

Barriers to and Strategies for Early Implementation of Pharmacy-Delivered PrEP Services in
Kenya: An Analysis from Routine Data

Hilma Nambili Nakambale

A thesis

submitted in partial fulfillment of the
requirements for the degree of

Master of Public Health

University of Washington

2022

Committee:

Andy Stergachis

Katrina Ortblad

Program Authorized to Offer Degree:
Global Health

© Copyright 2022

Hilma Nambili Nakambale

University of Washington

Abstract

Barriers to and Strategies for Early Implementation of Pharmacy-Delivered PrEP Services in Kenya: An Analysis from Routine Data

Hilma Nambili Nakambale

Chair of the Supervisory Committee:

Andy Stergachis

Department of Pharmacy and Department of Global Health

In settings where populations at high risk of HIV acquisition face challenges using clinic-based pre-exposure prophylaxis (PrEP) for HIV prevention, differentiated PrEP delivery models are needed to expand access and reach. During a pilot study testing a novel pharmacy-delivered PrEP model in Kenya, we identified early implementation barriers and actions that providers and study staff took in response.

We trained pharmacy providers at four private pharmacies in Kisumu and Thika, Kenya to initiate and continue clients at risk of HIV acquisition on PrEP using a prescribing checklist with oversight from remote clinicians. Research assistants stationed at the pharmacies completed weekly observation reports. Using content analysis, we analyzed reports from the first six months of implementation and notes from a subsequent member-checking meeting with pharmacy providers and research staff near study endline to identify multi-level barriers to implementation and actions taken in response. We organized identified barriers and actions by domains of the Consolidated Framework for Implementation Research (CFIR).

From November 2020 to May 2021, pharmacy providers screened 472 potential PrEP clients and initiated 211 (45%) on PrEP. Research assistants stationed at the pharmacies completed 74 weekly observation reports (~18 reports/pharmacy). We identified barriers to pharmacy-delivered PrEP across CFIR domains: high costs to clients (intervention characteristics), client discomfort discussing sexual behaviors and HIV testing with providers (outer setting), provider frustrations that PrEP delivery was time-consuming and disruptive to their workflow (inner setting), high provider turnover (inner setting), and provider hesitancy to deliver PrEP due to concerns about encouraging promiscuity (characteristics of individuals). To help address these, pharmacy providers implemented an HIV risk self-screening option for prospective PrEP clients, allowed flexible appointment scheduling, and conducted pharmacy PrEP trainings for newly hired providers.

Our study provides insight into early barriers to implementing pharmacy-delivered PrEP in Kenya and potential actions to mitigate these barriers. Future research is needed to understand client perspectives on this delivery model, to evaluate the feasibility and effectiveness of this model, and to assess late-stage implementation outcomes.

The purpose of this thesis (presented in manuscript format) is to fulfill the following aims:

- Aim 1: To identify the early implementation barriers and facilitators for the pharmacy-based PrEP delivery model at four pharmacy sites in Kenya
- Aim 2: To identify actions that pharmacy providers developed to address barriers and challenges encountered in the early implementation phase of pharmacy-based PrEP delivery at four pharmacy sites in Kenya

INTRODUCTION

HIV clinics are the mainstay of HIV prevention treatment in Kenya and provide oral pre-exposure prophylaxis (PrEP) for individuals at risk [1, 2]. Barriers to clinic-based PrEP delivery, such as long wait times and HIV-associated stigma, continue to limit the reach of PrEP services [2, 3]. In Kenya, there are over 6,000 registered private pharmacies that often serve as the first point of care for many individuals [1, 4]. In several high-income settings, pharmacy-based PrEP delivery has been demonstrated as a promising, novel strategy that has the potential to overcome existing barriers to clinic-delivered services, offer convenience and privacy to potential PrEP users, and extend the reach of PrEP services [1, 5, 6].

In most countries, retail pharmacies are involved in providing sexual and reproductive services such as contraceptives (e.g., condoms and birth control pills) and PrEP can be an important component to these services. Sexual and reproductive health services offered by pharmacies are integrated naturally into regular services, however there are not offered within frame of differentiated services thus there is no designed implementation framework for these services. Integrating PrEP in these sexual and reproductive health services offered by pharmacies requires an implementation framework for service delivery, follow-up, and linkage to care. Retail pharmacies are usually located in places where individuals routinely go for daily services such as shopping which makes them an ideal place to offer PrEP, thus, to address barriers such as stigmatization mostly associated with HIV prevention services accessed at the clinics. Additionally, offering PrEP as an integral part of sexual and reproductive health services in retail pharmacies can extend efforts to increase HIV testing, linkage to care, and early initiation of antiretroviral therapy [25, 26]. Therefore, integrating PrEP in sexual reproductive health services

offered by retail pharmacies would broaden the scope of sexual and reproductive health service that are currently offered and extend reach to individuals at a high risk of HIV acquisition.

Systematically documenting what works and does not work during the early implementation of a new delivery model is an essential aspect of formative evaluation, which provides valuable insights into the complexity of implementation projects and helps answer questions about context, adaptations, and response to change that can guide future implementation efforts[7, 8]. For example, documenting implementation activities provides information for key evaluation stakeholders to adapt and modify support activities to make them more relevant to practices, thus enhancing implementation [8]. This paper reports our findings on early barriers to PrEP implementation at private pharmacies in Kenya and the actions pharmacy providers and study staff took to help address these barriers during the first six months of implementation.

METHODS

Study setting

The “Pharm PrEP” pilot study (ClinicalTrials.gov: NCT04558554) took place at four privately-owned retail pharmacies in Kenya, two in Kisumu and three in Thika, which, at study baseline, each served between 100-300 clients per week [10]. Kisumu is an urban city in western Kenya with a generalized HIV epidemic and a population-level HIV prevalence of ~15% [11]. Thika is a peri-urban city located ~40 kilometers outside of Nairobi in Central Kenya with a concentrated epidemic and population-level HIV prevalence of ~6%. To participate in the pilot study, pharmacies had to be legally registered in Kenya and operated by authorized pharmacy providers (e.g., pharmacists and pharmaceutical technicians).

Pharmacy provider training & support

We trained pharmacy providers (licensed pharmacist and pharmaceutical technologists) to identify potential clients, based on products or services purchased suggestive of sexual behavior (e.g., condoms) or associated with risk of HIV acquisition (e.g., emergency contraception), and assess PrEP eligibility using a prescribing checklist (**Appendix I**). We designed this checklist, which is part of a care pathway for pharmacy-delivered PrEP services, in collaboration with key stakeholders from the Kenya Ministry of Health, National AIDS & STI Control Program (NAS COP), Pharmacy & Poisons Board (PPB), Kenya Medical Research Institute, and Partners in Health, Research, and Development (PHRD) [1]. The prescribing checklist outlined the study's core components, including screening for PrEP eligibility, HIV risk counseling, HIV testing (using provider-assisted HIV self-testing), and prescribing and dispensing of PrEP. In cases where pharmacy providers had questions or needed clarification on patient eligibility or other health concerns, a remote clinician was available for consultation via phone call or text message.

Individuals who met the following eligibility criteria were eligible to enroll in the study: self-reported behaviors associated with risk of HIV acquisition (according to Kenya's Risk Assessment Screening Tool [13]), age ≥ 18 years, confirmed HIV-negative status, no contraindications for PrEP use (e.g., no history of liver or kidney disease), and willingness to participate and give written informed consent.

Clients paid a service delivery fee of 300 Kenyan Shillings [KES] (~\$3 United States Dollars [USD]) to pharmacy providers for each study visit and were compensated 500 KES (~\$5 USD) for completing research-related activities (e.g., questionnaires) at each visit. Pilot pharmacies received 10,000 KES (~\$100 USD) per month for participating in the study.

Implementation observation reports

Throughout the study, a trained research assistant was stationed at each pilot pharmacy and completed participant questionnaires and observed interactions between pharmacy providers and clients. At the end of each week, research assistants recorded their observations in structured reports (**Appendix II**) that included: 1) descriptions of clients seeking/purchasing products or services indicative of sexual activity and/or HIV risk; 2) questions/concerns about PrEP raised by prospective clients and/or enrolled participants; 3) provider challenges delivering PrEP; and (4) practices providers implemented, with support by research staff as needed, to facilitate PrEP delivery.

Analysis

First, using Dedoose (v9.0.17, Los Angeles, USA), the first author (HN) coded all 74 reports according to the four main topics included in the report template. Next, authors AK, KO, MM, and HN reviewed 25% of the coded reports and identified additional topics to add to the codebook, and author HN coded the reports for these additional topics. Thereafter, authors HN, AK, KO, and MLM organized the findings by level of impact (client, provider, and pharmacy).

We next conducted member checking to confirm our preliminary findings by presenting to a subset of pharmacy providers (n=2), research assistants (n=7), study coordinators (n=2), and principal investigators (n=3). Attendees provided additional information on barriers and actions taken in response that were not captured in the weekly reports.

Lastly, we categorized identified barriers—along with actions taken in response—according to the Consolidated Framework for Implementation Research (CFIR). The CFIR contains 39 constructs

hypothesized to influence implementation of an intervention, organized into five domains: 1) intervention characteristics, 2) individual characteristics (i.e., characteristics of the individuals involved in implementing and receiving the intervention), 3) inner setting (i.e., the organization in which implementation occurs), 4) outer setting (i.e., the community or system), and 5) implementation process (e.g., how implementation is executed) [14, 15, 16]. We chose to use the CFIR because of its broad applicability to a variety of stakeholders (e.g., individuals directly and indirectly implementing the intervention; target recipients of the intervention) and its inclusion of factors that may affect implementation at different levels (e.g., individual, organization, community).

RESULTS

Table 1. Early implementation barriers to pharmacy-delivered PrEP and actions taken in response

CFIR constructs	Implementation barrier	Actions taken (in response to barrier)
INTERVENTION CHARACTERISTICS		
Cost	<p>Clients:</p> <ul style="list-style-type: none"> Some clients felt that the fee for PrEP services (300 KSh) was too expensive. <i>[Reported at all pharmacies]</i> <p><i>“In [this] pharmacy, most people do not want to pay anything [for PrEP] and only [agree to] pay as they are getting reimbursed [for participating in the study].”</i> – Notes recorded by research staff member during member-checking meeting</p>	<ul style="list-style-type: none"> Some providers encouraged clients to use the compensation they were receiving for pilot participation (500 KSH) to cover the cost of PrEP services.
OUTER SETTING		
Patient Needs and Resources	<p>Clients:</p> <ul style="list-style-type: none"> Some clients (especially older ones) did not feel comfortable discussing their sexual behaviors with pharmacy providers. <i>[Reported at all pharmacies]</i> <p><i>“Some couples who come to buy condoms, when talked to about PrEP by the provider, fear talking about their risks when together.”</i> – Weekly report,</p> <p><i>“Some clients aren't ready to talk about their sexual behaviors.”</i> – Weekly Report</p> <ul style="list-style-type: none"> Some clients are hesitant to test for HIV for fear of receiving a positive result. <i>[Reported at all pharmacies]</i> <p><i>“Some pharmacy clients want PrEP and don't want to be tested [for HIV].”</i> – Weekly Report</p>	<ul style="list-style-type: none"> Pharmacy providers reassured clients of the confidential nature of their interactions. Some pharmacies (Pharmacies B and C) let clients complete the HIV risk assessment tool on a tablet (vs. verbally over the counter) and only probed further about their sexual behaviors if necessary. During discussions with prospective PrEP clients, providers explained why HIV testing is an important and required step for PrEP initiation. Providers also reassured clients that HIV testing would be conducted in a private room with results kept confidential and encouraged them to come back if/when they felt ready. <i>“[Pharmacy providers] Reassuring participants of privacy and confidentiality”</i> – Weekly Report
INNER SETTING		
Compatibility	<p>Providers:</p> <ul style="list-style-type: none"> Some providers found initiating clients on PrEP to be time-consuming and disruptive to their workflow. <i>[Reported at all pharmacies]</i> <p><i>“The [PrEP] initiation process takes too long, and [pharmacy] providers have to attend to other clients.”</i> – Notes recorded by research staff member during member-checking meeting</p>	<ul style="list-style-type: none"> Some providers asked PrEP clients to come back at a time when they anticipated the pharmacy would be less busy and they would have ample time to serve the client. Some providers multi-tasked, completing other PrEP-related tasks and/or serving other clients during natural breaks in the PrEP delivery process (e.g., while waiting ~20 minutes for HIV test results).

		<p><i>"The pharmacy provider fills [out] the prescriber's checklist with the [study] participant as the HIV test still runs to save on time, especially for participants being enrolled who are in a bit of a hurry."</i> – Weekly Report</p>
Available Resources	<p>Pharmacies:</p> <ul style="list-style-type: none"> • Provider turnover was high at some pharmacies and newly hired providers were not familiar with PrEP pharmacies. <i>[Reported at Pharmacies D]</i> <p><i>"High pharmacy provider turnover [is a challenge]. New ones come [i.e., start working at the pharmacy] and don't know how to initiate PrEP [or] identify clients [i.e., potential PrEP clients]."</i> – Weekly Report</p>	<ul style="list-style-type: none"> • Study staff held trainings whenever needed to ensure newly hired pharmacy providers had the requisite knowledge and skills to deliver PrEP.
CHARACTERISTICS OF INDIVIDUALS		
Knowledge and Beliefs about the Intervention	<p>Providers:</p> <ul style="list-style-type: none"> • Some providers were hesitant to deliver PrEP out of concern that it would encourage clients to be promiscuous. <i>[Reported at Pharmacies A and D]</i> <p><i>"Pharmacy provider is not confident to engage on a PrEP talk."</i> – Weekly Report</p>	<ul style="list-style-type: none"> • Study staff held trainings whenever needed to ensure newly hired pharmacy providers had the requisite knowledge and skills to deliver PrEP.

From November 2020 to May 2021, research assistants stationed at the pilot pharmacies completed 74 observation reports (~18 reports/pharmacy). During this time, pharmacy providers screened 472 potential PrEP clients and initiated 211 (45%) on PrEP. In April 2021, five months into pilot implementation, one pharmacy dropped out of the study because they reported that did not want to be associated with the stigma of delivering HIV services; this pharmacy was replaced with a new pharmacy that same month. Below, we describe the barriers to implementation we identified, organized by CFIR component, and the actions taken by pharmacy providers and study staff in effort to mitigate these barriers. **Table 1** summarizes our findings, noting the level of impact, and features additional illustrative quotes.

Intervention characteristics

Cost. According to research assistants and pharmacy providers, many clients felt the price pharmacies were charging for PrEP services (300 KES) was too high. Some clients expressed a desire for the pharmacy to offer PrEP for free or at a lower price, as this would make it easier for them to afford obtaining PrEP from the pharmacy. To mitigate this barrier, providers encouraged clients to consider that they would receive 500 KES compensation for participating in research activities (e.g., questionnaires) and so, in a sense, were receiving PrEP “for free”. According to pharmacy providers, this reframing convinced some clients to initiate PrEP despite the service fee.

Outer setting

Patient needs and resources. Pharmacy providers and research assistants noted that some prospective PrEP clients were uncomfortable discussing their sexual behaviors during HIV risk assessment and/or were hesitant to test for HIV at the pharmacy for fear of testing positive. In response, some providers gave clients the option to screen themselves for HIV risk, allowing them

to read the HIV risk assessment questions (e.g., “In the past six months, have you had sex with more than one partner?”) on an electronic tablet and mark down their answers. Providers also helped ease fears related to HIV testing by reassuring clients that they would conduct the HIV testing in a private room and keep their test results confidential.

Inner setting

Compatibility. Reports indicated that delivering PrEP generally took providers more time than other services and that, when the single pharmacy provider on shift was busy attending to a PrEP client, this at times created backlogs. Providers were especially concerned when other pharmacy clients were kept waiting while they attended to PrEP clients, and research assistants observed that this sometimes led the provider to rush through parts of PrEP delivery, such as counseling:

“Some providers missed discussing all the details [of PrEP] due to other consumers [i.e., pharmacy clients waiting to be seen]” (Notes recorded by research staff member during member-checking meeting with all study pharmacy providers, June 2021).

To address this issue, some pharmacy providers asked PrEP clients to return to the pharmacy during times of the day when the pharmacy was less busy. Additionally, some providers delivered parts of the intervention concurrently, such as completing the prescribing checklist during the 20-minute wait for the HIV self-test to process.

Available resources. At one pharmacy, high turnover of pharmacy staff hindered implementation of PrEP delivery. To ensure service continuity, study staff and pharmacy providers held trainings whenever needed to ensure newly hired pharmacy providers had the requisite knowledge and skills to deliver PrEP.

Characteristics of individuals

Knowledge and beliefs about the interventions. A few providers were not comfortable providing PrEP because they believed it would encourage clients to be more sexually “promiscuous.” In response, study staff encouraged these pharmacy providers to take a non-judgmental approach when serving PrEP clients and reminded them that the goal of PrEP is to protect clients from HIV, regardless of whether they—the pharmacy providers—morally agree with clients’ sexual behaviors.

DISCUSSION

In the early implementation phase of a novel pharmacy-delivered PrEP model in Kenya, several implementation barriers were identified as were actions taken by pharmacy providers, with the support of study staff, to help mitigate these. We identified barriers to pharmacy-delivered PrEP services across the CFIR domains, including high costs to clients (intervention characteristics), client discomfort discussing sexual behaviors and HIV testing with providers (outer setting), provider frustrations with PrEP delivery being time-consuming and disruptive to workflow (inner setting), high provider turnover (inner setting), and provider hesitancy to deliver PrEP for concerns of encouraging promiscuity (characteristics of individuals).

In this analysis, we found that PrEP delivery was time-consuming for some pharmacy providers and disrupted their workflow. Pharmacy-delivered PrEP involves several steps (e.g., screening, counseling, provider assisted HIV self-testing, prescribing), many which involve a considerable amount of time for the provider to ensure that PrEP is being delivered safely to clients who could benefit from this intervention. During the pilot, pharmacy providers were attending to potential PrEP clients on a walk-in basis, which is the common practice for private pharmacies in Kenya, but often disrupted their normal workflow and achievement of daily delivery targets for other services. For future pharmacies considering PrEP adoption, implementation of a fixed scheduling

option for PrEP initiation and refill visits may help for the prevention of workflow disruptions and contribute to intervention sustainability. Fixed scheduling models could be online-based, determined on a client-by-client basis, or linked to certain pharmacy days or hours of operation that are typically less busy – as is ongoing in a pharmacy-delivered PrEP model in Atlanta, Georgia, USA [17]. Important in all these potential models are equity considerations, for example, with an online scheduling model only, potential PrEP clients who have no access to electronic gadgets may be excluded. For Kenya, short mobile phone text messages would be a feasible scheduling model as this method is more convenient and accessible to the majority of the potential PrEP clients.

During the pilot, clients (especially older clients) were hesitant to discuss their sexual behavior with pharmacy providers for fear of judgement, which limited their engagement with providers and potential uptake of services from which they could benefit. Stigma related to HIV treatment and prevention from either the providers or the community can pose significant barriers to the delivery of pharmacy PrEP services [14]. One pharmacy, for example, dropped out of the pilot five months into implementation citing concerns around HIV-related community stigma, that is, fear that their pharmacy would be labeled as a place serving individuals living with HIV and clients would avoid coming there for this reason. Further exploration of how stigma related to promiscuity and HIV prevention intersects with pharmacy-delivered PrEP and how it can be mitigated at the social and interpersonal level is crucial to improve pharmacy-delivered PrEP services [18].

We also found that some pharmacy providers lacked clear communication and confidence in PrEP due to personal beliefs such as that PrEP promotes indecent sexual behavior. To facilitate effective delivery of pharmacy-delivered PrEP, pharmacy providers need to be equipped with high quality

training especially in settings like Kenya where faith-based beliefs that condemn certain sexual behavior can potentially limit PrEP delivery (e.g., Christianity which is the most common religion in Kenya condemns sex work and homosexuality). Our findings also suggest that re-training of pharmacy providers is important in the early stages of pharmacy-delivered PrEP to reinforce the purpose of PrEP, ensure PrEP is delivered without judgement and to address concerns with high pharmacy provider turnover. Contrary to our findings, studies from other pharmacy settings revealed that pharmacy providers disagreed with the notion that widespread use of PrEP would contribute to increased rates of HIV transmission [17, 20, 23] and expressed their willingness and competency to talk with patient about sexual health. Considerations to scale up pharmacy PrEP in Kenya should include rigorous provider training addressing provider judgement of clients' sexual behavior and emphasizing the importance of HIV prevention and the benefits of PrEP to clients at high risk of HIV acquisition.

For models of pharmacy-delivered PrEP to be self-sustaining, services should be affordable, and reimbursement should be associated with service provision. Patients expressed that the service fee of 300 KES charged during the pilot study was unaffordable for long term PrEP services. This study highlights the need to provide affordable long-term pharmacy-delivered PrEP services, including drugs and HIV test kits, to increase uptake and access. This could be done through long-term financial support such as subsidized services (e.g., the Ministry of Health should have an agreement with private pharmacy providers for subsidizing PrEP). Studies done in other pharmacy settings also noted that some providers required reimbursement for their labor and time to offer PrEP services [23, 24]. During our meeting with pharmacy providers in Kenya, they did not express concern about getting compensation for offering PrEP services, which could be because they found the monthly compensation that they received to be sufficient.

Our findings have several limitations. First, our results are based on observations made by research assistants during the critical first six months model implementation in a pilot study; thus, we were not able to capture mid- and late-stage implementation barriers in this analysis. Second, the actions implemented to mitigate identified barriers were designed by pharmacy providers and study staff and did not incorporate the perspectives of pharmacy clients. We also did not measure the impact these actions had on increasing uptake and retention of pharmacy-delivered PrEP, information that would be useful to guide the scale-up of pharmacy-delivered PrEP services. Finally, the pilot only took place at four retail pharmacies in two settings in Kenya, thus the generalizability of these findings may be limited, especially considering the diversity of private pharmacies and their clientele in Kenya.

Our findings from the pharmacy-delivered PrEP pilot study give insight into important considerations for optimization of early implementation pharmacy-delivered PrEP in private pharmacies in Kenya and similar settings. Refining early-stage implementation of pharmacy-delivered PrEP programs by understanding barriers and identifying suitable actions to address these can significantly extend the reach of HIV prevention services to individuals at high risk of HIV acquisition and those who can benefit from PrEP. Future research should explore data from client interviews, refine strategies and understand their underlying mechanisms, and evaluate their feasibility and effectiveness in pharmacy-based PrEP delivery in Kenya.

REFERENCES

1. Ortblad, K. F., Mogere, P., Roche, S., Kamolloh, K., Odoyo, J., Irungu, E., Mugo, N. R., Pintye, J., Baeten, J. M., Bukusi, E., Ngure, K., Tsala, B., Cherutich, N., Mugambi, M., Sheikh, A., Mensah, M., Musyoki, H., Mbugua, B., Somoni, L., ... Stergachis, A. (2020). Design of a care pathway for pharmacy-based PrEP delivery in Kenya: results from a collaborative stakeholder consultation. *BMC Health Services Research*, 20(1), 1–9. <https://doi.org/10.1186/s12913-020-05898-9>
2. Kenya – PrEP Watch. <https://www.prepwatch.org/country/kenya/> Accessed: 2021-08-2021
3. *HIV and AIDS in Kenya | Avert.* (n.d.). Retrieved October 19, 2021, from <https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa/kenya>
4. Wafula FN, Miriti EM, Goodman CA. Examining characteristics, knowledge and regulatory practices of specialized drug shops in Sub-Saharan Africa: a systematic review of the literature. *BMC Health Serv Res.* 2012 Jul 27;12:223. doi: 10.1186/1472-6963-12-223. PMID: 22838649; PMCID: PMC3520114.
5. Crawford ND, Josma D, Morris J, Hopkins R, Young HN. Pharmacy-based pre-exposure prophylaxis support among pharmacists and men who have sex with men. *J Am Pharm Assoc* (2003). 2020 Jul-Aug;60(4):602-608. doi: 10.1016/j.japh.2019.12.003. Epub 2020 Jan 30. PMID: 32007364; PMCID: PMC7387144.
6. Tung EL, Thomas A, Eichner A, Shalit P. Implementation of a community pharmacy-based pre-exposure prophylaxis service: a novel model for pre-exposure prophylaxis care. *Sexual Health.* 2018 Nov;15(6):556-561. DOI: 10.1071/sh18084. PMID: 30401342.
7. Stetler, C. B., Legro, M. W., Wallace, C. M., Bowman, C., Guihan, M., Hagedorn, H., Kimmel, B., Sharp, N. D., & Smith, J. L. (2006). The role of formative evaluation in implementation research and the QUERI experience. *Journal of General Internal Medicine*, 21(SUPPL. 2), 1–8. <https://doi.org/10.1111/j.1525-1497.2006.00355.x>
8. Keith, R.E., Crosson, J.C., O'Malley, A.S. *et al.* Using the Consolidated Framework for Implementation Research (CFIR) to produce actionable findings: a rapid-cycle evaluation approach to improving implementation. *Implementation Sci* 12, 15 (2017). <https://doi.org/10.1186/s13012-017-0550-7>
9. Ortblad KF, Mogere P, Omollo V, Kuo A, Asewe M, Gakuo S, Mugambi M, Stergachis A, Odoyo J, Bukusi E, Ngure K, Baeten JM. Pharmacy-based PrEP initiation and continuation in Kenya: findings from a pilot study. Poster presentation at CROI 2022: 22nd Conference on Retroviruses and Opportunistic Infections, Virtual, February 12-16, 2022. Abstract 00928.

10. Mugo, PM; Micheni, M; Shangala, J; Hussein, MH; Graham, S; Rinkede Wit T, et al. (2017). Uptake and Acceptability of Oral HIV Self-Testing among Community Pharmacy Clients in Kenya: A Feasibility Study. PLoS ONE 12(1):e0170868. doi:10.1371/journal.pone.0170868
11. The 47 Counties Population and HIV prevalence in Kenya. Accessed October 19, 2021. https://en.wikipedia.org/wiki/Counties_of_Kenya
12. National AIDS and STI Control Programme, Ministry of Health, Kenya. Guidelines for HIV Testing Services in Kenya. Nairobi: NASCOP; 2015. <https://www.nascop.or.ke/hiv-testing-services/>
13. National AIDS & STI Control Programme (NASCOP), Ministry of Health, (2017). Framework for the Implementation of Pre-exposure Prophylaxis of HIV in Kenya, Nairobi, Kenya: NASCOP.
14. Roche SD, Wairimu N, Mogere P, Kamolloh K, Odoyo J, Kwena ZA, Bukusi EA, Ngure K, Baeten JM, Ortblad KF. Acceptability and Feasibility of Pharmacy-Based Delivery of Pre-Exposure Prophylaxis in Kenya: A Qualitative Study of Client and Provider Perspectives. *AIDS Behav.* 2021 Dec;25(12):3871-3882. doi: 10.1007/s10461-021-03229-5. Epub 2021 Apr 7. PMID: 33826022; PMCID: PMC8602157.
15. King DK, Shoup JA, Raebel MA, Anderson CB, Wagner NM, Ritzwoller DP, Bender BG. Planning for Implementation Success Using RE-AIM and CFIR Frameworks: A Qualitative Study. *Front Public Health.* 2020 Mar 3; 8:59. doi: 10.3389/fpubh.2020.00059. PMID: 32195217; PMCID: PMC7063029.
16. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci.* 2015;10(1):1–13.
17. Hopkins R, Josma D, Morris J, Klepser DG, Young HN, Crawford ND. Support and perceived barriers to implementing pre-exposure prophylaxis screening and dispensing in pharmacies: Examining concordance between pharmacy technicians and pharmacists. *J Am Pharm Assoc (2003).* 2021 Jan-Feb;61(1):115-120. doi: 10.1016/j.japh.2020.10.005. Epub 2020 Nov 16. PMID: 33214059.
18. Franks J, Hirsch-Moverman Y, Loquere AS Jr, Amico KR, Grant RM, Dye BJ, Rivera Y, Gamboa R, Mannheimer SB. Sex, PrEP, and Stigma: Experiences with HIV Pre-exposure Prophylaxis Among New York City MSM Participating in the HPTN 067/ADAPT Study. *AIDS Behav.* 2018 Apr;22(4):1139-1149. doi: 10.1007/s10461-017-1964-6. PMID: 29143163; PMCID: PMC5878834.
19. Kamaara E, Oketch D, Chesire I, Coats CS, Thomas G, Ransome Y, Willie TC, Nunn A. Faith and healthcare providers' perspectives about enhancing HIV biomedical interventions in Western Kenya. *Glob Public Health.* 2019 Dec;14(12):1744-1756. doi:


10.1080/17441692.2019.1647263. Epub 2019 Aug 7. PMID: 31390958; PMCID: PMC6779517.

20. Joshua P Havens, Kimberly K Scarsi, Harlan Sayles, Donald G Klepser, Susan Swindells, Sara H Bares, Acceptability and Feasibility of a Pharmacist-Led Human Immunodeficiency Virus Pre-Exposure Prophylaxis Program in the Midwestern United States, *Open Forum Infectious Diseases*, Volume 6, Issue 10, October 2019, ofz365, <https://doi.org/10.1093/ofid/ofz365>
21. Okoro O, Hillman L. HIV pre-exposure prophylaxis: Exploring the potential for expanding the role of pharmacists in public health. *J Am Pharm Assoc* (2003). 2018 Jul-Aug;58(4):412-420.e3. doi: 10.1016/j.japh.2018.04.007. Epub 2018 May 19. PMID: 29789257.
22. Rosengren, A.L., Lelutiu-Weinberger, C., Woodhouse, E.W. *et al.* A Scoping Review of HIV Pre-exposure Prophylaxis Stigma and Implications for Stigma-Reduction Interventions for Men and Transwomen Who Have Sex with Men. *AIDS Behav* **25**, 2054–2070 (2021). <https://doi.org/10.1007/s10461-020-03135-2>
23. Koester KA, Saberi P, Fuller SM, Arnold EA, Steward WT. Attitudes about community pharmacy access to HIV prevention medications in California. *J Am Pharm Assoc* (2003). 2020;60(6):e179-e183. doi:10.1016/j.japh.2020.06.005
24. Lopez MI, Grant RM, Dong BJ. Community pharmacy delivered PrEP to STOP HIV transmission: An opportunity NOT to miss! *J Am Pharm Assoc* (2003). 2020 Jul-Aug;60(4):e18-e24. doi: 10.1016/j.japh.2020.01.026. Epub 2020 Mar 9. PMID: 32165026.
25. Liu A, Cohen S, Follansbee S, Cohan D, Weber S, Sachdev D, Buchbinder S. Early experiences implementing pre-exposure prophylaxis (PrEP) for HIV prevention in San Francisco. *PLoS Med*. 2014 Mar 4;11(3):e1001613. doi: 10.1371/journal.pmed.1001613. PMID: 24595035; PMCID: PMC3942317.
26. Ford N, Geng E, Ellman T, Orrell C, Ehrenkranz P, Sikazwe I, Jahn A, Rabkin M, Ayisi Addo S, Grimsrud A, Rosen S, Zulu I, Reidy W, Lejone T, Apollo T, Holmes C, Kolling AF, Phate Lesihla R, Nguyen HH, Bakashaba B, Chitembo L, Tiriste G, Doherty M, Bygrave H. Emerging priorities for HIV service delivery. *PLoS Med*. 2020 Feb 14;17(2):e1003028. doi: 10.1371/journal.pmed.1003028. PMID: 32059023; PMCID: PMC7021280.

Appendix I

Pharmacy PrEP: Prescribing checklist

Pharmacy: _____ Provider: _____ Qualifications: _____ MFL code: _____

CLIENT PROFILE: Unique client record number: _____ / _____ / _____		Visit date: <i>dd / mm / yyyy</i> Initiating PrEP: <input type="checkbox"/> Yes <input type="checkbox"/> No
Name: First _____ Middle _____ Last _____ Telephone no: _____ Alien/National ID/passport/Birth Cert No: _____ Came to pharmacy for: _____		
PrEP initiation ONLY: Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female Date of birth: <i>dd / mm / yyyy</i> Age (years): _____ If age <19, attends school: <input type="checkbox"/> Yes <input type="checkbox"/> No Marital status: <input type="checkbox"/> Never married <input type="checkbox"/> Cohabiting <input type="checkbox"/> Married monogamous <input type="checkbox"/> Married polygamous <input type="checkbox"/> Separated/divorced <input type="checkbox"/> Widowed Population type: <input type="checkbox"/> Gen Population <input type="checkbox"/> Discordant couple <input type="checkbox"/> Key Population (Specify) _____ <input type="checkbox"/> MSM <input type="checkbox"/> MSW <input type="checkbox"/> FSW <input type="checkbox"/> PWID		
[If transferred in:] PrEP start date: <i>dd / mm / yyyy</i> Regimen: <input type="checkbox"/> TDF-FTC <input type="checkbox"/> TDF <input type="checkbox"/> TDF-3TC Facility transferred from: _____ MFL code: _____ County: _____		
PrEP SCREENING: Behavioral risk assessment: Mark all that apply (past 6 months) Sex partner(s) is HIV+ AND: <i>not on ART, or On ART <6 months, or suspected poor ART adherence, or detectable viral load, or couple trying to conceive</i> <input type="checkbox"/> Yes <input type="checkbox"/> No Sex partner(s) high risk & HIV status is unknown: <input type="checkbox"/> Yes <input type="checkbox"/> No Has sex with >1 partner <input type="checkbox"/> Yes <input type="checkbox"/> No Ongoing IPV/GBV <input type="checkbox"/> Yes <input type="checkbox"/> No Transactional sex <input type="checkbox"/> Yes <input type="checkbox"/> No Recent STI (past 6 months) <input type="checkbox"/> Yes <input type="checkbox"/> No Recurrent use of post-exposure prophylaxis (PEP) <input type="checkbox"/> Yes <input type="checkbox"/> No Recurrent sex under influence of alcohol/recreational drugs <input type="checkbox"/> Yes <input type="checkbox"/> No Inconsistent or no condom use <input type="checkbox"/> Yes <input type="checkbox"/> No Injection drug use with shared needles and/or syringes <input type="checkbox"/> Yes <input type="checkbox"/> No		
Counseling Willing to start/continue PrEP: <input type="checkbox"/> Yes <input type="checkbox"/> No Adherence counseling Done: <input type="checkbox"/> Yes <input type="checkbox"/> No Side effect counseling Done: <input type="checkbox"/> Yes <input type="checkbox"/> No Family planning counseling Done: <input type="checkbox"/> Yes <input type="checkbox"/> No		<div style="border: 1px solid black; border-radius: 15px; padding: 10px; background-color: #f0f0f0;"> <p style="text-align: center;">At HIV risk; CONTINUE with PrEP initiation at pharmacy</p> </div>
Medical safety assessment Signs & symptoms of acute HIV Infection <input type="checkbox"/> Yes <input type="checkbox"/> No Liver disease: <input type="checkbox"/> Yes <input type="checkbox"/> No Kidney disease: <input type="checkbox"/> Yes <input type="checkbox"/> No Diabetes: <input type="checkbox"/> Yes <input type="checkbox"/> No Other: _____ <input type="checkbox"/> Yes <input type="checkbox"/> No [If female:] Pregnant <input type="checkbox"/> Yes <input type="checkbox"/> No [If female:] Breastfeeding: <input type="checkbox"/> Yes <input type="checkbox"/> No		<div style="border: 1px solid black; border-radius: 15px; padding: 10px; background-color: #f0f0f0;"> <p style="text-align: center;">DO NOT start PrEP; refer to remote clinician</p> </div>
PrEP refills ONLY: Reported PrEP side effects: _____ Describe: _____ <input type="checkbox"/> Yes <input type="checkbox"/> No [if yes:] Side effects severe: _____ <input type="checkbox"/> Yes <input type="checkbox"/> No		<div style="border: 1px solid black; border-radius: 15px; padding: 10px; background-color: #f0f0f0;"> <p style="text-align: center;">DO NOT start PrEP; refer to remote clinician</p> </div>
HIV testing HIV test result: <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Indeterminate [Retest] [If retest:] HIV test result: <input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Indeterminate		<div style="border: 1px solid black; border-radius: 15px; padding: 10px; background-color: #f0f0f0;"> <p style="text-align: center;">DO NOT start PrEP; refer to remote clinician</p> </div>
PrEP DISPENSING: Regimen: <input type="checkbox"/> TDF-FTC <input type="checkbox"/> TDF <input type="checkbox"/> TDF-3TC # of months prescribed: _____ Date of initiation: <i>dd / mm / yyyy</i>		
Next appointment date: <i>dd / mm / yyyy</i> Provider initials: _____		

Appendix II

WEEKLY ACTIVITY SUMMARY

PHARMACY DELIVERY TO EXPAND THE REACH OF PrEP IN KENYA: PILOT STUDY

Pilot Pharmacy: Report by: Dates:

Summary for the week:

Number of potential PrEP users identified by the pharmacy provider	
Number of clients initiated PrEP previous week	
Number of clients initiated PrEP this week	
Number of clients initiating PrEP	
Number of follow up visits	Expected for month 1: No. seen for month 1:

Component	RA Observation
Describe the pharmacy clients that are most interested in/likely to uptake PrEP (<i>including services purchased at pharmacy</i>) Customers who come in to buy and/or ask for the following: <ul style="list-style-type: none"> • Condoms • Sex enhancers/boosters • Pregnancy test kits/pregnancy testing • PEP and/or PrEP • Oral contraception and/or Emergency contraception • HIV testing and/or HIVST Kits • STI treatment 	
What are common questions/concerns participants have about PrEP?	
Any challenges encountered? Elaborate	
What practices/solutions has the pharmacy instituted to make delivery easier?	
Highlight the discussion on the week's work with the pharmacy provider	
Remarks	

Appendix III

Manuscript Authorship

Hilma N. Nakambale¹, Stephanie D. Roche², Peter Mogere³, Victor Omollo⁴, Alexandra Kuo⁵, Andy Stergachis^{1,5}, Elizabeth Bukusi^{1,4,6}, Kenneth Ngunjiri^{3,7}, Katrina F. Ortblad², Melissa Latigo Mugambi¹

¹Department of Global Health, University of Washington, Seattle, USA

²Public Health Sciences Division, Fred Hutchinson Cancer Research Center, Seattle, USA

³Partners in Health, Research, and Development, Thika, Kenya

⁴Centre for Microbiology Research, Kenya Medical Research Institute, Nairobi, Kenya

⁵Department of Pharmacy, University of Washington, Seattle, USA

⁶Department of Obstetrics and Gynecology, University of Washington, Seattle, USA

⁷Department of Community Health, Jomo Kenyatta University of Agriculture and Technology, Nairobi, Kenya