CAB PrEP Introduction Situation Analysis in Kenya

LVCT HEALTH & AFTON BLOOM
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Maximizing Options to Advance Informed Choice for HIV Prevention

Overview of PrEP Introduction Situation Analysis

- This document summarizes findings from the **national situation analysis** that can support the creation of a national biomedical HIV prevention platform.
- The situation analysis aims to clarify critical steps for the introduction of biomedical HIV prevention products.
- This analysis is based on several **inputs**, including a desk review, secondary research, interviews with key stakeholders in Kenya and can be used by policymakers, implementers, and others **planning for introduction of CAB PrEP.**
- This analysis was completed in collaboration MOSAIC Consortium partner Mann Global Health who conducted a complementary analysis for the introduction of the cabotegravir injectable for ViiV Healthcare.
- Summaries of similar analyses for other HIV prevention methods and other countries are available on **PrEPWatch.org**.

Current situation of HIV prevention

Findings for CAB PrEP introduction planning

Sources and notes

Kenya has made significant progress on HIV prevention

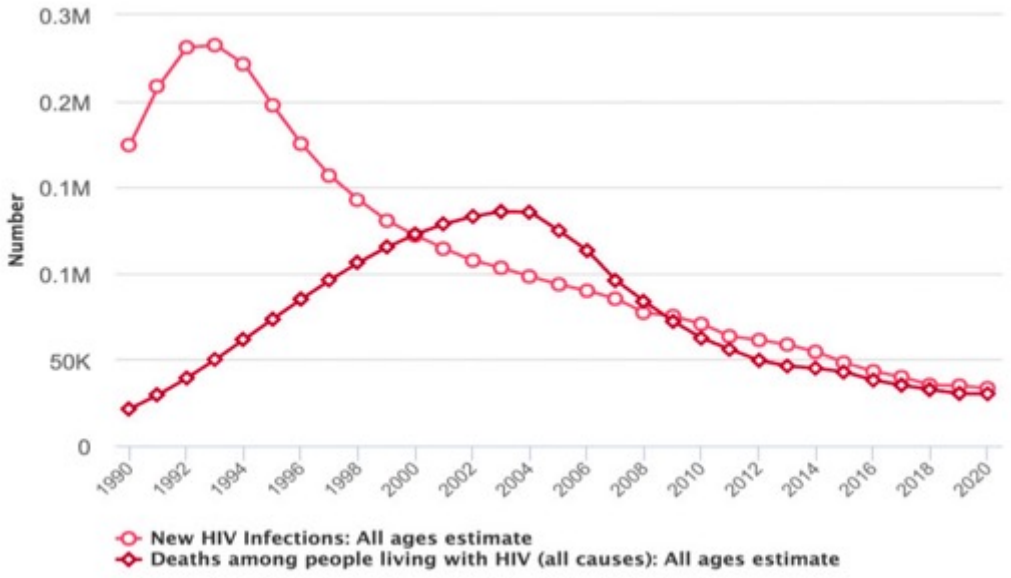
HIV-related deaths

↓ 63%

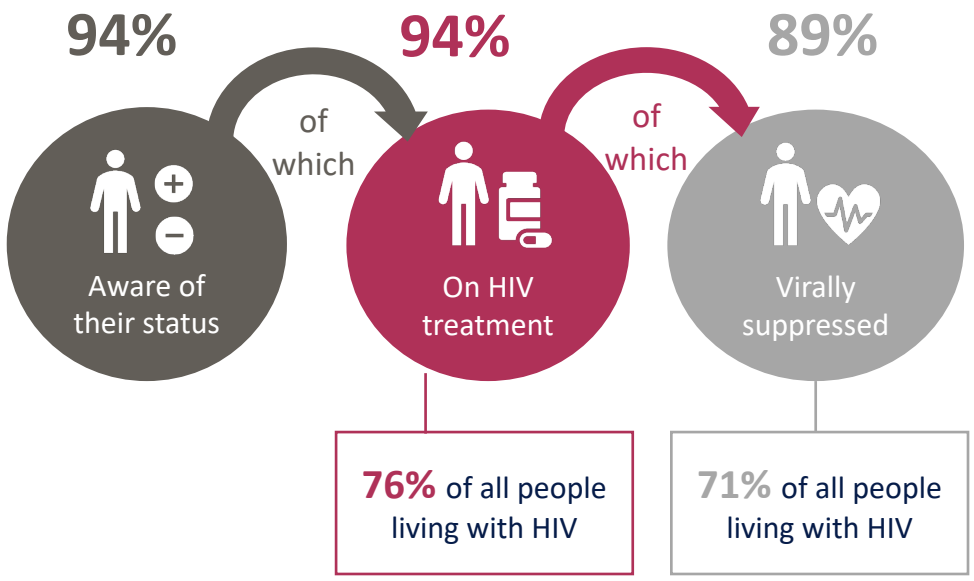
KEY STATISTICS

- About 1.4 million Kenyans live with HIV, with a national prevalence of 3.7% in 2023.[1]
- **New HIV infections have more than halved** since 2013 (by 68%), contributing to a **63% reduction in HIV-related deaths**. Still, an estimated 42,000 new infections and 21,000 HIV-related deaths occur every year.[2]
- Scaled up HIV testing and treatment services has moved Kenya closer to **95-95-95** goals, but knowledge of status lags.[2]
- Kenya has a robust HIV prevention program and was the 2nd country to introduce oral PrEP, a leader in achieving high VMMC coverage in targeted counties and maintains an established condom programme.[2]

HIV INCIDENCE AND AIDS-RELATED DEATH, ALL AGES, 1990-2020



PROGRESS TOWARDS 95-95-95 GOALS, AGE 15-64, 2022



Source: (1) National HIV Estimates in Kenya 2023; (2) UNAIDS Epidemiological Estimate 2021

Source: PHIA 2018 Kenya Report, UNAIDS data 2022, Kenya AIDS Strategic Framework II 2020

HIV risk for women in Kenya remains high

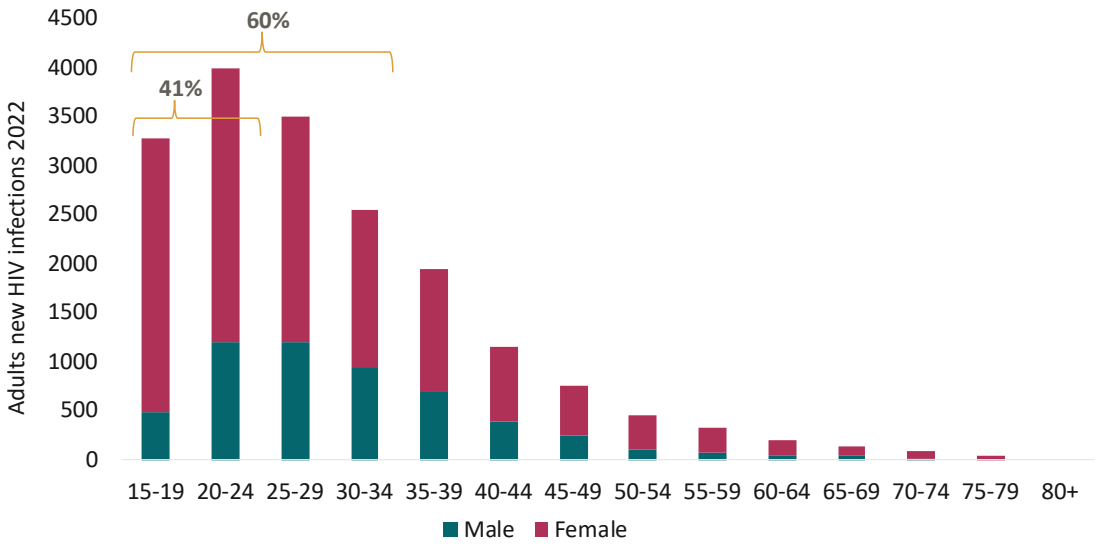
HIV disproportionately impacts young people. Adolescents and young adults aged 15-24 years contributed to **41% of all new adult HIV infections** in 2022.[1]

Adolescent girls and young women (AGYW) are twice as likely as young men to acquire HIV and account for nearly 1/3 of total new infections.[1]

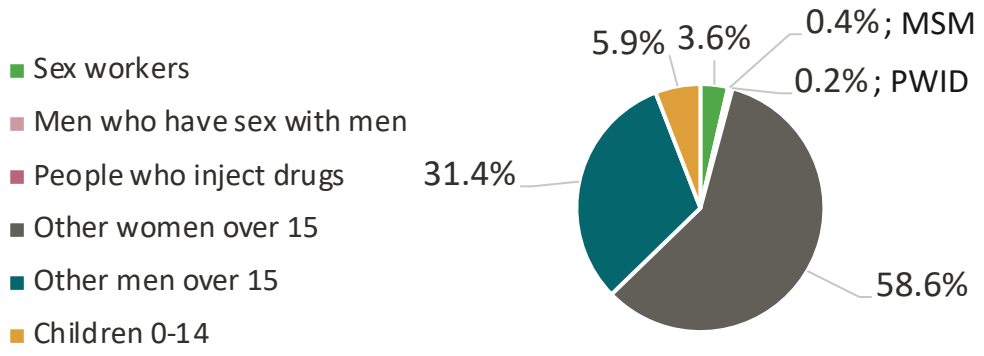
HIV prevalence for FSW
29%

HIV prevalence among key populations (KPs) is between 4-8 times and 7.8 times that of the general population. HIV prevalence is highest for **female sex workers (29.3%)**, men who have sex with men (18.2%), and people who inject drugs (18.3%).[1]

HIV INCIDENCE BY GENDER, ALL AGES, 2022 [1]



PERCENT OF POPULATION LIVING WITH HIV [2]



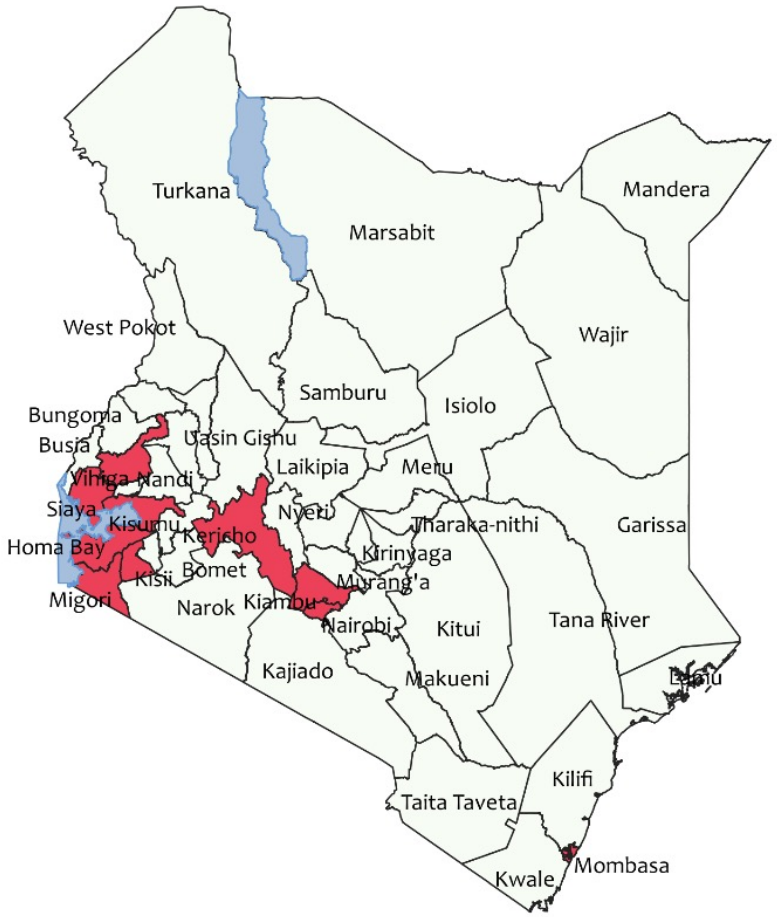
Source: (1) National HIV Estimates in Kenya 2023; (2) Preliminary KENPHIA 2018 Report and UNAIDS Data 2020

The Kenyan HIV epidemic is geographically concentrated in 10 counties

In 2022, **57% of people living with HIV (PLHIV) were concentrated in 10 counties** within Kenya. Kisumu, Nairobi County, and Homa Bay report the highest numbers of PLHIV.

Country	No. of PLHIV
Kisumu	128,091
Nairobi (County)	124,609
Homa Bay	120,600
Siaya	96,297
Migori	76,053
Nakuru	57,635
Mombasa	50,656
Kakamega	48,733
Kiambu	45,917
Kisii	42,210

HIV ACROSS COUNTIES IN KENYA



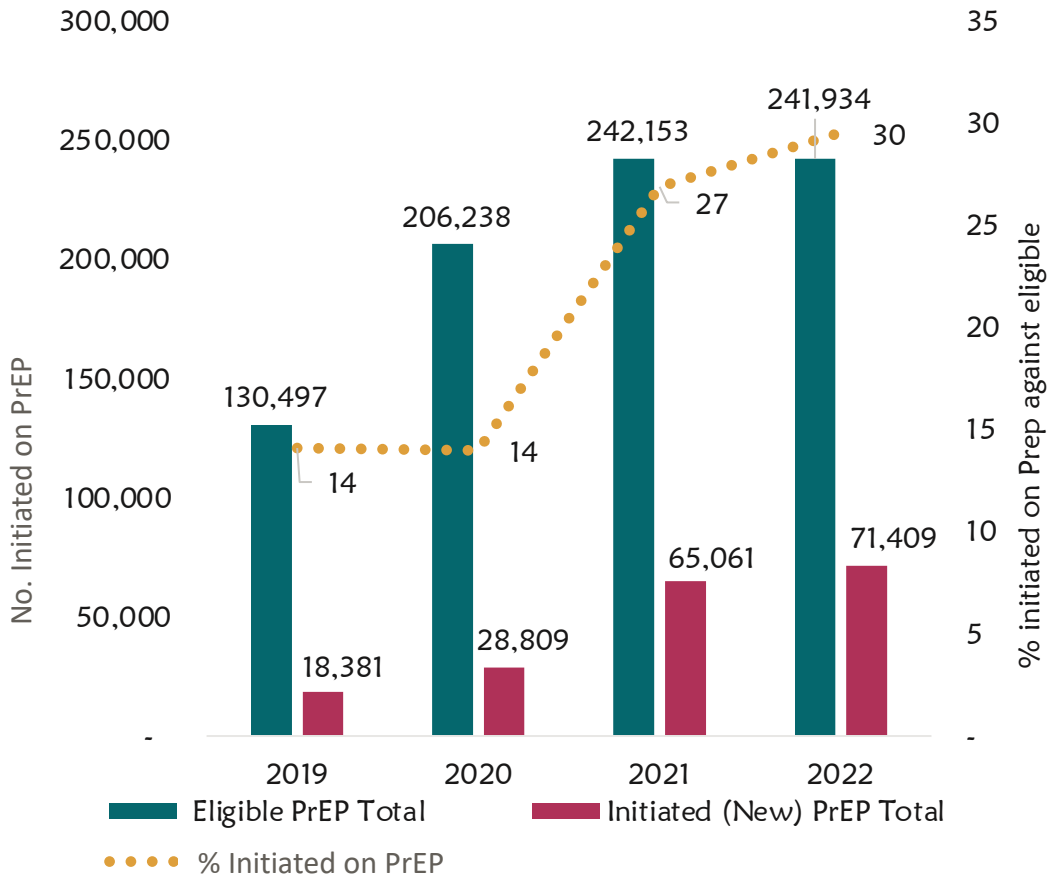
Source: National HIV Estimates in Kenya 2023

Oral PrEP rollout in Kenya has been successful and offers a strong foundation for the introduction of CAB PrEP

CURRENT SITUATION FOR ORAL PrEP

- As of 2022, only **30% of those eligible were initiated on PrEP,** with strongest uptake amongst eligible serodifferent couples (SDCs) (54%) and general population (62%), followed by MSM (26%), FSW (25%), and PWID (12%). [1]
- While PrEP initiation coverage remains low, there is a positive trajectory. Oral PrEP is **available in all 47 counties and in more than 2,000 facilities.**[2]
- Kenya designed a rollout plan for the **general population** (which includes AGYW), however donor-funded interventions have targeted key populations (KPs).
- Public sector distribution is primarily through **HIV treatment sites** (comprehensive care centers, or CCCs).
- Nascent pilots supporting **integration with FP clinics** in 5 counties, complemented by ad hoc, innovative county-led efforts integrating oral PrEP into maternal and child health clinics is informing distribution channel expansion.
- DREAMS and KP focused interventions provide the safe spaces/centers required to attract new users and support continued use.
- Pilots exploring feasibility of prescribing and resupplying oral PrEP through private pharmacies are poised to understand how channel expansion impacts uptake.

TRENDS IN PREP UPTAKE, 2019-2022 [1]



Source: (1) National HIV Estimates in Kenya 2023; (2) Mann Global Health CAB situation analysis for ViiV Healthcare; (3) PrEP Watch, 2021

Focus populations: CAB PrEP is an opportunity to expand the reach of prevention interventions to populations in need

- Consensus on importance of "focusing on a population" for CAB PrEP, which should include **AGYW, MSM, FSWs**
- But **"norming the product"** by positioning CAB PrEP as an HIV prevention option for a subset of the **general population at risk** is cited as a path to expand impact, while addressing pervasive stigma that inhibits uptake for all populations
- **Serodifferent couples** and pregnant & breastfeeding women were raised as sub-sets of the general population in need, and often missed in the prevention mix – **an important opportunity to demonstrate early wins for CAB PrEP**

	Who are they?	Population size estimate/ Contact Coverage /estimated Oral PrEP coverage[3]	Considerations
Key Populations (KP)	**Female sex workers**	170,000[1]/ 84% / 20%	KP benefit from the holistic and intensive support required to introduce then sustain use of PrEP through outreach and drop-in centers PEPFAR and GFATM funding have been primary funders of interventions targeting key populations
	Men who have sex with men	33,000[1]/ 100% /13%	
	People who inject drugs	16,000[1] / 73% /5%	
General Population at risk	**AGYW (15-24 yrs)**	~4,733,0002/ 22% / low%	Likely to **drive volumes and impact** AGYW programmes will ride on DREAMS interventions, which are less targeted and don't bring the intensity of support that KP benefit Men, pregnant and breastfeeding women need to be reached through the existing health system
	Serodifferent couples	NA/ ~5%/NA	
	Pregnant & breast-feeding people	NA	
	Men over 40	NA	
"Vulnerable Populations"	Fisher folk, populations in prison, truckers	~260,000-400,000[2]/NA/NA	Interventions specifically focusing on these populations are not well funded but included as GoK priority

"Oral PrEP has been good for SDCs, who appear be leading in adherence and acceptance…. CAB LA will be a good fit… especially when they are trying to conceive."
– Policy maker

"Make CAB LA for PrEP a prevention choice for anyone at risk…"
– Policy maker

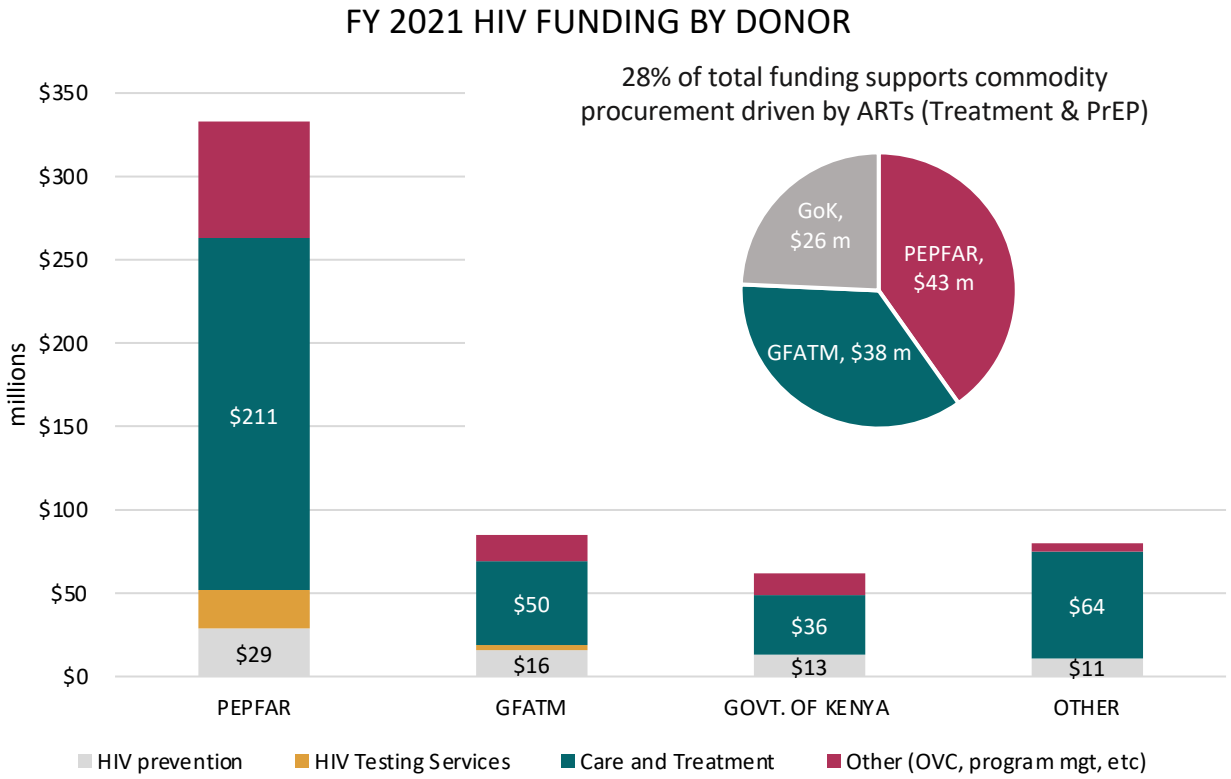
1. UNAIDS Epidemiological Estimate 2021
2. Planned Allocation & Strategic Direction' Jan 2021
3. Information Memo for Ambassador McCarter titled 'FY 2021 PEPFAR Kenya Country Operational Plan (COP) 2021 Strategic Direction Summary

*NA: Not available

However donor support for HIV prevention is declining

PEPFAR is still the leading donor in Kenya, but with Kenya reaching epidemic control and achieving a **lower middle income country status, United States Government (USG) funding is expected to decline by 7-8% in FY 23 from FY 2021 levels.**

- Total investment in Kenya for HIV was estimated at $557m USD, of which **~$69.4m was allocated for prevention,** and $26m for testing.
- **PEPFAR contributes ~60% of total funding in Kenya**, or $334m in 2021.
- 28% of total HIV funding in Kenya supports commodity procurement, which is driven by ARTs (most for treatment, and some for PrEP).
- PEPFAR contributes about **90% of the $18.5m budget available for viral load testing**



- *NOTE: Commodities are a subset of the total investment profile, and funding is drawn from the different categories of the total investment portfolio. Donors track spending using different categories – it's important that amounts are estimated and reflect the best information available when preparing this analysis.*
- *Source: Kenya COP21 Strategic Direction Summary*

Current situation of HIV prevention

Findings for CAB PrEP introduction planning

Sources and notes

Key findings from stakeholder consultations

- **NASCOP plays a strong and engaged leadership role** for planning the introduction of new HIV prevention methods such as CAB PrEP in Kenya. The HIV Testing Services & PrEP Committee of Experts (COE) will be critical stakeholders in overseeing CAB PrEP integration in existing policies and plans.
- Kenya has a **robust PrEP supply chain system** that is managed by NASCOP through a pull-driven system from facilities. There is a strong national coordination mechanism through the COE and Kenya Medical Supplies Agency (KEMSA) to oversee the planning of new products within the supply chain and stakeholders expect that CAB PrEP can build on the existing supply chain logistic systems established for oral PrEP.
- **Strong PrEP service delivery models exist in Kenya**, particularly through public HIV clinics (CCCs) to reach PrEP users. However there continues to be ART-related stigma associated with public facilities, particularly for AGYW. Community-driven Youth Peer Provider models have helped increase enrollment among AGYW at public health sites (e.g., Jilinde pilot project, DREAMS).
- **Integration of oral PrEP into SRH channels** is demonstrating early success through the NASCOP-led PrEP/SRH integration Young Women and Adolescents (PriYA) program across 5 counties (e.g., Kisumu, Kakamega, Migori, Kisii, Baringo). Increased access is translating into increased uptake and is an opportunity to mainstream access for CAB PrEP for women.
- However, there is a continued need to focus on **provider capacity building and sensitization for PrEP.** Provider biases and negative attitudes persist, particularly when counselling AGYW for PrEP uptake. Stakeholders expect that delivery through community health workers (CHWs) would help to provide AGYW-friendly services for CAB PrEP.

CAB PrEP 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 program monitoring systems.

CAB PrEP introduction situation analysis

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 and private sector providers/pharmacies				
Convene new or existing subcommittee or task team within HIV prevention or PrEP **technical working group.**	**Register** PrEP methods and include on the national essential medicines list, 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.	Update **supply chain guidelines and logistics systems** to include PrEP products.	Develop trainings and materials for **health care workers** on PrEP methods.	Address social norms/stigma to build **community and partner acceptance** of PrEP use.	Establish 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** research to inform policy and scale-up.
Include PrEP in national HIV prevention and other relevant **plans and policies** (e.g., HIV testing, FP).	Establish **procurement, commodity monitoring, and distribution** for PrEP products and associated materials.	Integrate support for **partner communication** and services for intimate partner violence 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 initial PrEP introduction and scale-up.				

COLOR KEY

- Opportunity to easily build on oral PrEP rollout
- Will require new effort, but no anticipated challenges
- Requires significant consideration specifically for CAB PrEP

Kenya PrEP introduction situation analysis

Findings from the Kenya situation analysis are summarized below, with details included on the following slides.

PLANNING & BUDGETING

- CAB PrEP can build upon **existing coordination mechanisms** from oral PrEP and HIV self-testing rollout and relevant policies, led by the HTS / PrEP CoE.
- The ring can build upon existing efforts to **integrate HIV prevention and SRH services**, led by NASCOP and the Department of Reproductive and Maternal Health.
- NASCOP will update Kenya HIV prevention and treatment guidelines through an addendum that will be developed together with HTS/PrEP CoE.
- There is a need for increased government support for PrEP programming given the decrease in donor funding in recent years. .
- There are plans to include CAB PrEP in the update to the **PrEP implementation framework** at the end of 2023 **–** a strategic guide for operationalizing PrEP delivery.

SUPPLY CHAIN MANAGEMENT

- **CAB PrEP has yet to be approved for use** by the Kenya regulatory drug authority or added to the essential medicines list.
- Once approved, stakeholders expect that CAB PrEP can be **easily integrated across Kenya's robust pull-driven supply chain** system.

DELIVERY PLATFORMS

- CAB PrEP can leverage numerous **service delivery platforms** established for oral PrEP.
- **PEPFAR supports a large number implementing partners** to reach AGYW (DREAMS) and key populations projects present opportunities to bring CAB PrEP closer to the user.
- Some healthcare worker training will be needed; however, stakeholders anticipate that there is only a modest expectation for **task shifting** early on, given it is healthcare workers are familiar with administering injections.

UPTAKE & EFFECTIVE USE

- **Experience with oral PrEP** provides abundant lessons to inform design of demand program, including archetypes, and user constraints.
- **However, there is very little funding for demand generation** from donors and no sustainable plan to ensure continuity of demand generation activities beyond initial activation.
- While PEPFAR & GFATM support targeted interpersonal channels (DREAMS & KP programs) there is need for more mass communication **to normalize** the product.
- **Technology enabled approaches are promising but** fragmented and under funded.

MONITORING, EVALUATION & LEARNING

- M&E systems established for oral PrEP through Kenya's national health information system (KHIS Aggregate) **have been updated to include CAB PrEP**. Disaggregation by PrEP method (oral PrEP, PrEP ring, and CAB PrEP) has already been included in the revised reporting tools across indicators.
- All of the PrEP methods (oral PrEP, PrEP ring, and CAB PrEP) have been integrated into a **new electronic health facility reporting tool** that will supports commodity tracking and communicates consumption rates. The new tools will be rolled out in January 2024.

Planning & budgeting key steps

	Current situation of oral PrEP	What is needed to introduce CAB PrEP
Convene new or existing subcommittee or task team within HIV prevention or PrEP **technical working group.**	• Following inclusion of PrEP in the national ARV guidelines, the Ministry of Health set up a PrEP Technical Working Group (TWG) in October 2016, chaired by NASCOP. The TWG is also known as the HIV Testing Services & PrEP Committee of Experts (HTS/PrEP CoE) and comprises of six sub-committees: 1) Operations and Service Delivery; 2) Monitoring and Evaluation; 3) Commodity Security; 4) Communications and Advocacy; 5) Research and Impact Evaluation, and 6) Resource Mobilization and Financing. • An HIV prevention/Sexual Reproductive Health (SRH) services integration subcommittee has been established for oral PrEP.	• CAB PrEP introduction will be led by NASCOP and the HTS/PrEP CoE. • Significant ongoing work to scale up oral PrEP and HIV Self-Testing (HIVST) and integrate HIV prevention and SRH services provides a foundation for CAB PrEP introduction but also requires time and attention from a small group of relevant stakeholders.
Identify **focus populations and set targets** for PrEP methods.	• During initial rollout of oral PrEP, the HTS/PrEP CoE developed a national scale up plan with prioritized targets, defined broadly for "populations at substantial risk".	• The MOH with support from the PrEP TWG will set national targets, including targets set by donors (e.g., PEPFAR), either directly for CAB PrEP or included in a bucket of PrEP products.
Engage **community stakeholders** to inform planning for PrEP rollout.	• With oral PrEP, engagement of religious leaders and parents for younger PrEP users was critical to allay fears and build buy-in. • The KP Consortium aims to create a joint voice of KP for advocacy, advocating for better health, increased funding, creating safe spaces, and relevant service delivery.	• Engagement with the KP Consortium and youth networks will be critical for the integration of CAB PrEP. Furthermore, community engagement is planned under the MOSAIC CATALYST study and led by LVCT Health - it will be important to leverage that effort. • There is a need to strengthen the voice and involvement of AGYW groups, which requires additional efforts given AGYW advocates are not as organized.
Include PrEP in national HIV prevention and other relevant **plans and policies** (e.g., HIV testing, FP).	• The National AIDS Control Council (NACC) is the lead agency on policy and planning documents. Oral PrEP was included in The Kenya AIDS Strategic Framework II 2021-25 and the HIV Prevention Revolution Roadmap, which were updated in early 2022. These policies focus on combination prevention approaches that include a focus on hotspots for HIV incidence and prioritize expanding choice for HIV prevention interventions. • Kenya's devolved government structure requires country-specific advocacy, program design, planning and engagement through a mirrored leadership structure at the county level with the County Health Management Team and County AIDS and STIs Coordinators (CASCOs).	• CAB PrEP will need to be included in the national policy and planning documents as well as in the county HIV Prevention strategies. • The registration of CAB PrEP for Kenya will trigger the development of updates and / or addendum on the new product. This process will be led by NASCOP and the HTS/PrEP CoE.
Issue standard **clinical guidelines** for delivery and use of PrEP methods.	• The Operations and Service Delivery sub-committee of the CoE was mandated to operationalize the PrEP guidelines for oral PrEP. The Guidelines for the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya were updated in early 2022 and provide overarching guidance for HCWs on oral PrEP and the PrEP ring. • The process for full guideline development is about one year: ~6 months to draft the guidance; ~4 months for reviews and approvals; ~2-3 months to train providers.	• In the recently updated ART guidelines, CAB PrEP was referenced as a "long-acting HIV prevention option in development". • A process to provide interim guidance for CAB PrEP has been developed "off cycle" through a circular overseen by NASCOP.
Develop an **implementation plan and budget** to guide initial PrEP introduction and scale-up.	• An oral PrEP Implementation Framework was developed in 2018 during the initial rollout of the product (Kenya Population-based Inmpact Assessment) and has been updated in 2023. • PEPFAR is still the leading donor; however PEPFAR and USG budgets expected to decline in Kenya; and the new funding cycle for the Global Fund (GFATM) is likely to follow.	• CAB PrEP missed inclusion in the 2023 PEPFAR budgeting cycle, but demonstration projects in late 2022 will set up planning for COP 2024. Funding for CAB PrEP can potentially be layered on existing GFATM and USG investments. • There is a need for domestic financing for HIV prevention within Kenya in order to ensure continuity and sustainability of PrEP programming. NASCOP will require an impact and cost-effectiveness analysis to justify investment in new products.

SUPPLY CHAIN MANAGEMENT

Supply chain management key steps

	Current situation of oral PrEP	What is needed to introduce CAB PrEP
Register PrEP methods and include on the national essential medicines list, if needed.	• The Pharmacy and Poisons Board (PPB) is the Drug Regulatory Authority in Kenya. Following WHO guidance, the PPB approved oral PrEP for Kenya in 2015 and the ring in July 2021. • WHO guidance and registration to the Kenya National Medicines Formulary (KNMF) is the dual trigger to kick off product introduction.	• The PPB must approve CAB PrEP for use in Kenya. • CAB PrEP will need to be included as part of the KNMF.
Update **supply chain guidelines and logistics systems** to include PrEP products.	• Supply chain of HIV commodities is managed by NASCOP with technical support from GHSC-PSM. • NASCOP oversees Kenya's pull-driven system for HIV commodities. Oral PrEP is managed via the ARV logistics management information system (LMIS), including donor-funded products (see more information about updates of these tools under "Monitoring key steps" on slide 22).	• Stakeholders expect that CAB PrEP can be layered on existing supply chain systems and technical teams.
Conduct **forecasting and/or quantification** to inform procurement of PrEP products.	• NASCOP plays an active role in managing pull-driven system, supporting counties to develop facility-level quantification for reorders and closely tracking and approving facility inventory and resupply. • MOH (NASCOP, National HIV Testing Lab), CHAI, PEPFAR (USAID & CDC), UN and GFATM meet annually at the beginning of each year for the forecasting and quantification reports to set annual targets. • Forecasting for PrEP was challenging as a new product with quickly evolving dynamics (e.g., client drop-offs, etc.) – however a new tool feeding into the LMIS is planned to improve the certainty of demand forecasts.	• Coordination with the HTS / PrEP CoE and NASCOP will be important to ensure CAB PrEP is included in forecasting and quantification. • Stakeholders anticipate similar challenges of irregular demand during the early years of CAB PrEP introduction, which may result in product stock-outs.
Establish **procurement, commodity monitoring, and distribution** for PrEP products and associated materials.	• GFATM and other funders of PrEP commodities procure, store and distribute their commodities through KEMSA. • NASCOP regularly provides the facility list for distribution of oral PrEP products to KEMSA in support of a demand or "pull-driven" system. KEMSA distributes oral PrEP directly to facilities, which also includes NGOs and FBOs. Facilities beyond the CCC, such as DICs must register to receive the product. • NASCOP can also support re-distribution of commodities (from facilities with over supply or that are facing stock disruptions). There are monthly meetings for both procurement plans as well as commodity security meetings to provide feedback on inventories, check potential stock levels, and establish excess stock for re-routing. • PEPFAR brought on the Mission for Essential Drugs and Supplies (MEDS) to act as a distribution agent for all PEPFAR-funded HIV commodities. MEDS manages the commodity logistics and the supply chain. Ordering from facilities is routed through counties to NASCOP and KEMSA, and then on to MEDS to initiate delivery. • There have been some challenges with stock ruptures of PrEP commodities at the facility-level, particularly for HIV self-testing.	• Stakeholders expect that CAB PrEP can be easily integrated within the existing structures for procurement, commodity monitoring, and distribution. • Strengthen the supply chain team at NASCOP and technical partners to consider quantification in the context of choice; reference this technical brief for further forecasting and commodity planning considerations. • Coordination in purchase and management of ancillary products (syringes, needles etc) will be needed.
Establish **storage and distribution systems** that maintain temperature controls for PrEP products, if needed.	• *Not applicable for oral PrEP*	• Stakeholders do not note any anticipated challenges for temperature-controlled distribution and storage (e.g., refrigerators, insulated storage space, etc.).

PrEP delivery platforms key steps

DELIVERY PLATFORMS

	Current situation of oral PrEP	What is needed to introduce CAB PrEP
Dedicate resources to conduct regular **HIV tests, initiate PrEP, and support ongoing PrEP use.**	• Oral PrEP is widely available across differentiated service delivery channels (see next slide), however it is primarily available within public HIV clinics (CCCs). • WHO requires that HIV testing follows the national algorithm. HIV self-testing is approved in Kenya; stakeholders are currently exploring how to expand the use of HIV self-testing. • There have been some shortages of HIV self-testing, which led to clients not being able to initiate on PrEP.	• Stakeholders expect that CAB PrEP can be smoothly integrated into existing service delivery systems, particularly within CCCs. • Opportunities to delivery CAB PrEP in community-based interventions and integrate into the NASCOP-led FP/PrEP pilots exist (however CAB PrEP will not be available for PBFP until approved).

Develop trainings and materials for **health care workers** on PrEP methods.	• NASCOP/CoE initiates the process to update training curriculum, provider toolkits and supportive M&E tools. Oral PrEP has already been included in ART guidelines and the SRH integration recommendations.
	• Once integrated into training, a two-tiered approach is used to train providers:
	  • National-level managers are sensitized and trained, followed by county-level managers (~2 day with 1 day orientation)
	  • Training is supported through a cascade: National => County => Subcounty => Health Facilities by national trainers
	• Stigma persists among HCWs and providers. Lessons from oral PrEP show that behavior change, values clarification and soft skills around counseling is required as much as technical training.
	  • Some providers see oral PrEP delivery to AGYW as “immoral”; AGYW report being counseled out of PrEP.
	  • Providers outside of HIV settings are often uncomfortable with client risk assessments and consider them lengthy and burdensome.
	  • Providers may hold product specific attitudes towards product forms which can impact uptake and exacerbate concerns about the tail of PrEP use and / or proper use of rapid testing.
		• Stakeholders do not anticipate any challenges to include CAB PrEP in existing HCW training materials for oral PrEP. Training will be rolled out through government-led and donor-supported efforts.
		• While the training curriculum to support new guidance is currently under revision (early 2022), addendums and circulars can be used to integrate component specific to CAB PrEP.
		• Provider training will also need to address the challenges around stigma for PrEP across all product forms.
		  • There is a need to engage in values clarification with providers. Experience shows that providers exposed to KPs appreciate different perspectives and become less biased over time.
		  • There is a possibility to engage other cadre (e.g., doctors, nurses, clinical officers, HIV Testing counsellors, and health records officers) / task shifting to offer counselling (e.g., drawing on ART experience). It will be critical to train multiple providers in a facility, as providers will rotate to different facilities with time. However, HCWs continue to struggle to provide PrEP to adolescents and young people.

Establish **referral systems** to link clients from other channels to sites providing PrEP.	• Referral systems between different facility and community-based services have been critical to support oral PrEP access and delivery.	• Stakeholders do not anticipate any challenges to leverage existing referral systems for CAB PrEP.
Integrate support for **partner communication** and services for intimate partner violence.	• Kenya guidelines currently include screening for IPV and referrals for support in all HIV service delivery. • Strategies to engage male partners via demand creation or couple-counseling have been included in the National Combination Prevention Communication Strategy.	• Stakeholders do not anticipate any challenges to integrate CAB PrEP within support for partner communication and services for intimate partner violence.

Potential delivery channels for CAB PrEP

DELIVERY PLATFORMS

Plans, systems, and processes to support service integration across priority delivery channels, including reproductive health/family planning and private sector providers/pharmacies

	Current situation of oral PrEP	What is needed to introduce CAB PrEP
Integration in **public sector HIV services** *Focus populations: AYP, FF, SDCs*	• Oral PrEP is readily available in public HIV facilities within counties and sub-counties through CCCs. The CCCs currently account for over 50% of PrEP initiations, with well-trained staff familiar with ART, counseling and referrals. CCCs are also available through NGO-supported initiatives. • However, public HIV services are highly stigmatized for HIV-negative women and men and associated with HIV treatment. • Youth Corners are also available as separate sites within public facilities and provide mostly free service.	• Some provider training will be required, primarily for task shifting, for CAB PrEP.
Integration in **public sector SRH / FP clinics** *Focus populations: Women (primarily 24+ years old)*	• Provision of PrEP in FP clinics is still limited; however, NASCOP-led PrEP/SRH integration pilots are running in the 5 counties of Kakamega, Migori, Kisii, Kitui, Baringo. Efforts to pilot integration of PrEP are also ongoing. • FP clinics are a key opportunity to expand PrEP programming given they serve 60% of women accessing contraception (3.7M women). However, there have been documented challenges for providers to counsel and screen for both FP services and HIV testing. • Mostly free services that can reach a range of income levels.	• FP providers need training in PrEP/ART provision and can build off of already existing integration pilots. • FP clinics could service as a key delivery channel for CAB PrEP given providers are already trained for IM injections in the buttocks.
Integration in **public sector MCH / ANC / PNC services** *Focus populations: SDCs, PBFP*	• PrEP is offered in ANC clinics and maternity wards through a few pilots; however, providers need significant capacity building including PrEP training, reporting and changing attitudes. • A pilot PrEP Implementation in Young Women and Adolescents (PriYA) programme is ongoing through DREAMS and provides PrEP in 16 public MCH clinics in Kisumu. Lessons show that more provider training is needed. • There is a key opportunity to expand oral PrEP programming since 50% of 1.6M deliveries annually take place in public MCH facilities and have widespread HIV screening services. • Mostly free services that can reach a range of income levels.	• Providers need training in PrEP/ART provision, although limited pilots currently supporting PrEP integration in MCH / ANC / PNC. • Furthermore, there are outstanding clinical safety and efficacy questions on PBFP.
Integration in **NGO clinics / social franchises** *Focus populations: AGYW, FSWs, MSM*	• Oral PrEP is also available at mission hospitals with CCCs or social franchise private facilities (e.g., Tunza). • PrEP is not covered by national insurance so payment is out of pocket or donor subsidized. • There are over 5 NGO managed social franchises that support ~1,000+ private clinics with potential for convenience and less stigma. While some provide oral PrEP there is an opportunity to expand programming. Social franchise / private clinics do not report through KHIS; therefore, this data is included in national reports to inform decision-making.	• Private providers require training, support and resupply; NGOs can manage this role with a franchise model but donors are reducing support for this approach. • Potential challenges for the supply of commodities can emerge if CAB PrEP is donor-subsidized.
Integration in **community-based models** (e.g., FBOs, mobile, DREAMS) *Focus populations: AGYW, KP*	• Community-based models offering oral PrEP include DREAMS, Drop-in centers (DICs), Mobile clinics, Outreach, and Safe Spaces. • These are successful models due to blended community mobilization and links to strong user-focused facilities, which are perceived as safe, friendly, fast, and discrete. These sites also provide intense support and follow-up that address the holistic needs of clients. • DICs and mobile clinics were particularly important during the early days of oral PrEP rollout, accounting for 83% of new PrEP clients. Now, there are roughly 50 sites with DICs or mobile clinics. • Heavily donor dependent, management intensive, and less likely to serve general population.	• Private providers require training, support and resupply; NGOs can manage this role with a franchise model but donors are reducing support for this approach. • Potential challenges for the supply of commodities can emerge if CAB PrEP is donor-subsidized.
Integration in **pharmacies** *Focus populations: AYP, FF, FSW, MSM, PWID*	• Approximately 12,000 pharmacies offer opportunity to expand access of PrEP programming to a broader swath of the population. Some early pilots to integrate oral PrEP are underway and paving the way for larger scale-up. • Data from pharmacies are also not reported through the KHIS. NASCOP is exploring how to ensure pharmacies can integrate within national reporting for PrEP implementation. • Private sector channels, including not-for-profit and for-profit channels, procure commodities from manufacturers or wholesalers, who would need to stock oral PrEP.	• Limitations can arise from private providers, for example capacity to administer IM injections, providing HTS counselling, linkages to public sector PrEP referral networks, and / or end users requiring out-of-pocket payment for PrEP.

DELIVERY PLATFORMS

Potential delivery channels for CAB PrEP

Strong service delivery models exist in Kenya: public HIV clinics (CCC) are most likely to reach PrEP users but are highly stigmatized due to strong associations with HIV treatment; FP and MCH clinics have reach and opportunity but require investment. Private channels such as DICs and NGO programs are reaching AGYW and KPs, though they are heavily dependent on donor funding.

	Access assessment			Capacity assessment		
Service delivery channels	Reach to HIV negative priority populations	Affordability of services for a range of income levels	Offers oral PrEP or other relevant products (e.g., condoms, FP, HIV testing)	Existing HIV counseling and testing services	HCW capacity to administer CAB PrEP injections and support follow-up	Link to national supply chain and temperature-controlled storage for CAB PrEP
Public sector HIV services / CCCs	Medium: although limited by stigma (e.g., people may not want to access CAB through CCCs)	High	Very high	Very high: 85% offer HTS	Limited: Follow-up for PrEP needs strengthening	Very high
Public sector SRH / FP clinics	Very high	High	Medium: Scale up of pilots for FP / PrEP integration is ongoing	Medium: ~50% offer HTS	Medium	High
Public sector MCH / ANC / PNC health services	Very high	High	Medium: Scale up of pilots for gov-supported FP / PrEP integration is ongoing	Medium: some offer HTS	Medium	High
NGO clinics / social franchises	High	Limited: High-cost model dependent on donor support for free services	High	Medium: some offer HTS	High: Strong follow-up within NGO settings	High
Community-based models (e.g., DICs, Mobile, DREAMS, etc.)	Very high: strong access to KP and AGYW	High: Although can be expensive to implement and scale; donor dependent	High	High	Medium: variable capacity / some training required	High
Private sector clinics and pharmacies	High: significant presence in cities / towns; potential with pharma networks	Limited	Limited: some pilots for PrEP	Limited: variable access to HTS	Medium	High

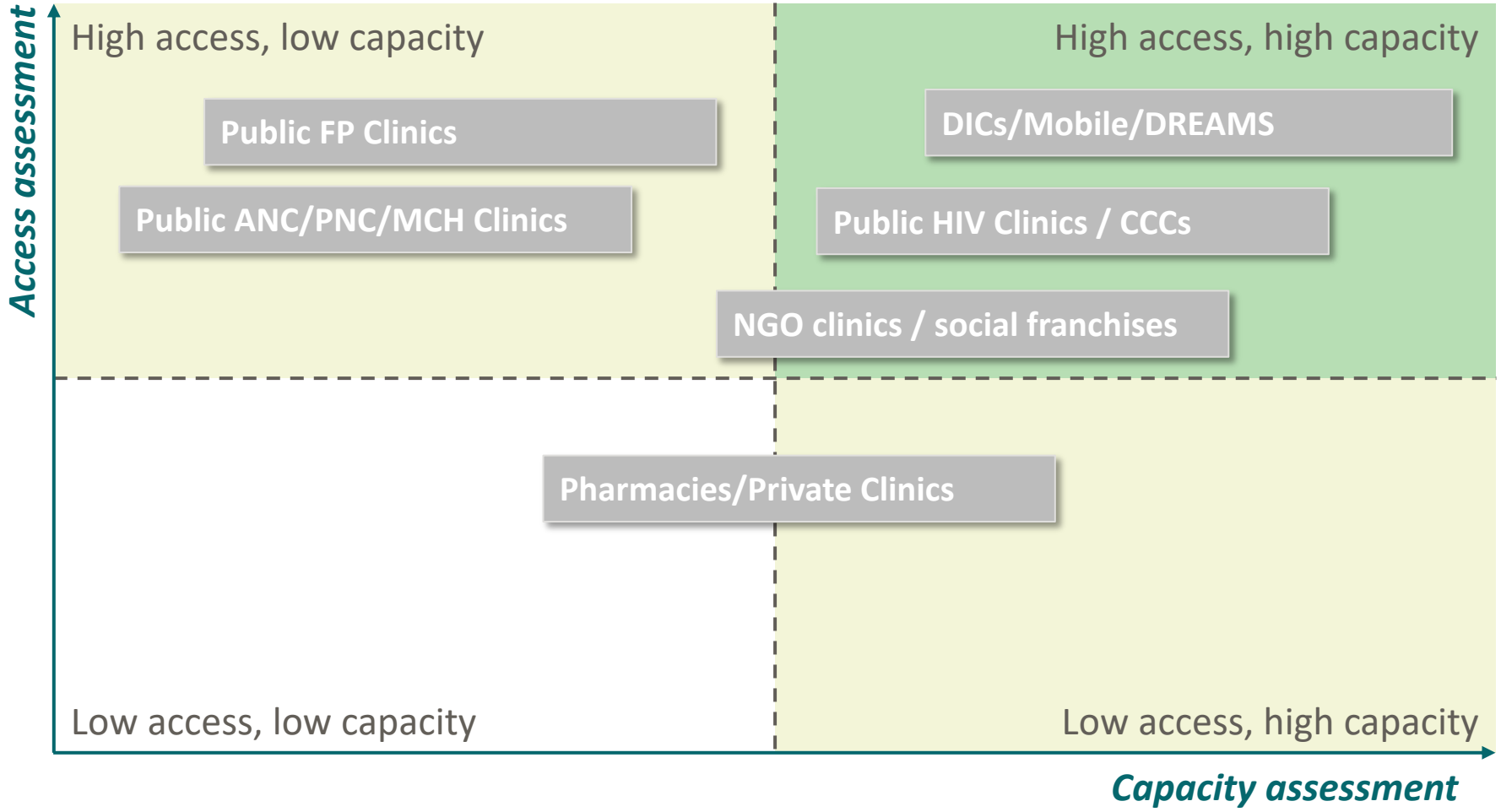
Rating key Very high / high access or capacity | Medium access or capacity | Limited access or capacity

Prioritizing delivery channels for CAB PrEP

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 integrate CAB PrEP within HIV prevention services and high access to priority HIV negative populations who would benefit from CAB PrEP
- Channels in the **upper left** have less capacity to integrate CAB PrEP, but have high access to priority HIV negative populations
- Channels in the **lower right** have less access to priority HIV negative populations but have high capacity to integrate CAB PrEP
- Channels in the **lower left** have neither the capacity or reach to effectively integrate CAB PrEP

Delivery channel prioritization



Uptake & effective use key steps

	Current situation of oral PrEP	What is needed to introduce CAB PrEP
Develop and implement **demand generation strategies** that include PrEP promotion.	• The National HIV Prevention Communication Strategy, 2019-2024 presents guidance and frameworks to develop demand generation interventions, including oral PrEP. • Campaigns supporting oral PrEP have struggled to maintain traction, and are characterized by short-term, geographically targeted interventions that target specific population groups (e.g., AGYW, KP). • Insufficient funding impedes sustained and strategic demand generation interventions for PrEP and prevention overall. • There is a need for more strategies that focus on the general population to familiarize the public with the product (e.g., TV, radio, etc.).	• The existing platforms for oral PrEP lay a great foundation for CAB PrEP. • Demand generation has been focused on oral PrEP and will need to pivot to a "choice" framing to include CAB PrEP. There is little guidance or support for this shift currently. • There are opportunities to explore and utilize digital platforms for ongoing demand generation.

Address social norms/stigma to build **community and partner acceptance** of PrEP use.	• Stigma is reinforced through providers, the community, parents, and partners, and manifests as prejudice and discrimination.
	• A Jhpiego study distilled stigma with AGYW into three distinct drivers:
	  • 1) Stigma derived associations with treatment
	  • 2) Association of PrEP with populations and behaviours that are frowned upon (FSW, MSM)
	  • 3) Identity (not living up to being a 'good girl').
	• Furthermore, there have been reports of intimate partner violence when using PrEP.
		• There will be a need to address the stigma and social norm concerns for all PrEP methods
		• Furthermore, an injectable product can invoke negative associations derived from vaccine hesitancy and concerns of infertility.
		• There will be need to address IPV and other forms of GBV as part of creating a conducive environment to access and use PrEP.

Develop **information and tools for clients** to support product choice.	• Poor awareness of PrEP, what it is, where offered and how it works was an early stumbling block. Where interventions were conducted, under 60% of population had never heard of PrEP.
	• A shift to community-driven models (e.g., Youth Peer Provider model) resulted in a sharp increase in AGYW enrolled and drove 80% of youth initiating uptake into facilities.
	  • Influencers play an important role in use: mothers and older women, sexual partners, and peers.
	  • Emphasizing individual choice and tapping into intrinsic motivation was more effective than a risk-based approach to PrEP eligibility.
	  • Interventions pairing incentivized referral mechanisms and peer-driven conversations contributed to 54% of AGYW enrolments in the Youth Peer Provider model.
		• Job aids and IEC materials might be leveraged to promote the uptake of new PrEP methods.
		• Messaging about the introduction of new PrEP products present the methods as expanding existing oral PrEP services and options for end users.

Support **effective use** of PrEP products.	• Effective use of PrEP was influenced by insufficient social support through fear of reprisal by partners or parents, and a dearth of positive advocates for PrEP, including members of peer groups.	• Key influencer engagement models (e.g., parents, peers, etc.) will be critical to allay fears and provide the support for prevention-effective use of the new PrEP methods.

Monitoring key steps

MONITORING, EVALUATION & LEARINING

	Current situation of oral PrEP	What is needed to introduce CAB PrEP
Update or establish **integrated monitoring tools** to support data collection and analysis on PrEP use across multiple products.	• M&E systems have been established for oral PrEP through Kenya's national health information system (KHIS Aggregate). PrEP M&E was a challenge during early oral PrEP rollout, but reporting has improved in recent years. • NASCOP and the National Syndemic Diseases Control Council (NSDCC) conduct quarterly supportive supervision visits and data quality assessments for PrEP, including a quarterly review of DHIS data (per CHAI). • While some facilities (primarily public HIV services) are using electronic tools, most facilities continue to use a hybrid mix or rely solely on paper-based tools. • All of the PrEP methods (oral PrEP, PrEP ring, and CAB PrEP) have been integrated into a new electronic health facility reporting tool that supports commodity tracking and communicates consumption rates directly to KEMSA. Rollout of the new tools will begin in January 2024.	• KHIS Aggregate has been updated to include CAB PrEP. Disaggregation by PrEP methods has already been included in the revised reporting tools across indicators. Key reportable PrEP indicators across the three PrEP methods (oral PrEP, the PrEP ring, and CAB PrEP) have been included: Number eligible for PrEP, number initiated (new) on PrEP, number continuing (refills) PrEP, number restarting PrEP, number currently on PrEP (New + refills + restart), number tested HIV positive while on PrEP, number diagnosed with STI, number discontinued PrEP. • CAB PrEP has already been integrated into the new electronic health facility reporting tools. Stakeholders hope that the new tool will improve accuracy in commodity monitoring in order to inform procurement, forecasting, and quantification, which will be particularly important for the additional of CAB PrEP.
Establish systems for **pharmacovigilance** and to monitor drug resistance.	• Pharmacovigilance systems are managed by the PPB, independent from the health systems information system. • Tracking and reporting for PrEP occurs with other ARVs and includes adverse reactions or events, suspected poor quality medicines, and drug reactions – this is largely conducted via end user reporting.	• Stakeholders do not anticipate any challenges to integrate CAB PrEP into existing systems for pharmacovigilance.

Conduct **implementation science** research to inform policy and scale-up.	• For introduction of oral PrEP, the NASCOP HTS/PrEP CoE Research and M&E Sub-Committee defined a research agenda with key questions to be answered – a similar approach would work well for CAB PrEP, especially to inform early demonstration/pilot projects. A new area of focus will be monitoring of method switching between oral PrEP, the PrEP ring and CAB PrEP.	• MoH emphasizes the importance of demonstration projects, focusing on the viability of implementation, while donors and others reference the need for implementation science to generate context-specific evidence (such as cost-effectiveness analysis and user uptake).
		• The MoH has not clearly defined evidence needs and could move forward with a dual approach – i.e., demonstration projects in two learning counties, coupled with MOSAIC/CATALYST implementation science study in three counties prior to rollout.
		• There are product features stakeholders hope to be understood through introduction research:
		  ◦ Feasibility of HIV testing approaches (e.g., RNA assay testing)
		  ◦ Data on PBFP is considered high priority given the large number of women who could use CAB PrEP
		  ◦ Concerns about managing the long tail

Current situation of HIV prevention

Findings for CAB PrEP introduction planning

Sources and notes

Key stakeholders interviewed

Interviews were conducted by Mann Global Health in partnership with ViiV Healthcare in 2022. LVCT Health team revised and updated findings from the CAB VCSA to represent the current situation in December 2023.

Name	Title	Organization	Contact information
Joab Khasewa	HIV Prevention Officer	NSDCC	jkhasewa@nsdcc.or.ke
Ruth Kamau	Service Delivery Coordinator	NASCOP	ruth.kamau@jhpiego.org
Moses Otieno		NASCOP	+254722348545
Dr. Mary Mugambi	HTS/PrEP Manager	NASCOP	mmugambi@nascop.or.ke
Dr. Sospeter	HIV Commodities Manager	NASCOP	+254 721393636
Dr. Newton Omale	Head of Planing/GF Project Manager	NASCOP	nomale@nascop.or.ke
Eunice Ndinda	HIV Program Manager /PrEP/ HST	PS Kenya	+254721712633
Dr. Daniel Were	Project Director	Jhpiego	daniel.were@jhpiego.org
Dr. Elizabeth Bukusi	Chief Research Officer	KEMRI	ebukusi@kemri.org/ebukusi@gmail.com (0720617503/0733617503)
Dr. Nelly Mugo	Head, Sexual Reproductive Adolescent Child Health-Research Program	KEMRI	nmugo@kemri.org/ rwamba@csrtkenya.org/ rwamba@uw.edu
Samuel Gachau	Quality Assurance Specialist	Kenya Red Cross Society	gachau.samuel@redcross.or.ke
Patriciah Jeckonia	MOSAIC Project Director	LVCT Health	patricia.jeckonia@lvcthealth.org
John Mungai	Program Officer	CHAI	jmungai@clintonhealthaccess.org

Name	Title	Organization	Contact information
Obwiri Kenyatta	Public Health Specialist	Center for Disease Control (CDC)	nzv7@cdc.gov
Leonard Soo	Public Health Specialist	USAID	Lsoo@USAID.gov; 0722741274
Dr. Patricia Rose Oluoch	Public Health Specialist	USAID	roluoch@usaid.gov
Solomon Wambua	National Coordinator	Key Population Consortium of Kenya	
Churchill Alumasa	Director	Discordant Couples Association of Kenya	
Jacque Wambui	Global Treatment Facilitator	AfroCAB Treatment Access Partnership	+254 734668809
Charles Kimutai		Sub-County MOH, Kericho	+254722269032
Paranita Bhattacharjee	Director, Programme Delivery- Insti. of Global Public Health	University of Manitoba	bhattacharjee.parinita@gmail.com
Vanessa Chelimo	Sub County CASCO	Embakasi East Sub county Mukuru	vchelimo20@gmail.com +254721202356
Dr. Elizabeth Irungu	Partners Scale Up Project	Jhpiego	eirungu@pipsthika.org/mugoiri_99@yahoo.com 0721861147
Jerald Mogaka	Facility In Charge	Mukuru Health Facility, Nairobi	N/A

Note on terminology

In efforts to be more precise and not contribute to the stigmatization 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.
- **Minimizing use of the terms "risk" and "risky."** The terms can have so many different definitions and may stigmatize certain behaviors, impose labels on clients, or stigmatize 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

AIDS	Acquired immunodeficiency syndrome
AGYW	Adolescent girls and young women
ANC	Antenatal care
ART	Antiretroviral Therapy
ARV	Antiretroviral
AYP	Adolescent and young people
CASCOs	County AIDS and STIs Coordinators
CCC	Comprehensive care centres
CDC	United States Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CHW	Community health workers
COVID	Coronavirus disease
COE	Committee of Experts
DHAPP	United States Department of Defense HIV/AIDS Prevention Program
DICs	Drop-in centers
DREAMS	DREAMS Initiative (Determined, resilient, empowered, AIDS-free, mentored, and safe)
DSD	Differentiated service delivery
FCDO	Foreign, Commonwealth & Development Office
FF	Fisherfolk
FP	Family planning
FSW	Female sex workers
GBV	Gender-based violence
GFATM	The Global Fund for AIDS, Tuberculosis, and Malaria
GHSC	USAID Global Health Supply Chain Program
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
IEC	Information, education, and communication
IPV	Intimate partner violence
KEMSA	Kenya Medical Supplies Authority
KP	Key populations
IM	Intramuscular
MCH	Maternal and child health
MEDS	Mission for Essential Drugs and Supplies
MoH	Ministry of Health
MOU	Memorandum of understanding
MSM	Men who have sex with men
NACC	National Aids Control Council (NACC)
NASCOP	National AIDS and STIs Control Programme (NASCOP)
NSDCC	National Syndemic Diseases Control Council
PBFP	Pregnant and breastfeeding people
PEPFAR	President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV
PNC	Postnatal care
PPB	Pharmacy and Poisons Board
PrEP	Pre-exposure prophylaxis
PriYA	PrEP Implementation in Young Women and Adolescents
PWID	People who inject drugs
SDC	Serodifferent couples
SRH	Sexual and reproductive health
TWG	Technical Working Groups
USAID	United States Agency for International Development
USG	United States Government
VMMC	Voluntary medical male circumcision
WHO	World Health Organization

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