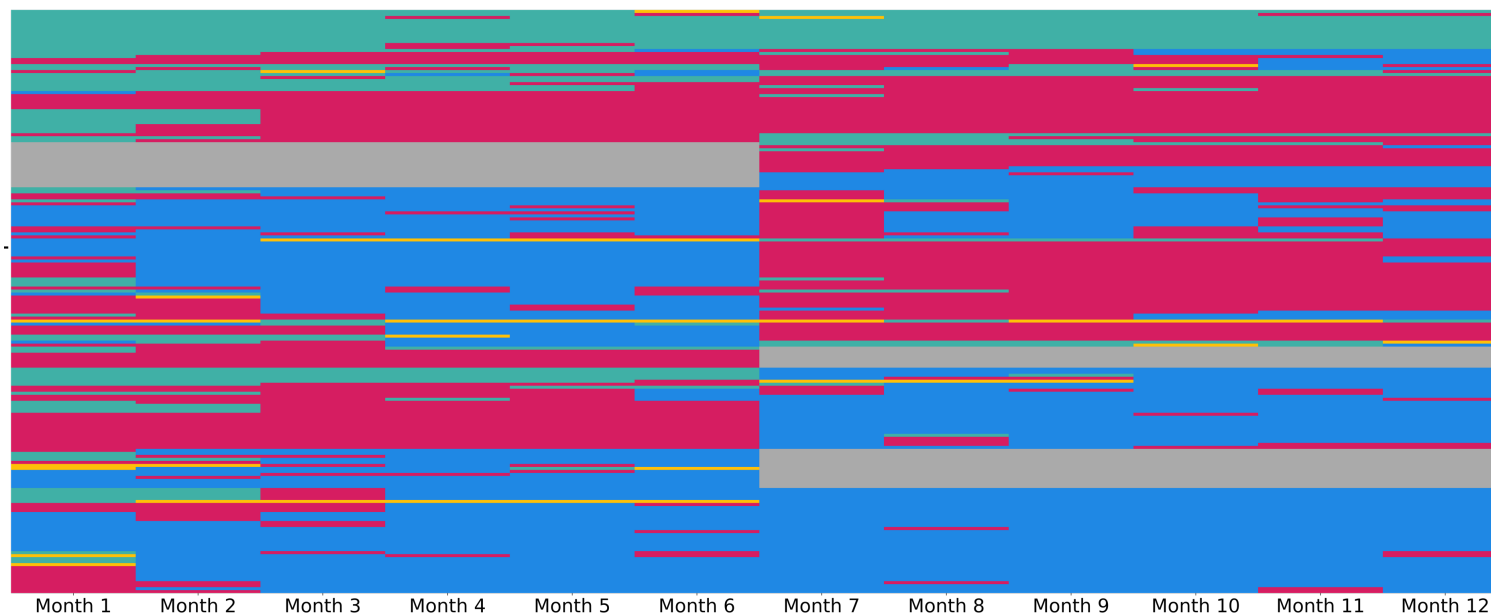


Intervention



PrEP and PEP use changed over time and according to HIV risk

SOC



# Primary Outcome: Follow-up time covered by PrEP or PEP

Dynamic Choice Prevention Intervention increased time covered by PrEP or PEP across 3 settings

Setting	N	Intervention coverage	SOC coverage	Increase in coverage
Antenatal <sup>1</sup>	400	69.6%	29.4%	40.2%
Outpatient <sup>2</sup>	403	47.5%	18.3%	29.2%
Community <sup>3</sup>	429	28.0%	0.5%	27.5%

*Intervention effect greater during periods of self-reported HIV risk*

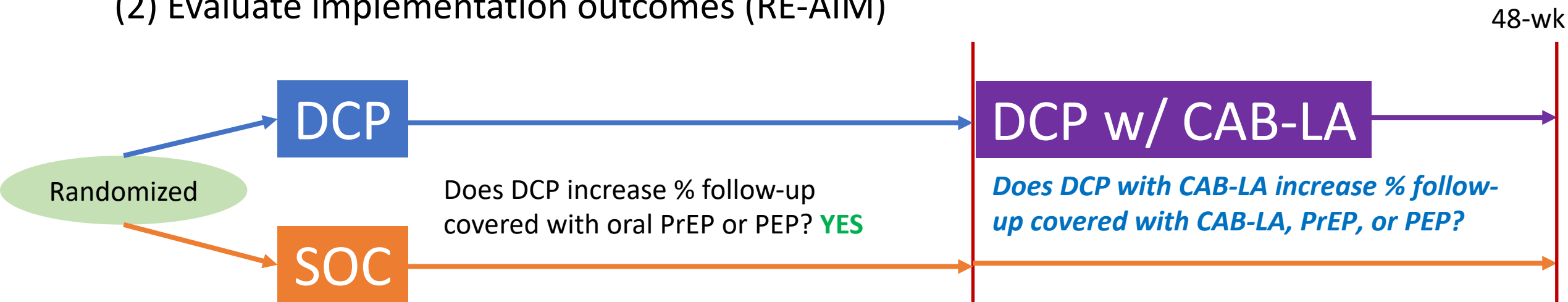
1. Kabami et al. CROI 2023. 2. Koss et al. CROI 2023. 3. Kakande et al. CROI 2023.

## Summary: Dynamic Choice HIV Prevention

- In 3 randomized trials, we tested a dynamic choice prevention intervention with choice of PrEP or PEP, HIV testing modality, and visit location, plus patient-centered care
- Intervention resulted in over *two-fold greater time covered by a biomedical prevention option* compared to SOC among both women and men
- Dynamic choice models promising approach to expand coverage of HIV prevention options as new products emerge and respond to client preferences
- Still **gaps in coverage** and need for additional products

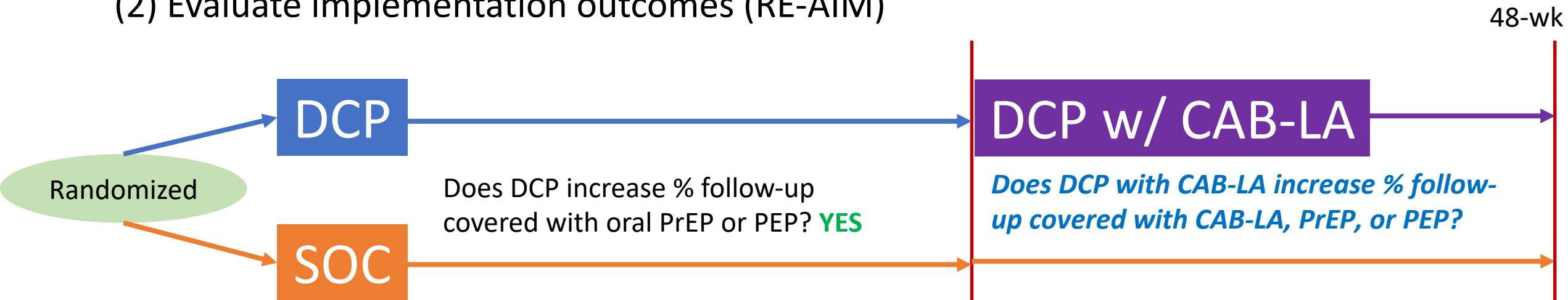
# CAB-LA extension in 3 ongoing DCP trials

- 48-wk extension of 3 ongoing randomized trials (NCT05549726)
  - Antenatal, outpatient department, community
- Offering choice of PrEP, PEP, **CAB-LA** in DCP intervention arm
- **Objectives:** (1) Evaluate the effect of DCP with CAB-LA as prevention option on biomedical prevention coverage, as compared to the SOC  
(2) Evaluate implementation outcomes (RE-AIM)



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## ACTION study – breakthrough infections on long-acting prevention products

- sensitive research assays for diagnostics, resistance, PK - and subsequent HIV treatment outcomes – partnering with SEARCH, CATALYST, MOSAIC

## Early learnings from SEARCH CAB-LA extension:

- High levels of interest in CAB-LA across the 3 trial settings  
Including in community settings  
(where PrEP, PEP uptake had been lower in DCP trial)
- Many who initiated CAB-LA were not previously using PrEP or PEP, despite having access to these products
- Strategies needed to ensure ongoing engagement and delivery, including outside of facilities



# Next step: Testing effect of dynamic choice prevention on HIV incidence in population-level study

- **SEARCH Sapphire Phase B** – 160,000-person community cluster randomized trial (NCT05768763) in 16 communities in rural western Kenya, southwestern Uganda
  - Primary endpoint HIV incidence
  - Launched March 2023
- Studying the population-level effect of dynamic choice prevention in the context of a **Community Precision Health Model**
  - Reach: Leverages existing facility-based outreach and engages community health workers
  - Delivery: Optimized dynamic choice HIV prevention and treatment interventions
  - Data + Analytics: Integrated data systems, machine learning
- **DCP product choices:** oral PrEP, PEP, DPV vaginal ring, planning for CAB-LA
- SEARCH will test whether Community Precision Health – leveraging existing infrastructure to reach, engage, and deliver health services with new products and analytics, in a multi-disease model – can accelerate progress to ending AIDS and improve community health.



# Acknowledgements: Study Participants and Communities

Republic of Kenya Ministry of Health, Republic of Uganda Ministry of Health

**Diane Havlir, Moses Kanya, Maya Petersen—PIs**

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James Peng

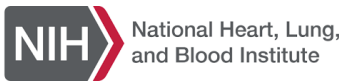
John Schrom

## National Institute of Allergy and Infectious Diseases

Melanie Bacon



**Thanks to sponsors and many others on the SEARCH team**



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Viiv: Study Drug donation



# **CATALYST Study**

Elizabeth M. Irungu, Jhpiego

# CATALYST: A multi-country implementation science study to inform the rollout of new PrEP products in East and Southern Africa

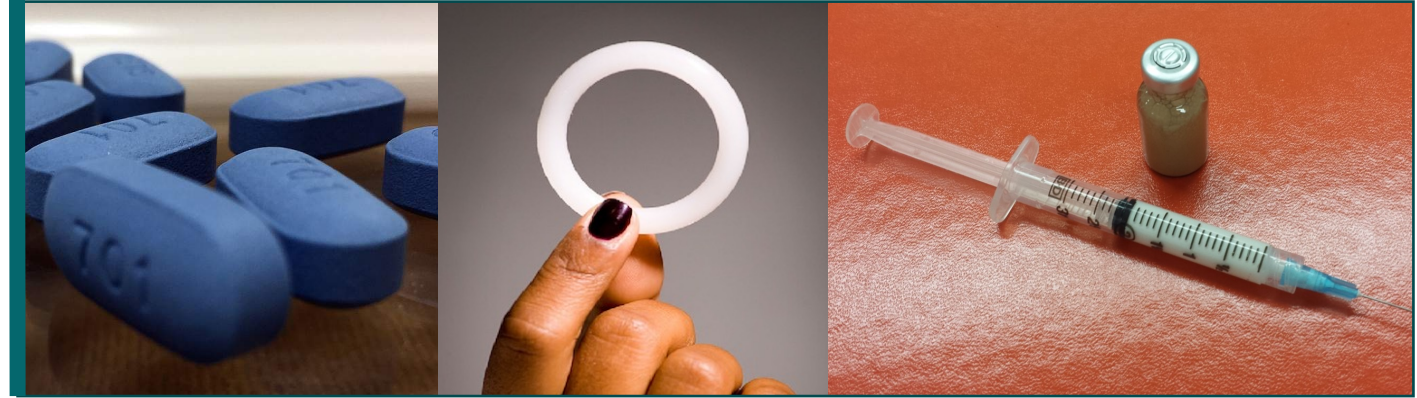
ELIZABETH IRUNGU, JHPIEGO  
JUNE 13, 2023





# Catalyzing access to new prevention products to stop HIV

The CATALYST study, under the MOSAIC project, will use mixed methods to characterize and assess the implementation of an enhanced service delivery package providing choice of PrEP products among women at PEPFAR delivery sites in Kenya, Lesotho, South Africa, Uganda, and Zimbabwe.



## OBJECTIVE 1

Characterize the implementation of an enhanced service delivery package for PrEP choice and assess individual-, provider-, facility-, community- and health system-level facilitators and barriers of the implementation process

## OBJECTIVE 2

Describe patterns of PrEP use and use effectiveness in the context of PrEP choice and assess sociodemographic and contraceptive use correlates of PrEP use patterns

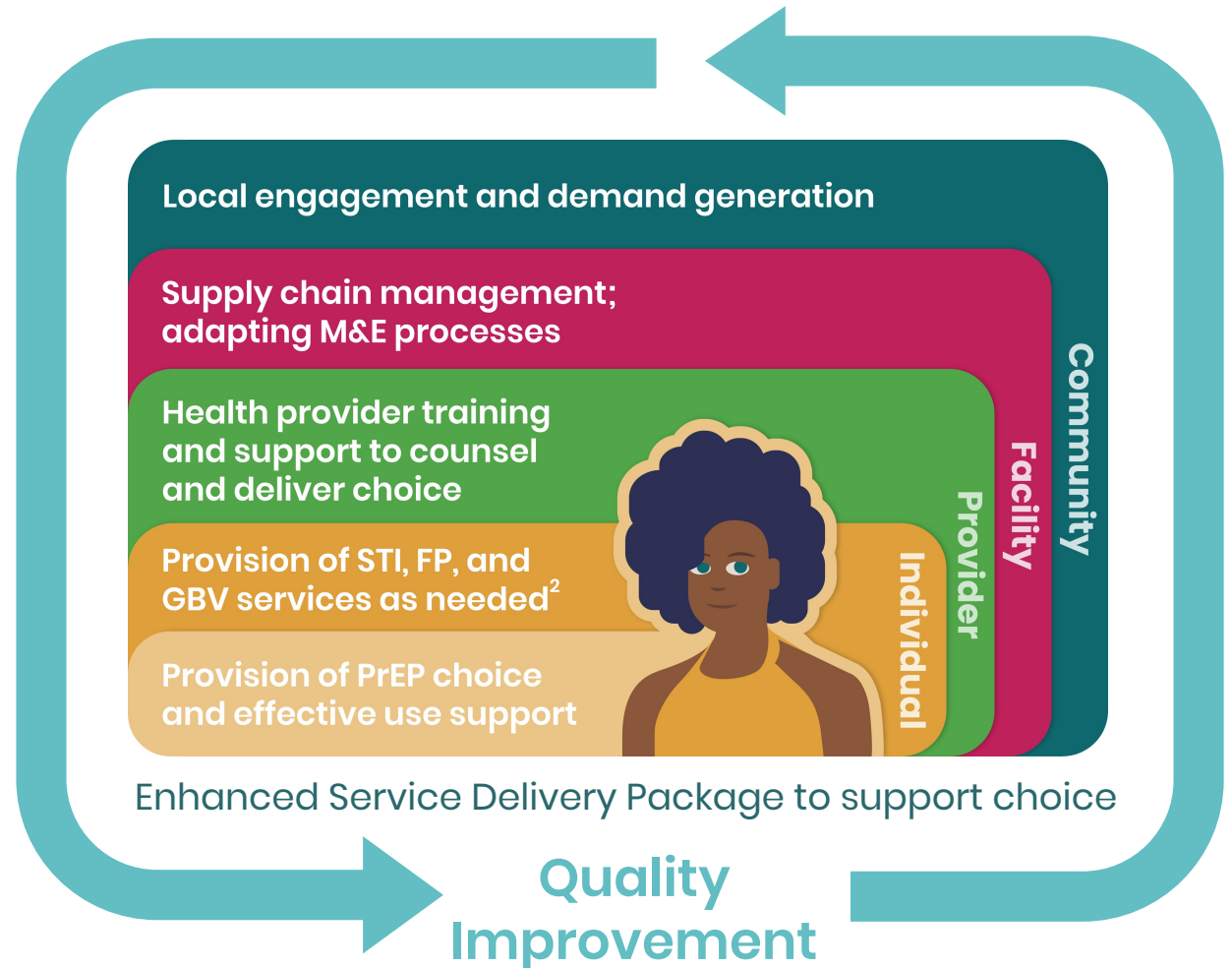
## OBJECTIVE 3

Describe clinically relevant indicators among PrEP users, including rates of HIV infection and drug resistance among PrEP users who acquire HIV following PrEP exposure

# CATALYST will implement an enhanced service delivery package that supports product choice

The **enhanced service delivery package** will...

- **Support choice** among the PrEP products that have regulatory approval in each country.
- Include components at the **individual**, **provider**, **facility** and **community** levels
- Use **quality improvement** methods to refine components and identify a core service delivery package for PrEP choice.



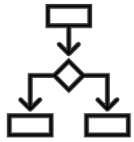
# Health provider training and support to counsel and deliver choice

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## AS PART OF THE CATALYST STUDY, PROVIDERS ARE TRAINED ON:

- Clinical aspects of each HIV prevention method (oral PrEP, PrEP ring, and CAB PrEP), including eligibility requirements of each method and how they work
- How to communicate with clients about choice of HIV prevention methods and help them select the method that best meets their unique lifestyle and needs
- Empathy-building to support counseling interactions with young clients and LGBTQIA+ clients using *Empathways*

# Choice counseling training: Learning objectives



Define what informed choice means in the context of counseling

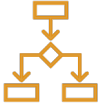


Understand how to talk about choice with your client



Become familiar with the tools available to you for choice counseling





**First, let's determine what is**  
**informed choice**

Individuals have the autonomy, knowledge, and freedom from coercion at any given time to select the best method for them in a specific market.

*Adapted from MOSAIC Choice Principles*

# Choice counseling is part of a **conversation**

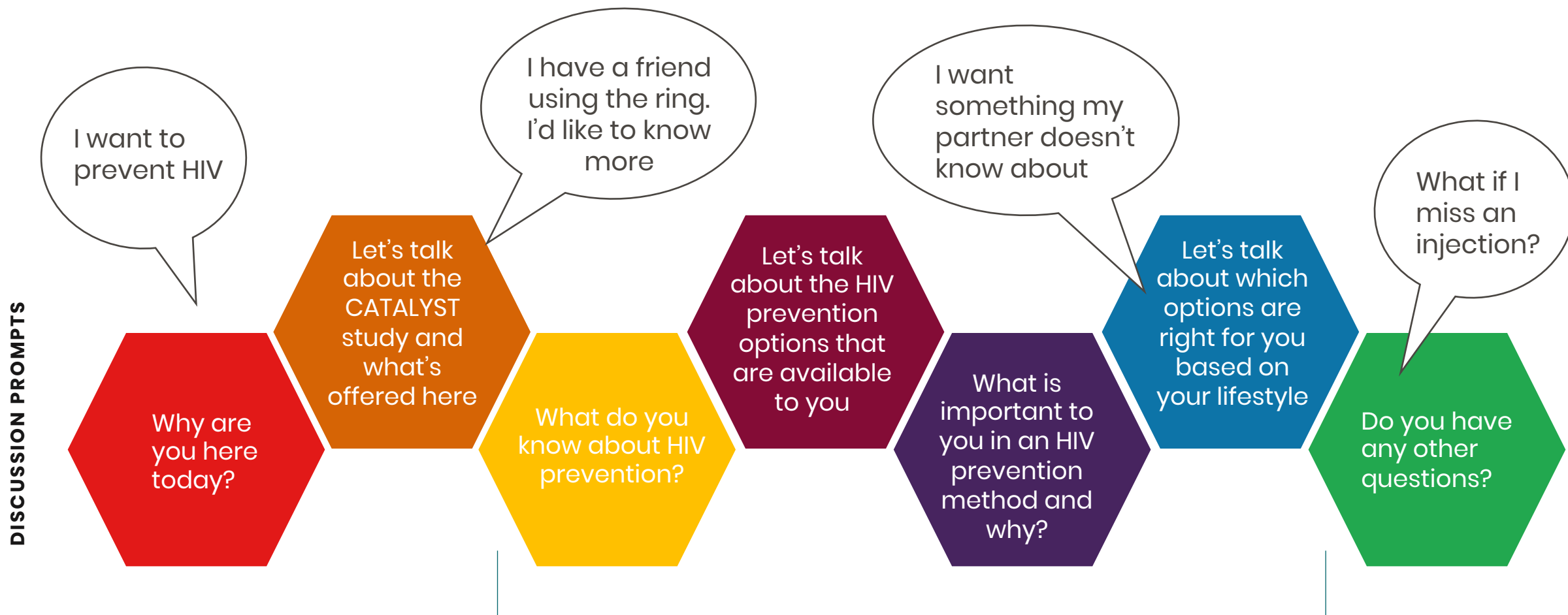


The discussion needs to be:

- ✓ Client-centered and client-led
- ✓ A two-way conversation
- ✓ Flexible
- ✓ Embracing both sexual reproductive health and HIV, as per the client's needs —especially issues such as contraception, planning for pregnancy, sexually transmitted infections (STIs), and gender-based violence (GBV)

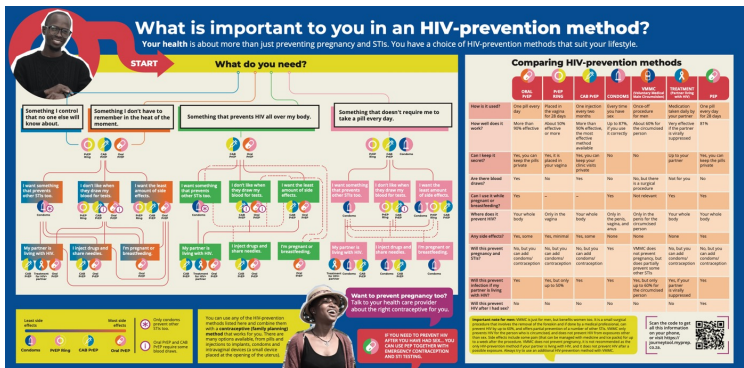


# Where does choice counseling fit into the conversation



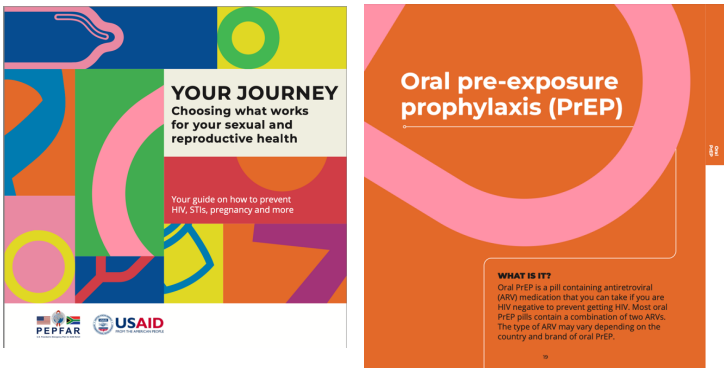
Use the client's **needs and knowledge** to determine the flow of the choice counseling conversation

# CATALYST tools for providers and clients to support informed choice



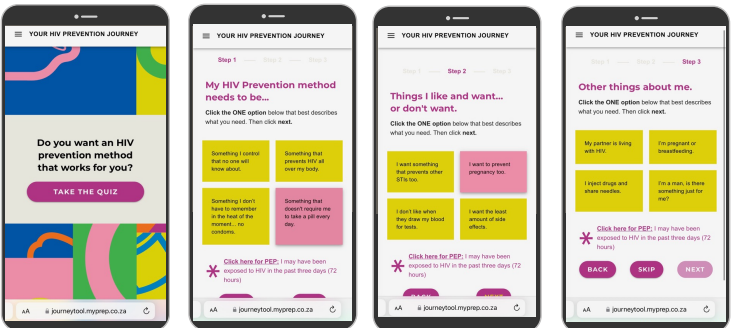
## HIV Prevention User Journey Info-Map

Poster, placemat, or other format depending on the setting, the info-map is for a provider and client to walk through together during a clinic visit or for use on the wall in the clinic setting. The info-map is meant to guide the conversation, with key information the provider needs to cover, leaving room for the provider to explain the information in terms the client will understand and relate to.



## Provider HIV Prevention User Journey Manual

The provider manual is an addendum to the map for reference that does not have to be used in front of the client, holding comprehensive information, in a digital or printed copy. *It can still be used flipchart style*—the language is accessible for both providers and clients.



## Easy-to-use, appealing digital tool

Digital tool for mobile phone use by AGYW outside or within clinic settings. Clients can bring in the information from using the tool into their counseling conversation.



# PrEP Product Factsheets

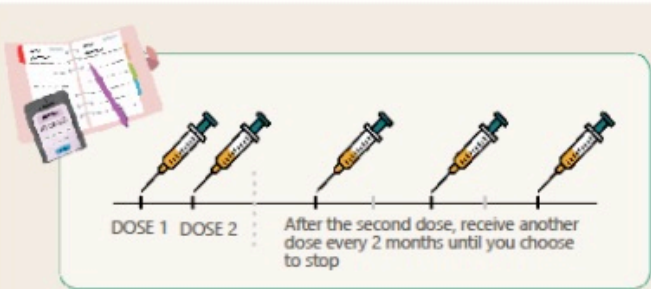


## About Injectable PrEP (CAB PrEP)



### How long-acting injectable cabotegravir for PrEP (CAB PrEP) works

Injectable cabotegravir (CAB PrEP) is one HIV prevention option that participants can choose in CATALYST. It is an antiretroviral (ARV) medication that is given as an injection every two months for HIV pre-exposure prophylaxis (PrEP). It can be taken by people without HIV to reduce the chance of getting HIV. Because ARVs circulate throughout the body, CAB PrEP prevents HIV during vaginal, anal and oral sex. CAB PrEP prevents HIV from entering human cells and multiplying itself. If the virus cannot multiply, it simply dies within the body.



CAB PrEP is more than 90% effective, which means it is the most effective PrEP method currently available. CAB PrEP starts preventing HIV for most people about one week after their first dose.

For maximum HIV prevention, it is important to keep regular appointments for injections and use condoms whenever possible.



## PrEP Ring Fact Sheet

### How the PrEP ring works

The PrEP ring is one HIV prevention option that participants can choose in CATALYST. It is a flexible silicone ring inserted in the vagina containing the antiretroviral (ARV) medication dapivirine. It slowly releases dapivirine into the vagina over one month. Dapivirine works by preventing HIV from making copies of itself inside the vagina. If the virus can't make copies of itself, it simply dies within the body.

The PrEP ring can reduce the chance of getting HIV through vaginal sex by about 50% or more when kept in place for a whole month. The ring must be in place for 24 hours before it provides maximum HIV prevention. For maximum HIV prevention, it is important to use PrEP ring in combination with condoms whenever possible.



### Using the PrEP ring successfully

- **USE WITH OTHER FORMS OF PREVENTION** – the PrEP ring does not prevent HIV during anal sex or injection drug use. The ring also does not prevent



## About oral PrEP



### How oral PrEP works

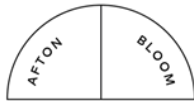
Oral pre-exposure prophylaxis (PrEP) is one HIV prevention option that participants can choose in CATALYST. It is a pill containing two antiretroviral (ARV) medications that can be taken by people without HIV to reduce the chance of getting HIV. The ARVs circulate throughout the body so that oral PrEP prevents HIV during vaginal, anal and oral sex. Oral PrEP prevents HIV from entering human cells and multiplying itself. If the virus cannot multiply, it simply dies within the body.

When taken as directed, oral PrEP reduces the chances of getting HIV by up to 90%. Most people will be protected after they have been taking oral PrEP for 7 days. For maximum HIV prevention, it is important to use oral PrEP in combination with condoms whenever possible.



# ACKNOWLEDGMENTS

Elmari Briedenhann and Melanie Pleaner, Wits RHI; Allison Cole, Emily Donaldson, Bridger Trap, and Rose Wilcher, FHI 360



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*Photo Credit: MOSAIC Consortium*





# Malawi Injectable PrEP Path to Scale Study

Sara Allinder, Georgetown University

Friday Saidi, University of North Carolina, Project Malawi

# Malawi Injectable PrEP Path to Scale Study

*PrEP Connection Webinar*  
*13<sup>th</sup> June 2023*

Sara M. Allinder, Co-Investigator, Obj 2 & 4  
Dr. Friday Saidi, Co-PI, Obj 3 & Co-Investigator, Obj 1



GEORGETOWN UNIVERSITY  
Center for Innovation in Global Health

## Building from Government of Malawi's BPS for Injectable PrEP Introduction & Testing

*Malawi's Injectable PrEP Path to Scale implementation science Study builds from the district/national Blantyre Prevention Strategy (BPS) platform and will be supported by its systems investments, thereby providing critical underpinnings to broader scale and sustainability.*

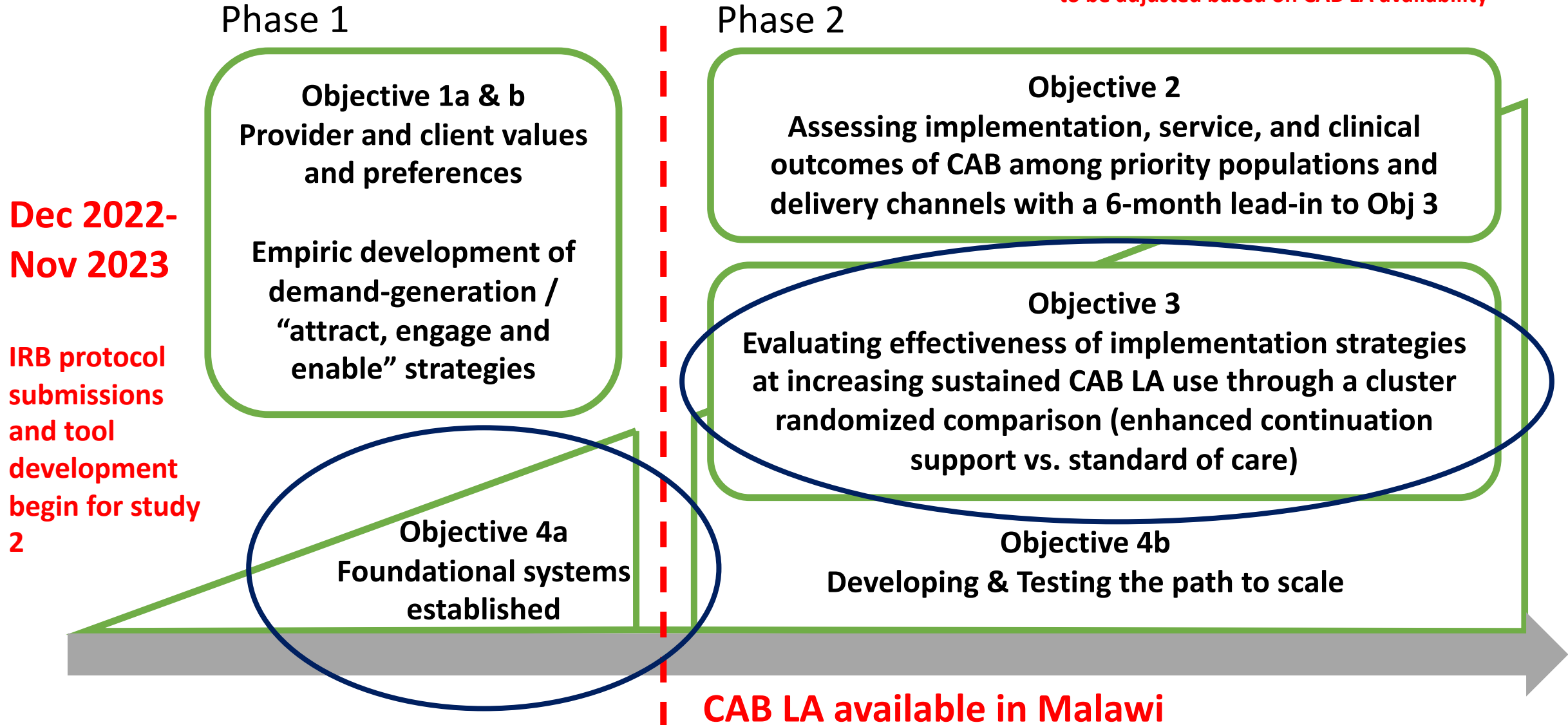
**Government leadership** from the very start & at every step  
**Capacity** and **sustainability** built from pre-clinical phase  
Benefits from **BPS functions**, from data use, community learning to quality  
An **iterative adaptive learning approach** where we learn & **course correct** along the way together  
Partners **collaborate** frequently to coordinate, share findings, etc.  
Intentionally generates more relevant learnings and **evidence** for the path to scale in Malawi & the region



# 4 Objectives across 2 phases

**~Oct 2023\*-Sep 2025**

**\*to be adjusted based on CAB LA availability**





# Downstream, Midstream, & Upstream Support for Clients & Path to Scale



# Client-Centered Support for Injectable PrEP

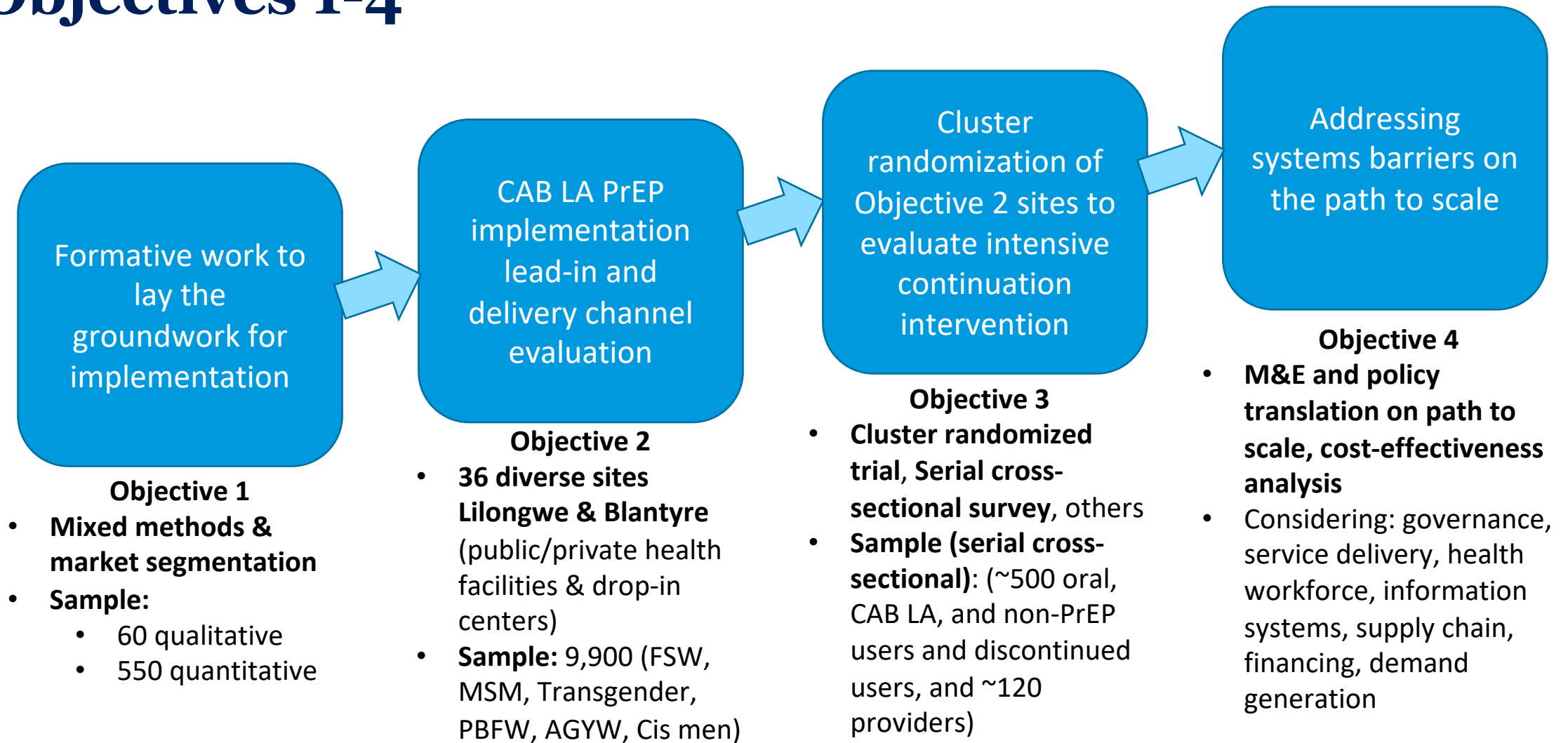
Dr. Friday Saidi, Co-PI, Obj 3 & Co-Investigator, Obj 1  
UNC Project-Malawi



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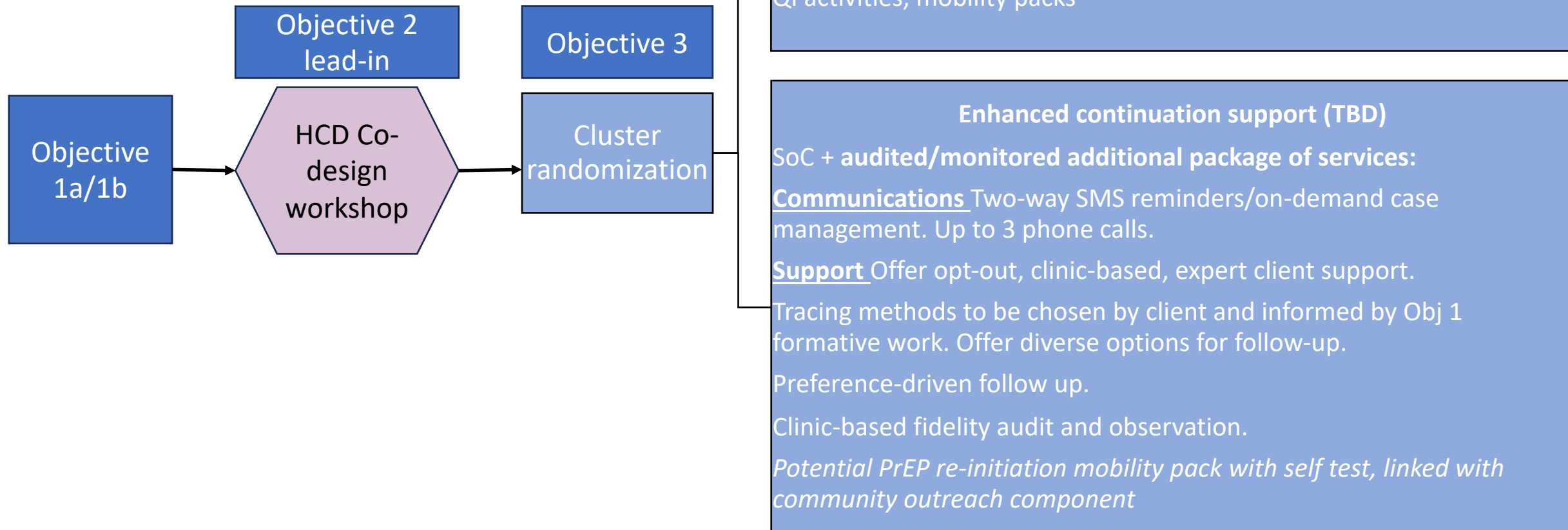
**UNC**  
PROJECT  
Lilongwe, Malawi

# Injectable PrEP path to scale in Malawi: Objectives 1-4



# Objective 3: SoC vs. Enhanced Continuation Support

Enhanced intervention packages will be **co-designed** with clients (building from quant/qual, segmentation, and DCE activities from Objective 1a/1b pre-product phase) and **piloted/iteratively refined during the Objective 2 lead-in period and HCD process**. Notional elements of each arm are detailed to the right:



# Systems Support for Injectable PrEP

Sara M. Allinder, Co-Investigator, Obj 2 & 4  
Center for Innovation in Global Health,  
Georgetown University



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# Adapting BPS Best Practices in Lilongwe to Support the Study and Future Path to Scale

## TARGETING

- **Data Pipeline** and Prevention Adaptive Learning and Management System (**PALMS**)
- Integrated Disease Surveillance and Response Pilot for HIV (**IDSR-HIV Pilot**)

## DEMAND

- **Human Centered Design** Community Labs & Continuous Feedback Loop
- **Health Communications**

## DELIVERY

- **Quality Improvement Collaboratives**
- Strengthening and/or Expanding **HIV Prevention Service Delivery Channels** (public, private, and community sectors)

## SUSTAINED USE

- **Structural Risk Reduction** Working Groups in Blantyre City

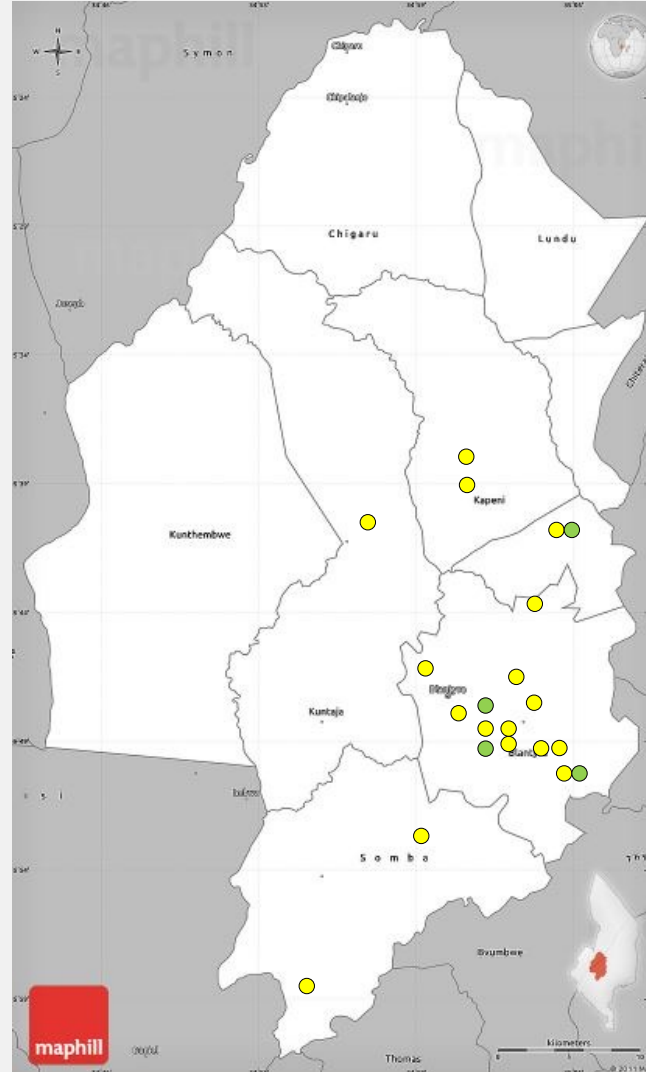
# BPS *PrEPUp!* Quality Improvement Collaborative

## Why a PrEP QI Collaborative?

A QI methodology that:



*“brings together groups of practitioners from different healthcare organisations, public health professionals and the community, to work in a structured way to improve one aspect of the quality of their service. It involves a series of meetings to learn about best practices in the area chosen, about quality methods and change ideas, and to share their experiences of making changes in their own local settings.”*

Ovretveit et al. (2002)



Blantyre DHO and Blantyre City Assembly selected 23 facilities to participate in PrEP QIC

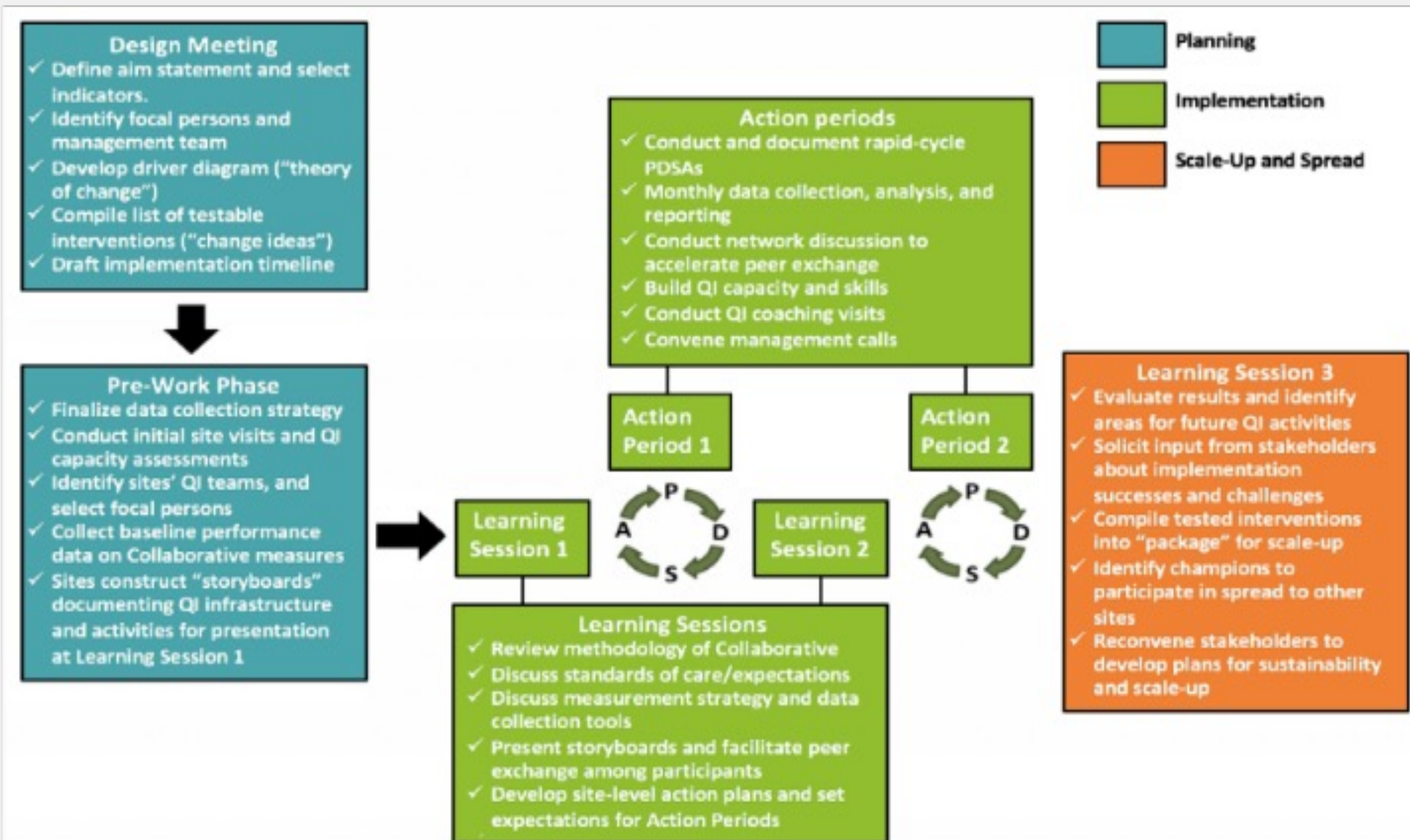
13 health centers, 2 hospitals, 4 drop-in centers, 1 Tertiary Education facility, 1 central hospital, 2 low-tier private hospitals

 Health Center  
 Drop-In Center

# Game Changer: Application of QI to HIV Prevention

- Prescient timing with the start of oral PrEP roll out nationwide
- PrEP-Up! Collaborative has robustly engaged District, City, PEPFAR IPs, public and not-for-profit facilities, and two private dispensaries added in Y3
  - Has improved District governance and coordination with facilities.
- Imbedding QI data in PALMS and accessing/utilizing broader data from PALMS is changing the way facilities do business
  - Also has identified important data gaps
  - Aligning with human-centered design community labs brings user input into QI change approaches

# Key Features of a Collaborative



# HCD-QI Interface – BPS PrEP Collaborative

## (12 to 18 months time frame)

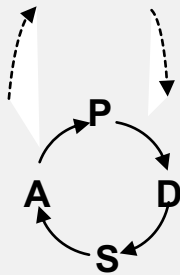
**LS – Learning  
Session**

**AP – Action Period**

**Develop  
Framework  
& Changes**

**Planning  
Group  
(HQ/MK/PSI/  
DHO)**

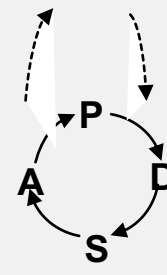
**HCD Community  
labs**



**LS 1**

**AP1**

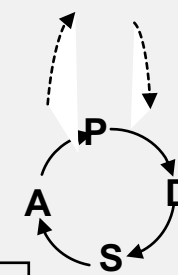
**HCD Community  
labs**



**LS 2**

**AP2**

**HCD Community  
labs**



**LS 3**

**AP3**

**Dissemination**

Holding the  
Gains  
Scale-Up  
Publication  
etc.

**Supports**

Weekly & Bi-weekly Visits

Phone Calls

Assessments

Monthly Team Reports



## *PrEPUp!* Quality Improvement Collaborative Learning

- A QI Mentors approach, with QI coaching, is key to building QI capacity at both district- and facility-level.
- **Successful strategies to integrate PrEP into existing health care facility services** include mapping of key entry points for clients seeking care, **regular demand creation activities with community input**, improving sexual history taking, and **addressing stigma, which has been identified as a key barrier to accessing services.**
- Affinity groups can evolve into communities of practice.
- **Establishing a community of practice through collaborative learning sessions (aligned with the national PrEP strategy and guidelines) is key for sharing learning and spread of best practices in HIV prevention, including oral PrEP, throughout the District and across IPs.**
- **Integration of data sessions with QI sessions at cluster level or facility level is required**
- Focus on change strategies to foster linkage from community STI clinics to accessible PrEP services.



# Zikomo! Thank you!



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BILL & MELINDA  
GATES foundation



PAKACHERE IDHC  
POTHERA NKHANI



Imperial College  
London





# **PrEP1519 Study**

Ines Dourado, Federal University of Bahia, Brazil

# PrEP<sup>15-19</sup> choices

Preparedness for effective HIV prevention with long-acting  
injectable cabotegravir (CAB-PrEP) among LGBTQIA+ adolescent  
15-19 years old in Brazil

Representative PI: Inês Dourado, MD, PhD



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SAÚDE



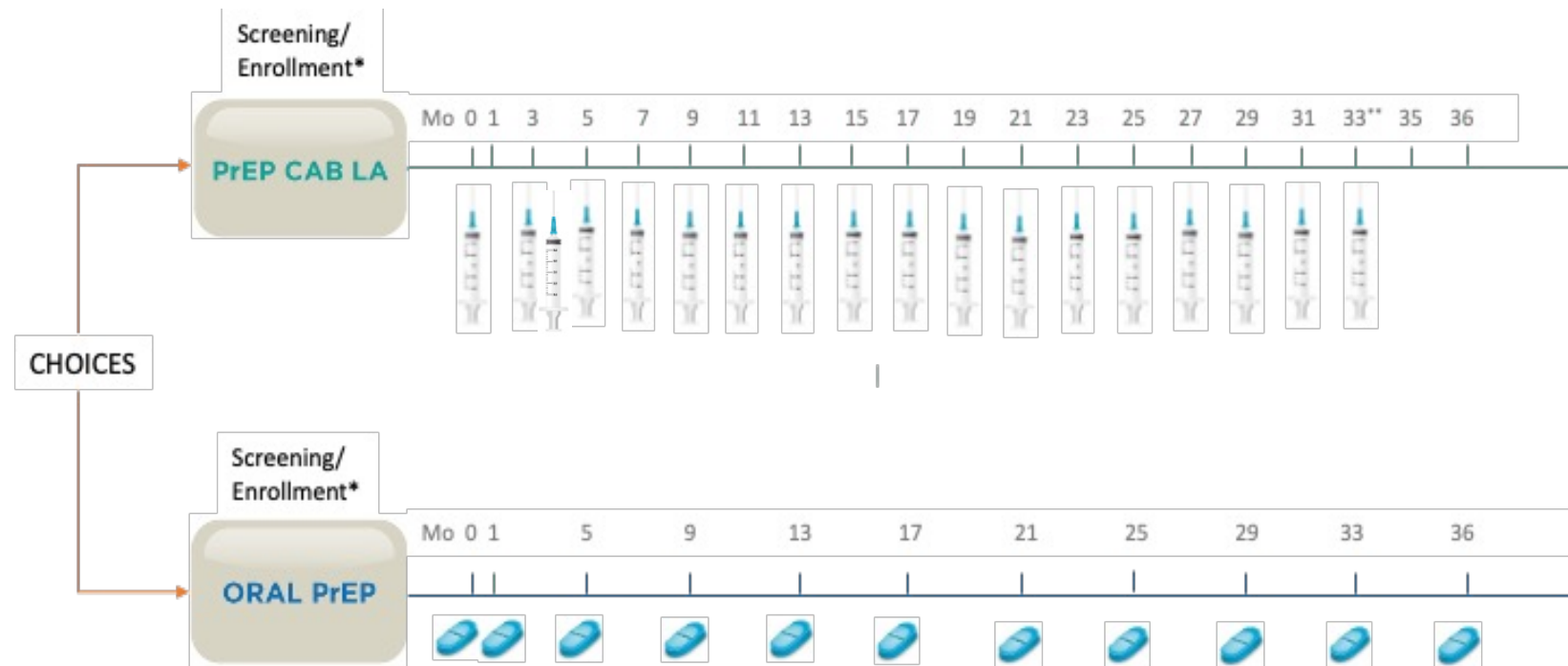
# Primary Objectives

- To evaluate the implementation of a PrEP protocol with three modalities (i.e., CAB-LA, event-driven and daily oral) for AMSM, non-binary assigned as male at birth, ATGW and ATGM, in contexts of increased vulnerability or risk of HIV infection, aged 15-19 years in public services aimed at adolescents in Brazil.
- To improve the diagnosis and management of STIs among PrEP users, through the implementation of a youth-centered approach.



# Study Design

- Multi-site (3), prospective, demonstration cohort study of PrEP modalities using a mixed-method design with quantitative and qualitative approaches, evaluation of diagnostic tests and economic analysis
- Follow-up: Up to 36 mo. (33 mo. using CAB-LA PrEP + 3 mo. for the tail phase)



\*Same-day initiation of CAB-LA PrEP in screening/enrollment, if negative HIV test results  
\*\* End of CAB-LA injections  
Deadline for switching for oral PrEP to CAB-LA PrEP: month 21  
Mo, month

## PrEP modalities

### Injectable CAB-LA

Two intragluteal injections of CAB-LA 600mg 4 weeks apart and every 8 weeks thereafter

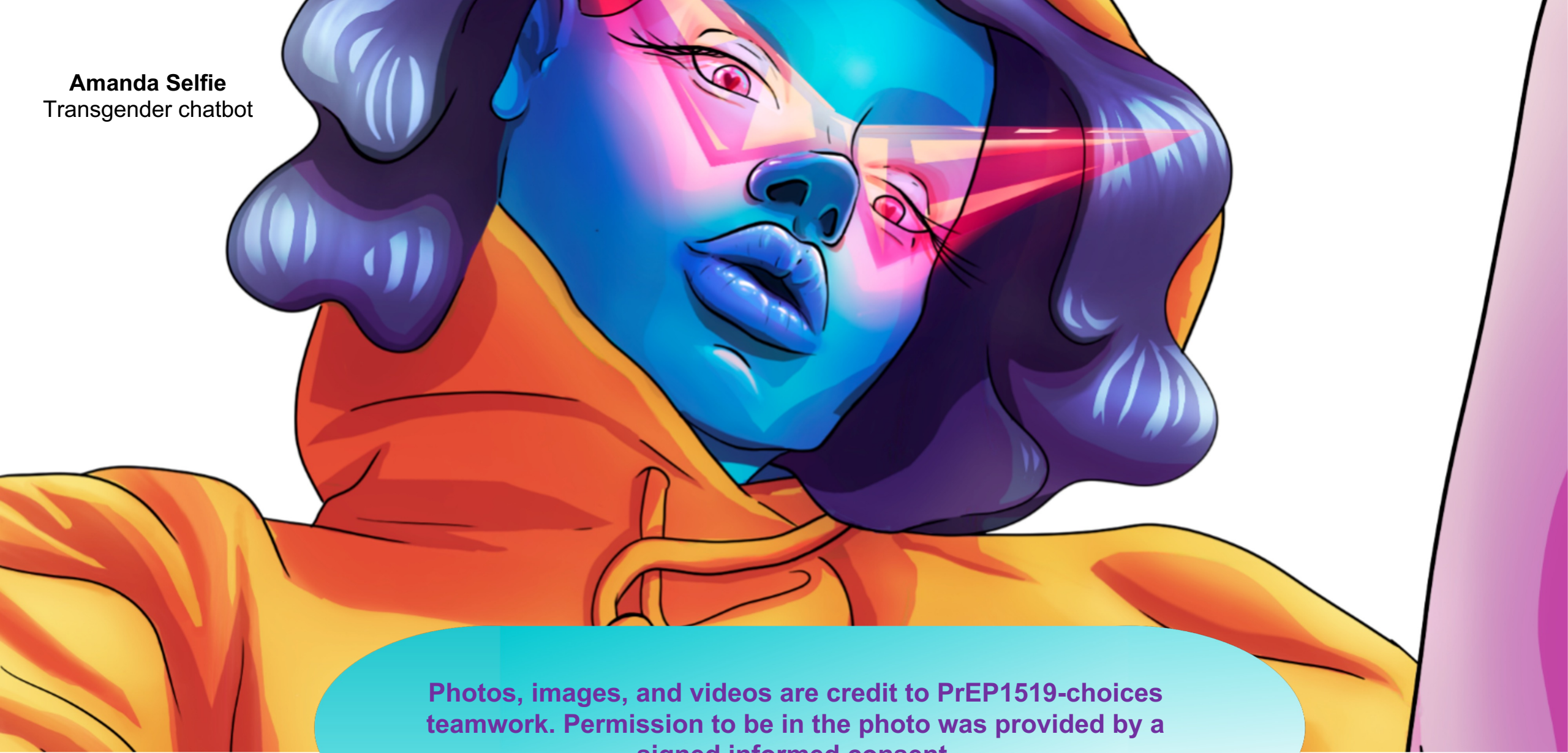
### Oral PrEP

Daily oral TDF/FTC (300/200 mg)  
or  
Event-driven PrEP TDF-FTC (300/200 mg, « 2 + 1 + 1 »)

# Sub- studies

- Diagnostic evaluation of HIV testing (describe HIV infections in PrEP users; drug resistance, HIV-subtype, viral load);
- Evaluation of linkage, retention and adherence strategies for PrEP modalities;
- Evaluation of oral PrEP provision by telehealth;
- Evaluation of strategies for partner notification for STIs;
- Acceptability of finger-stick whole-blood HIV self-test.

**Amanda Selfie**  
Transgender chatbot



Photos, images, and videos are credit to PrEP1519-choices teamwork. Permission to be in the photo was provided by a signed informed consent.


# Demand creation strategies are essential to reach adolescents



[Home](#) > [Archives of Sexual Behavior](#) > [Article](#)

Original Paper | [Open Access](#) | [Published: 25 July 2022](#)

## Reaching Out to Adolescents at High Risk of HIV Infection in Brazil: Demand Creation Strategies for PrEP and Other HIV Combination Prevention Methods

[Laio Magno](#) , [Fabiane Soares](#), [Eliana Miura Zucchi](#), [Marcos Eustórgio](#), [Alexandre Grangeiro](#), [Dulce Ferraz](#), [Dirceu Greco](#), [Maria Mercedes Escuder](#), [Ines Dourado](#) & [The PrEP1519 Study Group](#)

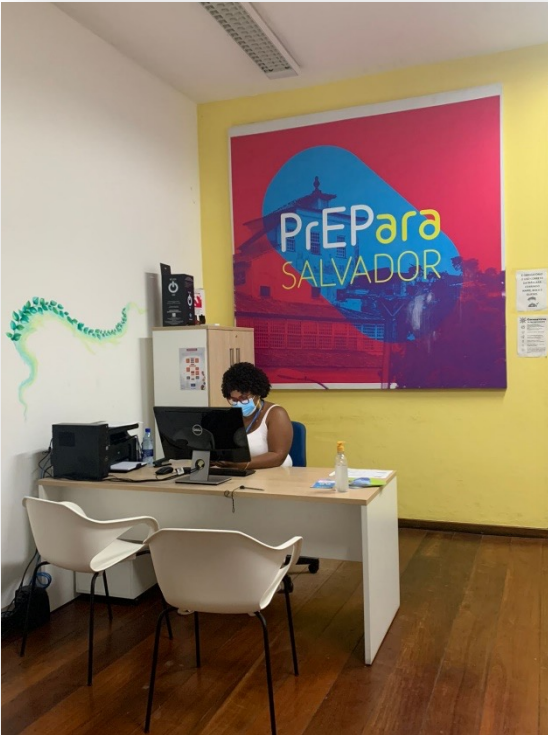
[Archives of Sexual Behavior](#) **52**, 703–719 (2023) | [Cite this article](#)

**1853** Accesses | **2** Citations | **1** Altmetric | [Metrics](#)

- Online strategies were less effective than face-to-face peer recruitment and reached more adolescents from higher socioeconomic backgrounds.
- Online interventions can be more cost-effective and easily scaled up to increase service coverage.
- Online and peer-driven face-to-face strategies provided a critical balance between offering comprehensive coverage and equitable sexual health services for adolescents of key populations from different socioeconomic backgrounds.
- We enrolled **1,216 adolescents** in daily oral PrEP in three years of follow-up (Phase 1).



# Environment matters!



Reception



St Cher Chapel



PrEPOs



Peer educators





# Making connections

Interactive approach using prevention games, Q&A with health team and youth LGBTQIA+ peer educators

Youth CBOs

Schools





# Youth engagement in action

## Peer educators in venues



At the beach



Peer educators at youth venues



**Summer:** beach, parties, prevention popsicle, distribution of prevention items, HIV self-test, mobilization of young LGBTQIA+



# Communication and information

## Flyers, Fans, Posters, Cards, Brochures

Colors inspired by  
the transgender and  
non-binary flags



QWERTYUIOP  
**A PREVENÇÃO  
COMEÇA BEM  
ANTES DA  
PEGAÇÃO**

**Já parou para  
pensar qual é  
o melhor método  
de prevenção  
para você?**

A PrEP dá mais autonomia para se prevenir do HIV. Ela impede a infecção pelo vírus e, aliada a outros métodos, pode te dar muito mais segurança na hora do sexo. E o melhor: no PrEPa Salvador a PrEP é grátis!

**Público alvo:** pessoas trans, não binária registradas, meninos cis gays e HSH, com idade entre 15 e 19 anos.



**Você pode usar  
de graça!**  
Entre em contato com  
o PrEPa.

Formas  
da PrEP

**Casarão da Diversidade**  
Rua do Tijolo nº 08 - Pelourinho, Salvador-BA  
71 99640-9030 @prepsalvador @prepsalvador

**SEXO E  
PREVENÇÃO?**

Se você é...

- Pessoa trans
- Não binária registrada no masculino
- Menino cis gay ou HSH
- Com idade entre 15 e 19 anos
- Você pode utilizar os serviços do PrEPa Salvador

**CONHEÇA A PrEP**

- Um medicamento que impede a infecção pelo HIV.
- No PrEPa Salvador, a PrEP é de graça.
- Você também tem acesso a outros serviços: testagem e tratamento para outras infecções sexualmente transmissíveis e aconselhamento.

**#Escolha PrEP**

A PrEP pode ser utilizada das seguintes formas:

- Comprimidos diários
- Sob demanda
- Injetável

Entre em contato para saber mais.



Venha no Casarão da Diversidade ou entre em contato pelo QR Code. Fale com a gente pelo Instagram!

@prepsalvador @prepsalvador 71 99640-9030

**Casarão da Diversidade**  
Rua do Tijolo nº 08, Pelourinho, Salvador-BA

Você sabe cuidar  
direitinho da sua

**SAÚDE  
SEXUAL?**

Fans

Graphics to easy  
the content about  
LAI-PrEP-  
QR code to  
facilitate access  
by young people  
to our social  
networks and  
contact channels



Brochures



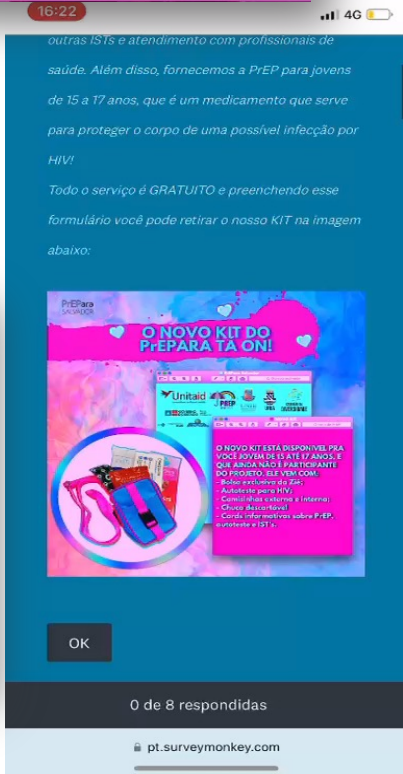
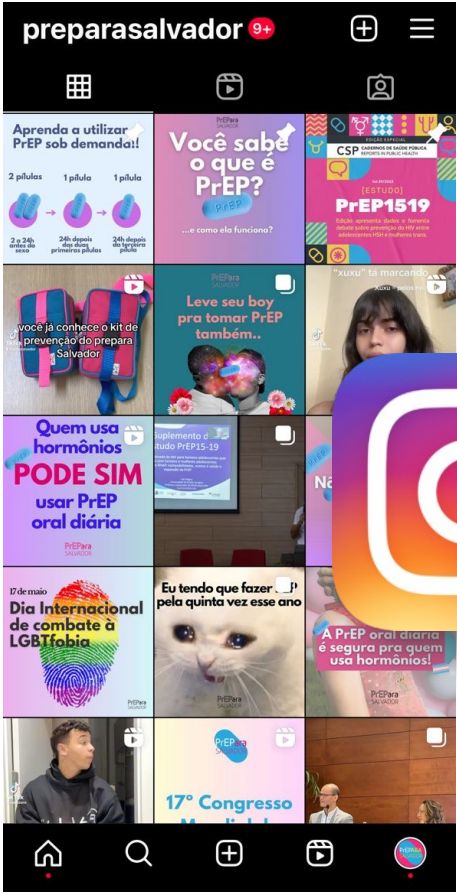


# Online connections

## Active role of peer educators on social media for recruitment

Instagram

Greater capture via boosted posts on Instagram



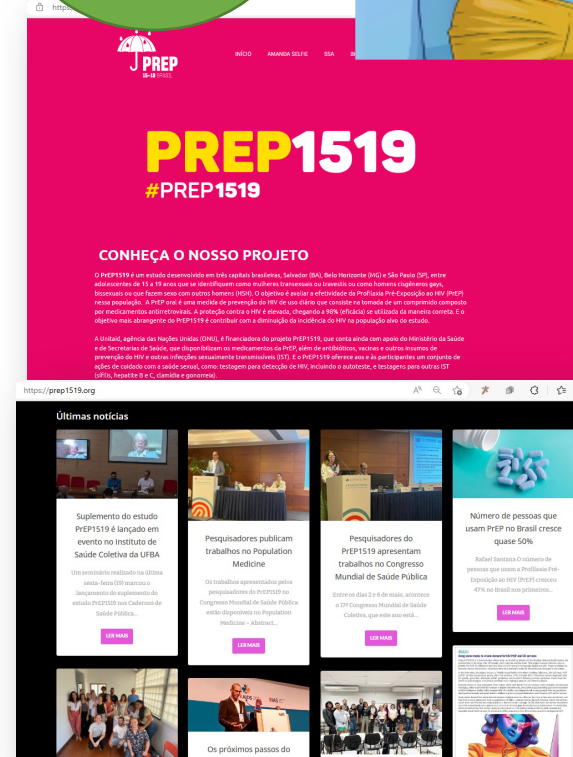
Being where young people are - on YouTube, Instagram, Tiktok, communication sites, using accessible language, using memes and personas from the LGBTQIA+ community

Transgender chatbot developed to address PrEP issues among youth and monitor adherence. Available 24/7 on WhatsApp.

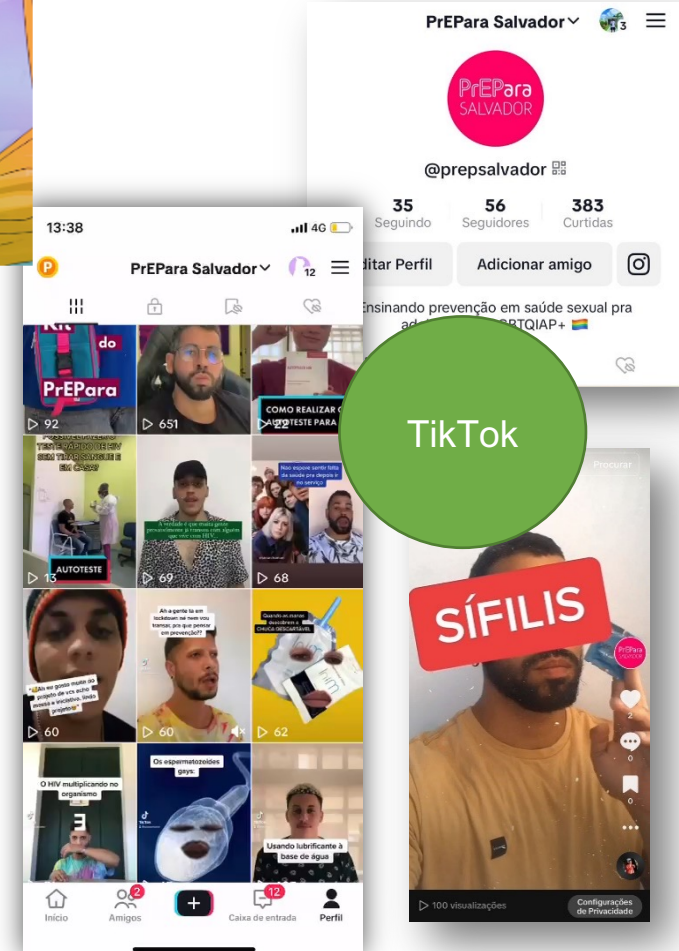
YouTube



Website



TikTok





# Fun pouch and prevention kit

Strategy to organize online recruitment – offering a pouch with a prevention kit to create demand and inform about HIV prevention and PrEP; Recruitment form to those interested in the prevention kit -invitation to participate.





# Online recruitment

## Using a customized game

**Game PrEP** was launched to enter the game world of young people, providing guidance on combination prevention and PrEP



Amanda Selfie's crew



The main character of the game is Augusto, a member of the crew.

PrEP1519 – The Game



PrEP1519 Clinic



Amanda is in the game as well



The storyline follows Augusto on his journey on HIV prevention and roadmap to PrEP services

# Telehealth - *TelePrEP*

Telehealth follow-up eligibility criteria for inclusion of participants using oral PrEP:

1. Have attended at least two face-to-face consultations (M0 and M1)
2. Be interested in the daily oral modality

Built on previous experience in the PrEP1519 phase-1 during C19 quarantine

Telehealth care and services aim to improve users' access and linkage with the service, eliminating possible barriers related to face-to-face care, facilitating clinical management, and promoting quick and timely access to care.

- Self-test for HIV at home;
- Tests for syphilis, HBV & HCV at the project laboratory or other;
- PrEP sent by mail to their home

Oral PrEP: face-to-face visit yearly or whenever a demand for care is identified.

CAB-LA PrEP: followed in the PrEP clinics. If necessary and requested, care can be provided remotely for intercurrents.

- Synchronous teleconsultation: real-time care conducted via video or phone call;
- Asynchronous teleconsultation: remote care conducted non-simultaneously, by filling out a questionnaire to be evaluated by the clinical team. If necessary, an appointment is scheduled with the participant in person or via video call



## Acknowledgments - teams

**Protocol Chair - São Paulo:** Alexandre Grangeiro  
([ale.grangeiro@gmail.com](mailto:ale.grangeiro@gmail.com))

**Protocol Chair - Belo Horizonte:** Dirceu Greco, PhD  
([dirceugreco@gmail.com](mailto:dirceugreco@gmail.com))



### BELO HORIZONTE

- |                        |                       |
|------------------------|-----------------------|
| • Dirceu B. Greco      | • Matheus Alves       |
| • Unaí Tupinambás      | • Tânia Faustino      |
| • Mateus Westin        | • Fernanda Soares     |
| • Marise Fonseca       | • Cinthia Alves       |
| • Carolina Oliveira    | • Fernanda Valadares  |
| • Yuppiel Martinez     | • Mariângela Carneiro |
| • Walter Ude           | • Alessandra Mancuzo  |
| • Marília Greco        | • Cristiane Cunha     |
| • Ana Paula Silva      |                       |
| • Érica Dumont         |                       |
| • Maria José Duarte    |                       |
| • Júlio Andrade        |                       |
| • Maria Cristina Abreu |                       |

### SÃO PAULO

**Alexandre Grangeiro**, Eliana Zucchi, Thiago Pinheiro, Paula Andrea Massa

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Oliveira, Aline Pilon, Ivo Patrick Oliveira Silva



# Obrigada! Thank you!



**Thanks to sponsors and many others  
on the PrEP1519 Choices team**



**Funding: Thanks to the generous  
support of Unitaid**



MINISTÉRIO DA  
SAÚDE





**OBRIGADO!  
THANK YOU!**





The background of the image is a light gray surface covered with numerous small, square wooden blocks. Each block has a dark gray question mark printed on it. The blocks are scattered across the frame, some overlapping and some slightly tilted. In the center of the image, the word "Questions?" is written in a large, bold, dark teal font.

**Questions?**

## Upcoming sessions

The MOSAIC Global PrEP Learning Network takes place **quarterly**.

The next session is planned for **September 2023**.



## 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.

Visit <https://www.prepwatch.org/global-prep-learning-network/> for more.



# ACKNOWLEDGMENTS



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



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



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*Photo Credit: MOSAIC Consortium*

