

BioPIC CAB for PrEP Study Compendium

Including activities relating to landscaping,
product introduction, introduction studies, and
implementation research

AVAC/July 2022

CAB for PrEP Study Compendium

Study Name	Implementer	Country(ies)
Project PrEP	Wits RHI	South Africa
ImPrEP/CAB-Brasil	Fiocruz	Brazil
CATALYST	FHI360/MOSAIC	Kenya, Lesotho, South Africa, Uganda, Zimbabwe
KP-Led Delivery of CAB for PrEP	IHRI	Thailand
SEARCH Sapphire	UCSF	Kenya, Uganda
Future PrEP	Kirby Institute	Australia
Prevenir/CohMSM	ANRS	France, Burkina Faso, Cote d'Ivoire, Mali, Togo
AMETHIST	CeSHHAR	Zimbabwe
FastPrEP	DTHF	South Africa
Pharmacy-delivered LA HIV PrEP in Kenya	University of Washington	Kenya
Thetha Nami ngithethe nawe ("Let's talk")	AHRI	South Africa
Axis	Ezintsha	South Africa

Wits RHI: Unitaid Project PrEP

Aims to improve the understanding of uptake and continuation of PrEP among AGYW and vulnerable groups in real world settings, and inform delivery models for service integration, by expanding PrEP choice through the introduction and integration of new biomedical prevention options (CAB-LA and DVR) into comprehensive sexual and reproductive health services.

STUDY OBJECTIVES

- To determine the most acceptable, feasible and effective **delivery models** for the integration of new PrEP products into SRH services
- To determine the most effective **demand creation and messaging strategies** for increasing uptake and promoting effective use of PrEP
- To determine the **patterns of PrEP uptake, switching and effective use** by PrEP agent
- To **monitor safety and adverse events**
- To assess the frequency of **HIV-1 drug resistance mutations** among PrEP clients who test positive after initiating PrEP

STUDY DESIGN

- Prospective observational cohort of PrEP users (DVR, CAB-LA and oral PrEP)
- Cross sectional diagnostic STI screening and management among a sub-set of AGYW
- HIVDR monitoring among PrEP users who seroconvert
- Qualitative FGDs and IDIs with PrEP users, PrEP providers, STI participants and STI service providers, Self-care package recipients
- Health systems capacity data
- Secondary analysis of routine programme data
- Human centred design approaches to inform project

STUDY POPULATION

- AGYW (15 – 24 years)
- Older women >24 years
- Men \geq 15 years

STUDY SIZE

- Observational cohort: 7455 PrEP users (2609 CAB-LA, 1566 DVR, 3280 oral PrEP)
- STI sub-study: 1 500 AGYW
- Qualitative FGDs and IDIs: 40 Health Care Providers and 180 service users

LOCATION

Four geographical clusters (8 primary care facilities and 4 linked mobile clinics) in South Africa with a high burden and incidence of HIV.

EVALUATION FRAMEWORK

RE-AIM: Reach, Effectiveness, Adoption, Implementation and Maintenance



The CAB-Brasil Study: An Implementation study of long-acting injectable cabotegravir (CAB-LA) for HIV Pre-Exposure Prophylaxis (PrEP) among young MSM, non-binary and transgender persons

GOAL

Implementation objective

Clinical objective

To **generate critical evidence** to inform national policies and program implementers about **optimizing delivery of CAB-LA PrEP** for MSM, non-binary and transgender individuals within public health PrEP services.

To assess **facilitators and barriers** to **integrating CAB-LA** into existing public clinic health services in Brazil.

To evaluate the **effectiveness** of CAB-LA PrEP at reducing risk of HIV acquisition in a study cohort of participants in a context where they exercise **choice** in their HIV prevention method (i.e., CAB-LA PrEP or daily oral PrEP).



Study Objectives, Population, and Location

Secondary objectives

- Describe initial PrEP choice, uptake, adherence to injection visits, switching, and discontinuation among study participants
- Evaluate acceptability, feasibility, and effectiveness of an mHealth education and decision support intervention
- Evaluate acceptability and effectiveness of sending WhatsApp appointment reminders for CAB LA injections
- Assess the acceptability and performance of an HIV testing strategy (e.g., types of testing and timepoints) when starting, taking, or stopping CAB-LA.
- Estimate HIV incidence in participants who receive CAB-LA for HIV prevention.
- Assess the safety and tolerability (e.g. weight changes, injection site pain, severe adverse events) of direct to inject CAB-LA PrEP.
- Characterize HIV infections, including drug resistance, viral load, and results from HIV diagnostic tests among those who are diagnosed with HIV infection after receiving CAB-LA injections
- Assess ART effectiveness among individuals diagnosed with HIV infection after receiving CAB-LA injections for PrEP

Location

6 PrEP public health services in 6 Brazilian cities (Rio de Janeiro, São Paulo, Salvador, Campinas, Florianopolis, and Manaus)

Study population

- 1200 HIV-negative MSM, non-binary or transgender persons
- Report having anal sex with a person assigned as male at birth in the last 6 months
- Aged 18-30 years
- PrEP naïve

The CATALYST Study: Catalyzing access to new prevention products to stop HIV

STUDY GOAL: To assess feasibility, acceptability, uptake and patterns of use with a service delivery package providing choice of oral PrEP, PrEP ring and CAB PrEP among women*, especially AGYW, at PEPFAR USAID delivery sites in Kenya, Lesotho, South Africa, Uganda and Zimbabwe

PROGRAM DESIGN: The study will implement an enhanced service delivery package that supports choice among the PrEP products that have regulatory approval in each country. The enhanced service package will include components at the individual, provider, facility and community levels and will use quality improvement methods to refine components and identify a core service delivery package for PrEP choice

STUDY DESIGN: Prospective observational cohort and mixed methods process evaluation

OBJECTIVE 1:

Describe the implementation of the service delivery package for PrEP choice for women in public health service delivery sites, and assess individual-, provider-, facility-, 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, assess implementation and sociodemographic correlates of PrEP use patterns and use effectiveness

OBJECTIVE 3:

Describe clinically relevant indicators among PrEP users, including rates of seroconversion and drug resistance among PrEP users who seroconvert following PrEP exposure

SAMPLE SIZE: At least 1400 PrEP ring initiators and 4225 CAB PrEP initiators

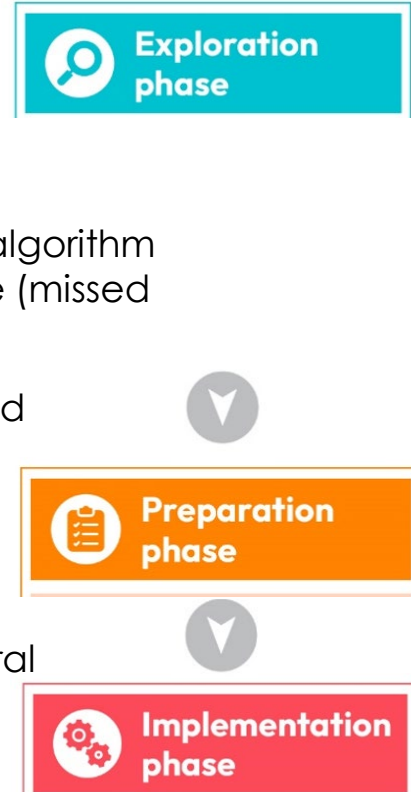
CURRENT STATUS: Protocol development and stakeholder engagement

**Inclusive of individuals assigned female at birth of any gender identity or individuals assigned male at birth who identify as women*

Key Population-Led Delivery of Long-Acting Injectable Cabotegravir for PrEP in Thailand: an Implementation Study

(funding under consideration by PEPFAR, no confirmation yet)

- 22% of 140,000 PrEP target reached by end of 2021, 82% of PrEP users in 2021 received PrEP from KP-led clinics
- **Aim 1. To identify barriers and facilitators for the integration of CAB-LA as a PrEP option in KP-led clinics.**
 - **System level:** economical, regulatory and policy factors in Thailand
 - **Organization level:** leadership buy-in in KP-led clinics, organization readiness
 - **Provider level** (doctors, nurses, lay providers): injection location, task shifting of injections, HIV testing algorithm (4th gen rapid test, 4th gen HIV self-testing, individual/pooled POC HIV RNA assay), and visit schedule (missed injection visit, switching between oral PrEP and CAB-LA, covering tail)
 - **Client level** (MSM and transgender women): preferences and concerns related to PrEP modalities and administration (e.g. location, by what type of provider, self-injection), oral PrEP experience
- **Aim 2. To design a KP-led CAB-LA service delivery model and multi-component implementation strategies based on identified barriers and facilitators.**
 - Training/virtual supervision of KP-lay providers in the administration of CAB-LA, fast-track hospital referral
- **Aim 3. To pilot the implementation of KP-led CAB-LA for PrEP delivery in 2 KP-led clinics in Bangkok.**
 - Safety, uptake, continuation, and effective use of PrEP: using ITS to compare pre- and post-implementation
 - Effectiveness of the implementation strategy: implementation outcomes - acceptability, feasibility, and fidelity



SEARCH Sapphire: Proposed CAB LA Extension

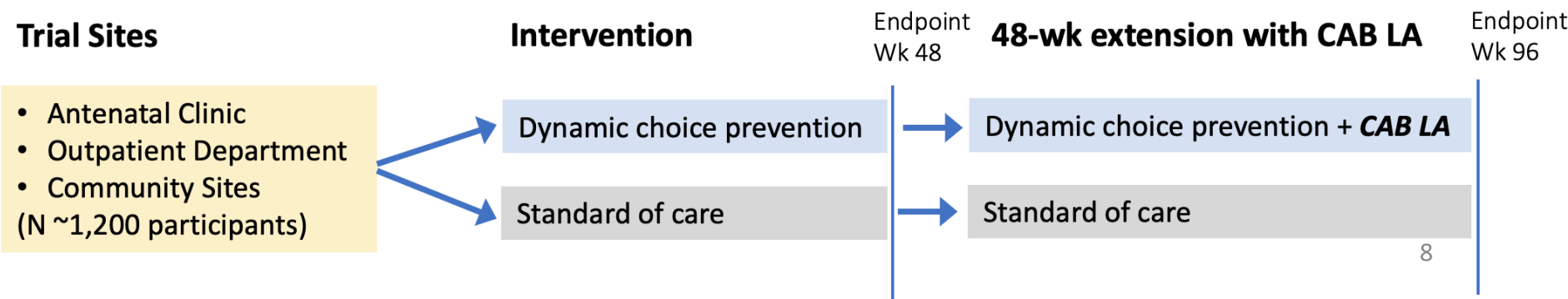


Ongoing, NIH-funded study¹ (UCSF/KEMRI/IDRC Uganda; PIs: Havlir, Kanya, Petersen)

- Builds on findings of SEARCH test-and-treat and population-level PrEP studies²
- Testing multi-disease and multi-sector HIV treatment and prevention interventions aimed at reducing HIV burden and improving health in rural southwestern Uganda and western Kenya
- Phase A: HIV treatment + prevention trials that will inform population-level study in Phase B
- 3 ongoing randomized trials of **Dynamic Choice Prevention** (oral PrEP, PEP, DVR when available) using a patient-centered delivery model (N ~1200 participants, 600 per arm)
 - Antenatal clinics, outpatient departments, and out-of-clinic community settings

Proposal to conduct 48-week extension including CAB LA (under review/consideration by Viiv):

- 1) Determine if adding the option of CAB LA as a prevention choice using a patient-centered HIV prevention delivery model increases prevention coverage (i.e. time covered by a biomedical prevention option) compared to the standard-of-care among participants in 3 ongoing trials of Dynamic Choice Prevention
- 2) Conduct a hybrid implementation study focusing on evaluation (using the RE-AIM framework) of initial implementation of a patient-centered model for CAB LA in intervention arm of the trials



1. U01AI150510; NCT04810650
2. Havlir NEJM 2019; Kanya CID 2021; Ayieko JIAS 2021; Koss PLoS Med 2021

Formative research: “Future PrEP”

- Funded by ViiV Healthcare.
- Data collection involves:
 - In-depth qualitative interviews with 30 PrEP service providers and stakeholders.
 - 5 qualitative co-design workshops with (potential) PrEP end-users (MSM, women from high prevalence countries, PWIDs, FSWs; PrEP-users, non-users, and former users).
 - 3 qualitative co-design workshops with PrEP service providers.
 - Quantitative survey on values and preferences towards current and future PrEP modalities.
- Development of a Concept Plan proposing the way forward for CAB-LA implementation research in Australia.
- Consultation with stakeholders and service providers on the Concept Plan.
- Development of research protocol for an implementation trial of CAB-LA.

Implementation trial (planned)

- Funding application based on the research protocol developed through the *Future PrEP* project.
- Led by the Kirby Institute, UNSW and the Alfred Hospital, Melbourne.
- Study populations:
 - Men who have sex with men
 - Other populations to be confirmed (e.g. women from high prevalence countries, PWID, FSW)
- Considerations about targeting within these populations (e.g. those with renal impairment, those who find difficulty with adhering to oral PrEP) given CAB-LA is unlikely to be considered superior to oral PrEP in Australia.
- Trial to be implemented through a network of private and public clinics with high PrEP caseloads, as well as community-based HIV testing sites (KP-led).
- Project partners will also include community-based organisations, the peak body for Australian HIV workforce (ASHM), and government policymakers.

Implementation Research on CAB for PrEP

Two Single-arm, multi-site, open-label, prospective clinical studies
Based on two PrEP demonstration projects among MSM

Study Design:

- Demonstration projects in two different settings.
- Multidimensional studies with implementation and social science components.
- 3 –year study aiming to enroll 400 participants.
- Population: MSM, naïve and experienced PrEP users (50% to 75% with on-demand PrEP)
- Similar endpoints: retention, acceptability, tolerability, safety, preferences, changes in sexual behavior, INSTI resistance.
- Testing strategy based on serological tests.
- Strong community commitment.



Burkina Faso, Cote D'Ivoire, Mali, and Togo

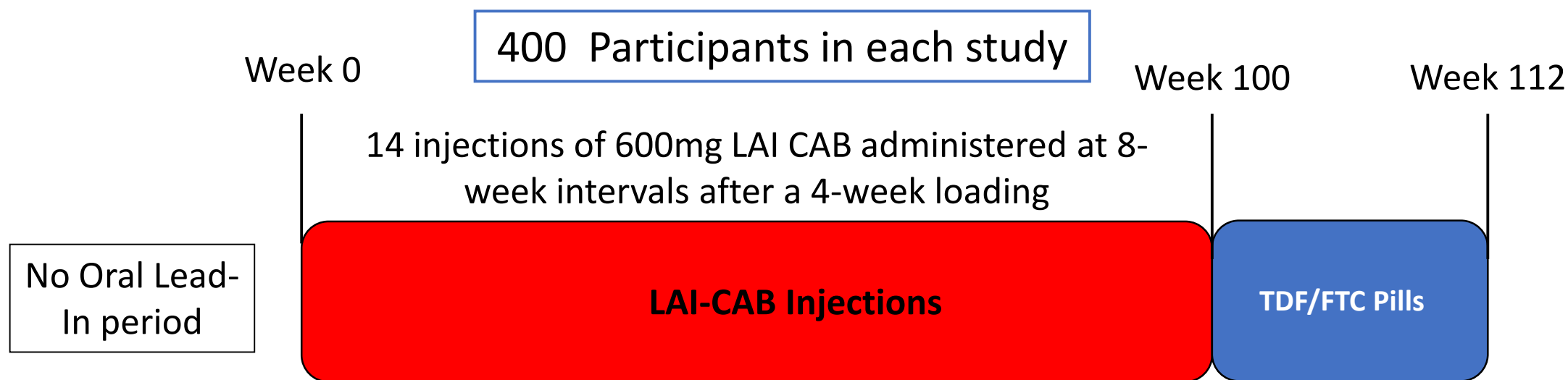


Paris Region, France

Key Outcomes:

- Acceptability of CAB for PrEP among MSM using on-demand PrEP.
- Adherence to CAB for PrEP among MSM with different patterns of adherence to oral PrEP.
- Real-world data on retention with CAB for PrEP in low- and high-income countries.
- Impact of prior PrEP use on CAB for PrEP acceptability, adherence and retention.
- Impact of a serological testing strategy in areas with low and high HIV incidence.
- Feasibility of CAB for PrEP in community centers in Africa.

Single-arm, multi-site, open-label, prospective clinical studies



Follow-up :

- HIV serological test at each study visit
- Regular testing for STIs
- Monitoring of injection site reactions
- Peer counseling by community members
- Regular questionnaires on acceptability and sexual behavior

Funding and Perspectives

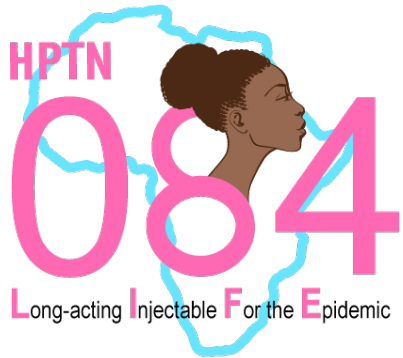
- ANRS-funded studies
- Demonstrate that LAI-CAB for PrEP is feasible in France and West Africa.
- To develop a partnership between the ANRS and ViiV.
- Product support \approx 12,000 doses of LAI-CAB.
- To accelerate the uptake of LAI-CAB for PrEP by health authorities in France and West Africa.



CAB Long-acting - Knowledge gap



66% lower risk of HIV infection
compared to TDF-FTC group
HR 0.34, 95%CI (0.18 to 0.62)



89% lower risk of HIV infection
compared to TDF-FTC group
HR 0.11, 95% CI (0.01 to 0.31)

**Implementation research is needed
to address real-world challenges**

- Testing strategies (before, during, after)
- Adherence to bimonthly injections
- Retention in care
- Preferences of users
- Starting, stopping, switching
- Populations & Geographies
- Delivery issues
- Demedicalizing CAB-LA

Complementarity of the studies



Population	Low adherence to oral PrEP	Highly adherent to oral PrEP
Primary Objective	To increase adherence	To increase retention
Enrollment	50% naïve PrEP participants	Switch study
CAB Delivery	Community centers	Hospitals
Background HIV incidence	Very High (10 per 100PY)	Medium
HIV incidence on oral PrEP	2.3 per 100PY	0.11 per 100PY
Setting	Low and middle income countries	High income country

These two studies will address real-world questions in two totally different settings

Implementation science study briefs

Sex workers in Zimbabwe

Frances M Cowan

Coordinating Implementation Science for CAB PrEP: Focus on Delivery Models

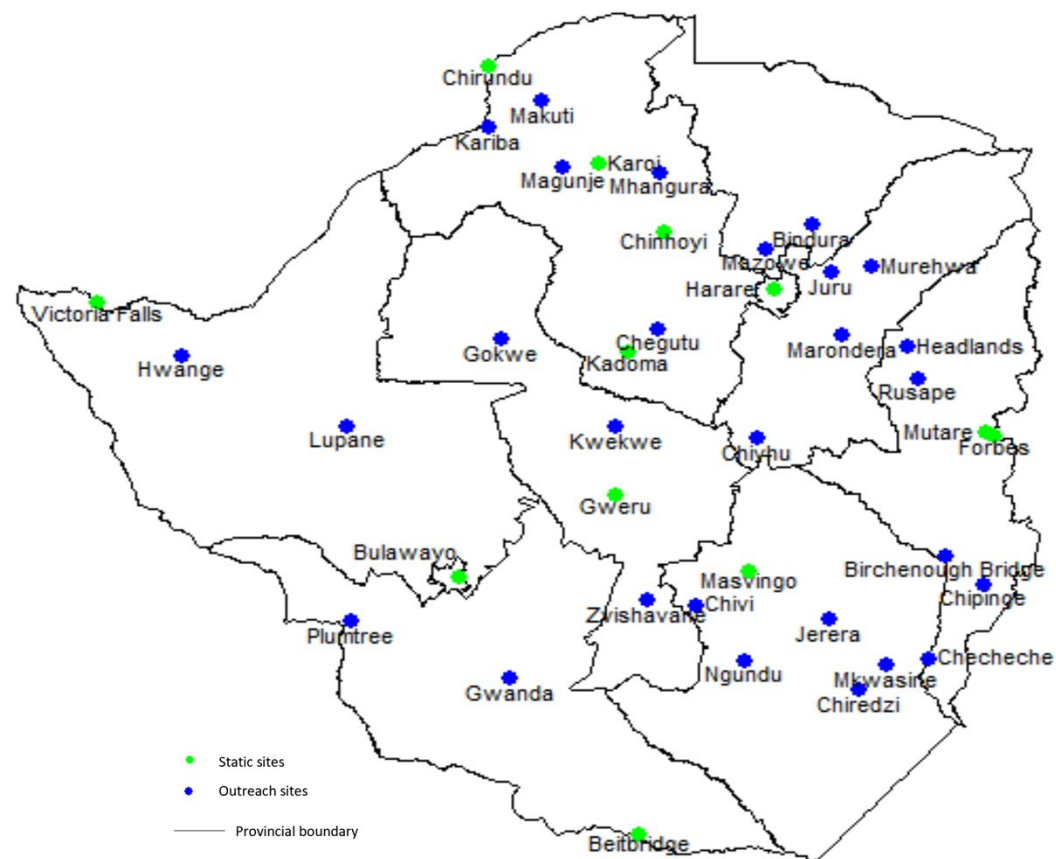
June 23rd 2022

Outline

- Values and preferences for long acting PrEP among individuals who sell sex in Zimbabwe
- The AMETHIST Intervention for supporting PrEP initiation and continuation as part of a comprehensive package of care
- Pharmacy supported PrEP



Zimbabwe Sisters Programme Sites



Values and preferences long acting PrEP among sex workers

Qualitative work – 28 FGDs – SW in their diversity 10 IDIs

RDS survey – 22 sites around Zimbabwe – 2400 FSW

DCE – 4 sites – 436 FSW

SW demonstrated a strong preference for long-acting PrEP products over Truvada (TDF/FTC)

- Pill burden – implications for adherence
- Perceptibility – whether or not the method was noticeable to others (injection is private)
- Lack of convenience – implications for adherence – pill daily / DPV ring perceived as unpleasant to insert
- The stigma associated with packaging -TDF/FTC bottle similar to ARV bottle

Long-acting PrEP

Which of these LA PrEP methods would you be interested in taking?	
Long-acting Injectable PrEP	1927/2568 (75.0)
Long-acting Dapivirine Ring	264/2568 (10.3)
Any of the two	63/2568 (2.5)
None of the above	314/2568 (12.2)
Would having long-acting injectable PrEP available that you had to take every 2 months make it easier for you take up PrEP than taking a daily tablet?	
No	307/2568 (12.0)
Yes	2076/2568 (80.8)
I don't know	185/2568 (7.2)
Would having long acting PrEP available in a vaginal ring that you have to change every month make it easier for you take up PrEP than taking a daily tablet?	
No	1288/2568 (50.2)
Yes	1057/2568 (41.2)
I don't know	223/2568 (8.7)
Would having long-acting injectable PrEP available that you had to take every 2 months make it easier for you take up PrEP than having long acting PrEP available in a vaginal ring that you have to change every month?	
No	499/2568 (19.4)
Yes	1906/2568 (74.2)
I don't know	163/2568 (6.3)

Results: DCE

We enrolled N= 436 FSWs of whom:

- 80% preferred sex worker/mobile clinic.
- 66% preferred not to pay
- 81% preferred to visit the facility once every two- three months (Preference for long-acting options and or multi-month dispensing)
- 95% preferred assisted administration by a health worker
- 95% preferred the injection over the ring
- 94% preferred more efficacy
- 82% preferred to access LA PrEP in their neighbourhood

Sex workers want access to long
acting methods

The AMETHIST Intervention- Risk-differentiated peer support

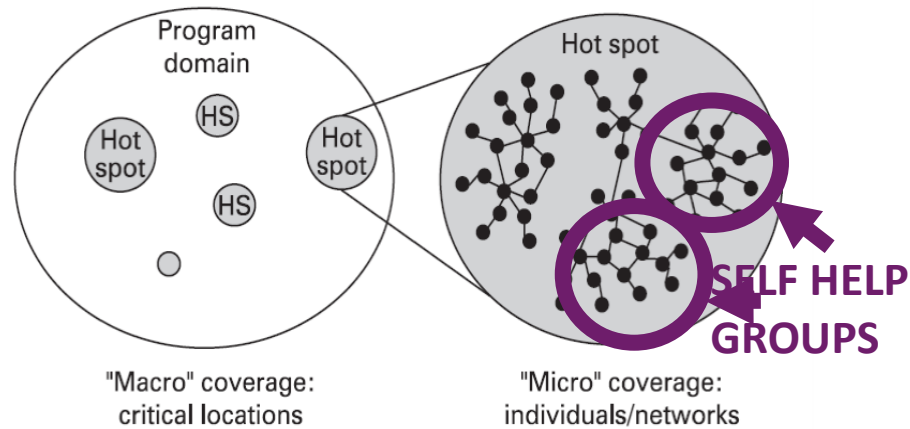


Figure Schematic representation of microplanning

RISK ASSESMENT TOOL			
Empowerment Worker Name			
SISTERS NUM		DATE	
1.	Young age (below 25 years old)	0	1
2.	New to sex work (below 6 months)	0	1
3.	High client numbers (10 and above)	0	1
4.	Inconsistent condom use	0	1
5.	Problematic drinking / drugs	0	1
6.	Problematic violence	0	1
Risk (Total Score)			

(L) LOW = 0 (M) MEDIUM = 1 – 2 (H) HIGH = 3 - 6

Factors likely to predict risk of future HIV acquisition or transmission

- Microplanning is regular, risk differentiated peer support
- Peer educators transition: generalised mobilisers for services individual SW in their cohort to plan and execute outreach ➤ actively using data from their hotspot and individual SW in their cohort to plan and execute outreach
- SW peer educators map all hotspots
- Hotspots validated
- SW peer educators enroll all SW in 'their' hotspot
- Assess their risk
- Provide risk differentiated contact
- Hotspots remapped 6 monthly
- Risk reassessed 3 monthly

AMETHIST Intervention

- Peer led
- Tailored to an individual sex worker's vulnerabilities needs and priorities
- Increases coverage – contact most frequent with those most vulnerable to HIV
- Supports ongoing individualised engagement in prevention (and care)
- Impact on HIV acquisition / transmission risk being evaluated in a cluster randomised trial – results imminent
- Note a small fraction of sex workers are particularly vulnerable and are likely to benefit most from CAB LA

AMETHIST – a peer-led risk
differentiated implementation model
which could easily be adapted to
include CAB LA

Pharmacy-based PrEP distribution strategy to increase FSW *motivation, access, and effective use* of PrEP – PI Sibanda/McCoy

1. Refine and operationalize pharmacy-based PrEP distribution including an escalating incentive with FSW and pharmacy owners to motivate FSW PrEP continuation.
2. Determine whether the addition of pharmacy-based PrEP distribution increases PrEP retention among FSW at 7 months compared to standard services at mobile sites.
3. Understand the PrEP pharmacy program's potential to scale to all FSW and FSW <24 years, and translate lessons learned into a future effectiveness study.

Output: A testable model that is adaptable to new PrEP modalities as they become available.



Zimbabwe MoHCC: Owen Mugurungi, Getrude Ncube

NAC: Raymond Yekeye, Amon Mpofu

CeSHHAR: Fortunate Machingura, Primrose Matambanadzo, Sungai Chabata, Collin Mangenah, Galven Malingwa, Gracious Jamal, Memory Makamba,

LSHTM: James Hargreaves, Joanna Busza, Liz Fearon, Calum Davey, Brian Rice

LSTM: Nic Desmond, Wezzie Lorrie

UCL: Andrew Phillips, Maryam Shahmanesh, Valentina Cambiano, Loveleen Bansi- Matharu

York: Paul Revill



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Western Cape
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Department:
Health
REPUBLIC OF SOUTH AFRICA

BILL & MELINDA
GATES foundation

FastPrEP: An implementation science project of PrEP scale up in a single health district in Cape Town.

In partnership with Klipfontein/MP subdistrict Health, City of Cape Town Health and RSA
National Dept of Health.

Funded by Bill and Melinda Gates Foundation.



DESMOND TUTU
HEALTH FOUNDATION

DTHF team:

*Linda-Gail Bekker, Boipela Sebesho, Elzette
Rousseau, Dvora Joseph Davey, Melissa Wallace,
Gina Itzikowitz, Redwaan Vermaak, Justine Stewart.*



FASTPrEP
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Young People Reference Group: Support they want



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- **EASY and Walkable Access** seen as greatest support for continued use
- **Peer or Near-Peer support important** (building in peer navigators, peer adherence clubs, peer-relevant adherence messaging on social media platforms)
- **Agency to decide for themselves** with informational support
- **CHOICE** in how where and from whom



FastPrEP hub-and-spokes model



FASTPrEP

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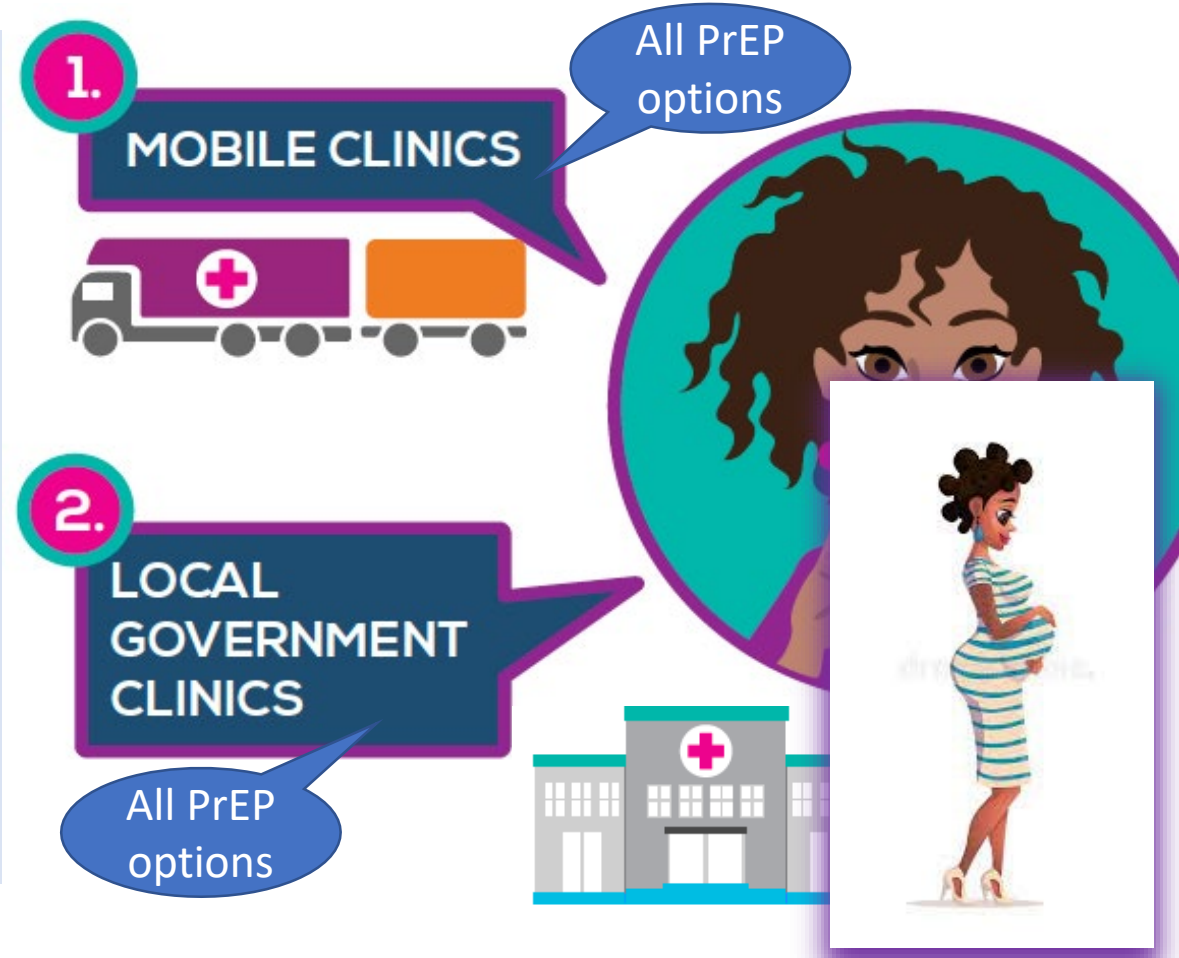


Offer de-centralized service to AGYW through a Facility-MOBILE-Community model: placing the *mobile as the hub* and a mixture of local clinics, community-based facilities/spaces, and homes (courier service) as the spokes

HUB: 12 x Local and 4 x Mobile Clinics

- *Initiation & Follow-up Services*
 - Comprehensive information/education/counseling at these services
 - Integrated services (bidirectional influence of PrEP and Contraception uptake)
 - Baseline and follow-up bloods (HIV, creatinine (if appropriate))
 - Baseline data collection: demographics, behaviour, relationships, etc.
 - Introduction to all support systems available (peer support platforms)
 - Introduction to other spaces PrEP refills are available
- Staff: HCT counselors, nurses, peer navigators

DTHF will place 2x peer navigators per local government clinic



Other things to consider at these platforms:

- High efficiency at these sites, fast tracking, interactive information before engagement with HCP to reduce counseling time
- STI management (screening and testing for CT/NG)
- The use of peer navigators at the facilities, optimized clinic flow for efficiency and SRH integration, and
- Tailoring the “youth zones” at the clinics which may be spatial but will be determined by preferred times/days for youth preferential services. These will be established and designed with young people reference groups and in collaboration with the respective clinics.
- All types of PrEP will be on offer from hubs with a decision tool to help “choice”. This will also be factored into choice of delivery mode.

Youth Club (Saturdays)

- In **youth clubs** build on the desire of **peer support** (facilitates uptake and continuation)
- **Quick depots** build on **fast and convenient** (taxi ranks and high foot-traffic spaces)
- PrEP information and PrEP refill services (incl contraception)
- Comprehensive information

Staff: HCT counselors, nurse, peer navigator

All PrEP options



FASTPrEP
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- Track individuals digitally and allows movement between various service points allowing for flexibility and convenience - maximising opportunities to stay engaged!
- Address diverse needs of AGYW without fragmentation - the “one stop shop”
- Cut out extraneous services not needed by the youthful, largely healthy community
- Decongest and reduce waiting times and wasted time - realise efficiencies both in the service and for the clients.

Injectable PrEP

6.

QUICK PrEP
DEPOTS



5.

YOUTH CLUB



4.

COURIER DELIVERY
SERVICE



Courier service

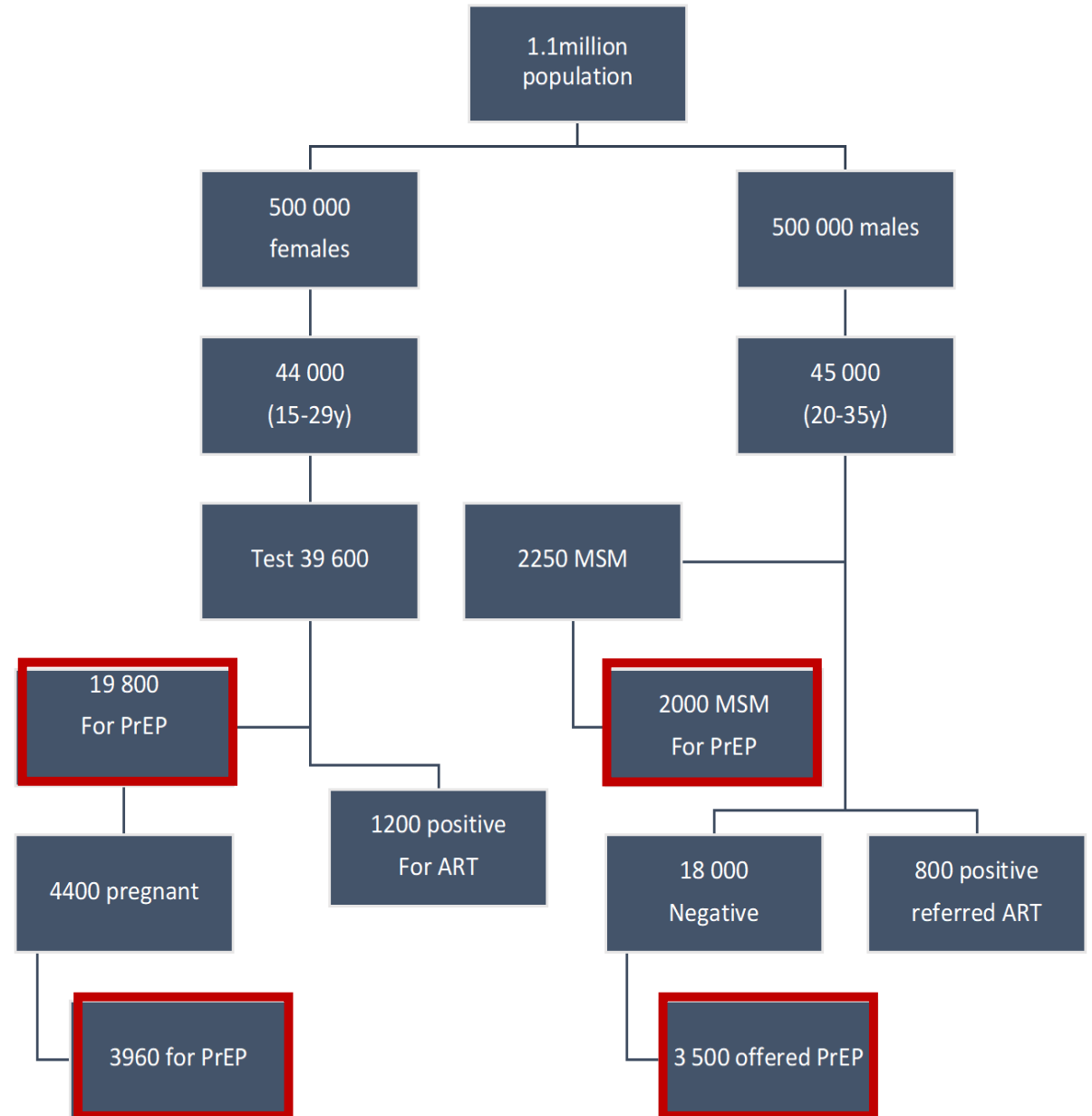
- Light-touch PrEP refill
- Include HIVST, PrEP (ring, oral) (potential for oral contraception and STI treatment delivery)
- Include brochure info on PrEP use

Oral and
DVR
options

Proposed Cohort

We will identify the following population in Klipfontein/Mitchells Plain District:

- Sexually active adolescent girls and young women (AGYW, 15-29) including:
 - pregnant and breastfeeding AGYW;
- AGYW/MSM sexual partners (any age)
- Young MSM (15-29)



Village Demarcation



Demand creation

- Tik tok videos
- Instagram
- Facebook
- Micro-influencers
- PrEP champions
- Bus rank adverts
- Taxi adverts
- Sponsorship at Hairdressing salons, Internet cafes, other key venues
- Engagement with youth CBOs, churches and faith based venues.
- Incentives for effective referrals

Track what works, CE of demand creation



Evaluation of demonstration with RE-AIM framework

Reach	<ul style="list-style-type: none"> What is the number and proportion of young people reached by sub-group (AGWY), male partner (MP) Pregnant or breastfeeding woman (PBFW), MSM of denominator (those testing HIV- and offered PrEP). <ul style="list-style-type: none"> Numerator: # of PrEP initiators and continuers (1m, 3m, 6m) Denominator: # of AGYW, men and MSM who test HIV- who are offered PrEP by modality Evaluation of the barriers and facilitators to continued and effective use of PrEP product Type of PrEP chosen and why.
Effectiveness	<ul style="list-style-type: none"> Does the intervention reduce HIV incidence in a sub-study of HIV regency in all those diagnosed with HIV comparing sub-district A, B to C, D? Assessment of negative consequences of PrEP use in young people (i.e., IPV, stigma) as reported by people on PrEP What combination of delivery approaches achieve best PrEP persistence for young people during periods of sexual activity? What are the conditions for young people's use of different PrEP delivery sites? PrEP choice switching and why?
Adoption	<ul style="list-style-type: none"> How representative are the clinics that adopt PrEP successfully vs others? Type and size of health facility vs type of community venue Assess representativeness of mobile facilities and service providers that are most effective at PrEP initiation and continuation compared to those with lower PrEP initiants and continuers Assess fidelity of intervention, counselling, and national policies Integration of different PrEP options and why.
Implementation	<ul style="list-style-type: none"> Evaluate the various barriers and facilitators at each of the sites for both uptake and continuation via surveys and in-depth interviews with a sub-set of implementers and users. Evaluate preferences for packaging, delivery of various PrEP modalities via in-depth interviews Evaluate modifications that were made to the intervention and why they occurred
Maintenance	<ul style="list-style-type: none"> % of young people by sub-group who continue on PrEP (and PrEP type) at 3m or 6m % of young people by sub-group who adhere to PrEP while sexually active % of coverage of at-risk populations % coverage of at-risk sexual events Extent to which the model is replicated by DOH/partners in other facilities and Districts



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Launch : 22 March 2022.



FASTPrEP

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- Start in Village A in March 2022
 - Control in B and C
- Move to Village B in July 2022
 - Control in C
- Move to Village C in July 2023
- Continue in A, B and C until numbers reached.
- Continue monitoring incidence in target populations in A,B and C
- Three year follow up

PrEP choice in addition to Delivery Choice!

- Add DapiRing – request to National DoH.
 - Choice and persistence in AGYW
- Consider Cab LA injectable PrEP in this context
 - “layered approach”
 - Three populations: AGYW, YMSM, Male Partners of any age
 - Persistence on CAB LA vs oral PrEP
 - Short term over 6 months (miss pill prescription/ miss shot)
 - Durability: time to missed pick up over 18 months
 - Assumption: CAB LA > 75% and oral PrEP <60%
 - Well powered with following possible numbers we have suggested to ViiV

Proposed addition of PrEP Choice

- **Approach:** Individuals who consecutively fall into a convenience sample within the broader FASTPrEP project initiating PrEP from a defined time at the hubs (mobile units and clinics) will be offered oral, vaginal or injectable PrEP until the sample size is met. From the time that CAB LA is offered, all individuals will be included in a subset of the FASTPrEP cohort, until the following sample is enrolled:
- 900 who select CAB LA (500 AGYW, 200 YMSM, 200 Partners)
- 600 who select Oral PrEP (400 AGYW, 100 YMSM, 100 partners)
- 300 who select vaginal ring (300 AGYW)
- All individuals will be tracked in terms of their choice of maintenance delivery options (spokes) and persistence will be measured as defined above.
- Expected monthly/two monthly visits will be tracked and missed expected visits monitored. This will be followed for 12 months.
- Where individuals “cycle back” this will be monitored. Cycling back will include any FASTPrEP enrollee who returns to FASTPrEP during the 36 months of the whole project.



Pharmacy-delivered LA HIV PrEP in Kenya: a differentiated service delivery approach

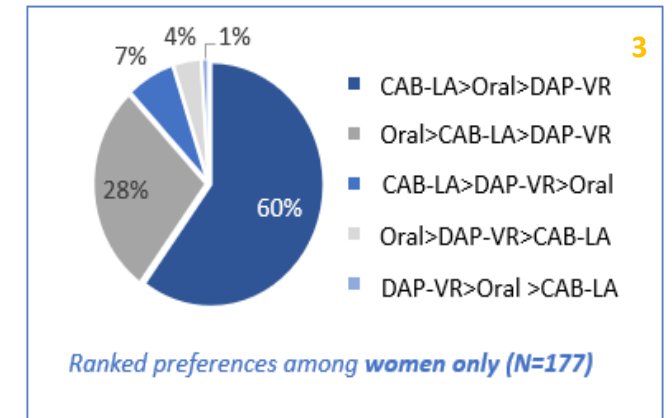
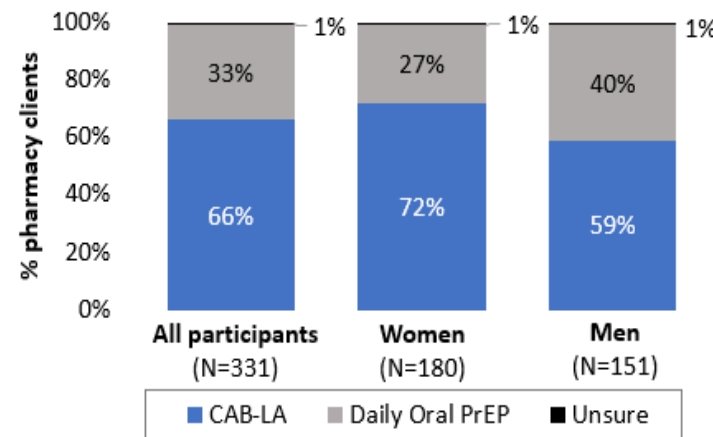
BioPIC Implementation Science Meeting – June 23, 2022

Katrina F. Ortblad, Victor Omollo, Stephanie Roche, Obinna Ekwunife, Parth Shah, Jennell Stewart, Patricia Ongwen, Daniel Were, Kenneth Ngunjiri, Elizabeth Bukusi

Background

- Long-acting HIV PrEP forms (e.g., the DAP-VR and CAB-LA) are **discrete, safe and highly effective** new alternative to daily oral PrEP.
- The delivery of PrEP care at private, community-based pharmacies has the potential to **overcome barriers to PrEP access and delivery** at public facilities and **reach new populations**.
- Pharmacy clients are interested in LA PrEP forms for HIV prevention and **prefer CAB-LA to other options**.

Client characteristics	Public clinics ¹ (N=4,898)	Private pharms ² (N=287)
Men	2257 (46%)	163 (57%)
<25 years	969 (20%)	126 (44%)
Married	4466 (91%)	108 (38%)
Partner living with HIV	4092 (84%)	9 (3%)
Partners of unknown HIV status	789 (16%)	240 (84%)
Multiple sexual partners	565 (12%)	151 (53%)



Objectives

- 1** Collaboratively **design an acceptable care pathway** for pharmacy-delivered PrEP that includes LA forms (e.g., the DAP-VR and CAB-LA) in Kenya
- 2** Pilot test the care **pathway** for pharmacy-delivered PrEP that includes LA forms in Kenya
- 3** **Evaluate implementation** of the pharmacy-delivered LA PrEP forms; **identify strategies for sustainability**

Existing model of pharmacy-delivered oral PrEP

Promotional materials for
pharmacy-based PrEP



Individual arrives at
pharmacy to initiate
(*refill*) PrEP

Pharmacy
provider initiates
eligibility checklist

Remote clinician oversight

Checklist Items 1-2

Counseling:

conduct risk assessment;
discuss (**assess**) HIV risk
reduction, PrEP adherence &
potential PrEP side effects.
Determine eligibility.

Unclear

Ineligible

Eligible

Support Link

Consultation
with remote clinician
and/or
Referral
to higher care

Checklist Item 3-4

Clinical safety:

Assess HIV symptoms;
disease history
(**side effect screening**);
document

Checklist Item 5

HIV testing:
assisted HIVST

HIV+

HIV-

if needed

Checklist Item 6

PrEP dispensing:
Dispense 30 days
(**90 days**); document

Based off the One-Step PrEP™
(Kelley-Ross) model
in Seattle, USA

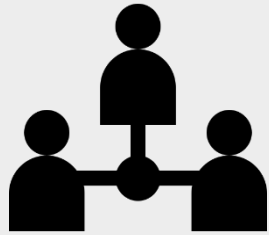
(Ortblad KF et al., BMC Health Serv Res 2020)

Pharm PrEP Pilot: in action!



Objective 1. Design an acceptable care pathway

a. Stakeholder analysis



- **Identify individuals** to engage in participatory processes to integrate LA PrEP forms into the existing pharmacy oral PrEP delivery model
- Use established *stakeholder mapping/analysis methods*

b. In-depth interviews



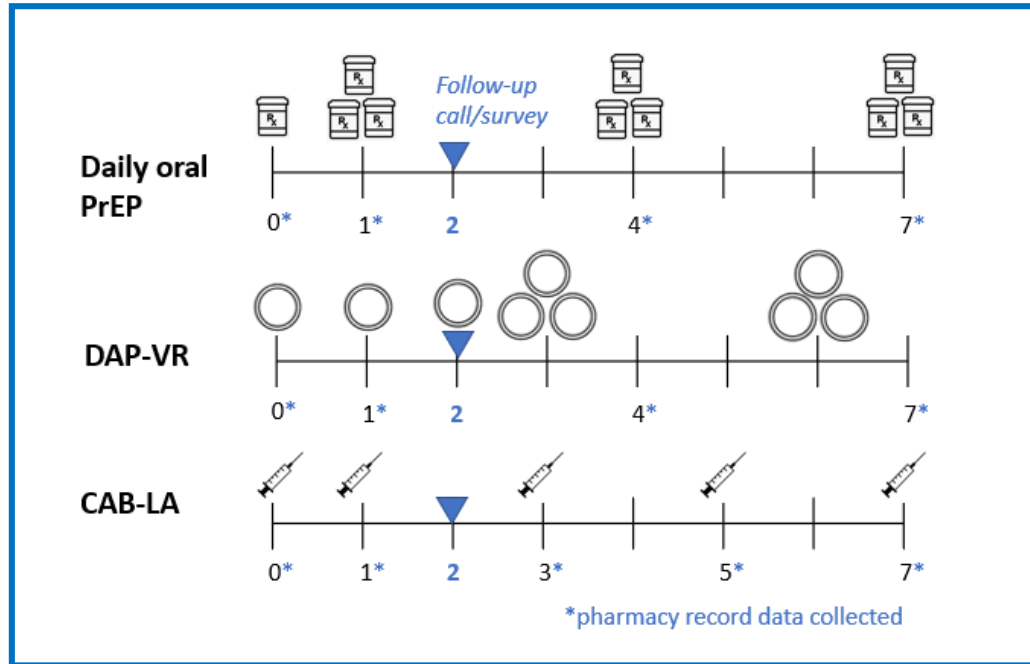
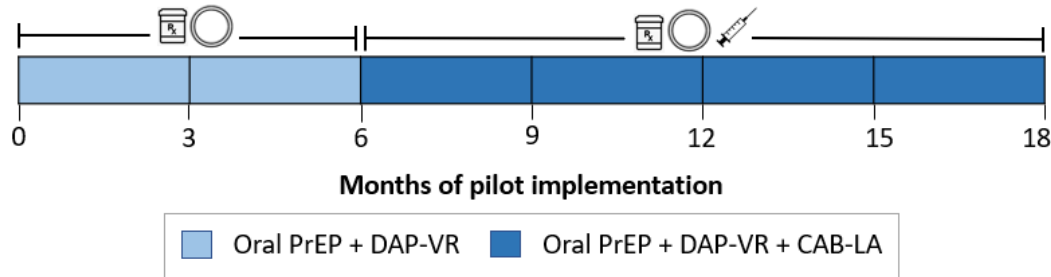
- **Identify potential barrier and facilitators** to the delivery of LA PrEP forms at private pharmacies
- Interview stakeholders (n=10) as well as oral PrEP pharmacy clients (n=10) and providers (n=10); guides informed by *IS frameworks*

c. Stakeholder meeting



- **Draft a revised care pathway** for pharmacy-delivered PrEP that includes LA forms
- Conduct a *stakeholder meeting* and use the *nominal group technique* to help build consensus

Objective 2. Pilot test the care pathway with LA PrEP



Pilot outcomes:

*primary outcomes

Client characteristics	Definition	Timing
Demographics	e.g., age, sex, marriage	M0
HIV risk behaviors	% reporting RAST items	M0
Utilization outcomes	Definition	Timing
PrEP initiation*	% take pills/ring or get injection	M0
PrEP selection*	% select oral PrEP, DAP-VR, CAB-LA among available options	M0
PrEP continuation	Any continuation; multiple continuation; stopping & restarting; switching PrEP modalities; adherence	M1-14
PrEP safety	injection site injury; side effects; adverse events; VL suppression among seroconverters	M0-18
IS outcomes		
Acceptability, feasibility, client-level satisfaction, fidelity	% clients reporting these outcomes using validated scales; % clients reporting receiving key services; determinants of these outcomes	M1-18
Costs	Unit costs; willingness to pay/provide	M1-18

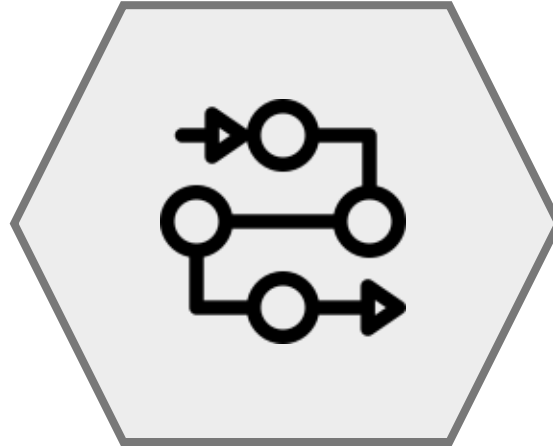
Objective 3. Evaluate implementation/sustainability

a. Client surveys & client/provider IDIs



- **Surveys** with clients (n>300) in the pilot
- **IDIs** with clients that selected (n=10)/didn't select (n=10) PrEP & providers (n=10)

b. Process flow diagramming



- To ID model **weak points** for refinement

c. Microcosting



- Generate **unit cost analysis** per client month on pharmacy PrEP (different forms)
- Informed by process flow diagramming

d. Stakeholder engagement



- ID **IS strategies** to address weak points & **business models** for sustainability



Katrina Ortblad, ScD, MPH
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 Fred Hutch Cancer Center
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THANK YOU



A stepped-wedge trial to evaluate the choice of long-acting PrEP on community-based PrEP delivery:

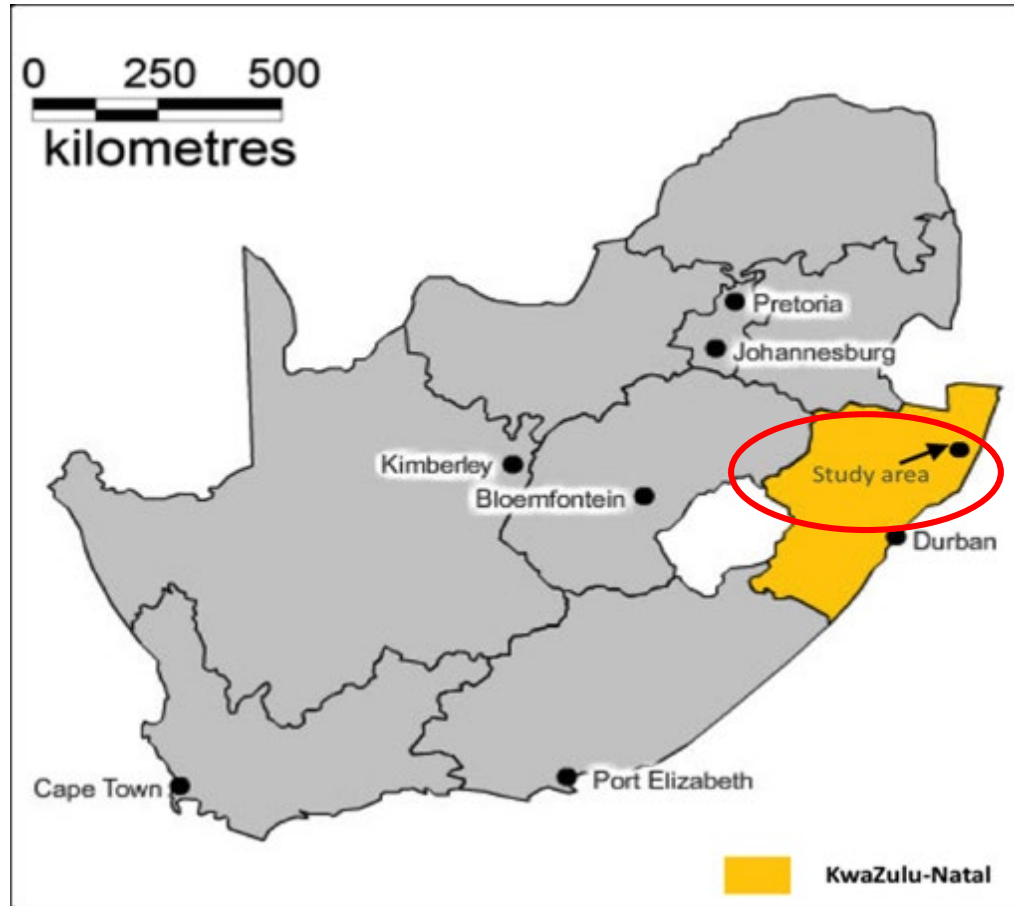
BILL & MELINDA
GATES *foundation*

Prof Maryam Shahmanesh PhD FRCP

23rd of June 2022

Setting

HIV Demographic Surveillance area in KwaZulu-Natal South Africa



Rural and poor area
>85% youth unemployment
Antenatal HIV prevalence ~40%

Background



- Despite effective HIV prevention there were 670,00 new HIV infections in eastern & southern Africa (2020)
- Social mobilization of youth by peer navigators & decentralized HIV care is acceptable and effective amongst youth most at risk^{1,2,3,4,5}
- 27% of 15-30-year-olds had sexually transmitted infection (STI) and teenage pregnancy is common⁶
- Innovations in STI, HIV self-tests and sampling, and virtual support were feasible and popular^{6,7,8,9,10}

1. Baisley et al *HIV Med* 2019
2. Chimbindi et al *AIDS Care* 2021
3. Shahmanesh et al, *BMC Public Health* 2021.
4. Shahmanesh et al, *BMJ Global Health* 2021
5. Adeagbo et al, *BMJ open* 2022
6. Francis et al, *PLoS Med* 2018
7. Adeagbo et al, *J Med Internet Res* 2019
8. Turbe et al, *Nature*, 2021
9. Zulu et al, *Progress in Development studies* 2021
10. Gibbs et al, *Social Science & Medicine* 2021

Thetha Nami ngithethe nawe (let's talk): Community based oral PrEP with SRH

Social
mobilisation

Youth groups

Area-based
peer navigators

Community
advocacy

All AYA living in the
AHRI HDSS are
eligible n>26,000

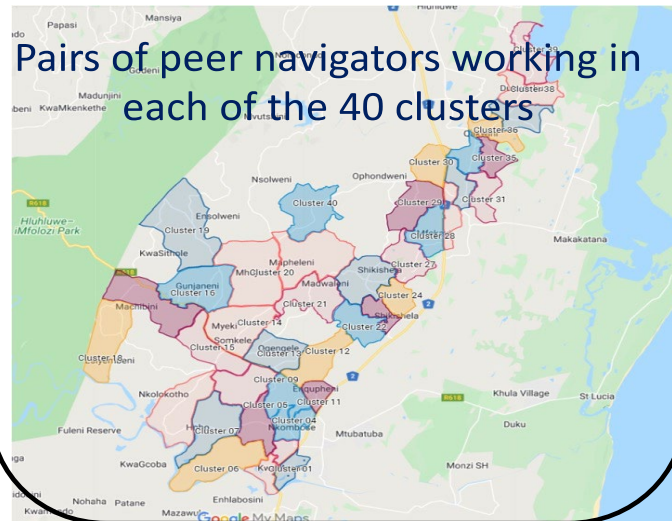
Community-based integrated HIV and sexual health care

Peer Navigators



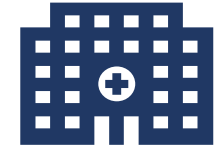
Structured psychosocial and
health needs assessment
Peer mentorship with tailored
psychosocial support
Provision of condoms, HIV self-
test, pregnancy tests
ART/PrEP adherence support

Pairs of peer navigators working in
each of the 40 clusters



Facility-based care

Fixed primary
health clinics



Work leading to intervention

1. Chimbindi et al *AIDS Care* 2021
2. Baisley et al *HIV Med* 2019
3. Shahmanesh et al, *BMC Public Health* 2021.
4. Shahmanesh et al, *BMJ Global Health* 2021
5. Adeagbo et al, *BMJ open* 2022
6. Francis et al, *PLoS Med* 2018
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8. Turbe et al, *Nature*, 2021
9. Zulu et al, *Progress in Development studies* 2021
10. Gibbs et al, *Social Science & Medicine* 2021



Mobile health
clinics

Nurse-led

Gender neutral
STI screening

Contraception and family planning

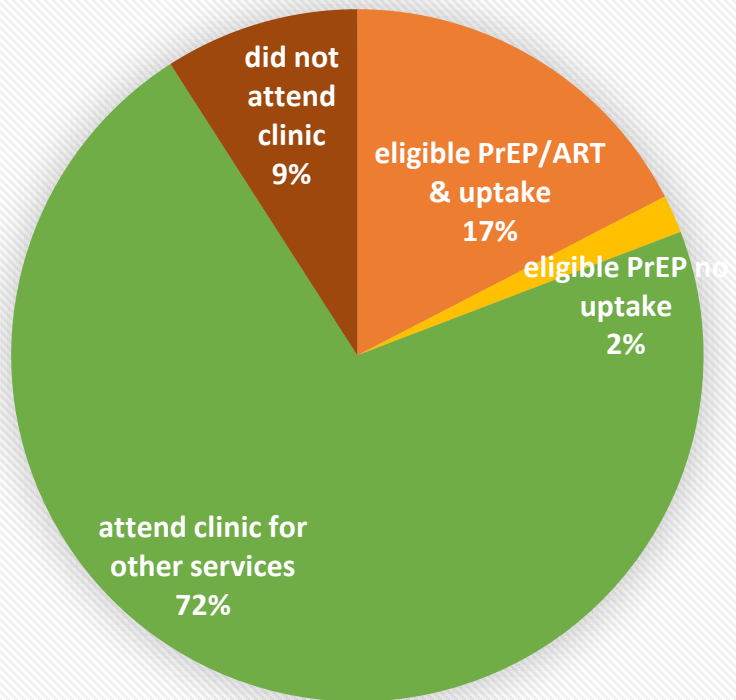
HIV test

ART if positive

Risk-informed HIV prevention incl. PrEP if negative

Community-based integrated HIV and SRH services

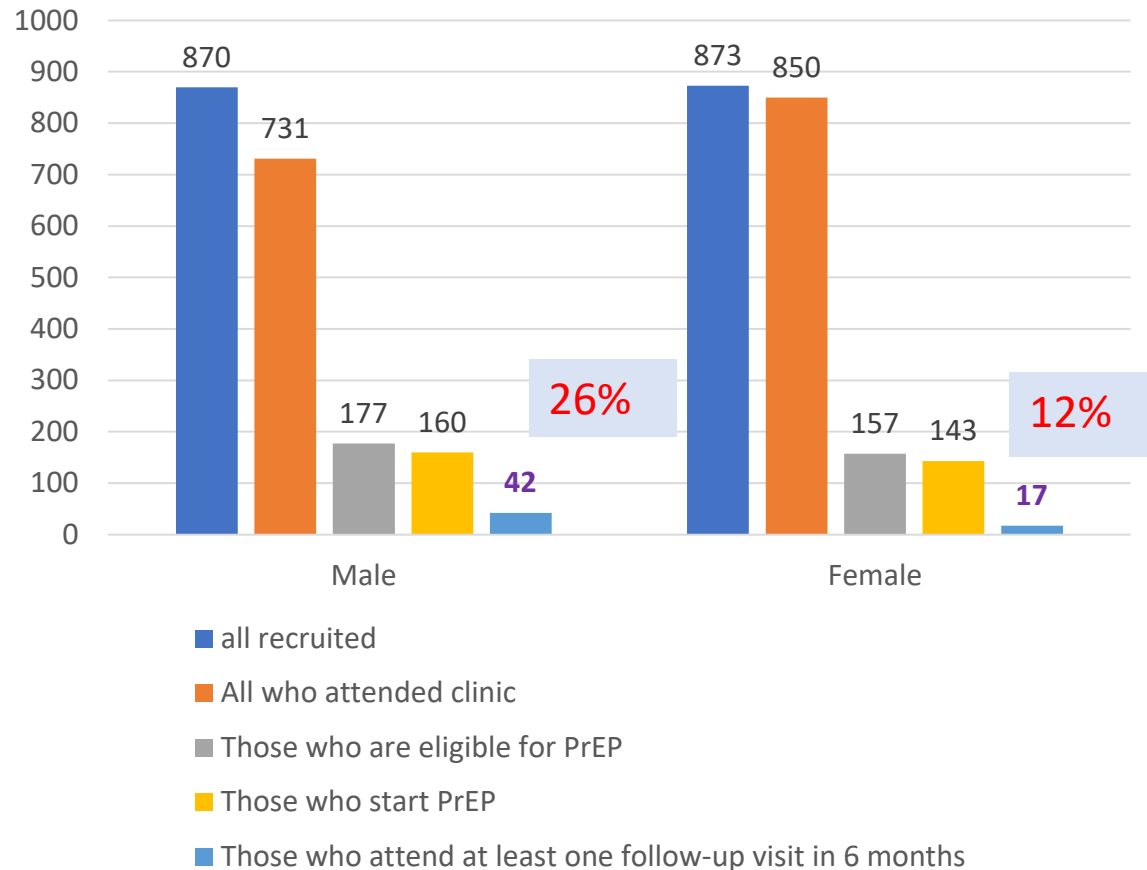
PrEP eligibility and uptake n=1740 16-29
year olds from HDSS



- Popular: 90% referred in attended services
- 19% were eligible for PrEP
- >90% of those eligible started oral PrEP

Poor oral PrEP persistence amongst AYA

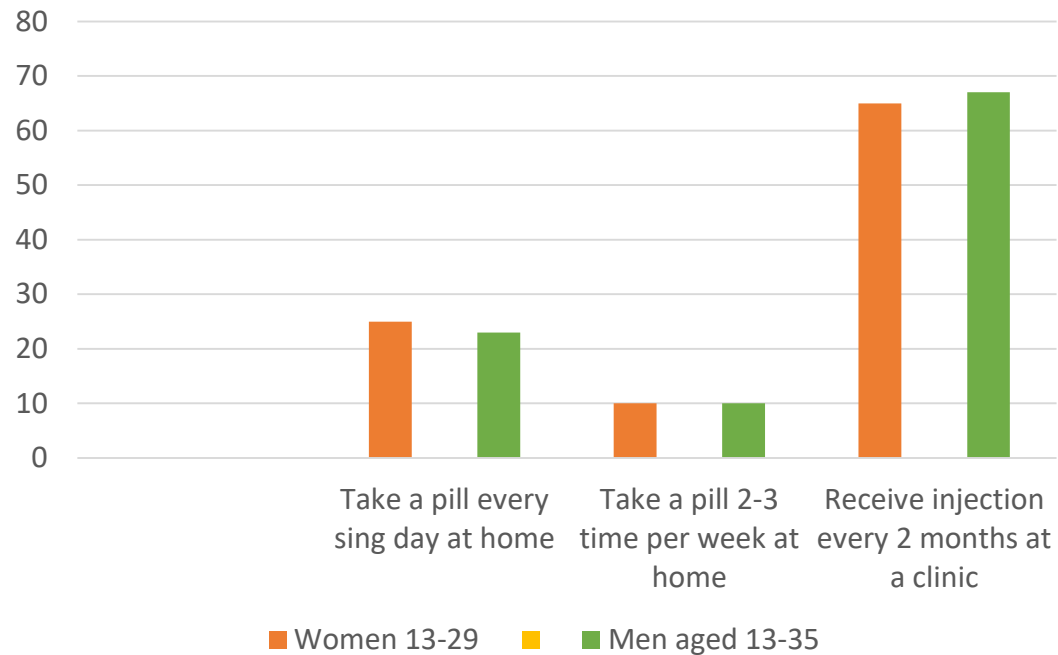
PrEP cascade n=1582 15-30 year olds



- 12% of women and 26% of men remain on PrEP
- 32% no longer at risk
- 26% stop due to challenges with pills

Injectables are desirable amongst AYA

PrEP preference in representative sample of n=5000 13-35 year olds (2017)



- 2/3 of young people prefer injectables for prevention
- Qualitive studies echo this

- **Hypothesize:** long-acting PrEP will overcome adherence, retention, and disclosure challenges of oral PrEP, especially amongst AGYW, and lead to reductions in sexually transmissible HIV.
- **Aim:** To evaluate the implementation of long-acting antiretroviral based PrEP (CAB-LA) within community-based nurse-led SRH for youth on uptake and retention of effective HIV prevention amongst adolescents and youth in rural KwaZulu-Natal (KZN), South Africa.

Objectives

1. To measure the **effectiveness** of the choice of oral and injectable PrEP on increasing ***effective uptake and retention of PrEP*** in AYA in rural SA, and to estimate the effect on transmissible HIV.
2. To explore the **acceptability, appropriateness and reach** of CAB-LA
3. To understand the **fidelity, affordability, and scalability** of delivering CAB-LA through community-based PrEP with SRH.
4. To evaluate **practical solutions to simplify** CABLA monitoring within nurse-led rural primary care settings

Methods

1. To measure the effectiveness of the choice of oral and injectable PrEP on increasing effective uptake and retention of PrEP in AYA in rural SA, and to estimate the effect on transmissible HIV.

A nested cluster RCT of the effectiveness of adding CAB-LA as a choice for PrEP on effective uptake and retention in PrEP

2. To explore the acceptability, feasibility, appropriateness and reach of CAB-LA
3. To understand the practicability, fidelity, affordability, and scalability of delivering CAB-LA through community-based PrEP with SRH.

Mixed method process evaluation and implementation research using RE-AIM to understand client and implementation outcomes.

4. To evaluate practical solutions to simplify CAB-LA laboratory monitoring within nurse-led rural primary care settings

Operational research comparing models of laboratory testing



Pharmacy-initiated antiretrovirals: Preparing for PrEP injection sites

Francois Venter
Ezintsha
University of the Witwatersrand
Johannesburg, South Africa

Thanks to all the pharmacists, SAHCS, GPs, HCWs involved in the design of the programme



Community Pharmacy Coverage in SA

Below is a summary of the SA Pharmacy Council's registered private community pharmacies. The table includes corporate and independent pharmacies, and covers urban and rural areas

PROVINCE	EASTERN CAPE	FREE STATE	GAUTENG	KWAZULU NATAL	LIMPOPO	MPUMALANGA	NORTH- WEST	NORTHERN CAPE	WESTERN CAPE	TOTAL
NUMBER OF COMMUNITY PHARMACIES	298	148	1173	554	205	263	177	63	470	3351

Pick n Pay

Dis-Chem
PHARMACIES

Pharmacists who care

 **Alpha Pharm**
your first step in healthcare

 **CLICKS**+

On offer: PrEP dream provision sites

- **An extensive primary care network that was seeing:**
 - People receiving emergency contraception, routine contraception
 - Advice on STDs, libido, fertility
 - HIV self-testing, condoms, lube
- **Clinical offering:** HIV testing, Confidential rooms, phlebotomy sites, meds, cold chains, data systems, wifi, guidelines
- **Long opening hours, open on Saturday, often on Sunday**
- **Oral Prep on offer soon; future CAB offering possible**



PIMART

- **Pharmacy initiated ART – treatment, PEP and PrEP**
- **Piloted in multiple pharmacies, training done, awaiting legislation**
- **Next: start delivering PrEP**
- **Gates supported project:**
 - In-pharmacy
 - Home
 - Online
 - (with measures of uptake, persistence, preference etc)

Materials developed

The screenshot shows the homepage of the #4EachOther website. The header features the logo and tagline "Connecting Keeps Us Strong" above a navigation menu with links for HOME, ABOUT US, CLINICAL INFO, RESOURCES, and CONTACT US. The main banner displays the slogan "You have grace, strength & courage" and encourages HIV prevention through PrEP. Below the banner, several informational cards are visible, including one about getting HIV tests and another about joining the provider network. A sidebar on the right highlights a "SPECIAL OFFER" for GP members.

#4EachOther
Connecting Keeps Us Strong

HOME ABOUT US CLINICAL INFO RESOURCES CONTACT US

You have *grace, strength & courage*
To prevent HIV, make PrEP part of your life.

Get it done
This is a safe and confidential space for HIV prevention, testing, treatment and support.

Life gets busy
We've made HIV treatment easy

HOW TO JOIN THE ACCREDITED PROVIDER NETWORK

To qualify as an accredited HIV clinician for the GP referral network, it is essential to successfully complete our online Advanced Clinical HIV Management Course. The standard course fee is R6,900.00 (VAT inclusive) and prepares trainees for the Diploma in HIV Management (CMSA), taking approximately 6 months to complete part-time while running a busy practice.

For more info email tshepo@sahivcs.org and quote the registration code "ACHM"

SPECIAL OFFER (VALID UNTIL 5 JUNE 2020)

To complete the full course and join the provider network in preparation for the roll-out of EPIC we are offering GP members in good standing "the opportunity to register at a discounted rate of **R2,450.00 (VAT inclusive)**. Email tshepo@sahivcs.org and quote the registration code "EPIC GP" to qualify for the discount.

JOIN THE SOUTHERN AFRICAN HIV CLINICIANS SOCIETY (SAHCS) ACCREDITED GP PROVIDER NETWORK

SAHCS initiated the Expanding PrEP/ART Innovation Consortium (EPIC), a consortium of partners who collaborate to strengthen HIV prevention and treatment in the South African health system.

EPIC has developed the first ever Pharmacy Initiated Management of Antiretroviral Treatment (PIMART) course, whereby Pharmacists who completed the course can prescribe Antiretroviral Treatment. All clients with HIV related comorbidities as well as sexual and reproductive health related conditions will be referred by the pharmacist to their GP referral networks.

One of the aims of EPIC is to enhance appropriate referral to trained and up-to-date GPs and other networks.

BENEFITS OF JOINING THE ACCREDITED PROVIDER NETWORK:

- Resultant referral
- Inclusion on the list of accredited providers

Sex has
Don't panic
To prevent HIV

#4EachOther
Connecting Keeps Us Strong

USAID
FROM THE AMERICAN PEOPLE

EPIC
EXPANDING ACCESS TO PREP AND ART IN RURAL AND URBAN SOUTH AFRICA

PIMART
PHARMACY INITIATED MANAGEMENT OF ANTIRETROVIRAL TREATMENT

Two posters for the #4EachOther campaign. The left poster features three men and the text "More men are talking PrEP. Make it part of your life." The right poster features three women and the text "You have grace, strength & courage. To prevent HIV, make PrEP part of your life." Both posters include the #4EachOther logo and tagline.

More men are talking PrEP
Make it part of your life
Ask the Pharmacist about HIV prevention, testing, treatment and support.

You have grace, strength & courage
To prevent HIV, make PrEP part of your life
Ask the Pharmacist about HIV prevention, testing, treatment and support.

#4EachOther
Connecting Keeps Us Strong

USAID PEPFAR

A photograph of a pharmacist in a grey uniform standing next to a large cardboard box filled with PrEP. The pharmacist is smiling and has his hand on the box. The box is labeled "PrEP" and "USAID". In the background, a sign lists "Clinic Services" including Blood Sugar Level Testing, Cholesterol Screening, and Blood Pressure Monitoring.

#4EachOther
Connecting Keeps Us Strong

Ask Your Pharmacist

- Medicine Usage Reviews
- Special Formula Compounding
- Natural Medicine Specialist

Clinic Services

- Blood Sugar Level Testing
- Cholesterol Screening
- Blood Pressure Monitoring

PrEP

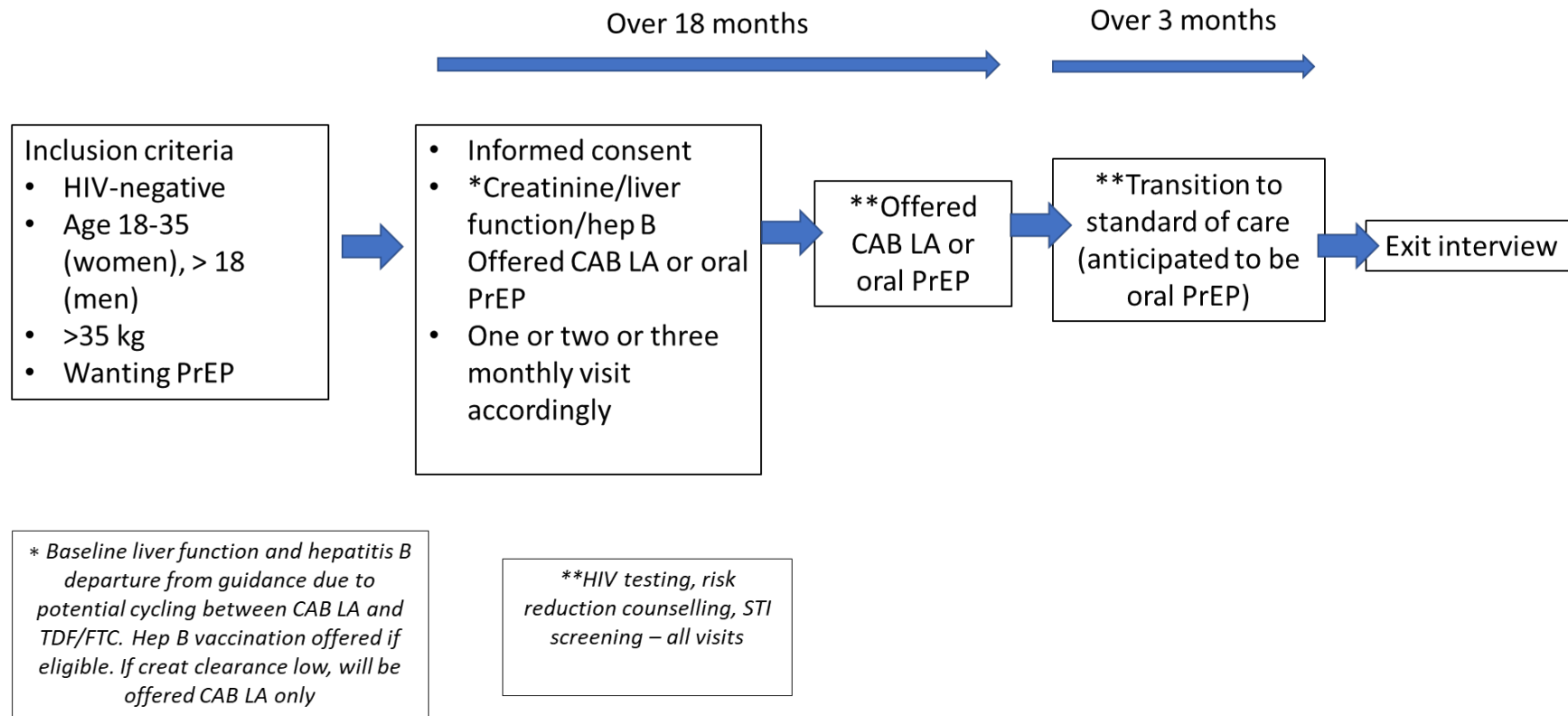
USAID

Cabotegravir proposal: Can we convince sceptics?

- **Public health providers AND health workers**
- **If we can demonstrate overwhelming patient preference AND better persistence – huge strike for guidelines**
- **Inspiration – ATLAS treatment study, but in real-world**
- **ATLAS dismissed by some – clinical trial**
- **Pharmacy situation allows a real-world-test of ATLAS-like situation**

What if we simply offer CAB vs TDF/3TC in 2-3 high volume PrEP pharmacies?

AXIS study: n=250-300



Outcomes:

- **Do they favour CAB over oral PrEP? Do they move from on to the other? Why?**
- **Persistence?**
- **Willingness to pay?**
- **Provider perspectives?**
- **But major objective is to provide operational experience, and provide convincing evidence that patients prefer CAB over oral PrEP**

