Kenya supply chain considerations for CAB PrEP introduction

LVCT HEALTH & AFTON BLOOM
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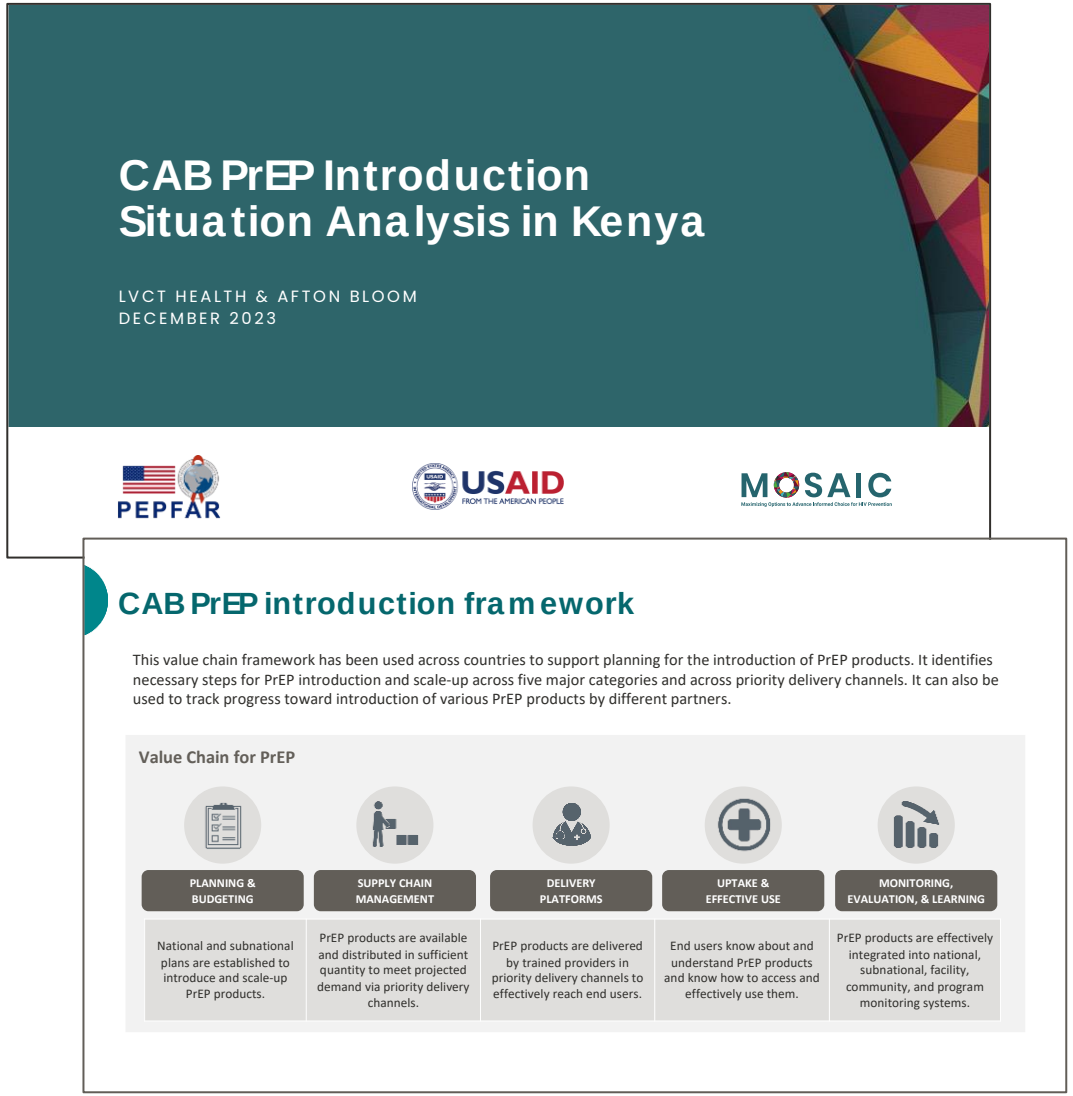
Introduction to the supply chain deep assessment

- In collaboration with NASCOP, partners of the MOSAIC consortium conducted a **CAB PrEP introduction situation analysis in Kenya in 2023** – also known as a value chain situation analysis (VCSA) – to clarify critical steps for the introduction of CAB PrEP in Kenya. You can find the findings from the situation analysis here.

- The CAB VCSA highlighted several areas of opportunities as well as potential challenges to integrate CAB PrEP within Kenya's supply chain system.

- The supply chain deep dive assessment is a supplementary analysis for the CAB VCSA that aims to identify considerations for **adding CAB PrEP to the PrEP supply chain in Kenya** based on interviews with key national and subnational stakeholders.



Areas to address in the supply chain deep dive

The CAB VCSA highlighted several areas where potential challenges could arise when integrating CAB PrEP into HIV prevention policy and programming, particularly:

- Conducting **forecasting and quantification** to inform procurement of PrEP products
- Establishing **procurement, commodity monitoring, and distribution** for PrEP products and associated materials

This **analysis will highlight what exactly is driving those barriers** and the key considerations as national stakeholders in Kenya look towards the integration of CAB PrEP.

	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 (slide 15)	•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 TWG 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 also supports re-distribution of commodities through KEMSA (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 •Coordination in purchase and management of ancillary products (syringes, needles etc) will be needed. •Consistent monitoring of HIV self-test kits to mitigate stockouts .
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.).

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

Overview of the national PrEP supply chain

Supply chain deep dive assessment

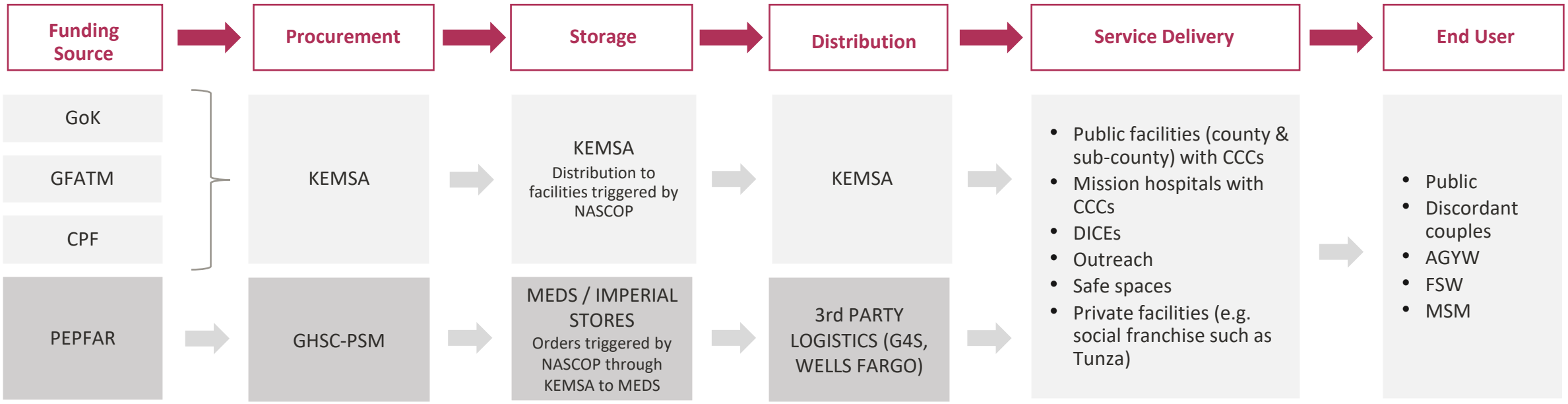
Sources and notes

The PrEP supply chain in Kenya

Kenya has a robust supply chain system led and managed by national stakeholders with support from external partners

- The Government of Kenya (GoK) integrated oral PrEP into the ARV logistics management system (LMIS) in 2017 for delivery to public HIV comprehensive care centers (CCCs). Facilities beyond the comprehensive care centers (CCC), such as drop-in-centers (DICEs), must register to receive PrEP products. The National AIDS and STIs Control Programme (NASCOP) plays an active role in managing PrEP through the pull-driven system from facilities to Kenya Medical Supplies Authority (KEMSA) and Mission for Essential Drugs and Supplies (MEDS).
- KEMSA oversees the procurement, storage and distribution of commodities funded by the GoK, Global Fund for AIDS, Tuberculosis, and Malaria (GFATM) as well as Kenya's counterpart-financing (CPF) requirement for procurement of ARVs and HIV test kits.
- PEPFAR runs procurement through the GHSC-PSM program managed by Chemonics, while storage and distribution is done by MEDs and its relevant 3PLs

Oral PrEP Supply Chain in Kenya



Source: Oral PrEP supply chain process has been visualized using analysis by Mann Global Health CAB PrEP situation analysis developed for ViiV Healthcare;
List of acronyms available on slide 17

Supply chain lessons from the rollout of oral PrEP

Consultations with key stakeholders elevated the following lessons from the introduction of oral PrEP.

What went well

- The **involvement of all stakeholders in planning and understanding their roles in the supply chain** helped with the initial rollout of oral PrEP (NASCOP, KEMSA, MEDS, county management teams, donors, partners, HCWs etc.).
- **Learning from implementation studies before rolling out oral PrEP** across delivery sites helped to manage some of the obstacles when scaling up oral PrEP.
- **Integration of oral PrEP is primarily in CCCs.** Differentiated service delivery remains sub-optimal; nevertheless, early efforts have shown improved uptake of PrEP across populations groups, particularly within MCH/ANC/PNC services, youth-friendly centers, and community outreach programs.
- Overall, stakeholders feel that there has been a **stable supply of a commodity availability** in public facilities, faith-based facilities, drop-in centers, and sex worker outreach clinics, despite some challenges, particularly over 2022-2023.

What was challenging

- The initial integration of oral PrEP focused on high burden counties. However, other facilities (that had not been trained on PrEP service delivery or M&E) also began ordering PrEP, creating **challenges to track where PrEP was available**. This led to the MOH conducting a facility assessment in 2018 as well as scaling HCW training on oral PrEP.
- The **scale-up of demand generation for PrEP towards pregnant and breastfeeding women (PBFW) and for event-driven PrEP was initially not well-aligned to stock levels at facilities**. PrEP access points ran out of tenofovir (TDF) and second line PrEP (TAF) needed to be offered to MSM and transgender women in its place. Stakeholders stress the need to ensure that demand generation activities are in line with available stocks.
- There have been **challenges around the availability of HIV testing kits**, leading to clients not being able to initiate PrEP. Delays in deliveries of HIV testing kits occurred primarily during the transition from KEMSA to MEDS for procurement and distribution of PEPFAR-funded products.
- In recent years, there have not been occurrences of major national-wide stock disruptions of PrEP and Kenya is now experiencing an overstock of 24 months of PrEP nationally in 2023. Stakeholders feel that that **low community awareness and demand generation coupled with the pull-based system for facility-level ordering has led to an overstock of commodities**. HCW attrition has exacerbated some of these challenges due to the movement of HCWs trained on PrEP service delivery and commodity management.
- **Stigma and ARV-associated misconceptions also persist**, particularly among the general population. Many end users who take up oral PrEP are dropping off, which has created challenges around ensuring adequate quantities are available at facilities.

Overview of national PrEP supply chain

Supply chain deep dive assessment

Sources and notes

Overview of considerations for CAB PrEP supply

In a series of interviews, we asked stakeholders to discuss the potential barriers to integrate CAB PrEP into the oral PrEP supply chain. Highlighted in blue are the area where stakeholders anticipate a different process will be needed to introduce CAB PrEP.
The following slides include details on each of these five areas.

5 ***Performance measurement and Logistics Management Information Systems (LMIS)***

Forecasting and quantification will need to be informed by more accurate data on PrEP consumption, KP size estimates and findings on end user preferences for CAB PrEP.

Integration of CAB PrEP will leverage existing importation, customs clearance, and procurement systems as oral PrEP.

Integration of CAB PrEP will leverage existing warehousing, distribution, and inventory management as oral PrEP.

There is a need to ensure a **strong workforce of trained HCWs** across PrEP access points when rolling out CAB PrEP to ensure accurate facility-level ordering and service delivery.

Integration of CAB PrEP will leverage manual and electronic LMIS tools. The rollout of the eLMIS will help improve commodity management and performance measurement across all of the PrEP methods. This will be especially important to inform forecasting and quantification.

Deep Dive: Supply Chain Planning

Supply Chain Functions	Current situation for oral PrEP	Required modifications for the introduction of CAB PrEP
Coordination with global donors, procurers, and manufacturers	• Coordination for oral PrEP began with the formation of the PrEP technical working group (also known as the HTS/PrEP CoE) and the commodity management subcommittee. • Stakeholders involved included NASCOP, KEMSA, donor agencies (primarily PEPFAR and GFATM), communities, partners and county management teams	• The Global Fund and PEPFAR are expected to be the primary donors for CAB PrEP. • Coordination with global donors, procurers and manufacturers are underway for CAB PrEP, however supply planning has not yet begun. Stakeholders are waiting for CAB PrEP to be approved for use in Kenya.
Forecasting and supply planning	• NASCOP, with support from GHSC-PSM, oversees forecasting, quantification and supply planning for oral PrEP. Initial forecasting and quantification (F&Q) of oral PrEP was based off of population size estimates and the PEP programming. The PrEP implementation plan and rollout scenarios also helped to define where, how, and to whom PrEP will be delivered. • In recent years, MOH (NASCOP, National HIV Testing Lab), CHAI, PEPFAR (USAID & CDC), UN, GFATM, and LVCT Health meet annually at the beginning of each year to make the forecasting and quantification (F&Q) reports and set the annual targets. F&Q has become more accurate with improved PrEP reporting and consumption data with the introduction of the PrEP-it tool supported by LVCT Health. • While there have been some challenges with F&Q due to the quickly evolving dynamics for the product (e.g., client drop-offs, fluctuations in demand, etc.), stakeholders expect that the rollout of a new electronic LMIS will improve the data that informs demand forecasts.	• F&Q will most likely layer on CAB PrEP as an additional product. Initial targets will most likely focus on MSM and FSW. • Stakeholders expect that F&Q will be informed by data on HIV prevalence and incidence, data on PrEP uptake, as well as findings from studies on preferences across the PrEP methods. • A survey of subpopulation groups across counties is also underway and will provide more accurate KP size estimates for F&Q (expected by June 2024). • Stakeholders also expect that rollout scenarios will inform which populations and counties to prioritize for CAB PrEP implementation. • Stakeholders expect PrEP targets to be disaggregated by PrEP method and include community level uptake to avoid overstock or stockout

Key findings

- While some obstacles are expected with the integration of a new product, stakeholders expect many of the **challenges with forecasting and quantification will be resolved** with more accurate KP size estimates, improved consumption data with the new eLMIS, and preliminary findings on end user preferences from implementation science to inform expected demand for CAB PrEP.

The integration of oral PrEP went well

Some challenges occurred when integrating oral PrEP but have been overcome

There continues to be persistent challenges that will likely affect the integration of CAB PrEP

Deep Dive: Procurement

Supply Chain Functions	Current situation for oral PrEP	Required modifications for the introduction of CAB PrEP
Importation and customs clearance	• Once the manufacturer provides the product, oral PrEP is delivered to Kenya through a port shipment that qualifies for a duty exemption. Products are received by the national order management team (comprising of both KEMSA and MEDS). • The Pharmacy and Poisons Board (PPB) approved oral PrEP for Kenya in 2015 and the ring in July 2021.	• There are no anticipated modifications or anticipated challenges for the importation and customs clearance of CAB PrEP. • CAB PrEP has yet to be approved by PPB for use in Kenya. This has been a bottleneck for planning for CAB PrEP.
Procurement of products into national supply	• GFATM and GoK-funded products are procured through KEMSA. • PEPFAR-funded products are procured through the GHSC-PSM program. • There have not been any significant challenges for the procurement of oral PrEP within Kenya. • Delays in deliveries of HIV testing kit occurred primarily during the transition from KEMSA to MEDS for procurement and distribution of PEPFAR-funded products.	• Stakeholders expect that the high estimated cost for CAB PrEP will limit the amount of doses procured by the GOK or donors. There may be a need to focus targets on those who really needs to be on CAB PrEP so that they are adequately protected. • Given procurement is done annually, some stakeholders feel that there may be a need to reserve funding mid-year to procure more stock of CAB PrEP if demand is higher than anticipated during the initial rollout.

Key findings

- Once **CAB PrEP is approved for use in Kenya, supply planning processes will begin.**
- There are no anticipated modifications or anticipated challenges for the importation or customs clearance of CAB PrEP in Kenya.
- Some considerations may need to be made to reserve funding mid-year for additional procurement of CAB PrEP if demand is higher than anticipated during initial rollout.

Source: (1) WHO Press Release, November 2022

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Deep Dive: Storage & Distribution

Supply Chain Functions	Current situation for oral PrEP	Required modifications for the introduction of CAB PrEP
Warehousing and storage	• KEMSA (for GFATM and GoK-funded products) and MEDS (for PEPFAR-funded products) are responsible for warehousing. • KEMSA has two national warehouses in Nairobi and regional eight depots if there is a breach in logistics at the national level.	• Stakeholders anticipate that KEMSA will smoothly integrate CAB PrEP in warehousing.
Product distribution	• 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. Community service delivery centres, such as DICEs, must register to receive the product, which has led to low integration of PrEP outside of CCCs. KEMSA delivers PrEP monthly to facilities that request PrEP through the LMIS. • There were some delays in product distribution from the national warehouse to counties during the COVID-19 lockdown. Ensuring PrEP stock is available at subnational warehouses would help to avoid potential logistical blocks nationally.	• Stakeholders expect that CAB PrEP will be easily integrated into product distribution based on facility-level order reported in the LMIS.
Inventory management	• NASCOP also supports inventory rationalization through re-distribution of products from facilities with over supply to those that need commodities. There are monthly meetings commodity security meetings to provide feedback on inventories, check potential stock levels, and establish excess stock for re-routing. • Challenges of over- or understock of PrEP primarily are experienced at the subnational level. Stakeholders note that commodity fluctuations are primarily due to underreporting from facilities. Recently challenges of overstock have been more prominent due to low demand generation which has slowed the pace of facility-orders given the supply chain is a pull-based system. • There have been shortages in HIV testing kit inventory, which have resulted in instances where providers were not able to provide PrEP. Fluctuations of inventory for ancillary products such as alcohol wipes, gloves, and syringes have also occurred given IPOs share the inventory at the county level.	• Stakeholders expect that CAB PrEP can be easily integrated into inventory management. Facilities will be able to maintain ambient room temperatures below 30°C with the addition of CAB PrEP. • However, there is a need to ensure adequate quantities of ancillary products will be available for facilities with the additional of CAB PrEP.

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Key findings

- Kenya has a **robust logistics system** that overseen by KEMSA and MEDS. Stakeholders do not anticipate any challenges to layer CAB PrEP within these systems.
- While there were some challenges with stockouts, **over the past 2 years there have not been any major challenges**. Fluctuations in stock levels now occur primarily at the facility or county level.

Deep Dive: Service Delivery

Supply Chain Functions	Current situation for oral PrEP	Required modifications for the introduction of CAB PrEP
Facility-level order and procurement	• During initial rollout of PrEP, facilities outside of high burden counties began ordering PrEP without training on facility-level ordering or PrEP service delivery. With the maturity of the program and development of standard operating manuals, facilities now typically have 1-2 trained HCWs on site. • Continued challenges around overstock or understock at the facility or county level have been driven by underreporting of required inventory and quantification based on inaccurate consumption data from the LMIS. Attrition of trained HCWs have also exacerbated some of these issues. Improvements to facility—level ordering are expected with the rollout of the eLMIS. • There have also been some challenges with FP/PrEP integration. There are policies and frameworks in place for integrated services, and NASCOP-led pilots have gone smoothly at HIV CCCs. However, integration has been a challenge at larger hospitals (e.g., in ANC services) particularly due to the segmentation of commodity ordering between departments. There are plans to integrate HIV/FP ordering.	• Stakeholders do not anticipate any challenges to train HCWs for commodity management of CAB PrEP. • Issues around HCW attrition will need to be addressed as CAB PrEP is integrated across facilities to ensure accurate facility-level ordering and procurement. • Some stakeholders feel that there is an opportunity to streamline facility ordering for CAB PrEP during the initial stages given product quantities will be low. Facilities could send orders directly to KEMSA through the eLMIS to speed up the ordering and delivery process. MoH may want to assure at least a year's supply of CAB for every individual initiating CAB. Close monitoring and ring fencing at facility level may be required.
Product selection and servicing clients	• Now with the standard operating manuals in place and scale up of oral PrEP, there are about 1-2 healthcare workers (HCWs) trained on PrEP in each public health facility. However, HCW attrition continues to be a barrier to ensure that staff have the training on how to service clients.	• Stakeholders do not anticipate challenges for HCWs to administer an injectable drug or manage temperature controls.

Key findings

- While there have not been any national stockouts of PrEP, there have been instances of **facility-level stock ruptures due to underreporting and inaccuracy in consumption data** that informed forecasting and quantification.
- **High HCW attrition** has also led to inaccurate PrEP reporting, commodity management and limited HCW-driven demand generation across PrEP sites. There is a need for more training to ensure that all providers have the capacity to deliver PrEP.
- Stakeholders feel that **sensitization of HCWs and communities will be critical** for CAB PrEP. Oral PrEP still has low community awareness and additional demand generation efforts may be needed.

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Deep Dive: Performance measurement

Supply Chain Functions	Current situation for oral PrEP	Required modifications for the introduction of CAB PrEP
Integration into Kenya Health Information Systems (KHIS)	• Initial oral PrEP rollout depended heavily on external partners for PrEP reporting, and many facilities were reporting inaccurate data or leaving reports blank. Gradually more facilities are using the PEPFAR reporting system to report more accurate data. Stakeholders note that consumption data has significantly improved over the past two years and provides reliable information for forecasting and quantification. • Facilities are using a hybrid mix of manual and electronic reporting. Facilities with an HIV care unit are using the tools built for ARVs and dispensing PrEP as an added product. Electronic reports have helped keep systems updated on stock levels of PrEP across facilities in order to initiate redistribution products in cases of over or under stocks across facilities.	• KHIS Aggregate has been updated to include CAB PrEP. Disaggregation by PrEP methods 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 supports commodity tracking and communicates consumption rates directly to KEMSA. Rollout of the new tools will begin in January 2024. • Stakeholders hope that the new tool will improve accuracy in commodity monitoring, which will be particularly important for F&Q across the portfolio of PrEP products. The new tool will also allow for facilities to streamline ordering directly to KEMSA without needing to go through subcounty, county, and NASCOP reporting lines.
Performance measurement	• Oral PrEP has been integrated within standard M&E training tools for HCWs. PrEP reporting has improved in recent years as more HCWs and facilities accurate use M&E tools	• CAB PrEP has already been integrated within M&E tools.

Key findings

- **CAB PrEP has been integrated into KHIS Aggregate** and there are plans to migrate all facilities to an electronic system in the coming years.
- Stakeholders expect that **supply chain logistics will improve as facilities use the electronic system**. Furthermore, facility-level ordering will be more streamlined as facilities will be able to send orders directly to KEMSA with the electronic system.

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What's needed to introduce CAB PrEP in the supply chain

There is high anticipation for CAB PrEP, and stakeholders expect that the key lessons from the ongoing implementation studies will help inform programmatic rollout. However, regulatory approval is needed to move forward on introduction planning.

- Pharmacy and Poisons Board (PPB), the drug authority in Kenya, needs to approve CAB PrEP for use in Kenya. NASCOP, the MOH, and other stakeholders such as LVCT Health have been working to prepare the HIV policies and plans for when CAB PrEP is approved and ready to be integrated into PrEP programming.
- There is high anticipation for CAB PrEP, particularly among national stakeholders as well as implementing partners, youth and key population advocates. Stakeholders hope that CAB PrEP will be accepted by end users, resolving some of the issues with oral PrEP such as pill burden and stigma related to ARV packaging.
- Continued community sensitization is needed for all PrEP methods, including CAB PrEP and other new prevention methods as they become available to increase uptake and inform F&Q. Continued low awareness of PrEP has been a major barrier for the PrEP program.

*"We are ready for CAB PrEP. We have reviewed the M&E tools, but **we are waiting for the product to be approved by the regulatory authority**. CAB PrEP will be layered on the existing program. There is no need for a new supply chain systems. It will be provided as an additional option."* ***– Ministry of Health***

CAB PrEP will also present specific considerations with the new injectable form for HIV prevention methods.

- Stakeholders expect that the supply chain and storage facilities will be able to manage ambient temperature controls to ensure the injectable product remains between 0-30°C.
- There is a need to consider how a shorter shelf life of CAB PrEP may influence the supply chain system due to the long process for procurement into the country. Learning from other injectable products, products may arrive at facilities with only 3-6 months before expiry. Streamlining the supply chain system may be needed to ensure products go to facilities more quickly.
- Furthermore, the government supply of ancillary products (e.g., alcohol wipes, gloves, syringes) often lead to stock-outs. There may be a need for implementing partners to purchase additional products contingent on availability of funds.
- Training of all health care providers to strengthen management and accountability of CAB PrEP

*"The **injectable may have a different shelf-life than oral PrEP** and that would affect the supply chain given the time it takes for ordering and delivery. We have other products in the health program that are injectable, and they come to facilities only 3-6 months before expiry."* ***– Technical assistance partner***

Deep Dive: Monitoring key steps

	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

Overview of the national PrEP supply chain

Supply chain deep dive assessment

Sources and notes

Key stakeholders interviewed

Name	Title	Organization
Eric Mutwiwa Mutua	Assistant Program Officer, Supply Chain and Pharmacovigilance	NASCOP
Dr. Elvis Oyugi	Prevention Manager	NASCOP
Ruth Kamau	Programme Officer	NASCOP
Dr. Phoebe Ombajo	Sub-County Pharmacist – Kisumu Central	MOH
Dr. Geoffrey Kabue	County Pharmacist – Nyandarua	MOH
John Mungai	Program Associate	CHAI
Judith Onsomu	PrEP service delivery	PATH
Nicholas Odiyo	Senior Technical Advisor	PATH
Dr. Muthoni Waruguru Kaminjuki	Pharmacy Lead	University of Nairobi

Source: Interviews were led by MOSAIC Consortium partners Afton Bloom.

Acronyms

AIDS	Acquired immunodeficiency syndrome
AGYW	Adolescent girls and young women
ANC	Antenatal care
ART	Antiretroviral Therapy
ARV	Antiretroviral
AYP	Adolescent and young people
CCC	Comprehensive care centers
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
CPF	Counterpart-financing
DHAPP	United States Department of Defense HIV/AIDS Prevention Program
DICEs	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
GoK	Government of Kenya
HCW	Health care workers
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
PBFW	Pregnant and breastfeeding women
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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