

Early learnings from CATALYST to inform PrEP choice delivery

ELIZABETH IRUNGU, MBCHB, PhD
JHPIEGO



Catalyzing access to new prevention products to stop HIV

The **CATALYST** study, under the **MOSAIC** project, uses 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.

- The **enhanced service package** offers PrEP products that have regulatory approval in each country
- **CATALYST includes a cohort study** of HIV-negative women and a **mixed-methods process evaluation**
- It uses **quality improvement (QI) methods** to refine implementation and identify a core service delivery package for PrEP choice

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

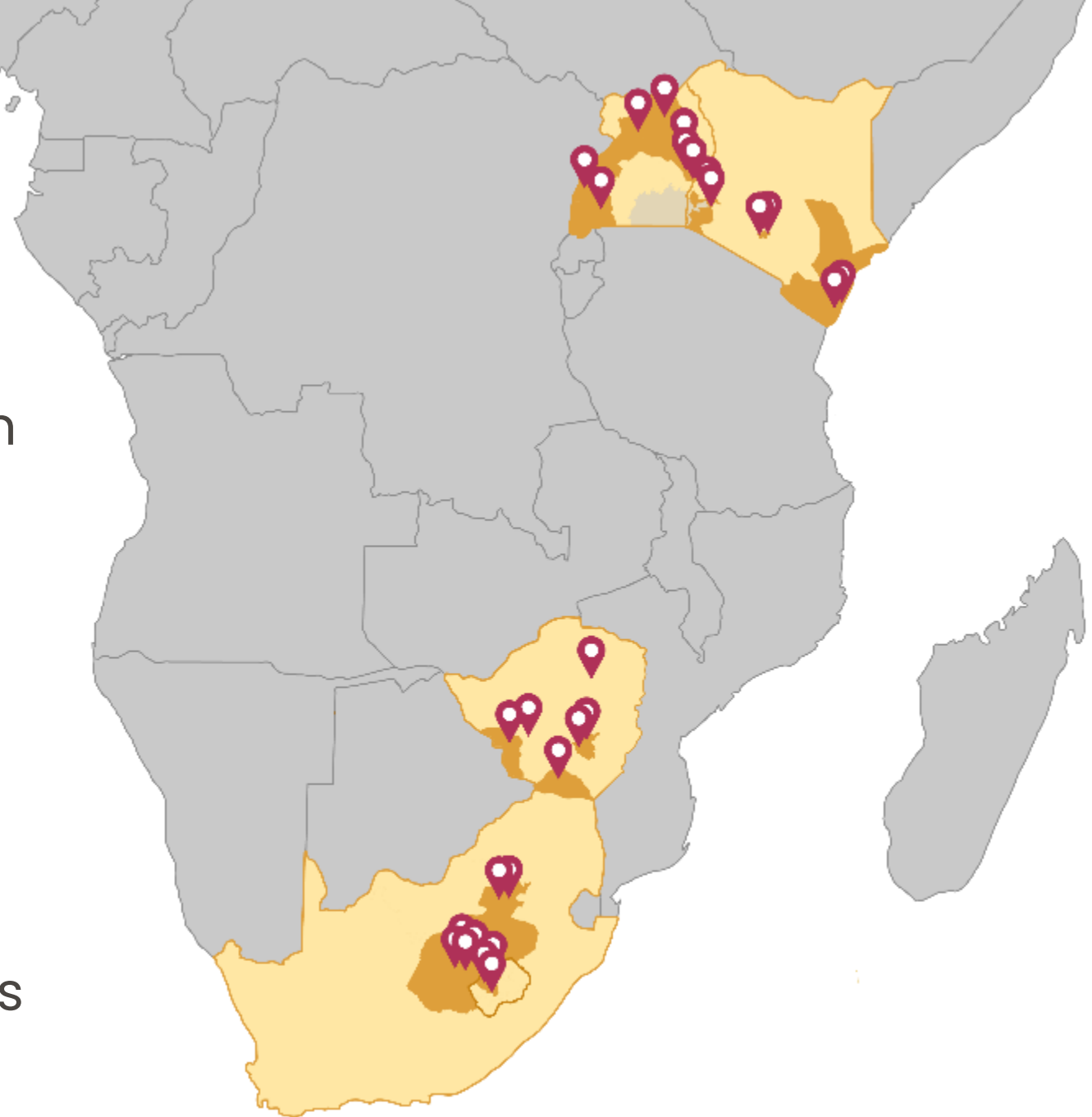
Describe patterns of PrEP use and use effectiveness in the context of PrEP choice and assess sociodemographic and contraceptive use correlates of PrEP use patterns

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 Study Sites

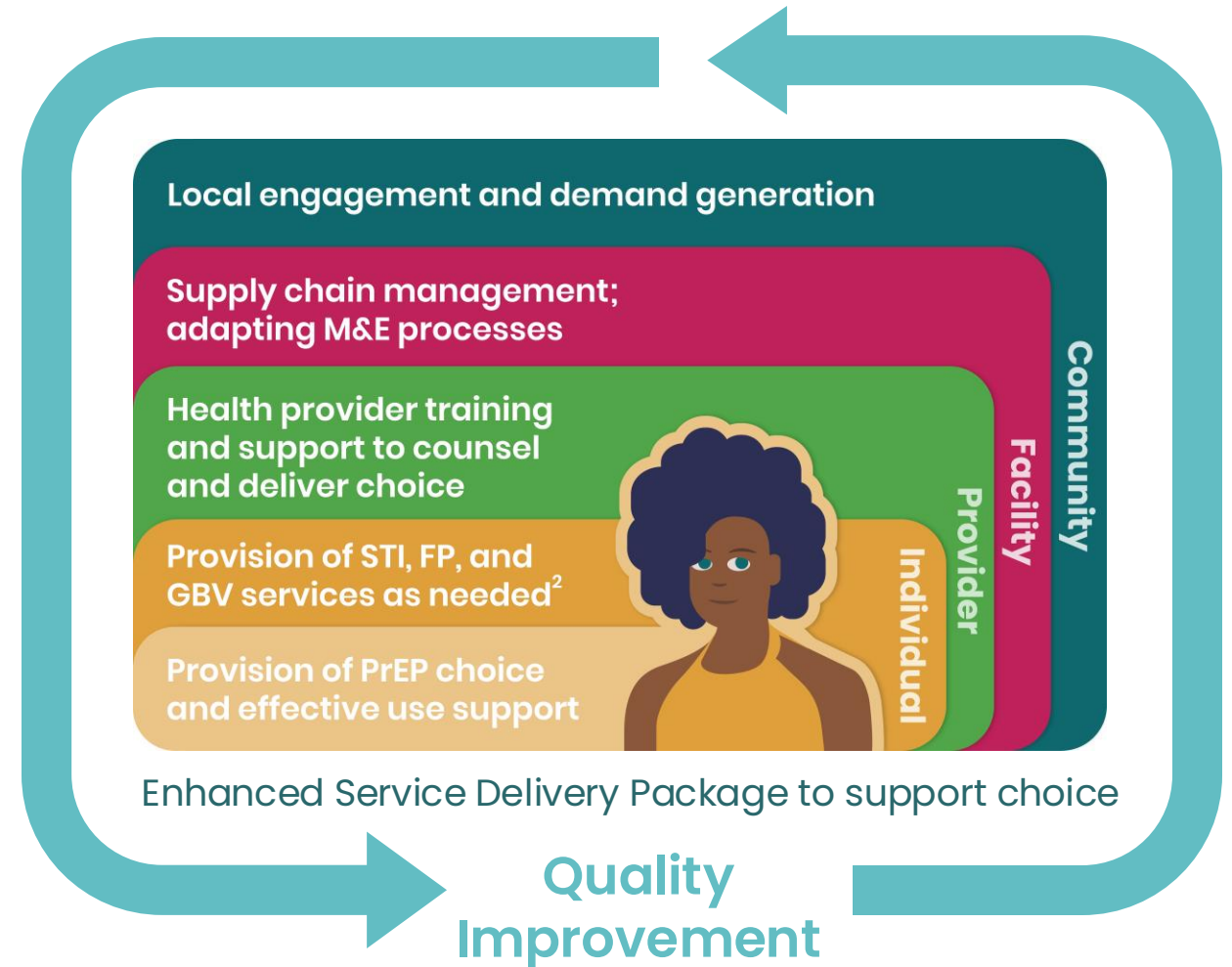
- Diverse mix of 28 public health delivery sites with PEPFAR PrEP targets
 - 6 in Kenya
 - 3 in Lesotho
 - 6 in South Africa
 - 7 in Uganda
 - 6 in Zimbabwe
- Mix of populations with some sites focused on adolescents, sex workers or pregnant women



CATALYST is implementing an Enhanced Service Delivery Package that supports product choice

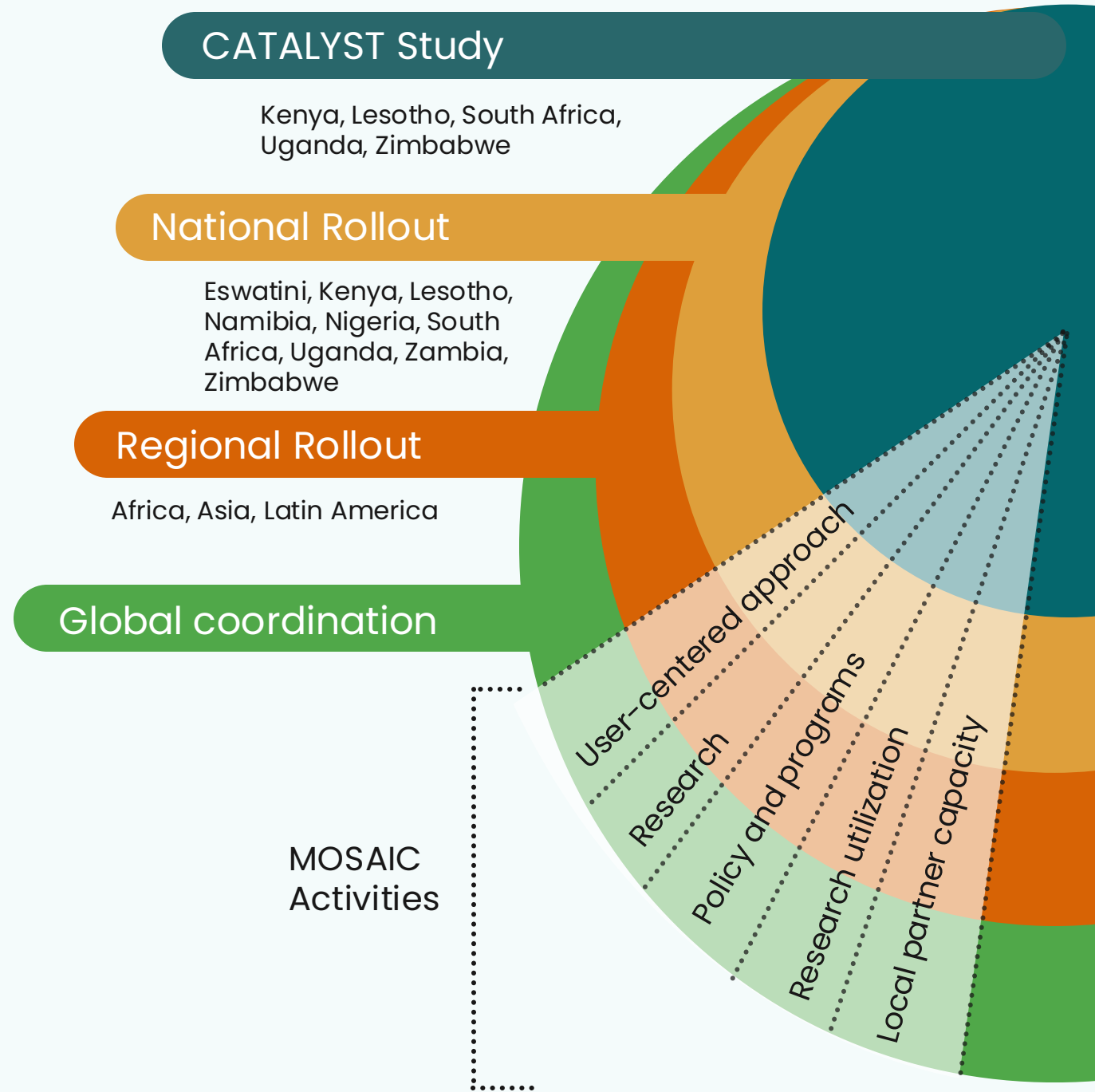
The **enhanced service delivery package** will...

- **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.



CATALYST functions as a learning lab

CATALYST serves as a **learning laboratory** for new product introduction. Learnings from CATALYST and MOSAIC activities **flow** across national, regional and global levels.



Current enrollment as of June 30, 2024

- Total enrollment in Stage I (choice between oral PrEP and PrEP ring): 3967
- Total enrollment in Stage II (choice between oral PrEP, PrEP ring and CAB PrEP): 614
 - Currently enrolling for Stage II in Lesotho, South Africa, and Zimbabwe
 - Anticipate starting Stage II in Kenya and Uganda in Q4 2024
- Country-specific product use guidance varies
 - PrEP ring use allowed during pregnancy in Kenya and Lesotho; ring use allowed during breastfeeding in Kenya, Lesotho, and Zimbabwe
 - CAB PrEP initiation and continuation allowed during pregnancy in South Africa; CAB PrEP continuation allowed during pregnancy in Zimbabwe

Preparing for new products

- In preparing for PrEP ring and CAB PrEP introduction through CATALYST, important lessons have emerged related to:

Development of clinical guidelines

Address the following:

- age and weight requirements
- use by pregnant and breastfeeding people
- dispensing schedule
- HIV testing and safety monitoring
- product switching and dual use
- product administration and disclosure

Operational set-up

Unlike oral PrEP, implementation of ring and CAB requires more attention to private, clean spaces and supplies to support in-clinic storage, administration, and dispensing

Training of providers

Dedicate adequate time for clinical training on

- new products
- choice counseling
- any necessary refreshers

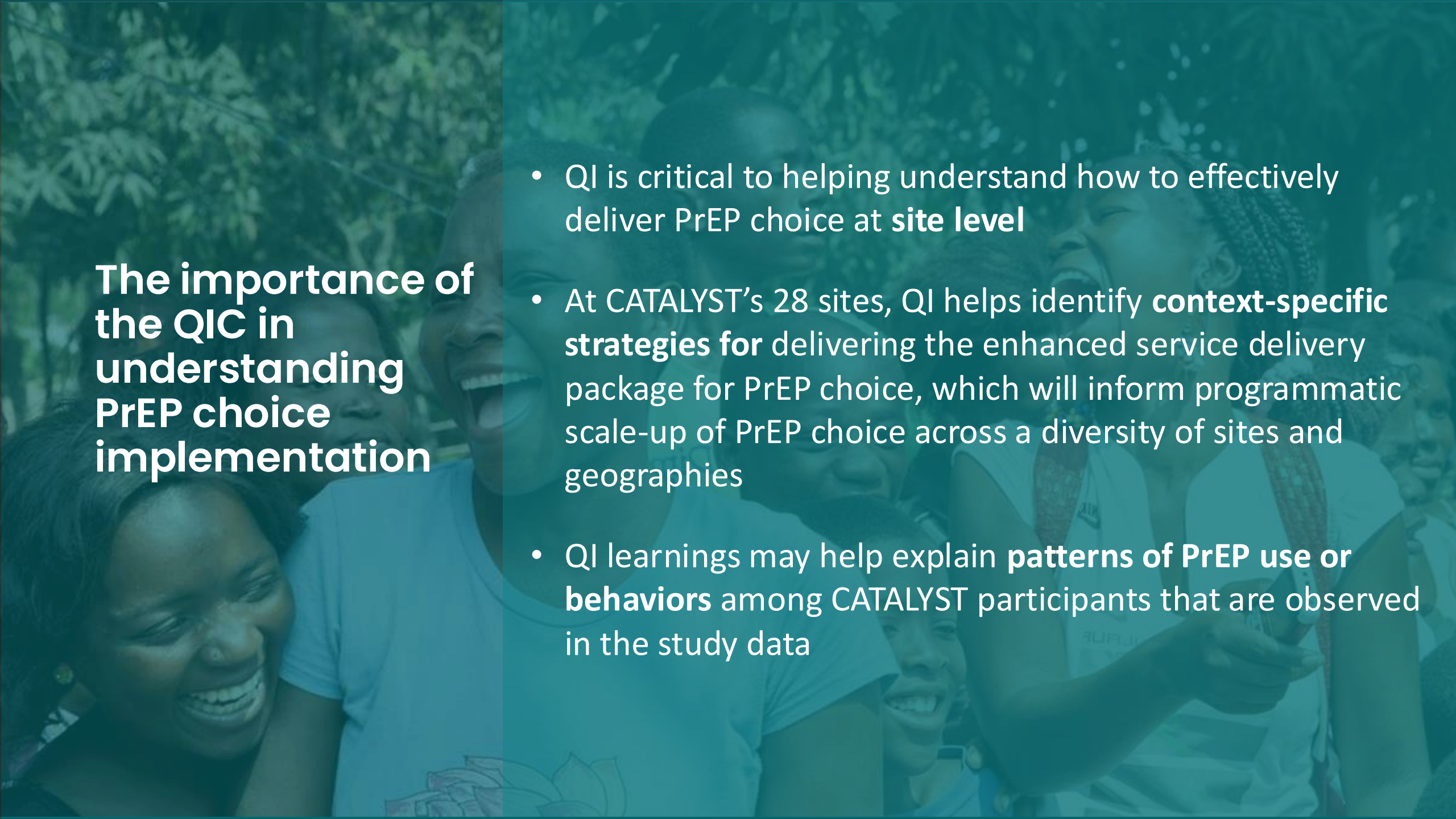
Develop a training plan that minimizes service delivery disruptions

Continued training is essential

Key takeaways from first interim analysis (May–November 2023)

- Participants take advantage of having choice; in Stage I, substantial numbers chose ring, particularly FSW and former oral PrEP users (not using at the time of enrollment).*
- While PrEP choice counseling sessions can be lengthy, providers find delivery of PrEP choice counselling appropriate, feasible, and acceptable.
 - Time and practice are necessary to master PrEP choice counseling.
 - Staff turnover is a challenge; invest time in routinely training providers on choice counseling and new PrEP methods and refreshing on oral PrEP.
 - Many clients have not heard of PrEP before and should be counselled accordingly.
- Gaps in integrated service delivery, especially GBV, have been observed.
- Through QI, study teams can explore ways to optimize PrEP choice delivery in each service delivery setting.

**Study data from Stage I will be presented and made publicly available at the HIVR4P conference in October 2024*



The importance of the QIC in understanding PrEP choice implementation

- QI is critical to helping understand how to effectively deliver PrEP choice at **site level**
- At CATALYST's 28 sites, QI helps identify **context-specific strategies** for delivering the enhanced service delivery package for PrEP choice, which will inform programmatic scale-up of PrEP choice across a diversity of sites and geographies
- QI learnings may help explain **patterns of PrEP use or behaviors** among CATALYST participants that are observed in the study data



CHANGE IDEAS

Increasing number of PrEP clients who make an **informed choice about PrEP**



- Conduct group health talks on PrEP in waiting areas at maternal/child health, outpatient, family planning, and antenatal care departments*
- Conduct individual PrEP choice counseling during HTS, maternal health, and outpatient visits*
 - Use a PrEP counseling job aid (e.g., Journey Tool, product fact sheets)*
 - Use a checklist to ensure all aspects of informed choice are covered during PrEP counseling*
- Community health workers sensitize all HIV-negative women on PrEP during household HTS visits

**Adopted in multiple sites*

Improving PrEP retention at one-month post initiation (M1 return)

- Counsel on the importance of M1 return at PrEP initiation (even if risk of HIV changes)*
- Implement an appointment diary system to track return dates*
 - Electronic health records system generates appointments
 - Paper-based system is maintained in the event of power outages
- Create a fast lane for M1 clients**
- Coordinate refill locations with mobile sites based on where it's most convenient for clients
- Call/SMS/WhatsApp clients prior to M1 return date* and after missed M1 visits
- Conduct in-person outreach prior to M1 return date *

**Adopted in multiple sites*

***Adopted in one site but abandoned at another site in a similar setting*

Improving client experience by reducing waiting time



- Dispense PrEP methods in the consultation rooms instead of the pharmacy *
- Escort clients between service delivery points (e.g., from HTS to PrEP consultation)*
- Expand PrEP to anywhere in the facility where HTS is offered*
- Create a one-stop shop for PrEP and integrated services, including FP and GBV

**Adopted in multiple sites*

An illustration on the left side of the slide shows several hands of different skin tones reaching up to hold a globe. A clock face is visible on the left, and several pills are scattered around the hands. The background is a light green color.

Improving integrated service delivery (FP, STI, GBV, and mental health services)

- PrEP counselors or providers screen all PrEP clients for GBV in the consultation room using a checklist to document clients' responses. The tool is then kept with the clients' records.*
- Counsel all STI clients who are HIV-negative on PrEP
- Nurse uses a mental health screening tool with all PrEP clients in the family/child health and outpatient departments. The PrEP register was adapted to document mental health screening

**Adopted in multiple sites*

CATALYST offers a variety of sample and template client-facing tools and job aids that are collaboratively developed with the global and country teams, including with input from priority populations.

Each country then chooses which tools to use and adapts them as needed to local contexts and national guidelines.

We observed that tool preferences vary by country and provider.

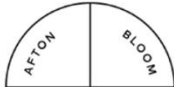


MENU OF TOOLS FOR PREP CHOICE

- [PrEP guideline](#) and [implementation plan templates](#)
- [PrEP ring clinical training](#)
- [CAB PrEP clinical training](#)
- [PrEP factsheets](#)
- [Pelvic models](#)
- [Demo ring kits](#)
- [Acute HIV infection screening job aids](#)
- [PrEP use support job aid](#)
- [GBV screening and disclosure counseling job aid](#)
- [PrEP ring initiation steps and counseling messages job aid](#)
- [CAB PrEP initiation steps and counseling messages job aid](#)
- [HIV Prevention User Journey Tool](#)

All resources can be found on the [CATALYST Study Implementation Materials](#) page on PrEPWatch. Scan the QR code to access the page.

ACKNOWLEDGMENTS



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Photo Credit: MOSAIC Consortium



Using Implementation Science to Accelerate the Path to Scale for Injectable PrEP in Malawi

Washington Ozituosauka

Directorate of HIV, STI and Viral Hepatitis, MOH Malawi

2024 Spectrum / Naomi / KP workbook* estimates (for 2023)

*KP estimates are not mutually exclusive and are subset of general population 15-49

Population	Age	Gender	Pop. size	PLHIV	HIV Prev.	New inf.	Incidence	AIDS deaths
General	All	All	21,162,000	991,600	4.7%	14,000	0.07%	11,300
	15+	All	12,297,000	941,000	7.7%	11,500	0.10%	9,700
		F	6,433,000	591,000	9.2%	7,400	0.13%	4,500
		M	5,864,000	350,000	6.0%	4,100	0.07%	5,200
General	15-49	All	10,688,000	717,000	6.7%	11,100	0.11%	6,900
<u>Pregnant</u>		F	680,000	34,000	5.0%	750	0.12%	
<i>FSW*</i>		F	39,000	19,500	50.0%	1,500	7.69%	
<i>MSM*</i>		M	35,400	4,500	12.7%	150	0.49%	
<i>TG*</i>		All	4,900	700	14.3%	20	0.48%	
<i>PWID*</i>		All	8,400	2,300	27.4%	70	1.15%	
General	15-24	F	2,341,000	57,000	2.4%	3,600	0.16%	600
General	0-14	All	8,865,000	52,000	0.6%	2,300	0.03%	1,500
	<1		664,000	1,400	0.2%	1,800		400

Background

- Declining HIV incidence: 0.1% (15-49 years)
- Generalized epidemic: distribution of 14,000 new infections
 - 70% in general population (excl. AGYW)
 - 20% in AGYW
 - 10% in KP
- 75% of new infections in southern region and major cities
- Challenges
 - Most new infections are dispersed in a large population
 - Identification of high-risk subpopulations

Background

- Malawi's Injectable PrEP implementation science work builds from district systems investments in two major cities (**Blantyre and Lilongwe**)
- An **iterative adaptive learning approach focusing on**
 - ✓ Data use
 - ✓ Quality improvement
 - ✓ Community engagement
 - ✓ Demand creation
 - ✓ Health communication
- Intentionally generates more relevant learnings and **evidence** for the path to scale in Malawi

Path2 scale study objectives

~Sep 2023* -Mar 2026

*to be adjusted based on CAB availability

Dec 2022-
Nov 2023

IRB protocol
submissions
and tool
development
beginning for
study 2

Obj 1a & b
Provider and client values
and preferences

Empiric development of
demand-generation /
“attract, engage and
enable” strategies

Obj 4a
Foundational systems
established

Obj 2
Testing and adaptive learning of CAB among
priority populations and delivery channels with a 6-
month lead-in to Ob 3

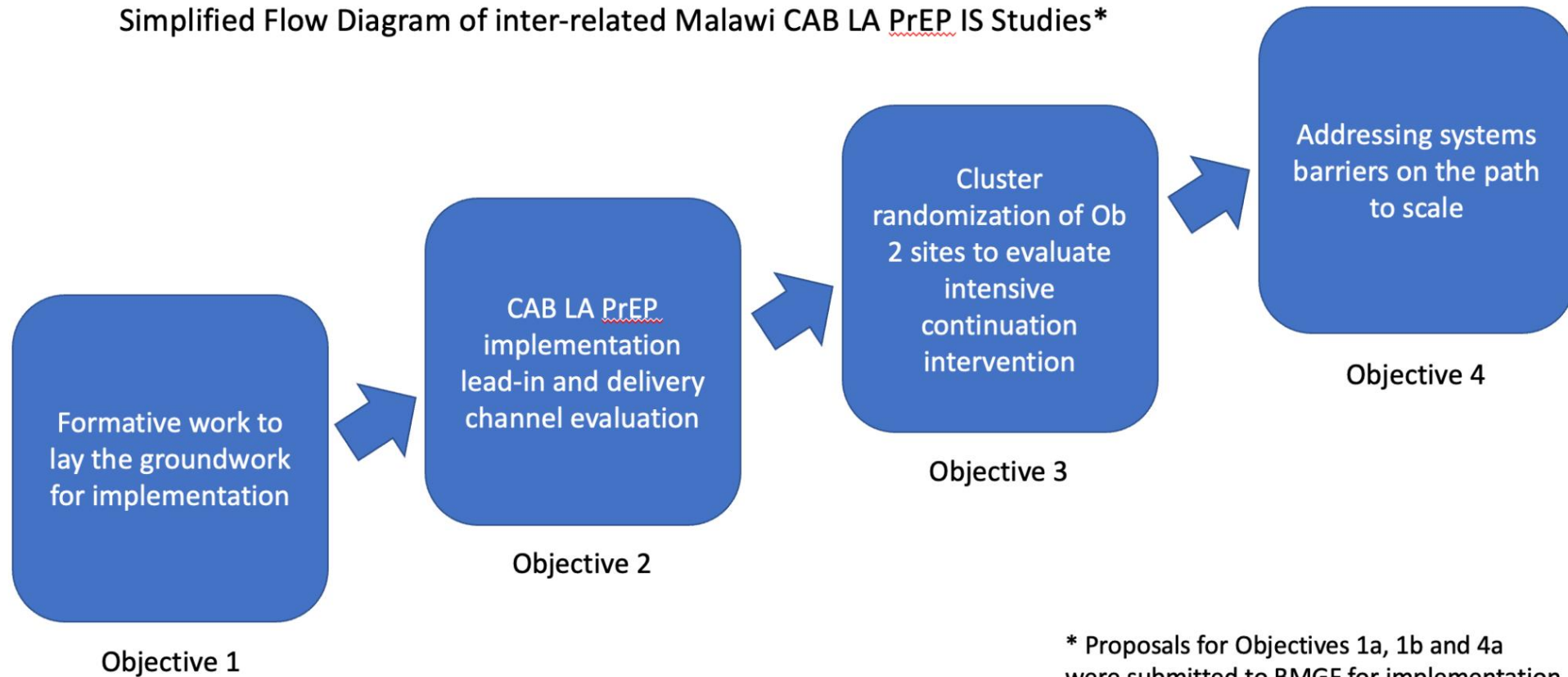
Obj 3
Evaluating effectiveness of implementation
strategies and understanding comprehensive PrEP
product scale-up through a cluster randomized
comparison (enhanced continuation support vs.
standard of care)

Obj 4b
Developing & Testing the path to scale

CAB LA available in Malawi

Simplified Flow Diagram of Path to Scale Objectives

Simplified Flow Diagram of inter-related Malawi CAB LA PrEP IS Studies*



* Proposals for Objectives 1a, 1b and 4a were submitted to BMGF for implementation prior to CAB LA availability

Preliminary Results: Formative study

Provider and Client preferences and dislikes

Mixed methods study

- In-depth interviews: 69 KVP members and 20 health workers
- Questionnaire: 550 KVP members with / without prior PrEP use
- Demand workshops: convenience sample from KP-led orgs.

Acceptability- Injectable PrEP:Likes

- All participants felt that scaling up injectable PrEP would increase the uptake and improve adherence to PrEP
 - There would be no pill burden
 - Easy to use, one shot every 2 months,
 - Long-acting-Assured of protection
 - Reduce stigma and misconceptions related to ART.
 - Privacy and use without partner knowledge. (GBV reported with oral PrEP use)
 - Reduce workload-less adherence counseling sessions, no pill count.



the most positive thought that I thought about is that it would improve adherence. It is a onetime thing so it means we have dealt with the issue of pill burden (PrEP Provider 17)

Dislikes/fear

The size of the injection, pain on the injection site

Fear of Side effects like headache, obesity, lipodystrophy

How to reverse side effects while having the drugs in the body after receiving the injection

It might be too strong unlike oral PrEP may weaken your body-having the injection for a long time in the body

My concern is on the side effects that maybe when I start getting injected it can change the shape of my body AGYW-BT-010

R: The concern that I have is about the side effects. Otherwise, injectable PrEP is more convenient. (MSM-001 LL)

Common misconceptions

Once seroconverted
will not respond to ART
and will eventually die
(FSWs)

Injectable PrEP may
weaken men leading to
sexual dysfunction

Injectable PrEP may
cause infertility t
women

Those taking injectable
PrEP are Promiscuous

Injectable PrEP is a
vaccine

If pregnant, it may
cause abortion or
malformation

Injectable PrEP as
contraception

Prolonged Injectable
PrEP use may cause
changes in the body
associated with
lipodystrophy

Common Views on use in pregnancy

- The majority felt they would recommend it because it would be safe during pregnancy and would protect the mother and the unborn child from HIV since some women might have unfaithful partners.
- The majority felt they would recommend use if it's proven to be safe in pregnancy.
- Some felt they could not recommend it due to fear that it may cause miscarriage or harm the baby or can be born with congenital abnormalities.
- Others felt breastfeeding women would not accept it due to fear that injectable PrEP can contaminate the breast and the baby can feed on bad milk.

Programmatic context of CAB-LA implementation

1 National strategic framework

Malawi Health Sector Strategic Plan III (2023-2030)

- Focus on integrated platforms of care
- Transition from HIV verticalization to service integration
- HIV Combination Prevention being integrated into SRHR & Maternal Health services
- Injectable PrEP integrated into STI, Family planning & Antenatal services

Programmatic context

2 Implementation guided by HIV burden

- Blantyre and Lilongwe City prioritized for early implementation based on high burden of HIV
- Existing oral PrEP services in public, private and faith-based facilities

Programmatic Preparations

National PrEP Service Delivery Guideline (2020)
revised to incorporate injectable PrEP

- Eligibility screening for PrEP
- HIV testing using 3 test algorithm
- Special Considerations for PrEP in pregnancy and breastfeeding women
- Revised Standard Operating Procedures & Job Aids



Malawi Service Delivery Guidelines and Standard Operating
Procedures for the Provision of HIV Pre-Exposure Prophylaxis
using Oral or Long-acting Injectable Options.



Programmatic preparations

-Revision of training materials, Job aids, M&E tools

- Training materials and other tools adapted for injectable PrEP (CAB-LA)
- Realistic case studies for application of theory
- Targeted education and counselling on injectable PrEP
- New PrEP clinic register and PrEP visit cards
 - Accommodates continuous oral, ED oral, CAB-LA with/without oral bridge
 - Customized for *ScanForm*® for easy digitizing of complete paper records from simple smartphone photo (already rolled out for testing services)

Programmatic preparations

-Capacity building of service providers

- Certified and experienced oral PrEP providers selected for new guideline training
 - Only certified state registered and enrolled nurses, medical officers and clinical officers can prescribe injectable PrEP
- Training supported by on site mentorship including digital tools

Programmatic preparations

-HIV testing

- Malawi adopted HIV rapid Testing using a 3 test algorithm in the National Integrated Testing Guidelines (2023)
 - To minimize risk of misdiagnosis (false positive) due to low positivity among clients getting tested for HIVs
 - Scaled up to >600 health facilities across the country including path to scale sites
- Professional, quality-assured, blood-based tests are needed to confirm negative status at PrEP initiation and follow-up
 - No test – no PrEP

Programmatic preparations

-Service delivery models

- Public, private, Faith based health facilities implementing path to scale study
 - Rural vs urban health facilities (hot spots)
- Deliberately targeting diverse entry points and populations
 - Drop-in centres: Key Populations
 - ANC clinic: pregnant women
 - Outpatient consultation rooms
 - Sexually Transmitted Infection Clinics

Programmatic preparations

-Supply chain

- CAB-LA vials and consumables incorporated in existing supply chain management and distribution system for HIV program
 - Use of existing toll-free hotline for stock challenges
 - Dedicated weekly inventory forms submitted by pharmacies and clinic rooms using *ScanForm*®
- CAB-LA demand outstrips available supply
 - No deliberate demand creation
 - MoH and implementing partners define client enrolment targets for each facility

Programmatic preparations

-Monitoring and Evaluation

- Revised existing National Oral PrEP tools from manual to digital tool (scan form)
 - Captures both oral and injectable PrEP
 - Linked to HIV, syphilis & Hep B testing data
 - Will be scaled up to all PrEP service delivery sites in phased approach

Conclusion

- Ongoing mentorship key in early stages of implementation
- Investment in Digital tools in HIV testing and PrEP service delivery eases follow up on previous testing results
- Incorporating Path to scale study in national programming allows for early learnings and revisions
- No demand creation due to Limited CAB-LA supplies
- Client continuity affected if transferred from registered site

Acknowledgements

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GEORGETOWN UNIVERSITY
Center for Innovation in Global Health



THE SEARCH DYNAMIC CHOICE HIV PREVENTION TRIALS



James Ayieko, MBChB, MPH, PhD
Research Scientist
Kenya Medical Research Institute (KEMRI)

For SEARCH Study

SEARCH TEAM



HIV BIOMEDICAL PREVENTION

People want choices

- What do you offer?
- How do you do it?
- What do you gain?



SEARCH DYNAMIC CHOICE HIV PREVENTION (DCP) PILOT STUDIES: OVERALL GOAL AND DESIGN- 2021



Objective: Evaluate impact of the DCP intervention compared to standard-of-care on **biomedical prevention use (“coverage”)**

Population: Adults aged ≥ 15 years, HIV-negative, at risk of HIV

Settings and designs

1. Antenatal Clinics (ANC)- Individually randomized
2. Outpatient Department (OPD) - Individually randomized
3. Community (delivery via community health workers [CHWs]) – Cluster-randomized

Primary Outcome: Biomedical Covered Time (“Coverage”)

- % of follow-up time for which a participant reported use of oral PrEP or PEP
- Assessed over 48 weeks
- Secondary: % of follow-up time at risk of HIV for which a participant reported use of oral PrEP or PEP

INTERVENTION: DYNAMIC CHOICE HIV PREVENTION

PRODUCT CHOICE¹

(+ option to switch products)

- Oral PrEP (TDF/XTC)
- PEP (pill in pocket)
- *CAB-LA
- DPV Vaginal ring

SERVICE LOCATION CHOICE

- Clinic
- Home / Community site
- Phone/virtual visit

HIV TESTING CHOICE²

- Rapid test
- HIV self-test option

REFILL CHOICE

- Up to 3 month PrEP refill**

PATIENT-CENTRED CARE

- **Structured assessment of barriers** to PrEP/PEP start/adherence, with **personalized plans** developed in response
- **Phone access to clinician** for PEP or PrEP starts, advice/questions (24hrs/7 days/week, including holidays)
- **STI service integration at ANC & OPD** (or referral by VHT/CHV)
- **Psychological support** – referrals to counseling for trauma/gender-based violence



PROVIDER TRAINING IN PATIENT CENTERED CARE, PATIENT EDUCATION

1. All clients offered condoms, lubricant.

If no product started at baseline, clients were followed for HIV testing and option to start PrEP/PEP/CAB-LA/ring anytime during follow-up.

2. Rapid blood-based HIV testing first-line. Option for HIV self-testing during follow-up (including PrEP/PEP monitoring).

* CAB-LA injections are restricted to the clinic

** If supplies available, with preference for longer fill if planning not to have in-person visit at week 4

Control: Standard-of-care

- Referral to HIV clinic for standard PrEP & PEP services

DYNAMIC CHOICE PREVENTION INCREASED SELF-REPORTED BIOMEDICAL HIV PREVENTION COVERAGE

Koss, *AIDS*, 2024; Kabami, *JAIDS*, 2024; Kakande, *JIAS*, 2023

Community
(n=429)

0.5%

Intervention

28%

28-40% increase in
biomedical HIV prevention
coverage across all trials

Outpatient
(n=403)

Control

18%

Intervention

48%

Antenatal
(n=400)

Control

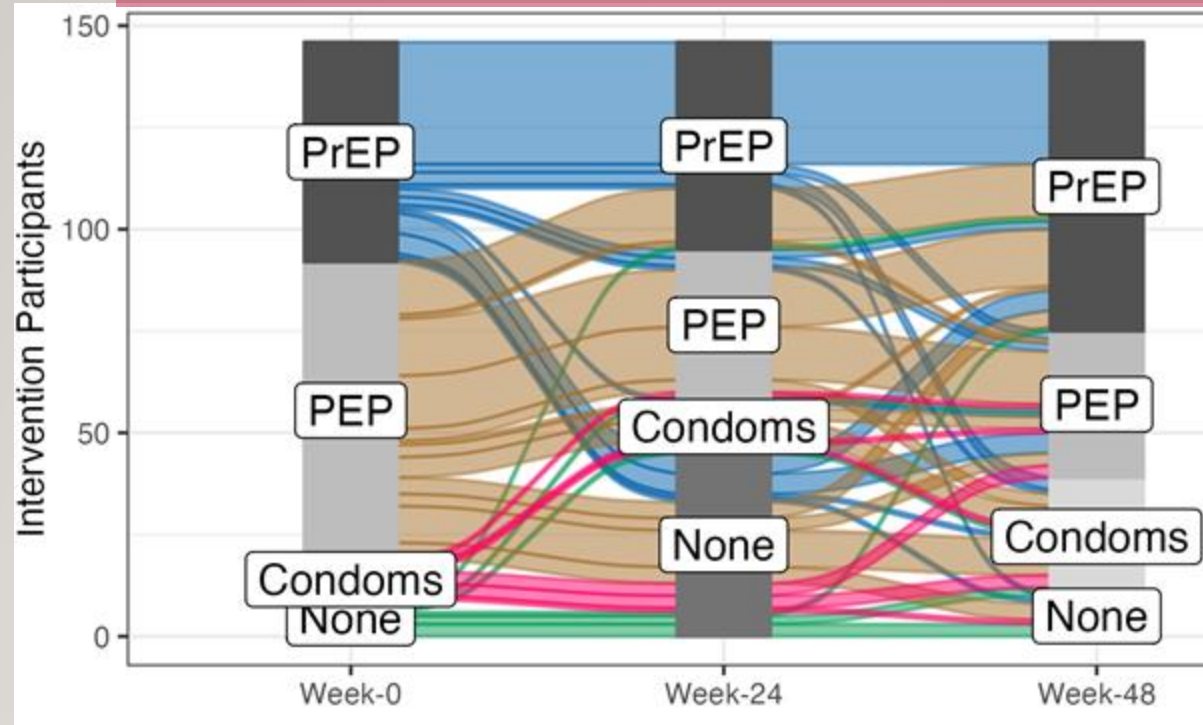
29%

Intervention

70%

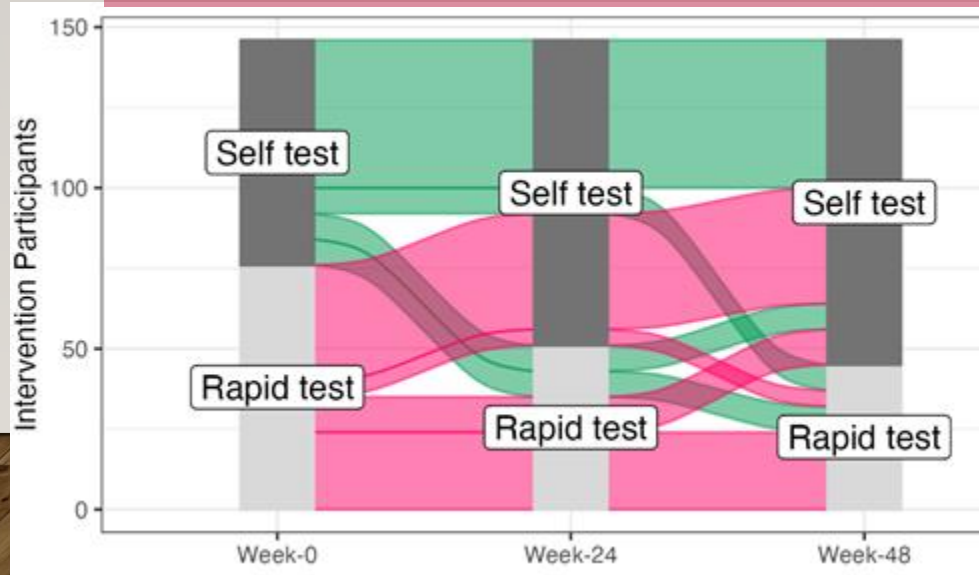
0% 10% 20% 30% 40% 50% 60% 70% 80%

Product Choice

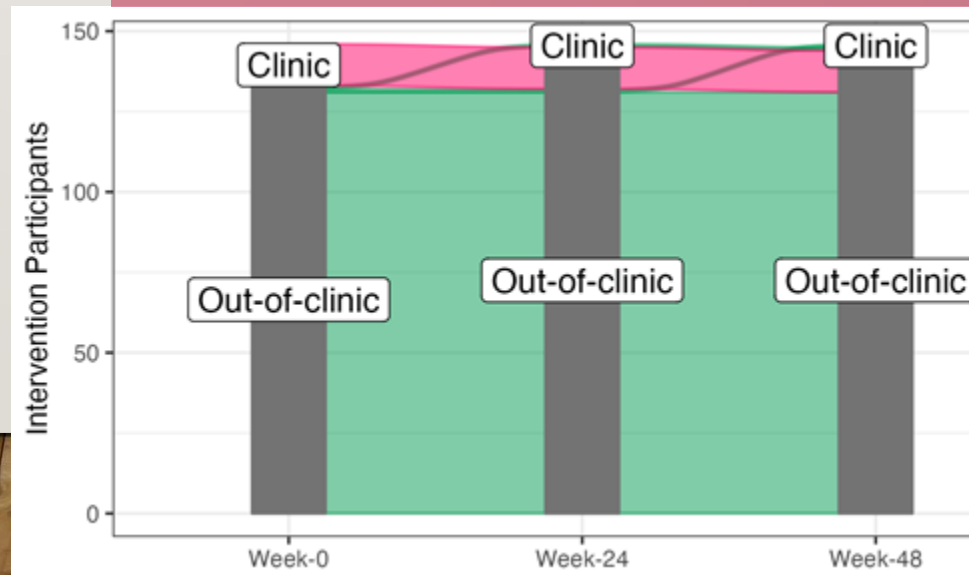


EX: DYNAMIC
CHOICE IN THE
COMMUNITY

Test Choice



Location Choice



MOTIVATION FOR THE SEARCH DYNAMIC CHOICE PREVENTION WITH CAB-LA EXTENSION STUDY - 2023



The SEARCH dynamic choice prevention intervention significantly increased biomedical HIV prevention coverage

But coverage remained sub-optimal

- Among intervention participants, only 48.5% of follow-up time, on average, was covered

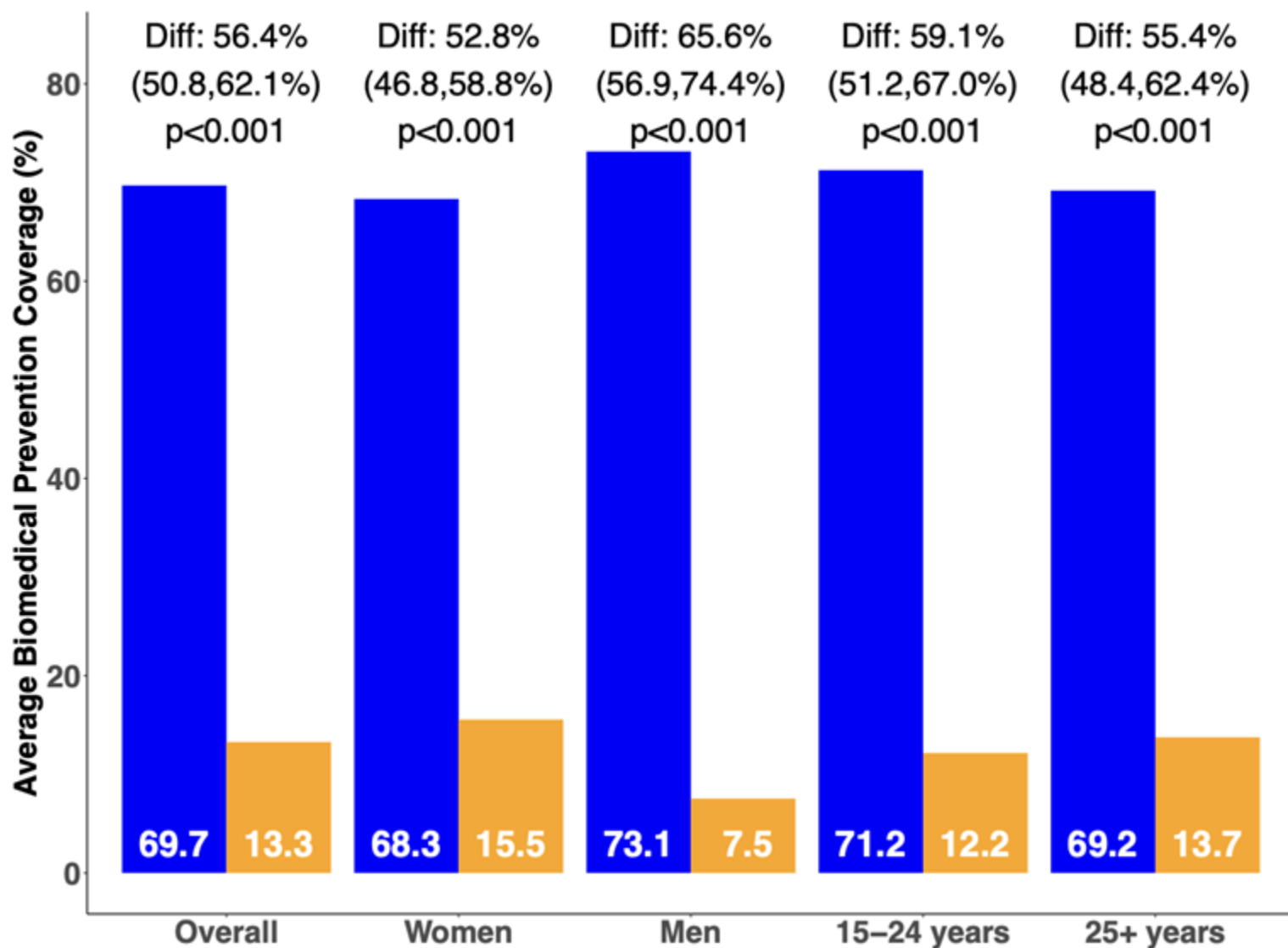
Globally, 1.3 million new HIV infections in 2023 despite expanded ART and oral PrEP

CAB-LA could increase overall coverage but implementation issues need to be addressed

- HPTN 083 & 084: Injectable long-acting CAB-LA more effective than oral PrEP at reducing incident HIV infections

Addition of CAB-LA to the DCP Package increased prevention coverage

Kamya, CROI 2024

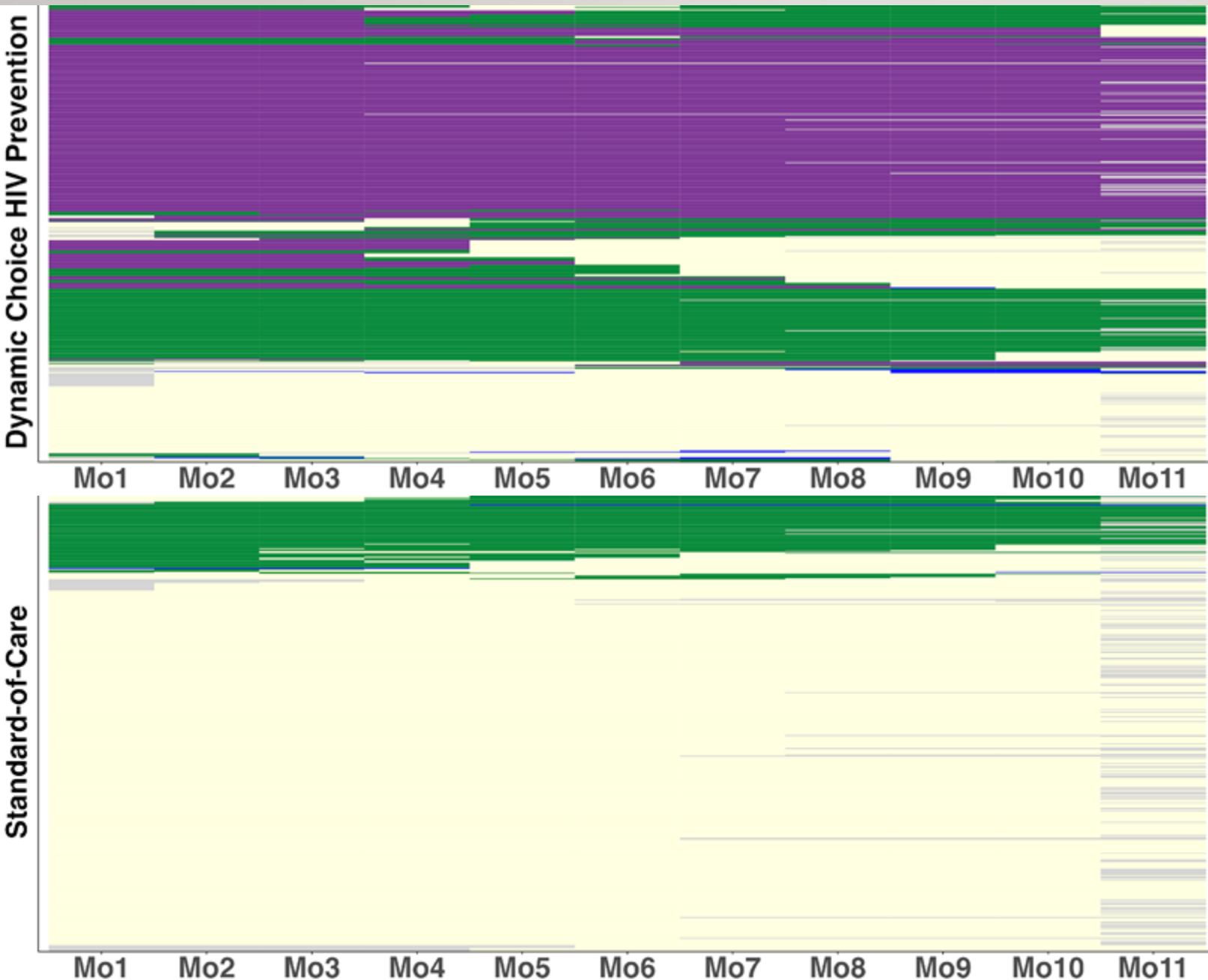


Average coverage was 69.7% in the intervention vs. 13.3% in the SoC; **Difference of 56.4%** (95%CI: 50.8-62.1%); $p < 0.001$

Significant increases across all subgroups ($p < 0.001$)

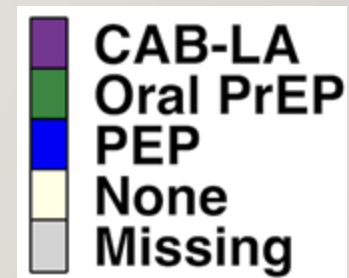
■ Dynamic Choice HIV Prevention
■ Standard-of-Care

HEATMAPS OF PRODUCT USE



Kamya, CROI 2024

Each row is a participant
Each column is follow-up month



RESULTS: SUMMARY OF PRODUCT USE

Kamya, CROI 2024

Ever use	Dynamic Choice HIV Prevention intervention	Standard of Care
CAB-LA	56%	0%
Oral PrEP	53%	19%
PEP	2%	1%
2+ products	28%	0.4%

- Over half of participants in intervention arm used CAB-LA during the study (both men and women)
- Of those starting CAB-LA at baseline, 42% were not on any prevention product in the prior month
- 28% of intervention participants used at least 2 different products during the study

SECONDARY OUTCOME: HIV INCIDENT INFECTION

Kamya, CROI 2024

	Dynamic Choice HIV Prevention intervention	Standard of Care
Overall	0/400 PY	7/390 PY
Women	0/293 PY	5/283 PY
Men	0/107 PY	2/106 PY
15-24 years	0/113 PY	1/122 PY
25+ years	0/287 PY	6/268 PY

- 7 participants in the SoC and 0 in intervention had incident HIV infection
- Incidence rate was 0% in the intervention vs. 1.8% in the SoC
- Difference of -1.8% ($p=0.01$)
- In addition, 1 infant born to participant in SoC was infected
Not included in incidence estimates

CAB-LA CLIENT EXPERIENCES

CAB-LA addresses barriers such as pill burden, associated with alternative HIV prevention options like oral PrEP.

“At the time when I was taking pills, it was difficult for me because sometimes, I would forget to take the pills. On some occasions, I had to travel to a burial ceremony, and I would forget to take my pills with me. In the long run, I would miss taking my drugs in time. But now the injection is much easier for me because when I take it, I become free.” – Female, Uganda

CLIENT EXPERIENCES WITH THE SEARCH DYNAMIC CHOICE HIV PREVENTION MODEL

- Clients like to be given the opportunity to choose what works best for them.

“I liked [being given a choice] but based on how he [the provider] told us about the injection, I felt it was the best method for me to use. I felt good because he left the decision-making part to us...” – Female, Uganda

WHY DID YOU CHOOSE CAB-LA?

- 64% chose CAB-LA because it was easier to take an injection and 49% because of difficulty remembering to take oral pills.
- 30% did not want to take pills because of stigma, more pronounced in women and youth

Response	Overall	Women	Men	15-24 yrs	25+ yrs
Easier to get an injection than to take pills	64% (170/264)	66% (115/175)	62% (55/89)	58% (44/76)	67% (126/188)
Do not want to take pills because I cannot remember	49% (129/264)	45% (79/175)	56% (50/89)	50% (38/76)	48% (91/188)
Do not want to take pills because someone will know I am taking them	30% (79/264)	33% (57/175)	25% (22/89)	42% (32/76)	25% (47/188)
Side effects of pills	18% (48/264)	19% (34/175)	16% (14/89)	17% (13/76)	19% (35/188)
Cannot take pills because my partner or friends will not let me	16% (41/264)	17% (30/175)	12% (11/89)	22% (17/76)	13% (24/188)
Other	6% (15/264)	5% (9/175)	7% (6/89)	4% (3/76)	6% (12/188)

CONTEXT FOR ADDING THE DAPIVIRINE RING TO THE DYNAMIC CHOICE HIV PREVENTION MODEL- 2024

Addition of CAB-LA to the Dynamic Choice HIV Prevention model increased biomedical prevention coverage to 70%

The SEARCH trial is built to accommodate and study more options for clients as they become available

Although the DPV Ring has lower efficacy than the other biomedical prevention options (may be higher with better adherence), it can reduce incident HIV infections

The DPV ring may be the only choice that is acceptable and works for some women.

SUMMARY

- SEARCH randomized trials showed that a person-centered model of dynamic choice HIV prevention offering oral PrEP, PEP and CAB-LA increased prevention coverage by five-fold and reduced HIV incidence.

Implementation research Learnings

- Choice is important;
 - Allows clients to make informed decisions about what works best for them
 - Respects client's needs and preferences
 - PEP is underutilized and can be a gateway to other prevention options
 - Additional options such as the Dapivirine ring could increase prevention coverage or expand the pie.
- For choice to be effective, it must be offered in a way that allows for flexibility
 - Providers must be trained on offering choice and empowering the client
 - Choices and HIV risk are dynamic



Implementation research Learnings

- Digital platforms are preferred to help navigate choices
- Provider access is Key for Counselling, advise, guidance on uptake and transitions
- Provider networking for linkages is crucial for continuity.
- Most common side effect observed with CAB LA was Injection site reactions. It helps to prepare clients to expect this.
- Sex preference of provider has been observed with Dapivirine ring

Acknowledgements

Study Participants and Communities

Republic of Kenya Ministry of Health, Republic of
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Diane Havlir, Moses Kanya, Maya Petersen – **Co-PIs**

SEARCH study team

University of California Berkeley

Maya Petersen
Laura Balzer
Josh Schwab

Infectious Diseases Research Collaboration,

Uganda

Jane Kabami
Elijah Kakande
Helen Sunday
Geoff Lavoy

Department of Medicine, Makerere University, Kampala

Moses R. Kanya

Kenya Medical Research Institute

James Ayieko
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Lessons from early introduction and research studies offering long-acting biomedical products for HIV prevention in South Africa

10 September 2024

Presentation overview

PrEP in South Africa

Introduction of biomedical HIV prevention

Coordination

Mapping of studies

Research priorities

Standardised implementation

Reporting and data collection

Summary data

Key lessons



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National context PrEP in South Africa lessons from oral PrEP implementation

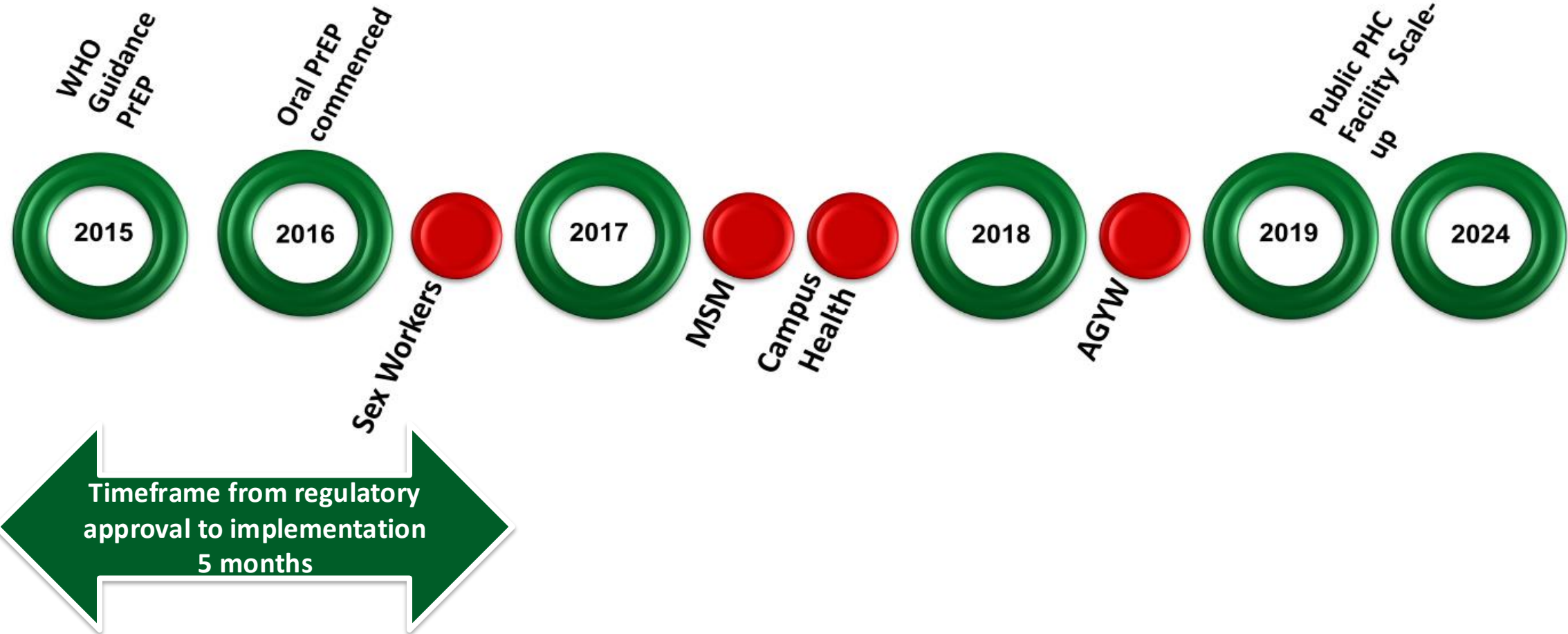


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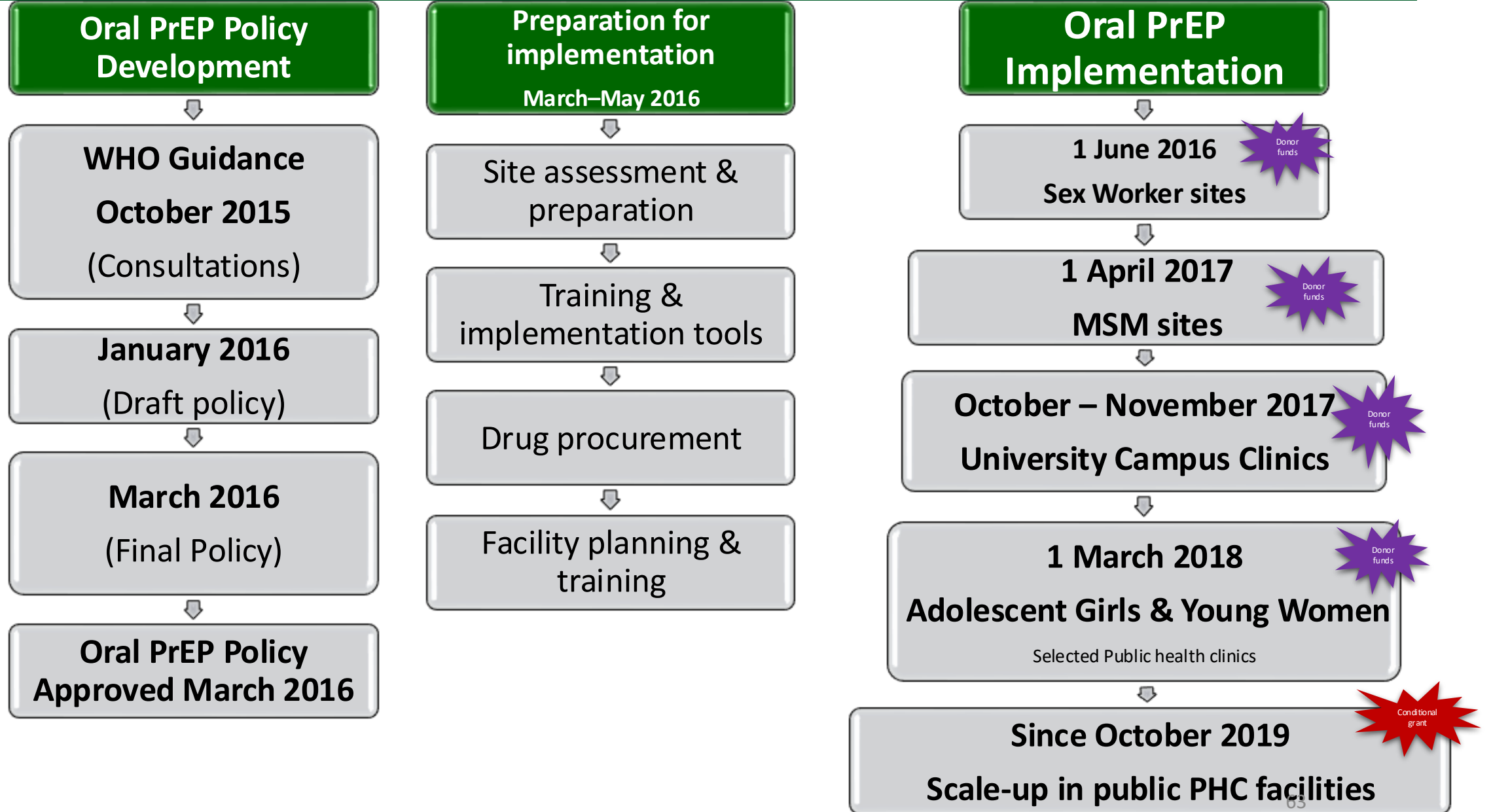
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Oral PrEP Implementation in South Africa 2016-2024



Oral PrEP Implementation Process 2015 – 2024



Methodology for annual oral PrEP initiation targets 2024-2025



INPUTS

- DHIS catchment area data: 3505 PHC facilities
- ICL/UCT district level HIV prevalence applied to catchment population
- Demand generation (adjustable input)
- HIV testing target (adjustable input)
- National PrEP M&E data (weighted average, 6.3%)
- National PrEP M&E data (20% of previous year's targets)

- Males & females age ≥ 15 years within catch. areas: **42.8m**
- HIV negative males and females age > 15 years: **35.3m**
- HIV negative males and females age ≥ 15 years, eligible for PrEP, reached with demand generation activities based on HIV incidence risk categorization: **7.7m**
- HIV negative males and females age ≥ 15 years to be tested (in alignment with 95-95-95): **7.3m**
- Oral PrEP targets calculated using national oral PrEP data: **401 430**
- Estimated continuations based on national oral PrEP data from previous year: **79 730**

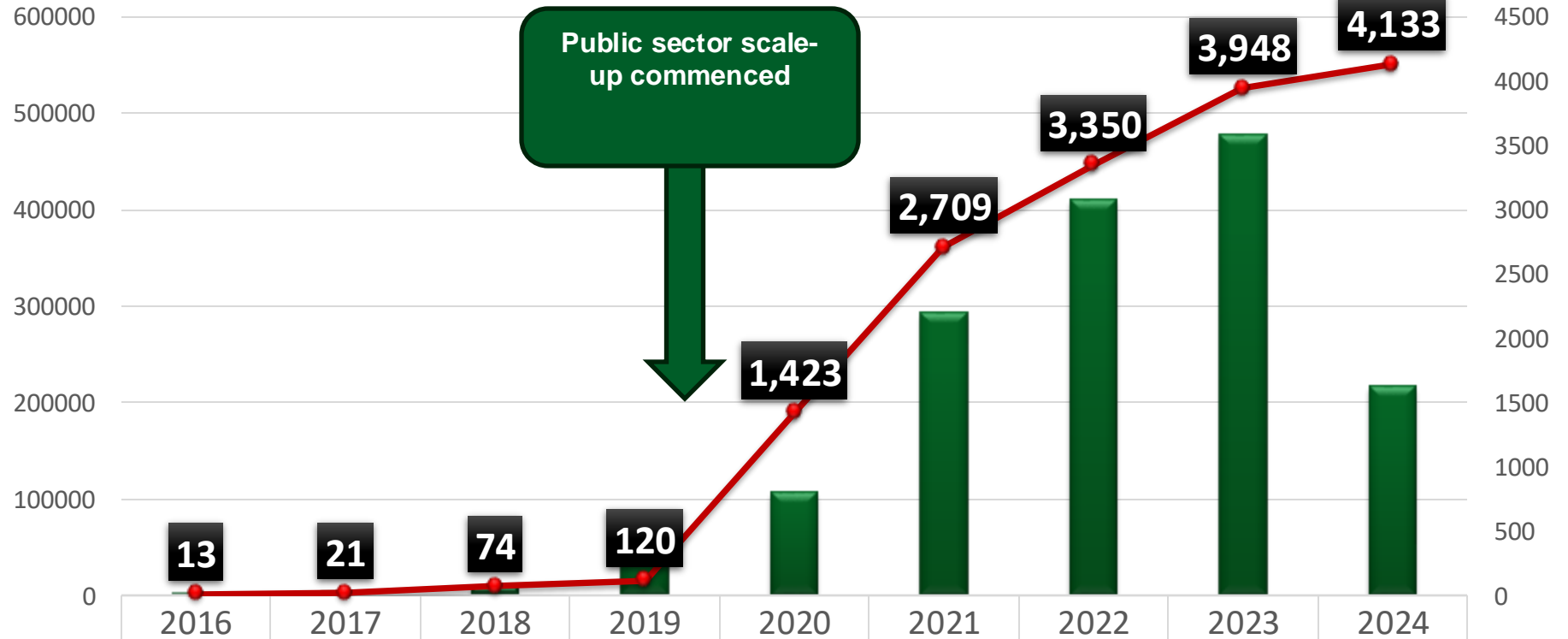
OUTPUTS

Oral PrEP Scale-up

**PrEP
initiations
1 566 145**

**94% public PHC
facilities offer
PrEP**

Oral PrEP Scale-up in South Africa 1 June 2016- 30 June 2024



Oral PrEP Initiations	771	3,196	8,593	45,576	106,402	293,019	409,750	477,267	216,288
Facilities Offering Oral PrEP	13	21	74	120	1,423	2,709	3,350	3,948	4,133

Introduction of biomedical HIV prevention products in South Africa



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Biomedical PrEP Products: Regulatory approval to implementation

Regulatory Approval & Policy	Implementation & Financial Planning	Service Delivery Preparation	Communication and Social Mobilisation
WHO PQ approval	Demand Forecasts and Impact Models	Develop National and Provincial Implementation Plans	Dev Social Mobilisation & Demand Generation Strategy
SAHPRA approval	Investment Case	Identify and delivery sites and health care providers required for delivery	Effective Interventions for Uptake & Continued Use
National Policy and Guidelines	Costing and Budget	Develop M&E Indicators and Systems	Development of communication, education and social mobilisation materials
National Health Council Approval	Procurement/ Supply Chain/Tender	Develop implementation tools, job aids & Training Materials	Commence implementation

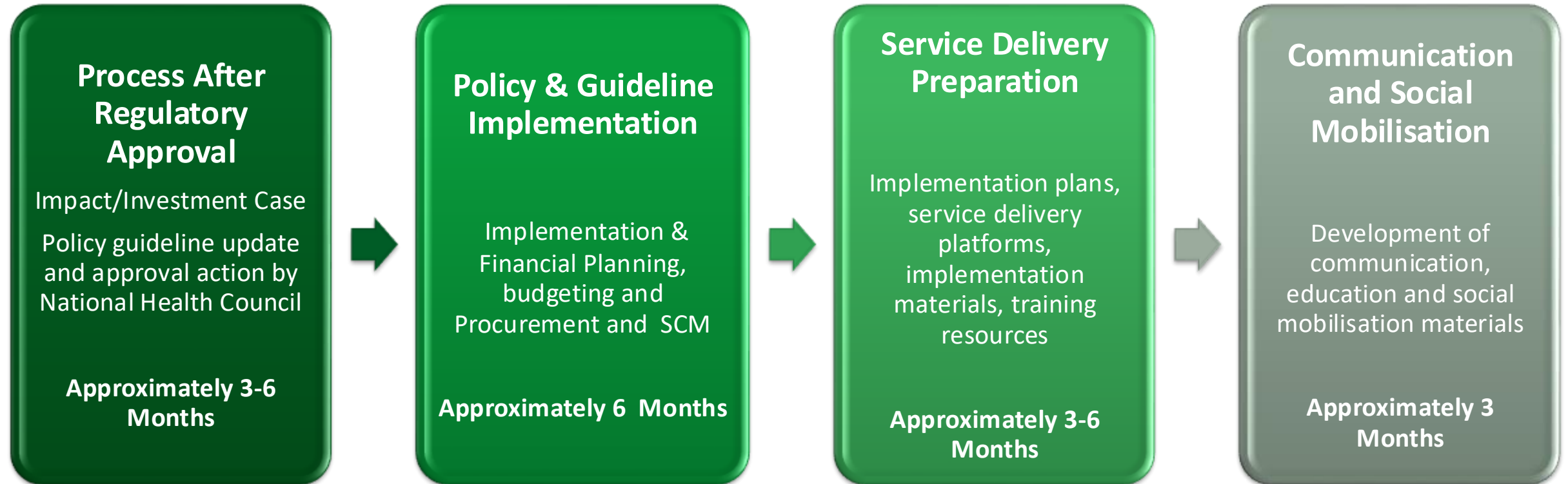


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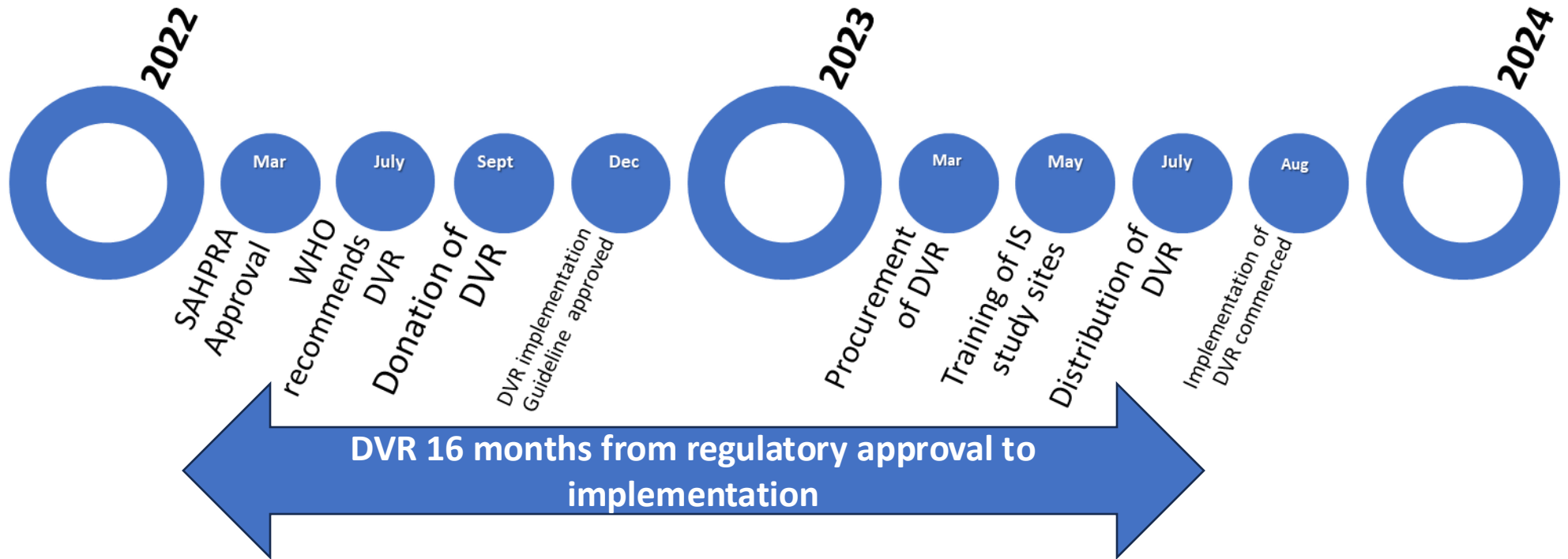
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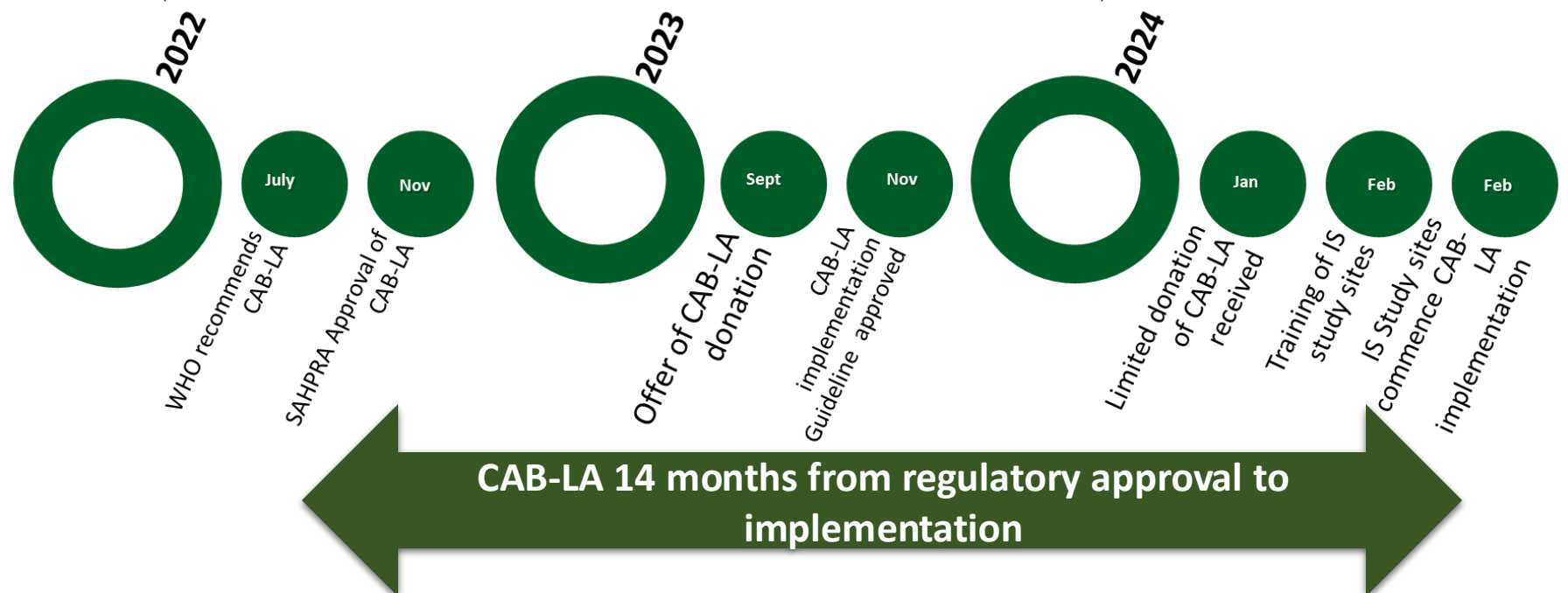
Estimated Time Frame for the Introduction/Inclusion of new Biomedical Products as an Additional HIV Prevention Option



Implementation dapivirine vaginal ring (DVR)



Implementation of cabotegravir long-acting injectable (CAB-LA)



Dapivirine vaginal ring and CAB-LA timeline from regulatory approval to early implementation

Dapivirine vaginal ring

- Guideline available 9 months after regulatory approval.
- Training conducted 5 months after guideline was approved (training delayed to coincide with product delivery)
- Product received 15 months after regulatory approval
- Implementation science studies commenced **16 months** after regulatory approved

Cabotegravir LA injectable

- Guideline available 11 months after regulatory approval.
- Training conducted 2 months after guideline was approved.
- Product received 13 months after regulatory approval.
- Implementation science studies commenced **14 months** after regulatory approved.

Oral PrEP

WHO released early guidance regarding oral PrEP September 2015
Regulatory approval December 2015 Guidelines approved March 2016,
Early implementation commenced on 1 June 2016 **5 months** after regulatory approval

Coordination of introduction of long-acting PrEP products in South Africa



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STAKEHOLDER MAP

Donors

Global Fund

*NACOSA

AFSA

Beyond Zero

USAID

MATCH, RTC, Broadreach, WRHI, Anova

CDC

TBHCA, SIN, Aurum

Unitaid

*WRHI

*DTHF

*AHRI

*Ezintsha

*HSRC

BMGF

*MOSAIC

HE²RO

WHO

SANAC

UNICEF

UNFPA

*MRC

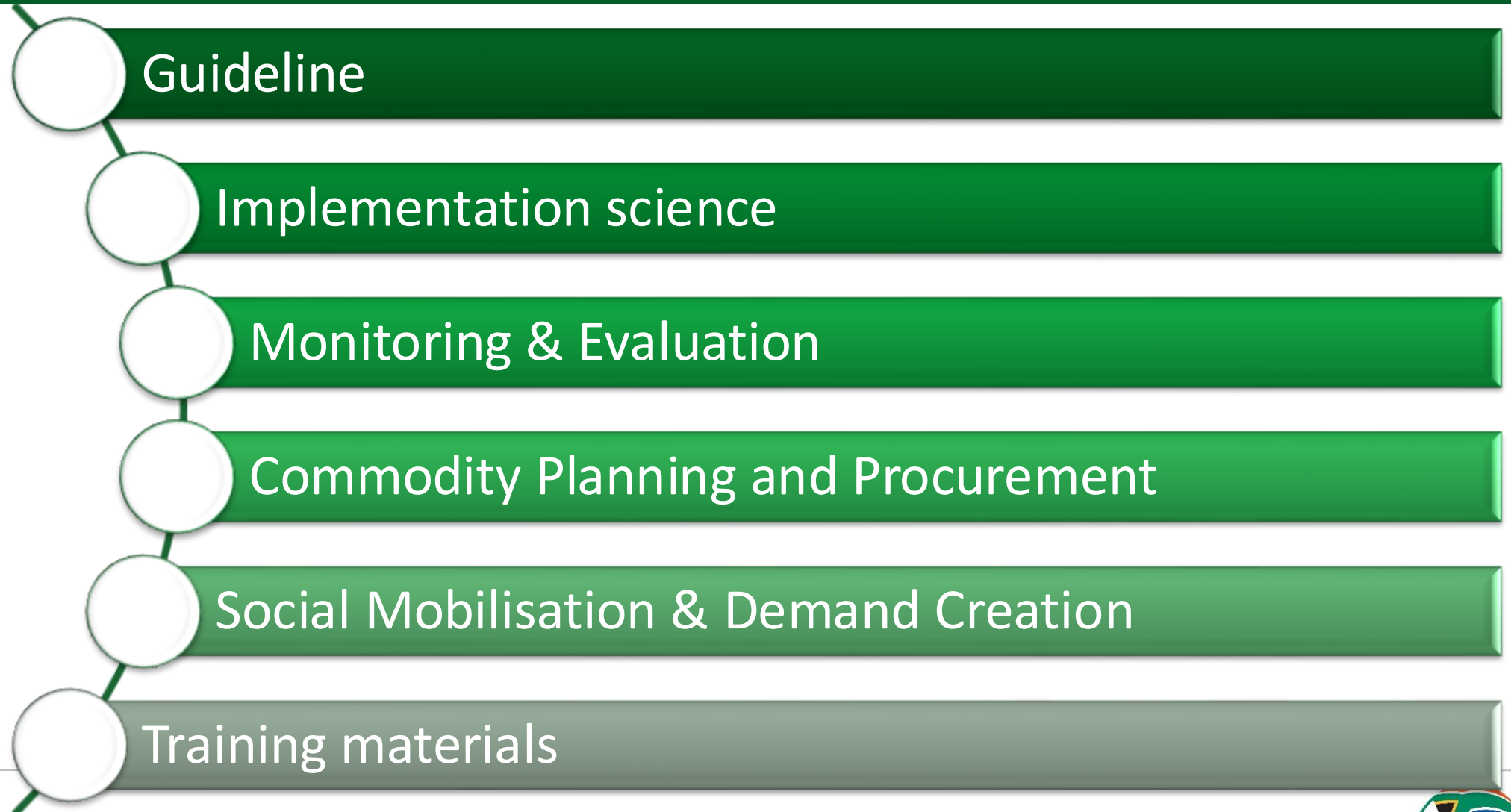
CHAI

Supporting Partners

* Partners conducting research

PrEP Technical Working Group

Working groups to support long-acting biomedical product introduction



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Study & pilot project location, research objectives, modality of delivery and research questions were mapped



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PrEP demonstration sites across regions in South Africa

The planned implementation science studies are spread across all 9 provinces and 18 districts representing a mix of urban, peri urban and rural settings.

Johannesburg Health District, Gauteng

Wits RHI, DREAMS
Wits RHI, CATALYST – Key Populations Sites (FSW and TNBP)
Wits RHI & Shandukani Research, Deliver & B-Protected

Tshwane, Gauteng

Wits RHI, Project PrEP
NACOSA, Global Fund*

Lejweleputswa (FS)

Wits RHI, CATALYST

Thabo Mofutsunyana (FS)

Beyond Zero, Global Fund*

Frances Baard (NC)

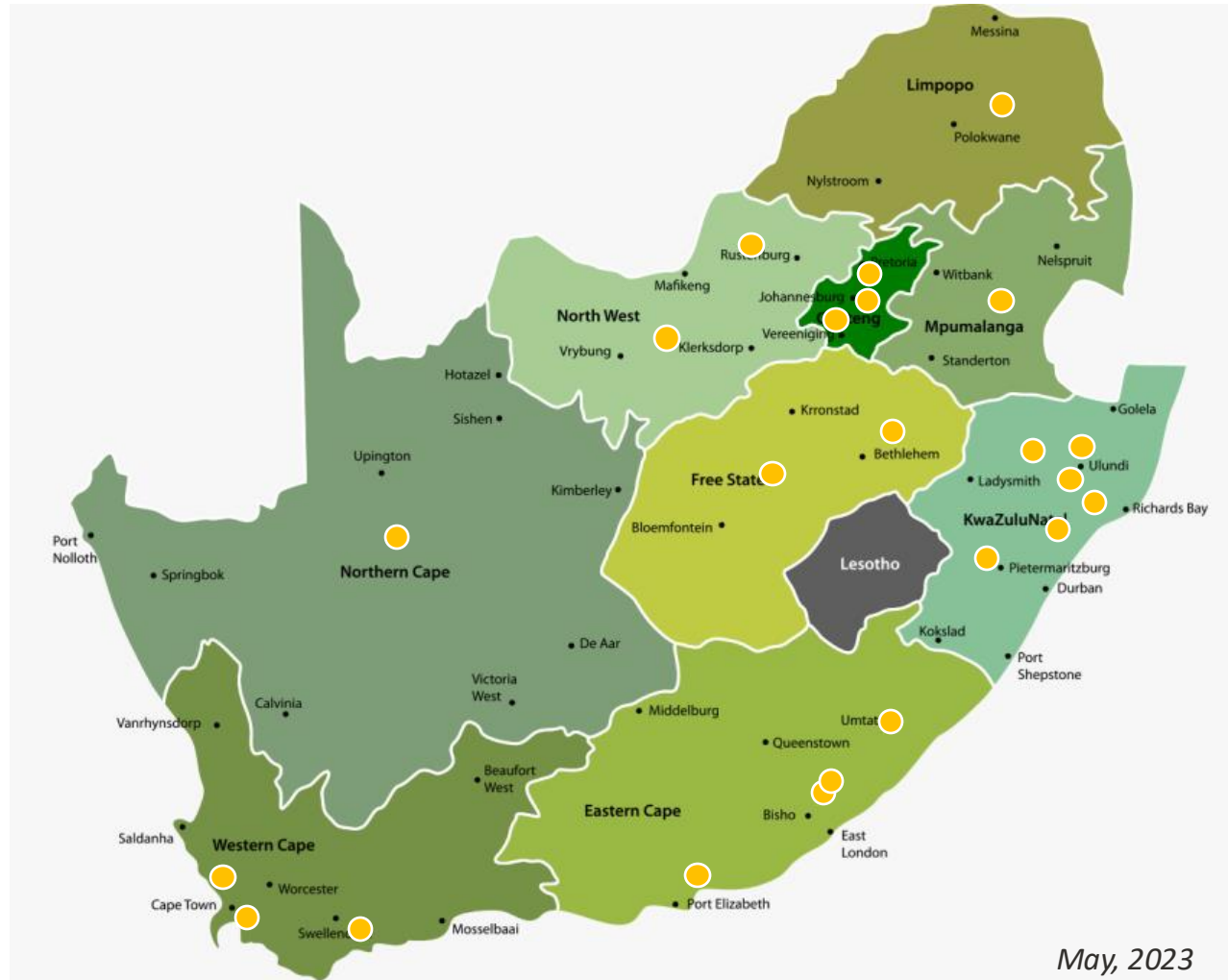
NACOSA, Global Fund*

Klipfontein Mitchell's Plain, Cape Town (WC)

DTHF, FastPrEP
NACOSA, Global Fund*
UTC, UCLA & DTHF, PrEP-PP & SCOPE-PP

Gqeberha

Wits RHI, Project PrEP



May, 2023

King Cetshwayo & Zululand (KZN); Ehlanzeni and Gert Sibande (MP), Sekhukhune (LP)

AfSA & Beyond Zero, Global Fund*

Newcastle, KZN and Moretele, Northwest

SA MRC & NACOSA, Imagine

Hlabisa, uMkhanyakude (KZN)

AHRI, Let's Talk & LAPIS

Msunduzi, Umgungundlovu (KZN)

HSRC & MGH, DO PrEP

eThekweni (KZN)

Wits RHI, Project PrEP

Nelson Mandela & Oliver Tambo (EC)

Beyond Zero, Global Fund*

Nelson Mandela, King Dalindyebo (EC)

Wits RHI, Project PrEP

Mthatha (EC)

Wits RHI, Project PrEP

*Global Fund funded program MyJourney or National SWP

Studies across PrEP methods

All of the implementation studies include either DVR and / or CAB-LA in addition to oral PrEP implementation.

Project Name	Oral PrEP	PrEP ring (DVR)	CAB PrEP (CAB-LA)	Sample size across PrEP methods	SAHPRA notification	IRB approval	NHRD approval
CATALYST	✓	✓	✓	1639 PrEP users across all three products in South Africa, of which 1440 DVR allocated for SA; TBC for CAB	Approved	Approved	Submitted, pending approval
Project PrEP	✓	✓	✓	7400 participants across all three products; estimated 1500 users on DVR, 2600 on CAB-LA, and 3300 on oral PrEP.	Approved for DVR in 2022	Approved March 2023	Approved for DVR March 2023
DREAMS	✓	✓		N/A	N/A	N/A	N/A
Deliver	✓	✓		N/A	N/A	N/A	N/A
B-Protected	✓	✓		N/A	N/A	N/A	N/A
Let's Talk & LAPIS	✓	✓	✓	26,000 15-30-year-olds; ~3000 PrEP users overall; 1300 CAB-LA and ~100 DVR - explore numbers of PrEP	In progress	Let's Talk approved LAPIS provisionally approved	Let's Talk approved LAPIS submitted
FastPrEP & PrEPared	✓	✓	✓	FastPrEP 20 000 young people for oral PrEP; 1800 on PrEPared to Choose sub-study DVR and CAB-LA	Submitted	Approved	Submitted, pending approval
DO PrEP	✓	✓	✓	2000 young people on oral PrEP (100 AGYW on ring; TBC for CAB)	N/A	N/A	N/A
My Journey	✓	✓		N/A	N/A	N/A	N/A
National SWP	✓	✓		N/A	N/A	N/A	N/A
Imagine	✓	✓	✓	N/A	N/A	N/A	N/A
PrEP-PP	✓			1306 pregnant and postpartum women	5 August 2019	October 2018 & yearly	May 2019
SCOPE-PP	✓			850 women	N/A	April 2022 & yearly	June 2022

Studies across target populations

Implementation studies focus primarily on AGYW, with some other priority groups included as end users. Only a few studies also include PrEP influencers as a target population for monitoring and evaluation.

	END USERS							PrEP INFLUENCERS				
	Adolescent girls and young women (AGYW)	Adolescents and young people (AYP)	Pregnant and breastfeeding people (PBF) and their infants	Female sex workers (FSW)	Women engaged in transactional sex	Transgender and nonbinary people (TNBP)	Men who have sex with men (MSM)	Male partners (e.g., of AGYW)	Providers and other site staff	Partners	Parents and / or caregivers	Community-based orgs. and other community leaders
CATALYST	✓		✓	✓	✓	✓			✓	✓	✓	✓
Project PrEP	✓	✓	**			✓		✓	✓	✓	✓	✓
DREAMS	✓								✓			✓
Deliver			✓									
B-Protected			✓									
Let's Talk & LAPIS		✓		✓	✓	✓	✓		✓			✓
FastPrEP & PrEPared to Choose	✓		✓			✓	✓	✓	✓			✓
DO PrEP		✓	**		✓		✓	✓	✓			✓
My Journey	✓											
National SWP				✓								
Imagine	✓		*									
PrEP-PP			✓						✓			
SCOPE-PP			✓						✓	✓		

* Included in the study for SRH services; however not a target population for PrEP initiation.

** Will track pregnancy outcomes if an end user falls pregnant while on PrEP.

Studies across PrEP delivery channels

Demonstration sites also cover a variety of delivery channels, with a focus on differentiated service delivery.

Project Name	Priority delivery channel approach	Fixed public HIV / ART clinics	Public mobile clinics	Community-based models	Nonprofit health clinics	Private health clinics / pharmacies	SRH / FP services
CATALYST	PEPFAR / USAID-funded public HIV facilities and NGO implementing partner (IP) sites that align with NDOH guidelines.	✓			✓		
Project PrEP	Fixed public health facilities and mobile clinics, including fixed decentralized service points for comprehensive SRH services.	✓	✓	✓		✓	✓
DREAMS	Public mobile clinics linked to community-based sites (secondary schools, TVETs, Universities, and layering in DREAMS IPs).	✓	✓	✓	✓		✓
Deliver	Wits RHI with connection to a private health facility.				✓	✓	
B-Protected	Wits RHI with connection to a private health facility.				✓	✓	
Let's Talk & LAPIS	Community models with peer navigators, nurse-led mobile clinics and fixed public facilities with connection to existing NDOH models.	✓		✓			✓
FastPrEP & PrEPared to Choose	PrEP initiation through public health facilities and community-focused models (e.g., mobile clinics, local clinics, schools, courier service, youth clubs, quick PrEP depots at pharmacies).	✓	✓	✓	✓	✓	
DO PrEP	Community-based delivery with linkages to public HIV facility and mobile.	✓	✓	✓			✓
My Journey	Integration in provincial DOH facilities and through community mobile units with a registered nurse.	✓	✓				
National SWP	Mobile clinics in hotspot areas and linked to provincial DOH facilities.	✓	✓				
Imagine	In-school youth friendly clinic and social spaces that also offer SRH services through social impact funding models.			✓			✓
PrEP-PP	Fixed public HIV clinics and community health centers (CHCs)	✓		✓			✓
SCOPE-PP	Public fixed HIV clinics with integration into ANC/PNC as well as community-based models.	✓		✓			✓

Primary PrEP delivery channel
 Connection to private or public HIV facility
 Linkage for follow-up support

Research priorities for long-acting PrEP products were identified including priorities for the essential medicines list (EML)



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Research priorities across implementation studies

PrEP Introduction Framework

Key questions for the Essential Medicines Committee

PLANNING & BUDGETING

1. **What is an affordable price and cost of PrEP delivery across multiple PrEP products?**

SUPPLY CHAIN MANAGEMENT - *Primarily answered through secondary research after implementation studies are complete*

PREP DELIVERY PLATFORMS

2. Which **delivery platforms and / or models** will best reach populations who need PrEP?
3. What are the **service readiness and delivery requirements** for the new PrEP methods?
4. What are **provider attitudes and beliefs** about the new PrEP methods, and what are we learning about how to inform or shape them?
5. How should the new PrEP methods be **integrated within oral PrEP provision** and / or existing PrEP programming?

UPTAKE & EFFECTIVE USE

6. Which **demand generation strategies** are most effective to support uptake and effective use of the new PrEP methods?
7. What are **end user preferences** across PrEP methods and how are they making decisions between them?
8. How do **key influencers** affect the uptake and effective use of the new PrEP methods, and how can they effectively be engaged?
9. **What evidence of social harms associated with PrEP use has emerged, particularly for the PrEP ring?**
10. What **tools effectively support choice** between the PrEP methods?
11. What approaches are most effective to **strengthen linkages between PEP and PrEP?**

MONITORING, EVALUATION & LEARNING

12. **What is the frequency and characteristics of seroconversion and HIV drug resistance for PrEP users across the new PrEP methods?**

Coverage of priority research questions

Question	# of studies	Summary
Q1 What is an affordable price and the cost of PrEP delivery across multiple PrEP products?	5	The cost of delivery will be widely assessed across delivery channels; there remains a gap for affordable pricing, particularly for CAB-LA.
Q2 Which delivery platforms and / or models will best reach populations who need PrEP?	10	The effectiveness of delivery channels to reach priority populations as well as the comparison across delivery platforms are widely covered.
Q3 What are the service readiness and delivery requirements for the new PrEP methods?	4	Several studies focusing on service readiness and delivery requirements for the new PrEP methods.
Q4 What are provider attitudes and beliefs about the new PrEP methods and what are we learning about how to inform or shape them?	6	Provider attitudes and beliefs will be widely assessed, with several studies including healthcare workers as a target population for evaluation.
Q5 How should the new PrEP methods be integrated within oral PrEP provision and / or existing PrEP programming?	4	Several studies focus on the integration of the new PrEP methods within oral PrEP provision; yet more coverage is needed across delivery channels.
Q6 Which demand generation strategies are most effective to support uptake and effective use of the new PrEP methods?	5	While each study includes demand generation approaches, only a few will assess the effectiveness of the strategies leveraged for PrEP uptake.
Q7 What are end user preferences across PrEP methods and how are they making decisions between them?	11	End user preferences (patterns of use, method switching, discontinuation and restart, etc.) are widely covered across all studies for all of the PrEP methods.
Q8 How do key influencers affect the uptake and effective use of the new PrEP methods, and how can they effectively be engaged?	8	A large number of the studies will focus on understanding key influencer attitudes and beliefs as well as how to effectively engage them.
Q9 What evidence of social harms associated with PrEP use has emerged, particularly for the PrEP ring?	9	Social harms will be tracked across several studies as a subcomponent for monitoring negative consequences of PrEP use.
Q10 What tools effectively support choice between the PrEP methods?	5	A few studies will study the effectiveness of support approaches for PrEP choice.
Q11 What approaches are most effective to strengthen linkages between PEP and PrEP ?	2	Only two studies will aim to strengthen the linkages between PEP and PrEP.
Q12 What is the frequency and characteristics of seroconversion and HIV drug resistance for PrEP users across the new PrEP methods?	9	PrEP efficacy across the methods for specific population groups as well as seroconversion and HIV drug resistance (HIVDR) data are widely tracked..

■ Significant coverage in studies (+6 studies)
 ■ Some studies address topic (3-5 studies)
 ■ 1-2 studies address topic

Standardised Ring and CAB-LA implementation guidelines, job aids, IEC materials, reporting tools and trainings were developed and used across all study and pilot sites.



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National Dapivirine Vaginal Ring implementation guidelines



Guidelines signed by Director-General
on 2 Dec 2022

Training aligned to guidelines

Clinical guidelines supported by
service delivery guidance and a
range of job aids to support
implementation



National CAB-LA Implementation Guidelines

Long Acting Injectable Cabotegravir
(CAB-LA)
National Implementation Guidelines

Version: 1 November 2023

Guidelines signed by Director-General
on 7 Dec 2023



Training aligned to guidelines

Clinical guidelines supported by service delivery guidance and a range of job aids to support implementation

Standardised recording, capturing & reporting



NDoH reporting tool: PrEP clinical form

PrEP clinical form

health NEW ZEALAND DEPARTMENT OF HEALTH		PrEP Clinical form (Initiation)								
First name	Folder #									
Surname	Phone #									
DOB dd / mm / yy	Gender: M / F / TG	Address								
ID Number										
<p>Instructions: Please use the below form to capture initiation, continuation, discontinuation, and re-initiation for ALL PrEP methods: Oral PrEP (TDF/FTC), Dapivirine ring (DVR), and Cabotegravir (CAB). If a client discontinues PrEP, continue the record with the corresponding date of discontinuation (section B). Should a client re-start or switch to another PrEP method, record with the corresponding date and PrEP method (section A), and all subsequent visits will be captured on this same form (section B). Additional clinical notes can be captured further below.</p>										
SECTION A: PrEP Initiation/Re-Initiation or Change of PrEP method										
Date of Visit	HIV Test Result	PrEP Counselling Conducted?	PrEP Baseline Assessments				PrEP method (select one):			
			Weight (kg)	Pregnancy	Hepatitis B	STI Screening		Creatinine (eGFR/sCr)		
/ /	+/-	Y/N		+/-/NA		+/-	TDF/FTC: DVR: CAB			
/ /	+/-	Y/N		+/-/NA		+/-	TDF/FTC: DVR: CAB			
/ /	+/-	Y/N		+/-/NA		+/-	TDF/FTC: DVR: CAB			
/ /	+/-	Y/N		+/-/NA		+/-	TDF/FTC: DVR: CAB			
/ /	+/-	Y/N		+/-/NA		+/-	TDF/FTC: DVR: CAB			
/ /	+/-	Y/N		+/-/NA		+/-	TDF/FTC: DVR: CAB			
/ /	+/-	Y/N		+/-/NA		+/-	TDF/FTC: DVR: CAB			
Original PrEP Initiation Date		/ /		Transfer in:						
				Date: / /		Clinic:				
SECTION B: PrEP continuation, monitoring and discontinuation										
# of months on PrEP	Next visit date:	Actual visit date:	PrEP Method (TDF/FTC, DVR, CAB)	Test results (if applicable)					Outcome (RIP, LTF, TFO, Sero, DNA, Disc)	Date of Outcome
				HIV Test	Weight (kg)	STI Screen	Pregnancy	Creatinine (eGFR/sCr)		
0	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
1	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
2	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
3	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
4	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
5	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
6	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
7	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
8	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
9	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
10	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
11	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
12	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
13	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
14	/ /	/ /	TDF/FTC: DVR: CAB	+/-		+/-	+/-/NA			/ /
Notes: Medical history/reason for discontinuation or change of PrEP method etc.										

NB: Please affix any copies of additional notes or laboratory results that are necessary.

PrEP clinical form

health NEW ZEALAND DEPARTMENT OF HEALTH		PrEP Clinical form			
First name					
Surname					
DOB	dd / mm / yy	Gender: M / F / TG			
ID Number					
History:					
Signature: _____		Date: _____			
Name: _____					

PrEP-HIV sero conversion form

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First name		Folder #	
Surname		Phone #	
DOB	dd / mm / yy	Gender:	M / F / TG
ID Number		Date of visit:	dd / mm / yy
Address			
<p>Instructions: Please use the form to document the circumstances/factors/situations pertaining to the seroconversion of the PrEP client. The available fields should be completed with the relevant information available at the time of reporting. Please complete and affix a copy of the PrEP clinical form and/or any relevant documentation.</p>			
PrEP drugs exposure before positive HIV test			
PrEP start date:	dd / mm / yy	Date of HIV+ Test:	dd / mm / yy
Drug name (s):			
PrEP History			
1. At the time of the positive test result, is the client still on PrEP?	<input type="checkbox"/> Y	Client is still on PrEP	Which PrEP method was used? <input type="checkbox"/> Oral <input type="checkbox"/> DVR <input type="checkbox"/> CAB LA
	<input type="checkbox"/> N	Client is still on PrEP	(Specify date when the last PrEP dose was taken): dd / mm / yy
2. In the last 3 months, has the client been taking/using PrEP effectively? i.e. without missing a dose or intermittent DV ring use or missed a Cab LA injection	<input type="checkbox"/> Oral PrEP <input type="checkbox"/> DVR <input type="checkbox"/> CAB LA		
	<input type="checkbox"/> 0	Never missed	<input type="checkbox"/> 0 Never missed
	<input type="checkbox"/> 1	Missed 1-6 days	<input type="checkbox"/> 1 Missed 1-28 days
<input type="checkbox"/> 2	Missed >7 Days	<input type="checkbox"/> 2 Missed >7 Days	<input type="checkbox"/> 2 Missed > 1 month
3. What is the clients partner/s HIV status?	<input type="checkbox"/> 1	Partner/s is HIV negative	<input type="checkbox"/> 3 Don't know partner/s HIV status
	<input type="checkbox"/> 2	Partner/s is HIV positive	
4. Did client use a condom with partner/s?	<input type="checkbox"/> 1	Always	<input type="checkbox"/> 2 Sometimes <input type="checkbox"/> 3 Never
5. Additional comments on circumstances relating to the seroconversion:			
Resistance Testing Results			
Date	Comments:		
dd / mm / yy			
dd / mm / yy			
dd / mm / yy			
Relevant medical history			

PrEP Register for Oral PrEP, DapiRing and CAB-LA

Aim: The aim of this register is to capture the Oral PrEP, DapiRing and CAB-LA initiations, continuations and outcomes.



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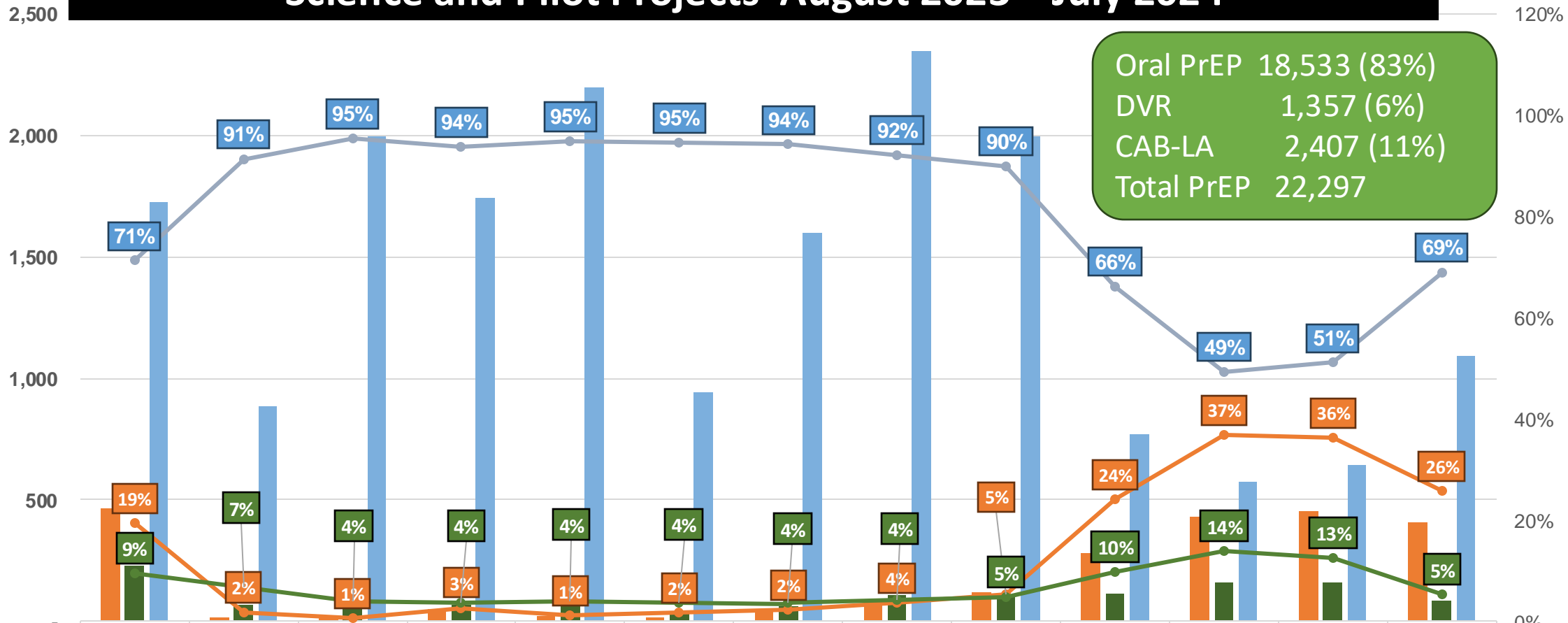
Fields Names	Instructions
	Do not populate field
Day	Select day between 1 and 31 from the drop down list.
Month	Select month between Jan and Dec from the drop down list.
Year	Select year between 2023 and 2027 from the drop down list.
Client Name	Enter the patient name and surname (e.g. Joe Bloggs).
Folder Number	Enter folder number as it is written on the patient file.
ID Number/Passport	Enter the patient ID Number or Passport (e.g. ID Number - 7503240000000, eg. Passport - A1234567)
Date of Birth	Enter the patient Date of Birth (Date of Birth 10/01/2002)
Gender	Select the gender from the drop down list (e.g. F=Female, M=Male or T=Transgender)
Age	Select the age from the drop down list (e.g. 0 - 14, 15 - 19, 20 - 24,)
HIV Test Result	Select HIV Tests Result from the drop down list (e.g. Pos = Positive or Neg = Negative)
Initiated on PrEP	Select the PrEP product that the client initiated on from the drop down (OP = Oral PrEP, Dring = Dapi-Ring, CAB = CAB-LA, DNI = Did not initiate)
STI Treatment	Was the patient treated for STI? (Yes/No)
Pregnant?	Was the patient treated for STI? (Yes, No or N/A (not applicable only applies for men))
Contraception (Type)	Select the contraception type that the patient is on at the time of the visit? (Oral, Injectable, Implant, IUD, F Condoms = Female Condoms, M Condoms = Male Condoms, N/A)
Continuation/Restart/TFI	Is the patient a Continuation, Restart or TFI (Transfer IN) ? Select from the drop down list.
Outcome (RIP/LTF/TFO/Sero/DNA/Disc)	What is the patient outcome? (RIP/LTF/TFO/Sero/DNA/Disc1/Disc2)
PrEP Switch PrEP Type	If the patient has switched the PrEP product type at the time of visit, select which product the client has switched to. (e.g. Switch to OP = Switch to Oral PreP, Switch to Dring = Switch to Dapi-Ring, Switch to CAB= Switch to CAB-LA)

Note:

Please note that implementing partners are required to submit one register per implementing site.

As soon as the register has been completed for the month, move to the PrEP Summary Export Steps tab for steps on how to export the PrEP Summary Reporting tab.

Uptake of PrEP: Oral PrEP, Dapivirine Ring and CAB-LA at Implementation Science and Pilot Projects August 2023 – July 2024



Oral PrEP 18,533 (83%)
 DVR 1,357 (6%)
 CAB-LA 2,407 (11%)
 Total PrEP 22,297

	Prior to Aug-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23	Jan-24	Feb-24	Mar-24	Apr-24	May-24	Jun-24	Jul-24
■ Total CAB	467	17	13	49	24	16	37	91	119	281	430	455	408
■ Total DRing	227	66	83	66	93	37	61	107	103	113	161	157	83
■ Total OP	1,724	887	2,000	1,747	2,201	942	1,602	2,347	1,998	772	576	641	1,096
—●— CAB Uptake	19%	2%	1%	3%	1%	2%	2%	4%	5%	24%	37%	36%	26%
—●— DRing Uptake	9%	7%	4%	4%	4%	4%	4%	4%	5%	10%	14%	13%	5%
—●— Oral PrEP Uptake	71%	91%	95%	94%	95%	95%	94%	92%	90%	66%	49%	51%	69%

Key lessons from implementation science and pilot projects

- Regulatory approval should preferably be for all populations
- The dosing regimens should be simple and uncomplicated
- Affordable prices for lower- and middle-income countries
- Certainty of supply following regulatory approval supply
- Donor support facilitates programmatic introduction
- Standardised implementation guidelines and training across all studies & pilots
- Guidelines, training and implementation resources for long-acting PrEP products can be developed and approved within a short period
- The delay in product availability for both the Ring and CAB-LA contributed to delays in implementation
- Donations of product should be centralised and made to ministry of health

Q&A

Thank you!