Implementation Guide on Pharmacy Pre- and Post-Exposure Prophylaxis (PrEP & PEP) Delivery

PharmPrEP

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Abbreviations

ARV	Antiretroviral Drug
CAPA	Corrective Action Preventive Action
CPD	Continuing Professional Development
cRCT	Cluster Randomized Controlled Trial
DSD	Differentiated Services Delivery
EQA	External Quality Assessment
FSW	Female Sex Worker
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
IPC	Infection Prevention and Control
KEMSA	Kenya Medical Supplies Agency
KEPH	Kenya Essential Package for Health
KP	Key Population
KPA	Kenya Pharmaceutical Association
MOH	Ministry of Health
MSM	Men Who Have Sex with Men
NASCOP	National AIDS & STI Control Program
NHRL	National HIV Reference Laboratory
OTC	Over the Counter
PEP	Post-exposure Prophylaxis
POS	Point of Sale
PrEP	Pre-exposure Prophylaxis
PPB	Pharmacy and Poisons Board
PSK	Pharmaceutical Society of Kenya
PvERS	Pharmacovigilance Electronic Reporting System
RAST	Rapid Assessment Screening Tool
RDT	Rapid Diagnostic Test
SMART	Specific Measurable Achievable Realistic Timely
SOP	Standard Operating Procedure
SRH	Sexual and Reproductive Health
STI	Sexually Transmitted Infection
WHO	World Health Organization

Executive Summary

Developing accessible, cost-effective delivery models that reach at-risk populations is a key prerequisite for maximizing the public health impact of pre-exposure prophylaxis (PrEP) for HIV prevention. Since the World Health Organization's endorsement of oral PrEP in 2015, countries have progressively introduced and scaled up oral PrEP, and many are poised to introduce longer-acting PrEP formulations. Kenya, one of the high HIV burden countries in sub-Saharan Africa, included PrEP in its national guidelines in 2016, and subsequently launched a national PrEP scale-up program in 2017. While the number of sites delivering PrEP expanded quickly, uptake has been progressive but suboptimal, falling short of the national scale-up targets. In addition to uptake, continued use remains a challenge, attenuating PrEP's protective benefit.

In Kenya, PrEP is primarily delivered through facility-based models. In the public sector, PrEP is available at several delivery points, but mainly in HIV clinics and outpatient departments, where PrEP access and delivery are hindered by client, provider, and system-level barriers, including long wait times, lack of privacy, stigma, understaffing, and inefficient workflows. Drop-in centers, often run by nongovernmental organizations, have had success reaching large numbers of self-identifying men who have sex with men and sex workers, but are challenging to access for those who do not identify as a key population. Consequently, many individuals at high risk of acquiring HIV, including adolescent girls and young women, are underserved by current PrEP delivery models.

In Kenya, as in many low- and middle-income countries, private retail pharmacies play a vital role in the health care system. Private pharmacies are ubiquitous and are often the first stop for many individuals seeking health-related products and services. In addition to dispensing and refilling prescriptions, retail pharmacies offer over-the-counter medications, health and wellness products, first aid supplies, health screening and monitoring, medication management, vaccinations, family planning and reproductive health products and services, and minor ailment consultations. Some of the barriers to accessing HIV prevention services, such as PrEP and post-exposure prophylaxis (PEP), may be mitigated by delivering PrEP and PEP services via retail pharmacies. Compared to public sector clinics, retail pharmacies are easily accessible and feature longer opening hours, shorter wait times, and greater client privacy. A growing body of evidence has demonstrated that pharmacy-delivered PrEP is generally feasible and acceptable in Kenya, and the time is ripe for countries to consider adopting the differentiated PrEP and PEP delivery model.

This implementation guide provides detailed guidance for **decision-makers** and **implementers** in countries aiming to establish or enhance pharmacy-based PrEP services. The guide summarizes key considerations for setting up a pharmacy PrEP delivery program. Key domains include pharmacy selection, training of pharmacy providers, demand generation, commodity access and management, strategic information, service delivery, infection prevention and control, quality assurance, costing, and advocacy and stakeholder engagement.

Decision-makers: People with the authority to make pharmacy-delivered PrEP services a reality through supportive policymaking and implementation, including funding, regulations, and laws. *Examples*: Representatives of funding or regulatory bodies, officials from the Ministry of Health, and regional health leaders.

Implementers: People with the authority to organize action plans and resources and put them into practice. *Examples*: Ministry of Health, implementing partners, and pharmacy owners.

The guide documents insights and lessons learned from pilot studies implemented in Kenya to test a pharmacy-based PrEP delivery model, and the implications for future delivery of PrEP and PEP services through this model. Adapting this guide to local contexts and regulations is essential to ensure successful delivery of PrEP services through pharmacies. Regular updates and collaboration with health care authorities are crucial for maintaining the implementation guide's relevance and effectiveness.

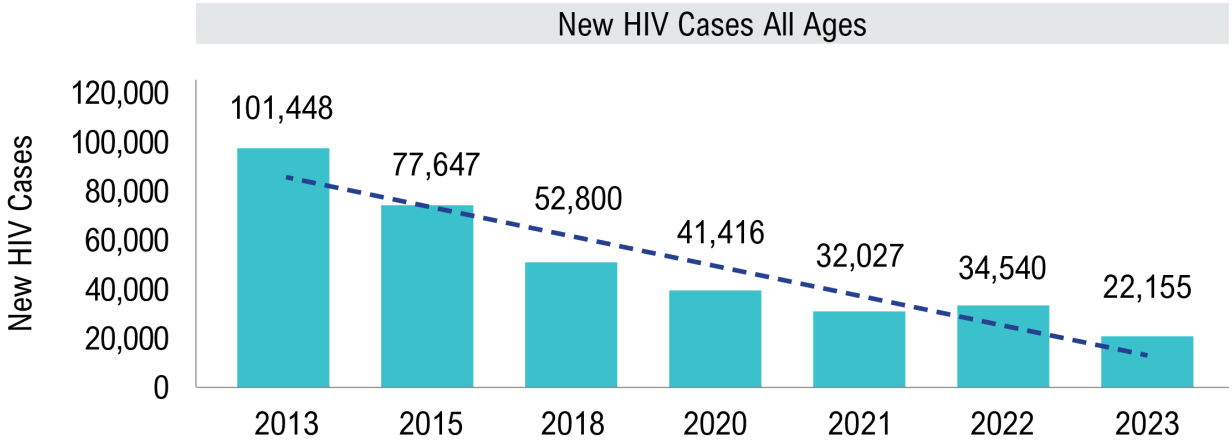
Introduction and Context

Studies have demonstrated that pre-exposure prophylaxis (PrEP) can effectively reduce the risk of HIV acquisition.[1,2] Since 2015, when the World Health Organization (WHO) recommended the use of oral PrEP by people at substantial risk of HIV acquisition, more than 1.3 million individuals have initiated PrEP globally.[3,4] Although the earliest PrEP users were mostly from the United States, uptake progressively increased in sub-Saharan Africa, rising from 4,154 users in 2016 to 1,921,389 in 2023.[4] However, this progress fell short of the Joint United Nations Programme on HIV/AIDS (UNAIDS) global target of three million people accessing PrEP by 2020.[5]

Kenya included PrEP in its national guidelines in 2016 and officially launched a national PrEP program in 2017.[6,7] This was followed by a progressive scale-up of PrEP across the country. A 2018 readiness assessment identified 856 facilities offering PrEP services one year after the launch.[8] By December 2023, the number of facilities had increased to over 2,000, with an estimated 438,003 clients reported to have initiated PrEP.[9]

In parallel, the country has seen a progressive 78.2% decline in new HIV infections over the past 10 years and has made significant progress toward achieving the Kenya AIDS Strategic Framework II target to reduce new HIV infections by 75% by 2025 (Figure 1).

Figure 1: Trend in new HIV infections in Kenya



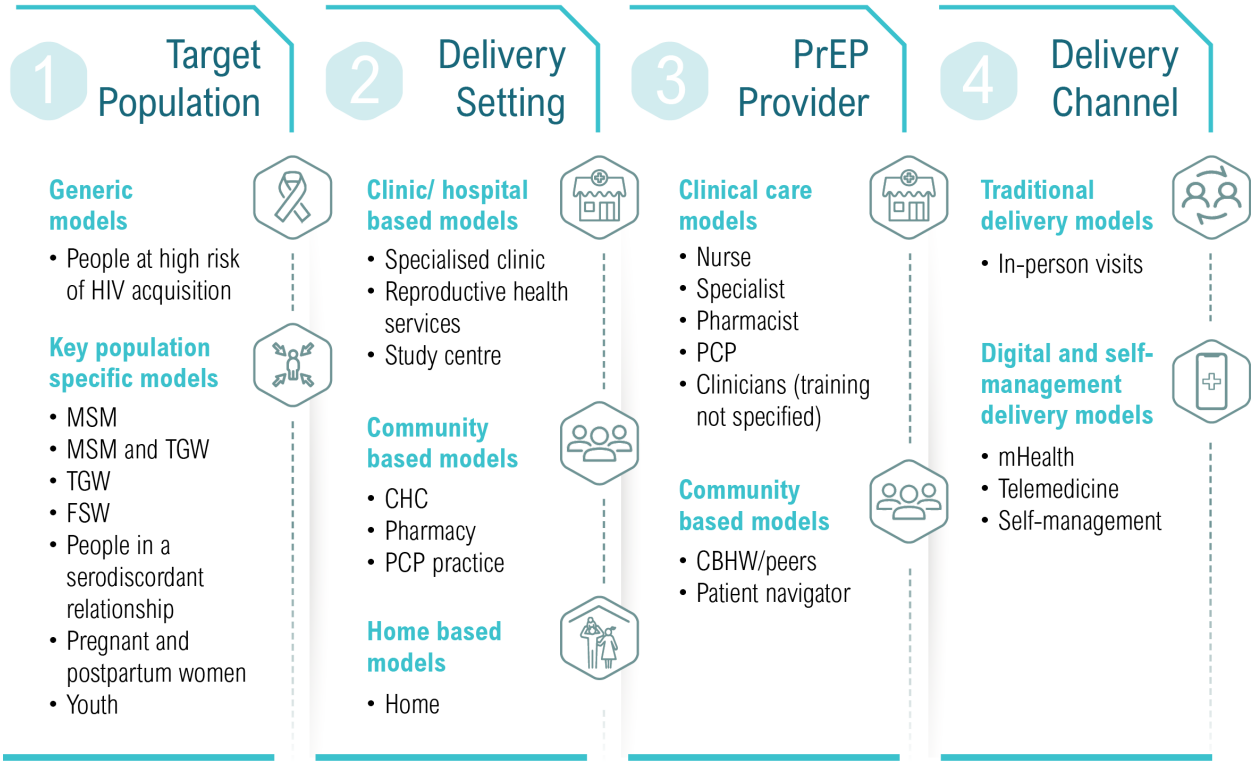
However, Kenya still has the seventh highest HIV burden globally, with an estimated 1.37 million people living with HIV. The HIV prevalence in 2022 was 3.7%, with a disproportionate distribution between men and women at 2.6% and 5.3%, respectively. In 2022, 22,155 new HIV infections were reported across all ages, with 17,680 occurring among adults and 4,464 among children aged 0–14 years.[10] The continuing high burden calls for concerted efforts to implement impactful interventions such as oral PrEP.

Data from Kenya and other sub-Saharan African countries indicate that PrEP has been primarily prescribed and provided through public health facilities. However, this platform faces many challenges, including long travel distances to clinics, long wait times, negative provider attitudes, and the need for frequent visits.[11,12]

Existing PrEP and PEP Service Delivery Platforms

PrEP and PEP service delivery models vary by setting and include clinic-/hospital-based models (specialized sexually transmitted infection [STI], HIV, and/or sexual health clinics), community-based models, and home-based models.[13] Figure 2 summarizes PrEP service delivery models by target population, delivery setting, PrEP provider, and delivery channel.

Figure 2: PrEP service delivery models



Notes: CBHW: community-based health worker; CHC: community health clinic; FSW: female sex worker; MSM: men who have sex with men; PCP: primary care provider; TGW: transgender women

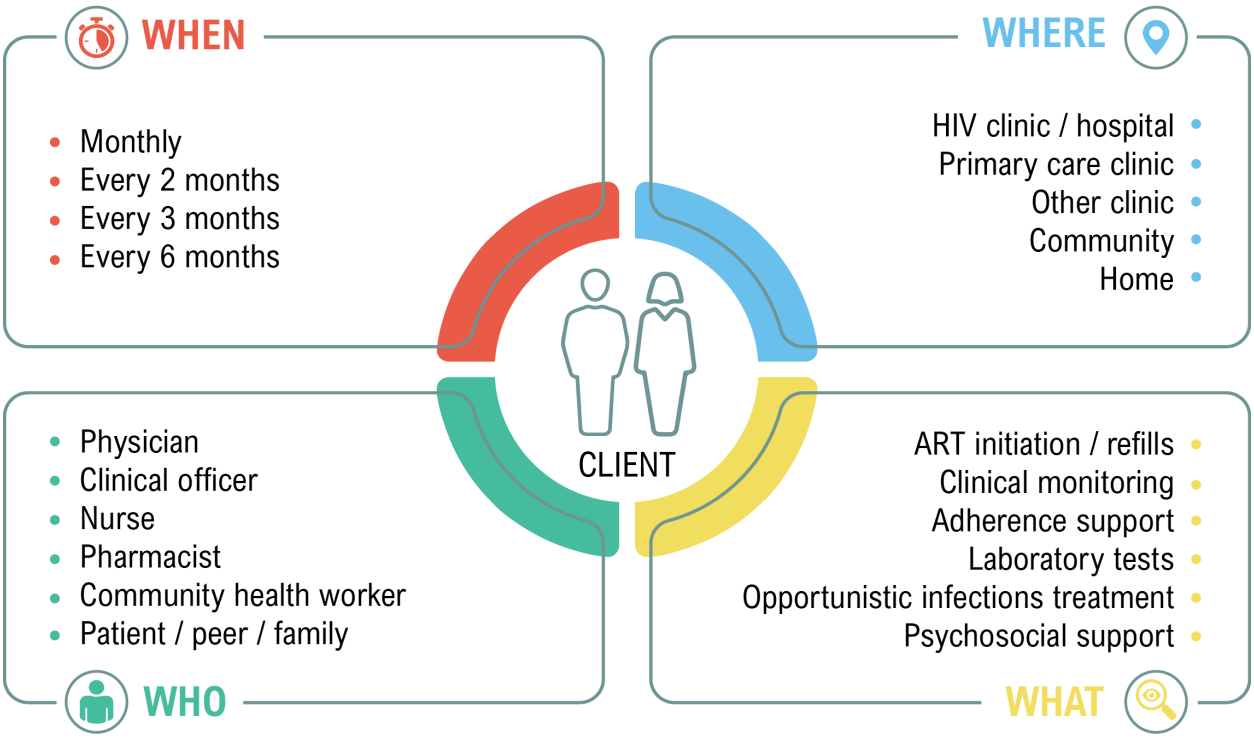
In Kenya, PrEP delivery has been primarily through clinic-/hospital-based models, with services mainly offered in HIV outpatient clinics and family planning clinics. Additionally, community-based models have been used primarily for key populations, including adolescent girls and young women. Although pharmacies are listed in the national framework for implementation as a PrEP service delivery point, delivery through the pharmacy model has been limited to the research context.

Differentiated PrEP Delivery

Recognizing the challenges and barriers associated with clinic-/hospital-based models, in 2022 WHO recommended differentiated PrEP service delivery.[14] Differentiated PrEP service delivery, as defined by WHO, is person- and community-centered and adapts services to the needs and preferences of people interested in PrEP and who could benefit from PrEP. As Figure 3 shows, the framework for differentiated PrEP service delivery uses four building blocks, which can vary for PrEP initiation and continuation:

- Where (service location)
- Who (service provider)
- When (service frequency)
- What (service package)

Figure 3: Building blocks for differentiated PrEP service delivery



Landscape of Pharmacies in Kenya

The Pharmacy and Poisons Act of 1957 (CAP 244) and 2017 Health Act govern private pharmacies in Kenya. As the regulatory authority, the Pharmacy & Poisons Board (PPB) manages registration and licensing of pharmacies. As of May 2024, there were 7,425 active registered retail pharmacies in Kenya, with a majority located in urban and peri-urban settings. There were 2,391 active registered pharmacists (with a Bachelor of Pharmacy degree) and 9,471 pharmaceutical technologists. In addition, there is an unofficial cadre of pharmacy assistants who routinely work alongside licensed actors. These pharmaceutical actors are overseen by two main professional bodies:

- Pharmaceutical Society of Kenya (PSK): A professional organization for pharmacists, the PSK advances the practice of pharmacy by creating and maintaining standards for professional conduct and a code of ethics for the profession.
- Kenya Pharmaceutical Association (KPA): A professional body for pharmaceutical technologists, the KPA promotes ethical pharmaceutical practice within premises and institutions, to the standards required and expected by society and the professional fraternity.

Kenya's regulatory framework does not authorize pharmacists and pharmaceutical technologists to prescribe medications, but they can administer injections and screen for HIV and other diseases, and they provide both prescription and over-the-counter (OTC) medicines. Pharmacies require valid licenses to operate in the country. Due to their accessibility and convenience, retail/community pharmacies have been identified as possible service delivery points for certain health service packages that are considered minor and manageable at that level. So far, pharmacies have been identified as a potential platform for malaria diagnosis using rapid diagnostic tests (RDTs), provision of reproductive health services, such as oral and injectable contraceptives, and HIV prevention services, all of which are offered for free in public health clinics.

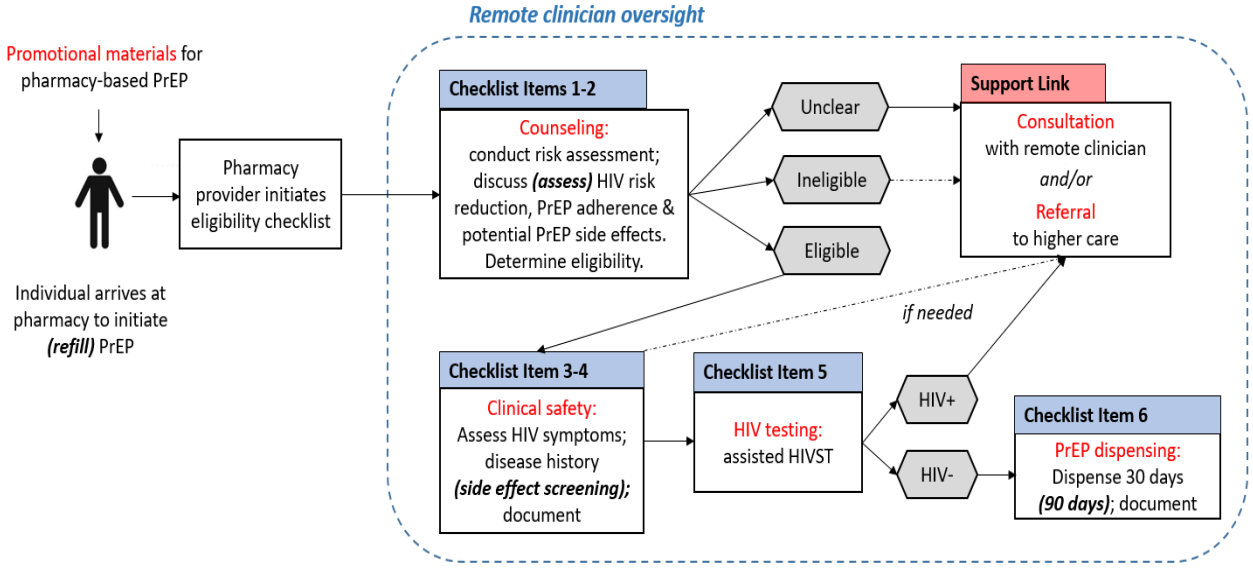
Pharmacy-based PrEP Delivery Model

The pharmacy-based PrEP/PEP delivery model entails the end-to-end delivery of HIV PrEP and PEP through community retail pharmacies. In this model, pharmacists and pharmaceutical technologists play a crucial role in service provision, including demand generation, behavior risk assessment, medical safety assessment, HIV testing, prescription dispensing and monitoring, and follow-up care. Development of this pharmacy PrEP delivery model has been through several research phases during which the model has been conceptualized and tested, and we continue to refine the model.
This model holds promise in circumventing some of the barriers, thereby enhancing access to PrEP and effective PrEP use, ultimately contributing to the reduction of HIV transmission, increased health equity, and the realization of global HIV prevention goals.

Preliminary and Ongoing Studies on Pharmacy-Delivered PrEP in Kenya

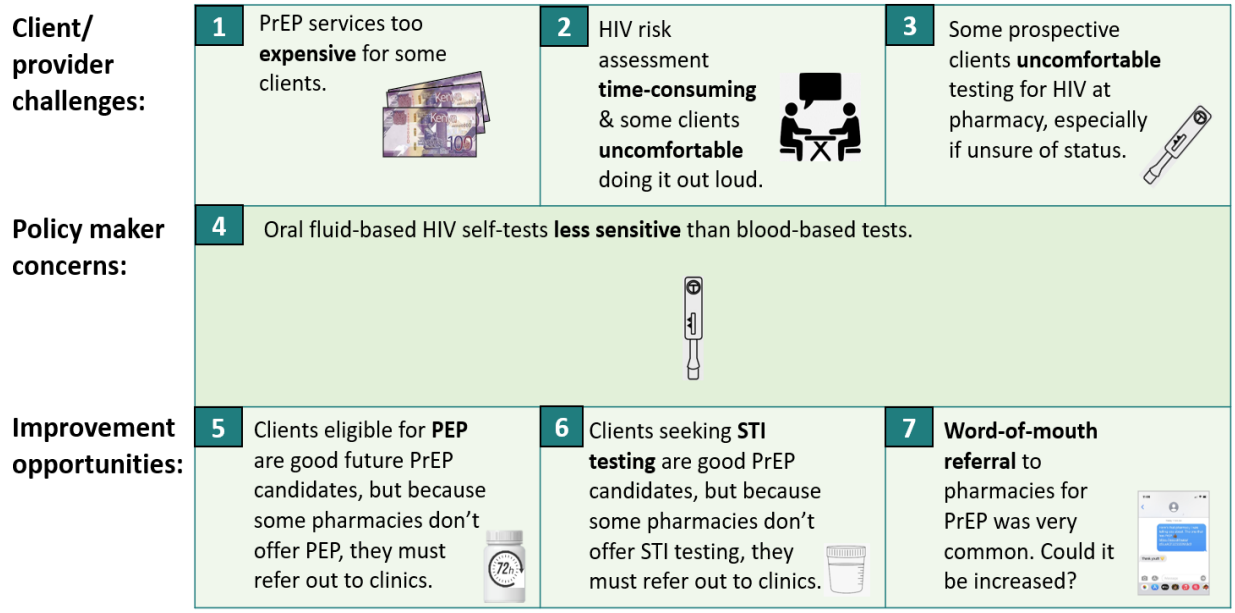
The pharmacy-delivered PrEP care pathway was developed by a team of researchers from the University of Washington, the Kenya Medical Research Institute, the Jomo Kenyatta University of Agriculture and Technology, and Partners in Health and Research Development, based on the One-Step PrEP™ Kelley-Ross model in Seattle, Washington, USA, and refined with inputs from 36 Kenyan stakeholders, including PrEP regulatory, professional, health care service delivery, civil society, and research organizations. Stakeholders participated in small and large group discussions to identify potential challenges and solutions. The key findings from these discussions were synthesized to develop the PrEP delivery pathway.[15] The anticipated core components of pharmacy-based PrEP delivery include counselling (with risk assessment), HIV testing, prescribing, and dispensing, all with remote clinician oversight. The pharmacy PrEP delivery model works best with self-driven and motivated providers. Figure 4 shows the care pathway that was developed and piloted in five pharmacies in Kenya with promising results.[12]

Figure 4: Pharmacy PrEP delivery pathway



During the pilot study's implementation, some challenges and opportunities were identified that informed modifications implemented for an additional six months in an extension of the pilot study. Figure 5 highlights some of the key challenges and opportunities.

Figure 5: Pharmacy PrEP pilot: Challenges and opportunities



ADAPTATION OF HIV TESTING STRATEGIES BASED ON STAKEHOLDER RECOMMENDATIONS

Initial pilot

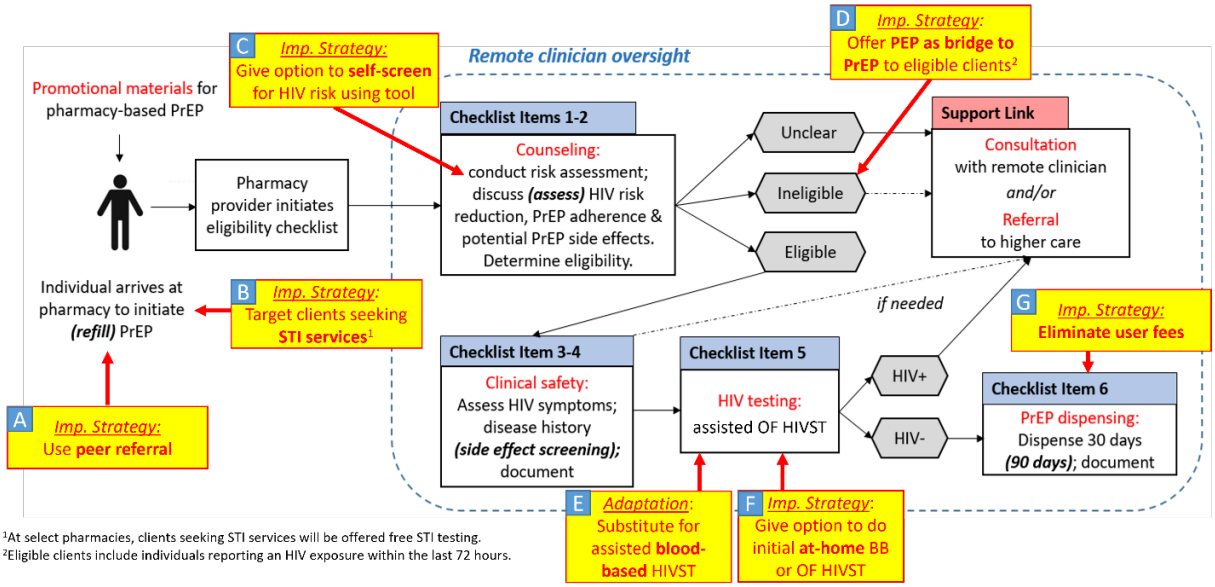
- **Policymakers' concern:** Oral fluid HIV self-tests are less sensitive than blood-based tests.
- **Policymakers' recommendation:** Shift from oral fluid to blood-based HIV self-testing.

Pilot extension

- **Policymakers' concern:** Blood-based tests are not part of the standard of care and would be an impediment to scaling up this model.
- **Policymakers' recommendation:** Align with the national algorithm on HIV testing, i.e., shift from blood-based HIV self-testing to provider-administered HIV rapid diagnostic testing.

To address some of the challenges, we modified the model as shown in Figure 6, and implemented it in 12 pharmacies for six months.

Figure 6: Pharm PrEP pilot extension care pathway



Key Findings from the Preliminary Studies on Pharmacy-Delivered PrEP in Kenya

During the initial pilot (November 2020 to December 2021) pharmacy providers screened 575 clients, 476 were determined to be PrEP-eligible and 287 (60%) initiated PrEP. Only two clients (1%) reported any prior PrEP use. Over half of the clients who initiated PrEP were men (57%, 163/287). Less than half were <25 years old (44%, 126/287) and were married (38%, 108/287).[16] PrEP continuation was 53% (153/287) at one month, 36% (103/287) at four months, and 21% (51/242) at seven months, which is higher than what has been observed in public health clinics.[12] Additionally, the perceived acceptability and appropriateness of pharmacy-delivered PrEP services was very high (>95%).[16]

During the six-month (January to July 2022) pilot extension study, pharmacy providers screened 1,028 clients and initiated 823 (80%) on PrEP (n=661) or PEP (n=162). About half of all clients were male (48%, 394/823) and under 25 years old (48%, 394/823), and the majority were unmarried (78%, 640/823) and not in known sero-different relationships (91%, 596/661). This population differed considerably from

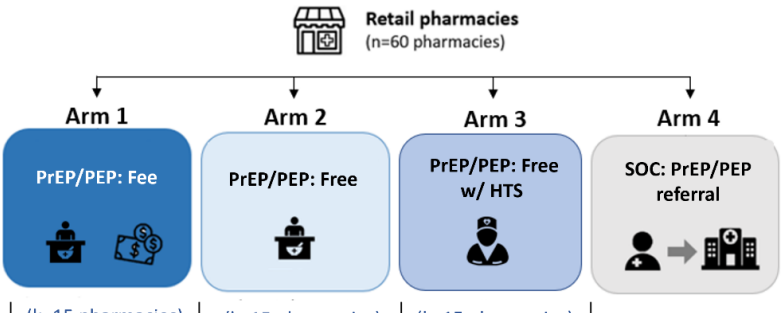
those served in public HIV clinics. PrEP continuation in our pilot extension was 72% (479/661) at one month and 51% (170/335) at four months among those eligible for follow-up; 19% (30/162) of PEP clients transitioned to PrEP upon PEP completion. Throughout the study, pharmacy providers appropriately consulted the study's remote clinicians, when needed, and, at follow-up visits, no participants were found to have seroconverted. The perceived acceptability of pharmacy-delivered PrEP and PEP services among pilot extension participants was high, with 70–100% of clients and providers reporting that they liked getting/delivering PrEP/PEP at the pharmacy and that getting/delivering PrEP/PEP at the pharmacy was not hard.

Overall, the pilot and pilot extension findings suggest that, when trained, pharmacy providers are capable of initiating and managing clients on PrEP and PEP in accordance with national guidelines. Additionally, these studies indicate that pharmacies may reach populations with HIV risk that are not well-reached by public health facilities—such as young men and individuals not in known sero-different relationships—and that clients are willing to initiate PrEP at private pharmacies. PrEP initiation was also high among clients who were initially seeking PEP or STI testing/treatment. If these study findings are indicative of how private pharmacies would perform in a scale-up scenario in Kenya, it is reasonable to expect that rates of PrEP uptake and continuation at private pharmacies might match or exceed those seen in public health facilities; moreover, our findings that pilot and pilot extension pharmacies reached and initiated PrEP-naïve individuals on PrEP suggests that pharmacies might be well-positioned to increase overall PrEP coverage.

More research is needed on different cost-sharing models that could inform the sustainability of the pharmacy PrEP delivery model, which uses national stock of commodities (e.g., PrEP/PEP drugs).

To further evaluate the pharmacy-delivered PrEP implementation model tested in the initial pilot and pilot extension, we are currently implementing a four-arm cluster randomized controlled trial (cRCT) in 60 pharmacies across six counties in Kenya (Figure 7). The cRCT is designed to test the effect of pharmacy-delivered PrEP services (free, for a fee, with HIV testing services [HTS] counselor support) compared to pharmacy referral to clinic-based services (the current standard of care).

Figure 7: cRCT design



	(k=15 pharmacies)	(k=15 pharmacies)	(k=15 pharmacies)	(k=15 pharmacies)
Provider leading screening & HIV testing	Pharmacy provider	Pharmacy provider	HTS counselor	Pharmacy provider
Client pays pharmacy*	**250 KES**	0 KES	0 KES	0 KES
Study pays pharmacy*	0 KES	**250 KES**	**100 KES**	**100 KES**

**Per HIV test completed or (if Arm 4) per referral*

Implementation Considerations

Delivering HIV prevention services, including PrEP and PEP, through community retail pharmacies requires investment in several critical elements to ensure that the right pharmacies are selected, capacitated, and provided with appropriate resources for safe and effective service delivery. Here, we highlight some of the key considerations for successful implementation of the PrEP/PEP pharmacy delivery model:

1. Pharmacy selection
2. Training of pharmacy providers
3. Demand generation
4. Commodity access and management
5. Strategic information
6. Service delivery
7. Infection prevention and control
8. Quality assurance
9. Costing and business case
10. Policy advocacy and stakeholder engagement

Pharmacy Selection

Effective delivery of HIV prevention services, such as PrEP/PEP, through community pharmacies should ensure not only the safety of clients receiving the services, but also their privacy and confidentiality. While community pharmacies are ubiquitous, not all pharmacies are suited to offering PrEP/PEP services. This is because many pharmacies are set up mainly to provide OTC services and do not have the appropriate infrastructure for service delivery. Thus, introducing PrEP/PEP services into a pharmacy may require some adaptations. Criteria to guide the selection of pharmacies is therefore needed. For our pharmacy PrEP pilot studies, we developed the following criteria to guide selection of pharmacies suitable for providing PrEP/PEP services:

- *Regulatory compliance:* The pharmacy must be registered with and have a valid license from the relevant regulatory authority. In Kenya, the PPB is the regulatory authority, so pharmacies must be registered and licensed by the PPB to qualify for inclusion.
- *Provider certification:* The pharmacy must have at least one licensed and certified pharmacist or pharmaceutical technologist on staff per shift to ensure services are offered by a competent provider.
- *Privacy and confidentiality*: The pharmacy must have an available private room for client consultation, counselling, and HIV testing.
- *Willingness to offer PrEP/PEP services:* Since pharmacies are commercial entities, the pharmacy owners and providers must demonstrate willingness to offer PrEP/PEP services.

These are the most critical factors for scaling up the model. However, because we implemented the model under a study protocol, the pharmacies also needed to commit to adhering to the study protocol

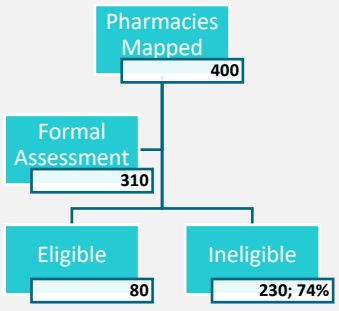
and study-related requirements (note that these were auxiliary criteria and may not be applicable in routine program settings):

- Willingness to be randomized into any of the four study arms.
- Willingness to use the Maisha Meds point-of-sale (POS) system for study data capture and reporting.
- Willingness to procure study commodities (i.e., rapid test kits, PrEP, and PEP donated by the Kenya Ministry of Health [MOH]) from nearby linked public health facilities.
- Willingness to prepare and submit recommended monthly reports (e.g., MOH commodity consumption reports).

Case Study: Pharmacy Selection for the Cluster Randomized Controlled Trial

To implement the PharmPrEP cRCT that is evaluating the effectiveness of the pharmacy PrEP delivery model, we needed to enroll 80 pharmacies (60 to participate in the study and 20 to serve as back-up pharmacies for quick replacement of any pharmacy that drops out of the study) across six geographical regions (counties) in Kenya. We selected the pharmacies using the following three steps:

1. **Identification and mapping of pharmacies:** Study team members visited trade centers, towns, shopping malls, and shops in residential areas to identify potential pharmacies to be assessed for the study. The team also identified additional pharmacies they came across in their travels and explored their interest in the study and willingness to be assessed. At each pharmacy, they gave a summary of the study and asked those present (whether the owner or a service provider) if they could administer a site assessment checklist to further inform us on the pharmacy's suitability to join the study. We worked in close collaboration with the respective subcounty health management team members to identify potential pharmacies. During this initial encounter, we primarily narrowed our list to pharmacies with an operating license issued by the PPB.
2. **Formal assessment:** Using an assessment checklist developed by the study, study team members conducted a physical visit to the pharmacies identified as having an operating license and administered the tool to assess their eligibility. The assessment mainly aimed to ascertain if the pharmacy met the criteria outlined above. Of the 400 pharmacies identified in step 1, 310 were formally assessed. We did not assess pharmacies where the owner was not present during the visit and the pharmacy providers were unwilling to provide contact details. Most of the pharmacies assessed (230; 74%) were ineligible.



Reasons for ineligibility included pharmacy owner reluctance (40%), unwillingness due to study requirements (37%), regulatory issues (16%), and reasons for declining participation not stated (7%). It is notable that some of the pharmacies declined participation or were ineligible due to study-specific issues. Some of these issues would unlikely impact their participation in a routine program implementation setting. Below we summarize the specific reasons for ineligibility.

Pharmacy Owner	Regulatory Issues	Study Requirements
• Pharmacy owner not willing to allow the pharmacy provider time off work for training	• Pharmacy not licensed by the PPB • Unqualified or unregistered pharmacy attendant	• Not willing to participate in a study • Not willing to stock government commodities: PrEP/PEP and test kits • Not willing to commit to study requirements, e.g., randomization to the different study arms

3. **Pharmacy agreements:** To ensure commitment to the study, we developed formal agreements for the pharmacies meeting the selection criteria. These agreements were signed by the site principal investigators and pharmacy owners.

Lessons learned	Implications for routine implementation
Despite the ubiquity of pharmacies, few met the selection criteria. Pharmacies located in peri-urban and rural settings rarely met the minimum regulatory requirements to operate.	Some high-risk geographies, such as sex worker hotspots, may not benefit from the pharmacy-based PrEP delivery model because of unlicensed facilities.
Some pharmacies declined participation since they did not want to be associated with provision of HIV services.	Demand creation efforts to normalize PrEP use are warranted to counter HIV stigma, which is prevalent and normalized in many communities.
The pharmacy's location is a likely determinant of the trends in service uptake. Pharmacies in areas with a concentration of high-risk groups tend to attract many clients. For instance, pharmacies near universities have a high demand for PEP, while pharmacies located in sex worker hotspots have a high demand for PrEP.	Sites with groups at an elevated risk for HIV in the locality should be prioritized for economy of scale.
Pharmacies with more than one qualified staff are likely to sustain uninterrupted services.	Level of staffing should be an important consideration for this model.

Recommendation

To scale up a pharmacy-based PrEP delivery model, it is essential to develop criteria outlining the minimum requirements that pharmacies need to meet in order to effectively deliver the relevant program components, in an environment that guarantees safety and quality services.

Training of Pharmacy Providers

As a new cadre in the delivery of PrEP and PEP services, the majority of pharmacy providers had no training in these and other HIV services. Few HIV services, including PrEP and PEP, are part of the pre-service training curriculum for pharmacists and pharmaceutical technologists. For this model to be successfully implemented, pharmacy providers need comprehensive training in HTS, PrEP, and PEP. Presently, the Kenya national training curriculum entails a four-day training on PrEP and PEP and a three-week training on HTS, including observed practice.

The challenge: Implementing the national training curriculum proved to be challenging owing to the unique nature of the community pharmacies. Because community retail pharmacies operate as a business, their economic interests precede other considerations. Many are small businesses run by one pharmacy provider (at times the owner), and hence it was practically impossible for them to close their businesses for extended periods to attend the training, as it could lead to significant loss of income. This challenge was a deal breaker for some to their participation in the study.

Blended Learning Approach

In consultation with the National AIDS & STI Control Program (NASCOP), we developed a blended learning approach[a] for pharmaceutical providers. The training was designed to rapidly build the capacity of pharmacy providers by updating their knowledge and expanding their skills on PrEP, PEP, and HTS. The approach combined virtual/mobile-enabled learning and on-the-job or other practical training sessions. The learning pathway was structured as follows:

- Three online self-paced courses (PrEP, PEP, and HTS) delivered over six hours.
- Two days of in-person training to reinforce and expand upon the online content.
- One-day practicum (observed practice) of HIV testing and counselling supervised by NASCOP-certified MOH trainers.
- Technical assistance visits to the pharmacies for mentorship and on-the-job training.

Online self-paced modules

The modules covered PrEP, PEP, and HTS. They were designed to be interactive, and included graphics, short videos, and quizzes to assess comprehension.

BLENDED LEARNING APPROACH

Many pharmacy providers were willing to offer PrEP and PEP services but were reluctant to close their businesses for an extended duration (four weeks) to attend the requisite trainings. To mitigate this challenge, we developed a blended training curriculum that adapted content from the national training curriculum. This training was delivered through a combination of online modules, physical sessions to reinforce materials learned in the online modules and for practicum, and continuous technical support and on-the-job training.

1. **Oral PrEP.** Training content on oral PrEP was adapted from the oral PrEP eLearning resource package developed by WHO in conjunction with Jhpiego (https://www.hivoralprep.org/). The Oral PrEP eLearning Tool for Clinicians course provides instructions for managing PrEP services in accordance with the WHO Implementation Tool for Pre-exposure Prophylaxis of HIV Infection. The course targets practicing clinicians around the globe who currently have a client population at high risk of contracting HIV and who provide—or will provide—oral PrEP or PEP.
2. **Management of PEP.** This module provides guidance on managing PEP in accordance with the Kenya HIV Prevention and Treatment Guidelines (2022 Edition), and targets health care workers providing HIV prevention, care, and treatment services.
3. **How to conduct HTS.** The HTS course was adapted from the Kenya HTS Orientation Package (2021) and offers guidance on how to conduct HTS in different settings in Kenya. The course targets health care workers providing HIV services who have completed previous trainings on HIV prevention, care,

[a] Blended learning is a combination of training delivery methods, usually involving digital learning plus hands-on practical skills training delivered in the workplace or at a simulation center.

and treatment, including pharmacists and pharmaceutical technologists, clinical officers, nursing officers, and any other health care worker providing HIV services.

The modules covered in the three courses are summarized below.

1. HIV testing services
    - Basic concepts of HIV
    - Population targeted for HTS, approaches and strategies
    - Communication and counselling for HTS
    - HTS service package
    - Performing HIV testing
    - Quality assurance in HIV
    - Commodity management
2. Oral pre-exposure prophylaxis
    - What is PrEP?
    - Identifying suitable candidates for oral PrEP
    - Initiating oral PrEP with a client
    - PrEP special situations
    - PrEP counselling and messaging consideration
    - PrEP management and follow-up
3. Management of post-exposure prophylaxis
    - What is PEP?
    - Eligibility for PEP
    - Management and follow-up of PEP clients
    - Special circumstances of PEP

These courses were hosted on the World Continuing Education Alliance platform, and each course had a pre- and post-test to assess providers' knowledge of HTS, PrEP, and PEP concepts; case studies; and a general course evaluation survey. The estimated duration of the online training was six hours but pharmacy providers were given one to two weeks to complete it. Upon completing the online training, providers were awarded certificates. They also received continuing professional development (CPD) points from their professional associations upon completion.

In-person training

As a follow-up to the online modules, we organized in-person trainings for pharmacy providers to reinforce the online content and conduct practical sessions for HTS. Additionally, because we implemented this model in the context of a study, the in-person workshops included training on research ethics; the study protocol and study procedures, including commodity access and reporting; documentation for service delivery and reporting; and how to conduct HIV testing and counselling. These trainings were conducted collaboratively by the study/project team with the MOH. Certified trainers from the MOH at the subnational level (county and subcounty) where the study sites were situated facilitated sessions on PrEP, PEP, and HTS, while the study team facilitated sessions on the study.

A critical consideration in organizing training is the availability of participants to fill a classroom. In our context, because we were preparing to launch a study in 60 pharmacies, we were able to gather a large group of pharmacy providers. Therefore, bringing together 20–30 pharmacy providers in one class was feasible and the in-person trainings were conducted centrally in each county. However, there may be scenarios where it is not possible to congregate several participants in one training course. For instance, as we continued implementation of the study, the need for continuous training arose as the program experienced attrition of trained pharmacy providers, necessitating the onboarding of new providers. However, because most of the pharmacies replacing providers were geographically dispersed and the replacements occurred at different time points, classroom-based training was not feasible. Therefore, we adopted a modular on-the-job training approach, where project staff staggered the content for the two-day training in modules and delivered them to individual providers in their respective pharmacies.

Practicum for HIV testing services

Upon completion of the in-person training, each pharmacy provider participated in a practicum session in a real clinical setting. In this instance, participants were situated in an HIV testing point in a high-volume health facility where they conducted HIV testing for three to five HTS clients. This session was conducted under the supervision of MOH trainers.

Technical assistance, mentorship, and on-the-job training

Beyond the online modules and in-person training, pharmacy providers require continuous support to master the content and skills needed to effectively deliver services under this model. Given that this was a new service for pharmacy providers, it was important to offer them continuous support to build their confidence and competence. We employed the following mechanisms to support the study participants to provide quality services:

- *Provision of job aids:* We provided job aids to support providers to offer appropriate services to clients during initiation and follow-up visits. We also provided job aids to support them through the process of HIV testing and interpretation of the results.
- *Remote clinician support:* Remote clinicians were available for consultation whenever the pharmacy providers needed guidance. Questions frequently asked by the providers fell into the following themes:
    - How to handle clients with side effects
    - Ruling out acute HIV infection
    - Contraindications for PrEP
    - Handling survivors of sexual violence
- *Mentorship by technical officers:* Technical officers are project staff who are clinicians with experience offering PrEP and PEP services, as well as mentoring health care workers. During the first three months of implementation, the technical officers visited the pharmacies on a weekly basis, with the frequency adjusted over time based on the unique situation of each pharmacy.
- *Quarterly supportive supervision:* We conducted quarterly supportive supervision sessions together with MOH officers from the respective counties. The feedback provided during these sessions further increased providers' confidence. The sessions also gave the MOH officers an opportunity to provide some oversight of the implementation of the study.

Lessons learned	Implications for routine implementation
Conventional off-site training approaches may be inappropriate for active, already employed pharmacy providers. Some pharmacy owners were willing to participate in the study but were unwilling to release their employees to attend the required in-person trainings on PrEP/PEP delivery (including a required observed practice to confirm competency in HIV testing and counselling).	PrEP/PEP delivery capacity-building approaches for private pharmacies should prioritize low-burden approaches to training, such as online modules with comprehension quizzes and on-the-job training.
Involvement of the MOH in development of the training curriculum, implementation of the training, and oversight is important for scale-up of the model. Including PrEP in pre-service training curricula could also minimize the training burden for in-service training.	Some adaptations to national curricula and approved training approaches would be warranted for this cadre.
Some pharmacy providers were not able to complete the online courses within the recommended time.	Allocating more time for completion of modules is necessary since other priorities and interests compete with training activities. Follow-up of pharmacy providers and introduction of certification is a critical entry point for delivery of services and may incentivize completion of training activities.
Attaching a reward to the training activities, e.g., CPD points, incentivized pharmacy providers to complete the training.	Accreditation of the training courses by professional associations is necessary to enable pharmacists and pharmaceutical technologists to earn CPD points.
Ongoing training and support are needed. Pharmacy providers continued to face numerous capacity gaps following the online modular and in-person trainings.	A one-off training course is not sufficient; a plan for continuous capacity-building is needed. Low-dose, high-frequency technical assistance may be needed, especially during the first three months post training.
Pharmacy providers scored an average of 53–56% on the pre-test for these topics but scored 22–31% higher on the post-test. These scores reflect how the online training improved providers' knowledge of HTS, PrEP, and PEP concepts.	Requiring pharmacy providers to complete the online training before the in-person training also meant that the in-person training could be dedicated to reinforcing concepts, answering questions, and practicing study procedures.

Recommendation

Innovative capacity-building approaches are critical when considering implementation of PrEP delivery models. The blended learning approach is one such flexible pathway that can enable wider reach, convenience, flexibility, and access to materials for future reference.

Demand Generation

Private pharmacies traditionally do not have defined demand-generation interventions and rely on walk-in clients for their operations and business traffic for curative services. Given that PrEP was a new addition, it was important to make pharmacy clientele aware of the new offering. To advertise these services, pharmacies need authorization from the regulatory body. In Kenya, to obtain authorization, applicants must submit detailed information about the product or service, the intended advertisement,

and any supporting evidence for claims made. The PPB reviews these applications to ensure compliance with regulations.

Pharmacies looking to advertise preventive services, such as HIV and sexual and reproductive health (SRH) services, should ensure their campaigns align with regulatory guidelines. They can leverage their existing client base by targeting walk-in customers already accessing other services or expand their reach through community-based demand-generation efforts. It is crucial to ensure their advertising practices comply with regulatory standards.

In our context, we aimed to target pharmacy clients purchasing HIV self-testing kits and SRH services or products indicative of HIV risk. We chose this approach because pharmacy PrEP delivery is not yet the standard of care, and we wanted to avoid introducing bias, considering the pharmacies were randomized into four arms representing the different models. Additionally, we provided posters to display in the pharmacies to communicate the availability of PrEP services. We also encouraged pharmacy providers to ask neighboring pharmacies to refer potential clients to them. To build the confidence of pharmacy providers in broaching the topic, we developed a recruitment script for them. Despite the high number of clients purchasing HIV-related and SRH services, the proportion initiating PrEP remained low.

Lessons learned	Implications for routine implementation
Given the stigma associated with HIV, some pharmacy providers are hesitant to introduce the topic to their clients for fear of losing business.	Additional demand-creation strategies are required to ensure that the request for these services comes from the clients themselves. There is a need to invest in community-level awareness creation to normalize PrEP delivery though pharmacies.
There is an overlap between the busiest times for pharmacies and when potential PrEP clients visit. As a result, pharmacy providers are conflicted between maximizing sales and providing free HIV prevention services.	For this model to succeed, pharmacies would need more than one trained provider working during peak hours.
The pharmacy PrEP delivery model works best with self-driven and motivated providers. Pharmacy owners who directly provide services demonstrated higher enthusiasm in creating demand for PrEP among clients than employee pharmacy providers. Some feel disincentivized because the fee for service is paid to the owner, and some have daily sales targets to meet.	To sustain access to services in a private pharmacy setting, it is important to prioritize working with providers who double as proprietors as this would spur innovations around demand creation that would aid in scaling up access to PrEP services. Also, exploring provider motivation prior to setting up PrEP services in the pharmacy is critical.

Recommendation

Many potential PrEP/PEP clients are already accessing other SRH services, but pharmacy providers are apprehensive and time constrained in eliciting their interest in PrEP/PEP services. Pharmacy providers should be supported with demand-creation strategies to elicit clients' interest in PrEP/PEP services with minimal effort.

Commodity Access and Management

To deliver PrEP and PEP services through this model, pharmacies need to access HIV test kits and PrEP/PEP commodities. Three important considerations include quality, affordability, and commodity security. The quality of the commodities needs to be guaranteed and must meet the required global (WHO) and national (MOH) standards in order to guarantee client safety. Similarly, pharmacies need to access products at costs that are affordable to clients since cost is a likely factor in influencing demand for PrEP/PEP services through this model. Lastly, pharmacies should be able to access commodities consistently so that clients' needs are met as and when they need PrEP/PEP. Frequent commodity shortages can negatively impact client confidence in the model. There are two potential commodity access pathways: 1) a public-private partnership model where public commodities purchased by the MOH or donors are distributed to private pharmacies who charge a nominal service fee in order to increase access to PrEP/PEP at minimal costs; or 2) a fully commercial model where private pharmacies procure and sell commodities at market rates and charge clients a service fee. Here, we describe a public-private partnership pathway that we employed for the pilot studies.

PrEP and PEP Commodities

Most private retail pharmacies do not routinely stock antiretroviral drugs (ARVs). To ensure availability of the required commodities (PrEP/PEP medication and HIV test kits) for the pilot studies and minimize costs, we negotiated with the MOH to facilitate access through the national HIV commodities pipeline. Under the national supply chain, procurement, warehousing, and distribution of ARVs are a function of the Kenya Medical Supplies Authority (KEMSA). The NASCOP works in close collaboration with KEMSA and the Mission for Essential Drugs & Supplies to manage the Health Products & Technologies for HIV programming. The supply chain is thus nationally managed, with HIV commodities centrally distributed to all health facilities that provide antiretroviral therapy services, and a few private facilities receiving their commodities via central sites (mainly public county and subcounty health facilities). Consumption data capture and reporting is done via a Kenya Health Information System with oversight and coordination at subcounty, county, and national levels for quality assurance.

Because health care is devolved in Kenya and service delivery is a function of the 47 counties, we engaged with the county health management teams in the counties where the study was hosted, and they committed to support the study with PrEP, PEP, and HIV test kits. The private pharmacies were linked with select public facilities for access to ARVs for PrEP and PEP as satellite sites. We also trained the private pharmacy providers on how to order, store, dispense, and report the donated products to linked public health clinics. An electronic data system, which also serves as a POS, was installed, and orientation and follow-up technical visits conducted to perfect its use. We also conducted regular supportive supervision on commodity management with county and subcounty pharmacists. In some instances, we facilitated the pharmacy providers to deliver reports and pick up PrEP/PEP from linked public clinics while others used their own resources. Whenever there were shortages of ARVs at linked facilities, we engaged the respective county pharmacists, who assisted in obtaining these commodities from other health facilities.

Rapid HIV Test Kits

Through national-level engagement, we secured an additional allocation for HIV test kits through the various counties where the study took place. The drawing rights/allocations for the regions were increased slightly to accommodate projected HIV test kits needs for the study. To ensure continued availability of HIV test kits, the study, in collaboration with other implementing partners, supported quarterly rapid HIV test kit allocation meetings. At these meetings, the county/subcounty teams

allocate HIV test kits to facilities for the quarter guided by the previous consumption rate. To report the HIV test kits received, the study printed and availed the necessary MOH reporting tools, which the pharmacies used to consolidate consumption data and share the data with the respective linked facilities before the fifth day of the following month. The MOH team conducted periodic site visits to appraise data quality and ensure HIV test kits are stored in the right condition. Modalities were put in place to ensure the pharmacies receive adequate HIV test kits and that they order using the recommended MOH tools (S11 form).

Lessons learned	Implications for routine implementation
Private retail pharmacies can be supported to access publicly procured commodities through linked public health clinics. We successfully linked private pharmacies to Kenya's national HIV commodities pipeline at no additional cost except for distribution and reporting costs.	Private pharmacies may opt to either buy and stock commercially available PrEP or access publicly procured PrEP if such arrangements exist in the country. Countries need to establish and map existing sources of health products required for PrEP, whether in the public or private sectors, and determine feasible procurement mechanisms for private pharmacies.
Without a proper follow-up monitoring, supervision, and mentorship system, it may be difficult to assure proper accountability for these commodities.	Instituting simplified and easy-to-use data capture and reporting tools in private retail pharmacies is likely to result in timely submission of reports to the MOH for resupply and accountability. To effectively implement a pharmacy-based PrEP delivery model, it is critical to establish a system for managing the PrEP inventory in terms of record keeping and reporting to national health information systems. Availing publicly procured products to private pharmacies needs to be managed (where possible via a policy or guidelines) since retail pharmacies are registered and licensed as medicine dispensing outlets.
Most private pharmacy owners prefer to have the products delivered directly to their premises rather than picking them up from the linked facilities.	Establishing last mile delivery systems is critical to incentivize pharmacy providers to offer PrEP and PEP services, since most of their drug supplies are delivered directly to the pharmacies.
Timely submission of monthly reports to the linked MOH facility by the private pharmacies is imperative to guarantee uninterrupted commodity supplies.	As countries plan to expand HIV prevention services to the private sector, an appropriate, easy-to-use, and acceptable commodity accountability mechanism must be put in place, especially for publicly funded products. Introducing such a system may require additional investments in procuring the software, hardware, and follow-on technical assistance for the pharmacy providers. Where one already exists, a POS, if adaptable, can be used; if a new solution is required, interoperability capabilities may be necessary.
Collaboration with local MOH leadership enabled restocking and exchange of short expiry commodities (HIV test kits and PrEP/PEP drugs). Pharmacy providers who maintained open communication with the MOH had an easy time accessing commodities.	To sustain the model, continuous collaboration between the provider and the linked facilities is vital for both reporting and restocking at the pharmacy and facility, as this will aid in accurate projection of quantity of commodities that will serve both.

Recommendation

No report, no product, no program; hence, a sustainable supply chain for PrEP in private pharmacies should be designed to allow seamless access to commodities, data capture, and reporting mechanisms for accountability.

To effectively support data capture and reporting at private pharmacies on PrEP delivery services, countries may deploy a user-friendly POS system in private pharmacies or integrate PrEP data requirements into existing pharmacy systems.

A pharmacovigilance system to monitor both adverse events and poor-quality products should also be incorporated to allow private pharmacy providers to prepare and submit reports electronically. An example of such a system is Kenya's pharmacovigilance electronic reporting system (PvERS), which can be found at *https://pv.pharmacyboardkenya.org/*

Strategic Information

In Kenya, PrEP delivery in the standard of care is documented using a national clinical encounter record form and appropriate registers that capture relevant information along the PrEP cascade. The pharmacy PrEP delivery pathway is based on a PrEP prescribing checklist that pharmacy providers use when offering PrEP services. The prescribing checklist guides providers through the delivery of services to the client and documentation of client-specific information, thus acting like a medical record. Pharmacy PrEP services can be documented using a paper-based or electronic records system. However, since PrEP client information needs to be documented and clients followed up with over time, paper-based systems become cumbersome to maintain and increase the risk of breaching client confidentiality. Therefore, digital platforms are preferable since 1) they simplify the documentation process by freeing pharmacy providers of the manual work of data collection and reduce the risk of missing data for reporting purposes; 2) they have better security features for protecting client confidentiality; and 3) they require pharmacy providers to upload an image of the test results and thus provide quality control of HIV testing. Because pharmacy providers are new to conducting HIV testing, uploading images of HIV testing results allows for the needed quality checks.

The project has been working with Maisha Meds, which has an existing POS system for pharmacies, to integrate the PrEP prescribing checklist. Through this collaboration, Maisha Meds built an additional program into their loyalty app that will assist pharmacies in the study to capture client information in the prescribing checklist, record program consent, and track stock of products that are provided on consignment. The application allows pharmacy providers to capture participants' demographics, then walks the provider through (and documents the outcome of) assessing the client's HIV risk and medical safety, obtaining informed consent, conducting the HIV test, dispensing the appropriate medication (PrEP or PEP) and amount, and setting the next appointment. Three key anticipated benefits to partnering with Maisha Meds were 1) its ability to handle financial transactions between pharmacies and clients; 2) its ability to collect details about PrEP/PEP services rendered at the individual client level, thus acting like a medical record; and 3) the system's ability to track inventory and autogenerate reports.

Data collected include age, sex, marital/relationship status, behavior associated with HIV risk, HIV test result, and dispensing data. Each client enrolled in the system is assigned a unique code using their national identification card and must have a handset through which they can receive autogenerated messages from the Maisha Meds system. The pharmacy provider generates monthly reports from the Maisha Meds app and submits them to the linked facility that provides their commodities.

Lessons learned	Implications for routine implementation
Manual reporting and submission of reports to the MOH are burdensome for pharmacy providers, making this model unattractive.	Considerations should be made for simplified and direct reporting to the national health management information system.
The data collection platform should be flexible and able to accommodate emerging needs, such as changes to the national HIV testing algorithms.	The technology solution adopted should be agile to promptly respond to emerging changes.
As pharmacies begin providing more services to clients beyond dispensing medicines, mostly OTC, the need to maintain high standards of confidentiality is imperative.	Pharmacies should be supported to develop and implement strict confidentiality policies and procedures to safeguard client information. Pharmacy staff should receive training on the importance of confidentiality and their responsibility in maintaining client privacy.

Recommendation

Programs intending to adopt a pharmacy-based PrEP model should use secure systems and technologies for storing client records and sensitive health information, including HIV results. This can be done through an electronic health record system, where records are encrypted and password-protected to prevent unauthorized access.

Service Delivery

As with any new service delivery platform, it is crucial to establish an efficient client pathway for offering PrEP services in private pharmacies to ensure that all essential services are delivered effectively. After potential clients are identified, subsequent discussions and services should take place in a private space, such as a back room, which is available in most pharmacies. The following are key components of the service delivery pathway:

- *Registration*: Registration can be conducted manually or electronically, depending on the context. During registration, clients are assigned unique identifiers essential for monitoring and follow-up. Client demographic information may also be collected during this step.
- *Risk assessment*: A standard risk assessment tool (RAST), administered by the pharmacy provider or by the clients themselves, is used for this purpose. We adopted the MOH-approved RAST for PrEP as a guiding aid during the risk assessment session. Additionally, we included questions to assess risk of exposure in the last 72 hours to screen for PEP eligibility.
- *Service candidacy determination*: Based on the risk assessment, a client is preliminarily determined to be eligible for PrEP or PEP.
- *HIV testing*: The client must be confirmed HIV negative before receiving PrEP or PEP services. Testing is performed according to the national HIV testing algorithm.
- *Medical safety assessment*: Given the limitations of the pharmacy setting, baseline laboratory tests are not feasible. Pharmacy providers are trained to use the client's medical history to screen for contraindications for PrEP. Providers inquire about the history of liver disease, kidney disease, diabetes, hypertension, and symptoms suggestive of acute HIV infection. The assessment varies depending on the type of visit. At follow-up visits, severe side effects are specifically assessed.

- *Adherence counselling*: It is important to develop counselling job aids to assist pharmacy providers in administering adherence counselling. This includes instructions on how to take the pills, discussion about potential barriers, and strategies to support adherence.
- *Side effects counselling*: Clients should be informed about potential side effects and how to manage them. In case of severe side effects, clients are instructed to contact the pharmacy provider, who in turn will contact a remote clinician for advice.
- *Dispensing and appointment*: Pharmacy providers dispense PEP or PrEP based on the clients' needs and eligibility. Visits are aligned with the MOH follow-up schedule, and the quantity of medication dispensed is consistent with the visit and the next appointment.
- *Referral (if needed)*: Referral forms, adapted from existing MOH community referral forms, are provided. Pharmacy providers fill in the client's details and the reasons for referral when necessary.

By following these steps, we can ensure a streamlined and effective service delivery pathway for clients seeking PrEP/PEP services in a pharmacy setting.

Access to remote clinicians: Clinical backstop and support to pharmacy providers

Pharmacy providers are not equipped to handle complex clinical cases that may present during PrEP delivery, so they may need a clinician to provide expert advice and recommendations in addition to clinical judgment on the next course of action. Thus, it is important to establish mechanisms for pharmacy providers to consult with clinical experts in HIV prevention and management. The cRCT study had six remote clinicians on standby to provide clinical consultation and guidance. In the retail private pharmacy-based model for PrEP, a clinical backstop provides support and oversight for pharmacists and pharmaceutical technologists managing PrEP services.

Follow-up visits: All enrolled clients receive a return appointment date for follow-up and continuation of prevention services. The PrEP and PEP return visits are aligned with the national guidelines. PEP clients return after 28 days while PrEP clients return after one month post-initiation and quarterly thereafter. At each visit, clients are rescreened for HIV risk and tested for HIV. In addition, the pharmacy provider evaluates their adherence and probes for drug side effects or adverse reactions. When a pharmacy provider suspects an adverse reaction, they contact the remote clinician, who evaluates the client virtually and guides on discontinuation if they confirm an adverse reaction. Clients who test HIV negative and have ongoing risk are issued PrEP medication, counselled on adherence, and given a date to return to the clinic. Those who test HIV positive are discontinued on PrEP, counselled, and referred for a confirmatory test at the link facility for further management.

Lessons learned	Implications for routine implementation
Pharmacy clients value privacy and are intolerant of disruptions during service provision.	Pharmacies offering PrEP services need to have more than one provider and a private room.
Quality service delivery requires ongoing support from remote clinicians and support material.	It is important to establish mechanisms for pharmacy providers to consult with clinical experts in HIV prevention and management.
Pharmacies experience a high turnover of trained pharmacy providers, which could be disruptive to service delivery.	Programs should put in place strategies that guarantee rapid training for replacement providers to ensure they are adequately equipped to continue offering the service.

Lessons learned	Implications for routine implementation
Pharmacies that had more than one service provider sustained PrEP/PEP service delivery even during peak times due to shared tasks among the providers.	Programs may consider mandating that pharmacies have more than one certified provider to effectively offer PrEP/PEP services.
Routine technical assistance visits by project staff and remote clinical support assisted pharmacy providers in troubleshooting and rapidly addressing challenges they faced during PrEP/PEP delivery.	Adequate mechanisms should be instituted to monitor delivery of PrEP/PEP services in pharmacies to ensure quality is maintained.

Recommendation

Pharmacies experience disruption in PrEP/PEP service provision during peak times (mostly in the afternoons and evenings) yet this is the time many potential PrEP/PEP clients come for services. Additionally, pharmacies experience high levels of attrition of trained pharmacy providers. Programs may consider prioritizing pharmacies with more than one provider for uninterrupted PrEP/PEP service provision. Self-care options such as use of HIV self-tests may also minimize some tasks on the pharmacy provider.

Infection Prevention and Control

Implementation of infection prevention and control (IPC) practices plays a key role in ensuring the safety of health workers involved in service delivery. Implementing IPC requires providing the appropriate equipment/items to manage waste, strengthening capacity of service providers, and availing job aids and standard operating procedures (SOPs) for reference.

To strengthen IPC and ensure compliance to IPC practices, we developed a comprehensive IPC training package for pharmacy providers, which was shared during in-person trainings. The package aimed to strengthen capacity of pharmacy providers to handle and manage waste and take precautions while providing HTS. We also provided pharmacies with IPC materials, including coded waste bins and liners (mainly black and yellow), sharps containers, dust coats, waste segregation job aids, and SOPs. In addition, the MOH staff and the project/study team members conducted periodic site visits to the pharmacies where they physically checked the bins for proper waste segregation as defined in the SOPs, and provided further training and mentorship on IPC. To ensure safe waste disposal, we further engaged the MOH, who permitted the pharmacies to deliver waste to the linked facilities for incineration. This was an important step for pharmacies offering HTS to avoid litigation by the statutory bodies and ensure adherence to recommended IPC practices.

Lessons learned	Implications for scale-up/routine implementation
Involvement of the Department of Public Health plays a key role in creating modalities for private pharmacies to get the necessary support to incinerate generated waste through the available government facilities.	It is important to consider alternative plans for waste incineration, including private agreements between the pharmacies and government or private health facilities.
Proper mechanisms should be put in place to address cases of accidental pricks, which may occur during the implementation phase.	Simple and clear SOPs/job aids should be developed and shared with participating pharmacies.

Recommendation

It is important to develop a plan for IPC practices that ensures the necessary equipment for waste management are availed, service providers are trained and provided support materials, and follow-up visits are conducted to ensure adherence to IPC standards.

Quality Assurance

Quality assurance is integral to HTS delivery, and every effort must be made to ensure that service delivery is of the highest quality. Thus, quality assurance systems must be in place at all levels, including testing, counselling, logistics, and data management, to ensure compliance with the quality standards stipulated in the national guidelines. We developed quality indicators for HTS delivered by pharmacy providers. The indicators focused on quality counselling, quality testing, and quality commodity management and reporting:

- *Quality counselling and testing:* Following the initial training, pharmacy providers participated in observed practice sessions supervised by MOH HTS providers to gain hands-on skills and knowledge to handle clients seeking PrEP/PEP services. A standard score form was used to assess various thematic areas, including client contracting, quality counselling, HIV testing, waste management (IPC), and client referral. Debriefing sessions were conducted immediately after the observed practice exercise to evaluate key areas of improvement and define follow-up support by the study team. In addition, job aids on HIV testing procedures were developed and shared with the pharmacy providers.
- *Quality HIV testing:* We collaborated with the national HIV reference laboratory (NHRL) and MOH teams to enroll pharmacy providers in external quality assessments (proficiency testing). Proficiency testing involves reconstituting known samples (panels) and sending them to the pharmacy providers to test and submit to the NHRL for scoring. The panels were sent via the linked facilities through courier services following in-country standard procedures for external quality assessment (EQA) panel distribution, with the respective MOH teams tasked with distributing them to the pharmacy providers. The MOH team ensured a 100% EQA response rate and submission of feedback to NHRL for scoring. A total of 63 pharmacy providers participated in the first EQA round and more than 97% performed satisfactorily. Corrective action preventive action (CAPA) was conducted in collaboration with the MOH team to reach the few pharmacy providers who received unsatisfactory performance reports; this was documented and filed at the pharmacy level.

Lessons learned	Implications for scale-up/routine implementation
Routine participation of HIV testers in proficiency testing has enhanced providers' confidence in offering quality service delivery.	There is need to establish a system of routine assessment of providers' skills and knowledge to ensure quality service delivery is adhered to by private pharmacy providers.
Joint supportive supervision of service delivery at private pharmacies has helped ensure the private pharmacy providers offer quality PrEP/PEP services.	There is need to have a structured mechanism with a check list for standardization of service across all the private pharmacies offering PrEP/PEP services.
Comprehensive training and ongoing support for pharmacy providers is essential.	To sustain quality assurance for service delivery in the private pharmacies, there is need to establish robust training.

Recommendation

Programs should develop comprehensive protocols and guidelines for the provision of PrEP within the pharmacy setting. These protocols should outline procedures for client assessment, prescribing criteria, monitoring parameters, and management of potential side effects.

Policy Advocacy and Stakeholder Engagement

The current pharmacy PrEP pilot studies were designed to generate evidence that would support the decision on whether to include this model in national policy to become the standard of care. The pharmacy PrEP delivery model is anchored in the WHO guidelines on differentiated PrEP delivery models and simplification of PrEP delivery to increase access.[14] Kenya has been a leader in the adoption of innovations and is spearheading efforts to generate evidence on pharmacy PrEP delivery models. The PrEP implementation models in Kenya are defined in the *Framework for the Implementation of Pre-Exposure Prophylaxis of HIV in Kenya*.[17] In these guidelines, the country acknowledges ongoing research studies to generate evidence on pharmacy PrEP models for future adoption. Given the promising evidence emerging from ongoing research in Kenya and other countries, the time is ripe for countries to begin considering adoption of pharmacy PrEP and PEP delivery models. Considering that successful policy advocacy is a process, we commenced policy advocacy from study design to ensure the study objectives were aligned to the kind of evidence and questions that the MOH was interested in. As such, the pilot studies resonated with the research agenda in the *Framework for the Implementation of Pre-Exposure Prophylaxis of HIV in Kenya*. Here, we describe the pathway adopted by the study team in efforts to generate and translate early evidence from implementation science research on the model to become the standard of care. Our advocacy efforts were primarily in three phases:

Phase I (study design)

- Engaged with the MOH (primarily NASCOP) on the research questions, study design, and policy exemptions.

Phase II (implementation support)

- Submitted the study protocol to PPB (the regulator) for permission to implement the study.
- Engaged NASCOP for support to access commodities (PrEP, PEP, and HIV test kits) from the national HIV commodities pipeline.
- Secured a letter of support that facilitated access to commodities for the pilot studies.
- Engaged the county health management teams for permission to implement the study and access commodities through linked health facilities.
- Continued engagement with stakeholders at the national level (through routine updates in the quarterly HTS/PrEP technical working group) and county level (review meetings with the CHTM, sCHMT, and pharmacy providers).
- Continued to make adaptations to the implementation model in alignment with national guidelines based on feedback from policymakers.

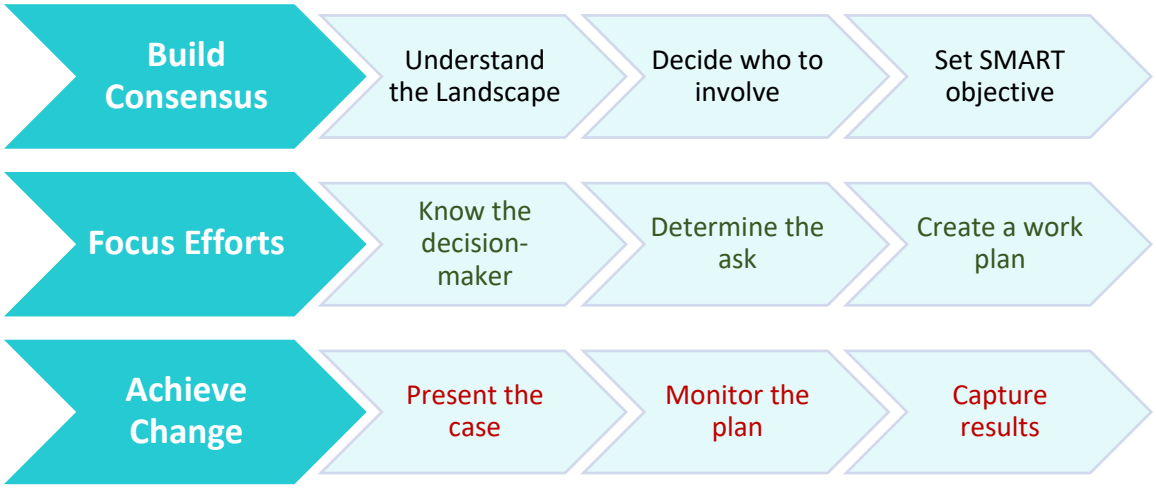
Phase III (policy change)

To enable policy change and translate this model to become the standard of care, review of four policy documents is critical to enable this success. These include:

- *Kenya HIV Prevention and Treatment Guidelines*, which define the cadres, setting, and process for providing PrEP and PEP services.
- *Pharmacy Practice Guidelines*, which define the scope of practice for pharmacists and pharmaceutical technologists.
- *The Kenya Expanded Package for Health (KEPH)*, which defines the type of services and facility levels that can offer those services. Community pharmacies are classified as level 1, yet PrEP and PEP services should only be offered from Level 3 facilities upward.
- *The Kenya Essential Medicines List (KEML)*, which, similar to KEPH, defines which medicines can be offered at what levels of the health system. The current guidelines prescribe that ARVs (including PrEP and PEP) can only be offered from level 3 facilities upward.

To maintain coherence in our policy advocacy activities, we adopted a SMART advocacy approach to navigate the complex policy pathways essential for steering the process of policy change and revision across various HIV prevention policies.[b] Figure 8 presents our three-phase, nine-step approach.

Figure 8: SMART advocacy strategy in nine steps



Our methodology was structured as follows.

Evidence generation and landscape assessment

We conducted a landscape analysis to identify existing policies where pharmacy PrEP delivery needs to be anchored, identified the policy gaps, mapped the policy revision cycles, and determined the evidence necessary to conduct successful policy advocacy. Through the landscape analysis, we identified policy windows since the time was aligned with the government's policymaking cycle and the environment was conducive to policy change.

[b] The SMART advocacy approach focuses on advancing long-term goals through short-term advocacy gains, assessing opportunities for collective action, identifying the right decision-maker, and anticipating what will motivate the decision-maker to act.

Stakeholder mapping

We identified key stakeholders to prioritize in policy advocacy efforts and created a stakeholder matrix. This matrix was instrumental in guiding subsequent engagements at both national and county levels. Notably, we identified NASCOP and PPB as the pivotal policy decision-makers, and the professional bodies (PSK and KPA) and county governments as pivotal stakeholders. Additionally, we identified the structures through which the policy review process would be undertaken. For NASCOP, this is mainly through the technical working groups and ad hoc committees dedicated to development of specific policy documents. For PPB, this is through special committees.

Stakeholder engagement for policy change

Sustained engagement with stakeholders remains essential for socializing stakeholders on the emerging evidence and prioritizing this model in the national policy review agenda. To facilitate this, we requested opportunities to present preliminary research findings in the national HTS/PrEP technical working group meetings on a regular basis (quarterly). Additionally, we identified key policy documents that the MOH had prioritized for revision, and participated in the review forums where we presented evidence and experiences implementing this model to stakeholders for discussion and consideration. Some of the milestones include:

- Contributed to ongoing reviews of the national core curriculum for training pharmacists and pharmaceutical technologists.
- Contributed to the ongoing review of the pharmacy scope of practice, defining the role of pharmacists and pharmaceutical technologists in the delivery of HIV preventive services.
- Contributed to the ongoing review of the Kenya HIV prevention and treatment guidelines and the differentiated service delivery guidelines.

Lessons learned	Implications for routine implementation
Identifying stakeholders early in the process and maintaining continuous engagement with them is crucial for consensus building on the practical implementation of the different components of the service pathway.	Advocacy for policy change needs continuous engagement of various players.

Recommendation

Countries need to create enabling policies, regulations, and guidelines to recognize and designate retail pharmacies as health care service delivery points.

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