

Online pharmacy PrEP and PEP

Technical considerations and
learnings from Kenya





2201 Westlake Avenue
Suite 200
Seattle, WA 98121 USA

www.path.org

© 2024 PATH. All rights reserved. The material in this document may be freely used for educational or noncommercial purposes, provided that the material is accompanied by an acknowledgment line.

Suggested citation:

PATH. *Online pharmacy PrEP and PEP: Technical considerations and learnings from Kenya*. Seattle: PATH; 2024.

Cover photo: Jhpiego

Contents

Acknowledgments.....	i
Abbreviations.....	ii
Executive summary.....	iii
Introduction.....	1
Program model.....	3
Business model overview.....	13
Demand generation.....	21
Overall learnings and recommendations.....	24
Appendices.....	28
Appendix 1. HIV prevention context in Kenya.....	28
Appendix 2. Implementation roadmap for ePrEP/ePEP.....	31
Appendix 3. The ePrEP/ePEP one-step delivery model, mapped to the International AIDS Society Differentiated Service Delivery building blocks.....	32
Appendix 4. One-step delivery journey details.....	33
Appendix 5. Telehealth licensure journey in Kenya.....	35
Appendix 6. Empathy-based counseling training materials.....	36
Appendix 7. Business sustainability analytics template for the ePrEP/ePEP model.....	37
Appendix 8. Business model for ePrEP/ePEP in Kenya.....	38
References.....	39



Acknowledgments

This guide reflects the efforts of partners who collaborated to enable effective pre- and post-exposure prophylaxis (PrEP/PEP) delivery through a telehealth and online pharmacy model (ePrEP/ePEP) in Kenya from 2022 to 2024. Key partners included:

- **MYDAWA**, a Kenya-based digital health company with an integrated platform for telehealth and e-pharmacy service delivery that provided ePrEP/ePEP in Nairobi and Mombasa during the pilot.
- **Jhpiego**, a nonprofit global health organization that provided technical assistance to ensure ePrEP/ePEP services met national requirements, supported stakeholder engagement to seek policy exemptions for the implementation research, and with the Johns Hopkins University School of Public Health, starting in January 2024 led research on the sustainability phase of this pilot.
- **Audere**, a nonprofit company working in digital health that built an artificial intelligence–facilitated digital photo capture and result interpretation system for HIV self-tests and rapid diagnostic tests.
- Research partners—the **University of Washington, Fred Hutchinson Cancer Center, Kenya Medical Research Institute, and Jomo Kenyatta University of Agriculture and Technology**—who evaluated the model and developed academic publications to inform policy.
- **HS Design**, a user experience partner that conducted usability analyses of the digital health company’s client and provider interface.

Several individuals made substantial contributions, including the following: Dr. Samira Abdulrashid (MYDAWA), Rouella Mendonca (Audere), Sarah Morris (Audere), Maeve Rafferty (MYDAWA), Dino Rech (Audere), Salima Saidi (MYDAWA), Dr. Micah Onenga Anyona (Jhpiego), Geoffrey Ochieng Odhyambo (Jhpiego), Paulami Naik (University of Washington), Dr. Monisha Sharma (University of Washington), Dr. Kenneth Ngure (Jomo Kenyatta University Of Agriculture And Technology), Dr. Katrina Ortblad (Fred Hutchinson Cancer Center), and Dr. Daniel Were (Jhpiego).

The guide was produced by PATH with a grant from the Bill & Melinda Gates Foundation. Ashley Jackson, Beth Balderston, Samuel Kibonge, Davina Canagasabey, and Dr. Christopher Obong'o led the guide’s writing and development. Dr. Kimberly Green provided review.

We appreciate the feedback and insights provided by Kenya’s PrEP Technical Working Group as well as Nicole Young, Chase Mertz, and Shirley Chen of the Gates Foundation.



Abbreviations

AI	artificial intelligence
AIDS	acquired immunodeficiency syndrome
AGYW	adolescent girls and young women
CO	clinical officer
COVID-19	coronavirus disease 2019
DREAMS	Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe
ePrEP/ePEP	online pharmacy service delivery of pre- and post-exposure prophylaxis
FGD	focus group discussion
HIV	human immunodeficiency virus
HIVST	HIV self-test
IQR	Interquartile range
KES	Kenyan shilling
KMPDC	Kenya Medical Practitioners and Dentists Council
MOH	ministry of health
MSM	men who have sex with men
NASCOP	Division of National AIDS and STI Control Program
NMS	Nairobi Metropolitan Services
PEP	post-exposure prophylaxis
PEPFAR	US President's Emergency Plan for AIDS Relief
PPB	Pharmacy and Poisons Board
PrEP	pre-exposure prophylaxis
Q1/Q4	quarter 1/quarter 4
QA/QI	quality assurance/quality improvement
RAST	Rapid Assessment Screening Tool
RDT	rapid diagnostic test
SD	standard deviation
SEARCH	Sustainable East Africa Research in Community Health
STI	sexually transmitted infection
WHO	World Health Organization

Executive summary

Scope and purpose of this guide

This document is intended as a how-to implementation guide for providing oral pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) via online pharmacy service delivery (ePrEP/ePEP) based on learnings and evidence from the ePrEP Kenya pilot study that ran from October 2022 through July 2024, when this guide was published.

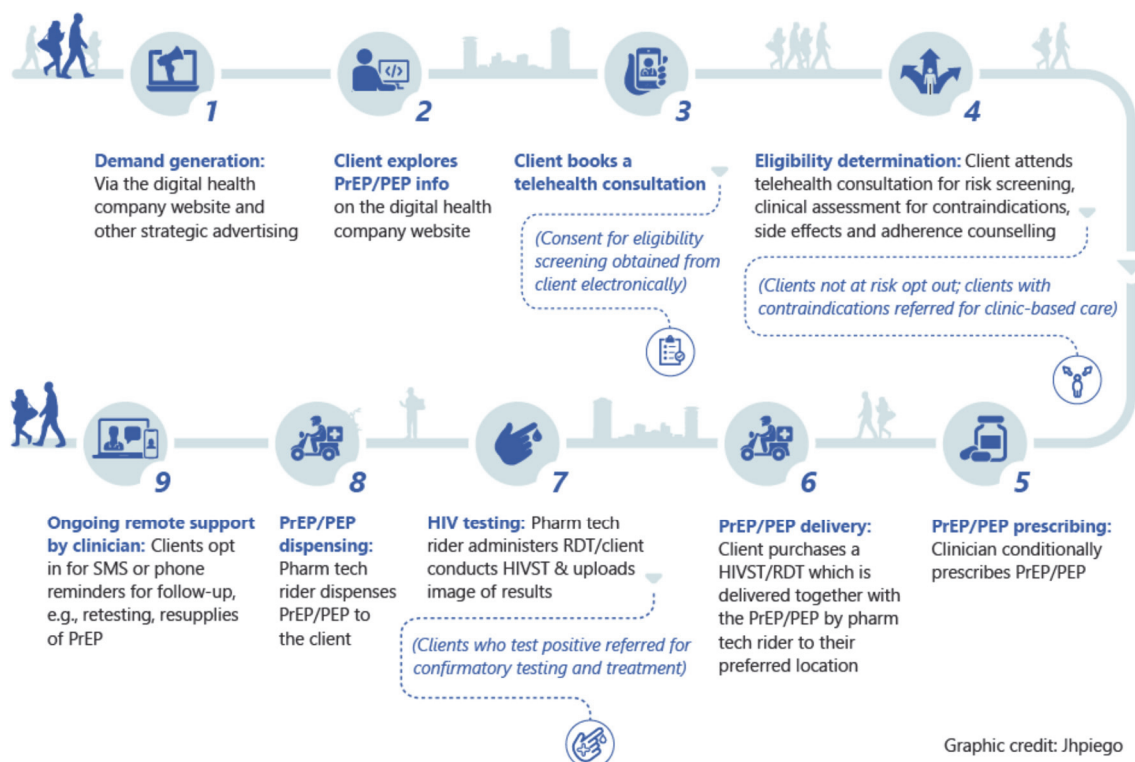
The guide outlines a suggested approach that can be tailored based on epidemiological, social, economic, health systems, and policy contexts. Service delivery partners should exercise flexibility and adapt these guidelines and tools to their specific operating contexts and circumstances, available resources, and infrastructure.

This document is intended to support ministries of health and their partners as they develop strategies for HIV prevention services—specifically, ePrEP and ePEP delivery (i.e., through a telehealth and online pharmacy model).

About the model

Through this model, clients accessed PrEP or PEP services through telehealth consultation and product delivery via a digital health company's online pharmacy in urban Kenya. Clients completed HIV risk assessment and counseling, got tested via a rapid diagnostic test (RDT) or blood-based HIV self-test (HIVST), and virtually received a PrEP or PEP prescription from a clinical officer (CO) employed by the Kenyan digital health company. The company delivered the HIVST or rapid diagnostic test kits, PEP, and PrEP to clients primarily through riders who are pharmaceutical technologists ("pharm techs") and trained on HIV testing. The company also offered counseling to support clients' PEP-to-PrEP transition and refills for PrEP continuation. Figure 1 shows the steps of the model from the perspective of clients.

Figure 1. ePrEP Kenya client journey.



Takeaways

Online pharmacy service delivery of PrEP and PEP was *feasible* as an option in urban Kenya and *acceptable* to clients with behaviors associated with HIV risk


- The model reached 1,757 clients with PrEP/PEP over approximately 14 months (October 19, 2022, through December 31, 2023).² An average of more than 100 clients per month accessed PrEP or PEP through the digital health company's online pharmacy platform during this pilot.
- This model reached a population that differs from those accessing PrEP/PEP at public clinic-based facilities: a larger number of men, unmarried individuals, and those with sexual partners with unknown HIV status, as well as men who have sex with men (MSM), who accounted for a sizable proportion of PrEP clients (22% or 45/208) but only 2% of PEP clients (26/1,549).² The proportion of PrEP clients who were MSM is notable given that the MSM population is much smaller than the general population. While marketing targeted many demographic groups with vulnerability to HIV, far more men than women used the service. Very few clients reported transactional sex or a partner with HIV. The majority of clients had no prior use of PrEP or PEP.
- Most clients screened for PrEP and PEP were eligible and received the service. This means they reported behaviors associated with vulnerability to HIV or recent exposure and had no medical conditions that could contraindicate PrEP/PEP safety.
- Privacy was a top consideration for clients using this model. Many clients did not turn on their video during their telehealth consultation and requested delivery at a location other than their home for privacy reasons.
- Convenience was another important reason clients gave for choosing this model, with the digital health company offering to deliver orders to a location of the client's choosing within four hours of submitting their order.

"I think [this model] is the most convenient because it is delivered to my doorstep, and it is delivered *discreetly* to my doorstep. I don't have to go to the pharmacy and wait in line or order the PrEP in front of people."

— 29-year-old male client¹

The online pharmacy model in Kenya had higher PEP uptake compared to PrEP

- Despite the initial focus of all online advertising and demand creation on PrEP (not PEP), PEP uptake was more than 7 times higher than PrEP uptake through the online pharmacy model. Over approximately 14 months, 1,549 clients received PEP, and 208 received PrEP.²
- Clients commonly confused PrEP and PEP when initially seeking services. Nearly all clients requested PrEP during the initial consultation, having been exposed to HIV within the preceding 72 hours, and had to be educated on the need to use PEP before considering a transition to PrEP. The median time between exposure and PEP delivery was 39 hours.²
- Only 6% of PEP clients transitioned to PrEP:²
 - After their 28-day PEP regimen, most clients said they did not intend to have another HIV exposure and did not need PrEP. Clients also reported the cost of taking another HIV test as a barrier to PrEP transition.
 - Nearly all clients who had successfully transitioned from PEP to PrEP were linked to one CO who provided empathy-based counseling and took time to encourage transition. Thus, the digital health company prioritized empathy counseling skills in CO qualifications



and training. The PEP-to-PrEP transition rate steadily increased from 2% (3/147 clients) during quarter 4 (Q4) 2022 to 12% (49/405 clients) during Q4 2023.

- Of PEP clients, 7% obtained PEP more than once during the pilot, and 14% had used PEP prior to this pilot.
- More than half of PrEP clients (58%) did not return for a refill after the first month, similar to discontinuation rates observed in other pharmacy models in Kenya.² Qualitative feedback indicated that clients discontinued PrEP due to side effects, pill burden, and/or a change in their perceived likelihood of future exposure to HIV.

Financial sustainability depends on access to low-cost commodities

- Clients were willing to pay for services at the prices offered through this model, which factored in PrEP and PEP commodity donations from the Kenyan government.
- The business sustainability model (see “Business model overview” section and the Appendix 7 template for business sustainability analytics) indicates that ePrEP/ePEP will break even or make a small profit. Pull-through revenue from general health consultations and prescription and product sales may support consistent revenue growth to make ePrEP/ePEP viable as a continued offering.



Introduction

Biomedical HIV prevention methods offer the potential to reduce new HIV infections and improve health outcomes among people vulnerable to HIV. In 2015, the World Health Organization (WHO) released its recommendation of daily oral pre-exposure prophylaxis (PrEP) for HIV prevention as part of combination prevention approaches for people at substantial risk of HIV.³ Since then, countries with high HIV prevalence have worked to scale up access to oral PrEP alongside post-exposure prophylaxis (PEP).

However, while oral PrEP adoption among key populations has been high in a number of settings, use generally remains low among adolescent girls and young women (AGYW) and men, despite its proven effectiveness, partially due to concerns about stigma, privacy, and potential side effects that deter effective use and continuation.^{4,5} In addition, PrEP services are largely limited to public-sector (government) health care facilities, which also can deter use, especially among populations who prefer services in alternative settings, such as community and private-sector outlets (e.g., pharmacies, recreation spaces).⁶ Even less is known about effective approaches for reaching clients with rapid PEP following possible HIV exposure. Clinical trials have established that several newer PEP regimens are better tolerated, yet use is low globally. Innovations are needed to reach more clients with PEP within 72 hours of possible HIV exposure, in addition to policy changes that facilitate uptake and completion of PEP.⁷

The COVID-19 pandemic accelerated the introduction and expansion of decentralized health service delivery models, including PrEP, outside of facility settings to enhance service accessibility. In 2022, WHO updated its PrEP implementation guidance to promote differentiated and simplified PrEP as a person- and community-centered approach that could increase PrEP acceptability, accessibility, uptake, persistence, and effective use.¹⁰ In its *2022 HIV Prevention 2025 – Road Map*, the Joint United Nations Programme on HIV/AIDS echoed this need for community-led, integrated, and differentiated approaches to combination prevention services, highlighting community, school, and private-sector models and virtual platforms as modalities for increasing access.¹¹

Private and community pharmacies and online pharmacy/telehealth platforms hold promise as discreet and convenient pathways for biomedical HIV prevention services.^{12,13} The WHO 2022 PrEP guidance emphasizes the potential of online pharmacy and telehealth models to enhance PrEP access, uptake, and effective use, noting that pharmacies are more accessible, acceptable, and convenient as access points than health facilities, especially in resource-limited settings. This guidance, as well as a separate review of mobile

Expanding range of biomedical HIV prevention options

Research and development are advancing a diverse suite of new PrEP/PEP products as biomedical prevention options to promote uptake by enhancing client choice. Injectable cabotegravir for PrEP (injectable PrEP) and the dapivirine vaginal ring, recommended as additional prevention choices by WHO in 2021 and 2022, respectively, have begun to enter markets. With preliminary results indicating the safety and efficacy of twice-yearly injectable lenacapavir for PrEP among cisgender women,⁸ six-month subcutaneous injectables and monthly oral pills could be introduced over the next few years, once approved as safe and effective. While this guide focuses on the role that telehealth and online pharmacies can play in expanding oral PrEP and PEP access, many of the recommendations may be applicable to other HIV prevention methods as they enter the market in the future, with modifications and considerations made to prescription and delivery processes for injectable and long-acting PrEP formulations.⁹

Program model

Overview

In Kenya, a group of partners with expertise in advocacy, policy, research, program implementation, technology, and commerce collaborated to design and implement an effective PrEP and PEP delivery model through online pharmacies (ePrEP/ePEP) from 2022 to 2024. The country-specific HIV prevention context for this pilot is provided in Appendix 1.

Phase 1 of the pilot took place from October 2022 through December 2023. Phase 1 was immediately followed by phase 2, which ran from January to November 2024 and involved studying the sustainability of the model after the end of donor support to the digital health company used in the pilot (MYDAWA).

Under this partnership, the digital health company received technical and financial assistance to:

- Design or leverage an existing online pharmacy system and procedures to enable distribution of PrEP and PEP.
- Design and conduct demand generation activities.
- Provide online-to-offline services for clients seeking PrEP or PEP, including offering telehealth/virtual services to counsel clients, conducting eligibility and medical safety screening, and conditionally prescribing PrEP/PEP pending HIV test results and in-person/home-based HIV testing services. Testing was conducted using either rapid diagnostic tests (RDTs) or HIV self-tests (HIVSTs), with artificial intelligence (AI)-assisted quality control for results interpretation and PrEP/PEP dispensing.
- Enable clients to order RDTs, HIVSTs, PrEP, and PEP online.
- Deliver the HIVSTs, RDTs, PEP, and PrEP to clients, primarily via riders who are also pharmaceutical technologists (“pharm techs”) trained by the Division of National AIDS and STI Control Program (NASCO) on HIV testing. In limited cases, through the two-step delivery model (see “Client Journeys” below), lay riders without medical training delivered HIVSTs.

There are several factors to consider when establishing ePrEP/ePEP service delivery through an online pharmacy. Appendix 2 provides a checklist of key topics and questions that stakeholders should consider when planning to introduce an ePrEP/ePEP model. Responses to these questions can inform the development of a customized ePrEP/ePEP introduction roadmap that partners can use during the setup phase.

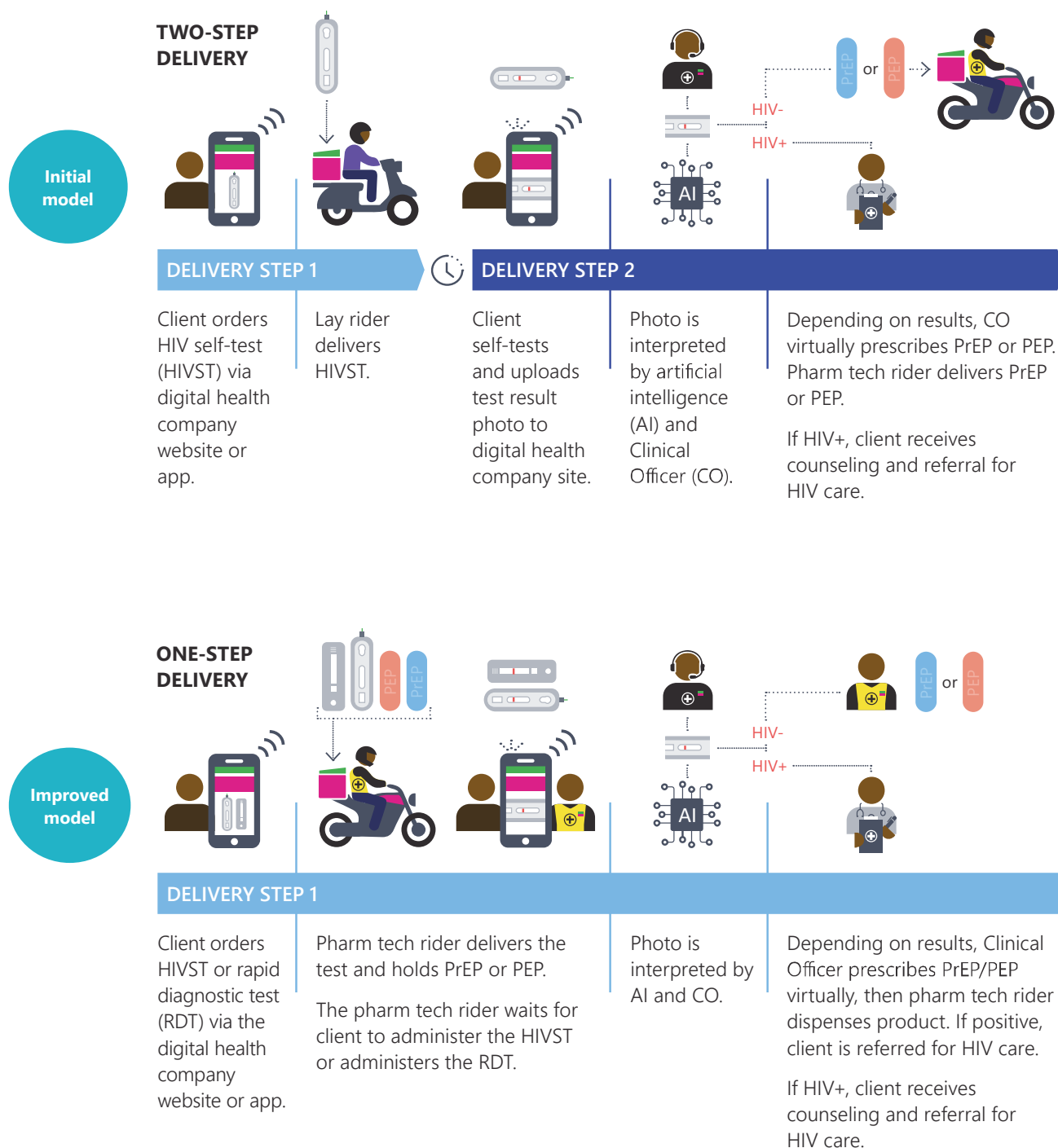
Client journeys

To ensure convenient PEP and PrEP access through an online pharmacy, client journeys were developed based on formative research and conversations with stakeholders, in line with national guidelines and practices.¹⁵ In this model, the client journey begins with a client in need of PrEP or PEP logging onto the digital health company’s web page and learning about available services. Figure 2 summarizes the steps of the journey for clients.


The digital health company tested two delivery options: two-step and one-step. Initially, only the two-step delivery process was offered, with the one-step option added during the pilot to shorten the time between conditional PrEP/PEP prescription and dispensing (especially for PEP clients) and to reduce costs to clients by reducing the number of delivery visits from two to one. *By early 2024, the vast majority (approximately 85%) of services were provided via the one-step delivery journey each month.*

The remaining 15% who continued to opt for the two-step journey was due to a preference for greater privacy, particularly among clients seeking PrEP refills. These clients did not want to have a pharm tech rider wait for the test to be completed and prescription confirmed by a CO* prior to dispensing.

Figure 2. Client journey for initiation of ePrEP/ePEP through the digital health company.



*A CO is a registered professional who is qualified and licensed to practice medicine. In Kenya, a registered CO is required to hold a diploma or degree in clinical medicine and surgery, as defined by The Clinical Officers (Training, Registration, and Licensing) Act (No. 20 of 2017).



Appendix 3 provides an overview of the service flow across the care cascade for the ePrEP/ePEP online delivery model, mapping the steps to the [International AIDS Society Differentiated Service Delivery building blocks](#). Since the one-step delivery model was much more widely used, the table in the appendix focuses on that model. In addition, Appendix 4 provides more detail on the client journey for one-step delivery.

Client profiles and preferences related to delivery model

The telehealth and online pharmacy model in Kenya reached clients with a distinct profile compared to those seeking services at existing clinic-based PrEP/PEP delivery locations. This includes more men, unmarried individuals, and clients with sexual partners with unknown HIV status, as well as men who have sex with men (MSM), who accounted for a sizable proportion of PrEP clients (22%, or 45/208) clients but only 2% (26/1,549) of PEP clients.² The proportion of PrEP clients who were MSM is notable given that this population is much smaller than the general population. While marketing targeted many demographic groups who were vulnerable to HIV, far more men than women used the service. Very few clients reported transactional sex or a partner with HIV, and the majority of clients had no prior use of PrEP or PEP. PEP uptake was particularly high, mainly driven by clients seeking PrEP, but initiated on PEP instead due to their recent potential HIV exposure.

“Because maybe meeting one-on-one you might not...you might shy away from asking all the questions that you have. Maybe you might be shy and not confident, but virtually you know you are not seeing the person, you are just hearing their voice, so I think virtual is better than one-on-one meetings.”

— 27-year-old female client¹

Privacy was a top consideration for clients choosing to access PrEP or PEP through this online pharmacy model. Many clients requested delivery at a location other than their home for privacy reasons. One disadvantage of the one-step delivery model was that pharm tech riders needed to wait 15 minutes for the HIVST or RDT result before they could dispense PrEP or PEP. In some cases, riders waiting for the HIV test result faced harassment from people other than the client (e.g., family members accusing riders of enabling HIV risk behaviors). One solution was for the riders to wait a short distance away from the client’s location rather than in the immediate vicinity.

Convenience was another important reason clients gave for choosing the ePrEP/ePEP model. The digital health company offered to deliver orders to a location of the client’s choosing within four hours of submitting their order.

Costs were lowest for clients who chose the one-step delivery journey with an RDT due to lower delivery costs (single visit) and test costs (RDT versus HIVST). It is unclear whether clients preferred the one-step delivery based on factors other than price. While some clients were willing to pay more for the two-step model with HIVST to have the privacy of reading their HIV test results alone rather than having them read by a pharm tech, the digital health company reports that the higher-cost two-step delivery model may not be financially sustainable at scale without a subsidy (see “Business model overview” section). In contrast, the one-step delivery model with an RDT shows promise as a financially sustainable model (despite requiring a pharm tech rider versus a lay provider), particularly among clients accessing PEP services, as it helped reduce delays for clients within the 72-hour post-exposure period.

Stakeholder engagement and policy considerations

Kenya's online pharmacy policy pathway

Kenya has developed several policy documents that pave the way for ePrEP/ePEP services. These include the [Framework for the Implementation of Pre-Exposure Prophylaxis of HIV in Kenya](#) (2017). The 2023 [Private Sector Engagement Framework for Delivery of HIV Services in Kenya 2023–2028](#) also provides a policy anchor for use of online pharmacy platforms (linked to physical pharmacies or public-sector HIV clinics) to deliver PrEP/PEP services.

In addition, recent policy changes have enabled online pharmacy services and delivery of PrEP and PEP services through online pharmacies in Kenya, including:

- [Guidelines for Internet Pharmacy Services in Kenya](#) (2022) established the policy framework for a wide range of services to be delivered through online pharmacies.
- The updated 2022 version of the [Guidelines on Good Distribution Practices for Medical Products and Health Technologies in Kenya](#) included provisions for online pharmacies, such as requirements for online pharmacies to be linked to a Pharmacy and Poisons Board (PPB)–approved physical pharmacy and pharmacists and pharm techs to have prescribing rights and qualifications approved by the PPB.
- Kenya's [Digital Health Bill, 2023](#) further lays the groundwork for scale-up of PrEP and PEP provision through online pharmacy platforms and provides a legislative foundation for digital health by recognizing e-health (including telemedicine and telehealth) as a delivery channel.
- Online pharmacies were noted as an additional PrEP delivery model in the 2022 revision of the [Framework for the Implementation of Pre-Exposure Prophylaxis of HIV in Kenya](#).

The ongoing review of the [Kenya HIV Prevention and Treatment Guidelines](#) in 2024 will present an opportunity for policymakers to weigh the evidence and consider inclusion of online pharmacy delivery of HIV prevention services in the national guidelines.

Policy exemptions for the online pharmacy pilot


A key goal of this pilot was to provide evidence to inform policy decisions and guideline updates related to the inclusion of online pharmacy delivery of PrEP/PEP as a service delivery platform. The pilot of this model required policy exemptions, since a number of the clinical procedures involved are not yet the standard of care in Kenya. Jhpiego, a nonprofit global health organization, provided advocacy leadership, engaging with NASCOP, the Kenya Medical Practitioners and Dentists Council, PPB, and Nairobi and Mombasa Counties as critical stakeholders for policy guidance and support for the implementation.

As of mid-2024 in Kenya, PrEP or PEP prescriptions from the digital health company used for the pilot that are based on an HIVST result and telehealth visit are available only through this research study. Through engagement with NASCOP, the pilot study had received an exemption to use HIVST for determining PrEP/PEP eligibility, but only in the context of this study. Based on advice from NASCOP, RDTs were later incorporated as a second testing option for clients, as the *Kenya HIV Prevention and*

Considerations for policymakers

“For PrEP to have impact, programs need to be well designed and resourced. The first step involves answering questions such as, Who is at highest risk for HIV acquisition, and to whom will PrEP be targeted? How much will this cost? Where will resources for prevention investments come from? This information can shape national guidelines and policies on PrEP.”

[AVAC PrEPWatch: Creating Policies, Plans and Budgets](#)



Treatment Guidelines did not include HIVST, and evidence was needed to support policy revision that would enable scale-up in the context of the existing HIV testing algorithm. During the consent process, all clients were informed that using HIVST to initiate PrEP/PEP or acquiring a prescription for the same through a telemedicine visit is not the standard of care in Kenya.

NASCOP also provided exemptions for:

- Assisted HIV testing (either assisting with the HIVST or performing the RDT).
- PrEP/PEP prescription through telehealth.

If policies change because of the evidence generated through the pilot, the model could be replicated by others in Kenya with no need to seek exemptions. In other countries, policy changes may be needed to enable replication of this model.

To support the pilot, Kenya Ministry of Health (MOH) input included:

- Government-procured PrEP and PEP commodities through the national supply chain pipeline.
- Guidance and support in setting up the clinic associated with the digital health company, achieving licensing for telehealth services by the Kenya Medical Practitioners and Dentists Council.

For more information about the digital health company's licensure journey, see Appendix 5. The study received institutional review board approval from Kenya's Scientific and Ethics Review Unit and Fred Hutchinson Cancer Center, the PPB, the National Commission for Science Technology and Innovation, and Nairobi and Mombasa Counties.


Capacity-building and quality assurance/improvement (QA/QI)

Provider capacity-building and technical support

Rolling out this model required provider capacity-building and technical support for provision of high-quality virtual clinical services. The team collaborated with NASCOP and Nairobi and Mombasa County Departments of Health to train all COs and pharm tech riders via a three-day training led by experienced PrEP implementors prior to pilot implementation. The team of partners adapted existing [national PrEP service delivery training materials and standard operating procedures](#) to integrate steps specific to the digital health company's online delivery model.

Training covered the core components of the care pathway for online PrEP/PEP service delivery (aligned with standard operating procedures for ePrEP/ePEP provision), use of the online tools to support implementation and documentation, and MOH reporting requirements for PrEP and PEP dispensing. These included:

- Prescribing guidelines, including drug interactions, contraindications, and side effects.
- Virtual counseling on PrEP/PEP, adherence, and sexual- and gender-based violence, including use of empathetic counseling to facilitate PrEP adherence and continuation (see Appendix 6).
- Linkages to HIV care monitoring and follow-up.
- Tools to document service delivery (e.g., commodity reports, referral tracker to record linkages to other services).



Training for pharm tech riders was conducted through a hybrid approach that included online modules, classroom training, and observed practice during practicum, focusing on:

- RDT administration.
- Commodities management and reporting.
- Waste management.
- Infection prevention.

Routine technical support, continuing medical education, and mentorship was required to ensure that providers offer high-quality services and address implementation challenges or gaps related to policy updates or changes in service delivery pathways. This support included joint mentorship through collaboration with the subcounty health management teams on a bimonthly basis, virtual continuing medical education, and learning forums to discuss challenges.

QA/QI

QA/QI was a key component of the pilot in tracking issues on a continuous basis and showing progress and modifications made to improve service delivery. Partners collaborated to ensure the quality of services provided and developed a clinical continuous QI plan for client care to help meet consumer needs. As part of provider training, the team worked closely with trained HIV Testing Service supervisors from the MOH to hold observed practice sessions on HIV testing services with pharm tech riders. During implementation, the riders were also enrolled in regular HIV Testing Service proficiency testing and external quality audits, including batch testing and post-market surveillance of test kits. The team also collaborated with the digital health company's providers to map complicated clinical situations and provide real-time virtual support and reviews of documented cases through a case management approach. Additionally, they enlisted a mental health counselor who engaged pharmacy providers and clinicians in sharing their experiences and challenges with service delivery and performance.

Site visits and supervision from Nairobi and Mombasa County personnel also helped ensure compliance with guidelines and high-quality service provision, followed by corrective and preventive actions, as needed. The National HIV Reference Laboratory also supported the pharmacy providers by conducting proficiency assessments with corrective and preventive action. The laboratory team also supported post-market surveillance by analyzing randomly selected HIV test kits to determine their quality.

Role of AI

An AI-facilitated digital photo capture and result interpretation system supported the digital health company's COs to remotely verify client's HIVST results as described below.

Assessing and improving photo quality

- Clients were provided with usability-tested visual guidance on how to take a good photo and interpret their HIV tests. After administering a test, the client would upload a photo of the test and their interpretation of the result.

Evidence supports use of HIVST for PrEP

Scaling up PrEP using HIVST has similar health impacts, costs, and low risk of drug resistance as those of provider-administered RDTs. Use of HIVSTs as part of six-month PrEP dispensing reduced the burden of clinic visits by half, without compromising testing, adherence, or effective use.^{16,17}

- The AI system then evaluated the photo quality. If the AI determined the photo to be of poor quality or a supported test was not detected,[†] the client was asked to upload a new photo (up to a maximum of three times).
- The AI system also cropped and enhanced images of the result window to enable easier interpretation by COs.

Assisting CO test interpretation and quality control

- The AI system identified and analyzed test and control lines to support the CO's interpretation and consequent prescription of PrEP/PEP or referral to care.
- A CO then reviewed the photo of the test, client interpretation, and AI interpretation before entering their own interpretation.
- The AI system was intentionally tuned to be highly sensitive to faint lines, even though this meant that the AI gave false positive readings to the CO in some cases, to reduce the risk that positive cases would be missed by COs and thus people with HIV mistakenly prescribed PrEP or PEP. The AI company fine-tuned the AI system to improve its specificity over the course of the pilot.
- When AI and CO interpretation of test results disagreed, the CO was in control of the final determination of result. In these cases, the CO proceeded based on their interpretation, and the system flagged the cases for closer examination by the CO's supervisor. In almost all cases of closer examination, a panel of experts determined that the CO interpretation was correct.


By integrating AI into this model, the ePrEP Kenya partners aimed to enhance quality control for HIVST interpretation. These procedures align with WHO's guidance on AI and protecting autonomy, stating that AI systems should be designed to assist humans in making informed decisions and allow COs to override the AI-generated decisions.¹⁸

Inclusion of AI support for results interpretation was not required by local health authorities or the ethical review board. It was an added feature to support the option of HIVST as part of the telehealth prescription of PrEP and PEP. While some clients opted for RDTs performed by pharm tech riders (a less expensive testing option for the client), many others chose the added privacy provided by the HIVSTs—even when delivered by a pharm tech who would wait nearby to dispense PrEP/PEP based on the results (one-step process).

The AI component may have averted the need for additional HIVST to be performed in the cases in which the AI flagged images that needed to be retaken due to poor image quality. The AI immediately flagged poor image quality for approximately 8% of tests (159 out of approximately 2,000) and prompted the clients to take another photo.¹⁹ Since the digital health company did not offer PrEP/PEP based on HIVST without AI, we do not know what would have happened without AI in cases of poor image quality.

AI also facilitated the digital health company's monitoring of HIV test interpretation by COs, prompting the respective CO supervisor to audit cases where AI and CO interpretation varied rather

[†] Initially, the only supported tests were the Mylan and Sure Check® HIV Self Test kits (Sure Check is a registered trademark of Chembio Diagnostic Systems, Inc.). The AI support for the digital health platform was extended in 2023 to include the Abbott Determine™ RDT, used by MYDAWA pharm tech riders. Nearly all WHO-prequalified HIVSTs are now supported by the digital health platform in Kenya, but they were not all included in the study protocol for this pilot and thus are not yet part of the ePrEP/ePEP offering. AI is capable of supporting a wide variety of tests following an investment in AI integration.



than requiring the CO to observe every single case. Discrepancies between AI and CO interpretation also helped indicate when certain COs needed additional training.

The costs of the AI component included an upfront cost of AI development for each HIV test supported in the model and ongoing costs for technology support, including troubleshooting. The upfront cost was high relative to ongoing costs and was covered by the donor. The cost of AI per client declines as the model scales, but AI remains a substantial component of overall per-client costs. Additional costs would be incurred to train the AI on new HIVST products as they enter the market.

The pilot study was not designed to test whether AI improved CO performance or to evaluate the cost-effectiveness of AI, which came with a cost that may not be feasibly covered in all ePrEP/ePEP models.

Linkages to care and follow-up support

Clients who test HIV positive must be linked to care in accordance with the Kenya *HIV Prevention and Treatment Guidelines*. During the pilot study, seven clients who had reactive HIVST results were counseled by a CO during a follow-up call on the importance of confirmatory testing and provided with an active referral to a health facility of their choice for retesting and follow-on care. Of those, three clients were confirmed true positive, and the other four were confirmed negative. To maximize linkages to care, it is critical to map pharmacies offering ePrEP services and to connect clients with health facilities offering HIV care services within their respective areas.

In addition, clients in need of PrEP/PEP services who had preexisting chronic conditions that could affect the kidneys or liver were referred to physical facilities for further assessment, close clinical monitoring, and potential initiation of PrEP. All clients also were assessed for adverse drug reactions associated with PrEP/PEP and, if needed, reported through MOH pharmacovigilance tools and referred appropriately to specialized care, in accordance with the *Kenya HIV Prevention and Treatment Guidelines*. An adverse drug reaction was only recorded for one ePEP client during the pilot, who was referred to a health facility for follow-up care.

New clients preferred calls to initiate PrEP, while follow-up clients preferred WhatsApp (over emails) for support. The trends of clients who dropped off and did not finish their medication for both PEP and PrEP service were not different than those of other delivery platforms. When asked by COs, clients tended to attribute their discontinuation to side effects, pill burden, and (for PrEP) changes in behaviors associated with HIV risk.



Photo: Jhpiego

💡 Key learnings: Program model

- The model reached clients with a distinct profile compared to clients seeking services at clinic-based PrEP/PEP delivery locations. PEP uptake was high, mainly driven by clients initially seeking PrEP who were instead initiated on PEP due to recent potential HIV exposure.
- Some PEP clients submitted an order through the online pharmacy platform when they were close to the end of their 72-hour window. The one-step delivery client journey and communication between COs and pharm tech riders helped reduce the risk of missing this window by making the test and PEP available during the same visit. Median time between exposure and PEP delivery was 39 hours.²
- AI prompted clients to take a clear image of their HIVST results if the one they uploaded was of low quality. AI also supported COs as they remotely interpreted photographed results of clients' HIVST, providing a second opinion to consider. This also enabled a CO's supervisor to check for possible misinterpretation by examining the very rare discrepancies between AI and CO test interpretation.
- QA and quality checks for PEP and PrEP commodities were critical to ensuring that commodities were stored in a manner that aligns with MOH standards.



Recommendations: Program model

- **Start with an implementation roadmap.** Appendix 2 provides a checklist of key topics that stakeholders should consider while planning to introduce the ePrEP/ePEP model. Responses to these questions can inform a customized ePrEP/ePEP introduction roadmap for partners' use during the ePrEP/ePEP setup phase.
- **Understand that while a single end-to-end digital health platform provided both telehealth services and online pharmacy deliveries in this model, integration of these components is not a requirement.** If telehealth and online pharmacy services are provided by separate companies, they can work together: clients can upload their telehealth prescriptions on the online pharmacy platform when ordering products. Start-up costs may be lower if existing telehealth and online pharmacy platforms are leveraged.
- **Be aware that in most policy contexts, this approach to PrEP and PEP delivery is not yet a standard of care or included within existing policies and guidelines.** If existing policies do not allow for ePrEP/ePEP, then policy revisions will be needed for service delivery that differs from approved, standard-of-care processes covered by existing policies and guidelines. For example, if the model includes initiation of oral PrEP/PEP based on HIVST instead of an RDT, an online pharmacy may need to seek an exemption or advocate for change to policy guidelines enabling use of HIVST for PrEP/PEP initiation.
- **Tailor the model to epidemic and population needs.** Given the financial resources potentially required to establish ePrEP/ePEP models, selection of target geographies is important. Countries should consider drivers of HIV transmission, current prevalence rates, and hot spots to identify where HIV prevention efforts should be ramped up, including additional access points to PrEP services. It is critical to consider internet connectivity and willingness to pay in these geographies as well.
- **Establish systems for virtual and in-person supportive supervision of telehealth providers and delivery riders, quality controls for commodities, and post-market surveillance.** As resources allow, consider integrating AI-assisted diagnostics to make HIVST results easier for telehealth providers to interpret and facilitate supervisors' monitoring of results interpretations.
- **Establish a client journey that maximizes privacy, convenience, and speed while minimizing costs.** A one-step model is recommended due to lower costs, as only one delivery is needed per client, saving rider time and fuel and enabling the lower-cost option of an RDT administered by a qualified rider as an alternative to HIVST.
- **Guarantee pharm tech rider safety by requiring clients to provide a safe location and prioritizing daytime travel to locations deemed unsafe after certain hours.** As an additional option, telehealth companies could explore whether HIVST and PrEP/PEP access through e-lockers might reach clients for a low cost and with fewer safety concerns for riders. Implementation research is needed to understand the feasibility of using e-lockers for PrEP and PEP, as this was not part of the ePrEP Kenya study.
- **For RDTs, ensure that the riders who administer tests carry all necessary medical supplies** (i.e., consumables such as buffer and lancets and additional tests in case of faulty testing). Test consumables must be packed in a portable sterile package.
- **Establish linkage protocols and recording referrals on a referral tracker** to ensure that clients who test HIV positive or need other care access the recommended care.

Business model overview

Business model and sustainability considerations

The value proposition for online pharmacies to integrate ePrEP/ePEP services into their online platforms is two-fold: (1) facilitating greater choice, comfort, and confidentiality for clients in receiving PrEP/PEP by offering online services (appointment booking, consultations, e-prescription, ordering system), product delivery, and a choice of HIV test kits; and (2) offering clients access to other telehealth services and commodities (beyond HIV prevention) through one access point.

As ePrEP/PEP is envisioned to be commercially self-sustaining, online pharmacy platforms should develop a business model and conduct a business sustainability analysis (see Appendix 7) to understand the financial sustainability of integrating ePrEP/ePEP into their platform. Appendix 8 presents a high-level illustrative business model for ePrEP/ePEP services in Kenya, with details provided below on cost-related assumptions and service metrics that should be considered while assessing the long-term financial viability of integrating ePrEP/PEP services.

“I think [ePrEP/PEP] is quite good, I don’t think that I would have gotten it, otherwise the process of getting the medication physically, the logistics can be quite challenging...even the stories that I have heard of people when they go to visit clinics, maybe even the judgement that you might get from the person who is serving you with something similar. So, with the online, one, I think it is very convenient, two, I think it provides a sense of confidentiality and safety.”

— 24-year-old male client¹

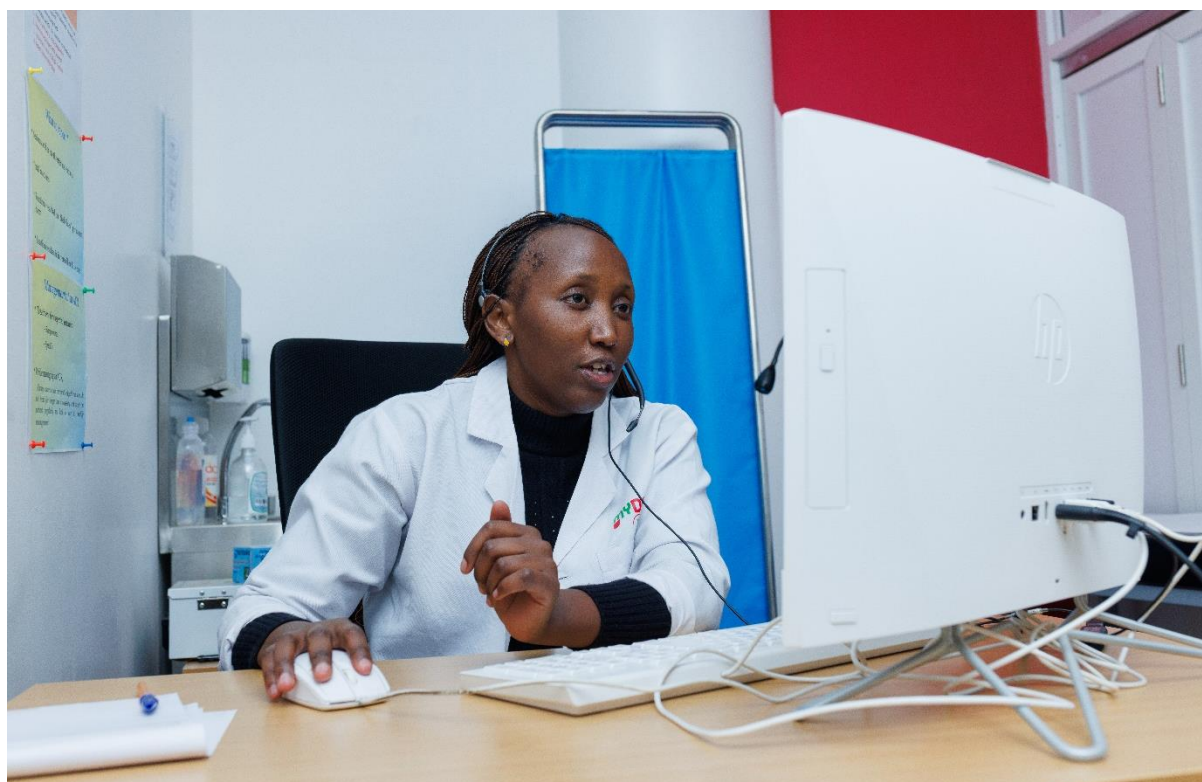


Photo: Jhpiego

Cost and revenue details

Involved costs

Labor and operational costs:

- Costs associated with running ePrEP/ePEP services—such as salaries (COs, pharm techs, lay riders, etc.), equipment, and overhead costs (office operations, technology expenses, etc.)—directly impact overall profitability. These are generally fixed costs that would increase over time as demand grows for ePrEP/ePEP and other offered services and products.
- Within this pilot, average monthly salaries for COs and pharm techs were 120,000 KES (US\$927.00) and 80,000 KES (US\$618.00), respectively, inclusive of benefits.
- In addition to ongoing operational costs for running ePrEP/ePEP services, there would also be initial start-up costs that online pharmacies may need to secure seed funding to cover. These costs could be for developing an ePrEP/ePEP online platform (for entities that do not have an existing telehealth/e-commerce platform) or conducting demand generation campaigns.
- The number of staff needed is determined by the number of consultations a CO can conduct during a shift and the number of deliveries of PrEP/PEP prescriptions or test kits a pharm tech or lay rider can deliver. Average consultation time by a pharm tech rider is 30 minutes (excluding delivery time), and average consultation time by a clinician is 30 minutes per client. Initial ePrEP/ePEP consultations are 30 minutes compared to 5 minutes for refill consultation visits. Each clinician is required to conduct 800 consultations per quarter (approximately 266 consultations each month).
- Incremental increases in personnel enable the model to be scalable over time as demand and revenue increases. Personnel increases also could ensure better quality as more clients enroll in the service, and the increased number of staff would enable more clients to be seen, thus increasing both PrEP/PEP and non-PrEP/PEP sales.
- Entities considering ePrEP/ePEP platforms could explore the possibility of alternative delivery options based on operating contexts, such as delivery lockers (e-lockers) that could potentially reduce delivery-associated costs or be more aligned with client preferences (for clients who may not want PrEP or PEP delivered directly to their homes).

Commodity procurements:

- Costs for the HIV RDTs or HIVSTs online made up a large portion of the costs of this delivery model, as the digital health company directly procured the tests at market price.[‡] PrEP and PEP would have increased costs significantly had they not been donated by the government.
- To reduce out-of-pocket payments by clients, governments or external donors could supply online pharmacy platforms with donated commodities (HIVSTs, RDTs, PrEP, and PEP) for either all clients or just clients with financial need.
- Without donated product, pharmacies would have to procure all commodities on the market or through available government procurement mechanisms, such as those outlined in Kenya's *Private Sector Engagement Framework for Delivery of HIV Services*, which could offer commodities at lower rates through pooled procurement mechanisms (see the “Commodity access” section below for further details).

[‡] In February 2024, the Kenyan government donated RDTs to the digital health company.



Revenue

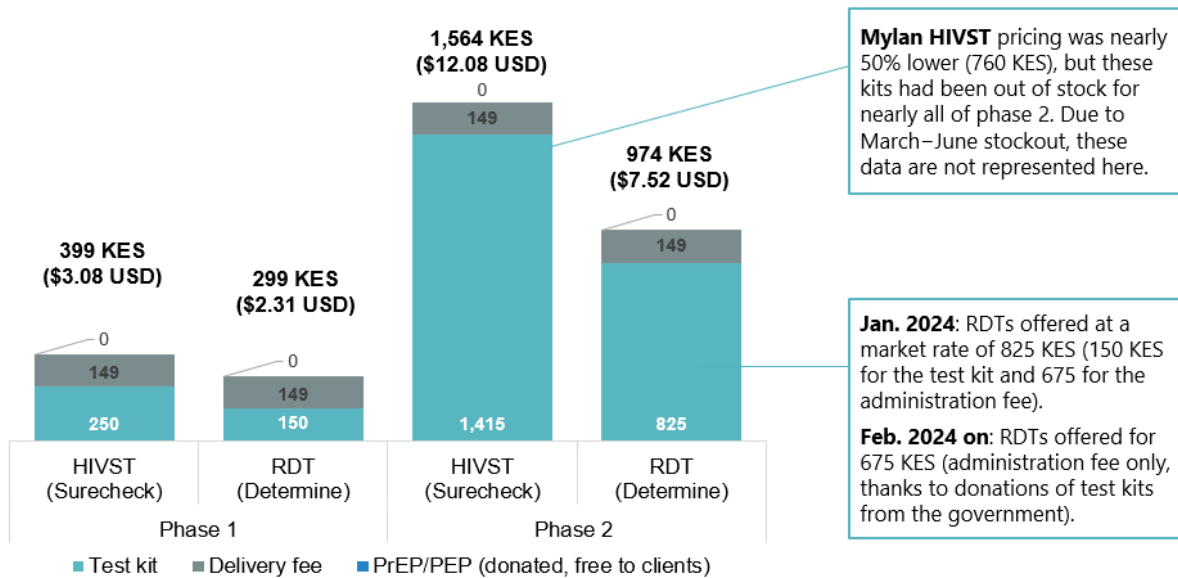
Consultations:

- Offering free ePrEP/ePEP consultations initially may be advantageous to generate client demand. In the long run, free consultations may not be financially viable for online pharmacy platforms unless the cost of telehealth consultation is integrated into either the costs of PrEP and PEP sold through the online pharmacy or the delivery fees.
- The digital health company did not charge consultation fees in either phase 1 or 2, but has plans for an eventual shift to a tiered consultation fee, with a higher cost for initiation visits (approximately 30 minutes) versus PrEP follow-up visits (approximately 5 minutes).
- Introducing an ePrEP/ePEP consultation charge could create space for ePrEP/ePEP services to generate additional revenue beyond product sales, but would come with the risk of deterring clients from seeking a consultation before they knowing whether they are eligible for PrEP or PEP. (The rationale behind consultations is addressed in the pricing strategy section of the digital health company's business case report.)²⁰
- Alternatively, consultation costs could be supported by national or private health insurance through government-support mechanisms or donors, at least as a short term solution.

PrEP/PEP and HIV test kit sales and delivery:

- Online pharmacies may charge clients for PrEP, PEP, and HIV RDTs or HIVSTs, with prices set based on unit cost, paid by the platform for the commodity, weighed against price controls and client willingness to pay to ensure affordability. Unit costs for PrEP, PEP, and HIV test kits could be subject to shifts to align with market-driven pricing variances. Figure 3 summarizes the total cost paid by clients during each phase of the ePrEP/ePEP pilot.
- Donated products (i.e., donated PrEP or PEP by the government or external funders) may have restrictions on the donation that preclude the online pharmacy platform from charging costs to the client for the commodity itself. Due to a government donation of generic PrEP or PEP, the digital health company did not charge clients for PrEP or PEP during phases 1 and 2.
- Due to the need for RDTs to be administered by a health care provider, online pharmacy platforms could charge a test administration fee. During the pilot, the digital health company charged an RDT administration fee of 675 KES (US\$5.21).
- Clients could be charged a delivery fee to offset the associated labor costs for a pharm tech rider or lay rider to deliver the commodities (i.e., HIV tests; PrEP or PEP). During the pilot, the digital health company charged a 149 KES (US\$1.15) delivery fee in Nairobi and offered free delivery in Mombasa (due to the smaller geographic area and thus shorter travel times). Clients who opted for the two-step model had to pay the delivery fee twice, adding to the total cost to the client.
- The digital health company also offered clients the option of uploading prescriptions issued by other/non-telehealth providers and purchasing PrEP and PEP from their online platform at market rate (30-day oral PrEP course for 7,740 KES or US\$59.77 [Truvada]; and 28-day PEP course for 3,700 KES or US\$28.57 [Acriptega]). Offering generic PrEP and PEP for sale would enhance their affordability, reducing costs to 725 KES (US\$5.60) for generic PrEP and 425 KES (US\$3.28) for generic PEP.

Figure 3. Fees paid by clients to access ePrEP/ePEP including HIV testing (in KES) during phase 1 and 2.



Abbreviations: ePrEP/ePEP, online pharmacy service delivery of PrEP/PEP; HIVST, HIV self-testing; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; RDT, rapid diagnostic test.

During the development of this model, the University of Washington led a discrete choice experiment with 772 survey respondents to understand client willingness to pay. They concluded that potential clients would be comfortable paying a median value of 1,059 KES (US\$8.10) to access ePrEP for one month (inclusive of any fees for the consultation, HIV testing, PrEP product, and delivery).²¹ This willingness to pay amount is very similar to the actual amount paid by clients in phase 2 if they chose an RDT rather than HIVST, and it would also be similar for HIVST clients if they could access the lower-cost HIVST option that was out of stock for most of phase 2. However, if clients will need to pay for PrEP itself (or PEP), the cost to clients in the future will exceed the median willingness-to-pay from this initial study. It will be important to track how sales volumes change if this additional cost to clients does get incorporated in the future.

Other model considerations

Pull-through revenue from other pharmaceutical products and prescriptions

- One potential revenue stream is to diversify beyond ePrEP/ePEP and offer other products and services to clients as they visit the online pharmacy or participate in consultations, where staff can convert prescriptions or suggest products beyond ePrEP/ePEP.
- During phase 2, the revenue from a client buying ePrEP/ePEP services was only less than half of the revenue the digital health company generated from the average cart for general health consultations that did not include ePrEP/ePEP.
- The digital health company has not tracked pull-through revenue for ePrEP/ePEP, nor has it tried to advertise other products, such as emergency contraception and condoms to clients buying ePrEP/ePEP services. However, the company has seen the sales of non-ePrEP/ePEP services grow over the course of this pilot.


- Understanding pull-through revenue and strategically working to increase it could contribute to the financial sustainability of ePrEP/ePEP and support clients in accessing other primary health care services they need.

Service use and performance metrics

- The business sustainability model requires data for evaluating business performance, tracking growth, understanding service demand, and measuring impact on revenue and profit. To aid with this, online pharmacies should develop and integrate metrics into ePrEP/ePEP models to continuously gather these data to inform sustainability modeling. Appendix 7 provides a template for a business sustainability analysis.
- Data that online pharmacies should consider collecting include:
 - Number of ePrEP/ePEP consultations provided.
 - Number of prescriptions dispensed (disaggregated by PrEP or PEP and generic or nongeneric).
 - Type of HIV test kits ordered as part of ePrEP/ePEP service package (disaggregated by HIVST or RDT kit and by kit model).
 - Value of other pharmaceutical products or services purchased by ePrEP/ePEP clients on the online pharmacy platform.
- Ongoing monitoring and evaluation of staff performance and service quality is essential for ensuring financial health—namely, considerations related to the ability of COs to be efficient in their work without compromising service quality. Therefore, online pharmacies should consider doing the following:
 - Conduct periodic performance reviews (at least semiannually) of COs and pharm tech riders to discover areas in need of follow-up to improve efficiency, as well as to identify high performers who could be placed on a career growth/development plan and low performers who could be placed on a performance improvement plan.
 - Gather client feedback to understand client satisfaction with service quality and identify gap areas that may impact client continuity and retention.
- An AI-assisted HIVST component assists clinical supervisors with performance reviews and may improve COs' accuracy by providing back-up support to their interpretations. However, false positive readings from the AI increased cost due to the need to follow up discrepant results. The AI system was initially tuned to be highly sensitive to detect faint lines, which resulted in a high number of false positive readings. (COs used their own interpretations, but these cases of discrepancies between AI and CO interpretation were flagged for further investigation by the COs' supervisors.) Fine-tuning the AI system over time improved its accuracy.

Net profitability of ePrEP/ePEP

Based on current demand levels, cost/fee structures, and the resulting revenues, the digital health company's business sustainability model indicates that its ePrEP/ePEP service delivery model can break even or make a small profit. PrEP, PEP, and HIV tests made up a large proportion of the digital health company's sales initially. As the company added products and services with higher margins, it was able to improve overall profits. Growth in general health consultations, prescriptions, and product sales can lead to consistent revenue growth to support the relatively low profits generated through the ePrEP/ePEP model.



Partnering with insurance companies is an important long-term solution for reducing out-of-pocket costs for clients and mitigating the barriers to ongoing PrEP use, thus broadening the ePrEP/ePEP client base. Online pharmacies and governments should explore the possibility of covering certain ePrEP/ePEP costs through national health insurance schemes (e.g., ePrEP/ePEP consultation fees; HIV test kits or PrEP/PEP commodities). Increasing the number of clients using the platform could lead to reduced operating costs from economies of scale, thus potentially increasing profits generated by ePrEP/ePEP services alone.

“With PEP and PrEP continuing to be donated by the county government, 12% of our business is PEP and PrEP as of April 2024. It contributes to our business, but we’re also doing it to meet a need. For the patients, we don’t want to switch off this source of access, especially for those who are continuing on PrEP.”

— Dr. Samira Abdulrashid,
Medical Officer In-charge, MYDAWA

Commodity access and public/private supply chain linkages

Current model

During the pilot, the digital health company received donated PEP and PrEP commodities from the MOH in the context of this research; the company was linked to the national commodities pipeline as a satellite site to subcounty health facilities in the counties of Nairobi (Westlands Subcounty Hospital) and Mombasa (Kaderbhoy Health Centre).

Continued availability of publicly procured PrEP and PEP doses was driven by submission of monthly PrEP/PEP commodity reports to the respective linked subcounty health facility in Nairobi or Mombasa. A standard operating procedure was developed to guide the digital health company’s team in generating the required monthly commodity reports in alignment with MOH expectations. Subcounty pharmacists conducted quarterly checks at the study sites for QA and quality control related to commodity receipt, storage conditions, and reporting processes. The steps taken to access public-sector PrEP and PEP stocks for ePrEP/ePEP clients during phase 1 of the pilot study are summarized below:

1. The digital health company extracted data for monthly stock and client counts.
2. These data were then shared with the respective CO supervisor, who calculated the necessary resupply quantity and submitted the final monthly reports to each subcounty health facility.
3. Each subcounty health facility reviewed the submitted monthly report to determine the quantity for replenishment by Nairobi and Mombasa’s respective subcounty hospitals.
4. The subcounty hospitals then submitted reports to the Kenya Health Information System.

Vision for commodity supply in the future

With the launch of Kenya’s *Private Sector Engagement Framework for Delivery of HIV Services*, in the near term, private-sector actors will be able to receive donated commodities procured via the MOH and dispense them to clients at a nominal dispensing fee. In the long term, private-sector partners will be able to source commodities through a pooled procurement mechanism with technical support from the government of Kenya and implementing partners to benefit from economies of scale. It is expected that cost savings due to increased purchasing power and efficiencies resulting in competitive pricing will be passed on to the clients who access private-sector HIV services. In settings without a private-sector engagement framework, a fully commercial model may be possible depending on costs and client willingness and ability to pay.



Photo: Jhpiego

💡 Key learnings: Business model

- The ePrEP/ePEP model offers dual benefits for online pharmacies: (a) making a social impact through addressing a critical health need for clients and (b) opening new or expanding existing revenue streams to reach new customers.
- The number of ePrEP/ePEP consultations remained steady (despite the anticipated decrease in demand) after the digital health company shifted to charging market rates for HIV test kits following the removal of subsidies for this commodity. It remains to be seen how demand might change if clients need to start paying for PEP and PrEP in the future; subcounty governments continued to donate these products for phase 2 of the study.
- The digital health company's business sustainability model indicates that ePrEP/ePEP will break even or make a small profit, assuming the same fee structure and level of client demand as observed during the pilot. However, the potential for pull-through revenue from general health consultations and resulting prescription and product sales may support consistent revenue growth, making the continued offer of ePrEP/ePEP services viable for the company post-study.



Recommendations: Business model

- **Secure seed investments** to cover upfront costs associated with developing the ePrEP/ePEP online platform (if an online pharmacy platform does not yet exist), optional AI-assisted HIV testing (if desired), and support for demand generation to drive awareness and establish a robust client base for ePrEP/ePEP.
- **Identify a source of HIV tests and HIV prevention commodities**, and then **set consumer prices** that balance affordability with financial sustainability, factoring in any relevant price controls.
- Before integrating an ePrEP/ePEP model into current services, **simulate a business sustainability analysis** (see template in Appendix 7) to understand the longer-term financial viability of such integration, as well as whether and when ePrEP/ePEP could be commercially self-sustaining.
- **Adjust pricing based on evolving market conditions**, as was done by the digital health company when market HIVST prices dramatically increased midway through the pilot. However, pricing is a delicate balance between ensuring price points are affordable and aligned with clients' willingness to pay while remaining competitive in the market and ensuring profitability. Reinforcing demand generation to increase clients' perceived value of PrEP and PEP could help to mitigate higher commodity costs due to market shifts.
- **Position ePrEP/ePEP as part of the platform's broader telehealth capability**, helping to broaden the client base beyond those interested in HIV prevention services and diversify revenue streams by attracting repeat customers for both HIV prevention and other health care needs. To enhance commercial viability of ePrEP/ePEP services, online pharmacies need to consider and offer other products ePrEP/ePEP clients may need during consultation appointments and/or as part of a bundled package[§] for various client types/needs (e.g., bundling PrEP and family planning, offering reduced or free HIV test kits to PEP clients interested in PrEP to encourage transition etc.).
- **Collect continuous and updated data** (from both ePrEP/ePEP and pull-through [non-ePrEP/ePEP] revenue) to evaluate business performance, track growth, understand service demand, and measure impact on revenue and profit as part of business sustainability modeling. Metrics to gather these data should be developed and integrated into the ePrEP/ePEP model.
- **Conduct ongoing monitoring and evaluation of the model's effectiveness** (uptake, continuity) **and staff performance** (COs, pharm tech riders, lay riders), as well as **eliciting client feedback on services** to assess the level of CO efficiency and service quality and make adjustments to implementation of the model, as needed.
- **Consider incremental increases in personnel** to be incorporated over time based on client demand and revenue increases, to maintain service quality and increase the staffing footprint, enabling more clients to be seen and thus further driving both PrEP/PEP and non-PrEP/PEP sales.

[§] Bundling was not part of the model tested in Kenya.

Demand generation

The JiPrEP campaign

The overarching goal of the project’s demand generation strategy was to raise awareness, educate the target audience, and drive adoption of PrEP and PEP, leading to an increase in access to, uptake of, and continuation of PrEP/PEP by individuals at risk of HIV acquisition.²² The online platform was positioned as a reliable, accessible, and confidential source for obtaining PrEP or PEP, while also destigmatizing use of the medication by promoting marketing materials to a wide variety of audiences, including less stigmatized groups.

Initially, marketing focused entirely on PrEP, with PEP added later in the campaign. Called *JiPrEP mapema ndio best* (“Early PrEP is best”), the campaign was developed with insights from Nigeria’s Gen-N PrEP program, global PrEP programs, and focus group discussion (FGD) feedback. Marketing focused on reframing PrEP as a contribution to a higher cause by creating a movement: join the [Gen-N community](#) (Figure 4). Gen-N refers to the “HIV-negative generation.”

The marketing strategy had four goals:

- Increase PrEP product and brand awareness.
- Drive engagement and conversations on the *JiPrEP* online platform.
- Generate interest in and drive traffic to the PrEP website.
- Promote PrEP use and continuation.

Marketing strategy development and deployment


Marketing activities initially were rolled out in Nairobi County and then expanded to Mombasa County. Demand generation strategy development and deployment had several components, as outlined below.

Audience segmentation and channels

The target market was individuals at high risk of HIV acquisition who could benefit from accessing PrEP and PEP through the e-commerce platform, particularly middle-class Kenyans with disposable income and a reliable internet connection. This included AGYW, serodiscordant couples, MSM, female

Figure 4. Promotional content for Gen-N.





sex workers, and other at-risk populations. The existing pharmacy customer base was included, with the goal of destigmatizing the use of PrEP through education.

The digital health company team conducted a market analysis to profile the target audiences, and data on demographics, behaviors, engagement, and attitudes were used to further segment these audiences. Specifically, demographics such as gender, age, education level, and location were assessed. Behavioral data consisted of purchase history, user attention on the platform, and devices used for browsing. Engagement data included users' interactions with the platform, likes and shares on social media, conversions, click-through rates, and website traffic. Attitudinal data included motivations and challenges, preferences, and customer satisfaction. Several data sources were reviewed—mainly, previous campaign profile reports; FGDs, reviews, and other feedback sources; and analytical tools, including Google Analytics and heat maps.

To avoid relying heavily on a single marketing channel, the team considered which media channels would support their objectives. The channel selection process drew from similar campaigns' market insights, as well as internal data analysis. In particular, learnings from Nigeria's *Ni Gen-N* campaign informed the channel selection and activities. The team leveraged an array of strategic channels including billboards, radio, social media, internet search engines, influencers, interpersonal communication, and posters. The most successful channels included adult sites, Google Search ads, and Facebook.

Initial asset development and FGDs

To understand what content and artwork would appeal to the target audience, the team organized FGDs to obtain feedback on marketing materials. This feedback was collated based on cohorts of populations prioritized in Kenya's national PrEP scale-up efforts, which included MSM, female sex workers, AGYW, and serodiscordant couples, as well as the general population.

Feedback heard across the groups indicated that the messaging should be positive, focusing on relationships and empowerment rather than messaging primarily about risk. Additionally, participants expressed a desire to see photos of people that resemble Kenyans rather than individuals from other countries or regions. They also felt that offering informational videos through the digital health company's online platform would help better explain the user journey.

Based on focus group feedback, the team revised the draft content to include positive language, photos depicting Kenyans, and testimonials, as well as educational content on the difference between PEP and PrEP. The team also developed instructional videos about PEP and PrEP, along with instructions for uploading HIVST images through the platform.

When developing materials, the team worked closely with internal and external regulatory experts, such as the PPB, to ensure that all marketing content and strategies were compliant with regulations.

Campaign launch

The team held both "soft" and "hard" campaign launches. The soft launch included publishing a press release announcing the project, social media adverts, and flyers in product packages for customers who purchased HIVSTs and emergency contraceptives. The soft launch enabled the team to identify and address any bugs in the online pharmacy platform, ensuring smooth operation in a live environment. They also recognized the need for staff with a broader skillset, including experience in demand generation strategy. As a result, rather than hiring a digital marketer as originally planned, the team opted for a telehealth marketing manager with expertise in strategy creation and implementation. The hard launch was conducted approximately two months later.

Refreshed demand generation strategy

While there was high uptake for PEP, but an initial low PrEP uptake, the team reviewed the strategy and conducted market research to better understand the current landscape. They concluded that a strategy refresh was needed. One key issue was that digital marketing tactics needed to expand to provide multiple touchpoints through which the target audiences can engage. Product demand was not generally correlated with marketing spending and was often more influenced by awareness-building activities such as social media engagement, influencer outreach, and on-the-ground events. They also found that the campaign provided insufficient information about the client journey.

The new strategy included the following changes:

- It provided accurate information to dispel myths and negative perceptions through targeted marketing to key audiences.
- It expanded the marketing channels and tactics to educate audiences and create opportunities and motivation for action.
- It prioritized raising awareness to ensure that the general population understands basic facts about PrEP and does not associate it only with certain populations.

Client engagement and insights

As noted above, marketing content focused on PrEP rather than PEP, and many clients confused the two products when initially seeking services. While nearly all clients requested PrEP during their initial consultation, because most had been exposed to HIV within the preceding 72 hours, they needed to use PEP before transitioning to PrEP. A key recommendation for future demand generation efforts is to promote both PrEP and PEP in the same advertisements, with simple and clear language highlighting the distinction between the two. In particular, demand generation campaigns should reinforce clients' understanding of the brief window for PEP effectiveness to ensure they access the product within 72 hours of HIV exposure, while also highlighting the value of PrEP as an HIV prevention method for those with ongoing exposure to HIV. The current marketing campaign is featured on the Gen-N website.

Key learnings: Demand generation

- Clients commonly confused PrEP and PEP when initially seeking services, and all online advertising focused on PrEP, not PEP. While nearly all clients requested PrEP during the initial consultation, because most clients had been exposed within 72 hours, they needed to use PEP before considering transitioning to PrEP.

Recommendations: Demand generation

- To help clients correctly identify which product they need and access PEP quickly if needed, **online pharmacies should promote both PrEP and PEP products in the same advertisements**, using simple language to clarify the distinction between the two and highlighting the brief window for PEP effectiveness for clients with potential recent exposure to HIV, as well as the value of PrEP as a protective method for people with potential ongoing exposure.
- **Marketing should be tailored to target audiences and messaging should be positive**, focusing on relationships and empowerment rather than negative messages primarily about risk.



Overall learnings and recommendations

Implementation research provided several insights into client profiles, the one-step delivery model, the role of AI in QA, and long-term sustainability of the model. Quantitative and qualitative analyses of the study are ongoing and will be reported in more detail by the researchers in forthcoming publications. Key findings that have been presented at academic conferences are highlighted below.

Programmatic and research learnings

Formative research can inform the design of the care pathway for ePrEP/ePEP services to ensure the approach aligns with stakeholder and user preferences

- Researchers engaged stakeholders from implementing, governmental, research, and private-sector organizations to design a care pathway for online delivery of PrEP and PEP services. This care pathway was based on an experimental care pathway for the delivery of PrEP and PEP services at brick-and-mortar pharmacies in Kenya.
- Researchers conducted a discrete choice experiment among potential online pharmacy users in Nairobi (n = 772) and found that participants preferred remote clinical consultation, HIVST, and phone/SMS user support—which emphasized that they value privacy in their HIV prevention care but want the option of speaking to COs for support, if needed.
- The median maximum that participants were willing to pay for a package of online PrEP delivery services was 1,059 KES, or US\$8.10 (interquartile range [IQR] \$6.50-\$15.80).²¹

Online pharmacy delivery of PrEP/PEP services was feasible to offer in urban Kenya and acceptable to clients

- The model reached 1,549 PEP and 208 PrEP clients over 14 months (from October 19, 2022, through December 31, 2023), an average of more than 100 PrEP or PEP clients per month.²
- Most clients (over 90%) found online PrEP/PEP delivery acceptable and indicated high satisfaction with the approach. The mean Client Satisfaction Questionnaire (CSQ-8) score for PrEP clients was 31.6 (standard deviation [SD]: 1.02) and for PEP clients, 31.4 (SD: 1.32). Most clients (over 85%) reported a positive experience with different components of the model, including the remote CO consultation, HIV test order and delivery, HIVST upload, and drug delivery.

Online delivery reached PrEP- and PEP-naïve populations with vulnerability to HIV exposure that are distinct from those accessing PrEP and PEP services at public clinics

- Few online PrEP clients had previously used PrEP (17%) or PEP (14%); similarly, only 1% of online PEP clients had ever used PrEP, and 14% had previously used PEP.
- Most clients accessing online PrEP and PEP services were over 25 years old, male, and unmarried; reported multiple sex partners; and/or did not know the HIV status of their sexual partners.² This is in contrast to PrEP clients at public clinics in Kenya, most of whom tend to be female, married, and in established HIV serodiscordant relationships.

Contrary to expectations, the pilot saw much higher online delivery of PEP compared to PrEP; continuation of both ePrEP and ePEP services was low

- Online PEP uptake was more than 7 times higher than that of PrEP over the pilot's duration.² This aligns with the digital health company's contraceptive product sales: emergency contraceptive and condom sales far exceed those for daily, oral contraceptive pills.
- Any PrEP continuation over the pilot duration (14 months) was 47%, with 42% continuation at 1 month, down to 14% at 7 months.² PrEP continuation with the online delivery approach is similar to that observed with the standard clinic-based delivery approach in Kenya. The most common reasons for online PrEP discontinuation—according to the digital health company's COs—were side effects, pill burden, and changes in clients' perceived likelihood of a future HIV exposure.
- Any repeat use of online PEP over the pilot duration was 13%, with 6% of PEP clients transitioning to online PrEP services and 7% returning to refill PEP via the online delivery platform.² Most online PEP clients said they did not anticipate another HIV exposure and did not see a need for PrEP. The percentage of PEP clients that transitioned to PrEP increased over the duration of pilot implementation, from 2% (3 of 147 clients) in quarter 4 (Q4) 2022 to 12% (49 of 405 clients) in Q4 2023, after the COs were trained on empathy-based counseling.

Facilitators of and barriers to ePrEP/ePEP remain, which could be addressed with novel implementation strategies

- Privacy was a top consideration for clients using this model. Very few clients turned on their video during their telehealth visit with the remote provider, and many requested that the products be delivered to a location other than home.
- Most PEP clients accessed online services within 72 hours of HIV exposure; only 37 prospective clients were not eligible for online PEP because they exceeded the 72-hour window. The average time from HIV exposure to PEP service delivery was 39 hours (IQR 25–51). Online pharmacies should emphasize the brief window for PEP effectiveness to ensure clients in need do not delay accessing online PEP services.²
- Qualitative interviews with participants found that client motivations for ePEP/ePrEP initiation and PrEP continuation included privacy, quick delivery, flexible delivery locations and times (e.g., weekend deliveries), and reduced stigma by health care providers, family, and peers. Additionally, clients reported that ePEP/ePrEP delivery was easy to navigate—booking for clinical consultation was “just one click away”—and that multiple communication channels allowed easy access to health care providers. Reasons for online PrEP discontinuation included financial constraints (associated with delivery fees), low HIV risk perception, relocation outside Kenya, and inability to find a private delivery location.
- The estimated cost for an online PrEP client 13,107 KES (US\$101.70) was higher than for an online PEP client 11,084 KES (US\$86.00). If ePrEP and ePEP were scaled to an annual client volume of 2,500, the financial costs would be 9,924 KES (US\$77.00) per PrEP client and 8,893 KES (US\$69.00) per PEP client. The largest financial cost drivers for this approach (as far as percentage of total cost) are courier delivery of HIV test kits and drugs (PrEP at 49.0%; PEP at 40.0%), demand generation (PrEP at 21.6%; PEP at 25.6%), and equipment, system development, and utilities (PrEP at 16.7%; PEP at 19.8%).

Commodity QA and quality checks were critical

- QA and quality checks for PEP and PrEP commodities were critical to ensuring that commodities were stored in a manner aligned with MOH standards.



Programmatic and research recommendations

The following recommendations are based on key learnings from the pilot for online pharmacy PrEP and PEP service delivery in Kenya. Stakeholders should consider these as they move forward with introducing, expanding, and/or sustaining the ePrEP/ePEP model.

Recommendations for MOHs and their technical assistance partners

Establish an enabling policy framework

Having a supportive legal and policy structure that enables the establishment of online pharmacies is critical for implementing an effective and sustainable ePrEP/ePEP model. This includes having policymakers adjust country HIV treatment and prevention guidelines to list ePrEP/ePEP as a recommended delivery model and collaborating with country regulatory entities to establish the regulatory framework and guidelines for operating online pharmacy-based health service delivery. Policymakers should consider other revisions to guidelines, as well, to simplify PrEP and PEP access, including considerations to mitigate barriers hampering transition between PrEP and PEP (e.g., enabling provision of a one-month starter supply of PrEP for anyone enrolling on PEP and/or providing free test kits to PEP clients who want to transition to PrEP).²³

Conduct formative work to tailor the model to population preferences

Given the significant financial resources required to establish ePrEP/ePEP services and ensure a financially viable model, it is essential to conduct formative research to obtain feedback from local government, online pharmacies, and the target population of potential ePrEP/ePEP clients to align service provision with user preferences and increase feasibility and reach. The ePrEP/ePEP study team spent a considerable amount of time designing a care pathway and assessing user preferences for services. The optimal care pathway will likely vary by setting, so countries will need to conduct formative research in their local contexts and should consider inclusion of additional PrEP products and other related health products in the ePrEP/ePEP platforms to expand product choice, especially as new PrEP products become available in-country (e.g., event-driven PrEP, PrEP vaginal rings, injectable PrEP products). Stakeholders should also ensure that client satisfaction surveys and other client feedback mechanisms are integrated into ePrEP/ePEP models to ensure services align with client needs and expectations; ensuring client satisfaction is a key factor for retaining and growing an ePrEP/ePEP customer base.

Consider integrating AI-assisted diagnostics

The integration of an AI-facilitated result interpretation system for HIVST in Kenya's ePrEP/ePEP pilot may have enhanced QA and quality control of HIV test results, although this has not been evaluated. For online pharmacy models that include HIVST as an option, implementers could consider integrating an AI component to make HIV test results easier for telehealth providers to interpret.

Recommendations for online pharmacies

Start with an implementation roadmap

Appendix 2 provides a checklist of key topics that stakeholders should consider (including as part of co-creation sessions) while planning introduction of an ePrEP/ePEP model. Responses to these questions could then inform the development of a customized ePrEP/ePEP roadmap that partners could use during the ePrEP/ePEP setup phase.

Secure seed investments for ePrEP/ePEP platform development and demand generation

Establishing an online pharmacy model necessitates significant upfront investment. Key areas for seed investment include establishing the online pharmacy platform (if it is not yet established) and supporting demand generation to drive awareness and uptake to establish a robust client base for ePrEP/ePEP. Partners and online pharmacy chains need to adequately budget for demand generation, including formative assessments to tailor campaigns to audience segments, campaign materials development, and strategies to continuously refresh campaign content for ongoing engagement among potential and existing ePrEP/ePEP clients. If the model will include AI-assisted diagnostics, this will require an upfront investment, as well as ongoing costs. Given the resources necessary to initiate such a model and the minimal profit potential for ePrEP/ePEP services in low- and middle-income countries without insurance coverage for these services, digital health companies may need support from country governments and/or donors to offset upfront costs to set up such a model.

Adjust pricing based on evolving market conditions

Pricing is a delicate balance between remaining competitive in the market and ensuring profitability. Online pharmacies will need to adapt pricing based on evolving market conditions, as the digital health company did when the price for procurement of HIVSTs dramatically increased midway through the pilot.

Secure a financially sustainable supply of commodities

For both phases of the ePrEP/ePEP pilot in Kenya, the subcounty governments of the two pilot counties (Nairobi and Mombasa) donated PrEP and PEP commodities to ensure that ePrEP/ePEP services were affordable for potential clients. Outside of the pilot, the same digital health company sold a one-month supply of brand name PrEP for 7,740 KES (US\$59.00) to clients with a prescription. If this PrEP cost were to be added to the phase 2 model, the cost to the client to access one month of PrEP would increase six to nine times (depending on which HIV test is used). If subcounty governments are able to continue donating PrEP and PEP supplies to online pharmacy chains during early market growth, this would help to ensure services are affordable and accessible to potential clients. Alternatively, online pharmacies could offer generic PrEP and PEP at prices much lower than those of the innovator brands. Adding the cost of PrEP and PEP would likely reduce the market size for initial uptake and discourage PEP-to-PrEP transition and PrEP continuation, but it would enhance sustainability of the model. For each component of the ePrEP/ePEP model (e.g., HIV test kits, PrEP, PEP, deliveries, consultation fees), willingness-to-pay research and experimentation with different price points are important to inform pricing that makes “business sense” while enabling a wide range of clients to access needed HIV prevention services.

Expand online pharmacy services to enhance sustainability

Private online healthcare businesses should position and market ePrEP/ePEP as part of their platforms’ *broader telehealth capability*, which would help to broaden the client base beyond those interested in HIV prevention services and diversify revenue streams, including by bringing in repeat customers not only for HIV prevention products but also for other health care needs across the board. To enhance commercial viability of the ePrEP/ePEP model, online pharmacies need to *target clients beyond ePrEP/ePEP services* by considering other products clients may need that could be offered to them during consultation appointments and/or as part of a bundled package for various client types/needs (e.g., bundling PrEP and family planning services and products). This could contribute to and ensure an increase in revenue streams.

Appendices

Appendix 1. HIV prevention context in Kenya

While Kenya has made great progress in reducing HIV incidence, additional efforts are needed to expand access and availability of HIV prevention services. The Division of National AIDS and STI Control Program has adopted a precision combination prevention approach that calls for access to multiple prevention options at facility and non-facility outlets. Building on the promise of physical pharmacies as a differentiated pre- and post-exposure prophylaxis (PrEP/PEP) delivery channel and telehealth as an emerging health care platform in Kenya, online pharmacies have the potential to offer an additional option for clients seeking private and convenient access to biomedical HIV prevention.

HIV epidemic in Kenya

Kenya has made significant strides in tackling its HIV epidemic, recording a 68.4% decline in new HIV infections between 2013 and 2021.²⁴ Despite this progress, Kenya ranks among countries with the largest HIV epidemics, with an estimated 1.4 million people living with HIV and 26,000 people newly diagnosed with HIV in 2022.^{25,26} Mombasa and Nairobi (both 100% urban) are among eight high-burden counties that account for more than half of all new HIV infections reported in Kenya.^{24,26}

PrEP and PEP use in Kenya


Kenya was the second African country to issue regulatory approval for oral PrEP,²⁴ which was introduced in 2016. Additionally, non-occupational PEP has been approved for survivors of sexual assault or violence and those who experience high vulnerability to HIV.²⁷ However, studies indicate low knowledge and use of PEP among sex workers, despite high interest, especially as an alternative to long-term PrEP use.²⁸ Per Kenya's 2017 PrEP implementation framework, the country aimed to provide PrEP to 500,000 Kenyans with substantial ongoing risk for HIV infection by 2022;²⁹ as of quarter 4 (Q4) 2023, the country had 438,003 cumulative PrEP initiations.³⁰

Existing PrEP and PEP service delivery platforms in Kenya

As in other sub-Saharan African countries, PrEP and PEP services in Kenya are primarily delivered through public-sector clinics,³¹ specifically HIV clinics, antenatal clinics, and key population or adolescent drop-in centers.³² Building on the 2017 *Framework for the Implementation of Pre-exposure Prophylaxis of HIV in Kenya* recommendation for additional delivery channels to more effectively roll out PrEP among priority populations,²⁹ there have been focused efforts to integrate PrEP into community platforms such as safe spaces and digitally-facilitated and home-based dispensing through the United States President's Emergency Plan for AIDS Relief's (PEPFAR) Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe (DREAMS) initiative (see "Community platforms" subsection below). Brick-and-mortar and online pharmacy-based PrEP delivery has the potential to increase access and contribute to financial sustainability of the HIV response.

Public-sector HIV care

As in other sub-Saharan African countries, PrEP and PEP services in Kenya are delivered primarily through public-sector HIV care clinics,³¹ with PrEP offered at HIV clinics, antenatal clinics, and key population or adolescent drop-in centers.³² The number of health facilities offering PrEP has grown from 107 in 2017 to almost 2,000 in 2020,^{24,33} with more than 438,000 cumulative PrEP initiations as of December 2023.³⁴ Kenya's 2022 PEPFAR Country Operational Plan highlighted gaps, including low PrEP uptake and high PrEP discontinuation rates, citing the concentration of PrEP services at public-sector HIV clinics, health worker attitudes and knowledge gaps, and stigma attached to HIV as



barriers.³⁵ Additional studies have found that low uptake and poor outcomes associated with public facility-based PrEP delivery are driven by barriers at both the client level (lack of privacy, fear of HIV-related stigma, transportation issues, and long wait times, including cost of lost income for missing work) and provider level (competing priorities, clinic overcrowding, and lack of PrEP and PEP knowledge).²⁷ Even in settings where PrEP uptake and persistence are high, objective adherence measures indicate that actual adherence to daily oral PrEP among enrolled clients may be far lower than the self-reported numbers.³⁶

Providers at public-sector HIV clinics in Kenya have adapted practices to address barriers limiting PrEP uptake and effective use. For example, providers at 25 high-volume public HIV care clinics in western and central Kenya involved in the University of Washington's [Partners Scale-Up Project](#) (2017–2020) noted initiating clients on PrEP without creatinine testing (if the client was otherwise healthy), issuing two to three months of PrEP supply (instead of the recommended one-month supply), “fast-tracking” PrEP clients, dispensing PrEP in clinic consultation rooms (instead of clinic pharmacies), and incorporating PrEP-related topics into routine health talks. All of these practices have led to higher PrEP initiation and above-average continuation at clinics adopting a mix of these practices.³⁷

Integration with public-sector family planning and antenatal care services

Demonstration projects integrating PrEP into family planning and maternal and child health clinics in Kenya revealed that only 20% of women screened and counseled on PrEP initiated PrEP, with only 50% who initiated returning for at least one refill visit. More recent analysis of PrEP use outside of a demonstration study during Kenya's early PrEP roll-out phase showed overall uptake to be even lower, at 7%, with PrEP persistence declining by more than half at six-month follow-up visits.³²


While integrating PrEP and PEP into existing HIV testing and counseling services at public-sector clinics was advantageous, the 2017 Kenya PrEP implementation framework noted a need for additional delivery channels for more effective PrEP rollout among priority populations.²⁹ And despite recent efforts to optimize delivery and availability of PrEP through public-sector channels, new and differentiated delivery models are needed to overcome barriers and provide current and potential new PrEP clients with options that fit their preferences. The *Frontline AIDS Kenya: HIV Prevention Shadow Report 2020* also calls for the need for more differentiated and contextualized approaches to PrEP provision.³³

Community platforms

There have been focused efforts to integrate PrEP into community platforms in Kenya, including through safe spaces and through digitally facilitated and home-based dispensing through the US President's Emergency Plan for AIDS Relief (PEPFAR) initiative for adolescent girls and young women (AGYW) called DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe), with a goal of addressing concerns related to stigma, privacy, and service convenience for AGYW.³⁸ Through the Sustainable East Africa Research in Community Health (SEARCH) trial in rural Kenya and Uganda, same-day PrEP initiation was offered to individuals testing HIV negative as part of integrated community testing for HIV, hypertension, diabetes, and malaria, with a flexible system for refill access at either a health facility or a community-based site.³⁹ In selected SEARCH trial communities, a multi-component intervention to expand PEP through enhanced community mobilization using community leaders, a PEP mobile phone hotline, and community-based medication delivery proved to be feasible and facilitated high PEP adherence and completion.⁴⁰

Brick-and-mortar pharmacies (pilot studies)

Pharmacy-based PrEP delivery holds promise for increasing PrEP access and decentralization, reaching individuals not accessing PrEP through facility and community models, with the added benefit of



being a self-sustaining delivery model.⁴¹ Results from the Pharm PrEP pilot in western and central Kenya showed that private pharmacy–delivered PrEP was highly acceptable to clients, with strong willingness to pay; resulted in PrEP initiation and continuation outcomes comparable or higher to outcomes at public facility–delivered PrEP; and was successful in reaching populations not typically reached through facility-based PrEP services, notably older men.⁴² Private pharmacy–delivered PEP also was evaluated through a six-month extension to the Pharm PrEP pilot. Results indicated high acceptability, and most clients and providers reported ease and a preference for pharmacy-delivered PrEP and PEP.⁴³ A cluster randomized control trial evaluating this model’s effectiveness is ongoing. These studies will provide evidence to inform national policy shifts to allow private pharmacies to deliver PrEP and PEP services.

Potential for online pharmacies to expand HIV prevention access in Kenya

Despite recent efforts to decentralize PrEP to other entry points, additional differentiated delivery models are needed to overcome continued barriers and provide current and potential new PrEP clients with options that suit their preferences. The *HIV Prevention Shadow Report 2020* for Kenya also calls for the need for more contextualized approaches to PrEP provision.³³ As mentioned previously, adding an ePrEP/ePEP option to brick-and-mortar pharmacy services has the potential to increase access and contribute to financial sustainability of the HIV response.

Spurred by COVID-19, online pharmacies have been gaining presence in Kenya, with the digital health company that participated in the pilot being the first to be licensed, leading to 17 online pharmacies providing direct-to-consumer health products by February 2022.⁴⁴ A recent landscaping of online pharmacy regulations in Africa noted Kenya as particularly primed to integrate HIV services into online pharmacy platforms relative to other African countries, given its high mobile penetration, network of 20 online pharmacies, existing underlying pharmacy and e-health policy frameworks, and online pharmacy regulations that allow pharmacists or pharmaceutical technologists (pharm techs) to dispense over-the-counter or prescription health care products online.⁴⁵

Appendix 2. Implementation roadmap for ePrEP/ePEP

The following is a checklist of key topics and questions that stakeholders should consider when planning to introduce the ePrEP/ePEP model.

- **Stakeholder engagement and advocacy for policy change:** An enabling policy environment is critical for the ePrEP/ePEP model to be viable. Assess what is required for telehealth and online pharmacy licensure. In most policy contexts, it will be necessary to collaborate with regulators to secure approval or a research exemption to use telehealth for PrEP and PEP prescriptions. If the model includes initiation of PrEP/PEP based on an HIV self-test (HIVST), the online pharmacy may need to seek approval or an exemption to enable this, as well. Review policy guidance on who is allowed to conduct rapid diagnostic tests (RDTs) and dispense PrEP/PEP to ensure that your model complies with these and other requirements or has an exemption.
- **Service delivery model:** Establish a client journey that maximizes privacy, convenience, and speed while minimizing cost (e.g., provider time, fuel for deliveries). Engage potential end users in co-designing the model with you to ensure that it aligns with their preferences and realities (e.g., how they want to learn about and access telehealth consultations, where and when they would want to receive delivery of HIV tests and PrEP or PEP, what type of follow-up communication is safe and acceptable to them).
- **Sourcing and pricing of commodities:** Identify a source of HIV tests and HIV prevention commodities, and then set consumer prices that balance affordability with financial sustainability. In some cases, the public supply authority may be willing to donate HIV tests and/or PrEP/PEP, particularly for implementation research, if the online pharmacy agrees to report service delivery and commodity consumption data to the public sector. If the source of supply is private distributors, confirm whether prices to pharmacies are open to market forces, subsidized, or controlled. Explore whether it is possible to accept public or private health insurance and what accreditation process may be required by insurance providers.
- **Provider training:** Train telehealth providers and the delivery riders who will engage with clients in person. Confirm their proficiency in HIV testing, PrEP/PEP prescription, follow-up, adherence counseling, and anything else relevant to their role and your model.
- **Quality assurance:** Establish systems for supportive supervision of telehealth providers and riders, quality controls for commodities, post-market surveillance, etc. As a quality enhancement, consider integrating AI interpretation of HIV tests to support telehealth providers in their interpretation of test results and enable more effective supervision of telehealth providers. Ensure that any integration of AI is aligned with policy guidance.
- **Linkages to care:** Review guidelines for how to handle positive test results in your country context. Establish protocols to ensure HIV-positive clients are linked to care.
- **Demand generation:** Raise awareness of service availability via a market campaign targeted toward likely users.
- **Monitoring and continuous improvement:** Establish a monitoring plan with key performance indicators that include measures of quality, as well as uptake. Conduct routine data quality audits. Schedule routine “pause and reflect” meetings to review monitoring data and determine how to improve the model.

Appendix 3. The ePrEP/ePEP one-step delivery model, mapped to the International AIDS Society Differentiated Service Delivery building blocks

Building blocks	PrEP/PEP assessment, initiation, and early follow-up (0–3 months)					PrEP continuation (>3 months)	
	Eligibility assessment*	Ordering	HIV test kit delivery and testing	Consultation, initiation or reinitiation	Initial clinical follow-up	PrEP refill	Clinical consultation
What	PrEP/PEP consultation comprising risk screening using Rapid Assessment Tools, PrEP/PEP eligibility assessment, PrEP/PrEP adherence counseling, and PrEP/PEP prescription (one-step model, if eligible)	HIV test (RDT or HIVST) and PrEP or PEP order	Delivery and administration of RDT or unassisted HIVST, based on client choice	Provision of PrEP/PEP	PEP clients: Initial check-in and follow-up with counseling on transition to PrEP PrEP clients: Initial check-in; follow-up for PrEP adherence counseling, refill need (if continuing on PrEP), and HIV retesting (RDT or HIVST)	HIV retesting adherence counseling and PrEP/PEP refill ordering and delivery	PrEP consultation and adherence counseling
Who	Telehealth clinical officer (CO)	Client	Pharm tech rider (test kit delivery and RDT administration) Client (HIVST administration/upload) Telehealth CO (remote HIVST interpretation)	Pharm tech rider (PrEP/PEP delivery) Telehealth CO (RDT/HIVST results interpretation, post-test counseling, PrEP/PEP order confirmation)	Telehealth CO	Telehealth CO	Telehealth CO
Where	Telephone consultation	Online through MYDAWA website or mobile app	Client household or other location of client's choice	Client household or other location of client's choice	Initial check-in via WhatsApp; follow-up via telephone consultation (or WhatsApp, if no response to telephone call) and in-person consultation	Online pharmacy website with delivery at client household or other location of client's choice	Telephone and in-person
When	Appointment booked online by client at a time of their convenience	Following PrEP consultation with CO	Delivery after order placed via website or app; testing as part of delivery	After telehealth CO post-test counseling and delivery authorization	Initial check-in after 7 days; follow-up after 28 days	Every three months	Every three months

*Clients were eligible for PrEP or PEP prescription if they met the criteria outlined in Kenya's [HIV Prevention and Treatment Guidelines](#), including confirmed HIV-negative status. Abbreviations: ePrEP/ePEP, online pharmacy service delivery of PrEP/PEP; HIVST, HIV self-testing; PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylaxis; RDT, rapid diagnostic test.

Appendix 4. One-step delivery journey details

Details of the client journey using one-step delivery are as follows:

1. The client books a PrEP/PEP consultation, which includes registering for an online pharmacy account, signing the website consent form, completing a pre-call [Rapid Assessment Screening Tool \(RAST\)](#) and then selecting a preferred time to be called by a clinical officer (CO).
2. The client's information (name, age, and risk score according to the RAST, if completed) is made available to the CO before the consultation begins.
3. The CO initiates the consultation with an introduction, followed by RAST follow-up questioning and then an assessment of eligibility for PrEP/PEP. This process is repeated during every scheduled follow-up for clinical reviews.
4. Once the client confirms residency in either Nairobi or Mombasa County, the CO initiates an SMS prompt that sends the consent form for the client to sign. The client may choose to end the consultation call at this point to allow time to read through the consent form or choose to read through it while still on the call with the CO. Once the client signs the consent form, the CO then proceeds to write a prescription for the HIVST and PrEP or PEP.
5. The client orders both the test and the PrEP or PEP at the same time, and this bundled package is delivered specifically by a pharm tech rider.
6. Upon arrival at the client's location of choice, the pharm tech dispenses the HIVST or RDT, and the client takes the test or the pharm tech administers the test, respectively. In cases of faulty self-testing or phobia of self-testing, the CO alerts the pharm tech rider, who can assist the client with the test, if needed.
7. Once the test results are ready, the client uploads a photo of the results for the CO's review, and the pharm tech notifies the CO that the test is done.
8. The CO then initiates a follow-up call with the client, during which the test result is verified. If the test result is negative, the CO gives the go-ahead to the pharm tech rider to dispense the PrEP/PEP being held for the client. If the test result is positive, the CO provides counseling and referral to a facility for the client to undergo a repeat HIV test, in accordance with the national testing guidelines.
9. During a PEP client's 28-day follow-up call, the client is advised on transitioning to PrEP use upon completion of PEP.
10. PrEP clients are advised to adhere to medicine refills, follow-up consultations, and HIV testing (at enrollment, after one month, and thereafter every three months), as per the 2022 *Kenya HIV Prevention and Treatment Guidelines*. (In this model, clients pay for these HIV tests.)

Figure 5. Rapid Assessment Screening Tool

MINISTRY OF HEALTH
NATIONAL AIDS & STIs CONTROL PROGRAM

PrEP Rapid Assessment Screening Tool (RAST)
Age: _____ Sex: _____ Date: _____

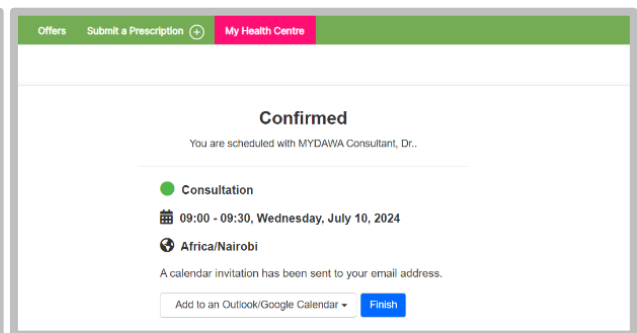
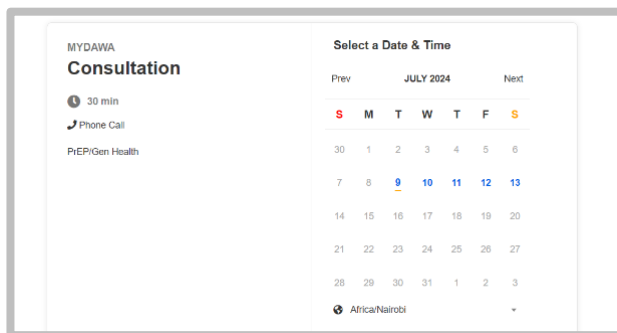
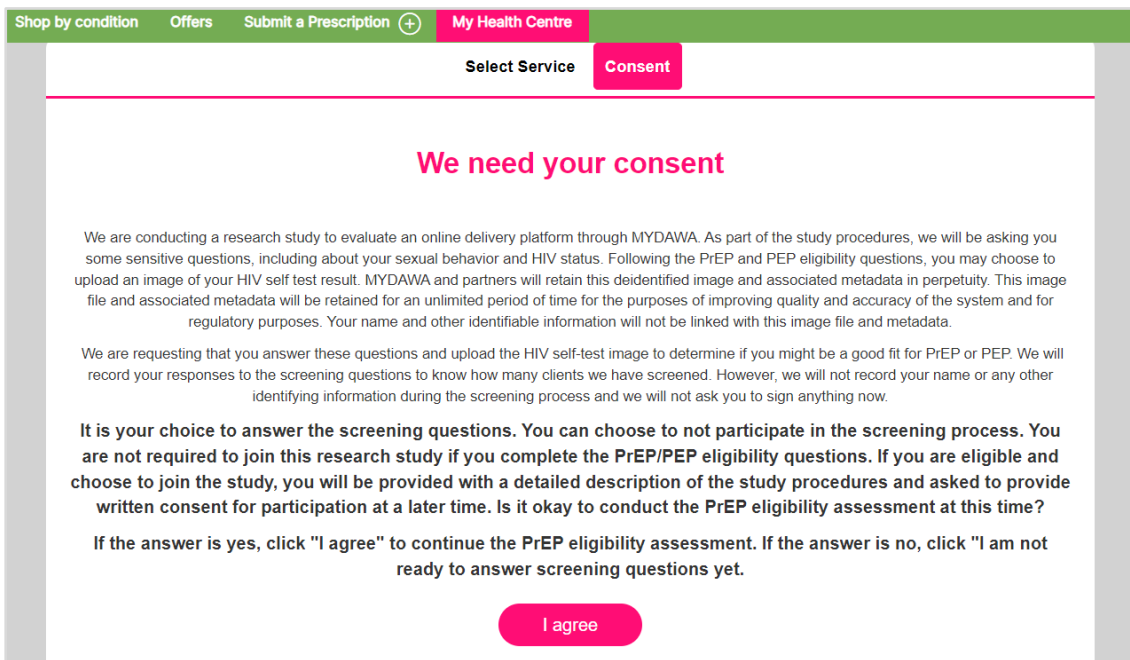
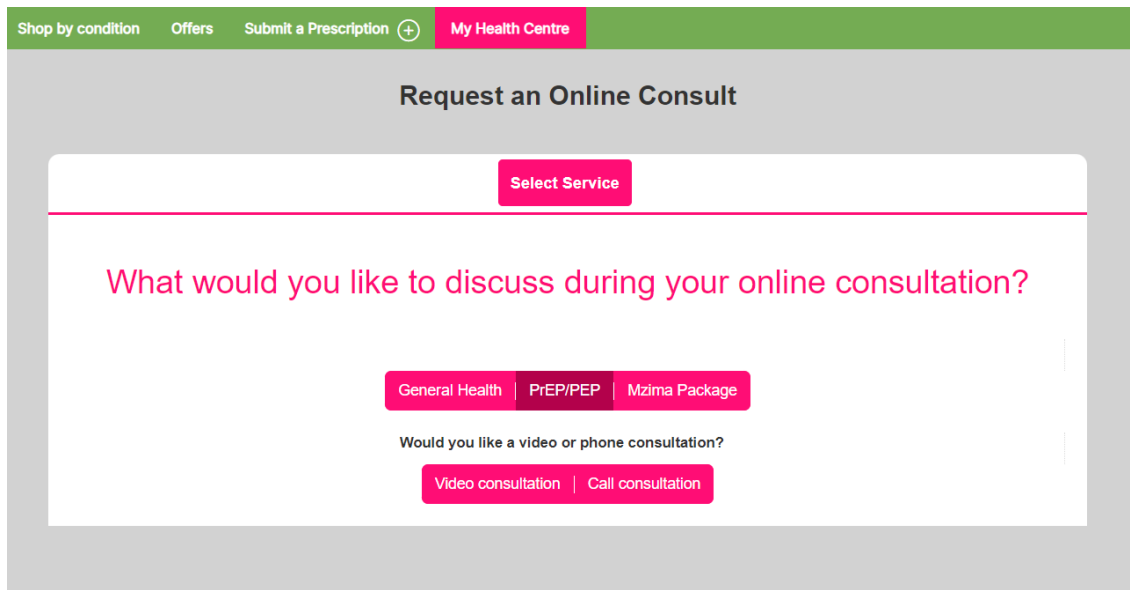
1. What is your HIV status? *(If response is positive discontinue assessment else administer all questions)*
 Negative Positive Unknown Unwilling to disclose
2. What is the HIV status of your sexual partner(s)?
 Negative Positive Unknown

In the past 6 months

3. Have you had sex without a condom with a partner(s) of unknown or positive HIV status?
 No Yes
4. Have you engaged in sex in exchange of money or other favors?
 No Yes
5. Have you been diagnosed with or treated for an STI?
 No Yes
6. Have you shared needles while engaging in intravenous drug use?
 No Yes
7. Have you been forced to have sex against your will or physically assaulted including assault by your sexual partner(s)?
 No Yes
8. Have you used post exposure prophylaxis (PEP) two times or more?
 No Yes

Refer the client for further PrEP assessment at the health facility if:
HIV status of the sexual partner(s) is Positive or Unknown
Any Yes to the screening questions

Figure 6. Example screenshots from the online pharmacy website





Appendix 5. Telehealth licensure journey in Kenya

The digital health company went through a licensure process to register a physical clinic and obtain permission for their telehealth service. The following steps describe that journey in Kenya (the process may look different in other countries):

1. The Kenya Medical Practitioners and Dentists Council (KMPDC) advised the digital health company to set up a physical clinic before being issued with a telehealth license.
2. The digital health company applied to Nairobi Metropolitan Services (NMS) to become a licensed level 2 facility.
3. The digital health company established a physical clinic according to NMS and Ministry of Health requirements and submitted an application for inspection.
4. The NMS conducted an initial inspection of the facility and provided feedback. After feedback was addressed and a second inspection was completed, the facility was certified.
5. The digital health company submitted an application to the KMPDC for level 2 facility registration. All documents were verified by a lawyer and then signed and completed by a medical officer.
6. The KMPDC approved the application and issued a license to the online pharmacy.
7. Once the level 2 license was received, (a) the digital health company applied to the subcounty government for Master Facility List inclusion and code assignment, which was granted upon inspection; and (b) the digital health company was eligible to apply for a telehealth license.
8. To register as a telehealth facility, a KMPDC registration number of someone employed at the facility is needed; hence, the digital health company hired a medical officer to meet this requirement.
9. Once these steps were completed, the digital health company was issued a telehealth license and approved to launch services.

Appendix 6. Empathy-based counseling training materials

The slides for the online pharmacy staff training on empathy-based counseling are [available here for download as a Microsoft PowerPoint file](#).



Appendix 7. Business sustainability analytics template for the ePrEP/ePEP model

The template for ePrEP/ePEP business sustainability analytics is [available for download here as a Microsoft Excel file](#).

	B	C	D	E	F	G	H	I	J	K	L	M
	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
2 Total Consultations - Non PrEP/PEP	650	670	690	710	732	754	776	799	823	848	874	900
3 Total Consultations - PrEP/PEP	200	201	202	203	204	205	206	207	208	209	210	211
4 Total Consultations (Including follow ups)	1275	1306	1337	1370	1403	1438	1473	1510	1547	1586	1626	1667
5												
6 Share of Non PrEP/PEP consultations	76%	77%	77%	78%	78%	79%	79%	79%	80%	80%	81%	81%
7 Share of PrEP/PEP consultations	24%	23%	23%	22%	22%	21%	21%	21%	20%	20%	19%	19%
8												
9 Non PrEP/PEP prescriptions written	572	589	607	625	644	663	683	703	725	746	769	792
10 PrEP/PEP prescriptions written	186	187	188	189	190	191	192	193	194	195	196	196
11 Total prescriptions written	758	776	795	814	834	854	875	896	918	941	964	988
12												
13 Non PrEP/PEP prescriptions Checked out	366	377	388	400	412	424	437	450	464	478	492	507
14 PrEP/PEP prescriptions Checked out	166	166	167	168	169	170	171	171	172	173	174	175
15 Total prescriptions checked out	532	543	556	568	581	594	608	622	636	651	666	682
16												
17 Total Revenue from Non PrEP/PEP	1,054,310	1,085,940	1,118,518	1,152,073	1,186,636	1,222,235	1,258,902	1,296,669	1,335,569	1,375,636	1,416,905	1,459,412
18 Total Revenue from PrEP/PEP	56,284	56,565	56,848	57,132	57,418	57,705	57,993	58,283	58,575	58,868	59,162	59,458
19 Total Revenue	1,110,594	1,142,505	1,175,366	1,209,206	1,244,053	1,279,940	1,316,895	1,354,952	1,394,144	1,434,504	1,476,067	1,518,870
20												
21 Profit Margin revenue from Non PrEP/PEP	210,862	217,188	223,704	230,415	237,327	244,447	251,780	259,334	267,114	275,127	283,381	291,882
22 Profit Margin revenue from PrEP/PEP	11,257	11,313	11,370	11,426	11,484	11,541	11,599	11,657	11,715	11,774	11,832	11,892
23 Total profit margin	222,119	228,501	235,073	241,841	248,811	255,988	263,379	270,990	278,829	286,901	295,213	303,774
24												
25 Number of Clinicians required	2	2	2	2	2	2	2	3	3	3	3	3
26 Total Consultation cost per clinician (Salary+equipment)	170,000	170,000	170,000	170,000	170,000	170,000	170,000	170,000	170,000	170,000	170,000	170,000
27 Number of pharmtech required	1	1	1	1	1	1	1	1	1	1	1	1
28 Total costs per pharmtech (Salary + equipment+tech+o	16,000	16,000	16,000	16,000	16,000	16,000	16,000	16,000	16,000	16,000	16,000	16,000
29 Total Costs	371,357	380,310	389,522	398,998	408,748	418,780	429,101	439,721	450,648	461,891	473,460	485,365
30												
31 Service charges	573,750	587,588	601,823	616,469	631,537	647,040	662,991	679,404	696,291	713,667	731,547	749,946
32												
33 Net profit (Gross profit less OPEX)	424,512	435,778	447,375	459,312	471,600	484,248	497,269	510,673	524,472	538,677	553,300	568,355
34												
35	5,315,572											

Appendix 8. Business model for ePrEP/ePEP in Kenya

<p>Activities and channels</p> <ul style="list-style-type: none"> • Administer telehealth platform comprising key features: <ul style="list-style-type: none"> ○ Appointment booking. ○ Virtual consultations. ○ Online ordering. • Provide telehealth clinical consultations and e-prescription services. • Offer delivery services for commodities. 	<p>Value proposition</p> <p>1. Choice, comfort, and confidentiality: Enables clients to receive more confidential, comfortable PrEP/PEP services by providing them with options: (1) online services at a location of their choosing; (2) commodities to be delivered directly to them at place of their choosing; and (3) HIV testing through RDTs or HIVSTs.</p> <p>2. Convenient, integrated services in one access point: Using a broader e-commerce pharmacy platform enables clients to order commodities or receive services for other health and wellness needs (beyond HIV prevention).</p>	<p>Partners</p> <ul style="list-style-type: none"> • Commodity suppliers (e.g., PrEP, PEP, HIV tests [RDTs/HIVSTs]). • Insurance entities (Kenya private health insurance agencies; Social Health Insurance Fund). • Government entities: <ul style="list-style-type: none"> ○ Kenya Ministry of Health. ○ National AIDS and STI Control Program. ○ Pharmacy and Poisons Board. 	<p>Customer segments</p> <p><i>Segmented by frequency of service use</i></p> <ul style="list-style-type: none"> • PEP clients. • Intermittent PrEP clients (those who cycle on/off PrEP during intermittent periods of vulnerability). • Longer-term/regular PrEP clients (those who have ongoing HIV vulnerability and require PrEP access for longer time periods).
<p>Involved costs</p> <ul style="list-style-type: none"> • Online pharmacy platform administration. • Labor (clinicians, pharm tech/lay riders), including salary & benefits, and transportation for deliveries: <ul style="list-style-type: none"> ○ CO: 120,000 KES/month, or US\$927.00. ○ Pharm tech rider: 80,000 KES/month (salary & benefits), or US\$618.00. ○ One-step model: ~30-minute consultation (regardless of HIV test type)→675 KES/consultation (US\$5.21) + transit time. • PrEP and PEP commodity procurement: In phases 1 & 2, supplied with PrEP and PEP through government donation.** • HIV test kit procurement: In phases 1 & 2, HIVST and RDTs procured by digital health company at market price (note: RDTs supplied by subcounties since February 2024). 	<p>Revenue</p> <ul style="list-style-type: none"> • ePrEP/ePEP consultation fees: For phases 1 & 2, 0 KES (fully subsidized by digital health company)→ planning for eventual shift to tiered consultation fee, with higher cost for initiation visits (~30 minutes) versus follow-up visits (~5 minutes). • PrEP/PEP sales: For phases 1 & 2, free generic PrEP or PEP (government donation). • HIV test kit sales and RDT administration fees: <ul style="list-style-type: none"> ○ HIVST: <ul style="list-style-type: none"> ▪ Phase 1: Mylan HIV Self Test or Sure Check® HIV Self Test: 250 KES, or US\$1.93 (partially subsidized). [Sure Check is a registered trademark of Chembio Diagnostic Systems, Inc.] ▪ Phase 2: Mylan HIV Self Test (540 KES, or US\$4.18) or Sure Check HIV Self Test (760 KES, or US\$5.89), up to 760 KES (US\$5.89) and 1,416 KES (US\$10.98), respectively, since late 2023.** ○ RDT: <ul style="list-style-type: none"> ▪ Phase 1: 150 KES, or US\$1.16 (partially subsidized). ▪ Phase 2: 825 KES (US\$6.40)→150 KES (kit) + 675 KES (US\$5.23) test administration fee. (Note: RDTs supplied by subcounties, with clients only paying administration fee, starting from February 2024). • Delivery fee: 149 KES (US\$1.15) in Nairobi; 0 KES in Mombasa (free delivery due to shorter travel times). 		

** PEP and PrEP commodities supplied by government with support from PEPFAR and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

** Pricing for HIVSTs increased in late 2023 due to inflation-driven increases in supplier pricing.

References

1. Kiptinness C, Naik P, Kareithi T, et al. Online delivery of HIV prophylaxis services in Kenya: Results from the ePrEP Kenya pilot study. Presented at: 25th International AIDS Conference; July 22–26, 2024; Munich.
2. Kiptinness C, Naik P, Kareithi T, et al. Online delivery of HIV prophylaxis services in Kenya: Lessons from the ePrEP Kenya pilot study. Poster presented at: 25th International AIDS Conference; July 22–26, 2024; Munich.
3. World Health Organization (WHO). *Guideline on When to Start Antiretroviral Therapy and on Pre-exposure Prophylaxis for HIV*. WHO; 2015. <https://www.who.int/publications/i/item/9789241509565>
4. Nyblade L, Ndirangu JW, Speizer I, et al. Stigma in the health clinic and implications for PrEP access and use by adolescent girls and young women: conflicting perspectives in South Africa. *BMC Public Health*. 2022;22(1):1916. <https://doi.org/10.1186/s12889-022-14236-z>
5. Vellozo J, Khoza N, Scorgie F, et al. The influence of HIV-related stigma on PrEP disclosure and adherence among adolescent girls and young women in HPTN 082: a qualitative study. *Journal of the International AIDS Society*. 2020;23(3):e25463. <https://doi.org/10.1002/jia2.25463>
6. Mataboge P, Nzenze S, Mthimkhulu N, et al. Planning for decentralized, simplified PrEP: learnings from potential end users in Ga-Rankuwa, Gauteng, South Africa. *Frontiers in Reproductive Health*. 2022;4:1081049. <https://doi.org/10.3389%2Ffrph.2022.1081049>
7. Mayer K, Allan-Blitz LT. Post-exposure prophylaxis to prevent HIV: new drugs, new approaches, and more questions. *Lancet HIV*. 2023;10(12):e816–e824. [https://doi.org/10.1016/S2352-3018\(23\)00238-2](https://doi.org/10.1016/S2352-3018(23)00238-2)
8. Gilead's twice-yearly lenacapavir demonstrated 100% efficacy and superiority to daily Truvada® for HIV prevention. Press release. Gilead Sciences, Inc.; June 20, 2024. <https://www.gilead.com/news-and-press/press-room/press-releases/2024/6/gileads-twiceyearly-lenacapavir-demonstrated-100-efficacy-and-superiority-to-daily-truvada-for-hiv-prevention>
9. Grimsrud A, Wilkinson L, Delany-Moretlwe S, et al. The importance of the “how”: the case for differentiated service delivery of long-acting and extended delivery regimens for HIV prevention and treatment. *Journal of the International AIDS Society*. 2023;26(Suppl 2):d26095. <https://doi.org/10.1002/jia2.26095>
10. World Health Organization (WHO). *Differentiated and Simplified Pre-exposure Prophylaxis for HIV Prevention: Update to WHO Implementation Guidance*. WHO; 2022. <https://www.who.int/publications/i/item/9789240053694>
11. Global HIV Prevention Coalition. *HIV Prevention 2025 Road Map: Getting on Track to End AIDS as a Public Health Threat by 2030*. Joint United Nations Programme on HIV/AIDS; 2022. <https://www.unaids.org/en/resources/documents/2022/prevention-2025-roadmap>
12. International AIDS Society Differentiated Service Delivery. “One-Step PrEP®” – A community pharmacy-based PrEP clinic. Accessed February 12, 2024. <https://www.differentiatedservicedelivery.org/models/one-step-prep-a-community-pharmacy-based-prep-clinic/>
13. Tung EL, Thomas A, Eichner A, Shalit P. Implementation of a community pharmacy-based pre-exposure prophylaxis service: a novel model for pre-exposure prophylaxis care. *Sexual Health*. 2018;15(6):556–561. <https://doi.org/10.1071/sh18084>
14. Global Fund to Fight AIDS, Tuberculosis and Malaria. *Information Note: HIV Information Note*. Global Fund; 2022. https://www.theglobalfund.org/media/4765/core_hiv_infonote_en.pdf
15. Ministry of Health Kenya. *The Digital Health Bill, 2023*. Nairobi, Kenya: Ministry of Health; 2023. <https://health.go.ke/sites/default/files/Digital%20Health%20Bill%20Final.pdf>
16. Ngure K, Ortblad KF, Mogere P, et al. Efficiency of 6-month PrEP dispensing with HIV self-testing in Kenya: an open-label, randomised, non-inferiority, implementation trial. *Lancet HIV*. 2022;9(7):e464–e473. [https://doi.org/10.1016%2FS2352-3018\(22\)00126-6](https://doi.org/10.1016%2FS2352-3018(22)00126-6)
17. Cox SN, Wu L, Wittenauer R, et al. Impact of HIV self-testing for oral pre-exposure prophylaxis scale-up on drug resistance and HIV outcomes in western Kenya: a modelling study. *Lancet HIV*. 2024;11(3):e167–e175. [https://doi.org/10.1016/s2352-3018\(23\)00268-0](https://doi.org/10.1016/s2352-3018(23)00268-0)
18. World Health Organization (WHO). *Ethics and Governance of Artificial Intelligence for Health: WHO Guidance*. WHO; 2021. <https://www.who.int/publications/i/item/9789240029200>
19. Mendonca R, Rech D, Frade S, et al. The role of artificial intelligence (AI) in improving confidence and trust in private-sector telemedicine models for HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) delivery. Poster presented at: 25th International AIDS Conference; July 22–26, 2024; Munich.
20. MYDAWA. *Business case report*. Nairobi, Kenya: MYDAWA; 2023.
21. Chen Y, Saldarriaga E, Montañó M., et al. Preference heterogeneity among potential users of online pre-exposure prophylaxis provision in Kenya: a discrete choice experiment. Poster presentation at: IAS 2023, the 12th IAS Conference on HIV Science; July 23–26, 2023; Brisbane, Australia. Abstract MOPEE09. https://www.iasociety.org/sites/default/files/IAS2023/abstract-book/IAS_2023_Abstracts.pdf
22. MYDAWA. *Demand Generation Technical Report*. MYDAWA; 2023.
23. Pebody R. People need pathways from PEP to PrEP – and back again. *aidsmap* blog. March 5, 2024. Accessed July 13, 2024. <https://www.aidsmap.com/news/mar-2024/people-need-pathways-pep-prep-and-back-again>

24. Ministry of Health. *Kenya World AIDS Day Progress Report 2013–2021*. Ministry of Health, Republic of Kenya; 2021. <https://nsdcc.go.ke/wp-content/uploads/2022/02/WAD2021Report.pdf>
25. Joint United Nations Programme on HIV/AIDS. 2022 Kenya HIV country factsheet. Accessed February 25, 2024. <https://www.unaids.org/en/regionscountries/countries/kenya>
26. National AIDS and STI Control Program. *Kenya HIV & STI Combination Prevention SBC Strategy, 2019–2024*. Ministry of Health, Republic of Kenya; 2024. <https://www.prepwatch.org/wp-content/uploads/2022/08/National-HIV-Combination-Prevention-Communication-Strategy.pdf>
27. National AIDS and STI Control Program. *Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infections in Kenya – 2016 Edition*. Ministry of Health, Republic of Kenya; 2016. https://prep.nascop.org/wp-content/uploads/sites/2/2019/03/Guidelines-on-Use-of-Antiretroviral-Drugs-for-Treating-and-Preventing-HIV-in-Kenya-2016-Edition_1.pdf
28. Restar AJ, Tocco JU, Mantell JE, et al. Perspectives on HIV pre- and post-exposure prophylaxes (PrEP and PEP) among female and male sex workers in Mombasa, Kenya: implications for integrating biomedical prevention into sexual health services. *AIDS Education and Prevention*. 2017;29(2):141–153. <https://doi.org/10.1521/aeap.2017.29.2.141>
29. National AIDS and STI Control Program (NASCOP). *Framework for the Implementation of Pre-Exposure Prophylaxis of HIV in Kenya*. NASCOP Kenya, Ministry of Health; 2017. https://www.prepwatch.org/wp-content/uploads/2017/05/Kenya_PrEP_Implementation_Framework.pdf
30. AVAC: The Global PrEP Tracker. Accessed March 14, 2024. <https://data.prepwatch.org/>
31. Kiptinness C, Naik P, Thuo N, et al. Online HIV prophylaxis delivery: protocol for the ePrEP Kenya pilot study. *Frontiers in Public Health*. 2023;11:1054559. <https://doi.org/10.3389/fpubh.2023.1054559>
32. Bien-Gund CH, Ochwal P, Marcus N, et al. Adoption of HIV pre-exposure prophylaxis among women at high risk of HIV infection in Kenya. *PLoS One*. 2022;17(9):e0273409. <https://doi.org/10.1371/journal.pone.0273409>
33. Frontline AIDS. *Kenya: HIV Prevention Shadow Report 2020*. Frontline AIDS; 2024. <https://frontlineaids.org/resources/hiv-prevention-shadow-reports-2020/>
34. PrEPWatch. Country overview: Kenya. Accessed March 1, 2024. <https://www.prepwatch.org/countries/kenya/>
35. US President's Emergency Plan for AIDS Relief (PEPFAR). *Kenya Country Operational Plan 2022: Strategic Direction Summary*. PEPFAR; 2022. <https://www.state.gov/wp-content/uploads/2022/09/Kenya-COP22-SDS-.pdf>
36. Tapsoba JD, Cover J, Obong'o C, et al. Continued attendance in a PrEP program despite low adherence and non-protective drug levels among adolescent girls and young women in Kenya: results from a prospective cohort study. *PLoS Medicine*. 2022;19(9):e1004097. <https://doi.org/10.1371/journal.pmed.1004097>
37. Irungu EM, Odoyo J, Wamoni E, et al. Process evaluation of PrEP implementation in Kenya: adaptation of practices and contextual modifications in public HIV care clinics. *Journal of the International AIDS Society*. 2021;24(9):e25799. <https://doi.org/10.1002/jia2.25799>
38. PATH. *Ensuring Continuation of Essential DREAMS Services in Western Kenya During COVID-19*. PATH; 2024. <https://www.path.org/our-impact/resources/ensuring-continuation-essential-dreams-services-western-kenya-during-covid-19/>
39. International AIDS Society Differentiated Service Delivery. POWER PrEP delivery model, Uganda and Kenya. Accessed March 1, 2024. <https://www.differentiatedservicedelivery.org/models/power-prep-delivery-model-uganda-and-kenya/>
40. Ayieko J, Petersen ML, Kabami J, et al. Uptake and outcomes of a novel community-based HIV post-exposure prophylaxis (PEP) programme in rural Kenya and Uganda. *Journal of the International AIDS Society*. 2021;24(6):e25670. <https://doi.org/10.1002/jia2.25670>
41. Ortblad KF, Mogere P, Bukusi E, Ngure K, Baeten JM. Pharmacy delivery to expand the reach of PrEP in Africa. *Journal of the International AIDS Society*. 2020;23(9):e25619. [10.1002/jia2.25619](https://doi.org/10.1002/jia2.25619)
42. Ortblad KF, Mogere P, Omollo V, et al. Stand-alone model for delivery of oral HIV pre-exposure prophylaxis in Kenya: a single-arm, prospective pilot evaluation. *Journal of the International AIDS Society*. 2023;26(6):e26131. <https://doi.org/10.1002/jia2.26131>
43. Roche S, Omollo V, Mogere P, et al. Pharmacy-based PrEP delivery in Kenya: Findings from a pilot study extension. Presented at: 2023 Conference on Retroviruses and Opportunistic Infections; February 19–22, 2023; Seattle, Washington. <https://www.croiconference.org/abstract/pharmacy-based-prep-delivery-in-kenya-findings-from-a-pilot-study-extension/>
44. Salient Advisory. *Online Pharmacy in Africa: Supporting Pharmaceutical Regulatory Agencies to Advance Access to Essential Health Products*. Salient Advisory; 2023. <https://www.salientadvisory.com/reports/report-online-pharmacy-in-africa-regulatory-landscape-opportunities-for-action/>
45. Salient Advisory. Pharmacies as a source of contraception in Africa: A pathway for advancing online pharmacy regulations. Presented at: Bill & Melinda Gates Foundation Learning Session, July 6, 2023; virtual.