Introduction of Long Acting Injectable Cabotegravir (CAB-LA)

Value Chain Situation Analysis

South Africa

June 2024

PEPFAR

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Maximizing Options to Advance Informed Choice for HIV Prevention

Overview

HIV in South Africa

HIV prevention in South Africa – current situation

Key findings for CAB-LA introduction planning

Sources and notes

Overview of this analysis

- This document summarises the findings from the value chain situation analysis (VCSA) for injectable cabotegravir (CAB-LA) in South Africa (Nov 23-March 24).
  - CAB-LA is a new biomedical HIV prevention method that can be integrated with much of the existing infrastructure, systems, and policies established for the introduction and scale-up of oral pre-exposure prophylaxis (PrEP). However, there will be specific considerations for CAB-LA, given it is a new method and a new product form.
- The analysis will help identify opportunities or gaps that should inform planning for the introduction and scale-up of CAB-LA and can be used by policymakers, implementers, and other stakeholders.
- The analysis is informed by a desk review, secondary research, and feedback from interviews with key stakeholders in South Africa *(hereafter referred to as interviewees).* These inputs have been analysed using a structured, comprehensive framework developed based on experience from the rollout and scale up of other HIV biomedical prevention methods.
- This analysis was completed in March 2024 by members of the MOSAIC consortium in South Africa.
- Summaries of VCSAs done in other MOSAIC countries are available on https://www.prepwatch.org/.

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HIV in South Africa

HIV prevalence

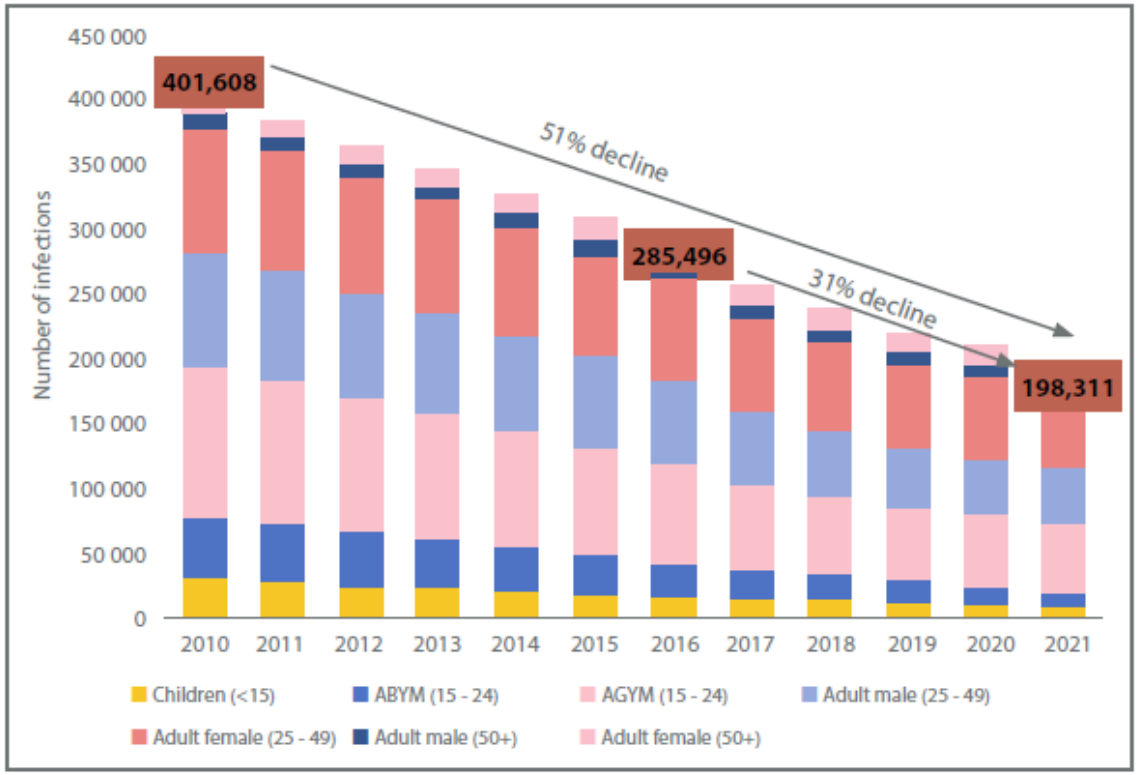
- HIV prevalence in South Africa (SA) is 13.5%, with 8 million people living with HIV
  - 5.1 million women; 2.7 million men; 248 605 children under 15
- Reduction in prevalence in pregnant women: 2017 – 27%, 2022 – 23.9%

HIV incidence

A 51% reduction in new HIV infections in SA from 2010 (401,608) to 2021 (198,311)

- HIV incidence per 1000 population (adults 15–49): 5.21 95% CI [3.58 – 7.28]
- HIV incidence per 1000 population (all ages): 3.15 95% CI [2.15 – 4.62]

Annual number of new HIV infections, 2010-2021



National Department of Health. National Strategic Plan for HIV, TB and STIs, 2023-2028. Pretoria: NDOH and SANAC; 2023.

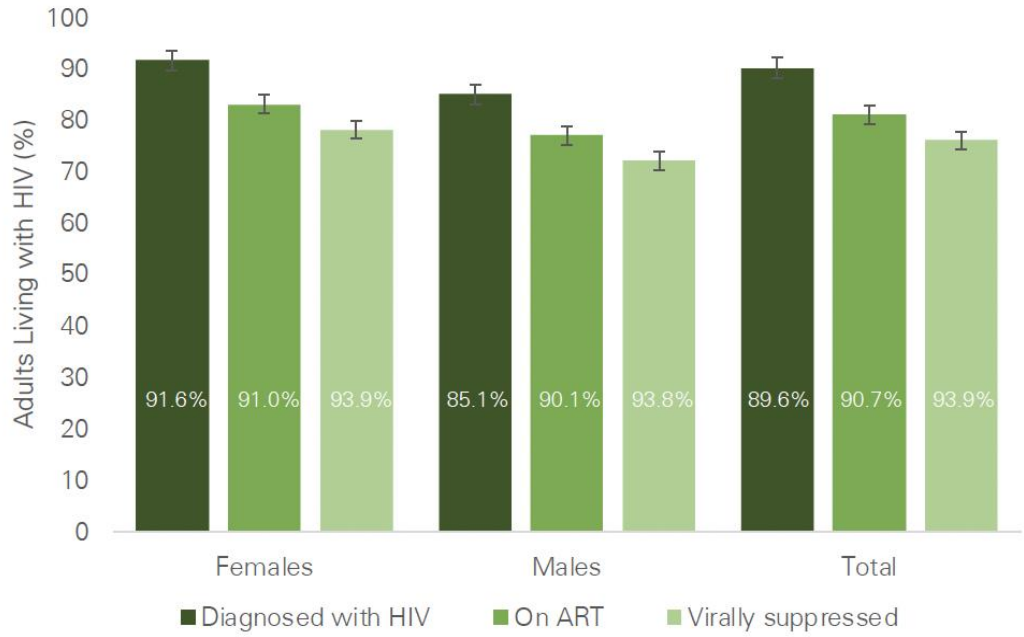
HIV in South Africa

South Africa has the world's largest HIV epidemic, with an estimated 7.8 million people living with HIV in 2022.

The Sixth South African National HIV Prevalence, Incidence, and Behaviour survey (SABSSM VI, 2023) reports that South Africa has made tremendous progress toward achieving HIV epidemic control: among people ages 15 years and older living with HIV in South Africa in 2022, **90% were aware of their status**, **91% of those aware of their status were on antiretroviral therapy (ART)**, and **94% of those on ART were virally suppressed**.[1]

- Among those ages 15+, HIV prevalence is **twice as high among women** (20.3%) than among men (11.5%).
- Compared to men, HIV prevalence was approximately 2-fold higher in women ages 15–19 (5.7% vs. 3.1%) and 20–24 years (8.0% vs. 4.0%) and 3-fold higher in women ages 25–29 years (19.5% vs 6.3%).
- HIV prevalence is **highest in women ages 35–39** (34.2%) and men ages 45–49 (27.1%)
- Viral load suppression is lower among young people ages 15–24 years (70.1%)

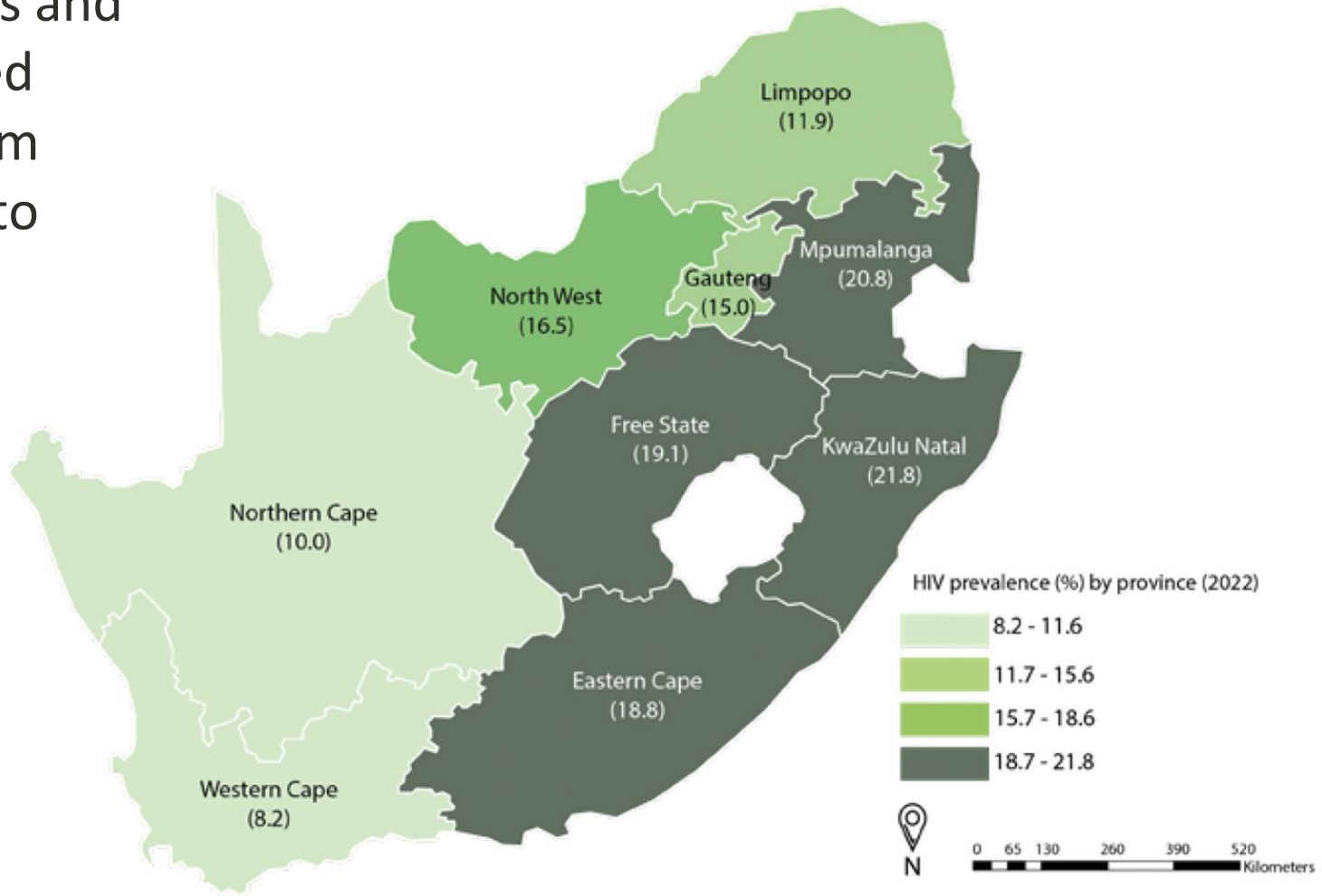
South Africa: 95-95-95 progress by sex



Slide data source: SABSSM VI Summary Sheet, October 2023

Geographic distribution of HIV in South Africa

Among adults ages 15 years and older, HIV prevalence varied geographically, ranging from 8.2% in the Western Cape to 21.8% in KwaZulu-Natal.

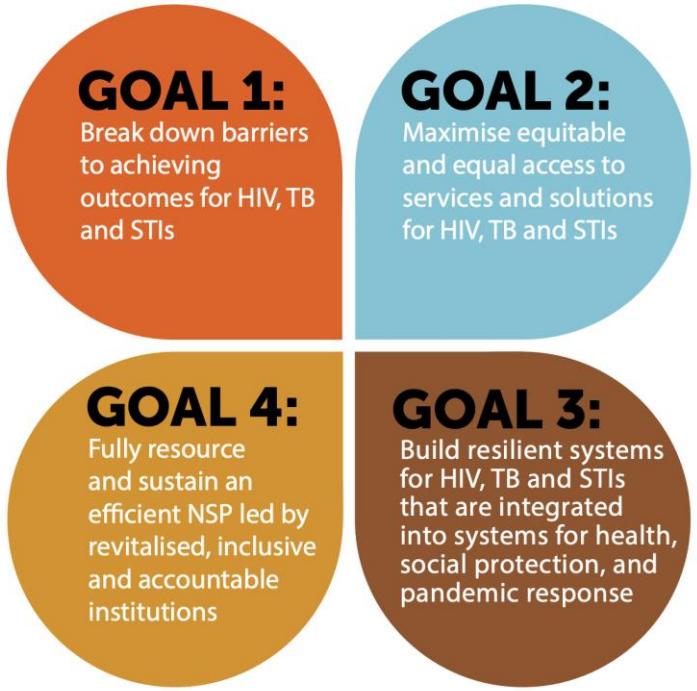


Slide data source: SABSSM VI Summary Sheet, October 2023

South Africa's NSP supports PrEP for prevention

South Africa remains the epicentre of the HIV epidemic. Although new HIV infections are on a downward trend, they are not declining fast enough, and South Africa did not achieve the globally agreed fast-tracked target of 75% reduction by 2020 from the 2010 baseline.
To achieve the global target of ending AIDS by 2030, South Africa must reduce new HIV infections from 189,000 in 2022 to 40,000 per annum.

- National Strategic Plan for HIV, TB and STIs 2023–2028



The National Strategic Plan for HIV,TB and STIs 2023-2028 (NSP) proposes to provide PrEP to all individuals who need it. The expansion of the PrEP programme includes new long-acting prevention technology as approved by regulators and adopted by the National Department of Health (NDOH).

Sub-Objective 2.2.4. Promote the availability of PrEP to all who need it and uptake by key and other priority populations. When PrEP was first introduced in South Africa in the NSP 2017–2022, it was prioritised for population groups with a substantial risk of HIV infection.

Regulatory Approval & Policy	Implementation & Financial Planning	Service Delivery Preparation Integrate with existing implementation tools	Communication and Social Mobilisation
WHO prequalification	Demand forecasts and impact models	Develop national and provincial implementation plans	Develop social mobilisation & demand generation strategy
SAHPRA approval	Investment case	Identify 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	Develop communication, education and social mobilisation materials
National Health Council approval	Procurement, supply chain, & tender	Develop implementation tools, job aids & training materials	Commence implementation pilot sites

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Green	Complete
White	Work in Progress

2030 NDP

South Africa was the first country in sub-Saharan Africa to approve oral PrEP

Lessons learned from PrEP rollout in SA

Stake holder engagement

- A dynamic, on-going process.
- Community engagement critical–particularly religious and traditional leaders
- The engagement of men and boys important – contributes to an enabling environment for PrEP use amongst AGYW

Social mobilisation and demand generation

- Needs to be appropriate, focused, innovative, and contextual.
- Community sensitisation, awareness and education about PrEP essential
- Shift narrative from risk - destigmatise PrEP and frame as an empowering HIV prevention tool

Differentiated service delivery

- Service provision needs to be flexible, accessible and adaptable

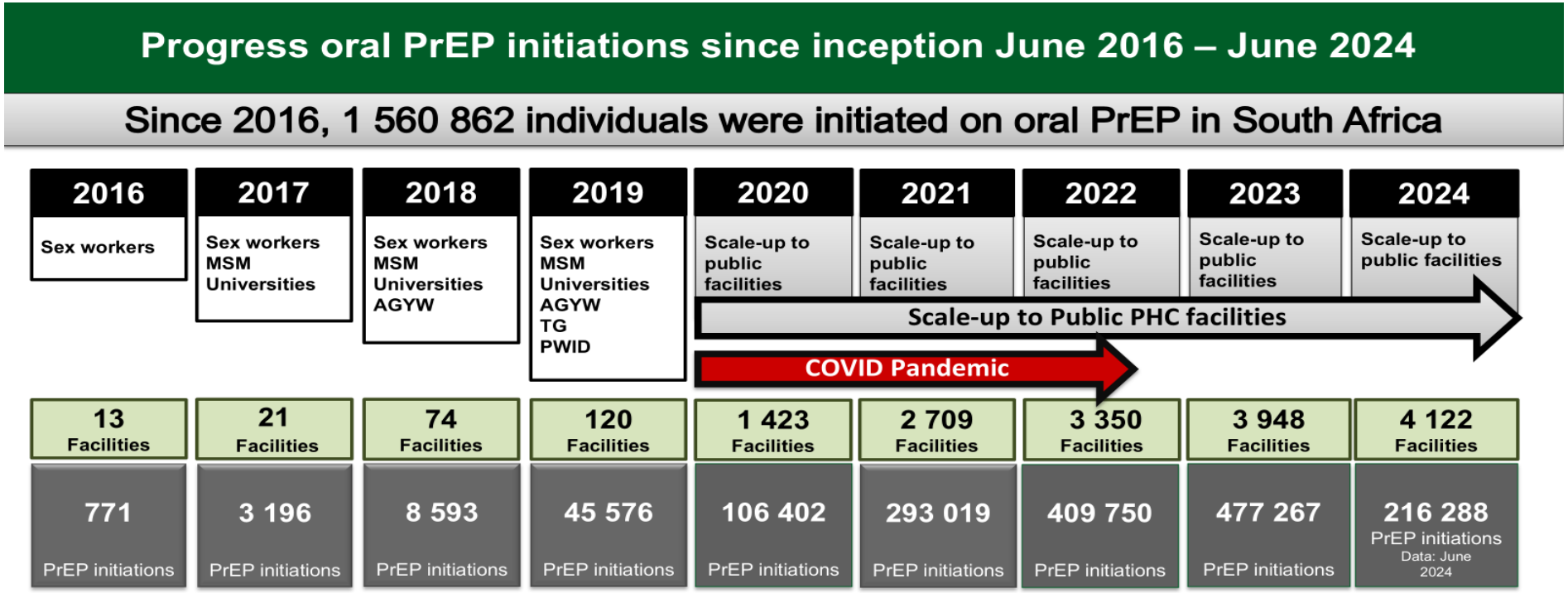
Health systems to support PrEP service delivery

- Requires strategies ensure PrEP supplies, and to mitigate supply interruptions
- Client centered care: focus on the individual's support needs to ensure effective use of PrEP.
- Ongoing training, mentorship and support
- Seek ways to cascading PrEP training, MyPrEP learning modules, increased access to training content

- Butler V et al. Implementing differentiated and integrated prevention services for adolescent girls and young women: experiences from oral PrEP rollout in primary care services in South Africa. J Adolesc Health. 73(6):S58–S66.
- Duby Z, et al. The HERStory Series: Lessons learned from implementing a PrEP programme for adolescent girls and young women in South Africa. Cape Town: South African Medical Research Council; 2022.

Progress in oral PrEP initiations, June 2016 to June 2024

South Africa was an early adopter of oral PrEP, invested significantly in demand generation, and is continuing to scale up



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Source:Consolidated from DHIS, TIER and implementing partner reports.

2030 NDP

Slide data source: NDOH PrEP Review Meeting, March 2024

Dapivirine vaginal ring (Ring) introduction in South Africa

- Dapivirine vaginal ring (Ring) was approved by the South African Health Products Regulatory Authority (SAHPRA) in March 2022.
- The National Dapivirine Ring Implementation Guidelines were approved in December 2022, and training was held in May 2023.
- Implementation of the Ring at limited study and pilot sites commenced in August 2023.
- Regulatory approval for the Ring makes provision for its use to reduce the risk of HIV-1 infection via insertive vaginal intercourse in HIV-negative individuals:
  - Assigned female at birth
  - Ages 18 years and older

As of February 2024:
695 Ring initiations reported across 57 sites in South Africa [IS studies and GFATM-supported programme]

Key findings for introducing CAB-LA in South Africa

The following is a summary of key findings from stakeholder consultations on the introduction of CAB-LA in South Africa:

- **The rollout and scale-up of oral PrEP provides a strong foundation for the introduction of new PrEP methods.** The existing structures, processes, and demand generation strategies for oral PrEP can effectively incorporate CAB-LA. Expanded community sensitisation on biomedical HIV prevention methods within the existing channels will be essential before CAB-LA introduction.
- **Decisions need to be made about funding mechanisms and cost.** To ensure delivery of CAB-LA in the country by the end of 2024, available resources (NDOH, PEPFAR, Global Fund to Fight AIDS, Tuberculosis and Malaria [GFATM]) must be confirmed. ViiV will fulfill and supply all procurement orders in accordance with approved product forecasted quantities. PEPFAR and GFATM procurement can proceed without CAB-LA inclusion on the Essential Medicines List (EML), to support NDOH.
- **The need for procurement planning and supply is urgent.** Forecasting and quantification cannot commence until CAB-LA is included on the Essential Medicines List (EML).
- **There is a lot of interest in CAB-LA; demand is anticipated to be high.** Interviewees believe that price should not be the only factor considered for approval; the benefits and expansion of options need to be considered. It is anticipated that CAB-LA may be favoured over other available PrEP methods..
- **Rollout of CAB-LA should begin as soon as possible.** Interviewees feel that plans for introduction and procurement need to start now, not to wait until implementation studies are in progress. CAB-LA should use the same delivery platforms as other PrEP methods and should be available for all population.
- **Different platforms for service delivery:** For the introduction of CAB-LA, public sector PHCs are the logical choice. There are also opportunities to explore different delivery platforms to ensure accessibility –such as private pharmacies, NGO/CBOs; key population sites

Quotes from interviewees about CAB-LA

"It's a win, win, win." – *Civil Society*

"Enable access, enable choice." – *Multilateral*

"Now is the momentum." – *Government*

"…but don't trash the current for the shiny new thing." – *Multilateral*

"…leave space for people to try out different products." – *Implementing Partner*

"It will remove the responsibility, 'the load' off people" – *Civil Society*

CAB-LA introduction framework

This value chain framework has been used across countries to support planning for the introduction of PrEP products. It identifies necessary steps for PrEP introduction and scale-up across five major categories and across priority delivery channels. It can also be used to track progress toward introduction of various PrEP products by different partners.

Value chain for PrEP

PLANNING & BUDGETING

National and subnational plans are established to introduce and scale-up PrEP products.

SUPPLY CHAIN MANAGEMENT

PrEP products are available and distributed in sufficient quantity to meet projected demand via priority delivery channels.

DELIVERY PLATFORMS

PrEP products are delivered by trained providers in priority delivery channels to effectively reach end users.

UPTAKE & EFFECTIVE USE

End users know about and understand PrEP products and know how to access and effectively use them.

MONITORING, EVALUATION, & LEARNING

PrEP products are effectively integrated into national, subnational, facility, community, and programme monitoring systems.

CAB-LA introduction – South Africa situational analysis overview

PLANNING & BUDGETING	SUPPLY CHAIN MANAGEMENT	DELIVERY PLATFORMS	UPTAKE & EFFECTIVE USE	MONITORING, EVALUATION, & LEARNING
Plans, systems, and processes to support service integration across priority delivery channels, including reproductive health/family planning (FP) and private sector providers/pharmacies				
Convene a new or existing subcommittee or task team within HIV prevention or PrEP **technical working group.**	**Register** PrEP methods and include on the Essential Medicines List (EML), if needed.	Dedicate resources to conduct regular **HIV tests, initiate PrEP, and support ongoing PrEP use.**	Develop and implement **demand generation strategies** that include PrEP promotion.	Update or establish **integrated monitoring tools** to support data collection and analysis on PrEP use across multiple products.
Identify **focus populations and set targets** to inform PrEP planning.	Include New PrEP methods into existing **supply chain mechanisms and logistics systems** to include PrEP products.	Develop training and materials for **health care workers** (HCWs) on PrEP methods.	Address social norms/stigma to build **community and partner acceptance** of PrEP use.	Include PrEP into existing systems for **pharmacovigilance** and to monitor drug resistance.
Engage **community stakeholders** to inform planning for PrEP rollout.	Conduct **forecasting and/or quantification** to inform procurement of PrEP products.	Establish **referral systems** to link clients from other channels to sites providing PrEP.	Develop **information and tools for clients** to support product choice.	Conduct **implementation science** (IS) research to support policy and scale-up.
Include PrEP in national HIV prevention and other relevant **policies and guidelines** (e.g., HIV testing, SRH, PEP).	Establish **procurement, commodity monitoring, and distribution** for PrEP products and associated materials.	Integrate support for **partner communication** and services for intimate partner violence (IPV) response.	Support **effective use** of PrEP products.	
Issue standard **clinical guidelines** for delivery and use of PrEP methods.	Establish **storage and distribution systems** that maintain temperature controls for PrEP products, if needed.			
Develop an **implementation plan and budget** to guide new PrEPmethod introduction and scale-up.				

COLOR KEY

- Completed/underway
- Additional effort is needed, but no challenges anticipated
- Requires significant consideration

South Africa CAB-LA introduction situation analysis

Findings from the South Africa situation analysis are summarised below, with details included on the following slides.

PLANNING & BUDGETING

- The existing Technical Working Group (TWG) for antiretroviral (ARV) prevention methods, chaired by NDOH, continues to lead on planning and introduction of new ARV prevention methods.
- National CAB-LA guidelines were approved in December 2023.
- For CAB-LA to be available in the public sector, CAB-LA must be listed on the essential medicine list (EML). **NEMLC has not yet recommended the inclusion of CAB-LA on the EML.**
- Several implementation and demonstration studies have been approved by SAPHRA, and CAB-LA is being used in 5 studies.
- A prerequisite for the product developer is that agreements with potential procurement entities are in place to support programmatic delivery.
- Interviewees believe that price should not be the only factor; the benefits and expansion of options need to be considered.

SUPPLY CHAIN MANAGEMENT

- CAB-LA is registered with SAHPRA.
- ViiV has provided the not-for-profit price, including distribution, to NDOH for consideration.
- Price and affordability of CAB-LA is a major consideration for availability in the public sector.
- CAB-LA will be easily integrated into existing pharmaceutical supply chain mechanisms .
- CAB-LA can be integrated into commodity tracking systems.
- For ViiV to plan future supply they need to know projected procurement.
- Public sector procurement cannot commence until CAB-LA is included on the EML.

PREP DELIVERY PLATFORMS

- Oral PrEP is widely available in public health and community-based platforms.
- CAB-LA will use the same delivery platforms as other PrEP methods—with consideration that CAB-la is an injectable and requires a suitable clinical environment.
- NDOH conducted a national training for all research partners implementing CAB-LA in February 2024.
- Interviewees believe incorporating CAB-LA will be relatively easy in the programmes that have already integrated oral PrEP.
- Primary health care (PHC) and key population-focused programmes are high priority for CAB-LA delivery.

UPTAKE & EFFECTIVE USE

- PrEP demand generation strategies have increased awareness and knowledge of oral PrEP. Similar campaigns will be needed to facilitate informed choice of all prevention products.
- NDOH is planning a more integrated approach to biomedical ARV-based prevention methods (i.e., integrated guidelines, tools, and messaging).
- Interviewees anticipate that CAB-LA may be more widely favoured than oral PrEP and the Ring.
- Consideration is needed to ensure messaging supports product choice.
- Switching between PrEP and HIV prevention methods will be promoted.

MONITORING, EVALUATION, & LEARNING

- Reporting tools for CAB-LA have been included in the current NDOH data collection and reporting tools.
- New PrEP methods be integrated into existing pharmacovigilance systems.
- Monitoring side effects and the effects of the “tail" after discontinuing CAB-LA, including drug resistance. Implementation research will provide critical evidence.
- Ongoing implementation studies will yield key insights into demand, uptake, and use to guide the rollout of CAB-LA for programmes.
- The demo projects can provide insights for the adaptation of implementation tools and IEC materials.

Planning & budgeting key steps

PLANNING & BUDGETING

	Current situation of oral PrEP and the Ring	What is needed to introduce new PrEP methods
Convene new or existing subcommittee or task team within HIV prevention or PrEP **technical working group.**	• The existing TWG for ARV prevention methods, chaired by NDOH, continues to lead oral PrEP and Ring implementation. • TWG is very well managed. NDOH and projects have had good collaboration and have been proactive in sharing lessons and evidence.	• TWG sub-working group for new PrEP products is mainly focused on researchers and IPs who are planning to implement CAB-LA IS and research studies. • Ongoing information sharing with civil society and other stakeholders is needed to inform introduction and scale-up plans (study-related data on uptake, patterns of use, delivery models that work, etc.).
Identify **focus populations and set targets** for PrEP methods.	• Oral PrEP is delivered in >4000 PHC facilities across South Africa to all populations. • PrEP targets are set annually and included in the HIV conditional grant. • NDOH uses a sophisticated tool for projecting PrEP targets. Focused on population, incidence, and geography, it drills down to the facility level.	• Interviewees feel CAB-LA should be made available to all populations through the public sector from the outset. • NDOH has utilised the existing PrEP target setting tool to project CAB-LA targets. NDOH will look at what contribution new products can add to the reduction of HIV incidence and will focus on high-incidence areas, looking at age group/gender. • Monitoring of CAB-LA use in pregnant and breastfeeding women is required through a pregnancy registry.
Engage **community stakeholders** to inform planning for PrEP rollout.	• Interviewees felt there is good involvement from a variety of stakeholders, including community engagement where research sites are based. • NDOH is committed to providing PrEP for all populations as per eligibility in guidelines.	• It is important to raise awareness about PrEP in the public at large. There is an opportunity to scale the PrEP is Choice campaign to promote PrEP as a category within the broader HIV prevention package. • Community engagement is critical, as some faith-based, community groups, and parents are still hesitant about PrEP provision, especially for AGYW. Dialogues with FBOs as influential bodies can ensure community buy-in and support. • Civil society Interviewees request to be more involved in receiving feedback on the findings of the research and to provide contextual information that is relevant to the communities they serve.
Include PrEP in national HIV prevention and other relevant standard treatment guidelines and policies (e.g., HIV testing, contraception, PEP etc).	• Oral PrEP was included in the NSP, and PrEP included in the NSP for HV, TB, and STIs (2023-2028), • Oral PrEP has been integrated into PHC services across the country. • The Ring is not included in the EML due to cost; therefore, it is implemented only through implementing partners (IPs) supported by donations and other donor support.	• **The inclusion of CAB-LA on the EML is a prerequisite for public sector CAB-LA procurement – the price and availability of CAB-LA is the major restriction.** • Only when CAB-LA is included on the EML can CAB-LA be included into procurement, then it is anticipated that CAB-LA will be incorporated into policies, the Standard Treatment Guidelines, annual implementation plans and budgets.
Issue **standard treatment guidelines** for delivery and use of PrEP methods.	• Oral PrEP was integrated into the South African Updated Guidelines for the Provision of Pre-exposure Prophylaxis (PrEP) to Persons at Substantial Risk of Infection (2021). • The Ring is included in the National Dapivirine Vaginal Ring Implementation Guidelines (2022) but is currently only offered at selected sites.	• The National Implementation Guidelines for Long-Acting Injectable Cabotegravir (CAB-LA) were approved by the NDOH on 7 December 2023; followed by a national training for implementation sites in February 2024.
Develop an **implementation plan and budget** to guide initial PrEP introduction and scale-up.	• Domestically funded, oral PrEP's rollout beyond initial research has paved the way for other biomedical HIV prevention products. Leveraging the established system, NDOH will evaluate new products against oral PrEP's cost-effectiveness.	• The CAB-LA investment case states that for cost-effectiveness, its price must be similar to oral PrEP. Interviewees insist that efficacy, benefits, health system impact, and the value of diverse PrEP options also be considered. • Pending NEMLC recommendation to include CAB-LA on the EML in South Africa, the NDOH will develop an introduction plan for CAB-LA, building on the implementation plans for oral PrEP. • Funding options include the NDOH HIV Conditional grant, PEPFAR, and the GFATM. A financing decision must be made; PEPFAR and Global Fund can procure without CAB-LA inclusion on the EML but require NDOH approval. Agreements are urgent for product arrival by late 2024. • There is a need to ensure coordinating structures between NDOH and Affordable Medicines Directorate are in place. • Recipients of the guideline dissemination and national training were partners approved to conduct CAB-LA demo projects/IS implementation science (IS) studies: DTHF, Ezintsha, Wits RHI, AHRI, MGH/HSRC, NACOSA.

Supply chain management key steps

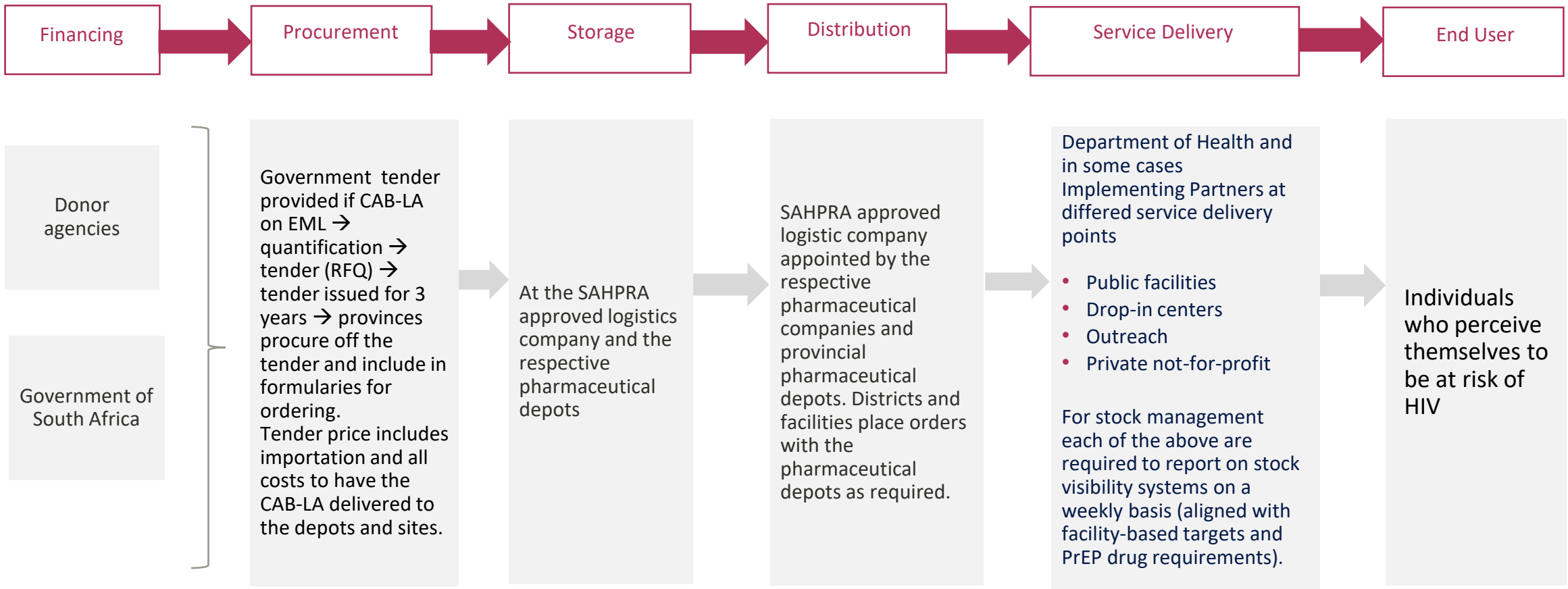
SUPPLY CHAIN MANAGEMENT

	Current situation of oral PrEP and the Ring	What is needed to introduce new PrEP methods
Register PrEP methods and include them on the Essential Medicines List, if needed.	• The greatest advantage of oral PrEP is that it was already on the NEML as an ARV. A tender was issued, and it could be procured through the existing mechanisms and systems. • CAB-LA and the Ring are registered with SAHPRA but not approved by NEMLC due to pricing (both products) and (for CAB-LA) a requirement for additional data on the tail phase.	• CAB-LA needs to be included on the EML to facilitate procurement and inclusion on provincial formularies. It is vital that provinces put CAB-LA on their formularies to facilitate ordering and availability at the facility level. • Although registered by SAHPRA, CAB-LA is not available in the public sector due to affordability concerns. ViiV has provided the not-for-profit cost, including distribution, to NDOH and NEMLC for consideration. • SAHPRA has approved IS studies by partner organisations previously mentioned. All studies are planned to start in 2024, with product made available through donations by ViiV.
Include new PrEP commodities into existing **supply chain systems**.	• Procurement and logistics systems are managed centrally by NDOH. • Pharmacies and social franchises procure commodities from accredited wholesale distributors (e.g., DSB, Alpha Pharm).	• CAB-LA needs to be included on the NEML to facilitate updates on the supply chain guidelines and logistic systems. The price and amount of product to be procured must be determined prior to these updates. • Interviewees anticipate that CAB-LA will be easily integrated into existing supply chain guidelines and logistic systems. The process will be similar to that of oral PrEP. • It is important that procured product and donated product have similar visibility.
Conduct **forecasting and/or quantification** to inform procurement of PrEP products.	• Targets for oral PrEP are based on the resources available for allocation.. • There have been challenges with for oral PrEP.	• CAB-LA needs to be included on the NEML to facilitate forecasting and quantification. If CAB-LA is approved, the NDOH will make assumptions on uptake, using modelling and taking into account findings from demo projects. • Data from IS studies will be valuable for informing demand forecasting and product manufacturing. • CAB-LA can be integrated into current commodity tracking programmes for PrEP/HIV prevention programmes, which aggregate stock reporting from PrEP sites monthly.
Establish **procurement, commodity monitoring, and distribution** for PrEP products and associated materials.	• Oral PrEP is available through national supply chain channels. • The affordable medicines team issues a tender; provinces procure against that tender.	• Interviewees do not anticipate any challenges around procuring CAB-LA or additional materials required for CAB-LA injection (e.g., gloves, alcohol wipes, syringes, needles); the systems are already well integrated for these products in public health facilities. • If PEPFAR procures CAB-LA, the recommendation is for routing to be managed by USAID, but NDOH would ultimately be responsible for distribution through office of the Director-General.
Establish **storage and distribution systems** that maintain temperature controls for PrEP products, if needed.	• Storage and distribution systems have already been established for oral PrEP, building upon existing systems for ART.	• Cold chain is not required for CAB-LA—the product can remain at room temperature. Monitoring of temperature excursions will be needed, integrated into routine pharmacy systems. • CAB-LA will not be a vertical intervention. It will be included in standard care and build off of the systems already in place for oral PrEP. • Interviewees/NDOH must determine whether to have a central storage mechanism or use direct suppliers.

Supply chain management for new PrEP methods

SUPPLY CHAIN MANAGEMENT

South Africa supply chain management for PrEP products (also relevant for CAB-LA)—note that CAB-LA supply chain still under review



Adapted from: Analysis and framework developed by Mann Global Health for the product introduction of CAB-LA in partnership with ViiV Healthcare

PrEP delivery platforms key steps

DELIVERY PLATFORMS

	Current situation of oral PrEP	What is needed to introduce new PrEP methods
Dedicate resources to conduct regular **HIV tests, initiate PrEP, and support ongoing PrEP use.**	• HIV testing is available and easily accessible across channels, including sexual and reproductive (SRH) services, at the national and subnational levels. • Oral PrEP is widely available in public health facilities (e.g., ART, ANC, STI) and community-based platforms (e.g. donor supported mobile sites). • Ongoing PrEP use remains a challenge.	• Delivery platforms for other PrEP methods exist. CAB-LA will be provided using the same delivery platforms—but must consider that CA-LA is injectable and can be provided only in clinical environments.
Develop training and materials for **health care workers** on PrEP methods.	• The TWG created national training materials to conduct national, district, and facility-level training. • There has been a broad training programme for HCWs in SRH, FP, and maternal child health services to receive PrEP training; every public SRH and FP facility has at least one HCW with PrEP training. • Provider attitudes remain a challenge, especially toward providing oral PrEP to AGYW. • Training material has been digitised and housed on MyPrEP.co.za for all HCWs to complete.	• The NDOH has developed and in early February provided training to the sites implementing demos/IS projects. Tools include job aids, quizzes, and information on the full spectrum of prevention choices. • Interviewees believe incorporating CAB-LA training will be relatively easy in the programmes that have already integrated oral PrEP. • Ensuring information, education, and communication (IEC) materials highlight client choice among PrEP methods is important.
Establish **referral systems** to link clients from other channels to sites providing PrEP.	• Oral PrEP has been fully integrated into primary health care services.	• CAB-LA should be integrated into PHC services. • There is an opportunity to provide CAB-LA during postnatal period and reduce rates of postnatal vertical transmission.
Integrate support for **partner communication** and services for intimate partner violence response.	• Screening for IPV is part of the oral PrEP delivery package and is included in guidelines for HIV prevention services.	• IPV screening should be strengthened where gaps are noted in service delivery, with integrated use of validated screening tools. • Strategies to engage male partners should be considered for all the PrEP methods to support clients who may be at risk of GBV. • CAB-LA may reduce the risk of social harms or IPV given that it is discreet.

Differentiated service delivery for PrEP: Channel analysis

DELIVERY PLATFORMS

South Africa delivers health services through a large public sector health system, which serves ~84% of the population, as well as a significant private sector, which services ~16% of the population.

Service delivery channels	Description
Public sector	
Public sector health services	Public sector primary health care facilities managed by provincial and district governments and offering a range of SRH services, including HIV testing and treatment, oral PrEP, FP, and antenatal care (ANC)/postnatal care.
Population-focused programmes	Facility-based and mobile services that reach specific populations (e.g., FSWs, AGYW), managed by the NDOH in partnership with implementing partners and focused on hotspots
Higher education health services	Facility-based and mobile health services offered at higher education institutions, including universities and technical and vocational education and training (TVET) campuses
Private for profit	
Private clinics or providers	Private for-profit health care that largely serves individuals with health insurance, including hospital groups (e.g., Netcare, Life Healthcare, Mediclinic) and smaller practices and individual clinicians
Corporate & community pharmacies	Private pharmacies, including several large corporate chains (e.g., Dis-Chem, Clicks), as well as independent community pharmacies (some are members of the Independent Community Pharmacy Association), typically staffed by a trained pharmacist and sometimes also staffed with a trained nurse
Private not for profit	
Non-profit clinic chains	Private not-for-profit clinics managed by NGOs offering subsidised health services; major networks dedicated to SRH include PSI, Marie Stopes South Africa, Society for Family Health, and Unjani Clinics

Differentiated service delivery for PrEP: Channels

DELIVERY PLATFORMS

	Current situation of oral PrEP	What is needed to introduce new PrEP methods
Integration in **public sector HIV services**	• Oral PrEP is widely available in public health facilities offering HIV services and ART.	• Interviewees feel CAB-LA should be introduced through the public sector, building on current oral PrEP provision. • Prescribing of ARV by nurses must be regulated through the provisions of section the Nursing Act of 2005 Act, section 56 provides the regulatory framework for the prescribing and dispensing of medicines by nurses.
Integration in **population-focused programmes**	• Oral PrEP is widely available in population-based programmes offering HIV services and ART. • PEPFAR-funded DREAMS sites focused on AGYW have expanded to 24 districts; oral PrEP is included at all sites.	• Existing community-based service structure offering oral PrEP need to be further strengthened the integration of CAB-LA. • Continuing to engage community leaders, end users, and peers will be important early in the planning processes to hear their perspectives on community rollout and build buy-in. • HCW training on CAB-LA guidelines will be required.
Integration in **higher education health services**	• The NSP recognises schools and universities as critical environments for reaching AGYW with SRH services via low-stigma delivery points. • Universities and colleges have on-site health centers that provide HIV testing and FP services, but they refer clients to PHC facilities to receive ART and other services. • Some higher education health facilities offer oral PrEP: some IP projects support delivery of PrEP.	• There is an opportunity to introduce CAB-LA through established campus health services.
Integration in **private clinics**	• Private hospitals and providers have advanced structures to support follow-up and manage care by on-site specialists and pharmacists. • These clinics are unaffordable for the 83% of the population without insurance due to high cost of products and services. • Oral PrEP costs US$23 per month (including labs). • Private sector providers and pharmacists are reliant on continuing medical education (CME) and medical detailing via pharmaceutical companies to learn about and engage with new products.	• Expanding access to CAB-LA in the private sector will be much more expensive than it was for oral PrEP (driven by profit and with higher infrastructure and resource costs, which are billed into the price of service). But for those who can afford private health care, CAB-LA is an additional, more discreet option. • Monitoring PrEP uptake in the private sector is a challenge.
Integration in **private pharmacies**	• Pharmacies increasingly offer on-site HIV testing and counselling via nurses and HIV self-testing. • Some pharmacies have nurses on staff in addition to pharmacists. These nurses can deliver ART as they are NIMART trained. Pharmacists are not approved to provide PrEP; pharmacist-initiated management of ART (PIMART) is not approved. • One IS study through Ezintsha is offering oral PrEP at private pharmacies.	• No information is available on whether medical aid would pay for CAB-LA. • Build on the lessons of demonstration studies. • Integration into pharmacies requires clinic room for client consultation and examination
Integration in **donor funded sites**	• Oral PrEP is available within PEPFAR-supported IP organisations.	• Interviewees feel that there are opportunities to build on existing oral PrEP programming for the introduction of CAB-LA. • HCW training on CAB-LA guidelines will be required.

Differentiated service delivery for PrEP: Channel analysis

DELIVERY PLATFORMS

For the introduction of new PrEP methods, public sector PHC facilities are the logical choice given their predominance in the country, with opportunities to prioritise population-focused programmes, nonprofit sites, and private and community pharmacies (potentially for referral systems).

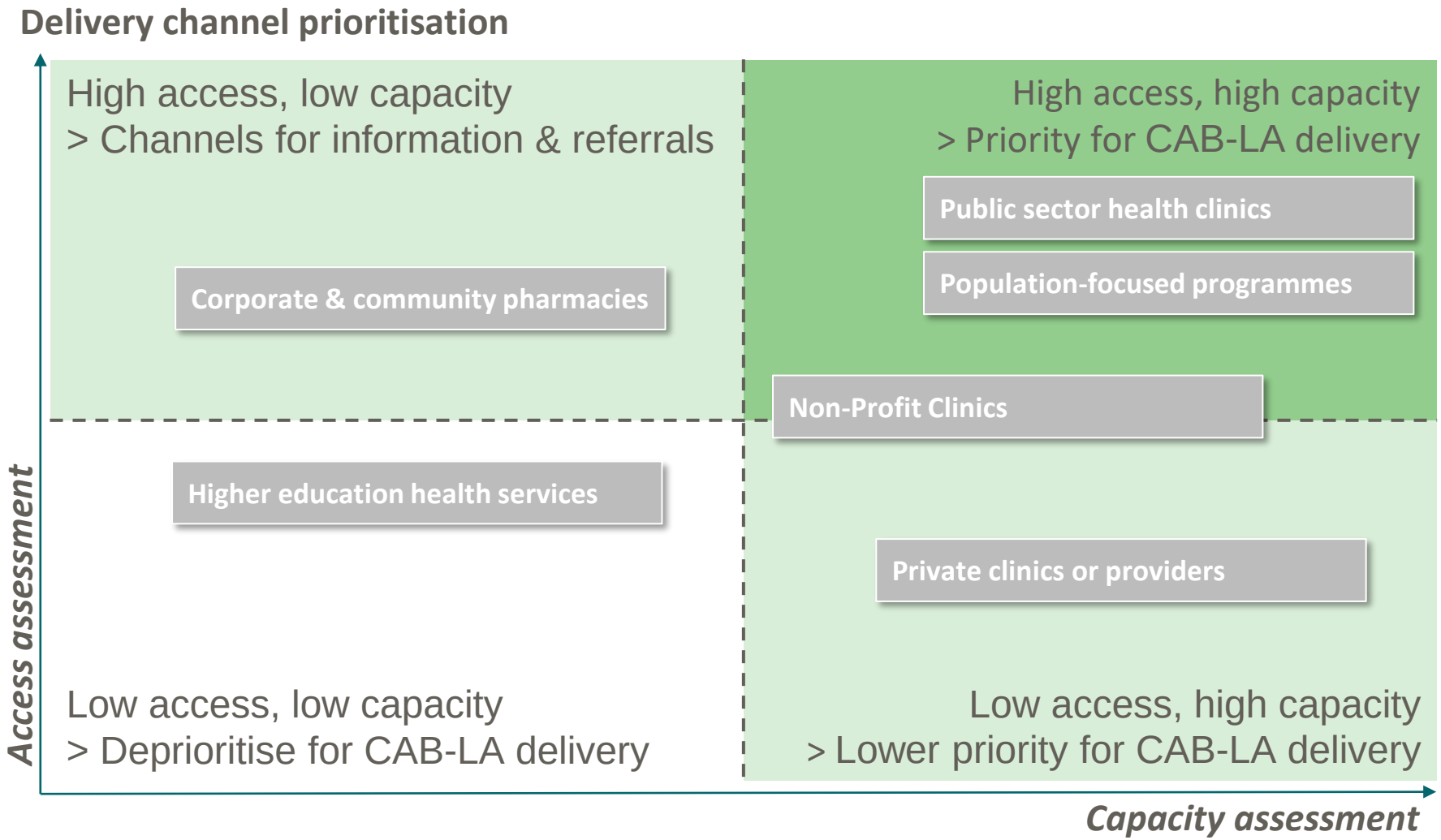
Service delivery Channel	Offer PrEP/HTS	HCW capacity (NIMART, provide injections)	Link to national supply chain	Reach (sand cost-effectiveness)	Potential impact (users served)	Overall
Public sector health services	High	High	Y	Very High	High	• 4,200 public health clinics across the country
Population-focused programmes (e.g. sec workers, MSM, DREAMS)	Very high; particularly for KPs and AGYW	High	Y	Very High	High	• Sex worker programmes aim to reach 70K women • Men who have sex with men (MSM) programmes – targets TBC • PEPFAR-funded DREAMS sites focused on AGYW expanded to 24 districts
Higher education health services	Medium	Not consistent	Limited	Limited	Limited	• Includes 26 universities and 50 TVET colleges
Private clinics	Medium	High	Y	Limited	Limited	• Largely serve the 17% of the population that is covered by medical insurance • Predominantly in urban areas, with 188 urban and 50 rural hospitals—nearly half of private hospitals are in Gauteng Province
Corporate and community pharmacies	Medium	PIMART blocked	Y	Limited; CAB-LA requires PIMART and training	Medium (long-term)	• Services delivered via ~3,000 sites across South Africa, with greater availability in urban areas • Attract a range of customers, across income levels • A new national NDOH programme is delivering medicines for chronic diseases through pharmacies
Nonprofit clinics	Very high; particularly for KPs and AGYW	High	Y	High	High	• Several relatively small networks; however, they often have greater reach in rural areas

Rating key:	Very high/high	Medium	Limited

Prioritising delivery channels for CAB-LA

DELIVERY PLATFORMS

- Bringing together the access and capacity dimensions allows us to assess delivery channels against **both criteria.**
- The channels in the **upper right corner** have both high capacity to deliver CAB-LA within HIV prevention services and high access to priority HIV-negative populations who would benefit from CAB-LA.
- Channels in the **upper left** have less capacity to integrate CAB-LA but have high access to priority HIV-negative populations.
- Channels in the **lower right** have less access to HIV-negative populations but have high capacity to integrate CAB-LA.
- Channels in the **lower left** have neither the capacity nor reach to effectively integrate CAB-LA.



Uptake & effective use key steps

UPTAKE & EFFECTIVE USE

	Current situation of oral PrEP	What is needed to introduce new PrEP methods
Develop and implement **demand generation strategies** that include PrEP promotion.	• Several successful demand generation strategies have been deployed for oral PrEP. The slogan *We are the Generation that will End HIV* was used in all NDOH IEC materials. • IEC materials were developed with inputs from multiple Interviewees, including potential recipients, and were adapted for each key population. • Research suggests that there is low awareness of and demand for oral PrEP, especially among AGYW.	• The NDOH is planning to take a more generic approach to HIV prevention, improving HIV prevention literacy. Instead of focusing on one product, they will build awareness of HIV, prevention, and the options for prevention. • National PrEP demand generation strategies and programmes will need to be updated to include all forms of PrEP, including CAB-LA. • Interviewees report that a lot of people want PrEP outside of facilities (community-based is more convenient), and there has been a good effort to demedicalise oral PrEP. As CAB-LA is introduced, facilities must take caution to not medicalise PrEP again. • Interviewees encourage leaving space for people to "try out" different PrEP products to find one that fits for them.
Address social norms/stigma to build **community and partner acceptance** of PrEP use.	• Stigma and myths/misconceptions continue to prevail for oral PrEP and will need to be addressed for the new HIV prevention products. Oral PrEP can be mistaken for HIV treatment. • Because the initial oral PrEP rollout was aimed at key populations (KPs), community sensitisation efforts were limited. Since scale-up to all PHC facilities, community sensitisation has increased.	• CAB-LA is expected to be more widely accepted than oral PrEP because injections are more discreet than tablets (e.g., for FSWs, MSM). • There is a need to adapt messages to promote PrEP for the general population and not perpetuate stigma and discrimination, highlighting the need for prevention beyond KPs. • Existing community and partner engagement activities for oral PrEP will need to be updated to include discussion of CAB-LA as an additional PrEP option.
Develop **information and tools for clients** to support product choice.	• Existing platforms, such as B-Wise and MyPrEP.co.za, help build awareness of and demand for different HIV prevention options.	• Existing oral PrEP tools and materials can be expanded to include information about all forms of PrEP. Consideration is needed to ensure messaging supports product choice. Resources will be limited, with a need to maximise delivering a particular product to those who will benefit from that product. • The demo projects can inform ways to introduce CAB-LA effectively in IEC materials. • The digital version of HIV Prevention Ambassadors training and implementation tools will need to be updated to include CAB-LA and widely disseminated. • Health care worker training should be focused not only on clinical skills, but also on how to provide empathetic, client-centered choice counselling.
Support **effective use** of PrEP products.	• The demand generation strategies have also served as successful models for supporting end users to effectively use oral PrEP after initiation of the method. • During the transition to dolutegravir for ART, we learned clinicians were hesitant with regards to a new product; even though we had the guidelines and product in place, clinicians were a barrier.	• Consideration of method switching from oral PrEP to CAB-LA will be needed (e.g., ensuring end users have the option to switch products through a collaborative and open discussion with a provider). • Additional information and preparation will be needed for end users to understand the potential side effects . There is a need to understand and improve people's motivations for taking PrEP.

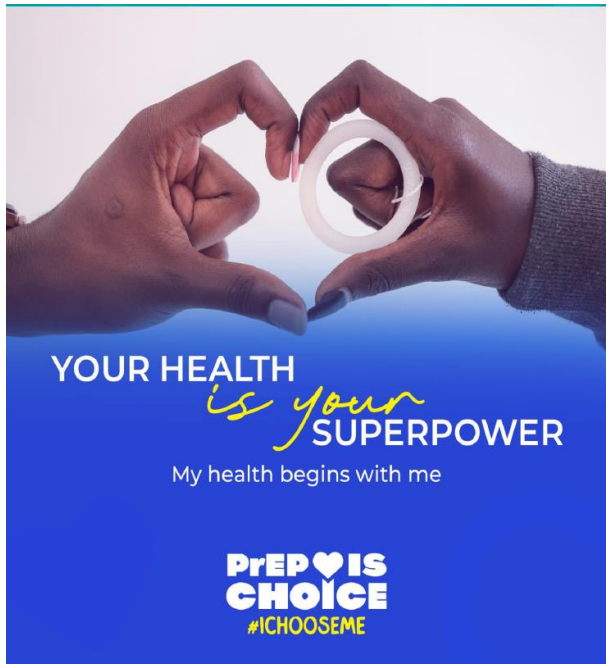
Uptake & effective use

An additional note on SBC strategy to support effective use –an example

An important component of CATALYST is looking at demand generation, choice counselling and continuation.

CATALYST will be implementing the following activities to support continuation:

- Digital grapevine – Piloting of a WhatsApp support tool to improve PrEP knowledge, persistence on PrEP for the first month and effective use over time
- PrEPisChoice or IChooseMe brand and positioning strategy - already incorporated into DOH PrEP materials and will be shared with PEPFAR local office for disseminating to all PrEP IPs. Guided by evidence from MOSAIC PrEP Category Positioning Work



Monitoring key steps

MONITORING, EVALUATION, & LEARNING

	Current situation of oral PrEP	What is needed to introduce new PrEP methods

Update or establish **integrated monitoring tools** to support data collection and analysis on PrEP use across multiple products.	• Current monitoring tools are fully integrated and include oral PrEP, the Ring, and CAB-LA. These tools include a PrEP clinical form, seroconversion form, and a longitudinal reporting tool submitted monthly by IPs for the research studies reporting new method introduction.
	• Reporting and tracking for oral PrEP are currently conducted at the facility level, with reporting up to the NDOH.
		• Some concerns remain about seroconversion; therefore, more evidence is needed for screening for HIV at initiation, while on method, and during the tail.
		• CAB-LA indicators have already been included in the monitoring tools:
		  • CAB-LA initiation
		  • Continuation of CAB-LA

Establish systems for **pharmacovigilance** and to monitor drug resistance.	• National pharmacovigilance procedures are in place, overseen by SAHPRA. • The pharmacovigilance system is an online reporting system for all medications, VigiApp. • PHC facilities are using online or paper-based systems, but any sites outside the formal health system do not report.	• Interviewees did not anticipate any challenges to integrating the new PrEP methods into existing pharmacovigilance systems. • Concerns about the side effects of CAB-LA and considerations for drug resistance must be considered.

Conduct **implementation science** research to inform policy and scale-up.	• An IS or demonstration study is typically required by the regulatory authorities and can be conducted with SAPHRA approval (prior to NEMLC approval and inclusion on the NEML) for study purposes.
	• Implementation studies were conducted for oral PrEP and greatly informed integration and rollout of PrEP within HIV prevention methods in South Africa.
		• Interviewees want to know what the role of the demo studies is and what key questions are being addressed.
		• All populations must be represented in IS studies.
		• Five studies are approved for CAB-LA:
		  • Project PrEP (Wits RHI)
		  • CATALYST (Wits RHI)
		  • Let's Talk & LAPIS (AHRI)
		  • FastPrEP & PrEPared (DTHF)
		  • AXIS (Ezintsha)
		• Sites started receiving donated CAB-LA from ViiV/GSK as of mid-February.
		• Interviewees feel that plans for introduction and procurement need to start now and not wait until IS are in progress.

Remaining key questions*

PLANNING & BUDGETING

- What is the potential demand? Need results of implementation research to determine demand in SA and assist with forecasting for example: Interim results of IS studies could assist in informing the NDOH to move ahead with programmatic procurement? MOSAIC/Avenir might be able to support this if desired.
- What is the cost of implementation? The results of costing studies? Will negotiations with ViiV on pricing successfully result in CAB-LA acceptance by the NEMLC (including non-profit and distribution costs)?
- What is the process for expediting generics?
- Will new, promising methods such as lenacapavir affect interest in scaling up CAB-LA?

SUPPLY CHAIN MANAGEMENT

- Will ViiV have product to meet demand if scaled up?
- Will NDOH purchase product for expanded availability?
- How to integrate CAB-LA supply chain mechanisms in terms of existing financing, procurement processes, sources, storage, distribution and delivery platforms?

DELIVERY PLATFORMS

- How can we leverage what we have learned from implementation research and current oral PrEP provision to transfer to public health facilities?
- Will the NDOH integrate CAB-LA within all public sector health facilities providing PrEP, or in a phased approach? And how will the facilities be prioritised for selection?
- How will health providers respond to the provision of an additional method?
- What is the potential for the private sector as a service delivery platform?

UPTAKE & EFFECTIVE USE

- What are the patterns of use found in the implementation research—especially where all three PrEP products are being provided?
- What have we seen in terms of effective use of CAB-LA? Key to this are return visits and continuation.
- How do we evaluate the tools, job aids, and IEC materials developed to ensure that they support providers and assist clients in informed decision making and choice, effective use, and understanding and taking ownership over their own HIV prevention?

MONITORING, EVALUATION, & LEARNING

- Are existing monitoring tools appropriate? (We need to continue the discourse about meaningful indicators.)
- How do we ensure that pharmocovigilance for CAB-LA is integrated into the existing pharmocovigilance system.
- Monitoring of drug resistance amongst CAB-LA users
- How do we sustain the implementation of monitoring, evaluation, and research to look at issues such as effective use; patterns of use and choice; HIV resistance; integration with SRH; side effects and their management; pregnancy and breastfeeding; HIV testing and screening for acute HIV infection; effective demand generation; providers' and PrEP users' experiences; and what happens when clients stop CAB-LA.

*Many of these questions to be answered by ongoing implementation studies such CATALYST.

Key stakeholders interviewed

Stakeholder group	Organisation	Individuals	Role
Government	National Department of Health	Hasina Subedar	Advisor to the NDOH, leading biomedical HIV prevention
Donor & Multilateral Stakeholders	USAID	Zandile Mthembu	Strategic Prevention Team Lead – Biomedical Specialist
	USAID	Rethabile Tsekoa	Supply Chain Specialist
	USAID Global Health Supply Chain	Rob Botha	Chief of Party – USAID Consultant
	USAID Global Health Supply Chain	Sue Putter	Senior Health System Strengthening Specialist/Deputy Chief of Party
	Gates Foundation	Liesl Page-Shipp	Senior Programme Officer for HIV, BMGF
	ViiV	Isla Harrap	Access to Medicines Strategy and Programmes Manager
NGO & Implementing Partners	Desmond Tutu Health Foundation (DTHF)	Elzette Rousseau	Social Behavioral Scientist leading FAST PrEP project
	Ezintsha	Joana Woods	Senior Research Clinician
Civil Society	Northern Hope CSO	Pinky Sekai	Project Manager
	Northern Hope CSO	Thapelo Mathibe	Finance and Administration
	Youth Gate Development CSO	Nomhle Khumalo	Director

Selected desk review sources

Sources
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Note on terminology

In efforts to be more precise and not contribute to the stigmatisation of people living with HIV or those who may benefit from HIV prevention products, we have made a few language shifts:

- **Serodifferent instead of serodiscordant**. This change reinforces that while the HIV status of people can be different, it does not put them in discord. It is completely okay for people to have different HIV serostatuses.
- **Minimising use of the terms "risk" and "risky."** These terms can have so many different definitions and may stigmatise certain behaviors, impose labels on clients, or stigmatise living with HIV itself.
- Using **gender-neutral terms when text is not specifically about gender**. The terms are more inclusive of various gender identities.

Acronyms

AGYW	Adolescent girls and young women
AHRI	Africa Health Research Institute
ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral
CAB-LA	Long-acting cabotegravir
DREAMS	DREAMS Initiative (Determined, Resilient, Empowered, AIDS-free, Mentored and Safe)
DTHF	Desmond Tutu Health Foundation
FP	Family planning
FSW	Female sex worker
GBV	Gender-based violence
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HCW	Health care worker
HIV	Human immunodeficiency virus
HSRC	Human Sciences Research Council
IEC	Information, education, and communication
IP	Implementing partner
IPV	Intimate partner violence
IS	Implementation science
KP	Key population
MCH	Maternal and child health
MGH	Mann Global Health
MOSAIC	Maximize Options to Advance Informed Choice for HIV Prevention
MSM	Men who have sex with men
NACOSA	Networking HIV and AIDS Community of Southern Africa
NDOH	National Department of Health
NEMLC	National Essential Medicines List Committee
NIMART	Nurse-initiated management of antiretroviral therapy
NSP	National Strategic Plan
PEP	Post-exposure prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PHC	Primary health care
PIMART	Pharmacist-initiated management of antiretroviral therapy
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
SA	South Africa
SABSSM	South African National HIV Prevalence, Incidence, Behaviour and Communication Survey
SANAC	South African National AIDS Council
SAHPRA	South African Health Products Regulatory Authority
SRH	Sexual and reproductive health
TVET	Technical and Vocational Education and Training
TG	Transgender people
TWG	Technical working group
USAID	United States Agency for International Development

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