Scaling up and out: Exploring options for differentiated delivery of pre-exposure prophylaxis in Kenya

Stephanie Roche

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Reading Committee:

Jared Baeten, Chair

Gabrielle O'Malley

Bryan Weiner

Program Authorized to Offer Degree:

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Abstract

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Stephanie Roche

Chair of the Supervisory Committee:

Jared Baeten

Departments of Global Health, Epidemiology, and Medicine

In Kenya, daily oral pre-exposure prophylaxis (PrEP) for HIV prevention is a key component of the country's national HIV/AIDS response. Since its approval by the Kenya national drug regulatory authority in 2015, PrEP has been rolled out predominantly in HIV clinics; however, the country's 5-year plan for implementing PrEP at scale calls for integration of PrEP into other service delivery models and more efficient use of available resources. Currently, there is limited implementation science research to inform PrEP scale-up (i.e., expansion to additional HIV clinics) and scale-out (i.e., expansion to new service delivery models and populations) in Kenya. Our objective was to identify barriers and facilitators of PrEP integration and/or optimization in three healthcare settings: HIV clinics, family planning (FP) clinics, and retail pharmacies.

In Aim 1, we analyzed data from a prospective cohort study delivering integrated PrEP-FP services to adolescent girls and young women (AGYW) at two FP clinics in Kisumu, Kenya. Using the Consolidated Framework for Implementation Research (CFIR) and the Expert Recommendations for Implementing Change (ERIC) compilation, we identified supply-side implementation strategies for integrating PrEP into routine FP services and contextual factors influencing strategy choice and outcome, as captured in routine monitoring and evaluation documents (n=213) and key informant interviews (n=15). We found that, overall, implementing PrEP was more labor intensive at a public FP clinic compared to a private, youth-friendly clinic because it required a series of implementation strategies to make the physical and social environment conductive to offering AGYW-centered care. Nevertheless, provider adoption of PrEP delivery was low at

both clinics, likely due to the widespread perception that PrEP was not within their scope of work. We recommend that PrEP implementers approach PrEP implementation, in part, as a behavioral intervention for FP providers and specifically assess the need for implementation strategies that support providers' clinical decision-making, address workload constraints, and establish clear worker expectations.

In Aim 2, we conducted a pilot study of a one-stop shop (OSS) model for PrEP delivery at four public clinics in Western Province, Kenya and evaluated whether this model could improve care efficiency and acceptability without negatively impacting PrEP uptake or continuation. Interviews with clients (n=15) and providers (n=14), technical assistance reports (n=69), and clinic flow maps indicate that the OSS achieved efficiency gains by redirecting PrEP clients away from bottlenecks, moving steps closer together (e.g., relocating supplies; cross-training and task-shifting), and differentiating clients based on the subset of services needed. Analysis of time-and-motion observations (n=47) revealed that, following OSS implementation, median client wait time dropped significantly from 31 minutes to 6 minutes (p=0.02) while median time spent with a provider remained around 23 minutes (p=0.4). Clients and providers expressed a strong preference for the OSS model and additionally identified increased privacy, reduced stigma, and higher quality client-provider interactions as benefits of the OSS model. Controlled interrupted time series analysis of PrEP initiations (n=1227) and follow-up visits (n=2696) revealed no significant difference between intervention and control clinics in terms of trends in PrEP initiation and on-time returns (all p>0.05). We conclude that the OSS model is a promising option for reducing variability in service time and increasing client and provider satisfaction without adding additional human resources.

In Aim 3, we conducted a formative research study to understand the acceptability and feasibility of retail pharmacy-based PrEP delivery. Using the CFIR, we conducted and analyzed in-depth interviews with 40 pharmacy clients, 16 pharmacy providers, 16 PrEP clients, and 10 PrEP providers from Kisumu and Kiambu Counties, Kenya. Most participants expressed strong support for expanding PrEP to retail pharmacies, though conditioned their acceptance on assurances that care would be private, respectful, safe, and affordable. Participant-reported determinants of feasibility centered primarily on ensuring that the intervention is compatible with retail pharmacy operations (e.g., adequate staffing; use of documentation

systems that meet PrEP reporting requirements). Our findings may inform the development of a tailored package of implementation strategies for integrating PrEP into routine pharmacy practice.

Table of Contents

CHAPTER 1. Introduction 1

Background 1

Specific Aims 2

Innovation 6

CHAPTER 2. Implementation strategies for integrating pre-exposure prophylaxis for HIV prevention and family planning services for adolescent girls and young women: a multiple case study from a PrEP demonstration project in Kisumu, Kenya 8

ABSTRACT 9

INTRODUCTION 10

METHODS 11

RESULTS 13

DISCUSSION 19

CONCLUSION 22

TABLES 24

CHAPTER 3. A one-stop shop model for improved delivery efficiency of pre-exposure prophylaxis in public clinics in western Kenya: A mixed methods implementation science study 30

ABSTRACT 31

BACKGROUND 32

METHODS 33

RESULTS 35

DISCUSSION 39

ACKNOWLEDGEMENTS 41

TABLES & FIGURES 42

APPENDIX 49

CHAPTER 4. Acceptability and Feasibility of Pharmacy-Based Delivery of Pre-Exposure Prophylaxis in Kenya: A Qualitative Study of Client and Provider Perspectives 53

ABSTRACT 54

INTRODUCTION 55

METHODS 56

RESULTS 57

DISCUSSION 62

CONCLUSION 65

TABLES & FIGURES 67

APPENDIX 73
CHAPTER 5. Conclusions 84
REFERENCES 91

List of Figures

Figure 3.1 Boxplots of client wait time and provider contact time before and after implementing the One-Stop Shop..... 42
Figure 3.2 Example breakdown of client movement and service time before and after implementation of the One-Stop Shop 43
Figure 4.1 Determinants of pharmacy-based PrEP delivery acceptability and feasibility..... 67

List of Tables

Table 2.1 Monitoring and evaluation documents collected and analyzed 24

Table 2.2 Demographic characteristics of interviewees 25

Table 2.3 Key differences between Site A and Site B at study baseline 26

Table 2.4 Implementation strategies used and determinants influenced 27

Table 3.1 Demographic characteristics of clients who initiated PrEP and who received follow-up PrEP care during the study 44

Table 3.2 Strategies used by sites to implement the One-Stop Shop and illustrative quotes on how changes affected delivery inefficiencies (wastes) 45

Table 3.3 Provider-reported challenges to implementing the One-Stop Shop model 47

Table 4.1 Participant demographics 68

Table 4.2 Anticipated relative advantages of pharmacy-based versus clinic-based PrEP delivery 68

Table 4.3 Determinants of acceptability of pharmacy-based PrEP delivery 70

Table 4.4 Determinants of feasibility of pharmacy-based PrEP delivery 72

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DEDICATION

For Luis.

CHAPTER 1. Introduction

Background

Although Kenya's HIV incidence has fallen by nearly 75% and prevalence by 50% since 2000,[1] Kenya's HIV epidemic remains a serious threat to public health. In 2017, with 1.5 million people living with HIV and 52,800 new infections that year,[2] Kenya had the fourth highest number of incident HIV infections in Sub-Saharan Africa, trailing only South Africa, Nigeria, and Mozambique.[3] As countries work towards the Sustainable Development Goal to end the AIDS epidemic by 2030,[4] one promising biomedical intervention for HIV prevention is pre-exposure prophylaxis or "PrEP." In the early 2010s, clinical trials provided evidence that once-daily oral PrEP is safe and effective at preventing HIV when adherence is high.[5–8] The PrEP treatment strategy, which includes HIV testing, PrEP counseling, and PrEP dispensing, received further endorsement as an evidence-based intervention from the U.S. Food and Drug Administration,[9] the U.S. Centers for Disease Control and Prevention (CDC),[10] and the World Health Organization (WHO).[11] In 2015, the WHO recommended offering PrEP to all populations at substantial risk of HIV infection. Across 23 countries in Sub-Saharan Africa, dozens of open label, demonstration, and implementation projects are underway, with Kenya leading in terms of total number of PrEP enrollees.[12] Despite a sizable private healthcare sector in Kenya, most of the country's 56,500 PrEP users obtain PrEP from public HIV clinics.[12]

In 2017, the Kenya MOH released a 5-year plan for implementing PrEP at scale.[13] This plan calls for efficient use of available resources and improvement of PrEP accessibility through integration into existing service delivery models. Currently, there is limited implementation science research to inform PrEP scale-up (i.e., expansion to additional HIV clinics) and scale-out[14] (i.e., expansion to new service delivery models or populations) in Kenya. Much of the evidence generated from PrEP delivery projects in Kenya and elsewhere has centered on client outcomes (e.g., adherence, seroconversion) and their correlates.[15–17] Few studies have focused on implementation strategies (the processes that facilitate uptake of PrEP into routine use by practitioners),[18] contextual factors affecting these processes, or implementation outcomes, such as feasibility. In short, there is a major gap in our knowledge about *how* to get PrEP to those who need it in a way that consistently maximizes this intervention's HIV prevention potential. Such knowledge is essential to reproducing the low seroconversion rates achieved by some PrEP delivery programs.

Specific Aims

The overarching goal of this dissertation was to generate evidence to inform the scale-up and scale-out of PrEP in low-resource settings. The specific objective was to identify barriers and facilitators of PrEP integration into three different healthcare settings—HIV clinics, family planning (FP) clinics, and retail pharmacies—that the Kenya MOH has designated as potential scale-up sites. Notably, PrEP expansion to each of these settings is currently in a different scale-up phase,[19] with PrEP officially available in over 100 HIV clinics, in fewer than 40 FP clinics, and in zero retail pharmacies. Our central hypothesis was that PrEP can be successfully implemented in each of these settings (e.g., delivered with high fidelity and acceptability), but that variations in key determinants[20]—such as provider knowledge and beliefs about PrEP, implementation climate, and patient needs and resources—will necessitate the use of different implementation strategies. This proposed research leverages a timely opportunity, as PrEP scale-up is a key priority for the Kenya MOH.

Using data from (1) a demonstration project in FP clinics, (2) a pilot study of a new delivery approach in HIV clinics, and (3) a formative study in retail pharmacies, we pursued three specific aims:

- **AIM 1:** To evaluate the integration of PrEP delivery and family planning services, we conducted a qualitative study using in-depth stakeholder interviews and program data from routine monitoring and evaluation activities.
- **AIM 2:** To measure the impact of implementing a "one-stop shop" approach on PrEP delivery efficiency in HIV clinics, we conducted a mixed methods study to assess its effect on (1) wait time, (2) care acceptability, (3) PrEP initiations, (4) on-time returns for PrEP follow-up care.
- **AIM 3:** To assess the acceptability and feasibility of pharmacy-based PrEP delivery, we conducted a formative, qualitative study using in-depth interviews with pharmacy providers, PrEP providers, and current and prospective PrEP clients.

The need for differentiated models for PrEP delivery

For PrEP to impact population-level HIV incidence, sufficient coverage—defined as "uptake and persistence with sufficient adherence"[21]—must be achieved, especially among high-risk groups. In Kenya, a one-size-fits-all delivery model is unlikely to reach the large, diverse, and geographically dispersed population that could potentially benefit from PrEP. Service integration is one potential pathway for creating diverse PrEP delivery models that leverage existing resources and expand PrEP access and availability.[22] Efforts to integrate PrEP with antiretroviral therapy (ART) began in 2012 with the Partners Demonstration Project and have continued with the Partners Scale-Up Study which, since early 2017, has integrated PrEP in about two dozen public HIV clinics across Kenya.[23] Although integrated delivery of PrEP and ART achieved high PrEP uptake and adherence among HIV-uninfected partners in serodiscordant couples,[24] some studies have found that client desire for HIV clinic-based PrEP is tempered by concerns about stigma, opportunity costs, long wait times, and limited privacy at these often overcrowded facilities.[25–27] In other PrEP demonstration projects, some participants identified FP clinics and retail pharmacies as desirable additional locations for PrEP delivery,[28,29] and in its 2017 framework for implementing PrEP, the Kenya MOH established research on the feasibility of integrating PrEP into FP clinics and retail pharmacies as "high priority."[13]

Given important differences between ART and PrEP in terms of objectives (treatment vs. prevention) and duration of use (lifelong vs. during seasons of risk), delivering PrEP alongside other preventive services may make sense. In 2018, PrEP was integrated with maternal and child health (MCH) and FP services at eight public health clinics in western Kenya as part of the PrEP Implementation in Young Women and Adolescent Girls (PrIYA) study, in which 22% (278/1271) of PrEP-eligible clients initiated PrEP and 41% (114/278) returned for at least one refill.[15] In addition to showing that sexually-active adolescent girls and young women (AGYW) have considerable interest in and willingness to try PrEP, these findings suggest that integration of PrEP and MCH/FP services in this high HIV burden setting may be an effective way to reach this priority population.[30,31] Still, additional PrEP service delivery points are needed, especially for reaching at-risk men and/or individuals who do not use facility-based care. In a CDC disease surveillance project in western Kenya that tracked 27,000 individuals from 2006 to 2008, only about 25% of care-seeking for fever, acute respiratory infection, and diarrhea was in healthcare facilities; the remaining 75% of care-seeking took place in non-facility-based locations, most commonly retail pharmacies.[32] Several other

studies have also found that Kenyans commonly purchase health products and services, such as malaria medicines and contraceptives, from private retail pharmacies even when these services are available for free in public health facilities.[33–35] With approximately 5,800 registered outlets across the country,[36] retail pharmacies represent a promising, novel pathway to increase PrEP accessibility and coverage among those who prefer pharmacy-based care.

PrEP and Implementation Outcomes

Most of the published research on PrEP delivery in Kenya and elsewhere does not examine implementation outcomes or determinants. With the exception of cost-effectiveness analyses,[37–39] the majority of PrEP delivery research studies focus heavily on client outcomes—such as uptake, adherence, persistence, and seroconversion—and their correlates.[15–17] Measuring client outcomes in PrEP delivery projects is warranted because most attempts to deliver the evidence-based intervention to a different population or setting than the one in which it was originally developed; in addition, because such projects often introduce adaptations that could alter the EBI's effectiveness.[18] However, PrEP delivery projects also represent an opportunity to systematically study the delivery environment and the operational activities that workers conduct to deliver the service. Yet few PrEP delivery studies examine barriers and facilitators to implementation or implementation outcomes, which Proctor et al. define as "the effects of deliberate and purposive actions to implement new treatments, practices, and services."[40(p.65)] Assessing implementation outcomes—such as acceptability and feasibility—and determinants can inform scale-up decisions by further contextualizing the client and service outcomes observed, identifying prerequisite conditions for implementation success, and guiding the selection of *implementation strategies* for future projects.[18,40,41] A handful of PrEP delivery projects currently underway—such as the PrEP Implementation for Mothers in Antenatal Care (PrIMA) study[42] in Kenya—plan to assess implementation outcomes but have not yet published their results.

One challenge to studying acceptability is that, as with other implementation outcomes, there is little consensus regarding the definition and operationalization of this concept,[43] and the psychometric qualities of existing quantitative measures of acceptability are largely unknown.[44,45] Many PrEP acceptability studies assess this construct qualitatively. In their Implementation Outcomes Framework, Proctor et al. define acceptability as "the perception among implementation stakeholders that a given treatment, service,

practice, or innovation is agreeable, palatable, or satisfactory."[40(p.67)] Within the PrEP literature, PrEP acceptability studies tend to fixate narrowly on product acceptability (e.g., feelings about pill size, daily pill-taking, and side effects)[43,46] rather than on the acceptability of how PrEP is delivered. Prior research, however, suggests that the manner of PrEP delivery (e.g., where it is delivered, by whom) also affects client and provider judgements about this EBI's acceptability. More research is needed to broaden our understanding of the determinants of PrEP delivery acceptability, which are likely related to how the EBI affects their personal needs, preferences, and expectations.[44] We also need additional research on the implementation strategies that are best poised to address acceptability barriers[18] and how these implementation strategies operate to affect acceptability (i.e., their mechanisms of change).[47]

Similar gaps in our knowledge exist for the implementation outcome of feasibility, defined by Proctor et al. as "the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting."[40(p.69)] PrEP delivery studies commonly interpret high rates of PrEP uptake and adherence and/or low rates of seroconversion among clients as proof of PrEP delivery feasibility.[16] Such client outcomes, however, do not elucidate the resources needed or circumstances under which the EBI can be carried out easily or conveniently.[44] For example, client outcomes alone do not indicate how PrEP delivery can be successfully integrated into a busy provider's existing workflow. Additional research that could help inform plans for PrEP scale-up include investigation of the implementation strategies used (e.g., task-shifting), how easy or difficult it was for providers to integrate PrEP delivery into routine practice, and what preconditions helped or hindered PrEP delivery feasibility. Other discussions of feasibility in the PrEP literature focus on the feasibility of PrEP use by clients, often through testing client-targeted behavior change interventions (e.g., SMS reminders).[48,49] Although understanding client-facing barriers to PrEP use and identifying effective interventions for supporting PrEP use is important, such knowledge has limited utility for determining how best to get providers to integrate PrEP into routine practice, a necessary prerequisite condition for any PrEP delivery program to be successful. In short, although dozens of PrEP delivery projects in Kenya and elsewhere have managed to initiate tens of thousands of people on PrEP, our knowledge about the processes used to implement PrEP delivery—and the contextual factors that affect these processes—is still lacking.

PrEP delivery efficiency

Ensuring PrEP delivery efficiency is important for maximizing PrEP's impact on population-level HIV incidence. In Kenya, approximately 70% of the national HIV response is funded by international donors.[50] As such, changes in external funding—such as the recent reduction in PEPFAR support from USD $500 million in fiscal year (FY) 2019 to $365 million in FY 2021—pose challenges to sustaining HIV programming in Kenya.[51,52] As PrEP services are integrated into already burdened healthcare facilities, the likelihood of sustained implementation success will depend, in part, on achieving efficiency, which the National Academy of Medicine defines as "avoiding waste, including waste of equipment, supplies, ideas, and energy."[53(p.6)] Early evidence of PrEP delivery inefficiencies include non-streamlined workflows and duplicative administrative transactions. Despite many calls for "PrEP delivery optimization",[54–57] few studies have actually tested different implementation strategies to see if they lead to efficiency gains. One exception is the PrEP Optimized for Mothers (PrOM) study, which is currently developing an optimized approach for integrating PrEP with MCH/FP services in Kenya.[58]

One potential pathway for improving PrEP delivery efficiency is a "one-stop shop" approach. Following the WHO's 2012 call to provide TB and HIV services at the same time and location, several countries in Sub-Saharan Africa implemented one-stop shop models for TB and HIV care. In some models, TB and HIV care are offered under the same roof but by different providers (co-location).[59,60] In other models, providers are trained to offer TB and HIV services simultaneously (e.g., concurrent TB and HIV screening).[61–63] Some before-after studies of these models reported benefits, such as increases in linkage to HIV care, rates of early ART initiation, and TB treatment completion.[61,62] Identifying whether and how a one-stop shop approach to PrEP delivery can produce efficiency gains may have important implications for PrEP scale-up. Specifically, the Kenya MOH and other PrEP implementers could benefit from detailed reporting of the implementation strategies used in a one-stop PrEP shop and the effects on implementation outcomes.

Innovation

This research is among the first to use an implementation science approach to simultaneously examine PrEP integration into three different delivery platforms—HIV clinics, FP clinics, and retail pharmacies—each

in a different stage of scale-up in Kenya.[19] As such, the research was well-positioned to identify context-sensitive considerations for scale-up and examine whether and how implementation determinants vary with implementation setting, target population, and scale-up stage. Since Ministries of Health operate within limited fiscal space, this implementation information may be useful for policy makers as they decide which settings and populations will represent the most effective public health investment.

The Kenya MOH is currently spearheading the first national effort to create a formal pathway for pharmacy-based PrEP delivery. This research provides key insights from pharmacy providers, clients, and other stakeholders so policy leaders can design effective scale-out approaches that bridge the public and private sectors. Although this research does not craft policy language, it does provide guidance from the frontlines that highlights barriers and facilitators to implementation success. Kenya's support for this research represents an innovative shift for national HIV prevention, which could reduce infection through improved access to prophylactics. Kenya's model could trailblaze a path for other countries in Sub-Saharan Africa, thus providing a template for other Ministries of Health to adapt.

CHAPTER 2. Implementation strategies for integrating pre-exposure prophylaxis for HIV prevention and family planning services for adolescent girls and young women: a multiple case study from a PrEP demonstration project in Kisumu, Kenya

Stephanie D. Roche[1§], Gena Barnabee[1], Victor Omollo[2], Felix Mogaka[2], Josephine Odoyo[2], Elizabeth A. Bukusi[1,2,3], Jennifer F. Morton[1], Rachel Johnson[1], Connie Celum[1,4,5], Jared M. Baeten[1,4,5,6], Gabrielle O'Malley[1]

[1] Department of Global Health, University of Washington, Seattle, USA
[2] Centre for Microbiology Research, Kenya Medical Research Institute, Nairobi, Kenya
[3] Department of Obstetrics and Gynecology, University of Washington, Seattle, USA
[4] Department of Medicine, University of Washington, Seattle, USA
[5] Department of Epidemiology, University of Washington, Seattle, USA
[6] Gilead Sciences, Foster City, USA

[§] Corresponding author: Stephanie D. Roche
325 Ninth Avenue,
Seattle, WA 98104, USA
Phone: 001 X
Email: sroche@uw.edu

ABSTRACT

Introduction: Across sub-Saharan Africa, ministries of health have proposed integrating pre-exposure prophylaxis (PrEP) for HIV prevention into family planning (FP) services to reach adolescent girls and young women (AGYW); however, evidence on effective implementation strategies, or actions for enhancing the adoption, implementation, and sustainability of PrEP delivery in these settings, is still limited. We conducted a qualitative, multiple case study of integrated PrEP-FP service implementation at two FP clinics in Kisumu, Kenya.

Methods: From June 2017 to May 2020, the Prevention Options for Women Evaluation Research (POWER) study enrolled 1,000 sexually active, HIV-negative AGYW age 16 to 25. Actions taken to implement PrEP delivery were captured prospectively in 239 monitoring and evaluation documents and, at study endline, via 15 interviews with PrEP implementers. We analysed data using conventional and directed content analysis methods, with the latter informed by the Consolidated Framework for Implementation research (CFIR) and the Expert Recommendations for Implementing Change (ERIC) compilation.

Results: POWER deployed a variety of strategies to train and educate stakeholders, provide interactive assistance, and change infrastructure. Overall, implementing PrEP proved less labor-intensive at a private, youth-friendly clinic than a public FP clinic, largely because the baseline structural characteristics and culture of the former were more conducive to offering AGYW-centered care. Nevertheless, provider adoption of PrEP delivery at both sites was low, likely due to the widespread perception that PrEP was not within their scope of work.

Conclusions: Some FP clinics may be “lower-hanging fruit” than others for PrEP implementation. Approaching PrEP implementation as a behavioral intervention for FP providers may help ensure that providers have the requisite capability, opportunity, and motivation to adopt the clinical innovation. In particular, PrEP implementers should assess the need for implementation strategies that support providers’ clinical decision-making, establish worker expectations and accountability, and address workload constraints.

Clinical Trial Number: NCT03490058

Keywords: pre-exposure prophylaxis; implementation science; Kenya; delivery of health care, integrated; family planning services; HIV infections

INTRODUCTION

In eastern and southern Africa, adolescent girls and young women (AGYW) bear a disproportionate burden of the HIV epidemic. In 2019, AGYW age 15 to 24 accounted for 26% of new infections and were 2.5 times more likely to acquire HIV than their male counterparts.[64] Per WHO recomendations,[65] many countries in the region have designated AGYW as a priority population for daily oral tenofovir-based pre-exposure prophylaxis (PrEP) for HIV prevention.[66] Since 2014, substantial investments have been made to expand PrEP services to AGYW in this region.[67]

Research about PrEP delivery to this population has focused heavily (1) understanding end-users and (2) tailoring delivery approaches to meet their care needs and preferences. Studies in this first domain have measured PrEP use (e.g., uptake, adherence) and its predictors[15,68,69] and engaged AGYW to understand their PrEP decision-making.[68,70–72] Qualitative investigations have identified a variety of barriers to AGYW PrEP use, such as low HIV risk perception;[73–75] high stigma for being sexually active;[76] lack of financial independence;[77] and low social support for PrEP use.[75,78–80] These findings have motivated the second major area of research, centered on developing and testing delivery models and interventions to support AGYW PrEP use. These models vary not only by location (e.g., community safe spaces, mobile clinics) and types of providers involved, but also by services offered alongside PrEP and use of delivery innovations, such as digital pillboxes with SMS reminders to support adherence.[81]

Although our understanding of the “demand-side” of the PrEP delivery equation has grown steadily over the past decade, our understanding of the “supply-side” has not kept pace. In particular, our knowledge about supply-side implementation strategies—“actions taken to enhance the adoption, implementation, and sustainability”[82] of PrEP delivery—is still nascent. Beyond where PrEP is delivered and by whom, most PrEP initiatives do not provide granular detail about implementation strategies used (i.e., what actions were taken to integrate PrEP delivery into routine practice) or on how these strategies affected, and were affected by, contextual factors relevant to implementation, such as organizational culture. Yet, this level of detail is, arguably, fundamental for helping PrEP implementers understand the “how” of PrEP implementation and for informing their decisions about where to scale. To fill this gap, two frameworks from the field of implementation science may be particularly useful. The Consolidated Framework for Implementation

Research (CFIR) is a meta-theoretical framework of 39 constructs (or "determinants") hypothesized to predict, moderate, or drive implementation outcomes.[20,47] To optimize the CFIR for use in low- and middle-income settings, Means et al. incorporated an additional 11 constructs.[83] Developed via a narrative review of the literature[84] and a Delphi process,[85] the Expert Recommendations for Implementing Change (ERIC) compilation is a compendium of 73 discrete implementation strategies that can be used prospectively to support "consideration of a broad array of strategies" or retrospectively to support "a more comprehensive accounting of the strategies utilized."[86(p.2)] Perry et al. subsequently revised the ERIC compilation and introduced three additional strategies.[87]

We utilized both frameworks to evaluate the implementation of integrated PrEP-family planning (FP) services at two FP clinics in Kenya. From June 2017 to May 2020, the Prevention Options for Women Evaluation Research (POWER) study enrolled 2469 sexually active, HIV-negative AGYW age 16 to 25 in Kisumu, Kenya (n=1000) and Johannesburg and Cape Town, South Africa (n=1469). Because the Kenya Ministry of Health (MOH) is interested in scaling PrEP to FP clinics,[13] this sub-study focuses on POWER's two FP clinic sites. Our objective was to identify the supply-side implementation strategies employed by POWER, map these to contextual determinants, and understand the potential implications for scale-up.

METHODS

Study Setting

POWER's two Kenya sites were located in Kisumu County, where HIV incidence is 6.3 per 1,000 population—3.5 times the national average.[2] Site A was an FP clinic housed within the Maternal and Child Health Department of a public referral hospital. Site B was a youth-friendly FP clinic within a private, NGO-run health facility. At both sites, POWER introduced paid staff to help prepare for PrEP implementation (e.g., design clinic flows) and demonstrate PrEP delivery to site staff.

Data Collection

This study uses two data sources. From April 2017 to June 2020, we collected routine reports and notes from meetings and calls among POWER staff to discuss program monitoring and evaluation (M & E). These

M & E documents were generated in real time by various individuals, commonly the Seattle-based research manager and Kenya-based study coordinators.

From October to December 2019, we conducted 15 key informant interviews (KIIs). Our sampling frame included local staff (employed by a study site) and POWER staff (employed by the study) involved in PrEP service delivery and/or program implementation. In addition, eligible individuals were age 18 or above and self-reported comfort communicating in English. We used purposive sampling to recruit participants of different roles and primary employers. The Kenyan study coordinator contacted eligible individuals, described the study's purpose, and informed them that they would be contacted by an external research assistant (RA) about participating in a confidential interview. The RA (author SDR) was an American, female PhD student with doctoral-level training in qualitative research and no prior relationship with interviewees. She conducted all interviews one-on-one, in English, in a private room or via phone call, using a de novo semi-structured interview guide informed by the CFIR framework.[20,83] The guide solicited information on participants' role in PrEP implementation; perceived advantages and disadvantages of the delivery model; strategies used to implement PrEP delivery; and recommendations for scale-up. Interviews typically lasted 85 minutes (interquartile range: 67-90 minutes), were audio recorded, and transcribed verbatim.

Data Analysis

We analyzed data using a combination of conventional content analysis and directed content analysis,[88] with the latter informed by Perry et al.'s modified ERIC compilation[85,87] and Means et al.'s modified CFIR framework. After repeated readings of the data,[89] two experienced qualitative analysts (authors SDR and GB) developed an initial codebook of deductive codes (relevant CFIR determinants and ERIC strategies) and inductive codes. The codebook was refined iteratively via independent applications to data subsets and subsequent discussion. All documents were coded in ATLAS.ti v.8 (Scientific Software Development GmbH, Berlin, Germany) by SDR and reviewed by GB.

Ethics

The institutional review boards of the University of Washington and the Kenya Medical Research Institute approved this study. Written informed consent was obtained from interview participants. M & E activities were determined to be exempt.

RESULTS

We collected 214 M & E documents (**Table 2.1**) and 15 interviews (**Table 2.2**). Our interviewee sample was predominantly female (9/15, 60%) and employed by the POWER study (10/15, 67%). Below, we describe four themes that emerged. Throughout, we reference key differences between Sites A and B at study baseline (**Table 2.3**), some of which drove implementation strategy selection. **Table 2.4** summarizes these strategies (denoted in the text in bold) and the CFIR determinants they influenced (denoted in the text in bold and italic).

Theme 1 (Learning Environment & Provider Support): At both sites, providers benefitted from a mix of support services to enable PrEP delivery, including urgent, on-demand clinical decision-making support and routine, cross-site meetings to strategize about ongoing implementation.

According to interviewees, frequent PrEP trainings (**ERIC strategy 19**) held by POWER staff helped dispel some providers' initial safety concerns about offering an ARV-based product to healthy individuals (***Knowledge and Beliefs about the Intervention***). However, to successfully deliver PrEP, providers needed more than just accurate knowledge and positive beliefs about PrEP's safety and efficacy. Interviewees described sometimes encountering cases that required additional PrEP expertise. In these situations, they turned to the study coordinator, a trained clinician who provided local technical assistance (**ERIC strategy 54; *Access to Knowledge and Information***) in the form of on-demand clinical decision-making support:

> *When providers … had a client with a positive Hepatitis B test, or a pregnant lady that had questions that they could not answer, or a client who had side effects and they wanted my input, I would go and see the client.* (POWER study coordinator)

M & E documents indicate that the study coordinator also coached providers in their PrEP delivery approach, advising them, for example, to give clients ample autonomy in their decision-making:

> *One nurse declined to issue [PrEP] because she [the client] did not have somewhere to store PrEP in her house and did not intend to tell her husband. [The study coordinator] advised that no one should be denied PrEP because of lack of somewhere to store it … so participants should just be given PrEP if they need it, and they will find a way of dealing with their issues at home.* (Meeting notes, November 2017)

Providers also reported that having protected time to reflect on progress facilitated PrEP implementation (***Reflecting and Evaluating***). POWER providers had a weekly standing meeting (**ERIC strategy 48**) to review M & E reports (**ERIC strategy 5**) and discuss how to improve PrEP delivery (***Goals and Feedback)***:

> *There's constant feedback [on implementation]. There's a weekly report showing us how many [clients] we enrolled, how many are continuing, how many discontinued or restarted. We look at this overview of how our work is going and usually find areas to improve on. Like if the retention has gone down, we see on how to restructure [delivery] and what can work best.* (Male POWER staff, KII 6)

M & E documents further detail how provider capability to implement PrEP was enhanced by shared learning between the Kenya and South Africa sites. During monthly calls, members of this learning collaborative shared their implementation experiences, including successes and challenges (**ERIC strategy 20; *Learning Climate***). Common topics included how to reach potential PrEP clients and support clients' continued PrEP use. Tactics that worked well at one site were often subsequently tried at others (***Cosmopolitanism***). Overall, many interviewees felt that successful implementation of PrEP in other FP clinics would require ensuring providers are well-supported, especially in the beginning months of implementation.

<u>Theme 2 (Physical Environment & Clinic Flow)</u>: Site B's designated youth-friendly space and more streamlined clinic flow made implementing PrEP delivery to AGYW easier compared to Site A, which required a series of changes to its physical environment to create an acceptable clinic experience for AGYW.

Overall, integrating PrEP into routine FP services required fewer implementation strategies at Site B than Site A. Characteristics that appeared to make Site B better positioned at the outset included its designated

private space for serving youth and its existing clinic flow, which entailed less room-to-room movement for clients. As such, to add PrEP services, Site B did not need to reconfigure its clinic space or make major changes to how clients and providers move through service delivery.

Initially, Site A offered PrEP like any other outpatient service, with clients receiving HIV testing services (HTS) at HTS points, PrEP counseling and clinical review in consultation rooms, and prescription dispensing at the pharmacy. Providers soon found, however, that this delivery configuration was not acceptable to AGYW who were not keen on queueing at each service delivery point and who did not want to discuss their sexual activity in crowded FP consultation rooms (***Patient Needs and Resources***). Site A, therefore, adapted its workflow and space configuration (**ERIC strategies 74 and 11)**, acquiring a separate, private room for PrEP clients:

> *We realized that the FP rooms are too small because there are a lot of interns [nursing students] in there with the nurse. There was not enough privacy. So the in-charge gave us another room.* (Call notes, November 2017)

Site A also began fast-tracking clients to the front of HTS queues and implemented in-room PrEP dispensing so clients could skip the pharmacy. A few interviewees, however, expressed uncertainty as to whether Site A would, in the long-term, be able to maintain this new delivery configuration without hiring additional staff (***Perceived Sustainability***). Still, when asked what they thought would be essential to scaling PrEP delivery to other FP clinics, several interviews highlighted the importance of streamlined service delivery:

> *[It will be important] to look at the setting and how well it will suit PrEP delivery in terms of privacy and waiting time. Because those are the little things that contribute a lot, especially the waiting time. If a client waits for long, then the client will disappear, even if they really are at risk [of HIV].* (Male POWER staff, KII 6)

<u>Theme 3 (Perceived Scope of Work)</u>: At both sites, getting providers to fully and consistently engage in PrEP delivery was challenging, in part, because most viewed PrEP delivery as falling outside their scope of work. Bringing in additional staff to demonstrate how to deliver PrEP to AGYW may have inadvertently lowered providers' sense of responsibility toward PrEP delivery.

Throughout the study, low non-POWER staff engagement in PrEP delivery was common. The study's original intent was to have POWER staff demonstrate PrEP delivery to providers at each site (**ERIC strategy 60**) and for these providers to assume an increasingly larger role in PrEP delivery over time; however, by the study's end, only a few providers at Site B took to PrEP delivery and attended to PrEP clients on their own. More commonly, staff referred clients to POWER staff who, ultimately, conducted the bulk of PrEP education, counseling, and clinical review at both sites:

> *We [POWER staff] are not supposed to deliver PrEP ourselves. We are supposed to bring these guys [site staff] on board to deliver PrEP. … [But] getting staff to embrace this PrEP thing, we have been struggling. … Some feel like it is an added work. … If the client tells them, "I've heard about this thing called PrEP—" they send the client over to us [instead of attending to the client themselves].* (Female POWER staff, KII 8)

Providers at Site B generally agreed with their clinic's decision to add PrEP services, while providers at Site A did not. Four key differences in the ***Implementation Climate*** of Sites A and B (described below) were posited as shaping providers' feelings about implementing PrEP delivery for AGYW.

Alignment with organizational mission

Interviewees reported that providing PrEP to AGYW aligned with Site B's organizational mission to holistically support adolescent sexual and reproductive health (SRH):

> *[Site B's] core goal is serving young women. … ensuring their safety and well-being. So adding PrEP to [Site B] was viewed as great for girls and women.* (Female POWER staff, KII 1)

The organizational mission of the MCH department of Site A, by contrast, was broadly focused on providing MCH and FP services, with no specific emphasis on HIV prevention or adolescent health.

Experience with integrated service delivery

Some interviewees hypothesized that Site B providers were generally more open to adding PrEP services because providers were already accustomed to offering a bundle of SRH services whose composition shifts from time to time:

> *[At Site B], we offer integrated services … We always promote our services as a package to promote good health. …. And now that package includes PrEP.* (Male non-POWER staff, KII 9)

At Site A, however, integrated service delivery was not the norm. As such, PrEP delivery represented, in the eyes of some Site A providers, an entirely new set of responsibilities:

> *Some health personnel [at Site A] view it as extra work because, for them, PrEP is another whole package. You need to confirm HIV status. You need to assess HIV risk. You need to counsel. So some of them feel like it is a lot of work.* (Female POWER staff, KII 3)

Leadership engagement

Although POWER staff engaged leadership (**ERIC strategy 40; *Leadership Engagement***) at both sites, Site B leaders reportedly took a more active role in promoting PrEP delivery. For example, Site B leaders had monthly PrEP enrollment numbers publicly displayed and reported at weekly all-staff meetings:

> *[At Site B] the director is very supportive [of PrEP delivery]. We have all-staff meetings every week, and she wants to know what's going on, how we're faring. … And she tells everyone, "We need to work together on this for the betterment of AGYW." So others hear it right from the top.* (Female POWER staff, KII 8)

According to interviewees, Site A leaders also supported PrEP delivery. For example, they welcomed POWER staff to hold trainings and information sessions and, early on, allocated a private room for PrEP delivery; however, their support for PrEP delivery was generally more subtle and potentially less visible to other staff.

Youth-friendly service delivery skills

Lastly, Site A and B providers differed in that the latter were generally more experienced with delivering youth-friendly SRH services. As such, they reportedly had fewer moral reservations about providing PrEP to AGYW than Site A providers, many of whom had initial concerns about promoting "promiscuity." POWER staff reported assuaging some of these concerns over time, often through one-on-one conversations in which they appealed to providers' sense of empathy and professional duty to protect AGYW from HIV.

Delineation of worker responsibilities

Although support for adding PrEP services for AGYW was higher among Site B providers, such endorsement did not directly translate to provider adoption of PrEP delivery. Interviewees attributed low provider engagement in PrEP delivery to a widespread perception among providers at both sites that PrEP was not within their scope of work, or at least not while the POWER study was ongoing. As outsiders, POWER staff lacked the authority to formally update providers' job descriptions to include PrEP responsibilities or hold providers accountable if they did not engage in PrEP delivery. Most site staff,

therefore, opted to prioritize delivering services that had historically been included in their scope of work (***Relative Priority***). When asked about scaling PrEP delivery to other FP clinics, some interviewees highlighted the need for management to clearly communicate that PrEP delivery is part of their job:

> *There should be adjustments in that [PrEP] responsibilities should be given to the existing staffs so that they add onto their role. [Staff should be told,] "Despite your doing this, this [PrEP delivery] is also your department." … They [managers] have to talk to them and sensitize them on what they want [providers] to do so that they know, "This is what is supposed to be done."* (Female non-POWER staff, KII 5)

The presence of POWER staff may have inadvertently reinforced providers' perception that PrEP delivery was not within their scope of work. Because POWER staff were being paid to implement PrEP during the study, site providers reportedly viewed POWER staff's requests to engage in PrEP delivery as akin to dumping their responsibilities onto them:

> *Some providers would say, "No, we can't [deliver PrEP]. We are not paid by the POWER team, so we can't do their work."* (Female POWER staff, KII 7)

Lastly, providers' perception of PrEP delivery as "unpaid, extra work" may also have been fueled by a precedent set by other research studies that paid site staff to assist with service delivery. Indeed, throughout the first year of the study, POWER staff had to repeatedly decline requests from site staff for additional pay:

> *One challenge we're experiencing is that one of the HTS providers [at Site A] is always asking to be reimbursed whenever he refers a participant for PrEP. We'll make him aware that there is no reimbursement and whatever he does is part of his work.* (Call notes, February 2018)

<u>Theme 4 (Workload)</u>: Even providers who are willing to deliver PrEP to AGYW may be thwarted by existing high workloads. Overcoming this barrier may necessitate hiring additional staff and/or finding ways to lighten provider workload.

POWER staff reported that some portion of providers' low engagement in PrEP delivery was likely due to high workloads. Throughout the study, workload-related service delivery disruptions and delays were common at both sites:

> *At the end of the month, clients struggle to be served at [Site B's HTS point]. HTS providers are busy doing reports. … Currently, PrEP clients coming for follow-up have to go to another [department's] testing point.* (Meeting notes, May 2019)

Most interviewees, therefore, anticipated that workload would be a barrier if PrEP were introduced to other FP clinics, especially public ones:

> *Getting them [FP providers at Site A] involved [in PrEP delivery] was tough. And it's tough up to now. So if you want to transition PrEP [delivery] to the government, it will still be difficult for them because of the workload. Because when you put it [PrEP] together with family planning, … it actually needs understanding. You have to talk to this lady. They have to ask questions, and you have 70 other women to attend to. It is not easy.* (Female POWER staff, KII 18)

When asked what it would take to successfully implement PrEP in other FP clinics, nearly all interviewees emphasized the need for sufficient human resources and anticipated these would have to come from outside:

> *[FP clinics adding PrEP services] will need to employ more staff because, at the end of the day, the quality of healthcare is determined by the number of people [delivering and receiving services]. You see, nurses are human beings; lab technicians are human beings. They can only do so much. … But if there are enough [staff] compared to the patient ratio, at least providers wouldn't have the issue of straining or burnout.* (Female POWER staff, KII 3)

Acknowledging that hiring staff may not be feasible, a few participants recommended that PrEP implementers explore other ways to lighten providers' workload:

> *Human resources can be a constraint. … [So it will be important to look at,] "How many [clients] do you have? How many people can they see in what sort of through-put time?... We may not be able to hire staff or change the remuneration, but what are some of the other things that help people be able to do a good job? And it comes down to things like good working environment. … How do we protect that time for a healthcare worker [to attend to] a woman who walks in and requires PrEP and is going to take an hour, when they could have seen 10 other people [in that time]. So there is that genuine pressure around time that needs to be addressed.* (Female POWER staff, KII 13)

DISCUSSION

Across sub-Saharan Africa (SSA), PrEP implementers eager to reach AGYW are in the early stages of integrating PrEP into routine FP services. Our study adds to the literature on integrated PrEP-FP service delivery by linking two frameworks—the ERIC compilation and the CFIR—to describe how certain implementation strategies affected, and were affected by, a range of determinants at two FP clinics in Kenya

and how this interplay shaped the overall implementation process. Though specific to Kenya, our findings may help inform other countries' approaches to implementation, particularly if the goal is to scale to both public and private facilities.

Our study found that new PrEP providers benefitted from clinical decision-making support, suggesting that training alone may be insufficient to enable providers to routinely and independently deliver PrEP. Light touch support early on may help new PrEP providers "get their feet wet" and create the right learning environment for them to quickly gain confidence in their ability to deliver PrEP. PrEP implementers could, for example, avail subnational-level PrEP technical advisors in person or remotely. Such clinician support services have proven successful in other settings, such as the California-based National Clinician Consultation Center, which, since 1993, has provided free and confidential phone consultations to providers on HIV testing and prevention, treatment, co-infections, post-exposure prophylaxis, and PrEP.[90]

Whereas the current literature on integrated PrEP-FP delivery often refers to "FP clinics" as a uniform delivery setting, our study revealed key points of heterogeneity between two FP clinics that influenced implementation (e.g., organizational mission, clinic flow). Our finding that the youth-friendly clinic was potentially "low-hanging fruit" for this clinical innovation is consistent with other projects and programs in Kenya,[68] South Africa,[80,91] and Malawi,[92] which similarly reported that providers at these venues were generally open to delivering PrEP and that AGYW like obtaining services in these settings. The implications of our findings for scale-up are even clearer when placed within the context of a typology of health facilities recently developed by Dunbar et al. based on their assessment of 20 facilities in Kenya and Zimbabwe.[93] This typology places facilities on a "youth-friendly and HIV/SRH integration continuum," ranging from 1 to 5. Using this continuum, we see that POWER Site A was, at study baseline, a "Level 1" facility in that it did not have any special accommodations for providing youth-friendly services and, if clients needed more than one type of service, they were referred internally, without being escorted to, or fast-tracked at, the next service delivery point. By contrast, POWER Site B was, at baseline, a "Level 4" facility because, there, providers trained in youth-friendly service delivery offered fully integrated services in private, "youth only" spaces. Through this lens, we see that several of the implementation strategies employed at POWER Site A were, in effect, an attempt to make this "Level 1" facility more like a "Level 4" facility. Ultimately, POWER

staff managed to streamline PrEP delivery at Site A and convinced providers to assume a more youth-friendly attitude toward AGYW PrEP use. The effort to achieve this, however, was substantial, and the sustainability of this new service delivery configuration without additional staffing remains unclear. As countries scale up integrated PrEP-FP services, it will be important to consider the potentially heavier "lift" of implementing at facilities lower down on this continuum and to plan accordingly. More research is needed to better understand how much additional effort (and cost) it takes to successfully implement at lower- vs. higher-level facilities.

Our finding that POWER struggled to get non-POWER providers to assume PrEP delivery responsibilities echoes the early experiences of other PrEP projects (including ones that did not add staff)[22,94] and serves as a reminder that implementing integrated PrEP-FP services requires FP providers to view PrEP as part of SRH services and, thus, within their scope of work. The low adoption of PrEP delivery practices among non-POWER providers indicates that the bundle of implementation strategies employed by POWER did not sufficiently address provider motivation. Here, Michie et al.'s concept of "intervention function" is useful. Using behavioral science theory, the authors identified nine "intervention functions" or means by which an intervention can change behavior. In reviewing the implementation strategies POWER employed, we see that most had education, persuasion, or modeling functions. Few, however, had an incentivization function (creating expectation of reward), coercion function (creating expectation of punishment or cost), or restriction function (using rules to increase engagement in PrEP delivery or decrease engagement in competing behaviors). The common provider perception that PrEP delivery was not within their scope of work suggests that getting providers to adopt this behavior may require leaders/managers to employ additional strategies, such as "mandate change" (ERIC strategy 44) to formally revise providers' job responsibilities, "audit and provide feedback" (ERIC strategy 5) to hold them accountable, and "alter incentive/allowance structures" (ERIC strategy 2) as part of broader carrot-and-stick approaches to motivate behavior change. Furthermore, our study suggests that bringing in outside staff to assist with PrEP implementation should be used with caution (e.g., with a way to monitor the transition of responsibilities and a clear timeline for phase-out).

Evidence from other PrEP implementation projects[95,96] lend credit to POWER staff's concern that high provider workloads could derail implementation. For example, "increased workload and documentation burden amid healthcare workforce shortages" emerged as a key challenge in the PrEP Implementation for Young Women and Adolescents (PrIYA) study, which, from 2017 to 2018, integrated PrEP into 16 MCH/FP facilities in Kisumu, Kenya.[97] Drawing again from Michie et al.'s theory of behavior change, this finding suggests that, before asking providers to take on the additional work of PrEP delivery, implementers should ensure that the delivery environment affords providers sufficient "physical opportunity"[98(p.63)] (e.g., time, access to necessary resources) to adopt the desired behavior. For example, time-and-motion studies could help implementers understand how much, if any, available capacity providers have for PrEP delivery. If providers are at (or very close to) maximum capacity and clinics are unable to hire additional staff, then implementation is unlikely to succeed unless other clinical responsibilities are removed from providers' workloads and/or inefficiencies eliminated from provider workflow. A variety of strategies, including some already in use in SSA, may be pursued to this end, including shifting PrEP tasks to lower-level cadres (e.g., peer educators),[99] modifying clinical practices (e.g., adopting multi-month scripting to reduce client volume),[99–101] and using client-facing interventions, such as HIV self-testing[102] and decision-support tools,[103] to expedite the clinical encounter.

Our study has limitations. We only examined two FP clinics, both of which delivered PrEP within the context of a formal research study. Although much of PrEP delivery is being carried out in ways that transition from research to implementation, some of our findings may not apply to, or may overlook factors relevant to, other FP clinics not engaged in research. We did not collect detailed data on strategy dose, thus limiting insight into how intensely strategies must be used to get the observed effect. Since we did not collect data after POWER staff were withdrawn, we cannot comment on the sustainability of these strategies or duration of their effect. Future research should specify implementation strategies at study baseline (e.g., actor, action target, and dose)[104] and assess use and effect both quantitatively and qualitatively.

CONCLUSION

With scale up of integrated PrEP-FP services imminent in many parts of SSA, the need to understand which implementation strategies work best under what circumstances is greater than ever. Instead of categorizing

potential scale-up sites by the services offered (e.g., “FP clinics”), PrEP implementers should develop a broader range of criteria for assessing sites’ potential for implementation success and link these criteria to implementation strategies that may be needed. This more nuanced approach would allow implementers to better identify “low-hanging fruit” to prioritize for scale-up. It might also enable implementers to better anticipate, and plan for, the heavier “lift” of implementing at facilities that, though less prepared to deliver PrEP to AGYW at baseline, are critical for reaching this population.

TABLES

Table 2.1 Monitoring and evaluation (M & E) documents collected and analyzed

M & E Activity (frequency)	No. (%) documents (N=214)	Activity participants	Document author(s)
Routine reports (bi-weekly)	76 (36)	Site study coordinators, study staff involved in direct service provision	Project coordinator and site study coordinator
Research team calls* (monthly)	53 (25)	PIs, project manager, project coordinator, site study coordinators, study staff involved in direct service provision, research assistants, other co-investigators	Various participants
Operations calls (monthly)	33 (15)	Project coordinator, site study coordinator, study staff involved in direct service provision	Project coordinator
Coordinator calls* (monthly)	27 (13)	Site study coordinators, project coordinator, research assistants	Site study coordinators
Site team meetings (quarterly)	16 (7)	Site study coordinators, study staff involved in direct service provision	Site study coordinator
Research meetings* (annually)	9 (4)	PIs, project manager, project coordinator, site study coordinators, study staff involved in direct service provision, research assistants, other co-investigators	Various participants

*POWER staff from both the Kenya and South Africa study sites participated.

Table 2.2 Demographic characteristics of interviewees (n=15)

Characteristic	Value
Age – median (IQR)	30 (29-42)
Female – no. (%)	9 (60)
POWER as primary employer – no. (%)	10 (67)
Primary occupational role* – no. (%)	
Healthcare provider	10 (67)
Clinician (nurse or clinical officer)	6 (60)
HTS counsellor	3 (30)
Other counsellor	1 (10)
Other key informant**	5 (33)
Primary site affiliation – no. (%)	
Site A	6 (40)
Site B	6 (40)
Both	3 (20)

*Based on participant's primary role vis-à-vis PrEP delivery and the POWER study. For example, a participant who is a doctor by profession but whose primary role in POWER was a study coordinator is counted as "other key informant."

**Held administrative roles within the POWER study or at a study site

Table 2.3 Key differences between Site A and Site B at study baseline

Characteristic	Site A	Site B
Sector	Public	Private, non-profit
Facility type	Regional teaching and referral hospital	Stand-alone facility
Governing body	MOH	Executive board
Services offered at facility	Wide range of primary, secondary, and tertiary care (e.g., diabetes screening, pediatric oncology, intensive care)	Primary and secondary care focused on reproductive, maternal, neonatal, child and adolescent health services
PrEP delivery history	Prior to and during POWER study, PrEP also offered at hospital's HIV clinic and in modular booths at hospital entrance	Facility did not offer PrEP prior to POWER study
Where POWER study delivered PrEP -Description	Outpatient/MCH department -13 consultation rooms (2 specifically for FP), 6 waiting bays, 2 HTS points, 1 lab, 1 pharmacy	Youth-friendly clinic (YFC) -2 consultation rooms and 1 waiting bay. Lab and pharmacy in separate clinic area serving entire clinic.
FP client volume	~50 FP clients per day	~4 FP clients per day
Pre-study FP service delivery configuration	Clients check in at registration desk, then move to different service delivery points for HTS (mandatory), FP services, lab exams (if needed), and pharmacy services (if needed).	Clients go directly to YFC and receive FP services and, if needed, HTS in the same room by same provider or with providers coming to them. Clients move for lab exam and pharmacy services, as needed.
Baseline plan for PrEP integration	Train FP providers to deliver integrated PrEP-FP services (e.g., counsel clients about both at the same time), with clients continuing to receive HTS, lab, and pharmacy services from their respective service delivery points.	PrEP added to existing bundle of services offered to AGYW clients that included HIV testing and counseling, FP counseling, and cervical cancer screening.

Table 2.4 Implementation strategies used and determinants influenced, according to participants

ERIC strategy number	ERIC strategy name	CFIR determinant(s) influenced	Description	Illustrative quotes
19	Conduct ongoing training	+ Knowledge and beliefs about intervention	POWER staff periodically held trainings to educate site staff about PrEP and encourage them to refer clients for PrEP services	*At first, I was like, "Why are they giving people ARVs before they are sick? They will form resistance and that will be an issue." We [FP nurses] did not understand PrEP until they [POWER staff] gave us the CME [continuous medical education]. Then I learned that this thing actually protects people from getting HIV. … Once I learned what it was, I really embraced it.* (Nurse, not employed by POWER, IDI 4)
54	Provide local technical assistance	+ Access to knowledge and information	POWER study coordinator was available on-demand to answer providers' questions and assist with complex cases	*[If I had questions,] I normally turned to the study coordinator. All my questions have always been answered, especially the technical ones, because we need an expert in the medical field to assist at times.* (Counselor, employed by POWER, IDI 2)
48[a]	Organize implementation teams and team meetings	+ Reflecting and evaluating	POWER staff held weekly meetings to review M & E reports, discuss challenges, and devise improvement plans to reach their goal of enrolling 1000 AGYW.	*Through the week, we come with the challenges, the successes. We are getting the information from clients when we are making follow-ups. So in the [weekly] POWER meeting, we come and weigh, "How should we do this to make a change in this?" [If the M & E report shows high lost-to-follow-up rates, we discuss,] "How can we make these clients who are missing to come back for PrEP?"* (HTS provider, employed by POWER, IDI 7)
5	Audit and provide feedback	+ Goals and feedback		
20	Create a learning collaborative	+ Learning climate +Cosmopolitanism	POWER staff from Kenya and South Africa study sites shared implementation challenges experienced and lessons learned during monthly calls	*[A staff member from the Kenyan sites] reported that, for the past two months, they've had a lot of follow-up visits. … [A South African colleague] asked how the clients they enrolled during recent outreach activities are different from the ones they had trouble retaining in the past. [The Kenyan colleague] said they are doing more intense [HIV risk] screening and counseling to try to make sure the people [they enroll] are really interested in PrEP. They've found that those who come [to the clinic to initiate PrEP] later [i.e., in the days after the outreach event] tend to be more dedicated than the ones who they got on the day of the event. … So now the girls who enroll are doing so because they want to enroll, not because they feel like they need to.* (Call notes, December 2018)

74[b] 11	Assess and redesign workflow Change physical structure and equipment	+ Patient needs and resources -Perceived sustainability[c] (Site A only)	POWER staff worked with sites to reorganize service delivery to meet AGYW care preferences (e.g., privacy, short service times), though some interviewees, expressed concern about sustainability.	*When we saw that working within the FP space was not going well, [the head of site A's outpatient department] gave us the other room [i.e., a separate room for PrEP delivery] for privacy. … Queuing at the pharmacy was also a challenge to our participants because those who come … for ARVs would take at that [same] pharmacy. So stigma was there. [Clients worried,] "They will see as if I'm also taking ARVs." So we decided we'd let the nurse or the clinician prescribe and dispense the medication [from the private room]. Clients preferred that.* (Other key informant, employed by POWER, IDI 17) *Transitioning [i.e., ending POWER's involvement in PrEP delivery] may be a challenge because the queueing we were trying to avoid [clients from having to do], now it will force them [to queue].* (Counselor, employed by POWER, IDI 7)
40	Involve executive boards	+ Relative priority	At Site B, leaders had POWER staff report out PrEP implementation progress at weekly all-staff meetings.	*[Site B leaders] are like 100% [in favor of PrEP]. They even ask for feedback at the weekly [all-staff] meeting: 'How is it [PrEP delivery] going?' And sometimes when we reach our [enrollment] target, they tell us [POWER staff] to stand up and the whole team appreciates [i.e., applauds us].* (Counselor, employed by POWER, IDI 12)

60	Shadow other experts	+ Knowledge and beliefs about intervention - Relative priority -Perceived sustainability[c] (Site A only)	The study hired nurses and HTS providers to introduce PrEP delivery at study sites so site providers could observe how to deliver PrEP (e.g., how to counsel AGYW about PrEP). This infusion of human resources, however, may have lowered some providers' sense of responsibility towards PrEP delivery. For some interviewees, it also raised some concerns about sustainability.	*[POWER] brought in some other staffs for them [providers at site B] to shadow … to have a feel of it [PrEP delivery] and understand that there is not much work [involved in delivering PrEP]. … And some [providers] bought [into] the idea. … So bringing in other people to overshadow each one of them, I think those played a role [in facilitating PrEP implementation].* (Counselor, employed by POWER, IDI 12) *As much as we had our own responsibilities, I just got to a point and told myself that having knowledge will not hurt you in any way. … The POWER staff were mentors. They guided us [on] how do you enroll? How do you counsel? What do you tell these girls? So that is how I got to learn [about PrEP delivery] and started helping out here. But for the other staff, it was just an added responsibility. Already they had their jobs, the things they had to do. … They really associated PrEP with POWER.* (Clinician, not employed by POWER, IDI 1) *The POWER study was able to offer timely services because they had more healthcare workers. When that is translated to a normal MOH facility without such support, that may negatively affect it because people [clients] will have long waiting hours and may start to prioritize other things [over PrEP].* (Other key informant, not employed by POWER, IDI 16)

[a]Strategy name modified by Perry et al.
[b]Strategy added to ERIC framework by Perry et al.
[c]Construct added to CFIR framework by Means et al.

CHAPTER 3. A one-stop shop model for improved delivery efficiency of pre-exposure prophylaxis in public clinics in western Kenya: A mixed methods implementation science study

Stephanie D Roche[1], Josephine Odoyo[2], Elizabeth Irungu[3,] Benn Kwach[2], Annabell Dollah[2], Bernard Nyerere[2], Sue Peacock[1], Jennifer Morton[1], Gabrielle O'Malley[1], Elizabeth A Bukusi[1,2,4], Jared M Baeten[1,5,6,7], Kenneth K Mugwanya[1,6]

[1]University of Washington, Department of Global Health, Seattle, USA
[2]Centre for Microbiology Research, Kenya Medical Research Institute, Nairobi, Kenya
[3]Partners in Health and Research Development, Nairobi, Kenya
[4]University of Washington, Department of Obstetrics and Gynecology, Seattle, USA
[5]University of Washington, Department of Medicine, Seattle, USA
[6]University of Washington, Department of Epidemiology, Seattle, USA
[7]Gilead Sciences, Foster City, USA

Address for correspondence and reprints:
Stephanie Roche, University of Washington, Department of Global Health, 325 Ninth Avenue, Seattle, Washington 98104; email: sroche@uw.edu; phone: +1.206.520.3808; fax: +1.206.520.3831

Running head: Improving efficiency of PrEP delivery in Kenya

ABSTRACT

Background: In public clinics in Kenya, separate, sequential delivery of the component services of pre-exposure prophylaxis (PrEP) creates long wait times for clients. We conducted a mixed methods study to evaluate whether a one-stop shop (OSS) model could improve care efficiency and acceptability without negatively impacting uptake or continuation.

Setting: 4 public clinics (and 4 control clinics) in western Kenya

Methods: We used controlled interrupted time series (cITS) to compare trends in PrEP initiation and on-time returns from a 12-month pre-intervention period (Jan-Dec 2019) to an 8-month post-period (Jan-Nov 2020, excluding a 3-month COVID-19 wash-out period). From intervention clinics, we analyzed 47 time-and-motion observations using Mann-Whitney U tests, 29 provider and client interviews, 68 technical assistance reports, and clinic flow maps.

Results: From the pre- to post-period, average monthly initiations at intervention and control clinics increased by 6 and 2.3, respectively, and percent of expected follow-up visits occurring on time decreased by 18% and 26%, respectively; cITS analyses revealed no significant difference between intervention and control clinics (all $p>0.05$). At intervention clinics, median client wait time dropped significantly from 31 to 6 minutes ($p=0.02$), while median provider contact time remained around 23 minutes ($p=0.4$). OSS achieved efficiency gains by moving delivery to lower volume departments, reducing room-to-room movement, and differentiating clients by services needed. Clients and providers strongly preferred the OSS model.

Conclusion: An OSS model significantly improved client wait time and care acceptability without reducing initiations or continuation, thus highlighting opportunities to improve PrEP delivery efficiency and client-centeredness.

Key words: pre-exposure prophylaxis; implementation science; quality improvement; organizational efficiency; HIV prevention; Kenya

BACKGROUND

In the 6 years since the WHO released guidelines recommending daily oral tenofovir-based pre-exposure prophylaxis (PrEP) for populations at substantial risk of HIV infection,[65] 21 countries in sub-Saharan Africa (SSA) have implemented pilot or national PrEP programs.[105] From 2016 to 2020, these programs successfully initiated on PrEP 500,000 individuals from diverse at-risk populations.[105] Still, PrEP uptake across the region has fallen short of UNAIDS targets, which aimed to have 3 million PrEP users worldwide by 2020.[106] Drawing on lessons learned from differentiated service delivery (DSD) for antiretroviral treatment (ART),[107] recent PrEP implementation efforts in SSA and globally have focused heavily on diversifying PrEP models in terms of delivery location, provider type, frequency of contact, and package of services offered.[108,109] Many DSD models have moved PrEP delivery outside of clinical settings[107,109] to circumvent barriers, such as long wait times, HIV stigma, insufficient privacy, and poor treatment from healthcare providers.[29,68,110–112] Less attention, however, has been given to improving existing models of PrEP delivery used in public healthcare facilities. Recognizing that such facilities will play a key role in achieving PrEP at scale, some PrEP implementers have called for "PrEP delivery optimization,"[54–57] including the Kenya Ministry of Health (MOH), which encouraged development of "facility-based fast track models"[113(p.61)] in its latest strategic AIDS framework.

Currently, in most public healthcare facilities, services are delivered sequentially by different providers at different delivery points (e.g., HTS delivered by HTS providers at HTS points; dispensing done by pharmaceutical technologists at the pharmacy) with clients moving between, and frequently queueing at, each. One promising option for optimizing PrEP delivery is a "one-stop shop" (OSS), a broad term for models that deliver all necessary services at a single touchpoint. Whereas some co-locate services so clients receive them "under the same roof," others further reorganize services so clients receive them in a single room and/or from a single provider.[114,115] Regardless of configuration, the underlying rationale is the same: to increase delivery efficiency and client satisfaction by eliminating unnecessary wastes, such as queueing and movement. In SSA, OSS models have primarily been used to integrate previously separate service lines, like HIV and TB[59–61,63] or family planning (FP) services.[116–121] An OSS model that consolidates the core components of the PrEP treatment regimen (HIV testing services [HTS], counseling, periodic clinical assessment, and drug dispensing) has yet to be implemented and evaluated within the context of

routine PrEP delivery in SSA. As countries scale up PrEP, they may benefit from understanding how some, or all, of these steps might be consolidated and the impact on client care experiences. We, therefore, conducted a mixed methods study at 4 public healthcare facilities in Kenya to understand if an OSS for PrEP could improve delivery efficiency and client and provider satisfaction without negatively affecting uptake and continuation.

METHODS

Study background and design

Beginning in 2017, the Partners Scale-Up Project (PSUP) catalyzed national scale-up of PrEP through provision of technical assistance (TA), initially to 25 clinics and later to over 100 clinics.[122] In late 2019, PSUP invited 4 clinics in Western province to pilot an OSS. Two clinics transitioned all PrEP care to their differentiated care clinics where stable clients receive express ART services. The other two clinics integrated PrEP services into the family planning (FP) clinic or gender-based violence (GBV) clinic while maintaining PrEP delivery at their HIV comprehensive care clinic (CCC).

Our study used a convergent mixed methods design,[123] with quantitative and qualitative data collected simultaneously and given equal weight during analysis.[124] To mitigate the influence of the COVID-19 outbreak on our study, we extended our original post-intervention period (from Apr. to Nov. 2020) and treated Apr.-Jun. 2020 as a wash-out period for quantitative data. This study was approved by the institutional review boards of the University of Washington and the Kenya Medical Research Institute, which did not require individual consent for client data collected as part of routine health services; written informed consent was obtained for interviews.

Data collection and analysis

Data Collection

Quantitative

PSUP staff abstracted data on demographics, HIV risk factors, and PrEP use from clinical records of individuals who initiated PrEP and/or received follow-up care from Jan. 2019 through Nov. 2020 and entered it into SurveyCTO (Dobility, Inc., Cambridge, USA). At study baseline and endline, trained PSUP staff used a structured tool to conduct 47 time-and-motion observations of PrEP initiation and follow-up

visits at OSS clinics. Total service time was divided into time spent with a provider (contact time) and time spent walking or waiting (wait time).

Qualitative

During the post-period, TAs conducted bimonthly clinic visits and generated reports (n=69) and clinic flow maps. In Oct. and Nov. 2020, Kenyan qualitative researchers (authors BK and AD) conducted interviews with (1) healthcare providers employed by an OSS clinic or the County Department of Health and (2) PrEP clients. Eligible individuals delivered or oversaw the delivery of OSS PrEP services (provider group) or obtained PrEP at an OSS at least once (client group), were age 18 or above, and self-reported comfort communicating in English. We used purposive sampling to recruit providers of different cadres and clients of different sexes, ages, and exposure (yes/no) to the clinic's pre-OSS model. We developed semi-structured interview guides that solicited, from providers, details about OSS operations, barriers and facilitators, and perceived advantages and disadvantages, and, from clients, OSS visit descriptions, perceptions of care quality, and recommendations for improvement. All interviews were conducted one-on-one, in English, in a private room or via phone, audio recorded, and transcribed verbatim by the interviewer, with transcripts spot-checked for quality by author SDR.

Data Analysis

Quantitative

Our primary outcome was client wait time, as captured in time-and-motion observations. We performed Mann-Whitney U tests to assess whether median wait times differed significantly from the pre- to post-periods. Secondary outcomes included clinic-level rates of PrEP initiation and percent of expected follow-up visits that occurred on time, with "on time" defined as "occurring within two weeks of the date the client would run out of PrEP pills, according to dispensing records." We assessed descriptive statistics of clients and collapsed data to obtain monthly counts of our outcomes. Using a controlled interrupted time series (cITS) approach, we compared the 4 OSS clinics to 4 control clinics with similar pre-intervention levels and trends in the outcomes. We modeled incidence rate ratios with negative binomial models with first-order autoregressive structure and included random intercepts and random slopes to account for clustering by clinic and clinic-level heterogeneity in intercepts and trends over time. Each model included fixed effects

for study month, treatment group (intervention vs. control), number of months since OSS implementation, and interactions for each pairwise combination to allow estimation of the pre- and post-implementation time trends and the immediate effect of implementation on the outcomes of interest. All quantitative analyses were conducted using RStudio (RStudio Team, version 1.4.999).

Qualitative

Interviews and TA reports were analyzed using a combination of directed and conventional content analysis.[88] Our codebook included deductive codes for the types of waste in Ohno's model for continuous quality improvement and change concepts identified by Langley et al.,[125,126] and inductive codes identified during repeated readings of the data.[89] Author SDR drafted interview memos with a summary of key points for each code, quotations, and analytic reflections[127] that drew comparisons across participants and datasets and synthesized findings into higher-level themes.[128] Memos were reviewed by the interviewers, with disagreements resolved through group discussion. Simultaneous integration[129] of qualitative and quantitative data was further achieved through the development of joint displays to determine common concepts and explore how results confirmed, contradicted, or expanded upon one another.[130] To highlight the relationship between actions and improvement, we organized the identified implementation strategies according to change concepts compiled by Langley et al.[126] Additional details on our methodology are included in the Supplemental Digital Content (**Table S1**).

RESULTS

Participants and data

PrEP clients

During the 12-month pre-intervention period, intervention and control clinics initiated 385 and 212 clients on PrEP, respectively. During the 8-month post-intervention period, intervention and control clinics initiated 410 and 220 clients on PrEP, respectively. In both groups during both periods, approximately 60% of clients were female and about 75% were 18- to 34-years-old and in a known serodiscordant relationship (**Table 3.1**). Intervention and control clinics had, respectively, 1276 and 620 follow-up visits during the pre-intervention period and 523 and 277 follow-up visits during the post-intervention period. Distributions of sex, age, and HIV risk factors were similar across groups and periods.

Interview participants

We interviewed 14 providers and 15 clients. Providers included 6 clinical officers, 4 nurses, 2 counselors, and 2 administrators; 43% (6/14) were female, and median age was 34 (interquartile range [IQR]: 33-38). The client sample was 53% female (8/15) and had a median age of 39 (IQR 29-41). Most clients (13/15) were married, and all had children. About half (7/15) experienced PrEP delivery under both the pre-OSS and OSS models.

OSS Impact on PrEP initiations and on-time returns

From the pre- to the post-period, the average monthly number of PrEP initiations increased by 6 at OSS clinics (from 7.6 to 13.6) and by 2.3 at control clinics (from 4.5 to 6.8); results of cITS analyses revealed no significant difference between OSS and control clinics with respect to immediate change in initiations at the time of OSS implementation (p=0.5) or over time (p=0.4). From the pre- to the post-period, the average monthly percent of expected follow-up visits that occurred on time decreased by 18% at OSS clinics (from 70% to 52%) and by 26% at control clinics (from 70% to 42%); cITS analyses again found no significant difference between OSS and control clinics with respect to immediate change (p=0.08) in this outcome or change over time (p=0.6).

OSS impact on service time

Median client wait time dropped significantly from the pre- to post-period (31 minutes [IQR 0-71] vs. 6 minutes [IQR 0-13], p=0.02), but median provider contact time remained the same (24 minutes [IQR 10-38] vs. 22 minutes [IQR 5-40], p=0.38) (**Figure 3.1**). Analysis of clinic flow maps, TA reports, and interviews suggests that five main strategies (**Table 3.2**) drove this efficiency gain.

Change Concept 1: Redirect away from bottlenecks

Although a few providers noted occasional back-ups at the OSS, all providers agreed that, on average, moving PrEP delivery to a lower volume department reduced client wait time:

> [At the CCC] we have both those who are on [ART] care and those who are coming for PrEP. … But here [at the OSS], we are only dealing with Gender-Based Violence [clients], which are less. So they [PrEP clients] spend shorter period here before they are attended to. *(Male clinical officer, clinic D)*

One provider felt that the OSS especially benefits PrEP follow-up clients who require little time with a provider:

> [Imagine] someone has just come for a [PrEP] refill. You know, [for a] refill, you just come, take your drugs, do a quick follow-up, and leave. So there's no need of putting these [PrEP] clients waiting for long at the [CCC] queue." *(Male clinical officer 2, clinic B)*

Clients similarly characterized the CCC as overcrowded and reported that moving PrEP delivery out of the CCC reduced HIV stigma:

> The wait time has gone down. Previously, I'd sometimes wait for 2 hours before being seen [at the CCC]. It's because we were mixed together with ART clients, which also wasn't good because some fear someone might look at you and say you're HIV-positive. *(Female PrEP client, clinic A)*

Providers, especially those new to PrEP delivery, expressed relief that OSS workload was manageable. Some also reported that the OSS reduced CCC providers' workload:

> [CCC providers] are happy that they have been relieved of [PrEP] delivery. They used to handle [ART] duties and then attend to PrEP clients as well. Now they are left with their key [ART] duties. *(Male peer educator, clinic A)*

Change Concept 2: Move steps closer together

Providers reported that the OSS model consolidated many of the core components of PrEP by relocating the necessary supplies to the OSS and shifting some PrEP delivery tasks to other cadres.

> In the CCC, the way it's designed there, the stations are at different points. The reception is at [a] different area, the pharmacy at [a] different area, clinical room at a different place. The One-Stop Shop is beneficial because you break the issue of … having these [PrEP] clients moving from one point to the other. You just have everything there. *(Male clinical officer 1, clinic B)*

Figure 3.2 further illustrates how eliminating stops at the registration, triage, and pharmacy areas reduced client movement and queueing.

In addition to the time and motion savings, most clients reported that this consolidation enhanced their privacy by reducing the number of providers they see and enabling them to skip the pharmacy.

> [At the OSS] they just give [PrEP] to you, you put it in your bag, and leave. No one will know I am taking PrEP because I don't have to go the pharmacy to queue with everyone else. *(Female PrEP client, clinic C)*

Some providers reported that centrally locating PrEP supplies reduced their movement around the clinic and facilitated more accurate, in-flow PrEP documentation.

HIV testing was the one component of PrEP delivery not performed within any clinic's OSS. Time-and-motion data indicated that traveling to/from an HTS point and queueing there typically accounted for 55% of clients' wait time (IQR: 39%-100%). About half of providers (7/14) and clients (7/15) recommended adding in-room HIV testing to the OSS.

Change Concept 3: Use differentiation

Two clinics differentiated PrEP clients from others by fast-tracking PrEP clients to the front of a designated OSS clinician's queue. A third clinic implemented fast-tracking at the HTS point. Three clinics additionally differentiated clients requiring clinician attention (e.g., clients initiating PrEP) from those who did not (e.g., follow-up clients with no issues) by allowing counselors to fully attend to the latter.

Implementation Challenges

General challenges

Early challenges (**Table 3.3**) included having few staff designated to deliver PrEP, initial resistance from providers who felt unprepared to deliver PrEP, and pushback against in-room HIV testing by one clinic's HTS Department. These were addressed through additional training, implementing staff rotations, and modifying OSS configuration to use HTS points.

COVID-19-related challenges

Clinics encountered several COVID-19-related challenges and adapted accordingly. For example, staffing shortages at two clinics necessitated moving the OSS clinician to the CCC to provide ART care.

> Last visit, we observed PrEP clients being escorted to the CCC to be seen by the [OSS] clinician there, who reported that it was tiresome/difficult for him to move back and forth to the OSS during busy ART clinic days. … But he [the OSS clinician] referenced plans to reorganize operations to involve the peer educator more. … We've since observed the peer educator seeing stable follow-up clients and only calling the clinician over when there's a new enrolment. *(TA report, June 2020, clinic A)*

The second of these clinics had to relocate its OSS to the CCC when the former space was appropriated for COVID-19 care.

OSS impact on service quality

Whereas some provider interviewees expressed hope that the OSS would eventually increase PrEP initiations and improve continuation, a few viewed the primary value of the OSS as better meeting clients' care preferences, a benefit also reported by many clients.

> I loved the time I had with the [OSS] providers because, before [at the CCC], they never took a lot of time with me to share the important things. … So I am seriously very happy. *(Female PrEP client, clinic B)*

> I liked the [OSS] experience. I didn't feel rushed at any point. They even offered me time to ask questions. … Today I was treated way much better as compared to before. … [Back] at CCC, they generally were not friendly. [They would say,] 'What do you want? Sit there.' … But a hospital needs a friendly atmosphere where someone will start recovering even before seeing a healthcare provider. *(Male PrEP client, clinic A)*

DISCUSSION

Delivery inefficiencies threaten to undermine the public health impact of PrEP by tempering both client willingness to access and continue PrEP and provider ability to deliver PrEP services at public health facilities. Our study adds to the PrEP delivery science by identifying a basic change package of low-cost, easy-to-implement strategies that enabled public clinics to significantly reduce client wait time and improve client and provider satisfaction. The reported benefits of the OSS included not only less waiting time (queueing and movement) but also reduced stigma, enhanced privacy, and higher quality client-provider interactions. Though specific to Kenya, our findings may have broad applicability to other public health systems in SSA that have similarly been organized around delivering curative care through highly differentiated service lines.[131]

Throughout SSA, PrEP is being added to public health systems that are already resource-constrained, resulting in challenges for provider buy-in.[132–134] Providers in our study, however, demonstrated their willingness to change how they deliver PrEP, even if this meant taking on additional work. Their emphasis on how the OSS made their clients happy suggests that clinicians were motivated, in part, by positive client feedback. This finding aligns with other qualitative studies with PrEP providers,[95,135] as well as theories from behavioral and implementation science which posit that provider willingness to adopt an innovation is driven, in part, by feelings of purpose[136] and belief that the innovation will confer a relative advantage.[20] Providers also may have been motivated to change their delivery practices because of the efficiency gains it created for them (e.g., less room-to-room movement), which freed up time for them to spend with other

clients. Overall, our findings suggest that, even in resource-constrained settings, providers may be more willing to take on PrEP delivery when the model is efficient and patient-centered. Ensuring that providers understand these benefits will likely be an important step for securing their support.

Task-shifting is a commonly used strategy for addressing human resource constraints across SSA,[137] especially for ART delivery.[138,139] Similarly, the clinics in our study task-shifted specialized tasks "down" to lower-level cadres, such as moving PrEP dispensing from pharmaceutical technologists to peer educators; however, contrary to prevailing practices, clinics also achieved efficiency gains by moving less specialized tasks "up" to higher-level cadres. For example, at times, clinicians, instead of peer educators, retrieved client files and took vital signs. Although in many contexts, task-shifting "up" would be considered a poor use of a rare resource (a clinician), our study found that, in the context of highly fragmented service delivery and unreliable wait times at other service delivery points, task-shifting "up" simple tasks with short cycle times makes sense as an improvement strategy. This strategy also worked well in this context because clinics relocated all necessary supplies to the OSS room, thereby ensuring that the time OSS providers spent with clients was predominantly "value-add" and not wasted searching for or retrieving materials from other clinic areas. In short, task-shifting "up" in this context corrects for some of the negative consequences of an organizational structure that prioritizes differentiation by function over coordination of functions.[140] Our finding that PrEP clients strongly prefer to see fewer providers also aligns with prior studies on ART client care preferences.[141–143] Future research is needed to investigate the impact of task-shifting "up" on PrEP clinician productivity and to evaluate client and provider satisfaction with alternative OSS models, such as ones with in-room HIV testing.

In African ART programs, differentiated models for stable and not-yet stable ART clients have emerged, in part, because client groups do not require the same subset of services.[144] Clinics in our study incorporated differentiation into their OSS models by separating PrEP clients from not-yet stable ART clients and by separating new PrEP initiators from those coming for PrEP refills. By building workflows around the different types of clients and their sets of needs, the OSS model created greater predictability in service times. Whereas high variation in service times often mars patient satisfaction with public facility-based services,[145–147] the PrEP clients in our study were deeply satisfied with the shorter, more consistent wait times.

Importantly, clinics reduced variation in service time without any additional human resources, making the OSS model a promising option for PrEP programs working within limited fiscal space.

Our study has limitations. We interviewed providers and clients willing to deliver or obtain OSS PrEP services at a public clinic in Kenya; their perspectives may not generalize to other providers and clients. We did not collect quantitative data on clinics' fidelity to their OSS model. Future research should capture this information to understand at what level of fidelity the model needs to be executed to achieve the same outcomes. Most clients obtained follow-up care at the OSS only once; it is possible that our post-intervention period was not long enough to capture a lagged effect on continuation.

For PrEP to succeed as a public health intervention, it not only needs to be available at scale, but also used by the target population with sufficient rates of uptake, persistence, and adherence.[21] An OSS approach to PrEP delivery may be useful not only for increasing through-put, but also for obtaining provider buy-in and making care more patient-centered such that clients are willing to come for this preventive service again and again.

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TABLES & FIGURES

Figure 3.1 Boxplots of client wait time (panel A) and provider contact time (panel B) at intervention clinics before and after implementing the One-Stop Shop

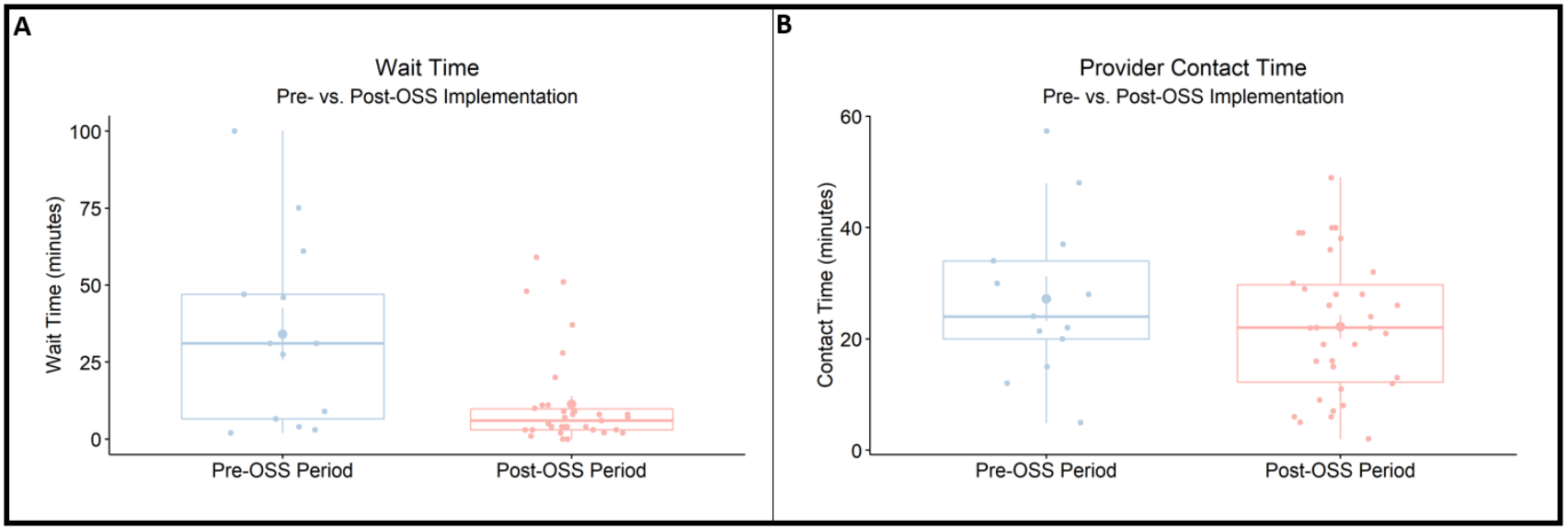

Figure 3.2 Example breakdown of client movement and service time before (panel A) and after (panel B) implementation of the One-Stop Shop

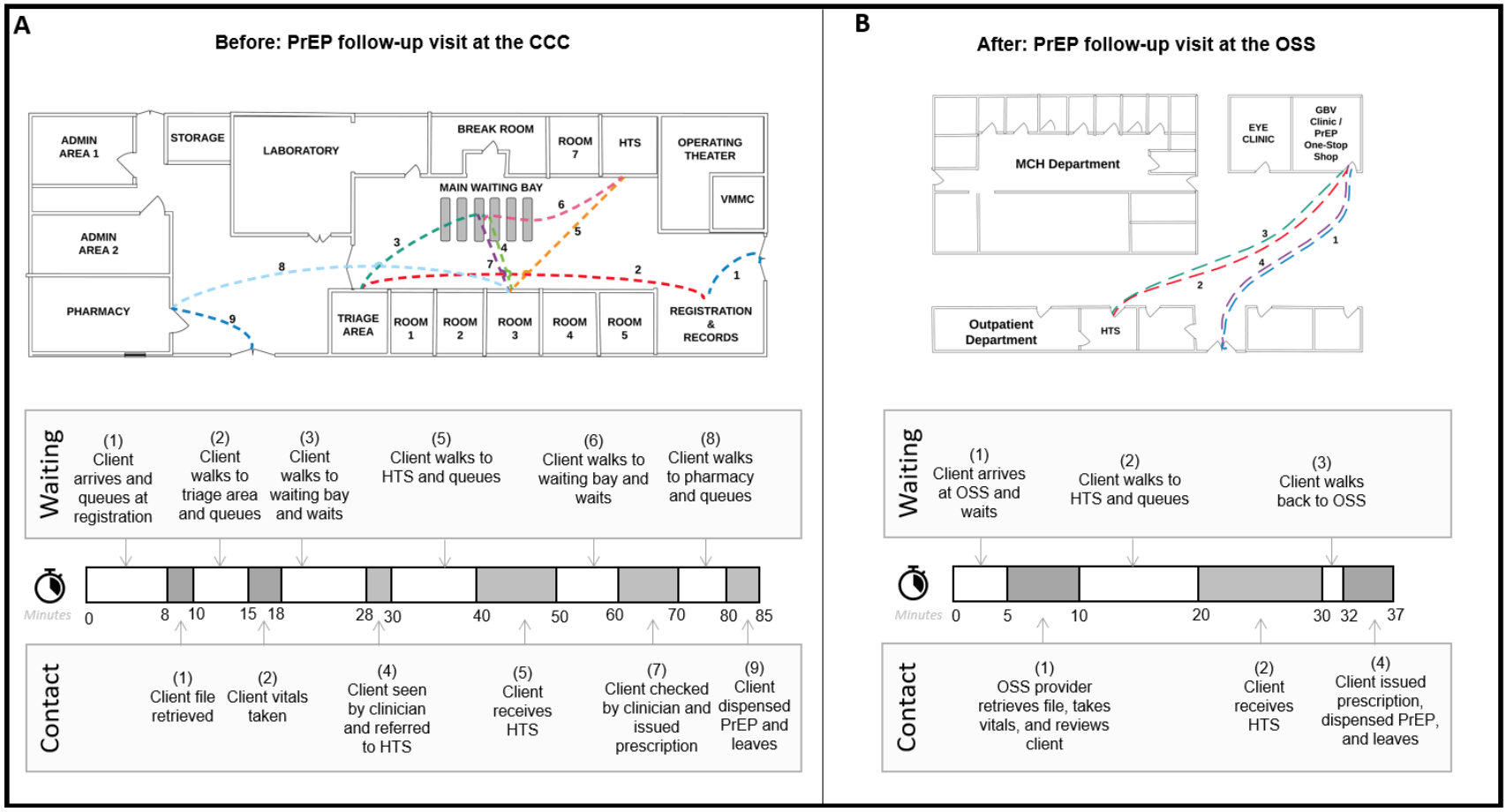

Table 3.1 Demographic characteristics of (A) clients who initiated PrEP and (B) clients who received follow-up PrEP care during the study

Analysis	Characteristic	Pre-intervention period[a]		Post-intervention period[b]	
		Intervention (N=385)	**Control** (N=212)	**Intervention** (N=410)	**Control** (N=220)
(A) PrEP initiations	Female sex – no. (%)	237 (62)	118 (56)	249 (61)	157 (71)
	Age – no. (%)				
	18-24 yr	128 (33)	52 (25)	115 (28)	80 (36)
	25-34 yr	156 (41)	106 (50)	197 (48)	76 (35)
	35-44 yr	62 (16)	29 (14)	70 (17)	41 (19)
	≥ 45 yr	39 (10)	25 (12)	28 (7)	23 (10)
	Married or cohabitating	342 (89)	171 (81)	340 (83)	129 (59)
	HIV risk factors – no (%)				
	Sex partner(s) HIV+	285 (74)	150 (71)	281 (69)	127 (58)
	Sex partner(s) high risk and HIV status unknown	90 (23)	47 (22)	119 (29)	50 (23)
	Multiple sex partners and no consistent condom use	45 (12)	13 (6)	28 (7)	13 (6)
		Intervention (N=389)	**Control** (N=241)	**Intervention** (N=332)	**Control** (N=155)
(B) PrEP continuation	Follow-up visits – no. (%)				
	1	126 (32)	79 (33)	204 (61)	71 (46)
	2	75 (19)	63 (26)	88 (27)	53 (34)
	≥ 3	188 (48)	99 (41)	40 (12)	31 (20)
	Female sex – no. (%)	237 (61)	149 (62)	199 (60)	97 (63)
	Age – no. (%)				
	18-24 yr	77 (20)	42 (17)	68 (20)	34 (22)
	25-34 yr	176 (45)	119 (49)	152 (46)	72 (46)
	35-44 yr	81 (21)	47 (20)	73 (22)	30 (19)
	≥ 45 yr	55 (14)	33 (14)	39 (12)	19 (12)
	Married or cohabitating	374 (96)	218 (90)	306 (92)	111 (72)
	HIV risk factors – no (%)				
	Sex partner(s) HIV+	339 (87)	197 (82)	275 (83)	109 (70)
	Sex partner(s) high risk and HIV status unknown	56 (14)	47 (20)	60 (18)	30 (19)
	Multiple sex partners and no consistent condom use	31 (8)	8 (3)	27 (8)	15 (10)

[a]Pre-intervention period: 1 January 2019 - 31 December 2019 for all sites except two in the intervention group whose pre-intervention period end date is 14 February 2020. [b]Post-intervention period: 1 January 2020 – 30 November 2020 (excluding wash-out period of 1 April 2020 – 30 June 2020) for all sites except two in the intervention group whose post-intervention period start date is 15 February 2020.

Table 3.2 Strategies used by sites to implement the One-Stop Shop and illustrative quotes on how changes affected delivery inefficiencies (wastes)

Change Concept[1] **-Specific Strategy Used**[2]	**Effect on Client/Provider**[2]	**Waste Reduced (for whom)**	**Illustrative Quotes**
Redirect away from bottlenecks (A) Moved PrEP delivery to a lower volume department.	Reduced time to service start, as the queue to see the PrEP provider at the OSS was generally shorter compared to previous delivery location.	Waiting (client)	**Lower client volume:** "The waiting time has reduced because, at this other side [the OSS], they are not as many [clients] as in the HIV clinic [CCC]." *(Female hospital administrator, Site C)* "[The CCC] is too small for the number of clients who go there. … There is congestion and the time taken to get PrEP is longer [compared to the OSS]." *(Male PrEP client, Site A)*
Move steps closer together (B) Relocated client files, equipment, and drugs to OSS. (C) Cross-trained and task-shifted so other cadres could complete parts of PrEP delivery (e.g., dispensing).	(B & C) Enabled client record retrieval, vitals assessment, and drug dispensing to take place in the OSS, thus eliminating client movement to (and potential queueing at) the records department, triage area, and pharmacy. (B) Reduced provider movement to obtain client files and PrEP register. (B) Enabled in-flow documentation, which improved accuracy and reduced time spent reconciling discrepancies.	Motion (client) Waiting (client) Motion (provider) Defects (provider)	**Less movement, fewer queues, fewer providers:** "Everything is done under one roof [at the OSS]. I get weighed, counseled, and just get PrEP from the same room, unlike [before at the CCC] … where I had queue in each and every point I went to because the providers were [busy] attending to other clients. … Today, I only saw one clinician. Before, there were many and, therefore, there was no privacy." *(Female PrEP client, Site C)* **Task-shifting:** "Currently, I can attend to the clients coming for refills … so as to reduce the time it would take for the clinician to come." *(Male peer educator, Site A)* **Less provider movement:** "All the commodities are within the [OSS] room, be it the [appointment] diary, the PrEP files—everything. When [PrEP] clients come in, the [OSS] provider just picks the client's file and does everything within the room, unlike [before at] the CCC, [where] when they get a [PrEP client] in a different room, he or she is forced to stand up and go to the room where things are being kept and take everything to the room, then to the [data] clerk, then to the client, etc. So there is less movement now." *(Female nurse, Site C)* **In-flow documentation:** "[Previously,] we had different providers giving PrEP the same week. So if there was a problem in the documentation, it was difficult to resolve. You had to talk to each clinician [who had provided PrEP care]. But at this point [the OSS], we have only one person [delivering PrEP] who is answerable to anything." *(Male clinical officer, Site B)*
Use differentiation[3] (D) Designated one clinician at a time to attend to OSS clients. (E) Fast-tracked PrEP clients to front of queue	(D & E) Reduced client waiting by allowing them to bypass other clients.	Waiting (client)	**Fast-tracking**: "Before [at the CCC], we tried to fast-track PrEP clients, but there was a lot of resistance especially from the CCC [i.e., ART] clients. … Now there is a provider [assigned to work] in the One-Stop Shop. … So they [clients] just come in, get attended to, and leave." *(Male clinical officer, Site A)*

	"[At the CCC,] some [ART] clients were so harsh, saying, 'You can't jump the queue!' … [They] would complain [to the providers] … so it would end up taking about 1 hour to be seen at that clinic [the CCC]. … [The OSS] is different. You go there, get PrEP, then leave. You are done." *(Male PrEP client, Site A)*

[1]From Langley et al.'s compilation of change concepts; [2]As reported by clients and providers in interviews and TA visits; [3]At two sites, the designated OSS clinician attend to PrEP clients as soon as s/he was next available. A third site implemented fast-tracking at the HTS point only.

Table 3.3 Provider-reported challenges to implementing the One-Stop Shop model

Implementation Challenge	Adjustments Made	Illustrative Quotes
Staffing		
Initially, only one clinician worked at the OSS, making PrEP delivery difficult when that clinician was on leave or unavailable *(clinics A and B)*	Clinics implemented a rotating schedule whereby different clinicians were assigned to attend to OSS clients on a weekly or monthly basis	"I was really finding it difficult, at times, to deliver PrEP on certain days. The other clinicians were fully engaged in ART delivery, and everything PrEP was on me. … A rotation is what helped remove this issue of aligning the [PrEP] service [delivery] to one person." *(Male clinical officer, site A)*
Initial pushback from provider designated to deliver PrEP at OSS *(clinic C)*	Additional PrEP training provided; hospital administration increased number of providers at OSS to two and implemented a rotating schedule	"It took us a few months for the One-Stop Shop to pick up. In the beginning, there was only one provider in the OSS. … But now we have two providers. Also, at first, there were some excuses, like, okay, complaints from staff that they had not been trained [to deliver PrEP], so additional trainings were held. … Then when the last rotation came about, the two providers who were allocated [to the OSS] had passion [for PrEP delivery], and it just picked [up] at once." *(Female nurse, clinic C)*
Initially, the OSS clinician was stationed at the OSS and responsible for attending only to PrEP clients; but following the COVID-19 outbreak, this clinician was stationed at the CCC and responsible for attending to ART clients at the same time *(clinics A and B)*	Non-clinician OSS staff attended to refill-only clients and completed majority of steps for new and follow-up clients on their own, calling the clinician over to the OSS as needed (e.g., for prescription writing).	"Most [providers] are on leave, and some are working on a rotational basis due to COVID. Currently, there is one clinical officer at the CCC who is also covering the PrEP OSS. … He's stationed at the CCC but will go attend to clients at the OSS when they come." *(TA report, April 2020, Clinic A)* "Whenever I am unavailable, [the peer educator] can do the refills. For the clients that need clinical encounter, the clinician is called in." *(Male clinical officer, clinic A)*
HIV testing		
HTS point closest to OSS temporarily closed as part of COVID-19 precautions *(clinics A and B)*	OSS clients sent to HTS point in other hospital department; OSS providers often tried to attend to other clients in the meantime, though this sometimes led to clients waiting upon return from HTS	"It is only unfortunate that we don't do the PITC [Provider-Initiated Testing and Counseling] at the OSS because this is not a [designated] testing point. … Currently, we use other departments to do the HIV testing. … I'm the one who takes time to escort clients to the service delivery point for PITC." *(Female counselor, clinic D)*
In-room HIV testing not implemented as planned due to political and logistical challenges (e.g., concerns about commodities management) *(clinic D)*		"When I came back [from HTS] to the [OSS] room, I found there was a client inside, so I also had to wait another 15 minutes [for the OSS provider to become available]." *(Female PrEP client, clinic D)*

Stigma Due to COVID-19, OSS relocated to the CCC, where some PrEP clients feel HIV-related stigma *(clinic B)*	OSS clients are fast-tracked to a separate room in the corner of the CCC	"Other clients are there [in the CCC], so that still brings the issue of stigma, but it is not as it was before because … they don't wait for long. If we find a specific PrEP client, we fast-track them and see them in one room." *(Male clinical officer, clinic B)* "I feel less stigmatized [at the OSS]. … The private room is good because I finish everything in that room. … And I'm not in the CCC corner. I'm handled directly like PrEP lady." *(Female PrEP client, clinic B)*

APPENDIX

Supplemental Digital Content

We provide additional details about our qualitative methodology in **Table S1** and interview participant demographics in **Table S2**.

Table S1. Consolidated criteria for reporting qualitative studies (COREQ) checklist

Domain	No. Item	Guide Questions/Description
Research Team and Reflexivity	***Personal Characteristics***	
	1. Interviewer/facilitator	Coauthors BK and AD, both Kenyan qualitative researchers, conducted all interviews.
	2. Credentials	SDR has a Master's in Public Health and a BA in Cultural Anthropology. BK and AD have extensive experience conducting qualitative interviews for HIV prevention research studies.
	3. Occupation	SDR is a research analyst and PhD candidate in Global Health Implementation Science at University of Washington. BK and AD are qualitative research assistants for the Kenya Medical Research Institute.
	4. Gender	SDR and AD are female, and BK is male.
	5. Experience and training	SDR has completed doctoral-level courses in qualitative research. BK and AD have extensive experience collecting and analyzing qualitative data and have authored or coauthored numerous articles and abstracts for qualitative studies.
	Relationship with Participants	
	6. Relationship established	Relationships were limited to interviews.
	7. Participant knowledge of interviewer	Prior to beginning the interviews, BK and AD provided participants with a general description of the study (e.g., its objectives and details of participation) and a brief personal introduction.
	8. Interviewer characteristics	We do not report additional interviewer characteristics.
Study Design	***Theoretical Framework***	
	9. Methodological orientation and theory	Our study draws on approaches from both conventional and directed content analysis. We created de novo semi-structured interview guides of open-ended questions. During analysis, we derived our coding categories directly from the text data, from Ohno's model for continuous quality improvement, and from Langley et al.'s

	compilation of change concepts. (Citations are included in the reference list.)
Participant Selection	
10. Sampling	We used purposive sampling to recruit healthcare providers employed by OSS clinics or the county department of health and PrEP clients. We intentionally sought out providers from a variety of professional cadres (e.g., clinical officers, nurses, peer educators) and clients of different sexes, ages, and prior experience with the clinic's pre-OSS PrEP delivery model.
11. Method of approach	Interviewers approached potential client participants as they exited the OSS. With TA assistance, interviewers identified eligible providers and approached them in person or by phone.
12. Sample size	29 interviews completed (14 with providers and 15 with clients)
13. Non-participation	All invited providers agreed to participate. We did not track the number of PrEP clients who were approached and declined to participate in an interview.
Setting	
14. Setting of data collection	All interviews took place in a private room at the study clinic or via phone.
15. Presence of non-participants	Aside from the interviewer and the participant, no other individuals were present during the interviews.
16. Description of sample	Adult PrEP clients and adult PrEP providers and/or clinic administrators.
Data Collection	
17. Interview guide	We developed and pilot tested two de novo semi-structured interview guides (one for providers and one for clients).
18. Repeat interviews	We interviewed each participant once (i.e., no repeat interviews).
19. Audio/visual recording	All interviews were audio-recorded with participant consent.
20. Field notes	We did not collect field notes.
21. Duration	Interviews lasted approximately one hour.

	22. Data saturation	We did not conduct interviews to the point of data saturation; however, given the tightly scoped nature of our research question, our analytic goals (to discern themes, rather than develop theory), and the relative homogeneity of our sample (all OSS providers and all OSS PrEP clients), we anticipated reaching code saturation after 12 interviews per group. We, therefore, aimed to interview 3 providers and 3 clients from each OSS clinic.
	23. Transcripts returned	Transcripts were not returned to participants for comment or correction.
	Data Analysis	
	24. Number of data coders	One (SDR)
	25. Description of the coding tree	SDR drafted interview memos that included a summary of key points for each code and quotations. Memos were reviewed by BK and AD, with disagreements resolved through group discussion.
	26. Derivation of themes	In each interview memo, SDR included analytic reflections that drew comparisons across participants and datasets and synthesized findings into higher-level themes.
	27. Software	NVivo 12 Pro
Analysis and Findings	28. Participant checking	Participants did not provide feedback on our findings.
	Reporting	
	29. Quotations presented	Illustrative quotes are presented in the body of the paper as well as Tables 2 and 3.
	30. Data and findings consistent	Yes
	31. Clarity of major themes	Major themes are presented in the results section under the sub-sections “OSS impact on service time”, “implementation challenges”, and “OSS impact on service quality”. We further discuss the relevance of these themes in the discussion section.
	32. Clarity of minor themes	Not applicable. (We do not present minor themes.)

Table S2. Demographic characteristics of interview participants

Characteristic	PrEP Providers (N=14)	PrEP Clients (N=15)
Female sex – no. (%)	6 (43)	8 (53)
Age – median (IQR)	34 (33-38)	39 (29-41)
Educational attainment – no (%)		
Less than high school graduate	0 (0)	5 (33)
High school graduate	0 (0)	5 (33)
Some college or college certificate/diploma	10 (71)	3 (20)
Some university or university degree	4 (29)	2 (13)
Occupation – no. (%)		
Clinical officer	5 (36)	0 (0)
Nurse	4 (29)	0 (0)
Healthcare counselor[b]	2 (14)	0 (0)
Healthcare administrator	3 (21)	0 (0)
Business/salesperson	0 (0)	4 (27)
Farmer	0 (0)	3 (20)
Hospitality/service industry worker	0 (0)	2 (13)
Other[c]	0 (0)	6 (40)
Married – no. (%)	-	13 (87)
Number of children – median (IQR)	-	3 (2-5)
Monthly household income in Kenyan shillings[d] – median (IQR)	-	30,000 (19,000-47,500)
Lives in rural area[e] – no. (%)	-	7 (47)

[a]In the Kenyan higher education system, college certificates, college diplomas, and university degrees generally take a minimum of 1, 2, and 4 years, respectively, to complete; [b]Includes psychologist, adherence counselor, identification and retention assistant, and peer educator; [c]Includes, for example, pastor, homemaker, caregiver, and clerk; [d]Approximately USD $270 ($170-430); [e]Self-reported by participant

CHAPTER 4. Acceptability and Feasibility of Pharmacy-Based Delivery of Pre-Exposure Prophylaxis in Kenya: A Qualitative Study of Client and Provider Perspectives

Stephanie D. Roche[1§], Njeri Wairimu[2], Peter Mogere[2], Kevin Kamolloh[3], Josephine Odoyo[3], Zachary A. Kwena[3], Elizabeth A. Bukusi[1,3,4], Kenneth Ngure[5], Jared M. Baeten[1,6,7], Katrina F. Ortblad[1]

[1] University of Washington, Department of Global Health, Seattle, USA
[2] Partners in Health and Research Development, Nairobi, Kenya
[3] Kenya Medical Research Institute, Kisumu, Kenya
[4] University of Washington, Department of Obstetrics and Gynecology, Seattle, USA
[5] Jomo Kenyatta University of Agriculture and Technology, Department of Community Health, Nairobi, Kenya
[6] University of Washington, Department of Medicine, Seattle, USA
[7] University of Washington, Department of Epidemiology, Seattle, USA

[§] Corresponding author:
Stephanie Roche
325 Ninth Avenue
Seattle, Washington, 98104, USA
Phone: +1.206.520.3808
Fax: +1.206.520.3864
Email: sroche@uw.edu

Running head: Pharmacy-based PrEP delivery in Kenya

ABSTRACT

As countries scale up pre-exposure prophylaxis (PrEP) for HIV prevention, diverse PrEP delivery models are needed to expand access to populations at HIV risk that are unwilling or unable to access clinic-based PrEP care. To identify factors that may influence implementation of retail pharmacy-based PrEP delivery in Kenya, we conducted in-depth interviews with 40 pharmacy clients, 16 pharmacy providers, 16 PrEP clients, and 10 PrEP providers from two provinces. Most participants expressed strong support for expanding PrEP to retail pharmacies, though conditioned their acceptance on assurances that care would be private, respectful, safe, and affordable. Participant-reported determinants of feasibility centered primarily on ensuring that the intervention is compatible with retail pharmacy operations (e.g., staffing levels, documentation requirements). Future research is needed to develop and test tailored packages of implementation strategies that are most effective at integrating PrEP delivery into routine pharmacy practice in Kenya and other high HIV prevalence settings.

Key words: pre-exposure prophylaxis; implementation science; Kenya; differentiated care; HIV prevention

INTRODUCTION

In the nearly 10 years since clinical trials confirmed the safety and efficacy of pre-exposure prophylaxis (PrEP) for HIV prevention, diverse PrEP delivery models have been implemented around the world, primarily in high-income settings.[148,149] In the U.S., home to the world's largest number of PrEP users, PrEP is delivered through a variety of clinic-based, pharmacy-based, and telehealth models.[150–152] In sub-Saharan Africa, where PrEP delivery remains largely confined to clinics, the need for differentiated PrEP delivery models that reach populations at HIV risk and reduce burdens on health systems remains high.[153] Even in Kenya, which has the second highest number of PrEP users in the world, findings from open label, demonstration, and implementation projects have found that client desire for public clinic-based PrEP delivery is tempered by concerns about stigma, opportunity costs, and limited privacy.[25–27,29] Moreover, clinic-based PrEP may not reach Kenyans at HIV risk who do not regularly frequent healthcare clinics.[154]

In 2017, the Kenyan Ministry of Health (MOH) released a 5-year plan for increasing access to PrEP[13], which includes scaling up PrEP delivery to additional public HIV clinics and scaling out PrEP delivery to other venues[14], including retail pharmacies. With approximately 5,800 registered outlets nationwide[36], retail pharmacies represent a promising platform for increasing PrEP accessibility and coverage in Kenya. Previous studies have found that Kenyans seeking treatment for minor ailments and preventive care often resort first to retail pharmacies, even when the desired product or service is available for free at public clinics.[32,34,35,155] In recent years, standalone pharmacy-based PrEP delivery programs have been successfully implemented in select parts of the U.S. (e.g., Seattle, San Francisco, Miami, Denver, St. Louis, Jackson, and Omaha).[152,156–161]

The acceptability and feasibility of pharmacy-based PrEP delivery has not been studied in a sub-Saharan African country. We conducted qualitative formative research to inform the design and implementation of a pharmacy PrEP care pathway in Kenya. Specifically, we aimed to understand perceptions among pharmacy PrEP stakeholders about the proposed intervention, including factors that may influence their ability or willingness to uptake or deliver PrEP at retail pharmacies.

METHODS

Participants

We purposefully sampled pharmacy clients, pharmacy providers, PrEP clients, and PrEP providers from two counties: Kiambu County in central Kenya and Kisumu County in western Kenya, where HIV prevalence is 4% and 16%, respectively. Trained research assistants (RAs) contacted providers to describe the research and invite them to participate. RAs approached potential client participants as they exited select retail pharmacies or HIV clinics in a variety of socioeconomic settings and scheduled interested, eligible individuals for an interview.

Eligible pharmacy clients self-reported being HIV negative and were assessed as at HIV risk using Kenya's Rapid Assessment and Screening Tool (RAST).[162] Eligible pharmacy providers were licensed pharmacists or pharmaceutical technologists employed at a registered retail pharmacy. Eligible PrEP clients and PrEP providers obtained or delivered PrEP services at a public HIV clinic. All participants were 18 years or older.

Data collection

We developed semi-structured interview guides to gather data on five domains, including health-seeking behaviors, experiences taking PrEP, delivery practices, anticipated benefits and drawbacks of pharmacy PrEP, and anticipated barriers and facilitators to pharmacy PrEP. We used the Consolidated Framework for Implementation Research (CFIR) [20], a meta-theoretical framework of constructs hypothesized to predict, moderate, or "drive" implementation outcomes, such as acceptability and feasibility[47,163], to frame questions related to barriers and facilitators. We captured participant demographics via close-ended questions. We translated, back-translated, and pilot tested the guides, and excluded pilot interviews from our analytic data.

From October 2019 to April 2020, Kenyan RAs conducted individual interviews with participants in their preferred language: English, Kiswahili, or Dholuo. Interviews took place in a private room at the pharmacy, HIV clinic, or study research office, typically lasted 51 minutes (interquartile range [IQR]: 40-63 minutes), and were audio-recorded. After each interview, RAs transcribed the recording and, if applicable, simultaneously translated it to English.

Author SDR checked the quality of each RA's first three transcripts and performed random spot-checks on all remaining transcripts. For non-English interviews, an RA fluent in the language performed the quality check.

Data analysis

A subset of the research team (SDR, KFO, and NW) with university-level training in qualitative methodology analyzed the interview data in Dedoose version 8.0.35 (SocioCultural Research Consultants, LLC, Los Angeles, USA) using conventional content analysis[88], an inductive approach that involves systematic review, reduction, and interpretation of the data.[164] These authors developed, tested, and refined a codebook based on a comparison of independently coded transcripts. SDR and NW coded the remaining transcripts and resolved disagreements via consensus. We conducted second cycle pattern coding to develop a coherent meta-synthesis of the data[89,127], dropping redundant or irrelevant codes, merging similar codes, and subdividing codes encompassing distinct concepts. We organized remaining codes into "meta-codes" representing determinants of acceptability and feasibility and mapped these onto the CFIR framework. Using RStudio (RStudio Team, 2016), we assessed descriptive statistics of participants' demographic information, including description of central tendency as frequency and percent or median and interquartile range, as appropriate.

Ethics

The institutional review boards of the University of Washington and the Kenya Medical Research Institute approved this study. We obtained written informed consent from all participants. The Electronic Supplementary Material (**Section 1**) contains additional details about our methodology presented using the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist.

RESULTS

We interviewed 82 individuals: 40 pharmacy clients, 16 pharmacy providers, 16 PrEP clients, and 10 PrEP providers (**Table 4.1**). Of the eligible 49 pharmacy clients invited to interview, 9 declined due to time constraints (82% participation). All remaining groups had 100% participation.

The median age of participants was 27 years (IQR: 23-35 years) and about half were female (43/82). The median time PrEP clients used PrEP was 11 months (IQR: 7-24 months). The sample contained roughly

equal numbers of medical doctors, clinical officers, nurses, and HIV testing service (HTS) counselors. With the exception of one pharmacist, all pharmacy providers were pharmaceutical technologists, and 75% (12/16) were pharmacy owners.

Below, we describe participant-reported relative advantages of pharmacy-based versus clinic-based PrEP delivery (**Table 4.2**) and determinants of acceptability and feasibility, organized by CFIR domain (**Figure 4.1**). Throughout, we reference illustrative quotes (**Tables 4.3** and **4.4**) by table number and letter (e.g., "Quote 2A" refers to quote A in Table II). The Electronic Supplementary Material contains additional results, including specific recommendations proposed by participants.

THEME 1: Stakeholders are interested in trying pharmacy-based PrEP delivery and anticipate several short- and long-term advantages over clinic-based PrEP delivery.

Nearly all participants said they would be interested in engaging in pharmacy PrEP, with some noting that demand for it already exists. Unprompted, about half (7/16) of pharmacy providers reported that clients routinely ask for PrEP at their pharmacy, and two such providers described occasionally acquiring PrEP for clients who request it. Similarly, two clients reported seeking PrEP at a pharmacy, one successfully. This client, however, later learned that the pharmacy provider's instructions for use (which were to only take PrEP on days she anticipated having sexual intercourse) were inaccurate.

Proximal advantages

Convenience. Citing the ubiquity of retail pharmacies, PrEP and pharmacy clients anticipated that pharmacy PrEP would save them travel time and fare, as most lived within walking distance of their preferred retail pharmacy (**Quote 2A**). PrEP clients reported a lower median travel time and fare to reach their preferred pharmacy than to reach their current PrEP clinic: 10 minutes (IQR: 5-30 minutes) and 0 Kenyan shillings (KSH) (IQR: 0-30 KSH) versus 45 minutes (IQR: 30-60 minutes) and 65 KSH (30-100 KSH). Clients also anticipated that wait time for PrEP at pharmacies would be shorter than that at clinics. The median time PrEP clients reported waiting to see a PrEP provider at public HIV clinics was 30 minutes (IQR: 20-75 minutes) (**Quote 2B**).

Many participants stated that pharmacy-based PrEP delivery would be more convenient than clinic-based PrEP delivery because retail pharmacies have longer opening hours (**Quote 2C**). According to provider responses about their own workplaces, pharmacies typically operate not only more days per week (7 days, IQR: 6-7 days) than public HIV clinics (5 days, IQR: 5-5 days), but also more hours per day (13 hours, IQR: 12-13 hours) than public HIV clinics (8 hours, IQR: 8-8 hours) (**Quote 2D**). Participants equated longer opening hours with fewer opportunity costs, such as having to take time off from work to get PrEP (**Quote 2E**).

Privacy. Participants, especially PrEP providers and clients, anticipated that pharmacy PrEP would circumvent stigma clients often face when accessing PrEP in HIV clinics. For example, many PrEP clients described fearing that friends, family members, or neighbors would see them at the HIV clinic and mistakenly think they are living with HIV. Noting that retail pharmacies offer a wide variety of products at the same counter, participants felt that clients would be able to obtain PrEP there discreetly without other customers knowing the reason for their visit (**Quote 2F**).

Autonomy. Reporting that the availability of clinic-based PrEP is largely restricted to select public HIV clinics, participants imagined that pharmacy PrEP (if expanded to numerous retail pharmacies) would give clients greater choice around when and where to seek PrEP care (**Quotes 2G** and **2H**).

Profit. Pharmacy providers viewed pharmacy PrEP as a potential source of profit (**Quote 2I**).

Distal Advantages

Reduced HIV incidence. Participants from all groups felt that pharmacy PrEP would address client barriers to clinic-based PrEP delivery and, in turn, lead to more individuals accessing, initiating, and adhering to PrEP. They felt that these shifts in PrEP use would ultimately contribute to reductions in population-level HIV incidence (**Quotes 2J-2N**). PrEP providers further noted that diverting some PrEP clients to pharmacies may help decongest public HIV clinics and enable PrEP providers to spend more time on cases requiring a higher level of PrEP expertise (e.g., serodiscordant couples) (**Quote 2O**).

***THEME 2*: The acceptability of pharmacy-based PrEP delivery hinges on meeting stakeholder expectations for quality of care.**

Most participants indicated they would find pharmacy PrEP acceptable so long as the quality of PrEP care delivered in pharmacies was on par with, or exceeded that, typically offered in clinics.

Intervention characteristics

In addition to relative advantages, participants reported that the acceptability of pharmacy PrEP would depend on its affordability to clients and profitability for pharmacies (**Quotes 3A-3C**). Acknowledging that not all individuals at HIV risk will have the means to purchase PrEP, most clients expressed a desire for the MOH to collaborate with retail pharmacies to make pharmacy PrEP available at no or low cost to clients. Pharmacy providers similarly expressed a desire for the MOH to subsidize the cost of PrEP delivery so they could support this public health initiative.

Inner setting

Nearly all participants anticipated that pharmacy PrEP would only be acceptable to clients if it took place in a private area of the pharmacy. Participants were particularly adamant that HIV testing and counseling, and any discussions about sexual activity, would need to occur in a separate counseling room out of earshot of other pharmacy clients (**Quote 3D**).

Characteristics of providers

Participants identified provider competency and professionalism as determinants of acceptability. Both clients and providers stated that they would only find pharmacy PrEP agreeable insofar as they felt confident that pharmacy PrEP providers were not “quacks” but possessed adequate PrEP knowledge and skills (**Quote 3E**). Noting that some components of PrEP delivery (e.g., HIV testing and counseling) are outside of the traditional scope of practice for pharmacy providers in Kenya, providers stressed that pharmacy PrEP providers would need additional training. Clients also explained that their acceptance of pharmacy PrEP would depend, in part, on pharmacy providers’ ability to maintain client confidentiality, treat clients with respect (e.g., not judge clients’ sexual behaviors), and prioritize clients’ well-being over profit-making (**Quotes 3F-3H**).

Outer setting

With respect to client-provider rapport, some clients anticipated wanting to get PrEP from a provider with whom they have an ongoing, close relationship (**Quote 3I**). Others stated that they would purposely seek

PrEP from a provider who did not know them (**Quote 3J**). Participants found both options viable if pharmacies offering PrEP were spread across different localities.

Many participants perceived retail pharmacies to be less strictly regulated than public clinics and conditioned their acceptance of pharmacy PrEP on the existence of regulatory policy (e.g., quality standards) and oversight (e.g., audits). Both groups of clients and PrEP providers alike viewed the involvement of authorities, such as the national drug regulatory agency of Kenya, as key to ensuring clients receive safe and appropriate care (**Quote 3K**).

THEME 3: For pharmacy-based PrEP delivery to be feasible, retail pharmacies may need to adapt their operations.

Intervention characteristics and inner setting

Pharmacy providers stressed that pharmacy PrEP would not be feasible to deliver in the absence of a private counseling room, sufficient staff, and consistent access to supplies (**Quotes 4A-D**). All pharmacy providers reported that their current daily workload was “manageable” or “very manageable” and that, during a typical day at their pharmacy, two providers (IQR: 1-2 providers) attended to roughly 45 clients (IQR: 34-100 clients), spending about 5 minutes (IQR: 5-10 minutes) with each. When asked the maximum amount of time they thought they could spend attending to a PrEP client, pharmacy providers’ median response was 30 minutes (IQR: 10-30 minutes). Most imagined that they would need to hire additional staff to carry out PrEP delivery, especially if the amount of time they spend serving a client (i.e., cycle time) is substantially higher for PrEP clients (**Quote 4E**). These providers noted that spending additional time with PrEP clients would only be feasible if the PrEP client volume and profit margin made it economically worthwhile. Profitability also emerged in discussions of supplies, such as HIV testing kits, with pharmacy providers reiterating their desire for government subsidies to offset these costs. Most pharmacy providers reported that if the MOH provided them with PrEP drugs for free, they would only charge the client a fee to cover the cost of drug dispensing, storage, and disposal.

Some PrEP providers noted that, if subject to the same reporting requirements as PrEP clinics, retail pharmacies may need to install systems for documenting PrEP care and tracking commodities (**Quote 4F**). Pharmacy providers, for their part, described using a wide variety of record-keeping practices, primarily to

monitor inventory, but identified some standard documentation they currently perform (e.g., for prescription opioids) as a potential foundation onto which pharmacy PrEP documentation could be added.

Characteristics of providers

Although most pharmacy providers stated that they routinely counsel clients, assess adherence, and monitor for side effects, they anticipated that pharmacy providers would require additional training to deliver PrEP, especially on pharmacovigilance, adherence counseling, and HIV testing and counseling (**Quotes 4H** and **4I**). Pharmacy providers typically felt that a 5-day (IQR: 3-5-day) training would suffice. Both pharmacy and PrEP providers thought trained pharmacy providers would be capable of safely prescribing PrEP to new clients. They further noted that provider support tools, such as the aforementioned RAST tool for assessing HIV risk and PrEP eligibility, could advance pharmacy providers' competency and enhance their sense of self-efficacy (**Quote 4G**).

Outer setting

Participants from both provider groups universally agreed that a care network through which pharmacy providers could consult PrEP experts and refer complex cases would increase the feasibility of pharmacy-based PrEP delivery (**Quote 4J**). Providers varied in their preferences for communication content, frequency, and platform, with some noting the need for an inter-provider collaboration protocol. Pharmacy providers reported that, currently, they seldom interact with prescribing clinicians, except to occasionally confirm an unusual dosage or request permission to alter a prescription for an out-of-stock medication.

DISCUSSION

Kenyan stakeholders found the concept of pharmacy PrEP delivery to be acceptable and conditioned their acceptance on assurances that care would be private, respectful, safe, and affordable. Similar to their counterparts in high-income settings,[165–167] pharmacy and PrEP providers in our study were open to task-shifting PrEP delivery to retail pharmacy providers, though did identify factors that could reduce the feasibility of pharmacy-based PrEP delivery (e.g., insufficient provider time). Overall, most participants considered retail pharmacies an ideal venue for reaching individuals at HIV risk who are unable or unwilling to obtain PrEP at public clinics.

Importantly, our study found evidence that pharmacy-based PrEP delivery is not only in demand but is also, to some extent, already happening without official approval or oversight. This is not a new trend for retail pharmacies in Kenya, some of which have met early demand for products and services, such as HIV self-testing kits[168] and injectable contraceptives[34], by offering them before the Kenyan MOH granted explicit authorization to do so. Still, these reports of informal pharmacy-based PrEP delivery highlight the need for a more formalized care pathway that safeguards care quality and maximizes the public health impact of this intervention. Taking an implementation science approach, pharmacy PrEP implementers may be more likely to succeed if they pursue strategies that specifically target the determinants identified in our study [169,170].

To address the determinant of intervention cost, strategies such as accessing new funding, developing resource-sharing agreements, and altering consumer fees may be necessary. Most pharmacy-based PrEP care in other countries, such as the U.S., is financed through private insurance or drug assistance programs sponsored by industry or the state that require little, if any, out-of-pocket payment from clients.[152,158] In Kenya, clinic-based PrEP care is primarily funded by PEPFAR and the Global Fund;[162] retail pharmacy services are not covered by the national insurance scheme;[171] and less than 5% of the population has private insurance.[172] Additional research is, therefore, needed to explore possible financing mechanisms for pharmacy PrEP and to identify a price point that balances affordability for clients with the commercial interests of retail pharmacies.

Formalizing a pharmacy PrEP care pathway also entails re-negotiating pharmacy providers' scope of practice. Currently, pharmacy providers in Kenya are allowed to carry out most, but not all, of the activities involved in PrEP delivery. For example, there is no legal provision in Kenya allowing retail pharmacy providers to prescribe PrEP or perform blood-based HIV testing, which is the only type of testing that the WHO currently recommends for initiating and continuing clients on PrEP.[173,174] As such, successful implementation of pharmacy PrEP in Kenya will likely require strategies, such as revising pharmacy providers' professional roles, conducting trainings, disseminating provider support tools, and providing expert consultation. Many U.S.-based pharmacy PrEP programs use formal agreements between PrEP prescribers and pharmacy providers known as "collaborative practice agreements" to give pharmacy

providers special permission to carry out PrEP-related activities.[152,156,158] Kenya's MOH could similarly decide to amend pharmacy practice to include PrEP delivery and work with the professional bodies for pharmacists and pharmaceutical technologists to integrate PrEP delivery competencies into continuing professional development education.[175] Participants in our study strongly supported the idea of establishing formal connections between pharmacy and PrEP providers who could provide expert consultation, when needed. Given that retail pharmacies and health clinics in Kenya are accustomed to operating independently, with little co-management of clients[176], pharmacy PrEP implementers may need to pursue various implementation strategies to enable inter-provider collaboration, such as establishing systems and protocols for provider communication and data sharing.

A final major consideration for implementers is quality assurance. Many participants in our study, including pharmacy providers, felt conflicted about for-profit PrEP services, anticipating, on the one hand, advantages over the free PrEP services in public clinics, but at the same time expressing doubt about "quacks" and "greedy" pharmacy providers who might prioritize money-making over client safety. Such concerns are not unfounded, as the Kenyan MOH has, in recent years, shut down hundreds of private pharmacies across Kenya that had expired or forged licenses, unqualified personnel, and/or counterfeit medicines.[36,177] Our findings suggest that, for pharmacy PrEP to succeed, implementers will need to not only monitor care quality but also actively address client misgivings about pharmacy PrEP providers' competency, professionalism, and motives. For the former task, implementers could consider whether and how existing quality monitoring tools[162] for clinic-based PrEP delivery might be integrated into the retail pharmacy setting. Instilling client confidence in pharmacy PrEP care quality will require a different set of strategies. For example, implementers could set up a system modeled after one established by the Kenyan MOH[178] whereby prospective PrEP clients can verify a provider's "PrEP credentials" (e.g., nationally-certified PrEP training certificate) by sending a free SMS to a specified number.

Our study has some limitations. Participants' perspectives on this hypothetical intervention may not accurately reflect how they would feel about it in a real-world scenario. We did not capture the perspectives of all pharmacy PrEP stakeholders, such as members of the Kenyan MOH. Because we did not interview

adolescents, our findings may not reflect the perspectives of this priority population for PrEP. Lastly, we did not explore determinants of other implementation outcomes, like sustainability.

CONCLUSION

For PrEP to impact the global HIV burden, sufficient coverage (i.e., uptake and persistence with sufficient adherence) must be achieved, especially among groups at high HIV risk. A one-size-fits-all delivery model is unlikely to reach the large, diverse, and geographically dispersed populations that could benefit from PrEP. If successful, Kenya's pharmacy-based PrEP model could help differentiate PrEP care delivery and serve as a template for other ministries of health in sub-Saharan Africa to adapt. Future research is needed to develop and test tailored packages of implementation strategies that are most effective at integrating PrEP delivery into routine pharmacy practice in Kenya and other high HIV prevalence settings.

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Author contributions

SDR, KN, and KFO designed this qualitative formative research study. ZAK provided expertise in the development of the interview instrument. PM, KK, and JO provided project administration support. NW conducted interviews in Kiambu County. SDR,

NW, and KFO analyzed the data. SDR wrote the first draft of the manuscript and finalized it based on coauthor feedback. KFO and JMB acquired funding and, with EAB and KN, conceptualized the larger pilot study. All authors read and approved the final manuscript.

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Data availability

Due to conditions of ethical approvals, we are unable to provide access to our full dataset on a public repository. However, we are willing to make partial de-identified transcripts available upon reasonable request. Interested persons should contact the corresponding author.

Declarations

Conflict of interest JMB has received donations of study medication from Gilead Sciences and serves on advisory committees for Gilead Sciences, Merck, and Janssen. For the remaining authors, none were declared.

Ethics Approval

The institutional review boards of the University of Washington and the Kenya Medical Research Institute approved this study.

Consent to Participate

We obtained written informed consent from all participants.

TABLES & FIGURES

Figure 4.1. Determinants of pharmacy-based PrEP delivery acceptability and feasibility. Factors influencing the acceptability and feasibility of pharmacy-based PrEP delivery, organized by domains of the Consolidated Framework for Implementation Research (CFIR)

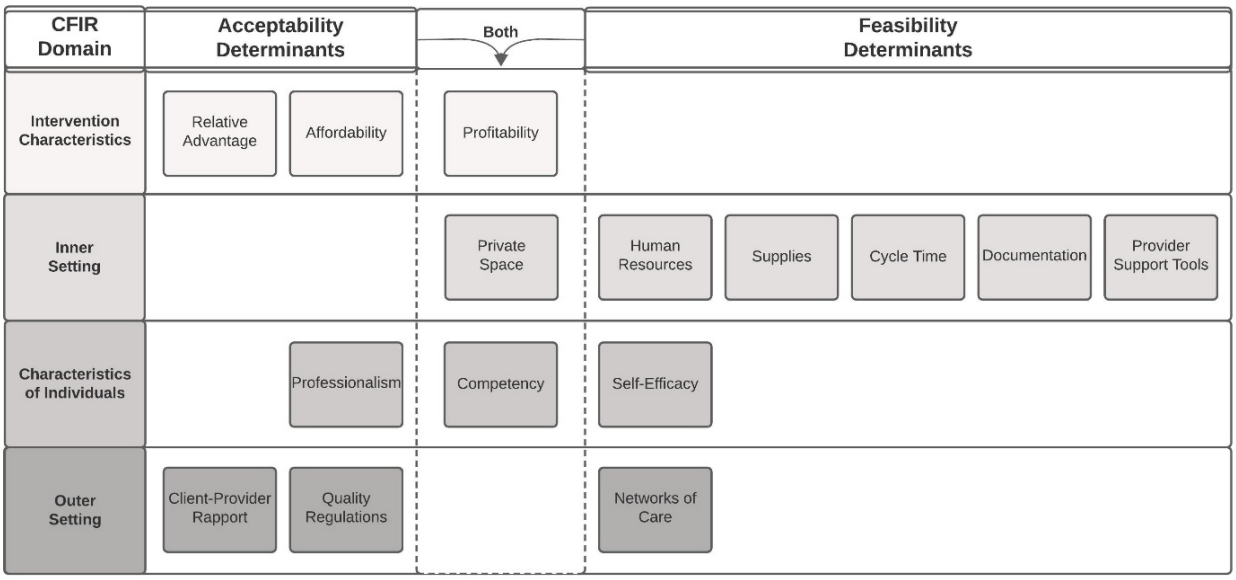

Table 4.1 Participant demographics

Variable	Clients		Providers	
	PrEP (n=16)	Pharmacy (n=40)	PrEP (n=10)	Pharmacy (n=16)
Age in years[a]	28 (23-29)	25 (22-28)	37 (35-40)	33 (27-35)
Female	9 (56%)	20 (50%)	7 (70%)	7 (44%)
Occupation				
Unemployed	2 (13%)	5 (13%)	-	-
Student	0 (0%)	4 (10%)	-	-
Business/sales	5 (31%)	12 (30%)	-	-
Hospitality/service industry	8 (50%)	3 (8%)	-	-
Medical Doctor	0 (0%)	0 (0%)	2 (20%)	0 (0%)
Clinical Officer	0 (0%)	0 (0%)	3 (30%)	0 (0%)
Nurse	0 (0%)	0 (0%)	2 (20%)	0 (0%)
HIV Testing Services (HTS) Counselor	0 (0%)	1 (3%)	2 (20%)	0 (0%)
Pharmacist	0 (0%)	1 (3%)	0 (0%)	1 (6%)
Pharmaceutical Technologist	0 (0%)	1 (3%)	0 (0%)	15 (94%)
Other	1 (6%)	13 (33%)	1 (10%)	0 (0%)
Recruitment location[b]				
Urban area - informal settlement	4 (25%)	7 (18%)	1 (10%)	6 (38%)
Urban area - non-informal settlement	9 (56%)	14 (35%)	2 (20%)	3 (19%)
Peri-urban area	0 (0%)	9 (23%)	4 (40%)	4 (25%)
Rural area	3 (19%)	10 (25%)	3 (30%)	3 (19%)
Educational Attainment[c]				
Less than high school	6 (38%)	1 (3%)	-	-
High school graduate	5 (31%)	9 (23%)	-	-
Some college or college certificate/diploma	3 (19%)	18 (45%)	-	-
Some university or university degree	2 (12%)	12 (30%)	-	-
Married	9 (56%)	6 (15%)	-	-
Number of children[a]	1 (1-2)	0 (0-1)	-	-
Monthly household income in Kenyan shillings[a,d]	20,000 (11,750-28,750)	30,000 (20,000-55,000)	-	-
Months on PrEP[a]	11 (7-24)	-	-	-
To reach PrEP clinic				
Travel time, in minutes[a]	45 (30-60)	-	-	-
Travel cost, in Kenyan shillings[a,e]	65 (30-100)	-	-	-
To reach preferred retail pharmacy				
Travel time, in minutes[a]	10 (5-30)	6 (5-10)	-	-
Travel cost, in Kenyan shillings[a,f]	0 (0-30)	0 (0-0)	-	-

[a] Presented as median (interquartile range); [b] Location of healthcare clinic or pharmacy where provider worl or where the client obtains pharmacy or PrEP services; [c] College certificates, college diplomas, ar university degrees generally take a minimum of 1, 2, and 4 years, respectively, to complete; [d] Approximate USD $190 ($110-270) for PrEP clients and $280 ($190-510) for pharmacy clients; [e] Approximately US $0.60 ($0.28-0.93); [f] Approximately USD $0 ($0-0.28) for PrEP clients. Most (45/56) client participan reported a transportation cost of 0 KES because they walk to their preferred retail pharmacy.

Table 4.2 Anticipated relative advantages of pharmacy-based versus clinic-based PrEP delivery

Advantage	Beneficiary	Illustrative quote	
Proximal Advantages			
Convenience	PrEP clients	(A)	*Ubiquity*: "The beauty is that pharmacies are all over. I could be walking [back to work] from lunch and decide to pass by a pharmacy [to] get my PrEP." *(Kiambu PrEP Provider 10)*
		(B)	*Fast service time*: "[At the pharmacy,] you can take like 20 minutes, and you are out, rather than going to queue for the whole day [at a hospital]." *(Kisumu Pharmacy Client 6)*
		(C)	*Long opening hours*: "You can go to the pharmacy any time because some even work up to midnight. So it [getting PrEP at the pharmacy] wouldn't disrupt you from your work, unlike the hospital, which closes at 5pm." *(Kiambu PrEP Client 5)*
		(D)	*Open weekends*: "In the hospital, you might go [to get PrEP] on a Friday, and they tell you, 'No, we stopped giving [PrEP] at 1 PM. Come back on Monday'…[But] at the chemist, you will get the drugs even if it is on a Sunday. There's no limit on the days." *(Kiambu PrEP Client 8)*
		(E)	*Low/no transportation cost*: "[With pharmacy PrEP], you don't have to travel to the hospital to get PrEP. It is just readily available near where you live, so you would be able to save the [transportation] cost." *(Kiambu PrEP Provider 4)*
Privacy	PrEP clients	(F)	"There are people who would be afraid of being seen at the [HIV] clinic [when getting PrEP] … The advantage [of pharmacy PrEP] is that there is no stigma. No one knows which medicine you are getting there [at the pharmacy]." *(Kiambu PrEP Client 2)*
Autonomy	PrEP clients	(G)	*Choice of location/care provider*: "[I would] prefer going to a person [pharmacy provider] that doesn't know me … So I would go to a distant chemist where I will be comfortable." *(Kiambu PrEP Client 8)*
		(H)	*Choice of care timing*: "Here [with pharmacy PrEP] is also what we call 'time efficiency' because if you decide to walk to this pharmacy and see that it is crowded and you are in a hurry, you have the authority to move to the next pharmacy." *(Kiambu PrEP provider 10)*
Profit	Pharmacies	(I)	"[PrEP] can be a source of income to the pharmacy." *(Kisumu Pharmacy Provider 6)*
Distal Advantages			
Expanded access	PrEP clients	(J)	"[Pharmacy PrEP] could be a better option, especially for those [clients] who cannot reach the bigger hospitals where PrEP is available." *(Kisumu Pharmacy Client 13)*
Increased uptake	PrEP clients	(K)	"I think it [pharmacy PrEP] would improve PrEP uptake in our country because it would remove the barriers [to clinic-based PrEP], especially for adolescents and male populations who feel more comfortable going [to pharmacies] to buy [PrEP]." *(Kiambu PrEP Provider 10)*
Increased adherence	PrEP clients	(L)	"[Pharmacy PrEP] would improve adherence because sometimes people run out of PrEP and feel lazy to go all the way to the hospital or they don't have the [transportation] fare, so they delay. But if it is [available] at the chemist, you will just go and buy because it is near." *(Kiambu PrEP Client 12)*
		(M)	"Sometimes they [PrEP clients] forget their medication and they've traveled far … [It would be great] if we could tell them, 'You can walk to a nearby chemist' and they can continue taking the medication." *(Kiambu PrEP Provider 10)*

Reduced HIV incidence	Society	(N)	"If it [PrEP] is made available in pharmacies, it would really reduce the rate of [HIV] transmission … We are struggling to achieve 90-90-90 [targets] … [Pharmacy PrEP] will encourage more people to test and know their [HIV] status." *(Kiambu PrEP Provider 3)*
Decongested clinics	PrEP clients, providers	(O)	"If we get pharmacy-based PrEP delivery services, it will relieve the work of this [PrEP] clinic very much. And it is to the advantage of those other [PrEP] patients that need a lot of time [with clinic-based PrEP providers]." *(Kiambu PrEP Provider 8)*

Table 4.3 Determinants of acceptability of pharmacy-based PrEP delivery, organized by components of the Consolidated Framework for Implementation Research

CFIR Domain	CFIR Construct: Specific Determinant		Illustrative Quote
Intervention Characteristics	**Relative advantage**:[a] Relative Advantage	(A)	"If those who feel stigmatized queuing here [at the hospital] can pick it [PrEP] from somewhere else, it will decongest [public PrEP clinics]." *(Kiambu PrEP Provider 3)*
	Cost: Affordability	(B)	"[Whether I will get PrEP at a pharmacy] will depend on the cost. I may find that I have run out of drugs and I don't have money. So that may be a challenge." *(Kiambu PrEP Client 10)*
	Cost: Profitability	(C)	"This is a business also … so you can't expect someone to handle [PrEP] clients unless they bring money." *(Kiambu Pharmacy Provider 4)*
Inner setting	**Available resources**: Privacy	(D)	"[The HIV testing and PrEP counseling] must be done in a private room in the chemist … Clients want to feel relaxed and secure." *(Kiambu PrEP Client 14)*
Characteristics of individuals	**Knowledge & beliefs:** Competency	(E)	"[Pharmacy PrEP could work] as long as whoever is mandated [to deliver PrEP at the pharmacy] is well-trained and they understand the importance of PrEP and what it does, what is going to happen if it is misused, the benefits, and all that." *(Kiambu PrEP Provider 4)*
	Other personal attributes: Professionalism – Ethics – Respect – Integrity	(F) (G) (H)	<u>*Ethics*</u>: "[Pharmacy PrEP acceptability] is all about the [ability of the] pharmacist at the chemist to keep clients' confidentiality because PrEP has stigma." *(Kiambu PrEP Client 14)* <u>*Respect*</u>: "[Pharmacy PrEP providers] should not have a judgmental attitude… If you tell them you had unprotected sex recently … [they need to] be understanding." *(Kiambu Pharmacy Client 12)* <u>*Integrity*</u>: "Here [at the hospital] I will follow the rules and say [to a client], 'If you are not [HIV] tested, I will not issue the [PrEP] drugs.' But in the pharmacy … they may be interested in the money over the testing." *(Kiambu PrEP Provider 9)*
Outer Setting	**Patient needs & resources**: Rapport	(I) (J)	"[Pharmacy PrEP providers] should have good relationships with their clients … [The provider] there at the pharmacy [I go to], we are like friends. He knows my medical history." *(Kisumu Pharmacy Client 8)* "[Some clients] will not feel comfortable … if [the pharmacy PrEP provider] knows them personally. So they will prefer to pick them [PrEP drugs] from another chemist." *(Kiambu Pharmacy Client 10)*
	External policies & incentives: Quality Regulations	(K)	"Clients should be protected … [and] assured that they will get good health services … Chemists that offer PrEP should meet some minimum standards to handle patients." *(Kiambu PrEP Client 14)*

[a] For additional results on relative advantages, see Table II.

Table 4.4 Determinants of feasibility of pharmacy-based PrEP delivery, organized by components of the Consolidated Framework for Implementation Research

CFIR Domain	**CFIR Construct:** Specific Determinant	**Illustrative quote**	
Intervention Characteristics	**Cost**: Profitability	(A)	"[To make PrEP financially sustainable for pharmacies to deliver,] there must be a fee [you can charge] … Then you'll be able to afford the space, the record-keeping, the [time and resources for client] follow-up." *(Kiambu Pharmacy Provider 6)*
Inner Setting	**Available resources**: Space	(B)	"Maybe when I open another pharmacy with more space, [I'll deliver PrEP] … But in this pharmacy, I can't because I only have a dispensing area … You can't do counseling when other people are standing there [at the pharmacy counter] … You need privacy." *(Kiambu Pharmacy Provider 6)*
	Available Resources: Human Resources	(C)	"The challenge can be if the person working [at the pharmacy] is only one … because if you are only one person who is counselling and also selling the drugs, then it becomes a challenge." *(Kisumu Pharmacy Provider 4)*
	Available Resources: Supplies	(D)	"[One potential challenge] is you might run out of stock of PrEP." *(Kisumu Pharmacy Provider 2)*
	Compatibility: Cycle Time	(E)	"Most pharmacies are very busy. [Typically,] you only give a client maybe 2 to 5 minutes. But [initiating a client on PrEP] … will take time—maybe around 30 minutes. Giving one client 30 minutes to 1 hour means you will serve less clients." *(Kiambu Pharmacy Provider 7)*
	Compatibility: Documentation	(F)	"For DDA [drugs specified in the Dangerous Drugs Act], the Pharmacy and Poisons Board already requires us to keep a register with the client's name, age, what is prescribed, number of pills, and the date … [For pharmacy PrEP,] we can keep a similar record of how we gave them PrEP." *(Kiambu Pharmacy Provider 6)*
	Access to Knowledge & Information: Provider Support Tools	(G)	"[PrEP providers] have a checklist for [assessing] PrEP eligibility: the RAST [Rapid Assessment Screening Tool]. They [pharmacy PrEP providers] can use that one, too." *(Kiambu PrEP Provider 7)*
Characteristics of Individuals	**Knowledge & Beliefs**: Competency	(H)	"We [pharmacy providers] need information that will help in identifying eligible clients [for PrEP]. We need to get detailed information about side effects, how to manage, which ones to refer." *(Kiambu Pharmacy Provider 3)*
	Self-efficacy: Self-Efficacy	(I)	"[Say] somebody comes for HIV testing…and you did not give enough or adequate counseling, and then you hear the following day somebody has hanged himself or herself … I would be a bit worried [to do HIV testing and counseling]." *(Kiambu Pharmacy Provider 5)*
Outer Setting	**Cosmopolitanism**: Networks of Care	(J)	"It is important sometimes to consult further and make referrals where necessary. [For pharmacy PrEP,] we need a system that is integrated with the pharmacies that are offering PrEP so that they are networked and there are contacts." *(Kisumu Pharmacy Provider 6)*

APPENDIX

Electronic Supplementary Material

Additional details about study methodology

Table S1. Consolidated criteria for reporting qualitative studies (COREQ) checklist

Domain	No. Item	Guide Questions/Description	Section Where Reported
Research Team and Reflexivity	***Personal Characteristics***		
	1. Interviewer/facilitator	Trained research assistants conducted all interviews.	Methods
	2. Credentials	KFO has a ScD in Global Health and Population and a Master's in Public Health. SR has a Master's in Public Health and a BA in Cultural Anthropology. NW has a BA in Sociology. Other research assistants (RAs) who conducted interviews have university training in qualitative research and/or extensive prior field experience conducting qualitative interviews for HIV prevention research studies.	Title Page
	3. Occupation	Population Health Scientist (KFO), Research analyst/candidate for PhD in Global Health Implementation Science (SR), and research assistant (NW and other RAs who conducted interviews)	Not included
	4. Gender	Male and female	Not included
	5. Experience and training	KFO, SR, and NW have taken university-level courses in qualitative research. They and the other RAs who conducted interviews have prior experience collecting, analyzing, and publishing results from several qualitative research projects.	Methods
	Relationship with Participants		
	6. Relationship established	Relationships were limited to interviews.	Not included
	7. Participant knowledge of interviewer	Prior to interviews, RAs provided general descriptions of the study	Methods

		objectives, details of participation, and a brief personal introduction.	
	8. Interviewer characteristics	No interviewer characteristics are reported.	Not included
Study Design	***Theoretical Framework***		
	9. Methodological orientation and theory	Our approach is informed by Corbin and Strauss's (2015) content analysis and Hsieh and Shannon's refinement of it. In line with this approach, we collected data primarily through open-ended questions and derived our coding categories directly from the text data.	Methods
	Participant Selection		
	10. Sampling	We used purposive sampling to obtain participants from HIV clinics and retail pharmacies located in a variety of socioeconomic settings. Additional details not included in the methods section are that we purposefully sampled to have roughly equal numbers of men and women and clients above and below the age of 25 years in the two client samples. Also, we sampled PrEP clients across a range of durations of PrEP use and PrEP providers across a range of provider roles.	Methods
	11. Method of approach	RAs contacted pharmacy and PrEP providers in person or by phone to describe the research and invite them to participate. RAs approached potential client participants in person as they exited select pharmacies or HIV clinics and scheduled interested, eligible individuals for an interview.	Methods
	12. Sample size	82 total interviews completed	Results
	13. Non-participation	Of 49 eligible pharmacy clients invited, 9 declined to participate due to time constraints. All other participant groups had 100% participation.	Results
	Setting		
	14. Setting of data collection	All interviews took place in a private room at a pharmacy, HIV clinic, or study research office.	Methods

	15. Presence of non-participants	Only the participant and interviewer were present during the interviews.	Not included
	16. Description of sample	Current adult pharmacy and PrEP clients and providers.	Methods, Results, and Table 1
	Data Collection		
	17. Interview guide	We developed and pilot tested a de novo interview guide for each participant group.	Methods
	18. Repeat interviews	Each participant was interviewed once (i.e., no repeat interviews).	Methods
	19. Audio/visual recording	We audio-recorded all interviews with participant consent.	Methods
	20. Field notes	We did not collect field notes for this study.	Not included
	21. Duration	Each interview lasted approximately one hour.	Methods
	22. Data saturation	We did not conduct interviews to the point of data saturation.	Not included
	23. Transcripts returned	We did not return transcripts to participants for comment or correction.	Not included
Analysis and Findings	***Data Analysis***		
	24. Number of data coders	Three: KFO, SR, and NW.	Methods
	25. Description of the coding tree	We provide a general description of how we first developed codes inductively and then used second cycle pattern coding to map our findings onto the Consolidated Framework for Implementation Research. We do not include a coding tree.	Not included
	26. Derivation of themes	Our reported themes emerged directly from the text data.	Methods and Results
	27. Software	Dedoose version 8.0.35	Methods
	28. Participant checking	We did not provide participants with feedback on our findings.	Not included
	Reporting		

	29. Quotations presented	We present participant quotes illustrating our findings. Each quote is accompanied by a participant number.	Tables 2, 3, and 4
	30. Data and findings consistent	Yes	Results
	31. Clarity of major themes	Our three major themes are identified by subheadings within the Results section. We discuss the relevance of these themes in the Discussion section.	Results and Discussion
	32. Clarity of minor themes	The specific determinants of pharmacy PrEP acceptability and feasibility are akin to minor themes. We discuss these in detail in the Results and Discussion sections.	Results and Discussion

To ensure participants anchored their responses to the same understanding of PrEP and pharmacy-based PrEP delivery, interviewers presented participants with the following standard description of PrEP and pharmacy-based PrEP delivery prior to soliciting their perspectives:

Pharmacy PrEP description:

I'd now like to shift topics to discuss a medication called pre-exposure prophylaxis or PrEP, for short.

Have you ever heard of PrEP before? ***[Pause for answer. Then proceed.]***

As you may know, in 2015, the Kenyan Ministry of Health approved the use of PrEP for HIV prevention.

If taken consistently every day, PrEP is a safe and effective way for individuals not living with HIV to reduce their risk of acquiring HIV. Currently, PrEP is only being delivered in select healthcare clinics in Kenya.

One of the objectives of this study is to understand **whether and how** PrEP might be delivered in private pharmacies, such as the one where you work.

At a minimum, in a pharmacy-based PrEP program, pharmacy staff would do the following:

[GIVE PARTICIPANT HANDOUT AND READ ALOUD]:

- HIV testing
- Counseling on HIV risk reduction strategies and PrEP, including the risks and benefits and importance of adherence

- Prescribing PrEP with remote physician oversight (likely using a checklist to assess eligibility, with items such as *"Does the client know the HIV status of his/her sexual partner(s)?"*)
- Dispensing and refilling PrEP
- Assessing adherence
- Screening for PrEP side effects and symptoms of HIV infection

Table S2. Characteristics of provider participant workplaces

Variable	Health Clinics[a] (n=9)	Pharmacies (n=16)
Sector		
Public	9 (100%)	0 (0%)
Private	0 (0%)	16 (100%)
County[b]		
Kiambu County	9 (100%)	10 (63%)
Kisumu County	0 (0%)	6 (38%)
Location		
Urban area - informal settlement	1 (11%)	6 (38%)
Urban area - non-informal settlement	2 (22%)	3 (19%)
Peri-urban area	3 (33%)	4 (25%)
Rural area	3 (33%)	3 (19%)
Number of days open per week; median (IQR)	5 (5-5)	7 (6-7)
Number of hours open per day; median (IQR)	8 (8-8)	13 (12-13)
Number of private consultation rooms[b]		
None	0 (0%)	4 (25%)
1	1 (11%)	9 (56%)
2	3 (33%)	2 (13%)
3 or more	5 (56%)	1 (6%)
HIV testing options available[c]		
None	0 (0%)	6 (38%)
Provider-assisted testing only	9 (100%)	3 (19%)
Self-testing only	0 (0%)	1 (6%)
Both provider-assisted and self-testing	0 (0%)	6 (38%)

[a] At 7 of the 9 health clinics, PrEP was delivered exclusively in the Comprehensive Care Clinic (CCC) where clients living with HIV receive care and treatment services. At one clinic, PrEP was additionally available in the Prevention of Mother-to-Child Transmission (PMTCT) Clinic, and at another clinic, PrEP was additionally available in the outpatient department on weekends and public holidays; [b] Within the department where PrEP is delivered (for health clinics) or within the pharmacy (for pharmacies); [c] "Provider-assisted testing" includes blood- and oral fluid-based HIV tests conducted and interpreted on site by a healthcare provider. "Self-testing" includes the sale of blood- or oral fluid-based self-testing kits to clients who conduct and interpret the test off site (e.g., at home).

Table S3. Participant recommendations to ensure acceptability of pharmacy-based PrEP delivery

Specific Determinant	Definition	Recommendation	Illustrative Quote
Privacy	Whether pharmacy has sufficient space to ensure client privacy	– *MOH/implementers*: Consider only allowing PrEP in pharmacies that have a private space for seeing clients. – *Pharmacy PrEP providers*: Consider delivery mechanisms that can enhance client privacy, such as phone-based PrEP counseling for prospective clients.	"The chemist should have a private room where they can engage the clients on confidential issues." *(Kiambu Pharmacy Client 12)* "[I'd feel more comfortable asking for PrEP at a pharmacy] if they had a number you could call and discuss, and then pick [up the drugs from the pharmacy] without talking much [in-person at the pharmacy]." *(Kisumu Pharmacy Client 11)*
Competency	Whether pharmacy providers have adequate knowledge and skills to deliver PrEP properly	– *MOH/implementers:* Require pharmacy providers to undergo PrEP training. – *Pharmacy PrEP providers:* Display PrEP credentials where clients can see them.	"The government should intervene and make that everyone working in a chemist [delivering PrEP] is a professional." *(Kiambu PrEP Client 2)* "It is a must for them to advertise their [PrEP training] certificate." *(Kiambu PrEP Client 13)*
Professionalism	Whether pharmacy providers maintain confidentiality, treat clients with respect, and prioritize client well-being over profit-making	– *MOH/implementers:* Incorporate skills for maintaining confidentiality into PrEP training for pharmacy providers. – *Pharmacy PrEP providers*: Reassure clients that their information will be kept confidential, especially before commencing HIV testing and risk assessment.	"I think they [pharmacy PrEP providers] should just be trained on confidentiality so they may also assure their clients that there is 100% confidentiality." *(Kiambu Pharmacy Provider 6)* "I think they [pharmacy PrEP providers] should reassure the client that 'Whatever we are going to discuss is private. No one is going to hear this.' And they make sure no one is hearing about it. At least that will relieve anxiety and make someone comfortable to share [their information]." *(Kisumu Pharmacy Client 6)*

Rapport	Whether the pharmacy provider and client have an ongoing, close relationship	– *MOH/implementers*: Train pharmacy providers on rapport-building skills – *Pharmacy PrEP providers:* Consider ways to organize delivery such that PrEP clients can see the same provider each time (e.g., designate one pharmacy provider to deliver PrEP; give clients the option to book an appointment); to increase client comfort discussing sexual activity, have clients fill out a questionnaire and use their responses to guide counseling.	"The people [PrEP providers] in the chemist, they should be well-versed on how to create rapport and create a friendly environment because the approach matters a lot." *(Kiambu PrEP Client 14)* "Some clients prefer they should have just that one person who should be taking care of their private health conditions. So maybe they should assign just one person in their chemist who should be taking care of such patients." *(Kisumu Pharmacy Client 15)* "Maybe if they have questionnaires…you can read through it by yourself and write their answers…[This would help clients who] can't say it with their mouths." *(Kiambu PrEP Client 4)*
Quality Regulations	Whether regulations instill confidence in quality of pharmacy PrEP care	– *MOH/implementers*: Only allow PrEP in registered pharmacies; designate entities responsible for monitoring pharmacy PrEP in pharmacies; establish a system for pharmacies to acquire PrEP commodities and a protocol for documenting PrEP dispensed and client information.	"The Pharmacy & Poisons Board can make sure that whichever people we have on the counter [at the pharmacy] are qualified personnel, in conjunction with the Kenya Pharmaceutical Association." *(Kiambu Pharmacy Provider 2)* "We have the SASCOs [Sub-County AIDS and STI Coordinators] who could do that [monitor the pharmacies] at the sub-county or county level." *(Kiambu PrEP Provider 4)* "Maybe we [the PrEP clinic] give [the pharmacy] 100 doses [of PrEP]. The pharmacy should always have the list of [PrEP] patients and [record] when it [dispensing] was done and when the client is due for their next refill—for the accountability of drugs." *(Kiambu PrEP Provider 9)*

			"[Pharmacy PrEP providers must have] adequate training and supervision…[The government must] follow up with those pharmacy providers to see, 'Are they able to deliver it in the right way?'" *(Kiambu PrEP Provider 10)*
Affordability	Whether at-risk clients can afford pharmacy PrEP	*-MOH/implementers*: Consider the possibility of standardizing the price of pharmacy PrEP across pharmacies; consider subsidizing pharmacy PrEP to increase affordability to clients.	"The pharmacies should not determine [the price]. The Ministry [of Health] should put the price because you will find someone [some pharmacy] selling the way they want [i.e., at the price they want] such that people [in need of PrEP] will not benefit." *(Kiambu Pharmacy Provider 9)* "About the pricing, I think the Ministry [of Health] should come up with a fixed price [for PrEP] the same way it happens in hospitals … [Then,] the Ministry of Health should sensitize the public that the [PrEP] drugs can be accessed through the pharmacy but you will be charged for those services." *(Kisumu Pharmacy Provider 4)* "Maybe the government can cost share and kind of sponsor clients to get this service." *(Kiambu Pharmacy Provider 3)* "The government should be sponsoring this [pharmacy PrEP], just like it has done for HIV and AIDS drugs." *(Kisumu Pharmacy Client 13)*
Profitability	Whether PrEP generates sufficient revenue for pharmacies	*-MOH/implementers*: If setting a standard price that pharmacy PrEP providers can charge, take into consideration the full range of costs incurred by pharmacies.	"[We would be doing] testing, counseling, and dispensing… and remember that the Public Health [Department] charges per kilogram of waste product. So disposing unused drugs will also come with the cost of offering the service." *(Kiambu Pharmacy Provider 3)*

Table S4. Participant recommendations to ensure feasibility of pharmacy-based PrEP delivery

Specific Determinant	Definition	Recommendations	Illustrative quote
Space	Whether pharmacy can ensure client privacy	-*MOH/implementers*: Consider whether a private space should be a prerequisite for pharmacies delivering PrEP.	"You cannot answer such questions [about your sexual activity] at the [pharmacy] counter. There must be a place … a private room, where they [pharmacy providers] can engage clients on a bit of confidential issues." *(Kisumu Pharmacy Client 19)*
Human Resources	Whether pharmacy has sufficient staff	– *Pharmacy PrEP providers:* Assess whether hiring additional staff is necessary; recommend that PrEP clients come during certain days/time of day when client volume is low.	"I will see how it will be working. If we don't have enough time [to serve PrEP clients], I think we'll have to add another employee." *(Kiambu Pharmacy Provider 1)* "I would give them [PrEP clients] a specific time, like, 'Come around 10 A.M. There are usually no customers here then.'" *(Kiambu PrEP Provider 5)* "[I would have PrEP clients come] in the morning hours because we'll have enough time to deal with the client then … In the evening, it's a bit hectic, so that person might be forced to wait for long … So we should be specific on the time [we suggest PrEP clients come]." *(Kisumu Pharmacy Provider 1)*
Supplies	Whether pharmacy has consistent access to supplies	– *MOH/implementers:* Establish reliable supply chains, especially for PrEP drugs and HIV testing kits; provide pharmacies with educational materials to give to current and prospective PrEP clients; consider giving pharmacies	"They [pharmacy PrEP implementers] need to make them [PrEP drugs] available for the common distributors. They should not be lacking—at least not in a place like Thika [the largest town in Kiambu County]." *(Kiambu Pharmacy Provider 10)*

		some supplies for free to keep costs to clients low.	"The government…[should] provide the [PrEP] medication and those [HIV testing] strips [and ensure] that they don't run out in the pharmacies." *(Kiambu Pharmacy Provider 9)*
Cycle Time	Whether the time it takes to serve a PrEP client aligns with the pharmacy's workflow	*(See Human Resources, above)*	*(See Human Resources, above).*
Documentation	Whether the pharmacy's record-keeping system can support pharmacy PrEP documentation	*MOH/implementers*: Establish a protocol for documenting pharmacy PrEP care and tracking PrEP clients across delivery points.	"[It would be easier for pharmacy PrEP and PrEP providers to work together] if pharmacies had the same PrEP registers [we have at the hospital] where you write a lot of information about the client and then the file that you will use in seeing the client." *(Kiambu PrEP Provider 1)*
Provider Support Tools	Whether pharmacy PrEP providers have access to tools that facilitate PrEP delivery	– *MOH/implementers*: Adapt existing PrEP provider support tools for pharmacy providers and create new tools where needed.	"I have seen a checklist for ART [antiretroviral therapy] management. We can get something similar to that [for pharmacy PrEP]." *(Kisumu Pharmacy Provider 6)* "You know that form [for] assessing adherence [that] we use in the [public health] facilities? You can also have that one [in pharmacy PrEP] so that at least when they [PrEP clients] come [for refills], you can ask them a few questions … [so] you'll know how they're doing." *(Kisumu Pharmacy Provider 1)* "They could come up with a questionnaire just to guide you [and]…to standardize things so that it can be easier for you to go through it very fast with clients. Then you can tell about their adherence." *(Kiambu Pharmacy Provider 3)*
Competency	Whether pharmacy PrEP providers have adequate knowledge and skills to deliver PrEP properly	– *MOH/implementers:* Hold trainings, including regular CMEs, on PrEP.	"One thing that should be put in place is a regular CME [continuous medical education]. Science is so dynamic. We need to be equipped with the day-to-day knowledge that comes up." *(Kisumu Pharmacy Provider 5)*

		– *Pharmacy PrEP providers*: Consider hiring a clinician with PrEP expertise,	"There should be a doctor [working at the pharmacy] who knows about the issues of [PrEP] drugs." *(Kiambu PrEP Client 16)*
Networks of Care	Whether pharmacies and PrEP clinics are deliberately interconnected, thus allowing pharmacy PrEP providers to access PrEP expertise, as needed	– *MOH/implementers*: Establish connections between retail pharmacies and PrEP clinics and a protocol for consultations and referrals.	"[It would be good] for you to talk with those [PrEP] doctors and then … tell us, 'This will be your [PrEP] doctor [you can consult] … In case there is a problem, please call this one.'" *(Kiambu Pharmacy Provider 8)* "[Provider collaboration would work] if there's someone who's standing by so when there's any issue, you can be able to contact them immediately and get an answer directly." *(Kisumu Pharmacy Provider 1)* "We should have a common shared database so you are able to track [clients] … with unique identifiers … You get to learn that, 'Ok. Last time, they [the client] picked [PrEP] from this place. They were given drugs for 1 month.' It even improves tracking adherence [because] you might see … they didn't go back [for their refill] but they said they have been on continuous risk." *(Kiambu PrEP Provider 10)*
Profitability	Whether PrEP generates sufficient revenue for pharmacies	– MOH/implementers: Consider subsidizing the cost of PrEP delivery to retail pharmacies.	"Being subsidized by the government in terms of the counseling costs [would help]." *(Kisumu Pharmacy Provider 3)* "Whoever is sponsoring this [pharmacy PrEP] should also give [pharmacies] personnel to do it." *(Kiambu Pharmacy Provider 6)*

CHAPTER 5. Conclusions

"*PrEP works if taken*."

This routine counseling message delivered to prospective PrEP clients highlights the importance of adherence. At the same time, it is also a statement about the PrEP research agenda. Multiple clinical trials that demonstrated PrEP's safety and efficacy justify the first half of the counseling message: "*PrEP works*". Yet, the second half — "*if taken*" — is a reminder that this highly efficacious HIV prevention intervention will be 0% effective if it fails to get into the mouths of those who want and need it. With national scale-up of PrEP in many countries across sub-Saharan Africa (SSA) imminent (or ongoing), there is a significant need to identify granular details about where and how to scale PrEP. Implementation science can help address these needs. This dissertation contributes to filling this "know-do gap" by identifying determinants of acceptability and feasibility of PrEP implementation, and potential strategies for addressing these determinants, in three delivery settings in Kenya: HIV clinics, FP clinics, and retail pharmacies.

The implications of this research are evident when considering the broader trajectory of HIV/AIDS programming in SSA. Launched in 2003, the President's Emergency Plan for AIDS Relief (PEPFAR) was a turning point in the HIV/AIDS epidemic. In the 10 years prior, the U.S. spent an average of $274 million per year on HIV/AIDS,[179] and those funds were not well-coordinated.[180] In the pursuant 18 years, U.S. spending on HIV/AIDS has averaged $3.3 billion per year,[179] and PEPFAR has been widely considered a political and public health success, with millions of HIV infections and deaths averted.[181] Under PEPFAR, many countries have significantly expanded their public health infrastructure and human capacity, and a broad array of HIV services (e.g., ART, PMTCT) have been normalized as a mainstay of health systems. Several countries, such as Kenya, South Africa, and Ethiopia, also advanced their economies during this period, in part, because of their ability to control the deleterious effects of the HIV/AIDS epidemic.

The prolonged support of PEPFAR, however, has meant that much of our knowledge about effective HIV service delivery at scale in SSA has been generated within the context of considerable external aid. As PEPFAR "graduates" countries and phases out financial support, this change will affect program operations (e.g., staffing) and will necessitate modifying delivery approaches to enable countries to "do more with less." At the same time that PEPFAR is transferring ownership of HIV/AIDS programs fully to countries, national

governments are accelerating the de-verticalization of HIV care, treatment, and prevention as part of its pursuit of the Sustainable Development Goals (SDGs). Achieving the SDGs, particularly #3 (Good Health and Well-being) and #5 (Gender Equality), will require a wide range of changes at the policy, operational, and clinical level. Although not comprehensive, this dissertation research has generated evidence that may help move towards the integration that countries are seeking. This learning is relevant for a few different constituencies.

1. **Clients**. If delivered at scale, PrEP provides another opportunity to help clients live healthy and productive lives and ensure that clients, especially adolescent girls and young women (AGYW), have more control over the decisions that affect them. Our research adds to the growing body of evidence that, regardless of age, sex, and relationship status, current and prospective PrEP users desire services that are private, convenient, respectful, and safe. It also identified a number of strategies that could be implemented to this end. For example, strategies to increase client privacy include changing infrastructure (as POWER did), moving delivery location (as the One-Stop Shop did), and expanding to entirely new delivery platforms (e.g., retail pharmacies). Tactics to increase convenience include lowering travel distance to PrEP services (e.g., adding PrEP to neighborhood pharmacies) and reducing service times (which the One-Stop Shop achieved through a bundle of strategies). As new modalities of PrEP, such as long-acting injectable PrEP[182] and the dapivirine vaginal ring,[183] become available, additional research will be needed to understand where, from whom, and how these services can be delivered in a way that meets these client care preferences.

2. **Providers.** This work has demonstrated that, for providers to uptake PrEP delivery as a routine practice, they must have sufficient means, motive, and opportunity.

    - ***Means*:** Collectively, these three papers identified four key factors that enhance provider capability to deliver PrEP: (1) training and support; (2) sufficient and appropriate physical space; (3) access to supplies; and (4) an efficient process for handling PrEP clients. Our research also revealed variation in these factors both within and across delivery platforms. For example, the POWER study revealed that, even among facilities of the same "type" (e.g., FP clinics), some are better poised to provide the aforementioned means to providers than others.

- ***Motive***: At retail pharmacies, providers were highly motivated to deliver PrEP, in large part, because they anticipated that offering this service would bring in additional clients and revenue. However, for providers who do not stand to directly profit financially from PrEP delivery, instilling motivation will likely require other strategies. Hiring additional staff or offering financial incentives to deliver PrEP may not be viable strategies for public sector facilities, particularly those receiving increasingly less PEPFAR support over time. However, as observed in the One-Stop Shop study, eliminating waste from provider workflow and sharing positive client feedback with providers may motivate them to take on the additional work of PrEP delivery. Moreover, some providers, such as those with a passion for serving particular client populations (e.g., AGYW), may be more intrinsically motivated to deliver PrEP if they view it as an additional tool for promoting that sub-population's health and well-being.

- ***Opportunity***: In addition to having the requisite knowledge and skills, resources, and motivation, providers also need to be prompted with opportunities to deliver PrEP. Such prompts may include, for example, clients requesting the service, as well as other service providers within the delivery setting referring clients for PrEP. Addressing deficits in opportunity may require implementation strategies focused on the supply side (e.g., managers clarifying the intersection of providers' responsibilities so they know to whom to refer prospective PrEP clients) and/or demand-side implementation strategies (e.g., demand creation activities to get more PrEP clients in the door).

Our understanding of PrEP providers' means, motives, and opportunities is still in its early stages. Additional research is needed to develop and test tools for assessing provider readiness to deliver PrEP. A good starting point for such work would be the Organizational Readiness for Implementing Change (ORIC) tool,[184] which could be adapted specifically for PrEP delivery in the target setting. Future research should also explore specific implementation strategies that target provider means, motives, and opportunities and measure their effect on implementation outcomes[40] (e.g., adoption, penetration, and sustained engagement in PrEP delivery among providers).

3. **Subnational governments**: District and provincial leaders are often the recipients of limited budgets and have little financial freedom to conduct operations research for efficiencies. As more services are

offered to clients, these subnational leaders are hungry for ways to integrate care so that each incremental burden does not break the back of the health system. Our learning from the One-Stop Shop study demonstrates that redirecting away from bottlenecks, task shifting, and differentiating clients based on the subset of services they need can reduce client wait time and improve their satisfaction; however, additional research is needed to understand the impact of these changes on provider productivity. Our findings that not all delivery platforms are equally ready to implement PrEP suggests that sub-national leaders should consider quickly scaling PrEP to those facilities that are ready (the "low-hanging fruit") while continuing to test ideas at less-prepared facilities.

4. **Private Sector**: Retail pharmacies represent a largely untapped part of the private sector that is ripe for PrEP delivery in SSA. Our formative research revealed high interest among Kenyan pharmacy and PrEP clients and providers in pharmacy-based PrEP delivery. In Kenya and South Africa, small-scale pilot studies are currently testing the feasibility of PrEP delivery via retail pharmacy providers,[185] similar to programs in several U.S. cities.[152,157–161,186] Private pharmacists could also play a role in telehealth models, such as the Iowa TelePrEP model currently used in select parts of the U.S. state of Iowa,[150] through which clients have video call visits with PrEP-trained pharmacists, obtain requisite laboratory tests in their local communities, and receive PrEP drugs through the mail. If regulations around PrEP prescriptions are loosened, then private pharmacies could supply PrEP directly to clients. As of mid-2020, the U.S. state of California allows pharmacies to dispense a 60-day supply of PrEP without a prescription.[151] And in the United Kingdom, PrEP is available for purchase via the internet without any prescription at all.[187–189]

5. **National Governments**: Although a significant victory for health and human rights, the inclusion of ART, PMTCT and other associated HIV services into the public health system has placed additional budget and operational strain on national governments. This strain is only likely to increase with the phase-out of PEPFAR's financial support. Therefore, in addition to delivering an increasing set of services efficiently, national governments are also seeking ways to lower the burden of PrEP delivery on the public health system. The role of national governments vis-à-vis PrEP delivery largely centers around their ability to enable or restrict implementation via regulation. To further enable PrEP delivery,

national governments could increase engagement with the private sector, as described above. Getting private pharmacy-based PrEP delivery to succeed at scale will require policy changes at the national level (e.g., changing pharmacy providers' scope of work to include prescribing ARVs outright or under the supervision of a remote clinician). The Kenya Pharmacy and Poisons Board (the national drug regulatory authority) might consider the path taken by the South Africa Pharmacy Council, which recently approved a new qualification called "pharmacy-initiated management of antiretroviral therapy" (PIMART) that will allow pharmacy providers to independently prescribe and dispense PrEP, PEP, and ART.[190] National governments could also remove or loosen existing restrictions to facilitate PrEP scale-up. National drug regulatory authorities could, for example, consider rescheduling or descheduling PrEP so that it can be provided by lower-level cadres or sold over the counter. National ministries of health could also revise PrEP guidelines to simplify PrEP delivery. For example, in light of growing evidence that PrEP use carries low risk of impaired kidney function[191] and low harm to liver function among individuals with Hepatitis B (HBV) infection,[192] ministries of health could consider eliminating the requirement for creatinine and HBV testing for initiating and/or continuing PrEP.[107] Eliminating these laboratory tests would lower the burden of PrEP delivery on providers (especially those who currently have to refer clients elsewhere for testing) and decrease access barriers for clients who cannot afford to pay out of pocket for these tests.

In addition to its regulatory function, national governments also play a key role in PrEP implementation via their budget allocation decisions. National governments may, for example, consider increasing their investment in youth-friendly health facilities to further reach AGYW. They might also incentivize facilities that are heavily accessed by PrEP priority populations (e.g., HIV comprehensive care clinics, FP clinics) to transition to "one-stop shop" PrEP services, as our research suggests that such a delivery configuration is generally more efficient and satisfying for clients. Where appropriate, national governments could subsidize PrEP delivery and/or pursue financial interventions to channel clients towards particular delivery platforms, such as providing low-income clients with vouchers to obtain free or discounted pharmacy-based PrEP services. Lastly, additional funding could also be earmarked for the development of provider support tools, such as a national provider hotline or app that connects new

PrEP providers with PrEP experts who answer questions and offer clinical decision-making support, to proactively address deficits in knowledge, skill, and confidence that may hinder provider adoption of this new clinical practice.

Overall, this dissertation research highlights the value of focused implementation research into context-specific implementation challenges. PrEP is not the first, nor will it be the last, set of services that will be added to health systems in SSA. As national governments bring PrEP and other services to scale, they may consider creating sub-national "implementation units" of dedicated change managers who can track implementation challenges at the front line in real time and identify for senior leadership which aspects of implementation should move ahead quickly and which require additional support (e.g., places where bottlenecks or other defects are occurring). These implementation units should use a standard set of indicators for implementation progress (e.g., "median service time," "percent of PrEP-trained providers attending to 1+ PrEP client per week") so that senior leadership can easily compare facilities, identify high performers, and investigate factors driving their "positive deviance." Importantly, these units could enable rapid innovation-to-scale not just for PrEP but also for the wider range of services included in countries' PHC packages, thus accelerating countries towards good health and well-being (SDG #3) and gender equality (SDG #5).

In addition to those already mentioned, the following areas are ripe for investigation:

- ***New biomedical HIV prevention technologies***: Although this research focused on daily oral tenofovir-based PrEP, its findings may inform the future implementation of other ARV-based prevention tools, such as long-acting injectable PrEP and the dapivirine vaginal ring. Additional research will be required to understand whether and how implementation of these products will work both in the delivery platforms examined in this dissertation (HIV clinics, FP clinics, and retail pharmacies) as well as other settings not yet explored.
- ***Lay providers***: Similar to differentiated ART programs,[144] the DREAMS initiative has implemented community-based PrEP refills to AGYW via community health workers (CHWs) in several countries across SSA.[193] However, CHW-delivered PrEP services have not been studied in depth among

other PrEP priority populations (e.g., serodiscordant couples). Future research should explore the potential role of CHWs in PrEP delivery, particularly for low-income populations with limited access to public facilities offering PrEP and limited financial means to purchase private sector-based PrEP services.

- ***Integration into primary health care:*** Advances in HIV treatment and prevention have turned HIV infection into a chronic disease to be prevented and managed.[194] Although primary care providers' knowledge and attitudes toward PrEP have been explored in high-income countries,[195,196] comparatively less research on this topic has been conducted in SSA. Further investigations are needed to understand whether and how PrEP might be delivered by providers in PHC settings.

In global health, we often assume that the effectiveness of an intervention will translate to its rapid, enthusiastic uptake and sustained use. However, PrEP is a strong example of a highly efficacious intervention whose implementation is challenged by a wide range of factors, such as pharmacists' scope of practice, physical layout of facilities, and public sector worker perceptions of their jobs. This dissertation provides insight into those implementation challenges and offers solutions that may translate to interventions even beyond PrEP. Failure to acknowledge and actively solve these implementation challenges will inevitably delay service delivery and lead to fewer patients receiving the message we should all keep in mind: "PrEP works *if taken*."

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