

Establishing a pharmacy-based PrEP program for young women who sell sex in Zimbabwe: Protocol for a randomised control trial

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Abstract

Background: Sex workers (SW) are at risk of acquiring HIV infections. Despite this, SW have low uptake of relevant preventive measures such as HIV pre-exposure prophylaxis (PrEP). Community-based programs that make PrEP convenient and accessible have potential to drive PrEP continuation and reduce HIV risk.

Objective: This paper describes the co-development and piloting of the TOPAZ study – which encompasses an intervention providing SW with the opportunity to access PrEP refills through pharmacies in Zimbabwe.

Methods: Using a participatory process, the TOPAZ study will be collaboratively developed with pharmacy owners and SW. The TOPAZ study comprises provision of safe and convenient spaces for PrEP refill pick-ups bundled with a gift voucher incentive at pharmacies. Formative research will inform development of the preliminary model (Aim 1). A cluster randomised pilot trial of the PrEP in pharmacy intervention compared to clinic pick up in the Key Populations program (standard of care) will be done to evaluate the impact of the intervention on PrEP retention at 3, 6, 9, and 12 months after initiation (Aim 2). Finally, a mixed methods study will be conducted to understand the potential for scaling the PrEP in pharmacy program for SW, and based on the findings, translate lessons learned into the design of a future effectiveness trial (Aim 3).

Results: NA

Conclusions: The findings from this work will also be disseminated through peer reviewed publications, and conference presentations at local, regional, and international levels. Clinical Trial: ClinicalTrials.gov NCT06348069

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Original Manuscript

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Abstract

Background:

Sex workers (SW) are at risk of acquiring HIV infections. Despite this, SW have low uptake of relevant preventive measures such as HIV pre-exposure prophylaxis (PrEP). Community-based programs that make PrEP convenient and accessible have potential to drive PrEP continuation and reduce HIV risk.

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This paper describes the co-development and piloting of the TOPAZ study – which encompasses an intervention providing SW with the opportunity to access PrEP refills through pharmacies in Zimbabwe.

Methods:

Using a participatory process, the TOPAZ study will be collaboratively developed with pharmacy owners and SW. The TOPAZ study comprises provision of safe and convenient spaces for PrEP refill pick-ups bundled with a gift voucher incentive at pharmacies. Formative research will inform development of the preliminary model (**Aim 1**). A cluster randomised pilot trial of the PrEP in pharmacy intervention compared to clinic pick up in the Key Populations program (standard of care) will be done to evaluate the impact of the intervention on PrEP retention at 3, 6, 9, and 12 months after initiation (**Aim 2**). Finally, a mixed methods study will be conducted to understand the potential for scaling the PrEP in pharmacy program for SW, and based on the findings, translate lessons learned into the design of a future effectiveness trial (**Aim 3**).

Conclusion

The findings from this work will also be disseminated through peer reviewed publications, and conference presentations at local, regional, and international levels.

Trial registration: ClinicalTrials.gov NCT06348069

Key words: HIV; PrEP; FSW; key populations; HIV/AIDS; PrEP continuity

Article Summary**Strengths and Limitations of this study**

- This protocol describes the Together Optimizing PrEP Access in Zimbabwe (TOPAZ) study, which was co-developed with pharmacists, sex workers, and policy-makers to improve PrEP continuation among sex workers.
- The TOPAZ pilot study comprises of a two-arm randomised controlled trial to evaluate the impact of adding pharmacy-based PrEP refill, to PrEP continuation among sex workers, compared to standard of care.
- A process evaluation to determine the acceptability, adoption, appropriateness, feasibility, fidelity, and penetration of the intervention to optimise future versions of the program.
- This preliminary study will pave the way for a future effectiveness trial to evaluate the impact of having pharmacy-based PrEP access in PrEP continuation.

- Our study is limited in that we will use prescription refills, and self-reported adherence as a measure for PrEP continuation.



Introduction

Sex workers (SW) are disproportionately affected by HIV and contribute a four-fold higher HIV prevalence than adults in the general population [1]. Relative risk of acquiring HIV among SW globally is 9-times higher than the general population, while in Sub-Saharan Africa, the relative risk of HIV acquisition is 11-times higher in SW than the general population [2]. Data from generalized HIV epidemics in Sub-Saharan Africa reveals that SW and their clients account for over 30% of HIV infections and 17% of incident HIV infections [2, 3]. In Zimbabwe, HIV prevalence among FSW is over 50%, and the annual estimated incidence is 4%, translating to a 10-fold higher incidence than women in the general population [4, 5]. New entrants into sex work and young women who sell sex are at the highest risk of HIV infection [5-8]. For example, HIV prevalence increases sharply from 2% for a 16-year-old female sex worker (FSW) to >50% for a 24-year-old FSW in Zimbabwe [4, 6-9]. These alarming statistics underscore a need to strengthen the effective use of HIV prevention for FSW, particularly among younger FSW, both to protect them from HIV and to support broader HIV epidemic control efforts [10-12].

Oral pre-exposure prophylaxis (PrEP) has demonstrated high efficacy in clinical trials, preventing more than 92% of new HIV infections when taken as prescribed [13]. Implementation in real world contexts, however, has been disappointing with low uptake and suboptimal continuation. Thus, strengthening motivation, capability, and effective use of PrEP among SW, including younger FSW, has the potential to reduce the rate of new infections among both SW and the general population more broadly [5]. Mathematical modelling data from South Africa anticipates that high uptake and continuity of PrEP could theoretically lead to a population-level reduction in HIV incidence by 40% [7-8].

Although PrEP uptake reduces HIV risk, effective PrEP use and continuation is very low among high-risk populations such as SW [14-16]. Studies from Benin (45%), Rwanda (22%) and Senegal

(27%) reported lower PrEP discontinuation within 12 months when compared to South Africa (91%) and Zimbabwe (86%) [16-21]. These differences underscore the need to identify barriers to PrEP continuation, towards developing context-specific interventions. A host of factors impede PrEP uptake and continuation among FSW, but of relevance to this intervention is fear of stigma associated with PrEP and lack of convenient access [20,22]. The World Health Organisation recommends differentiated service delivery to diversify PrEP delivery, overcome barriers to access, and strengthen PrEP continuation [23]. Developing interventions outside the 'brick-and-mortar' health clinics *e.g.*, private pharmacies, may decentralise PrEP services and improve access [24-28]. Pharmacies are proven community-based channels that advance self-care initiatives in sexual and reproductive health and may be tailored to deliver PrEP for high-risk individuals. Developing pharmacy-based PrEP service delivery models for SW could make PrEP more accessible and improve PrEP uptake and continuation.

Successful delivery of pharmacy-based PrEP is contingent on collaborative efforts between policymakers, communities, and pharmacists [14-15, 29-35]. Our study aims to explore whether providing SW with the option of PrEP refill supported by HIV testing through community-based pharmacies is feasible, acceptable and increases effective use of PrEP in Zimbabwe. Given that research shows that small, short-term incentives can also be used to increase habit formation and motivation to continue PrEP [36-38], our trial also includes provision of small incentives to motivate PrEP continuation. Our *Together Optimising PrEP Access in Zimbabwe* (TOPAZ) study develops and tests this pharmacy-based PrEP intervention for FSW in Zimbabwe.

Methods

Study aims

The overall goal of the TOPAZ study is to increase PrEP continuation among FSW through a co-developed pharmacy-based intervention. Specific aims are:

Aim 1: Refine and operationalize pharmacy-based PrEP distribution including an escalating incentive with FSW and pharmacy owners to motivate FSW PrEP continuation.

Aim 2: Determine whether the addition of pharmacy-based PrEP distribution increases PrEP retention among FSW at 6 months compared to standard services.

Aim 3: Understand the PrEP in pharmacy program's potential to scale, and translate lessons learned into a future effectiveness study.

Overview

A mixed-methods approach will be used to develop and pilot the PrEP in pharmacy refill intervention for SW as summarised in Figure 1. The PrEP in pharmacy refill intervention will be available to all SW in their diversity, including male and transgender; however, this study will formally assess outcomes among FSW. During Aim 1, formative research to co-develop the intervention with SW and pharmacists will be conducted. In Aim 2, the intervention will be piloted through an existing Key Populations (KP) program. A 1:1 cluster randomized control design will be used to allocate 8 suburbs to 4 intervention or 4 standard of care suburbs. In Aim 3, a process evaluation will be conducted using a mixed-methods implementation science framework to determine the feasibility, acceptability, and scalability of the intervention and to optimise future versions of the program.

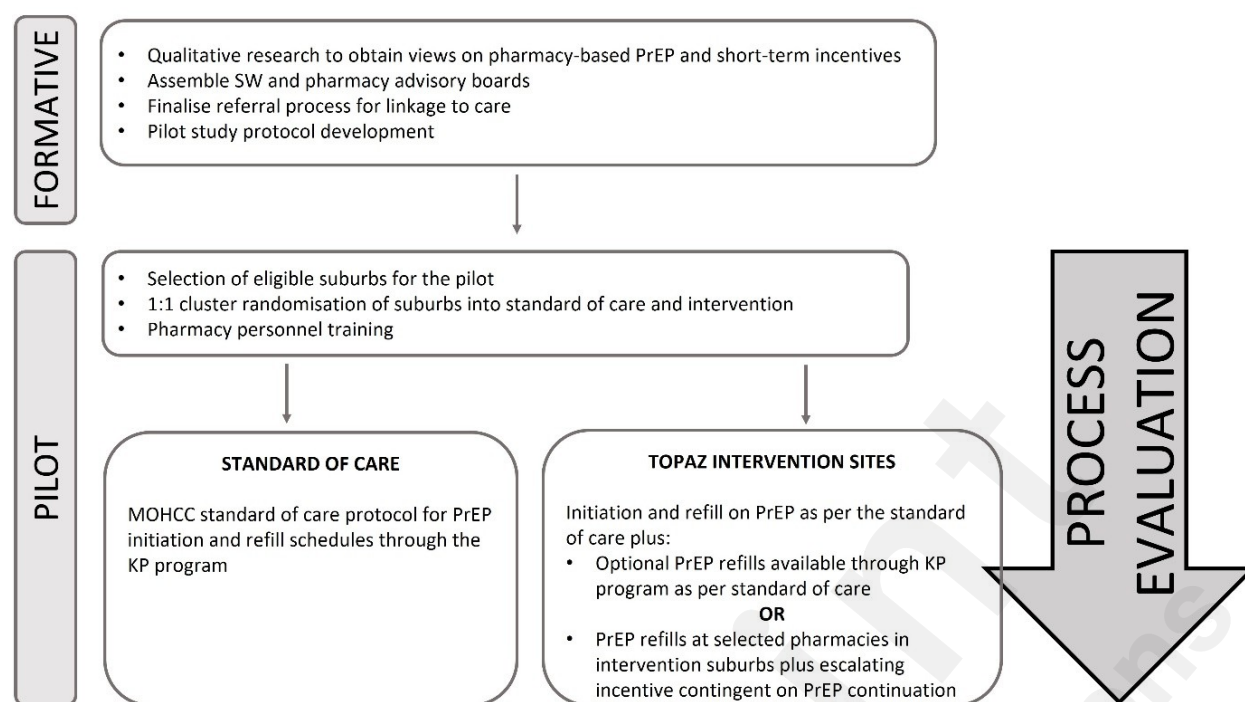
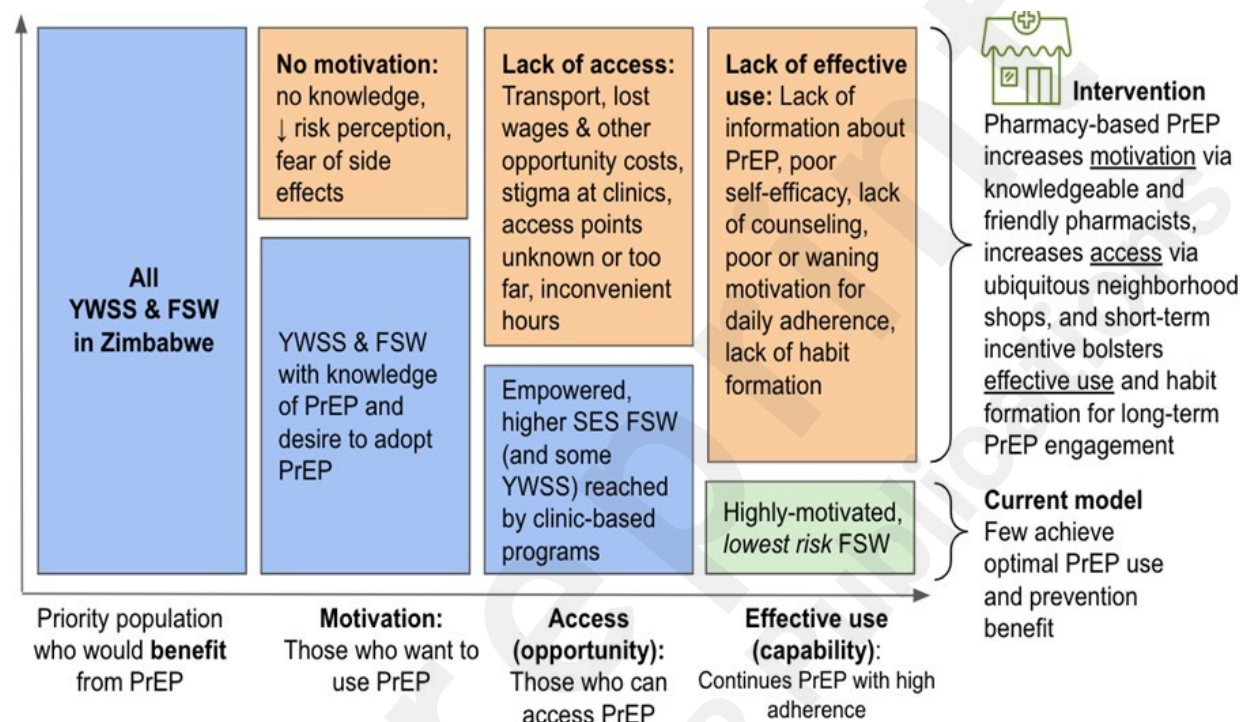


Figure 1. Overview of the TOPAZ study design. Foot note: PrEP = pre-exposure prophylaxis; SW= sex workers; MOHCC= Ministry of Health and Child Care of Zimbabwe; KP = key populations.

Theoretical model informing the implementation

This research draws on two primary theoretical models of behaviour change: the COM-B model of behaviour change and behavioural economics (Figure 2) [37-38]. The pharmacy intervention will be designed to increase *motivation* through knowledgeable and friendly pharmacists plus the peer outreach and support services already provided by the existing KP program. In addition, small incentive gift vouchers that can be redeemed for pharmacy products offered to FSW for collecting PrEP refills at pharmacies will also increase *motivation*. *Access* will be increased through PrEP provision at pharmacies; and *effective use* will be increased both through improving access via pharmacies coupled with short-term, escalating incentives (gift vouchers) to continue refilling PrEP [38]. Underpinning the incentive component of the intervention is behavioral economic theory which posits that using simple, scalable ‘nudges’ (norms, commitments, incentives) that capitalize on

common biases can influence behavior [39]. This approach is particularly useful when applied to behaviors that are new (like taking PrEP) or those that can be viewed as unimportant or inconvenient (like collecting PrEP refills, especially due to present-biased preferences) [40]. Escalating incentives leverage the behavioral economics concept of *loss-aversion*; increasing “losses” are faced each time a refill visit is missed; a simple yet powerful motivator to stay engaged with PrEP [41-43].



Figure

2. Application of the COM-B model in the current PrEP delivery in Zimbabwe and the contributions of the proposed intervention which provides friendly, pharmacy-based PrEP distribution by informed pharmacists plus financial incentives (Adopted from Schaefer and collaborators [44]). Footnote: YWSS: young women who sell sex; FSW: female sex workers; PrEP: pre-exposure prophylaxis; SES: socioeconomic status.

Study setting and population

This intervention will be nested within the existing KP program, a nationally scaled programme for SW run by Centre for Sexual Health, HIV and AIDS Research (CeSHHAR) Zimbabwe on behalf of Ministry of Health and Child Care (MOHCC) and National AIDS Council (NAC). The program aims to reduce HIV acquisition/transmission via the provision of comprehensive sexual and reproductive health services at mobile and static clinics tailored for KP and supported by peer-led community

engagement activities [5]. As of 2023, the KP program services include contraception, sexually transmitted infections syndromic management, mental health screening and treatment, gender-based violence prevention and referral, HIV testing, initiation of antiretroviral therapy (ART), HIV post-exposure prophylaxis, and PrEP. The KP program operates mobile outreach clinics in 14 suburbs across Harare, from which 8 TOPAZ study suburbs were selected. Eligible suburbs needed to have 3 or more pharmacies that have a private area to implement the intervention and were willing to implement the intervention. Consequently, the PrEP in pharmacy intervention will be conducted in: Mabvuku, Glen Norah, Mufakose, Epworth, Glen View, Highfield, Kuwadzana, Mabvuku, and Kambuzuma.

Pharmacy selection process

A mapping exercise will be conducted in the selected suburbs to identify pharmacies that meet the TOPAZ pharmacy criteria. A sensitisation process will be used to assess the pharmacy owners' interest in participating in the study. A total of 3 pharmacies per suburb will be shortlisted, and in instances where there are more than 3 qualifying pharmacies in a suburb, distance from a neighbouring TOPAZ study pharmacy will be considered in selection of the three participating pharmacies to ensure pharmacies are well-spaced within the suburbs.

Design

In Aim 1, a qualitative study will be conducted. The Aim 2 study is a cluster randomised control trial, with suburbs as the unit of randomisation. Eight suburbs will be randomised to either standard of care, which is collecting PrEP services from the KP program (*comparison condition*); or standard of care KP program PrEP services *plus* the option of pharmacy-based PrEP refills which includes the offer of a financial incentive of a gift voucher for pharmacy products (*intervention condition*). FSW

in the KP program who are newly initiated onto PrEP will be recruited into the TOPAZ study prospectively, and outcomes will be measured at 3, 6, 9 and 12 months after PrEP initiation. Aim 3 will utilise a mixed-methods approach to determine feasibility, acceptability and scalability of the PrEP in pharmacy intervention.

AIM 1: FORMATIVE RESEARCH

Formative research activities will be conducted to ensure that the proposed approach addresses barriers to PrEP retention on both the supply (pharmacy) and demand (SW) sides. Two key stakeholder groups, the pharmacists and SW will be engaged to establish advisory boards. The SW advisory board will ensure the final intervention design will work with and for the needs and preferences of the SW. The pharmacist advisory board will be key to operationalise the PrEP in pharmacy intervention and ensure it is integrated into routine business operations within pharmacies. Consultative meetings will be held monthly to develop the intervention process (Table 1).

Table 1. Qualitative approaches to be applied in the formative research phase of the TOPAZ study implementation

Group	Method	N ^a	Inclusion/Exclusion parameters	Contribution
Pharmacy advisory board	Consultative meetings	15	Inclusion criteria: • Pharmacies that are officially registered • Pharmacies located in Harare • Available to participate in board meetings during the intervention	Inform intervention development from a pharmacy perspective.

SW advisory board	Consultative meetings	5	Inclusion criteria: • Enrolled in the KP program • Demonstrating knowledge about PrEP • Residing in Harare • Available to participate in board meetings over 24 months Exclusion criteria: • SW intending to move out of Harare during the intervention	Inform development of the intervention from a SW perspective.
SW	Semi-structured In-depth interview	20	Inclusion criteria: • >16 years • exchanged sex for money or gifts in the last 6 months^b	• Barriers on PrEP retention. • Mitigating PrEP related stigma. • Using pharmacies for PrEP refills. • Procedures for using and reporting HIV test results • Referral services. • How to create a welcoming environment.
Pharmacy personnel^c	Semi-structured In-depth interview	6	Inclusion criteria: • > 18 years • Own or work at a pharmacy in Harare	• Perspectives of engaging FSW in their shops. • Attitudes and beliefs about SW. • Perceived roles in community-based health provision. • Relationship with referral facilities and staff. • Views on the viability of pharmacies as distribution sites for daily oral or other forms of PrEP, HIV tests. • Which pharmacy personnel would implement

				intervention. • Comfort with prescribing PrEP and providing HIV testing. • Existing facilities in pharmacy or around that provide HIV testing and counselling.
Community leader	Key informant interview	6	Inclusion criteria: • Aged 18 years or older • Work with MOHCC, City of Harare, or organisations that may be impacted by the intervention	• Seek reactions on main insights from IDIs. • Invite input on the proposed pharmacy-based approach. • Identify potential implementation barriers • Facilitating roles they can assume.
KP program	Formal meeting		Inclusion criteria: • KP program staff at the frontline of outreach	• Formal appointments • Referral procedure preferences. • Tracking continuation and missed appointments.

^a indicates number of interviews;

^b indicates pharmacy owners and staff

^c indicates not limited to SW enrolled in the KP program;

Abbreviations: PrEP- pre-exposure prophylaxis; KP- key populations.

Qualitative studies

Trained social science researchers will conduct qualitative interviews to solicit insights that can be applied to strengthen the PrEP in pharmacy intervention (*e.g.*, how, and where HIV testing should be conducted, how to identify study participants, confidentiality and privacy). In-depth interviews will be held with SW and pharmacy personnel, and key informant interviews with community leaders and

policymakers using guided questions summarised in Table 1. All interviews will be audio-recorded, but in instances where individuals want to be interviewed but prefer not to be recorded, written note-taking methods will be applied. Analytic notes will be written and summarised for synthesis of information into a report that will be presented to the advisory board and stakeholders. Written informed consent will be obtained among all qualitative study interview participants. A rapid qualitative analysis approach will be used to interpret interviews in real time to facilitate intervention finalization [45]. Taken together, data from in-depth and key informant interviews, and formal discussions with advisory boards members will be used to develop the PrEP in pharmacy intervention protocol.

Development of the PrEP in pharmacy intervention

A workshop including the SW and pharmacy advisory boards, and pharmacists from pharmacies that qualify to implement the PrEP in pharmacy intervention, will be held to finalise the intervention protocol. Key outputs will be a detailed intervention protocol that has a:

- (i) Feasible implementation plan that has been endorsed by advisory boards.
- (ii) Training component for pharmacy personnel on HIV testing, PrEP, stigma reduction and the referral procedures.
- (iii) Training component for KP program staff on how the strategy will be integrated with usual services, and a referral plan acceptable to pharmacists and KP program staff.
- (iv) Final structure for the escalating incentive (gift vouchers).

AIM 2: PILOT FOR THE PrEP IN PHARMACY INTERVENTION

A two-arm pragmatic cluster-randomized trial design will be used to determine whether the addition

of pharmacies as an optional PrEP refill collection point increases retention on PrEP among SW compared to the standard of care services offered in the KP program (Figure 3). A 1:1 cluster randomization process will be conducted using covariate-constrained randomization [46] in R software (R version 4.1.3; R Foundation for Statistical Computing, Vienna, Austria). A public randomisation event will be held in which the Community Pharmacists Council, MOHCC and other key stakeholders will participate. There will be no masking at cluster level (suburbs), and SW will be informed of the intervention. SW newly enrolled in the standard of care suburbs will not be explicitly informed about the intervention. This trial is not blinded.

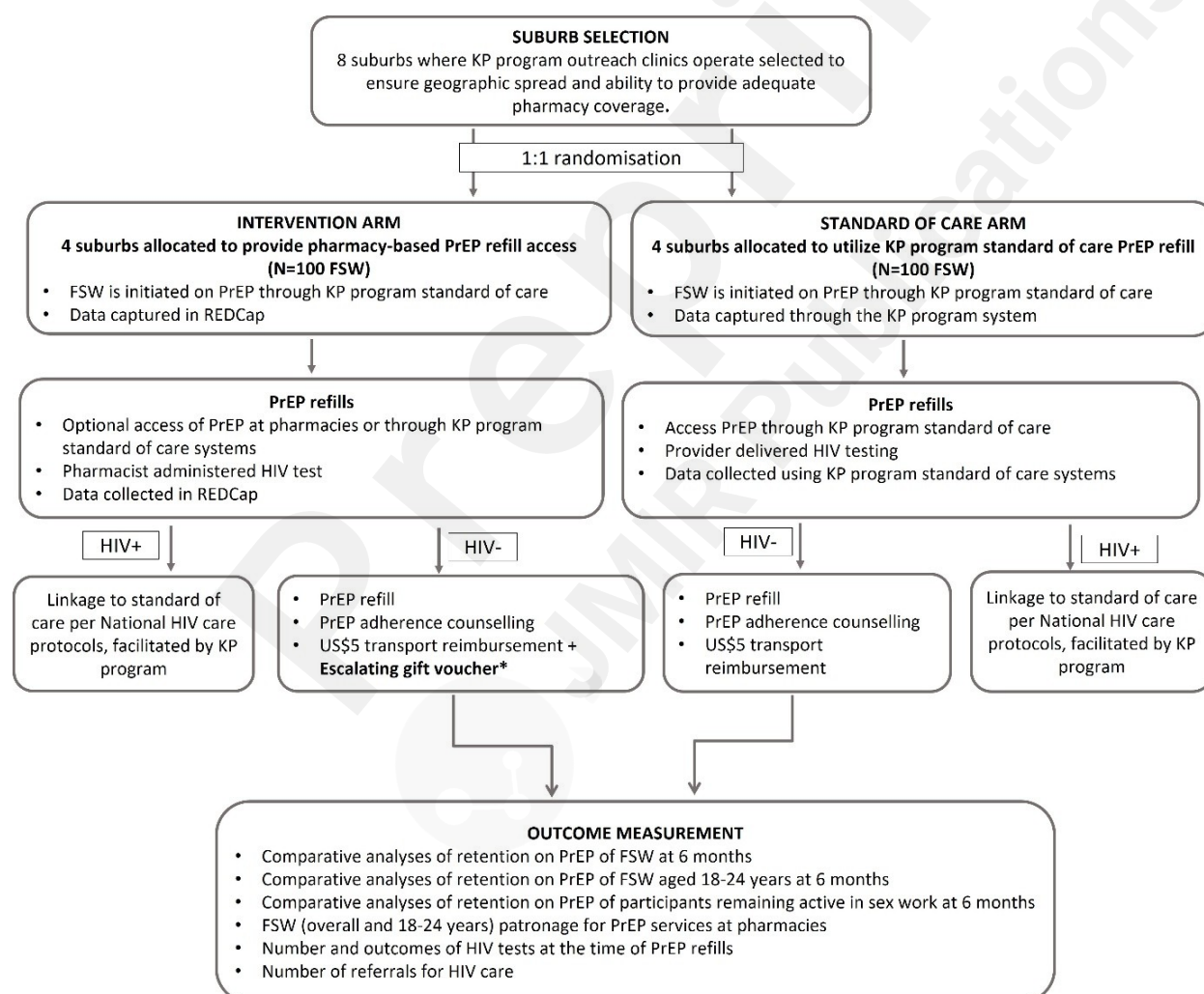
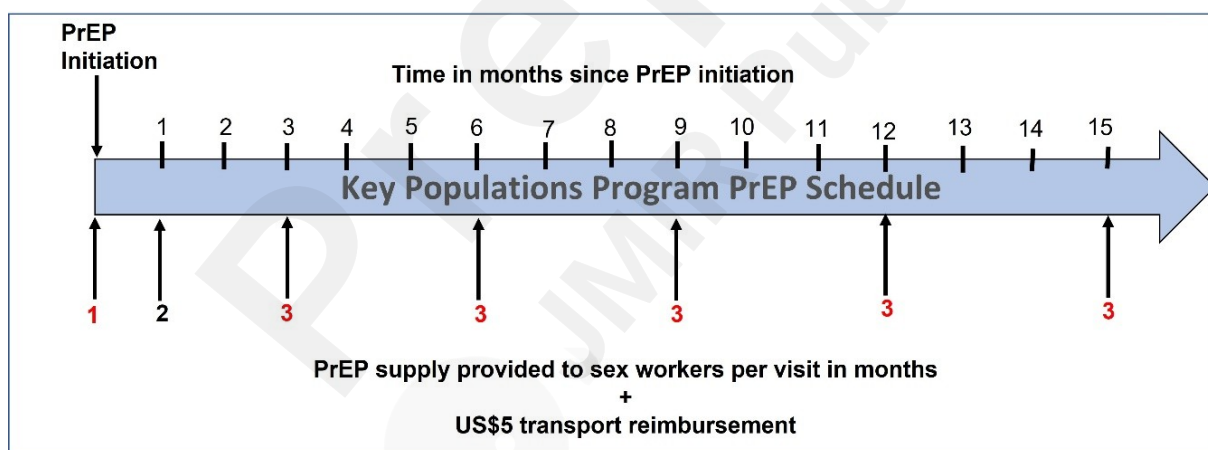


Figure 3. Overview of the PrEP in pharmacy intervention implementation strategy. Foot note:

* Escalating gift voucher structure= month 1 refill is provided a US\$5 voucher worth, month 3 refill=US\$6 worth voucher; month 6 refill provided with US\$7 worth voucher

Overview of PrEP services in the KP program

The KP program requires verbal consent from SW to dispense PrEP, which is freely available [5]. MOHCC implementation guidelines include free oral rapid HIV testing that is provider delivered at initiation along with provision of a 1-month supply of PrEP. The first refill provides a two-month supply of PrEP, and then three-month supplies thereafter (Figure 4). Free oral rapid provider delivered HIV testing will be offered every 3 months, and only those with confirmed HIV seronegative results are offered future PrEP refills in accordance with the national PrEP guidelines [47]. KP programme data is collected on paper-based forms for all SW who initiate PrEP routinely; these are used to generate a unique identification number for the SW, and an associated KP program file, which is essential for PrEP refill collection. People who do not return for refill visits are routinely followed up via phone calls, WhatsApp reminders, and peer outreach. SW are offered a US\$5 transport reimbursement when collecting their PrEP refills routinely, in the program.



Figure

e 4: The PrEP refill schedule utilized by the KP program, in accordance with the Zimbabwe national PrEP refill algorithm. Each PrEP refill is supplied with US\$5 transport reimbursement *Foot note: Refill months indicated in red highlight where an HIV test is required to receive PrEP.*

Procedures for the standard of care arm

SW enrolled as part of the TOPAZ study in the standard of care arm will initiate on PrEP following the KP program standard operating procedures. They will be recruited through the KP program

outreach clinics, undergo HIV testing and if HIV negative, provide verbal consent for PrEP initiation and collection of subsequent refills. At each visit, SW will receive PrEP plus counselling on the importance of adhering to PrEP uptake as scheduled by healthcare providers. PrEP refills will be recorded on standardised paper-based data collection tools, per the KP program standards, and will be analysed from the program records.

Inclusion criteria for enrolment into TOPAZ standard of care arm is:

- (i) Initiated onto PrEP through the KP program mobile outreach clinics running in one of the four standard of care suburbs.
- (ii) Aged >16 years.
- (iii) Have exchanged sex for money in the last 6 months.
- (iv) Providing verbal consent.

All participants will receive a US\$5 transport reimbursement at the end of each visit. Participants in the standard of care arm will be advised that they can collect PrEP refills from the KP program clinics as is standard procedure. Participation in the intervention will continue for 12 months.

Procedure for those enrolled through the PrEP in pharmacy intervention arm

FSW initiated onto PrEP through the KP program mobile outreach clinics running in the intervention suburbs will be informed about the intervention, namely, the opportunity to access PrEP refills either from selected pharmacies within the suburbs or through KP program clinics. In addition, the participants will also be informed that PrEP refills in the pharmacy warrant gift vouchers for the first 6 months of the trial, and no vouchers will be available for the remaining 6 months of the trial. Intervention arm participants initiating PrEP will be given a TOPAZ referral slip which they can

redeem at any participating pharmacy or KP program clinics. The same services provided at standard-of-care sites will be available through the pharmacy, namely, HIV testing, PrEP refills, adherence counselling, linkage to additional services and the US\$5 transport reimbursement in line with the KP program care. In addition, FSW that opt to refill PrEP in pharmacies will be offered an incentive, in the form of a gift voucher redeemable for products in the pharmacy wherein the refill was collected. The incentive will be continued until month 6 and will escalate in value at each visit. Months 1, 3 and 6 will receive gift vouchers valued as US\$5, US\$6, and US\$7, respectively. To measure retention on PrEP without incentive, participants will not receive a gift voucher in the last two refill visits of the intervention, *i.e.*, months 9 and 12, however, data will be collected. Implementing pharmacies will be given a TOPAZ study handbook with standard operating procedures for the intervention. In addition, the KP program will carry out support visits to implementing pharmacies on a weekly basis.

Recruitment of FSW in PrEP in pharmacy intervention suburbs

FSW initiating PrEP will be informed that enrolling as an intervention participant is voluntary and their refusal will not interfere with the KP program standard of care including their ability to access PrEP. FSW will also be given information about the intervention, and the associated risks in detail. Interested FSW will be given an information flyer and consent to participate will be obtained verbally. Information flyers will be available in the three main languages spoken in Zimbabwe, English, Shona, and Ndebele. The eligibility criteria to participate in the intervention arm is:

- i. Initiated onto PrEP through the KP program mobile outreach clinics running in one of the four intervention suburbs.
- ii. Aged >16 years.

- iii. Have exchanged sex for money in the last 6 months.
- iv. Provide verbal consent to enrol into the TOPAZ study.

Data collection for the PrEP in pharmacy intervention arm

Data for the intervention participants will be captured onto a mobile health tool, REDCap [48], operating on tablets. Built-in eligibility parameters, refill scheduling, and dispensing information, as well as prompts to guide pharmacists and KP program staff through the PrEP refill process will be programmed. To protect the privacy and confidentiality of the FSW, at each refill, only data that pertains to the specific refill will be visible to the pharmacists through the refill interface.

Pharmacist enrolment to implement the PrEP in pharmacy intervention

Pharmacies will be selected to implement the PrEP in pharmacy intervention, based on the following criteria, and will be notified.

Inclusion criteria of the TOPAZ intervention pharmacies:

- (i) Valid pharmacy operating license
- (ii) Interested in administering PrEP to SW in their diversity according to professional standards described in the written agreement
- (iii) Private room or cubicle present in the pharmacy, where the HIV testing and PrEP can be administered

Participating pharmacies will be requested to provide written consent to participate, agreeing to ensure professional, ethical, and respectful conduct towards SW. All pharmacy personnel that are responsible for administering prescriptions within the pharmacy will undergo a series of mandatory trainings to prepare for implementation, including protocol training and MOHCC-certified course for HIV testing.

Pharmacy refill pick-up procedure

TOPAZ intervention participants will present the TOPAZ referral slip, or their KP program number to the pharmacy, and the pharmacy personnel will usher them into the private room for study-related activities, including HIV testing and PrEP refills (if eligible). Those FSW testing HIV positive will be referred to the KP program for linkage to care.

Sample size and power calculations

Data from our previous work indicate that current PrEP retention at 6 months post-PrEP initiation is 14% among FSW in Harare. With 8 suburbs (4 per arm) and enrolling a target of 25 SW per intervention suburb for a total of 100 people enrolled in the intervention suburb (with an ICC of 0.12), translates to $\geq 80\%$ power to detect an increase in the proportion of FSW retained on PrEP of 36 percentage points (from 14% in the standard of care arm to 50% in the intervention arm). Note that this is a pilot trial and, as such, is only powered to detect large effect sizes. If retention is lower than expected in the comparison group (e.g., 10%), we will have at least 80% power to detect an increase in PrEP retention of 34 percentage points *or greater*. Likewise, if retention is higher than expected in the comparison group (e.g., 30%), we will be adequately powered at 80% to detect increases in retention of 38 percentage points *or greater*.

Outcomes

Outcome 1: Retention on PrEP at 6 months. This will be measured as attendance within a +/- 7-day window (before and after) of the scheduled refill visits at 6 months. Outcome 1 will be expressed as the proportion of 6-month visits completed as scheduled, overall and by arm.

Outcome 2: PrEP retention at 6 months among FSW 18-24 years of age. This will be measured as attendance within a +/- 7-day window (before and after) of the scheduled refill visit at 6 months. Outcome 2 will be expressed as the proportion of visits completed as scheduled, overall and by arm.

Outcome 3: FSW (overall) and FSW (18-24 years) patronage for PrEP services at pharmacies, defined as the proportion of all PrEP refill pick-ups (1, 3, 6 and 12) in intervention suburbs occurring at pharmacies, overall and by pickup month.

Data analysis in Aim 2

For retention outcomes at 6, 9, and 12 months, the KP program database will be used to compare the number and proportion of FSW retained on PrEP as defined above by study arm. We will conduct an intent-to-treat analysis to estimate the intervention's effect using a cluster-based permutation test applied to the individual-level binary outcome (retained on PrEP/not retained on PrEP) using the `cptest` function in the R `cvcrand` package (or a similar function). The permutation test will be conducted with the same covariates used during the constrained randomization process at the suburb level (expanded from the values of the cluster-level covariates, according to which cluster everyone belongs). This approach will be repeated for the other outcomes. To produce a measure of effect, a GEE model will also be constructed to generate a risk difference of PrEP retention among people initiating PrEP in intervention versus comparison suburbs and a 95% confidence interval. As per CONSORT, unadjusted estimates will be reported, and the pre-registered analysis plan at ClinicalTrials.gov will specify an adjusted model in the case of baseline imbalances. Overall, this analysis framework permits causal attribution.

Aim 3: Determine the feasibility and scalability of the pharmacy-based PrEP program

A mixed-methods evaluation, guided by Proctor's implementation science framework [49], will assess implementation outcomes and how well findings link with our conceptual model *i.e.*, how capability, opportunity and motivation are affected. We will use the following data collection methods: 1) IDIs with FSW and pharmacy owners and staff, KP PrEP outreach workers, and community stakeholders; 2) direct observations at intervention pharmacies; and 3) feedback from both the SW and the pharmacist Advisory Boards. Collectively, data from the pilot, IDIs and pharmacy observations will be synthesized to determine if the approach is feasible and acceptable, towards optimising the intervention for an effectiveness study.

Data Collection Approaches

Triangulation of multiple data sources to evaluate Proctor's implementation science outcomes [49]: acceptability, adoption, appropriateness, feasibility, fidelity and penetration (**Table 2**) will be conducted. Specifically, the following data collection approaches will be used and combined with administrative data from the existing KP Program to assess the implementation outcomes.

TABLE 2. Implementation Outcomes and Data Sources.

Outcome	Analysis Level	Available Measurement
Acceptability	FSW	IDIs, observation at pharmacies
	Pharmacist	Number of trained and retained over study period
Adoption	FSW	Number opting to refill at pharmacy vs. KP program Clinic
	Pharmacist	Number of pharmacies dispensing PrEP refills
Appropriateness	FSW	IDIs, observation at pharmacies, advisory board feedback
	Pharmacist	IDIs, observation at pharmacies, advisory board feedback
	Community	Donors, KP program forum interviews

	MoHCC	MoHCC, City of Harare Pharmacy, Health Care Staff IDIs
	KP program Staff	KP program staff interviews
Feasibility	FSW	IDIs, advisory board feedback
	Pharmacist	IDIs, advisory board feedback
Cost	Beyond the scope of this proposal	
Fidelity	Pharmacists	FSW IDIs, pharmacist interviews, observation at pharmacies
	KP Program	Referral data, self-test kit data, refill prescriptions data
Penetration	Donors, KP program	Scaled to other programme sites beyond Harare
Sustainability	Beyond the scope of this proposal	

Abbreviations: KP- key populations; FSW- female sex workers; IDI- in-depth interviews; MOHCC- Ministry of Health and Child Care

In-depth interviews

A trained social scientist researcher (who is not part of the KP Program) will conduct in-depth interviews with FSW, pharmacy staff, KP program staff, and community leaders as summarised in Table 3. All interviews will be conducted by a single interviewer, according to the participant's language of choice.

Table 3. Summary of qualitative studies to be conducted in the implementation framework study.

Group	Interview	N ^a	Inclusion/Exclusion parameters	Interview guide
FSW	Semi-structured in-depth interview	20	Inclusion criteria: - Aged 16 years old or older - Initiated on PrEP during the study period - At least half of the interviewed participants should be aged 16-24 years - Users/non-users of	- About their experience being part of the study, being on PrEP - Why they did or did not use the pharmacy for PrEP refills - I relevant, their experience going to the pharmacy for PrEP refill pick-up (focusing on interactions at the shop and perceived stigma) as well as getting HIV testing or utilizing and reporting results with the

			pharmacies • Retained/not retained on PrEP • Willing and able to provide written informed consent (or witnessed thumbprint/mark for those who cannot read and write) Exclusion criteria: • Too physically or mentally unwell to participate, as determined by staff observation	HIVST. • Their perspectives on the short-term incentive. • About how we might improve the pharmacy experience and increase general interest in pharmacy-based PrEP refill visits. • About how we might improve the pharmacy experience and increase general interest in pharmacy-based PrEP refill visits. • Other KP program services they might want transferred to pharmacy
Pharmacy personnel from pharmacies that were involved in TOPAZ^b intervention	Semi-structured In-depth interview	24	Inclusion criteria: • Aged 18 years or older • Own or work at a pharmacy in Harare • Pharmacists located in the KP program suburbs	• Implementation challenges and strengths • Enthusiasm for the approach • Reactions to catering for FSW and distributing PrEP refills and HIV testing • Opinions on the design of an expanded future program • Benefits for the clientele and business' profitability/reputation/professional self-worth/ job satisfaction • Strategies for longer term sustainability and opportunity/barriers for further market expansion
Community leader	Key informant interview	5	Inclusion criteria: • Aged 18 years or older • Work with MOHCC, City of Harare, NAC, or any organisations that may be impacted by the intervention	• To assess the appropriateness of the pharmacy-based intervention • Potential for scale throughout Harare and beyond.
KP program	Semi-structured In-depth interview	5	Inclusion criteria: • Age 18 or older • Employee of the KP program (including outreach workers) in one of the 8 study suburbs of Harare • Employee of the KP program for at least 60 days • Directly involved in the initiation and retention of	Explore the appropriateness of the pharmacy-based PrEP intervention.

			FSW on PrEP	
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^a number of interviews

^b indicates pharmacy owners and staff

^c indicates not limited to sex workers enrolled in the KP program;

Abbreviations: PrEP- pre-exposure prophylaxis; FSW- female sex workers; KP- key populations; MOHCC- Ministry of Health and Child Care; NAC- National AIDS Council; HIVST- HIV self-testing; TOPAZ- Together Optimising PrEP Access in Zimbabwe

Direct observations at intervention pharmacies

Trained social science researchers will conduct direct observation at 2 pharmacies per intervention suburb using a structured data worksheet. Pharmacy owners and staff will be informed of the plans for direct observation during the informed consent process for participation in Aim 2. Direct observations will be scheduled ahead of time to coincide with times where there is an expected high number of refill visits, based on REDCap data. Pharmacies will be informed of the observation by the social scientist upon arrival. A random selection of observation date and time per pharmacy will be performed using R software (R version 4.1.3; R Foundation for Statistical Computing, Vienna, Austria).

Data analysis in Aim 3

Analysis will proceed according to the rapid qualitative analysis approach described in the formative research (Aim 1). Interviews will be linked to pilot study data (Aim 2) including pharmacy-level data to triangulate findings on FSW satisfaction with pharmacies, outcomes, and opinions solicited about feasibility and acceptability of the program. To synthesize recommendations for refining the intervention, in addition to using the Proctor framework as guidance, transcripts will be analysed with a focus on scale-up and adjustments that could be further optimized and tested in a future effectiveness study. Results of direct observations will be analysed to assess implementation fidelity

and will also be triangulated with the findings from the in-depth interviews.

Description of indicators to proceed or not to proceed

The traffic-light system will be applied to determine if the intervention will progress to a hybrid implementation effectiveness trial. Indicators for the implementation effectiveness will be considered using a qualitative assessment (Table 4). If all four indicators have a positive response, that denotes a green light to proceed. If any of the indicators show need for changes that are modifiable, and none that are *not* modifiable, the intervention will be assigned an orange light, while a red light is denoted by one or more indicators requiring changes that cannot be made.

Table 4: Criteria to progress to a hybrid implementation effectiveness trial

Indicator	Method of assessment
1. Was it a feasible to implement the pharmacy-based intervention?	Observation of intervention delivery; program data; process evaluation interviews
2. Was the pharmacy-based intervention acceptable to beneficiaries?	Program data; process evaluation interviews; C-RCT outcomes
3. Was the pharmacy-based intervention acceptable to pharmacists and stakeholders?	Programme data; process evaluation interviews; facilitators' questionnaire; C-RCT outcomes
4. Were the evaluation methods acceptable and feasible?	Completeness of program to allow outcome assessment
Indicators (decision) GREEN: <i>Very strong indication to proceed = All four categories have positive response.</i> ORANGE: <i>Moderate indication to proceed, perhaps after intervention refinement= One or more categories have opportunity for improvement that can be addressed.</i> RED: <i>Indication of doubt as to whether to proceed = One or more categories that cannot be addressed.</i>	

Discussion

The TOPAZ intervention aims to co-develop and implement a pharmacy-based model for enhancing access to and continuation on PrEP among FSW, fostering a key partnership between the national KP program and the private sector. The study provides a unique opportunity to explore the role of pharmacies in HIV programs. Success of the intervention will likely pave way for greater

involvement of pharmacies in HIV testing, prevention, and treatment programs. Of note, Zimbabwe MOHCC is currently reviewing whether HIV self-tests can be used for supporting PrEP continuation. If this is approved, we anticipate this will further simplify the program and enhance its accessibility and feasibility.

Conclusion

This paper describes a protocol for applying pharmacies in PrEP distribution, towards the WHO's recommended differentiated service distribution. Privately owned pharmacies are easily accessible in the community and can be applied as a sustainable conduit for PrEP delivery especially for SW and other groups who could benefit from PrEP.

List of abbreviations

ART= anti-retroviral therapy;

CeSHHAR= Centre for Sexual Health, HIV/AIDS Research;

FGD= Focus group discussions;

FSW= Female sex workers;

HIV= Human Immunodeficiency Virus;

IDI= In-depth interviews;

KP= Key populations;

MOHCC= Ministry of Health and Child Care;

NAC= National AIDS Council;

PrEP= Pre-exposure prophylaxis;

SW= Sex workers;

TOPAZ= Together optimizing PrEP access in Zimbabwe;

RCT= Randomised controlled trials.

Declarations

Ethical approval and consent to participate - The TOPAZ study has obtained ethical approval from the national ethics review committee in Zimbabwe, the Medical Research Council of Zimbabwe (MRCZ/A/2988) and the University of California Berkeley Committee for Protection of Human Subjects (2022-11-15783). Participant data will be stored in secure databases, with identifiable data such as full names (only in the informed consent) stored separately.

Consent for publication – N/A

Availability of Data and Materials – Datasets will be deposited in publicly available repositories when available.

Competing Interests – The authors have no conflict of interest to declare.

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Supplementary Files

CONSORT (or other) checklists

SPIRIT figure.

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