



Insights from New Product Introduction Support

SHARP: Strengthening the HIV Response with Precision Prevention

Dani Resar, CHAI

Project Background: Through SHARP, CHAI provides targeted technical assistance to countries accessing the PrEP Matching Fund, in partnership with selected country organizations



PrEP Matching Fund

Country	PrEP Matching Fund GC7 Eligible Amount (USD)
Kenya	\$3 M
Mozambique	\$3.75 M
Nigeria	\$6.5 M
South Africa	\$5.75 M
Uganda	\$3 M
Zambia	\$3 M

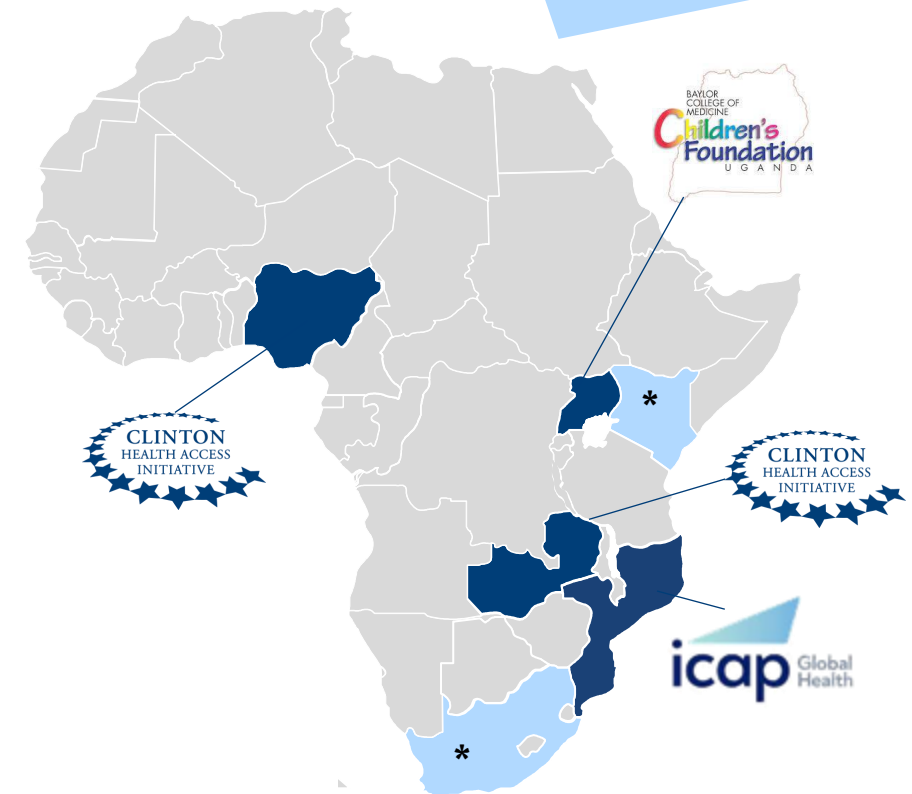
Accessed through the GC7 Global Fund allocation if countries meet **criteria***

- ✓ Plans to introduce new PrEP product (DVR and/or CAB-LA)
- ✓ Financial matching (1.5x eligible amt. put towards PrEP in GF allocation)
- ✓ Expansion of innovative demand and delivery models

*Non-exhaustive list

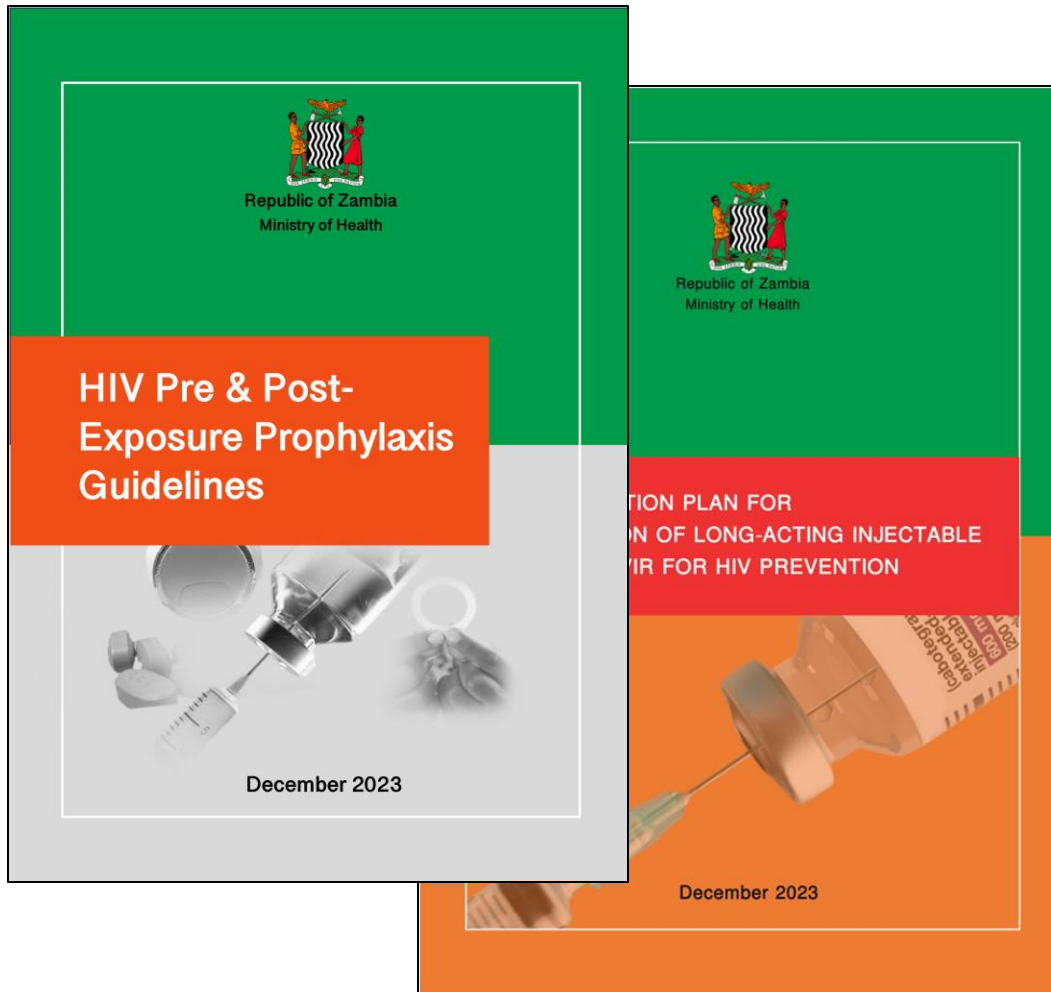
SHARP Technical Assistance

Technical assistance is flexible and defined based on Ministry-identified priorities



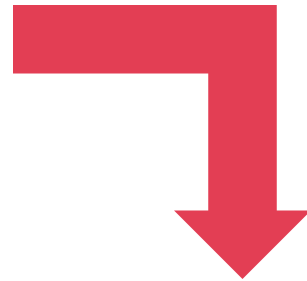
*Project is not yet active in Kenya or South Africa

Learning 1: Mechanisms for rapid policy / guideline updates are critical



- Activating **focused technical working groups / task forces / guideline development groups** for rapid updates is essential
- Needs for HIV treatment, testing, and prevention guideline updates may not emerge at the same time - **separate guidelines and/or focused addendums** may allow for more agile policy development
 - ... but it is essential that guidelines speak to one another*
- **Guideline revision processes should not be limited to new product updates** - for efficiency, countries should consider needs to update to broader PrEP guidelines (e.g., HIVST for oral PrEP)

Learning 2: Plan ahead for M&E for new products



Pre-exposure prophylaxis (PrEP)		
PRV.2 ●	Total PrEP recipients	Number of people who received PrEP at least once during the reporting period
PRV.3 (NEW)	PrEP coverage	% of people prescribed PrEP among those identified as being at elevated risk for HIV acquisition
PRV.4 (NEW) ●	Volume of PrEP prescribed	Total volume of PrEP product prescribed
Post-exposure prophylaxis (PEP)		
PRV.5 (NEW)	Number of PEP recipients	Number of people prescribed PEP during the reporting period
PRV.6 (NEW)	PEP completion	% of PEP recipients completing PEP course
PRV.7 (NEW)	HIV in PEP recipients	% of PEP recipients testing HIV-positive three months after PEP was prescribed

- New products often benefit from enhanced monitoring approaches, but **parallel reporting systems are unsustainable** and likely to create challenges as scale-up progresses
- Consider **multiple approaches for evidence generation** and evidence-based decision-making: enhanced data collection at sentinel sites, routine data, research studies
- Identifying a **minimum set of indicators** for integration into national M&E systems is critical
- Define success... but make it **prevention-specific!**

Learning 3: Strategize around commodity constraints



- While available volumes are limited, countries are making use of **PEPFAR-donated CAB-LA**, procurement through the **Global Fund**, and **implementation studies**. For example, Nigeria is complementing PEPFAR donation with Global Fund procurement
- When setting targets and quantifying commodities, consider **real-life use patterns ...** PrEP use is not always continuous
- Identify **evidence generation needs** to support wider scale delivery of injectable PrEP once more affordable generic options are available

Cabotegravir 200 mg/mL extended-release injectable suspension, 3mL single-dose vial, pack of 25 vials (Currently 0.0/5 Stars, 0 ratings)

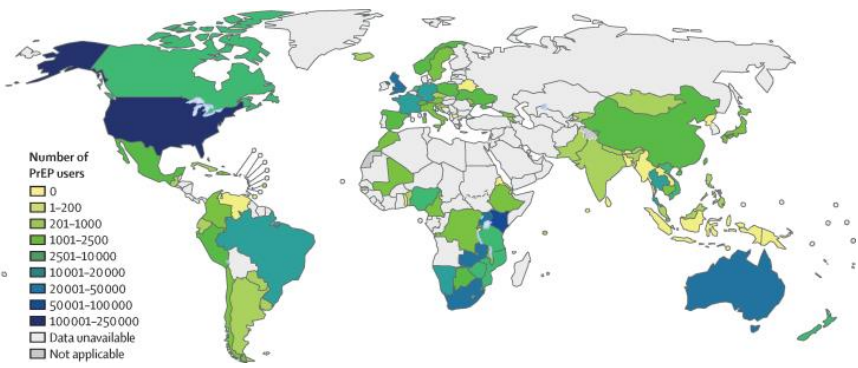
3mL single-dose vial, pack of 25 vials Cabotegravir 200 mg/mL extended-release injectable suspension,

Supplied by TGF-Stichting Iplussolutions 760.00 USD

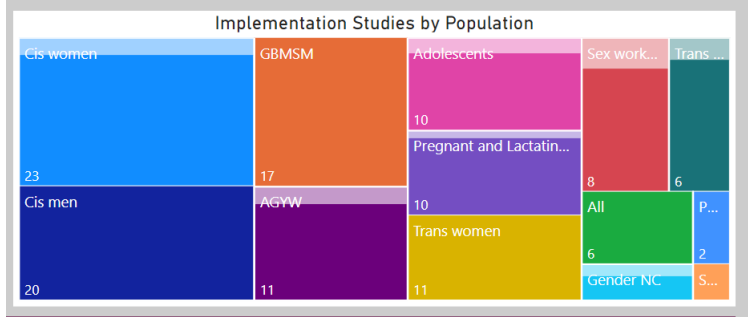
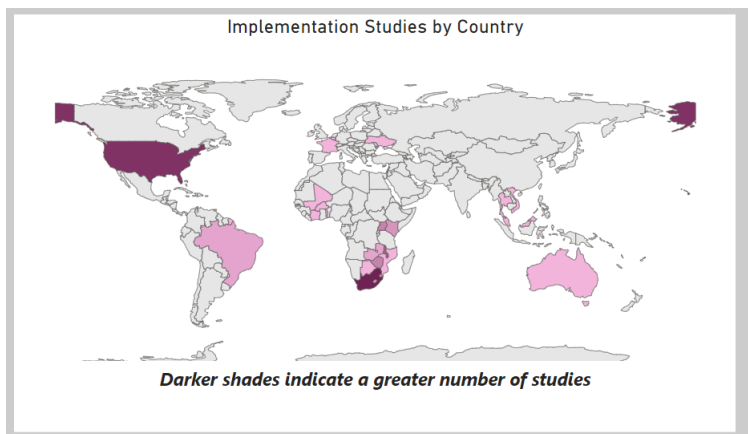
Supplier part | PLUS GENERIC-30418 1,000 Pack [Add to Cart](#)

Manufacturer None

Learning 4: Country specific approaches to accelerate introduction



- Is a formal study protocol required or can evidence be generated through programmatic delivery?
- If a study is required, what mechanisms can be implemented to support continuous data-sharing and interim learning? What broader adoption milestones should be considered when establishing study timelines (e.g., planned guideline revisions, procurement, tendering processes)?
- Following study completion and/or limited launch, how can expansion be accelerated? What does phased scale-up look like?
- Consider evidence generation on new products *and* health systems (what training approaches work best? Where can virtual platforms be leveraged? How can data back-logs be avoided?)



Learning 5: Don't forget about the rest of the PrEP program!



De-medicalizing PrEP: task-sharing, use of HIVST, decentralized delivery



Expanding delivery channels: pharmacies, one-stop-shops, youth-friendly services



Integrating PrEP delivery into other SRH services: contraception, STI, ANC/PNC



Strengthening M&E systems and data-driven decision-making: revising PrEP indicators, consolidating data, integrating reporting systems



Demand generation and community engagement to normalize PrEP use: virtual channels, peer support, social networks, community leaders



Provider training and referrals: what health system and non-health system entry points should be strengthened as points of PrEP referral? What other providers can be trained on PrEP? How can PrEP training be institutionalized?

THANK YOU!

ASANTE!

PrEP Matching Fund Partners:



Country Technical Assistance Partners:





MINISTRY OF HEALTH

Highlights from

Programmatic Rollout of CAB-LA in Zambia

Dr Chimika Phiri
August, 2024

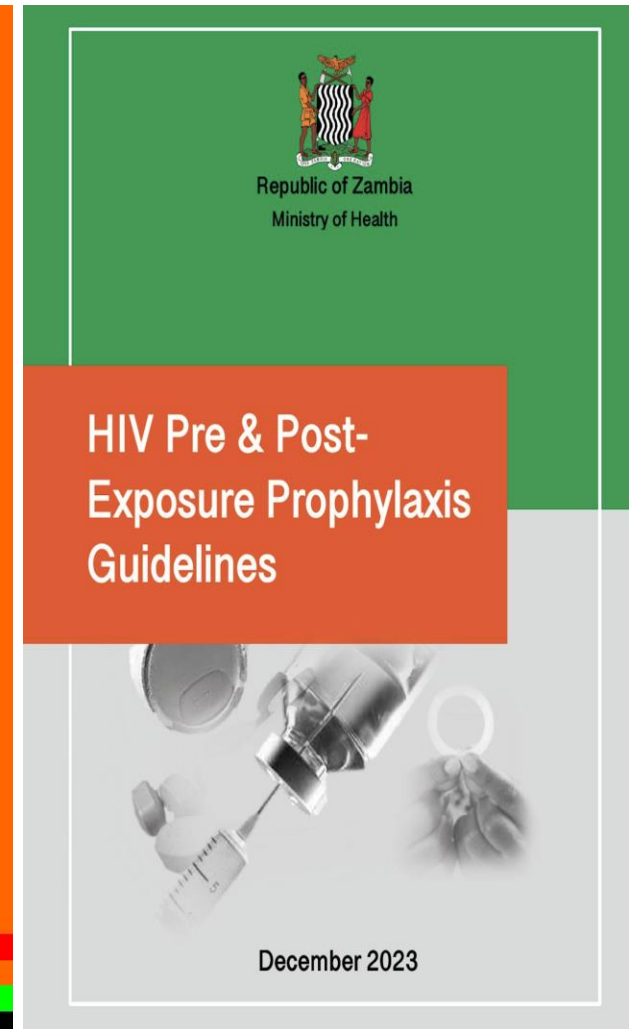
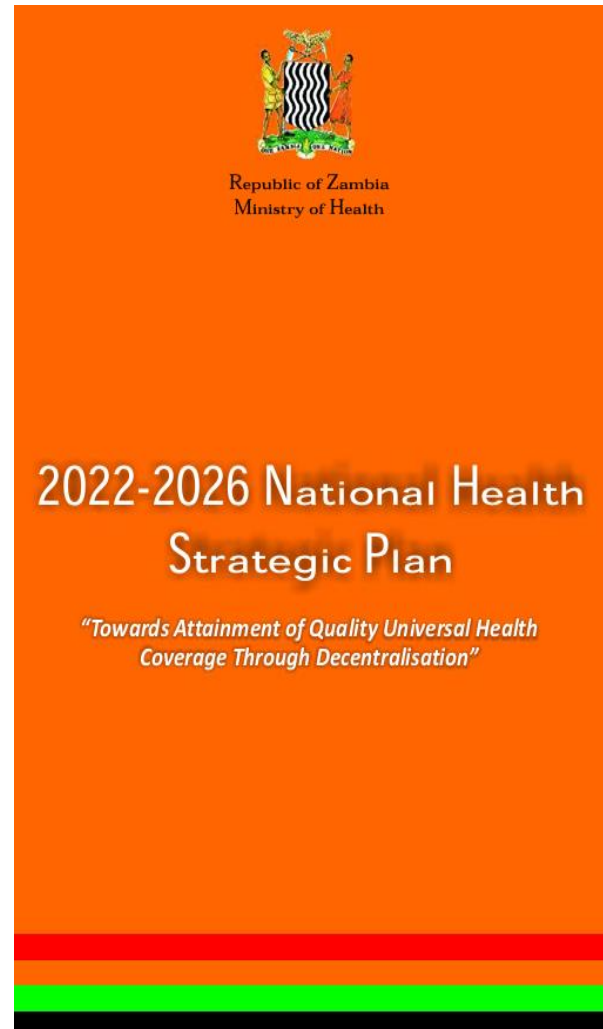


Presentation outline

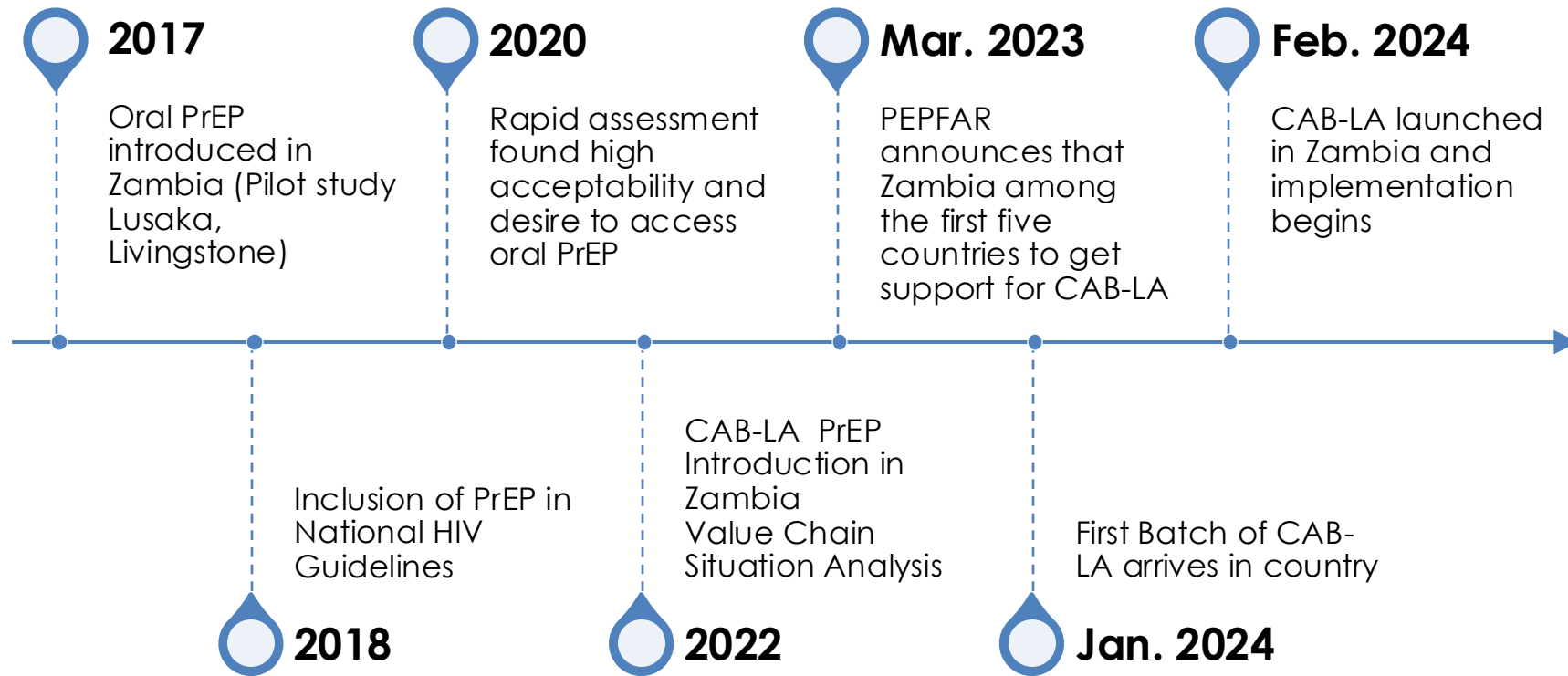
- PrEP introduction in Zambia
- CAB-LA introduction and Implementation Approach
- Best Practices on CAB LA roll-out
- Challenges in CAB-LA implementation

PrEP introduction in Zambia

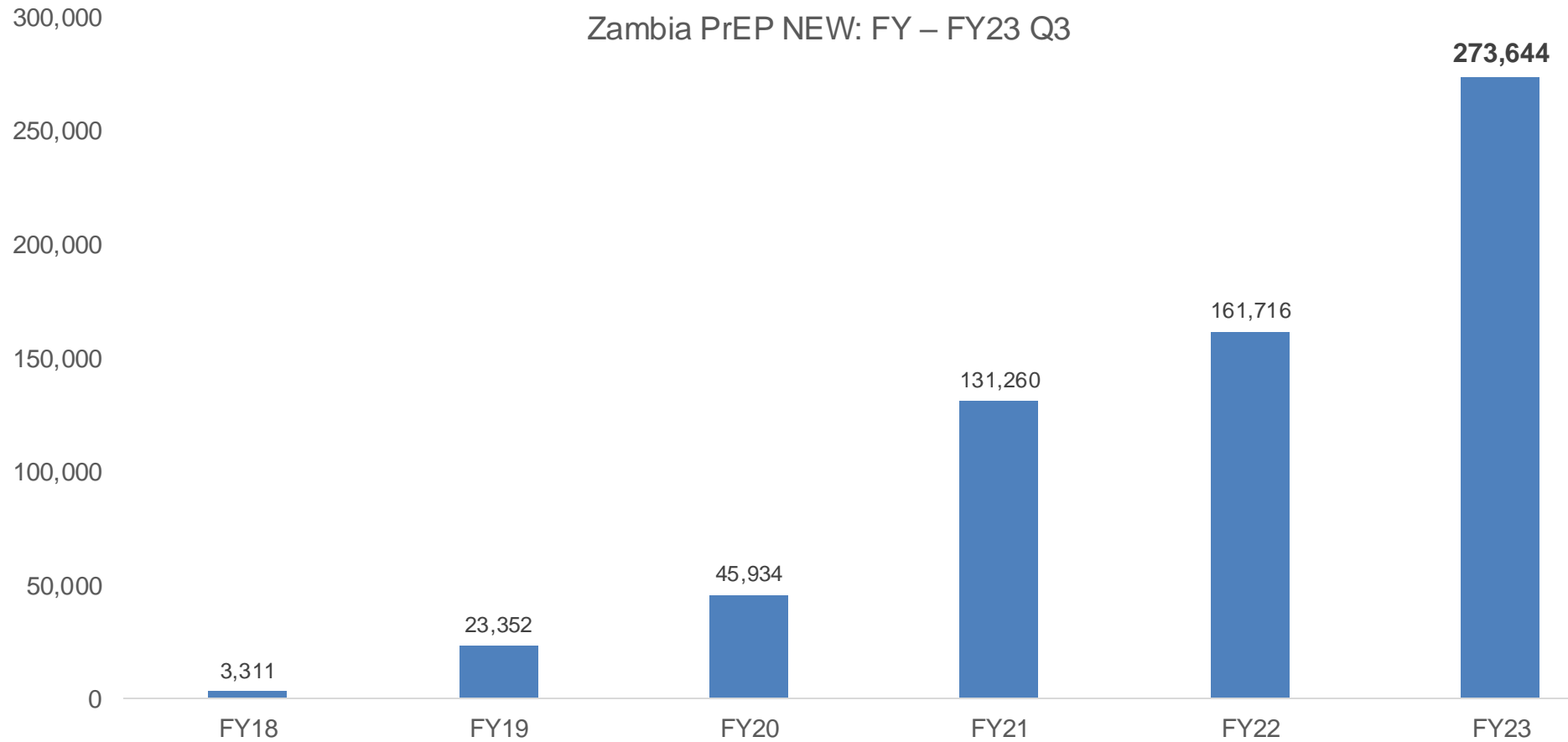
PrEP program implementation guided by key strategic policy documents to reduce new HIV infections to 18,000 from 30,000 (NHSP, NASF, ZCG, PREP guidelines)



PrEP introduction in Zambia

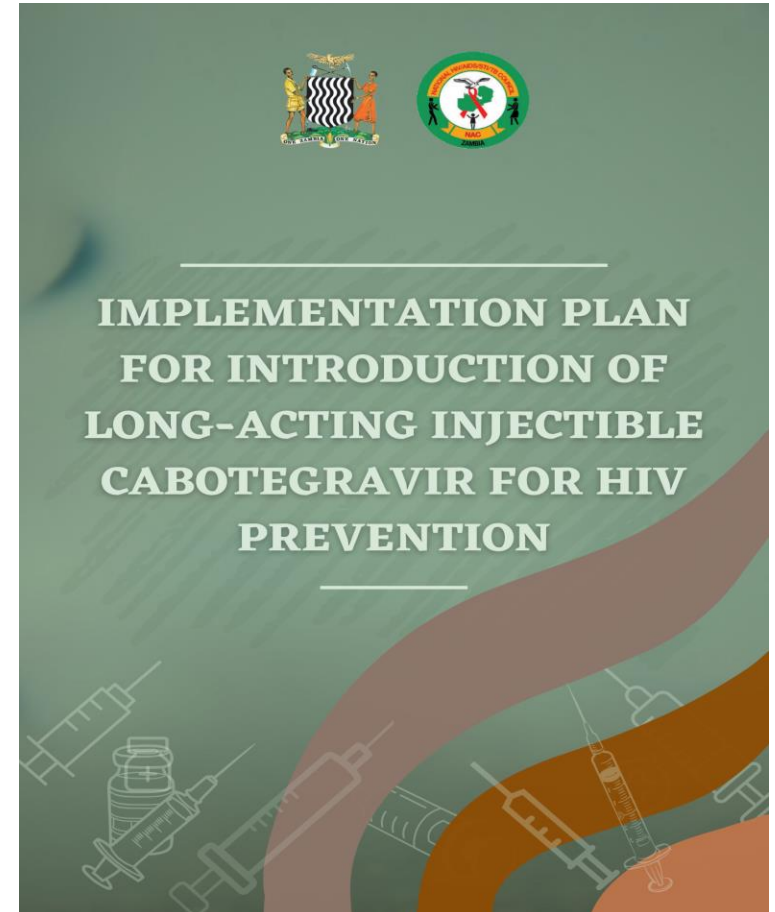


Zambia's PrEP story – from 4 sites to national coverage in 7 years!



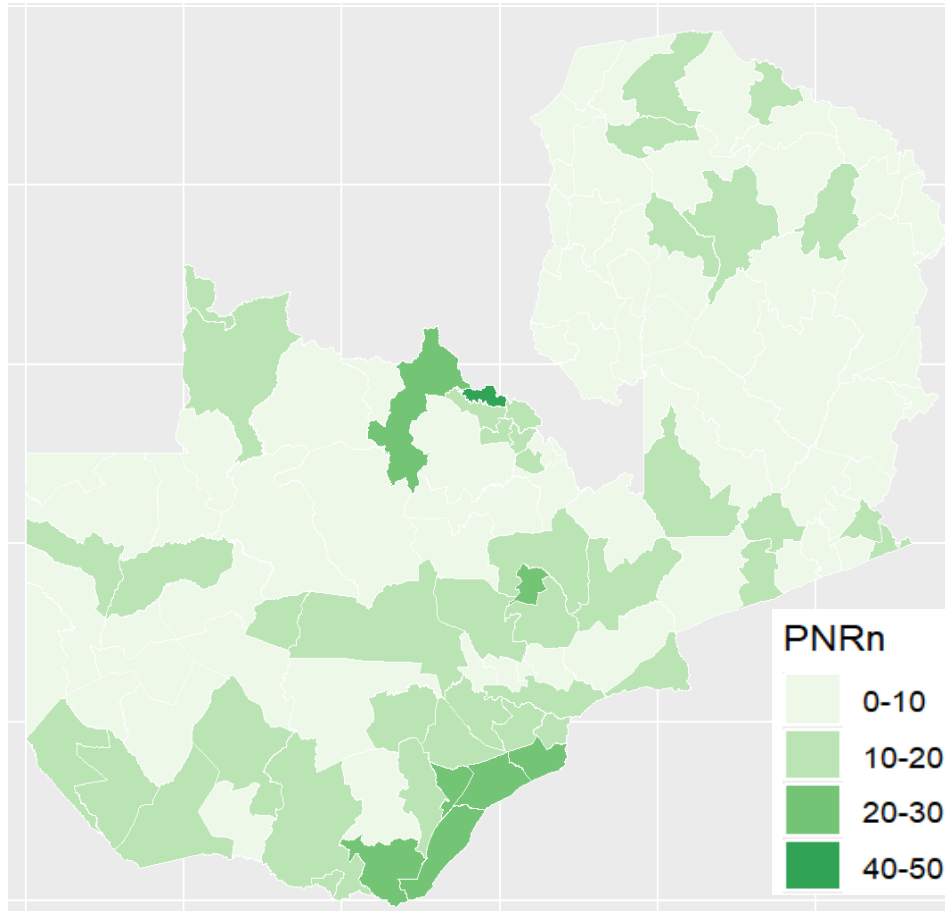
CAB LA Implementation approach

- Formation of Taskforce
- Value chain situation analysis to identify critical steps for the introduction of biomedical HIV prevention products
- Development of the implementation guidelines
- Essential Health Systems for Implementation
 - Demand Creation and User Support Recommendations
 - Supply chain management
 - Service Delivery
 - Human Resources



Description: Site Preparation & initiation criteria for CAB-LA

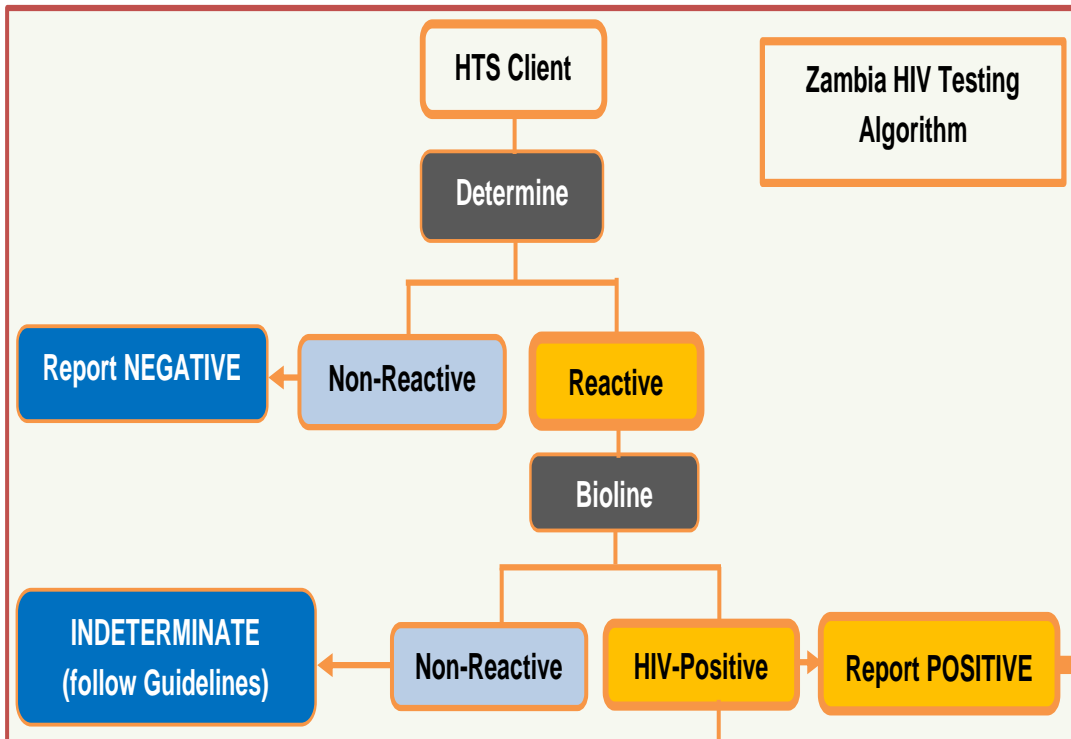
PrEP-Need-Ratio (New Infections)



- Phase 1 involved 9 sites
- Phase 2 has an additional 12 sites
- Selection based on PrEP Need- Ratio and the areas with high new infections were prioritized (shown on the Map)
- Training done for clinicians, nurses, laboratory and psychosocial counsellors

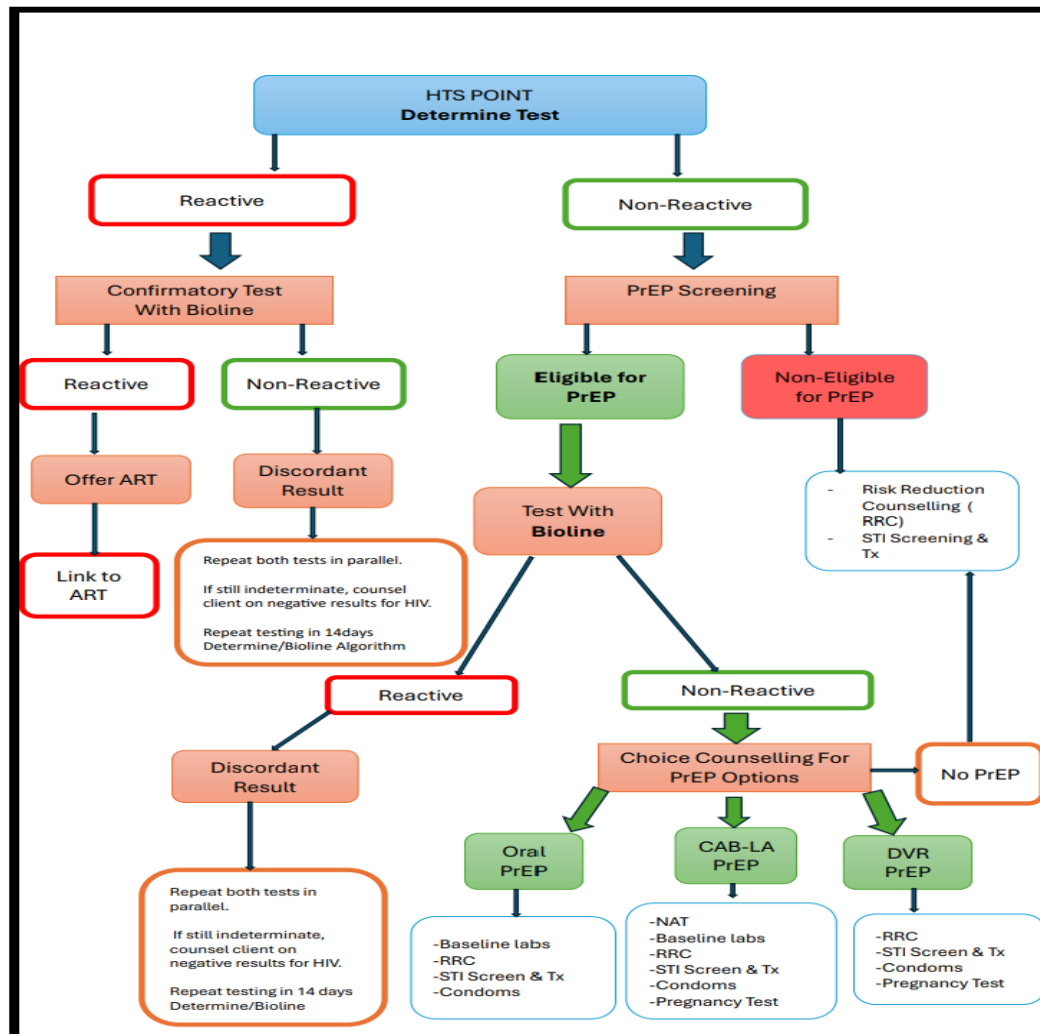
Clinical and Laboratory eligibility screening for CAB-LA

WHO recommend using routine HIV testing algorithm



- Screening for Acute HIV Infection (AHI) using paper-based tool
- HIV Testing
 - Standard national testing algorithm using rapid tests (A1: Determine HIV-1/2)
 - Blood sample collected for Nucleic Acid Amplification Test (NAAT)
 - NAAT not pre-requisite for injection initiation
 - If HIV RDT and AHI screening is negative → 1st CAB-LA initiation injection is administered
 - 2nd CAB-LA injection is given one month later after confirming continuation eligibility

Revised Testing Algorithm for PrEP initiation

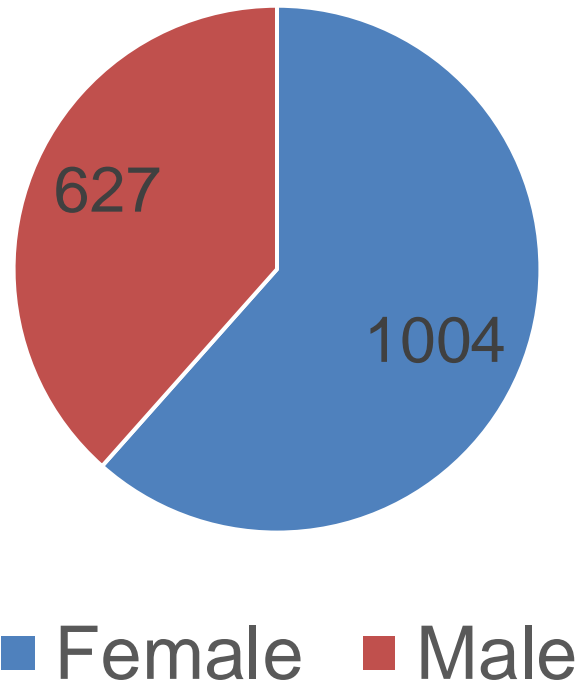


- Clients need two non-reactive HIV RDT tests to be initiated on PrEP (both oral and Injectable)
- For clients who chose CAB-LA, a blood sample for NAAT is collected (not a pre-requisite for initiation)

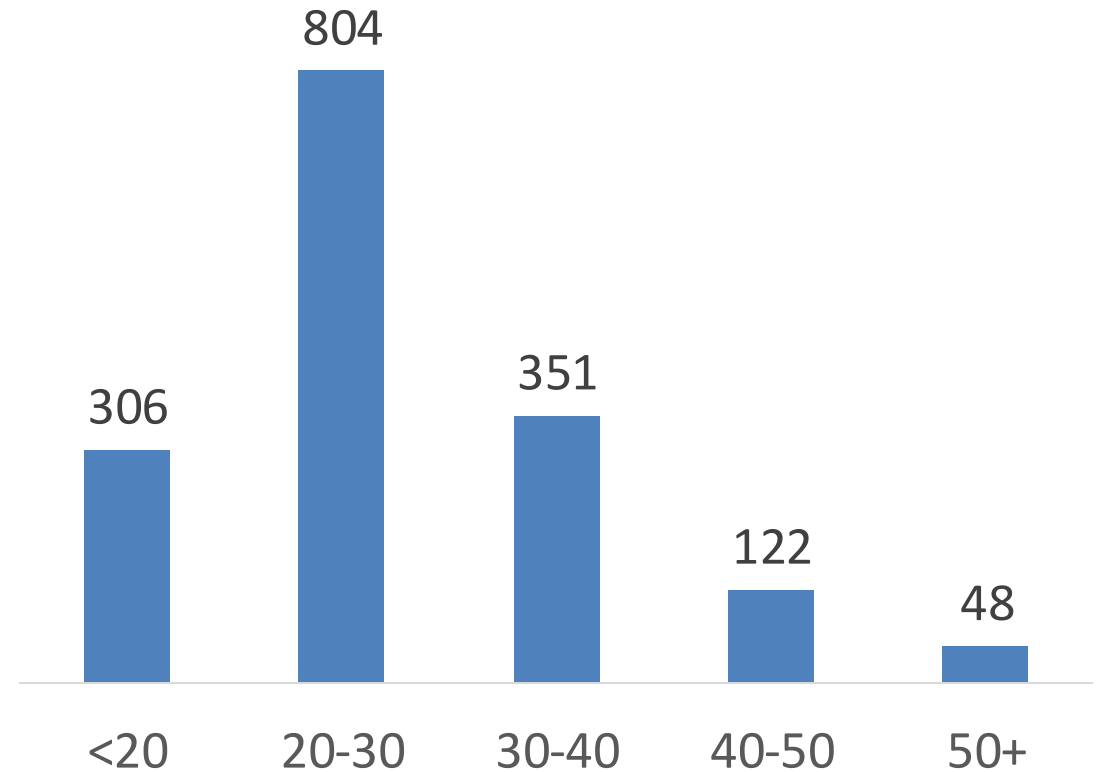


CAB-LA initiations-August 2024 (N=1631)

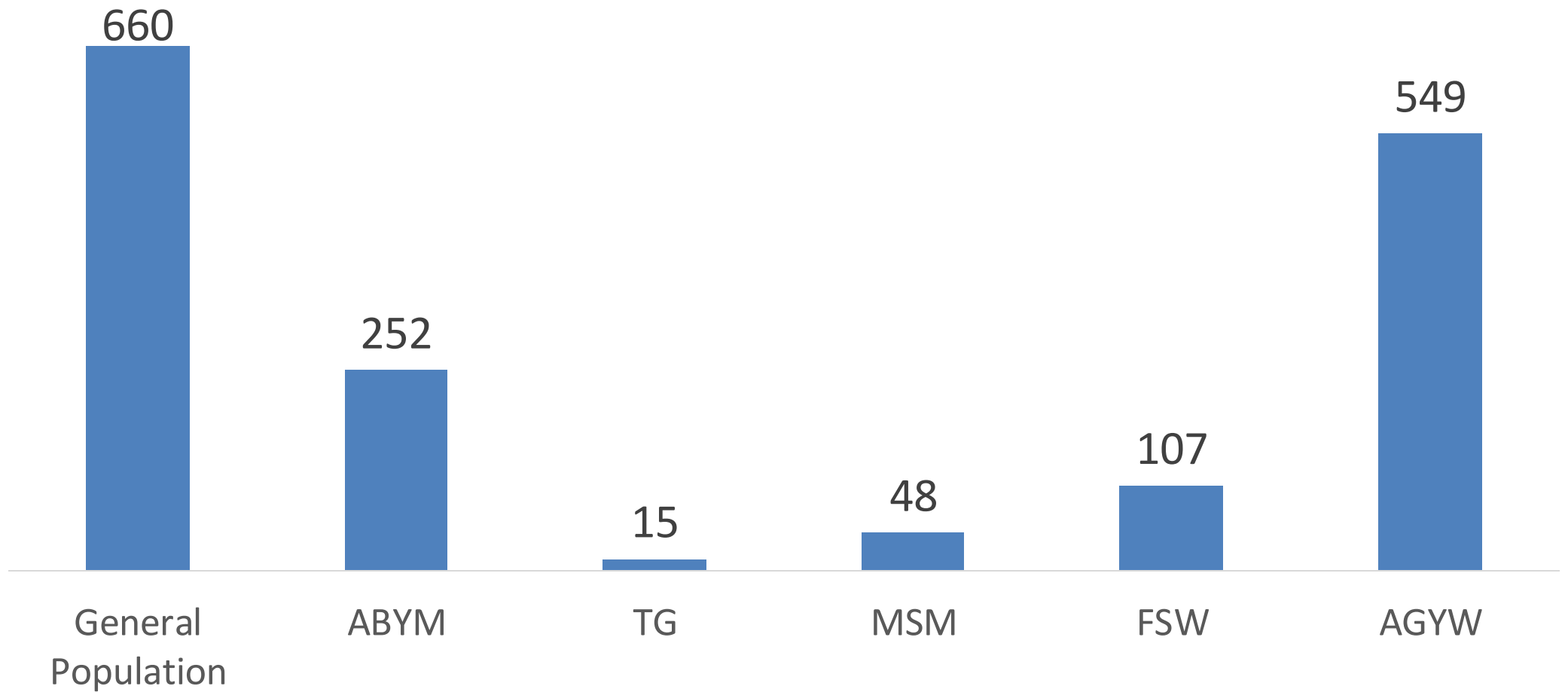
CAB-LA initiation by sex



CAB-LA Initiation by Age Group



CAB-LA initiation: By population-August 2024 (absolute figures)



CAB-LA Scale-up in Zambia: Best Practices



- **Enabling environment** and strong **leadership** by the Ministry of Health
- **Strong collaboration** between the PEPFAR, Ministry of Health, National HIV/AIDS/STI/TB Council, and Civil Society organizations
- Provision of PrEP as a layered service for Adolescent girls and young women (AGYW) in DREAMS
- Continued **capacity building** and **mentorship** for providers



Challenges

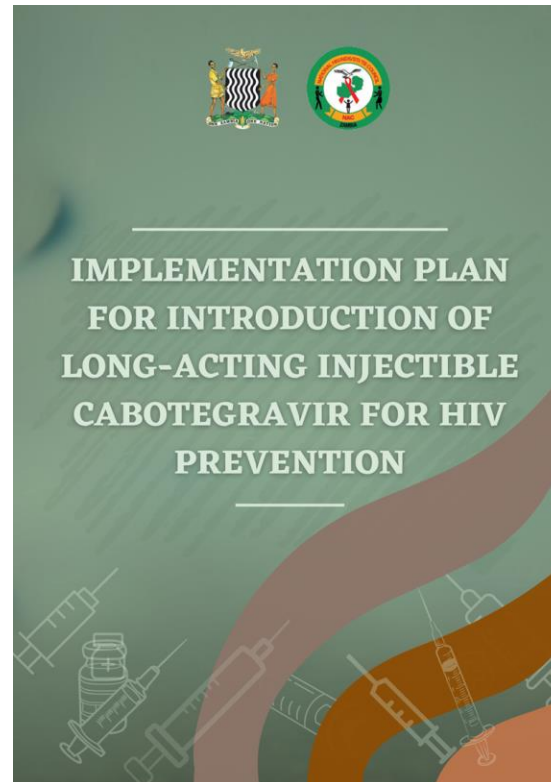
- AHI being missed following the WHO-recommended single Rapid HIV Negative test for PrEP initiation
- Unavailability of standard care for women with incident pregnancy and their babies with exposure to CAB-LA



Thank you!

Acknowledgements

- MOH
- NAC
- WHO
- USAID
- PEPFAR
- CDC

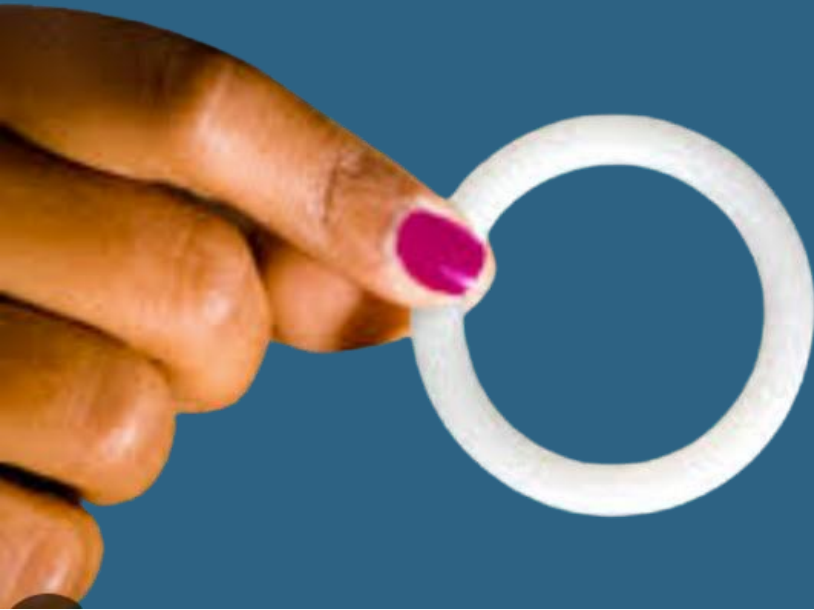


- Ciheb Zambia
- CIDRZ
- MOSAIC
- USAID CHEKUP II
- USAID ACTION-HIV

Introduction of new PrEP products in Eswatini

Sindy Matse
Ministry of Health

9 Sep 2024
Nairobi



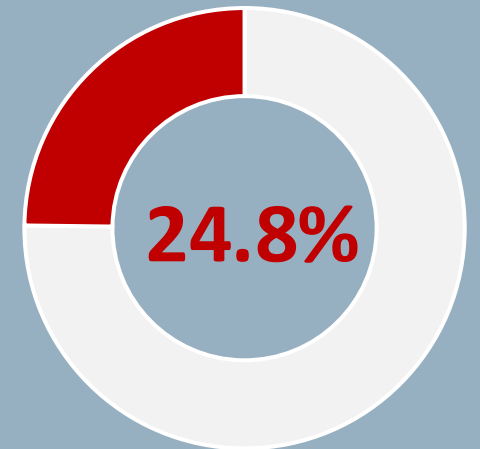
Introduction

- Despite a massive reduction of HIV incidence in the last decade, AGYW and PPs are still at high risk to acquire HIV infection in Eswatini.
- Similar to other countries, oral PrEP uptake and continuation is sub-optimal and the MoH is committed to make more PrEP products available to individuals who can benefit from PrEP.



Total population
1,160,164

National HIV prevalence
age 15+



HIV incidence 1.13

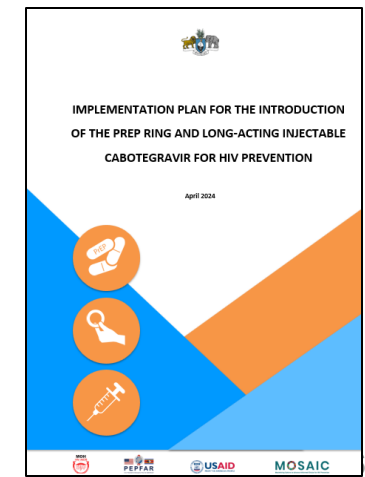
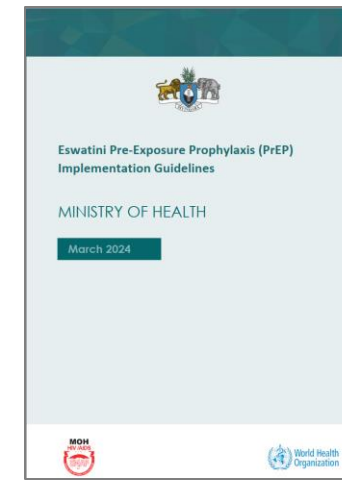
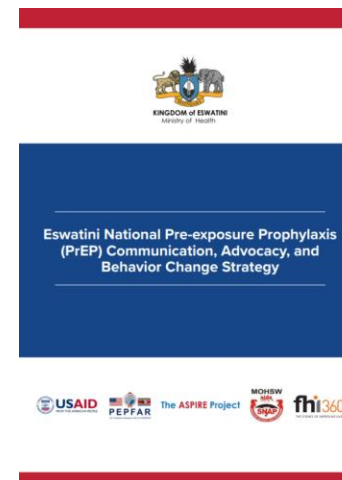
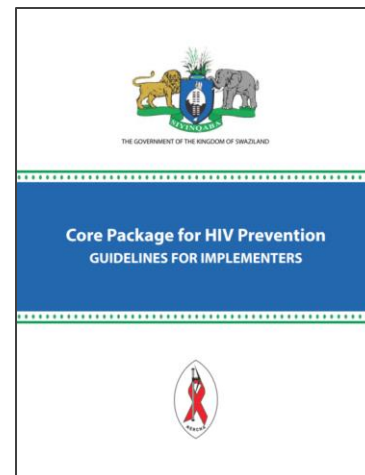
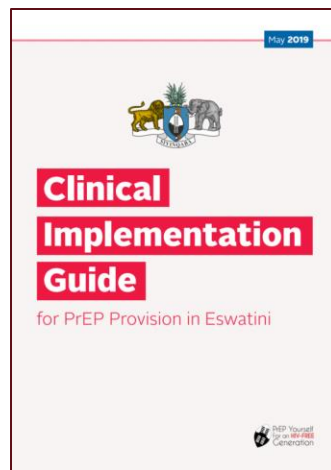
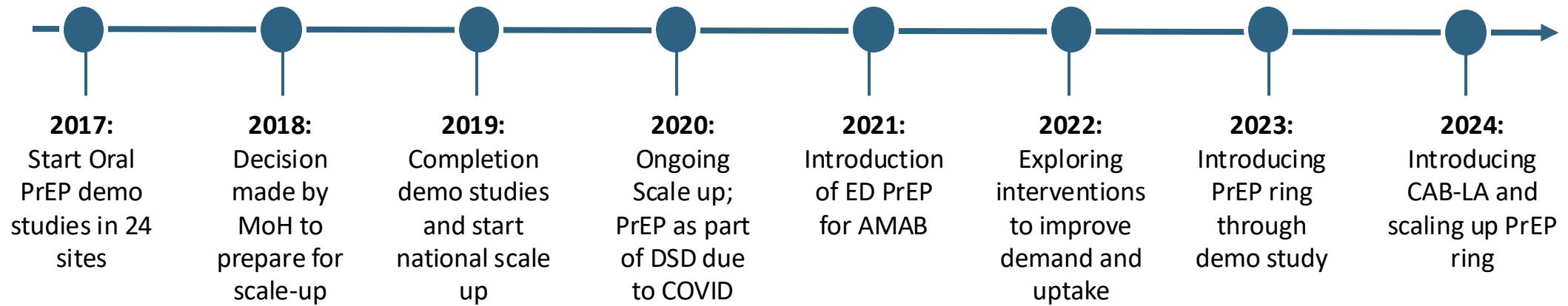


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Overview of the PrEP Program in Eswatini



Eswatini PrEP ring study overview

Study goal: To characterize and assess the feasibility, acceptability, uptake and patterns of use of an enhanced service delivery package providing fully informed choice of oral PrEP and the PrEP ring among women in Eswatini.

Objectives:

- Characterize the implementation of the service delivery package for informed PrEP choice for women and assess individual-, provider-, facility-, and health system-level facilitators and barriers of the implementation process.
- Describe patterns of PrEP use in the context of informed PrEP choice and assess sociodemographic and contraceptive use correlates of PrEP use patterns.
- Describe clinically relevant indicators among PrEP users, including rates of seroconversion and drug resistance among PrEP users who acquire HIV following PrEP exposure.



Prospective cohort study of women coming for HIV prevention services at **9** selected study sites.

Sample size: Open enrolment until ~end of **August** or until **750** women have been initiated on the ring.

Mixed-methods process evaluation involving implementers that will document implementation of an enhanced service delivery package, assess ongoing perceptions of service delivery among **providers** and **end users**, and document other important implementation considerations including the integration of PrEP and family planning (FP).





Early lessons learned

- Counselling on PrEP choice takes time but is important for users to be able to make an informed choice.
- High proportion of enrolled women chooses the PrEP ring
 - ring is only available through the study
- Reasons for choosing the ring includes:
 - Ease of use
 - No need to swallow pills
 - Discreet/partner won't know
- Majority of ring users (85%) says its easy to use
- Majority of clients satisfied with PrEP Choice service delivery

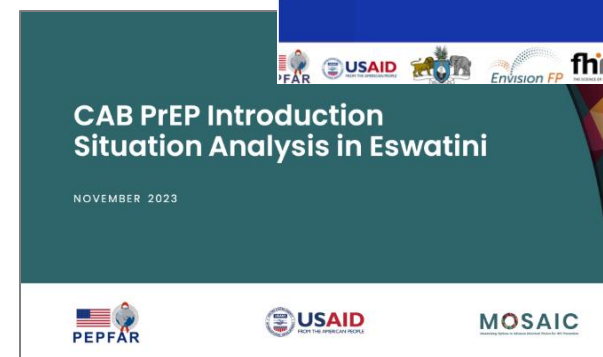


Stakeholder engagement

- The decision to introduce new PrEP products was informed by several consultative meetings with civil society, including AGYW and KPs.

Early lessons from ring study

- Since the start of the study, early lessons of the ring study have been shared at TWG's, PITT meetings and other stakeholder meetings.
- Lessons learned played an important role preparing for a national scale up.





Product introduction supported by PEPFAR and GF

- New products were included in the GF application.
 - Savings from GC6 were used to procure the PrEP ring
 - Small amount to procure CAB-LA under GC7
- Support from PEPFAR to procure CAB-LA for introduction of CAB prior to available funds from GF
 - Initial tranche of 4,250 vials received
- Ring study findings were used to make assumptions related to PrEP choice





Preparations for PrEP product introduction

- Adaptation of **Electronic Clients Monitoring Information System (CMIS)** to allow capturing of different products.

Create PrEP Enrollment

PrEP Eligibility Checklist Fields marked by ★ are mandatory.

Is willing/able to come for followup appointments ★	Yes
Indication for PEP (HIV exposure past 72 hours) ★	Yes
AHI signs and symptoms ★	Yes
HIV exposure (past 14 days) ★	Select
Is not suspected to have AHI ★	Select
Is at substantial risk for HIV infection ★	Select
Prep Method ★	Select

Initiation type: First Initiation

PrEP Follow-up

PrEP Follow-up

Visit type ★	Select
HIV test type and results ★	RDT negative
Switch product ★	Select
Switched to	
Switch reason	

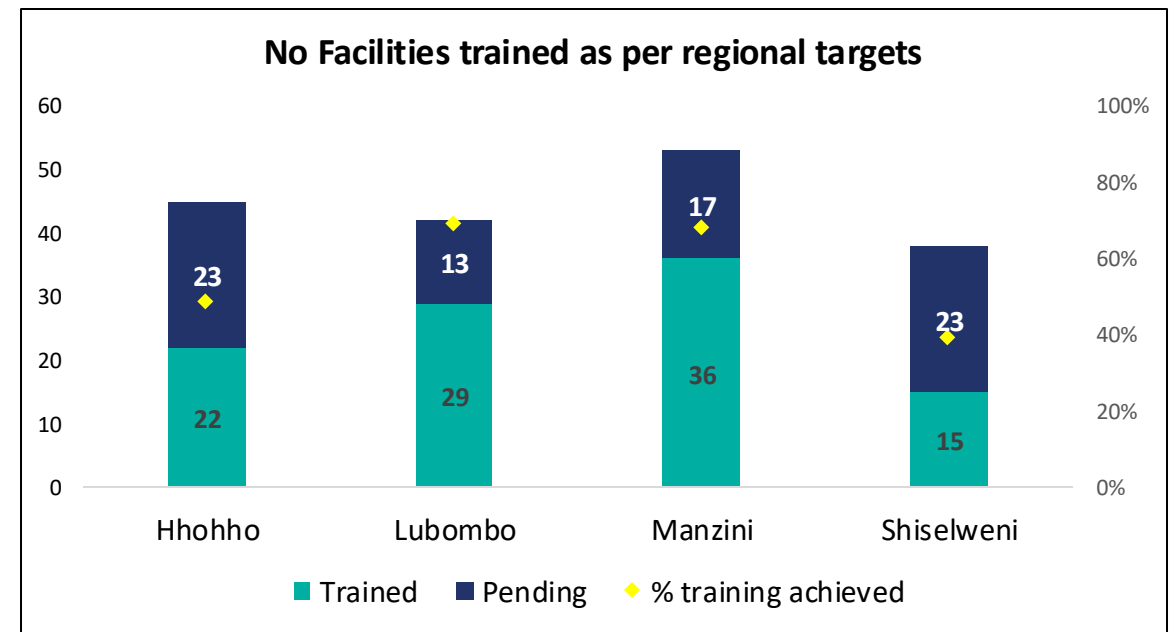




Preparations for PrEP product introduction

- **Training** in new PrEP products

- Initial TOT was followed by a mixture of national trainings and partner supported on-site trainings.
- Contents of training was modified as per facility need with more comprehensive CAB-LA information for selected CAB-LA sites.
- For ring, all PEPFAR supported (166) facilities are targeted for training and ring introduction before the end of 2024.





Preparations for PrEP product introduction

- Site readiness assessments conducted by implementing partners

Site readiness assessment for new PrEP products

Date:	DD MM YYYY
Facility name:	
Region:	
Name and contact of Site manager:	
Name(s) and title (s) of assessment team:	
New PrEP product(s) to be introduced: (tick all that apply)	<input type="checkbox"/> CAB-LA <input type="checkbox"/> PrEP ring

Site Operations		Comments
Implementing partner support: (Only one option)	<input type="checkbox"/> EGPAF <input type="checkbox"/> GU <input type="checkbox"/> URC <input type="checkbox"/> FHI 360 <input type="checkbox"/> Other: _____	
Does the site have a copy available of the 2024 PrEP implementation guidelines?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Does the site use CMIS? If not, indicate reporting channels to MoH.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Commodity Management		Comments
How is the site ordering/ receiving HIV testing and PrEP commodities?	<input type="checkbox"/> Direct ordering from CMS <input type="checkbox"/> Receiving through mother facility. <input type="checkbox"/> Other: _____	
Does the site have sufficient storage space for new products?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Is the storage space dry, cool and clean?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Is there a storage place for new products with temperatures between 2° to 30°C?	<input type="checkbox"/> Yes, describe. <input type="checkbox"/> No	
Is there a temperature monitoring device available in the main storage area?	<input type="checkbox"/> Yes, describe. <input type="checkbox"/> No	
Are there stock cards available to monitor product dispensing?		
Is there a system in place to ring-fence RDTs and CAB-LA vials for clients initiated on CAB-LA? Describe.		

Human Resources	Staff	Total nr	CAB trained	Ring trained
Indicate the nr of staff on site and how many have been trained in providing CAB-LA and the PrEP ring.	Doctor			
	Nurse			
	HTS/ Phleb			
	EC/ M2M			
	Other			

Tools	
Which of the following job aids and counselling tools for new products are available? (tick all that apply)	<input type="checkbox"/> PrEP method comparison/ choice counseling <input type="checkbox"/> PrEP visit checklist <input type="checkbox"/> Missed CAB-LA visit <input type="checkbox"/> Rule out pregnancy checklist <input type="checkbox"/> Screening for PEP and ruling out AHI <input type="checkbox"/> PrEP journey tool <input type="checkbox"/> Other: _____
Is there an anatomical model for ring insertion demonstration?	<input type="checkbox"/> Yes <input type="checkbox"/> No Notes: _____
Is there a demo ring available?	<input type="checkbox"/> Yes <input type="checkbox"/> No Notes: _____

Infrastructure		Comments
Is there a private room for HIV testing and counselling?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Notes: _____
Is there a private room with a handwashing station for demonstration of PrEP ring insertion and for clients to practice ring insertion?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Notes: _____
Does the site have a system in place to follow up PrEP clients that miss their appointment? Describe e.g. appt reminders/register, CMIS, cellphone? Who is responsible for this?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Notes: _____
Is there a facility SOP available for PrEP?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Notes: _____
Is the facility providing FP commodities?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Notes: _____

Demand creation		
Does the site have IEC material available for PrEP ring?	<input type="checkbox"/> Yes <input type="checkbox"/> No	List available material: _____
Does the site have IEC material available for CAB-LA?	<input type="checkbox"/> Yes <input type="checkbox"/> No	List available material: _____

Overall comments

Site ready to introduce:	
CAB-LA: <input type="checkbox"/> Yes <input type="checkbox"/> No	If site is not ready for CAB-LA introduction: <ul style="list-style-type: none"> Document barriers Action points to resolve barriers.
PrEP ring: <input type="checkbox"/> Yes <input type="checkbox"/> No	If site is not ready for CAB-LA introduction: <ul style="list-style-type: none"> Document barriers Action points to resolve barriers.





Preparations for PrEP product introduction

Development of job aids

- Adapted from RISE and MOSAIC materials with feedback received from providers during the initial trainings.
- Will be further adapted based on feedback from providers.

Checklist to rule out Pregnancy

Oral PrEP is recommended for HIV negative pregnant (and breastfeeding) women due to the increased likelihood of HIV acquisition.

CAB-LA and the PrEP ring are currently not recommended to use in pregnant and breastfeeding women and all women initiating or coming for follow-up using CAB-LA or the PrEP ring should be screened for pregnancy.

Instruction:

- Ask the client questions 1-6.
- As soon as the client answers "yes" to any question, stop and follow the instruction below.

Yes/No	Question	Yes
No	1. Did your last menstrual period start within the past seven days?	Yes
No	2. Have you obtained from sexual intercourse since your last monthly bleeding, delivery, abortion, or miscarriage?	Yes
No	3. Have you been using a reliable contraceptive method consistently and correctly since your last monthly bleeding, delivery, or miscarriage?	Yes
No	4. Have you had a baby less than six months ago AND you are exclusively breastfeeding AND have you had no miscarriage or abortion in the past seven days?	Yes
No	5. Did you have a baby less than six months ago AND you are exclusively breastfeeding AND have you had no miscarriage or abortion in the past seven days?	Yes
No	6. Have you had a miscarriage or abortion in the past seven days?	Yes

Note: To prevent unplanned pregnancies, all women not on family planning should be offered family planning during their PrEP visit.

If the client answered YES to at least one of the above questions, you can be reasonably sure she is not pregnant.

If the client answered NO to all of the above questions, pregnancy can not be ruled out. Use a pregnancy test to rule out pregnancy.

Comparing PrEP methods

The best PrEP method for you is the one that fits best with your lifestyle. Think about what will most help you continue using it as long as you need protection.

	LONG-ACTING INJECTION Injection in the buttock	ORAL PrEP Swallowing pills	VAGINAL RING Soft silicone ring placed inside the vagina
PROTECTION	Highest protection. Lowers chances of HIV by about 80% more than Oral PrEP does.	Lowers chances of HIV about 90% compared to not taking Oral PrEP.	Lowers chance of HIV from vaginal sex by about 50% or more compared to not using it. Does not protect against HIV from anal sex.
PRIVACY	Nothing to carry. May have visible bruising and/or swelling at the injection site for a few days.	You may have to carry your pills; other people might see your pills or pill bottle.	Other people could find rings you are keeping or have thrown away. Partners don't usually feel it during sex, but some may.
DOSE FREQUENCY/EASE	Must be able to return to the clinic for injections, usually every 2 months.	Must remember to swallow pills every day while using and return to the clinic for refills initially every 1-3 months*.	Should leave the Ring in place every day while using and return to the clinic for refills initially every 1-3 months*.
HOW FAST IT WORKS	Starts protecting about a week after first injection, though may take longer in some.	Cis Women**: Starts protecting after taking single pill for 7 days in a row. Cis Men: Starts protecting 2-24 hours after the first double dose.	Starts protecting 24 hours after putting it inside the vagina.
HOW LONG IT STAYS IN THE BODY	Protection lasts for 2 months after last injection. Low levels of drug remain in body for about a year, which may carry risk of developing drug resistance if you acquire HIV during this time.	Leaves body quickly after stopping. Cis Women: must use daily pills during period of exposure and for 7 days. Cis Men: must continue daily pills for 2 days after last sexual exposure.	Most drug is only in the vagina and quickly disappears after the ring is removed; Must remain in place for at least 24 hours after last sex.
HIV TREATMENT RESISTANCE	Possibility the main HIV treatment could be less effective if you get HIV. Risk of developing this problem could last about a year after final injection.	* Possibility that some HIV treatment could be less effective if you get HIV. Risk of developing this problem is short-term after stopping oral PrEP.	No risk that HIV treatments would be less effective if you get HIV.

* Clients that used oral PrEP or the ring effectively for at least 4 months, might be eligible to get 6 months refills with use of an assisted HIVST in between.
** Transgender women, if using gender-affirming hormones, starting/stopping same as for cis women; if not using gender-affirming hormones, starting/stopping same as for cis men.

Resuming vs. Restarting CAB-LA After Missed Visit - Quick Tips

What was the last injection type?

If the last injection before the MISSED VISIT was INITIATION INJECTION #1 then....	If the last injection before the MISSED VISIT was INITIATION INJECTION #2 OR REINJECTION then....
<p>If 2 months (60 days) or less since prior injection</p> <p>RESUME with INITIATION INJECTION #2 today despite delay</p>	<p>If 3 months (90 days) or less since prior injection</p> <p>RESUME REINJECTION today despite delay</p>
<p>If more than 2 months (60 days) since prior injection</p> <p>RESTART with INITIATION INJECTION #1 today due to delay</p>	<p>If more than 3 months (90 days) since prior injection</p> <p>RESTART with INITIATION INJECTION #1 today due to delay</p>

CAB-LA Clinical and Counseling Services by Visit Type

INITIATION Visit 1

- Assess client CAB-LA eligibility
- Rule out HIV infection using a rapid diagnostic test as per national algorithm
- Assess indication for PrEP (exposure to HIV <72 hours)
- Screen for Acute HIV infection (exposure within last 14 days and signs of AHI)
- Confirm client is Age 18, not pregnant or breastfeeding and has no other CAB-LA contraindications
- Counseling: Ensure Client understands benefits and limitations to CAB-LA, time to reach maximum protection, frequency of PrEP appointments, possible side-effects, when and how to contact facility.
- Provide other services as needed (PrEP, STI screening, GBV screening, Hepatitis B screening)
- PrEP prescription: Administer intramuscular injection of CAB-LA INITIATION INJECTION 1
- Counseling to support on-time return in 2 months for INITIATION INJECTION 2

INITIATION Visit 2 and REINJECTION Visits

- Rule out HIV infection using a 3-step approach:
 - Rapid diagnostic testing
 - Assess for PrEP need
 - Screen for Acute HIV infection
- Assess indication for PrEP (exposure to HIV <72 hours and poor adherence to PrEP product)
- Screen and/or test for pregnancy as per need
- Provide other services as needed (PrEP, STI screening, GBV screening)
- Counseling on recommended use of CAB-LA PrEP prevention, including oral PrEP or the PrEP ring or other HIV prevention strategies if other PrEP methods are declined or not a suitable option.
- PrEP prescription: Administer intramuscular injection of CAB-LA INITIATION INJECTION 2 or REINJECTION INJECTION 1
- Counseling to support on-time return in 2 months for REINJECTION visit

CAB-LA Discontinuation Visit and Post-Discontinuation Visits

- Rule out HIV infection using a 4-step approach:
 - Rapid diagnostic testing
 - Assess for PrEP need
 - Screen for Acute HIV infection
 - Assess indication for PrEP (exposure to HIV <72 hours and poor adherence to PrEP product)
 - Screen and/or test for pregnancy as per need
 - Provide other services as needed (PrEP, STI screening, GBV screening)
 - Counseling on recommended use of CAB-LA PrEP prevention, including oral PrEP or the PrEP ring or other HIV prevention strategies if other PrEP methods are declined or not a suitable option.
 - PrEP prescription: Administer intramuscular injection of CAB-LA INITIATION INJECTION 2 or REINJECTION INJECTION 1
 - Counseling to support on-time return in 2 months for REINJECTION visit

Oral PrEP/ PrEP ring Clinical and Counseling Services by Visit Type

INITIATION Visit

- Rule out HIV infection using an HIV self-test
- Assess indication for PrEP (exposure to HIV <72 hours)
- Screen for Acute HIV infection (exposure within last 14 days, signs of AHI and poor adherence to PrEP product)
- Confirm product-specific eligibility criteria:
 - Oral PrEP: No contraindications for use of TDF
 - PrEP ring: Age 18 and not pregnant or breastfeeding
- PrEP prescription: Provide 1 bottle (30 tabs) of oral PrEP or 1 PrEP ring
- Counseling to support on-time return after 3 months

FOLLOW-UP Visit

- Rule out HIV infection using an HIV self-test
- Assess indication for PrEP (exposure to HIV <72 hours and poor adherence to PrEP product)
- Screen for Acute HIV infection (exposure within last 14 days, signs of AHI and poor adherence to PrEP product)
- Screen and/or test for pregnancy as per need
- Provide other services as needed (PrEP, STI screening, GBV screening)
- Counseling on recommended use of CAB-LA PrEP prevention, including oral PrEP or the PrEP ring or other HIV prevention strategies if other PrEP methods are declined or not a suitable option.
- PrEP prescription: Provide up to 3 bottles (90 tabs) of oral PrEP or 3 PrEP rings
- Counseling to support on-time return as per scheduled appointment

PrEP method SWITCH visit

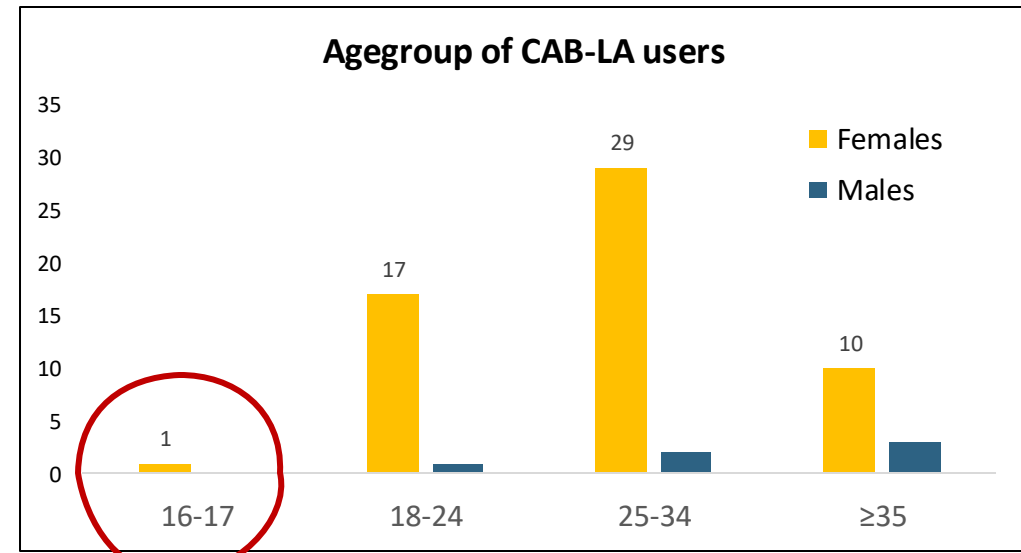
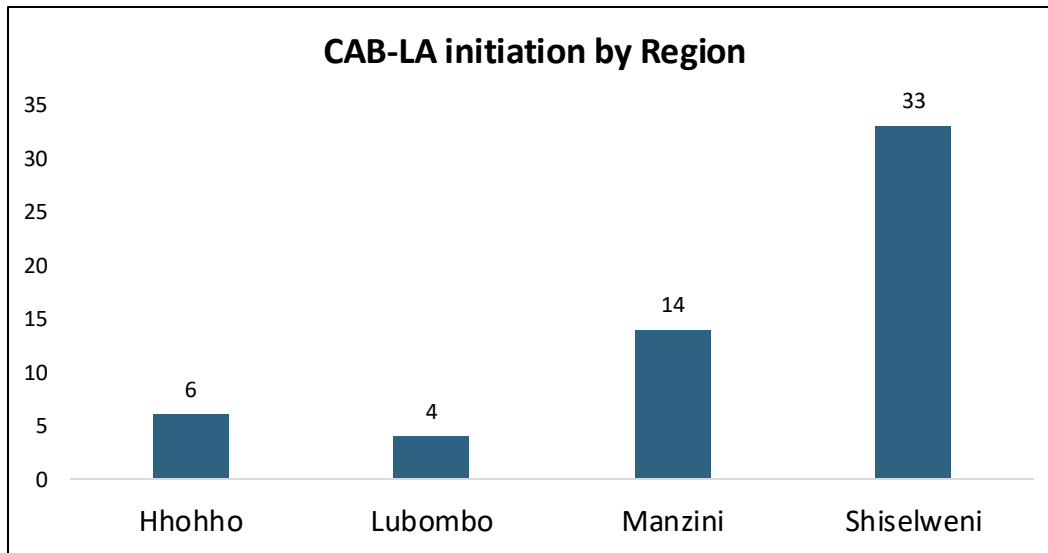
- Rule out HIV infection using an HIV self-test
- Assess indication for PrEP (exposure to HIV <72 hours and poor adherence to PrEP product)
- Screen for Acute HIV infection (exposure within last 14 days, signs of AHI and poor adherence to PrEP product)
- Screen and/or test for pregnancy as per need
- Provide other services as needed (PrEP, STI screening, GBV screening)
- Counseling on recommended use of CAB-LA PrEP prevention, including oral PrEP or the PrEP ring or other HIV prevention strategies if other PrEP methods are declined or not a suitable option.
- PrEP prescription: Provide up to 3 bottles (90 tabs) of oral PrEP or 3 PrEP rings
- Counseling to support on-time return as per scheduled appointment





CAB-LA introduction status

- 4 facilities started offering CAB-LA, first initiation on 8th Aug.
- Targeting AGYW's, women 25-34 year and KPs
- 2nd tranche of CAB-LA vials (10,275) have arrived in country.
- 4 more facilities expected to start offering CAB-LA this week. Further selecting roll out sites by core team to follow.
- Data collection through electronic system and a temporary paper based weekly reporting form.



*Data until 7 Sep 2024



A weekly CAB-LA tracking sheet is used to monitor product use and ensure facilities do not exceed the maximum nr of CAB-LA initiations of 40/ months/facility

WEEKLY CAB-LA TRACKING

Month: _____

Facility name: _____

Demographics				Injection type				F/U date	Comments
Date	CMIS nr/ Client ID	Sex	Age	Initiation injection 1	Initiation injection 2	Re- injection	Waste	Next scheduled injection	Comments
CAB-LA VIALS USED				a	b	c	d	Implementation challenges:	
TOTAL CAB-LA VIALS USED (a+b+c+d)									
CAB-LA BALANCE AT FACILITY								Lesson learned/ best practice:	
CAB-LA ALLOCATED DETERMINE TEST STIP BALANCE									

Submitted to IP on _____ by _____



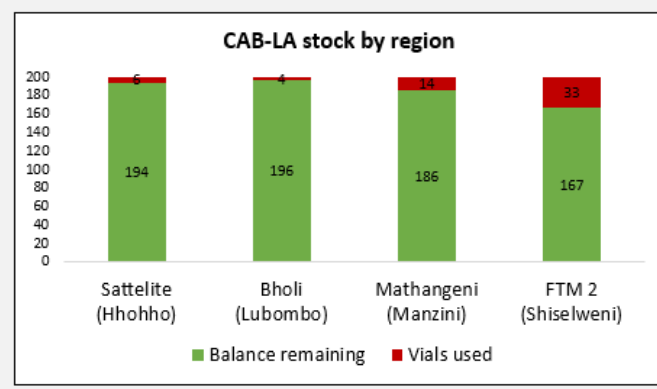
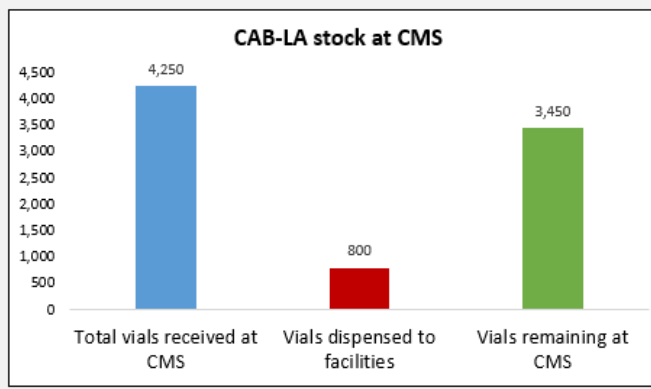
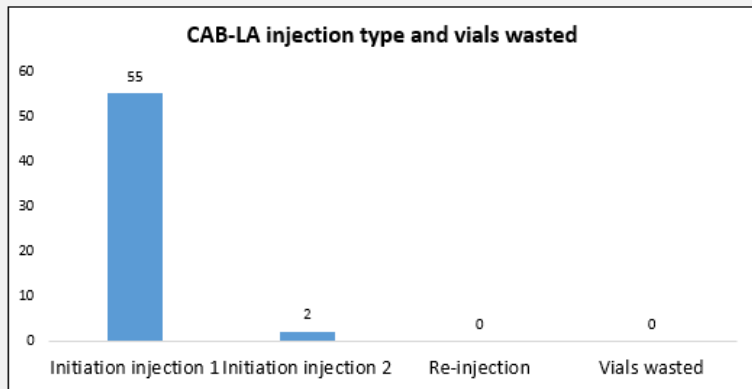
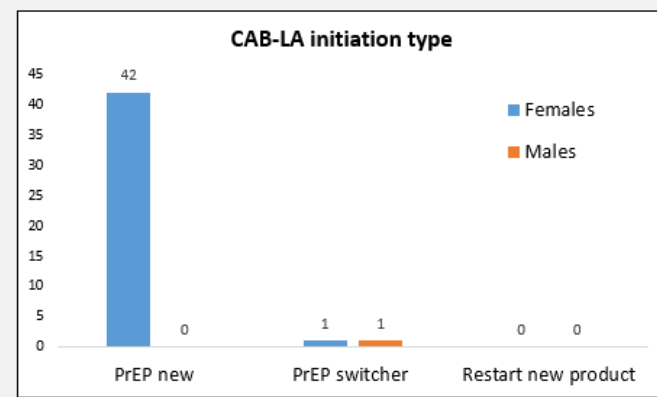
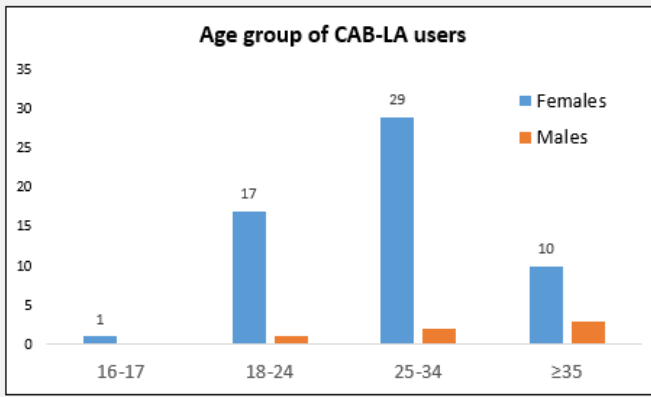
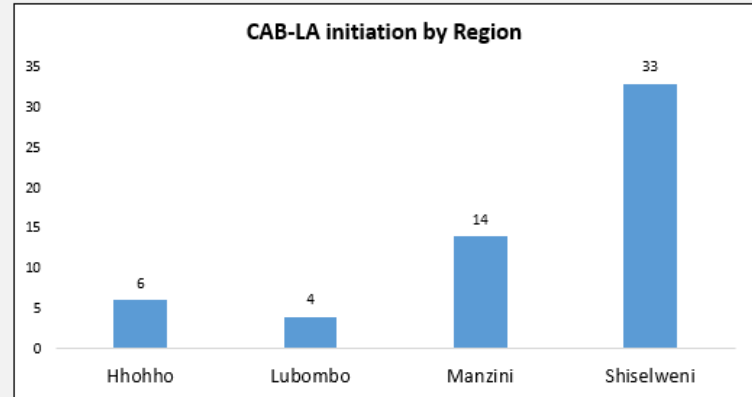
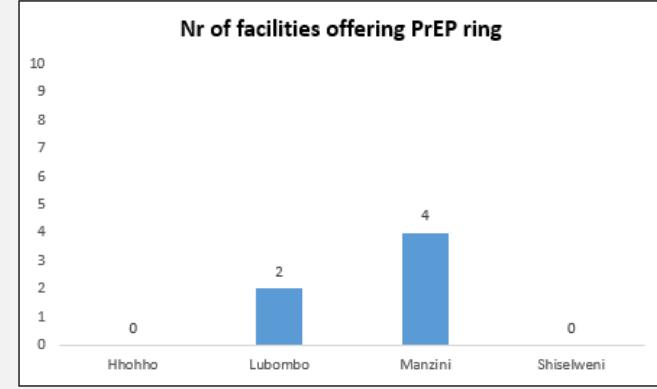
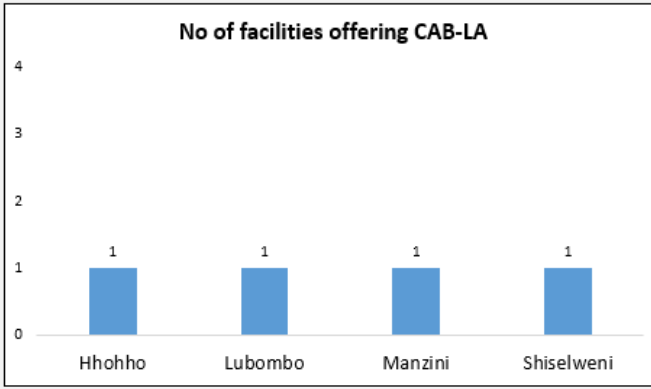
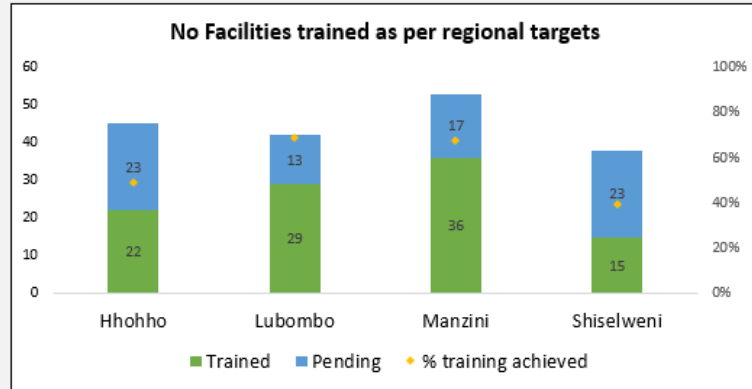


Ring introduction status

- 166 sites targeted for ring scale up before the end of 2024.
- Currently 102 facilities trained (61%)
- Orders have been placed at CMS for site distribution.
 - 6 (4%) facilities have received the PrEP ring and started offering the PrEP ring.
 - Additional sites are expected to start this week.
- 4 regional road shows are being conducted by MoH to sensitize people about the ring.
- Data collection will be done fully electronic.
- Ring will **not** be offered to pregnant or lactating women or women <18 years.



New PrEP Product Introduction dashboard





Acknowledgements



GEORGETOWN UNIVERSITY



Elizabeth Glaser
Pediatric AIDS Foundation
Fighting for an AIDS-free generation





Cabotegravir Injection for HIV Pre-Exposure Prophylaxis: Early Lessons from Zimbabwe



Presented by Dr Idah Moyo
HIV Prevention KP Clinical Officer
MOHCC AIDS and TB Programme
September 2024

Presentation Outline

Country Context- HIV Epidemic

1

CAB-LA Pre-Implementation Activities

2

Performance to Date

3

Lessons Learnt

4

Challenges and Remedies

5

Recommendations and Next steps

6



Zimbabwe National HIV Strategy



Vision

An AIDS free Zimbabwe generation where all populations have healthy lives and wellbeing.



Goal

To accelerate country's response towards ending AIDS as a public health problem in Zimbabwe by 2030.



Sub-Goals

- To reduce HIV incidence in Zimbabwe by 50 % from 0.5 in 2018 to less than 0.25 by 2025.
- To reduce AIDS related deaths in Zimbabwe by 60% from 21,800 in 2018 to less than 10,000 in 2025.
- Significantly reduce HIV and AIDS related stigma and discrimination among all populations by 2025.

HIV Epidemic Highlights

Epidemic Snapshot

Approximately 1.3 million people living with HIV (all ages):

- 785,083 females
- 105,095 young people aged 15-24
- 66,576 AGYW 15-24
- 68,099 children aged 0-14

10.5% HIV prevalence amongst adults aged 15-49:

- 8.9% among females, all ages
- 3.3% among young people aged 15-24
- 4.2% among adolescent girls and young women aged 15-24

0.16% HIV incidence amongst adults aged 15-49:

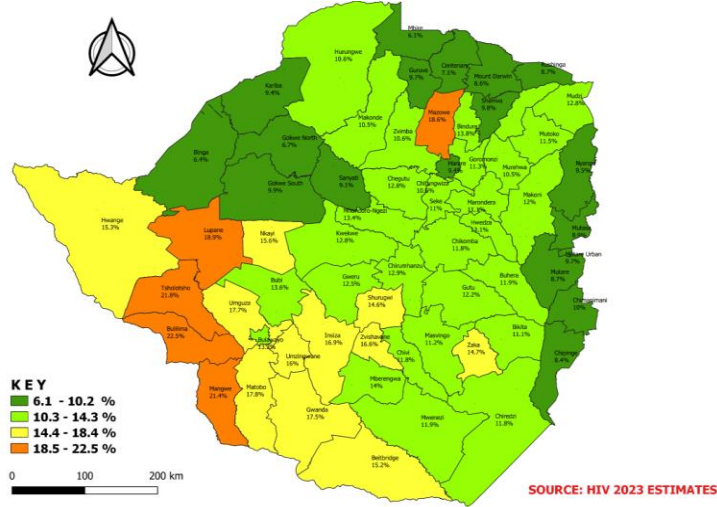
- 0.17% among young people aged 15-24
- 0.26% among AGYW aged 15-24, 3.7x more than their male counterparts

12,930 New HIV Infections amongst adults aged 15-49:

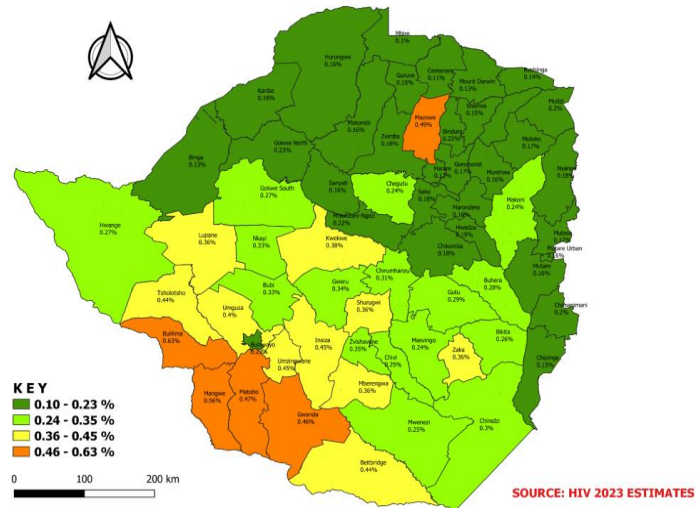
- 8,274 among females
- 5,033 among young people aged 15-24
- 3,888 among AGYW aged 15-24, 3.4x more than their male counterparts

Source: Naomi-Spectrum (September 2023), UNAIDS (accessed on 12.07.2024)

HIV Prevalence by District



HIV Incidence by District



Progress Towards 95-95-95 Targets

All ages (2022)

- 95% of PLHIV know their status
- 98% of people who know their status who are on ART
- 95% of people who are on ART achieve viral suppression

Children aged 0-14 (2022):

- 65% of PLHIV know their status
- 98% of people who know their status who are on ART
- 86% of people who are on ART achieve viral suppression

Females 15+ (2022):

- 98% of PLHIV know their status
- 98% of people who know their status who are on ART
- 96% of people who are on ART achieve viral suppression

Males 15+ (2022):

- 96% of PLHIV know their status
- 97% of people who know their status who are on ART
- 95% of people who are on ART achieve viral suppression

PrEP Roadmap in Zimbabwe

2016

MoHCC adopted the WHO guidance on Oral PrEP as an option to include within the HIV prevention package.

2021

Implementation of the joint Health Sector Response for HIV, AIDS and STIs Strategy (2021-2025), with the objective of ensuring that 90% of people at substantial risk of HIV have access to and utilise PrEP.

November 2022

Zimbabwe is the first country in Africa to announce regulatory approval for CAB-LA for HIV prevention.

2018

An Implementation Plan (2018-2020) was developed to provide oral PrEP as part of a combination HIV prevention approach, to people at high risk of HIV infection.

July 2021

Medicines Control Authority of Zimbabwe approved the Dapivirine Vaginal Ring, with MOHCC recommendation that it should be implemented under research settings.

April 2024

Administration of the first injection of CAB-LA in Zimbabwe.



Implementation Strategy for CAB-LA

Governance and Coordination

- PrEP TWG - coordinates implementation of all biomedical HIV prevention including the introduction of new technologies through the respective forums. Comprises of funding and implementing partners, CBOs, Research Institutes, Logistics, Pharmacy Laboratory, NAC, and CSOs.
- CAB-LA Taskforce - Established to inform the implementation of CAB- LA. Key activities include development of training guidelines selection of pilot sites and populations, and review of the screening tool for eligibility criteria.

Planning and Budget

- National and subnational plans are established to introduce and scale-up PrEP products.
- Planning and coordination through the PrEP TWG.
 - Development of detailed CAB-LA guidelines.
 - Sensitization of MOHCC district and provincial leadership.
 - Sensitization of community stakeholders.
 - Development and utilization of site readiness assessment tool

Supply Chain Management

- PrEP products are available and distributed in sufficient quantity to meet projected demand via priority delivery channels.
- Procurement of consumables.
 - Delivery of PEPFAR programmatic CAB-LA
 - Delivery of CATALYST CAB-LA

Delivery Platforms

- PrEP products are delivered by trained providers in priority delivery channels to effectively reach end users
- Regional RISE/MOSAIC trainer of trainers (ToT) for 8 trainers.
 - RISE/MOSAIC curriculum adapted to Zimbabwean context.
 - National ToT.
 - Provider trainings and ongoing post-training support & mentorship
 - Sensitisation of community footprint
 - CAB-LA layered onto existing oral PrEP program.

Uptake and Effective Use

- End users know about and understand PrEP products and know how to access and effectively use them.
- Development of IEC materials – CAB-LA animation script, pamphlets, billboards.
 - Communications think tank meeting
 - Development of a CAB-LA Scheduling Wheel.

Monitoring, Evaluation and Learning

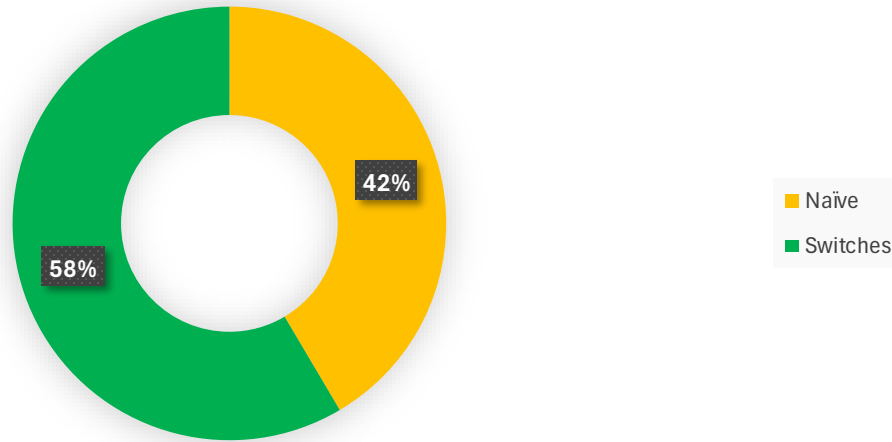
- PrEP products are effectively integrated into subnational, facility, community, and program monitoring systems.
- Monthly update meetings with implementing partners (IPs) and key stakeholders.
 - Support visits at implementing site.
 - Weekly reports by IPs to MoHCC and local missions.
 - Prepare evidence briefs on CAB-LA implementation.
 - Share updates at national and regional level as requested.

HIV Drug Resistance Surveillance

- Track seroconversions of clients on PrEP and enrol in a surveillance study for drug resistance and follow-ups through a 12-month period.
- HIVDR study protocol approved by local IRB.
 - Developed job aids, SOPs, and study procedure manual.
 - Lab and clinical staff trained.

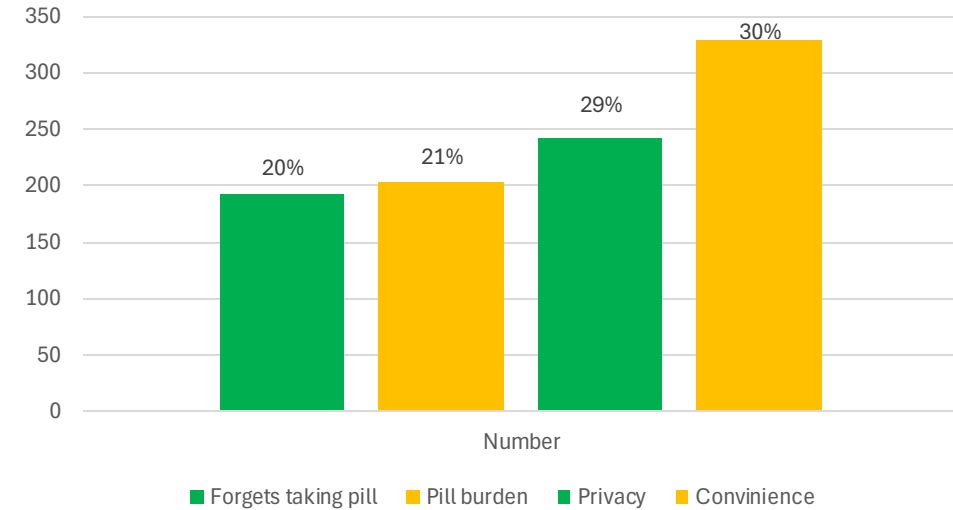
CAB-LA Implementation Performance

Number of Clients Enrolled Disaggregated By Prep Experience Status

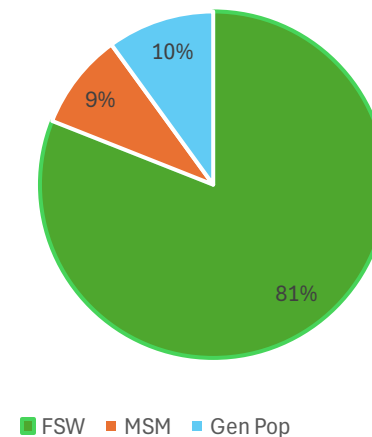


- 1653 RoC initiated on CAB-LA between April to August 2024.
- The majority (81%) were female sex workers
- Most 967 (58%) of CAB-LA users were switching from either oral PrEP (876) or DPV-VR (91).
- 42% of RoC were PrEP naive

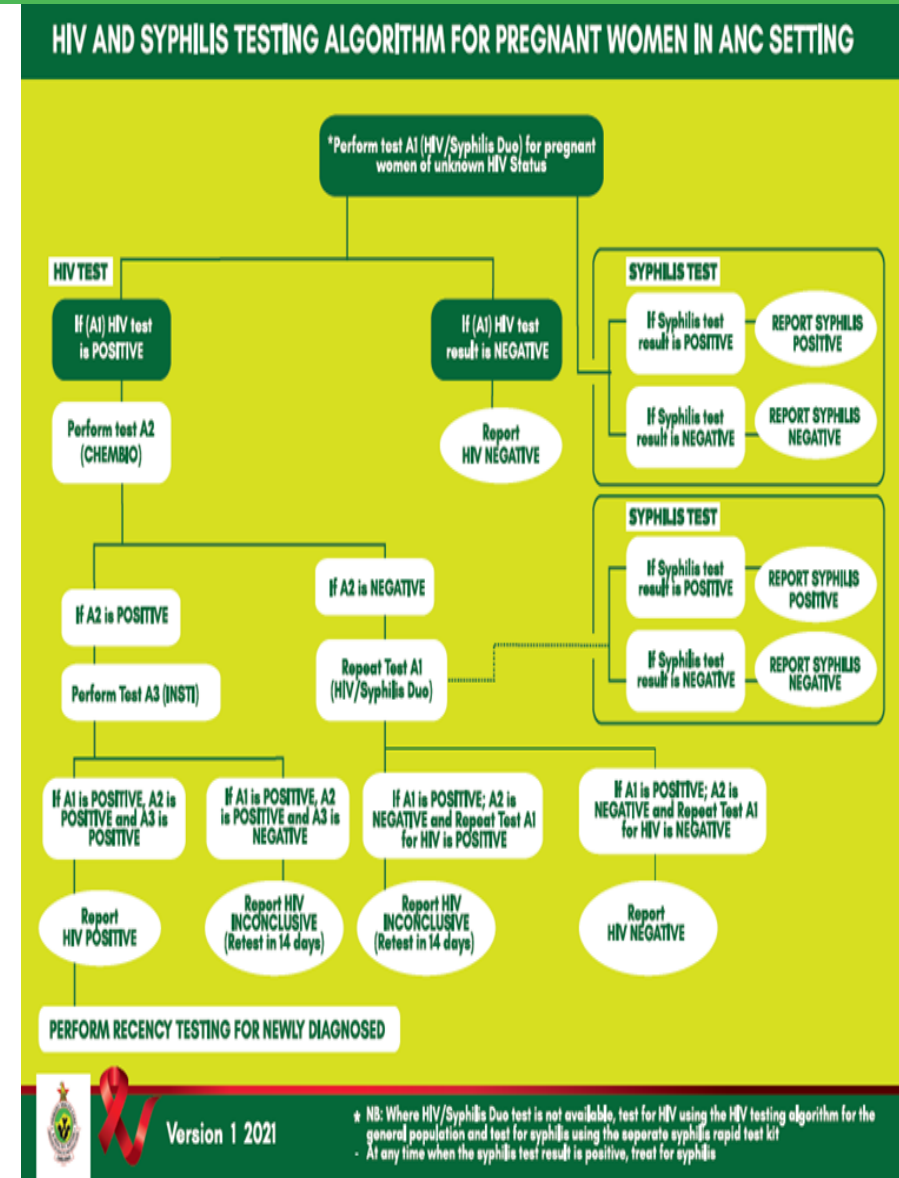
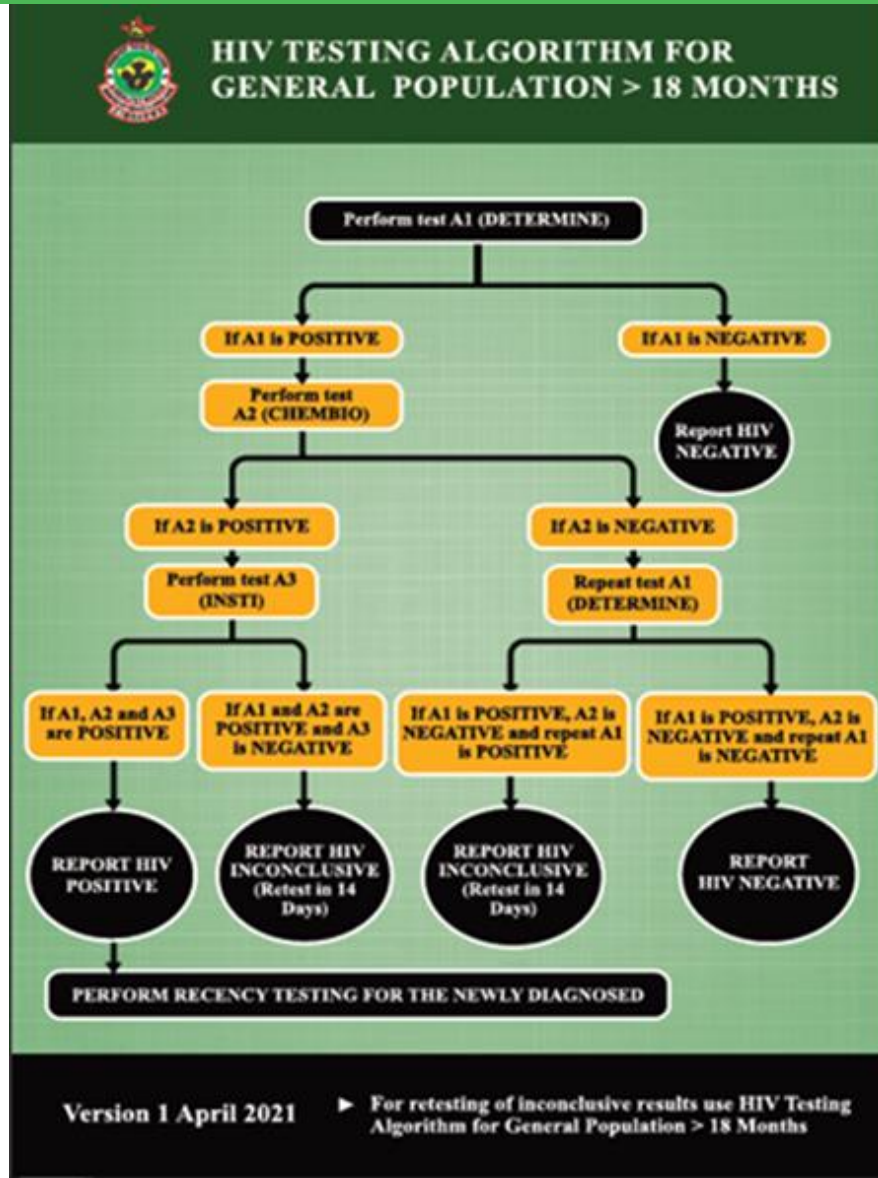
Reasons for Switching to CAB LA (%)



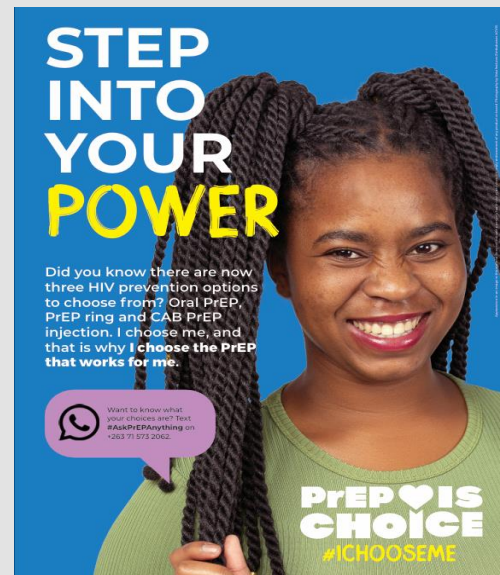
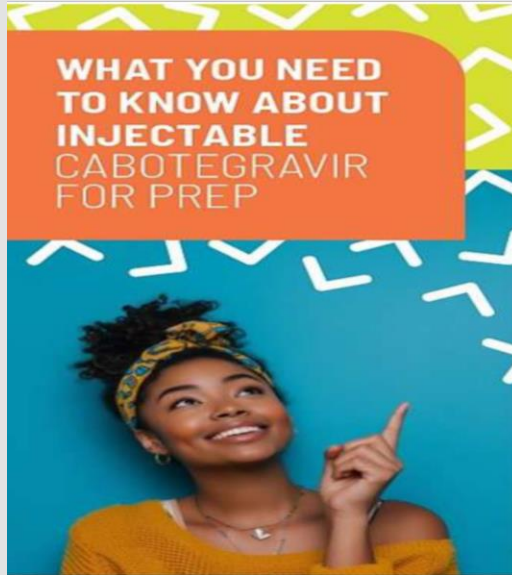
CAB-LA enrolment by sub-population (N=1653)



HIV Testing Algorithms



Examples of CAB-LA Materials



Preliminary HCW Perspectives and Qualitative Insights from RoC

Demand Creation and Choice Counselling

- PrEP recipients are keen to take up CAB-LA because of the convenience of not having to remember to take a pill every day.
- The discreet nature of the injection makes it a better option.
- Some participants are concerned about the pain during the injection.

Injection Technique

- Ventrogluteal injection position and Z-track technique are initially difficult but gets better with practice.

"I heard about CAB-LA from a trusted friend who has had the injection. It is convenient and user friendly though there is pain post injection. The service experience seems rather long at first but necessary for an in-depth understanding. I would recommend it to my peers, it is easy to manage."

FSW (26), Mutare



"When I went for the CAB-LA first injection I was anticipating a lot of side effects but so far, I have not experienced any. I'm very happy with CAB-LA and recently I referred my friend for CAB-LA."

FSW (26), Harare

"I was taking oral PrEP and I heard on the news that the injection was now available, I was really excited about cause yoo, taking a pill every day was really hard, a friend of mine went with me to the clinic to get the injection."

MSM, Harare

Image Credit: Population Solutions for Health (First recipient of CAB-LA in Zimbabwe)



Innovations

- Development of resources (tools) -CAB_LA Scheduling wheel for scheduling follow up visits
- Development of the CAB LA referral directory to facilitate continuity of services
- Continuous Quality Improvement Initiatives
 - PrEP readiness assessment tool-guides the providers of care on key parameters to explore in assessing the RoC `s readiness to take up PrEP as an HIV prevention strategy
 - For standardization purposes the program is in the process of finalizing managing side effects/adverse events (use of a pain rating scale)
- The country has a CAB LA think tank comprising technical teams for Quality Assurance and continuous learning.
- The program has developed a standardized system of line listing and tracking CAB LA users through a cohort system.

Early Lessons from CAB-LA Implementation

1. Early and ongoing collaboration between MOHCC, IPs, multilateral partners, and funders is crucial for successful implementation of new HIV prevention interventions.
2. The participants (MSM and FSW), are exhibiting a preference for transitioning from oral Pre-Exposure Prophylaxis (PrEP) to Cabotegravir Long-Acting (CAB-LA), citing reduced pill burden.
3. The transition to CAB-LA has successfully addressed key concerns associated with oral PrEP, including pill fatigue, privacy, discreteness, stigma, and convenience, leading to enhanced user experience.
4. More than 90% of CAB-LA users received their second injection on schedule, indicating high adherence and engagement in care.
5. Facility-based service delivery may exclude clients in hard-to-reach areas, creating geographical barriers that hinder access to CAB-LA (outreach model has been utilized).
6. No severe side effects identified to date indicating high level safety of this regimen.
7. Absence of standardized patient-held records for CAB-LA patients which can affect continuity of care (small booklets utilized).

Challenges and Proposed Remedies

1. FSWs' high mobility requires flexibility in service delivery and referral to other implementing partners for their injections (CAB LA referral network directory)
2. The program is addressing inconsistent PrEP-type documentation by the introduction and use of a standardized, integrated register to enhance accurate tracking and data management (a system of line listing and tracking is done per cohort)
3. The program's current scope, primarily targeting FSW and MSM, warrants expansion to encompass additional key and general populations that exhibit similar risk profiles. A revision of the eligibility criteria for CAB-LA recipients is being considered to ensure equitable access and address the unmet needs of other vulnerable groups

Next Steps

- 1 To continue enhancing the capacity of healthcare providers through sustained coaching, mentorship, and skills development, ensuring they remain equipped to deliver high-quality PrEP services and address evolving healthcare needs
- 2 A strategic approach to demand creation, leveraging on Social Network strategy is crucial to generate awareness, address misconceptions, and drive uptake of CAB-LA among key populations.
- 3 Prepare evidence briefs and knowledge-sharing outputs for relevant platforms
- 4 Evidence from CATALYST study will be used to inform the rollout and scale-up of the ring and CAB LA in Zimbabwe
- 5 Enhance pharmacovigilance for CAB-LA, ensuring robust monitoring and surveillance to detect and manage adverse events, and inform data-driven decisions on drug safety and efficacy

Thank You!

HIV
prevention
starts
with **ME.**

