Acceptability and accessibility of pre-exposure prophylaxis modalities for HIV prevention (oral daily PrEP, dapivirine vaginal ring and long-acting cabotegravir injectable) among female sex workers in Salt River, Cape Town: A cross-sectional study

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Thesis presented in partial fulfilment of the requirements for the degree of Master of Philosophy in the division of Health Systems and Public Health in the Faculty of Medicine and Health Sciences at Stellenbosch University.

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December 2022

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Acceptability and accessibility of pre-exposure prophylaxis modalities for HIV prevention (oral daily PrEP, dapivirine vaginal ring and long-acting cabotegravir injectable) among female sex workers in Salt River, Cape Town: A cross-sectional study

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Abstract

Background: Female sex workers (FSWs) are at high risk of contracting HIV and have poor access to health care. Evidence is being collected in real world settings on the acceptability and accessibility of pre-exposure prophylaxis (PrEP) amongst FSWs. We explored oral PrEP accessibility, associated factors and acceptability of alternative PrEP modalities.

Methods: This cross-sectional study involved 100 HIV-negative FSWs aged ≥18 years receiving services at the Wits RHI Sex Worker Clinic in Salt River. We tested the association between oral PrEP uptake status and independent variables using logistic regression models. Poisson regression models were used to identify factors associated with oral PrEP accessibility levels. Linear regression was used to identify factors associated with acceptability of alternative PrEP modalities.

Results: FSWs with median age 32.6 years (interquartile range 11.7 years) participated in this study, with 97% indicating that they were at risk for HIV infection. Oral PrEP uptake was 33%**.** Condom use with the main partner (OR = 0.2, 95% CI: 0.0-0.9, sometimes vs. never) was negatively associated with oral PrEP uptake and no previous experience with long-acting drugs (OR = 5.4, 95% CI: 2.2-13.4) was positively associated with oral PrEP uptake.

Accessibility of oral PrEP was lower among FSWs for whom sex work was their secondary source of income compared to those for whom sex work was a primary source of income (aIRR for accessibility score = 0.8, 95% CI: 0.7 – 0.9). Acceptability of alternative PrEP modalities was lower among FSWs with previous treatment for sexually transmitted diseases (differences in acceptability scores -5.1, 95% CI: -14.9– 4.6).

Long waiting times (72% of participants), PrEP unavailability (27%), PrEP side effects (38%), limited privacy (31%) and nurse unavailability were the main barriers to PrEP uptake. The perceived risk of HIV infection, and the availability (43%) and cost (71%) of PrEP uptake were PrEP uptake facilitators.

Conclusions: Oral PrEP uptake among FSWs is currently low. Limited privacy and side effects were the main barriers to PrEP uptake. FSWs were willing to use the new PrEP modalities when available. This study provides valuable lessons for a successful introduction of new PrEP modalities.

Keywords

Female sex workers, Pre-exposure prophylaxis modalities, HIV, South Africa

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Background

Sex workers and their clients, men who have sex with men (MSM), people who inject drugs, and transgender people and their sexual partners, accounted for around 70% of new HIV infections globally in 2021 (1). Female sex workers (FSWs) are at high risk of HIV infection since they have multiple sex partners and sometimes engage in unprotected sex (2). A high prevalence of HIV infection has been observed among FSWs in high-income countries (HICs) where there is low prevalence in the general population. An example is the United States of America, where a systematic review by Paz-Bailey et al. (3) estimated a 17.3% HIV prevalence among FSWs, compared to a general population prevalence of below 0.01%.

Unsurprisingly, given the disproportionate concentration of the burden of the global HIV epidemic in this region, studies in various countries in sub-Saharan Africa have reported HIV prevalence among FSWs that is substantially higher than those observed in HICs. This is the case of Uganda (4), with an observed prevalence of 37%, and particularly South Africa, a middle-income country which records the highest number of people living with HIV in the world, followed by Nigeria (5).

In 2015 a rapid enumeration was done at selected hotspots in all nine provinces of South Africa, with the estimated number of sex workers being around 1% of the adult female population (6). In 2013-2014, HIV prevalence among FSWs in three South African major cities was estimated to be 40% in Cape Town, 54% in eThekwini and 72% in Johannesburg (7). Moreover, a cross-sectional study by Coetzee et al. (8) that was carried out in Soweto, a large township on the outskirts of Johannesburg, reported a 53.6% HIV prevalence among FSWs.

To reduce the number of people living with HIV, condom use is one of the strategies in use. Condoms, if used consistently rather than occasionally, are effective in reducing HIV transmission. A study in Rwanda by Nsanzimana et al. (9) projected that by 2027 a 30% improvement in consistent condom use among FSWs will result in a reduction of HIV prevalence among FSWs, sex work clients and the general population by 8%, 6% and 0.2%, respectively.

According to the UNAIDS 2016 report, condom use at last sex varies from more than 80% in some Latin American and European countries to less than 30% in some African countries (10). In Zimbabwe, a 2020 survey on condom use among young women who sell sex (11) reported that 58% used condoms consistently with their three most recent sexual partners. However, a study in South Africa by Pillay et al. (12) reported that 80% of 140 FSWs claimed that they used a condom the last time they had sex with a client. Some of the problems leading to inconsistent condom use among sex workers in South Africa (13) include clients who become violent when sex workers insist on condom use and clients who offer to pay more for unprotected sex and the criminalisation of sex work. This increases vulnerability and reduces sex workers' agency, as sex workers are reluctant to report crimes committed against them.

These challenges related to condom use call for the need to integrate it with other prevention strategies. Among these alternative strategies is pre-exposure prophylaxis (PrEP), which refers to the administration of antiretroviral (ARV) medications to people who have not yet been infected by the virus, to prevent the acquisition and spread of the HIV infection (14,15). PrEP can be an integral part of comprehensive packages of preventive strategies offered to persons who test negative, together with condom distribution, risk reduction counselling, regular HIV testing, STI screening and treatment, and group counselling.

Condom use is perceived to interfere with intimacy and therefore less likely to be used than PrEP (16). A study by Pillay et al. (12) in South Africa reported that, among FSWs currently using PrEP, condom use with main partners (at 38%) was lower than condom use with casual partners (70%). However, the same study reported that current oral PrEP users (70.2% of 57 FSWs) were more prepared to use both condoms and oral PrEP simultaneously as compared to a mere 18.6% of 43 past PrEP users. PrEP use among main partners was reported to preserve valued relationships and to reduce fear during sex as it empowers the FSWs to take control over their own protection, rather than relying on partners or clients to use condoms (17).

PrEP is an important prevention modality, yet its efficacy is hampered by low uptake and low continuation. Several studies have reported on PrEP uptake in South Africa and regionally. An observational study by Matambanadzo et al. (18) in Zimbabwe found that in 2020 uptake rates among FSWs were less than 25% per month before the occurrence of the Covid-19 pandemic and increased to 51% at initiation in September 2020. A qualitative study by Jackson-Gibson et al. (19) in Kenya, reported that barriers to PrEP use include stigma associated with the use of ARV drugs, drug side effects, limited resources for routine screening and medication monitoring, and a limited number of qualified health care workers for PrEP distribution and administration. Preliminary results of a prospective observational study in urban South Africa (20) showed that 224 out of 241 HIV negative FSWs were eligible for PrEP and 221 out of 224 initiated oral PrEP, despite the fact that a mere 22% remained on PrEP at the 12-month follow-up.

In sub-Saharan Africa, the only PrEP modality available consists of daily oral combination of tenofovir and emtricitabine (TDF/FTC, commercial name Truvada™) or a combination of tenofovir alafenamide and emtricitabine (F/TAF, commercial name Descovy™). However, new long-acting modalities of administration such as vaginal rings and injectables have been

developed. The new modalities may simplify the use of ARV medications and enhance prevention outcomes.

Among these new biomedical technologies, the long-acting cabotegravir injectable (CAB LA) and the dapivirine vaginal ring (DPV VR) may contribute substantially to containing the HIV epidemic, and hold promise for high-risk women who may have limited capacity for condom-use negotiation.

CAB LA is an ART drug for PrEP in HIV-uninfected people including women and MSM (21,22). For PrEP it is administered by intramuscular injection at a dose of 600 mg, with the first two injections administered four weeks apart and subsequently an injection every eight weeks (23). The WHO's *Guidelines on long-acting injectable cabotegravir for HIV prevention* describe CAB LA as an effective way of preventing the spread of HIV with little or no safety risks, and support the statement with the results of a systematic review by Fonner et al., which estimated that the use of CAB LA provides a 79% reduction in HIV risk compared to oral PrEP (23). A review study in the USA found that this drug could offer a better choice for women at substantial HIV risk who do not want to take a tablet daily or who need a reliable reminder to take the oral pill (24).

The dapivirine vaginal ring is a small, soft, plastic ring that women can place in their vagina. It releases dapivirine and can be inserted for a month or longer without the need to adhere to any prescribed dosing regimen (25). This is one of the non-oral PrEP delivery options developed by the International Partnership for Microbicides (IPM) in African countries in collaboration with the WHO and the Food and Drug Administration (FDA). A DVP VR trial conducted with high-risk women in several African countries has shown high acceptability of and willingness to use the ring if it were proven to be effective (26). A recent review of evidence on the acceptability and

preference of a vaginal ring among women in the general population in low and middle-income countries (LMICs) suggested that it was acceptable and easy to use, despite some participants reporting it to be a cognitive and emotional burden, having an impact on sexual intercourse, and presenting some issues with expulsion (27). The WHO currently recommends that DVP VR may be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches (28). However, little is known about the acceptability of the DVP VR among FSWs (29).

Despite these promising findings related to the use of CAB LA and the DVP VR, FSWs continue to have limited access to PrEP in general, and long-acting modalities in particular, an issue further compounded by stigma, discrimination, and poverty. Although FSWs face a higher risk of HIV infection, they have poorer healthcare access compared to the general population (30) and accessibility and acceptability are important concerns for the successful implementation of PrEP not just in South Africa, but also globally.

The accessibility of an intervention refers to how challenging the steps are, that are required for the user to get it (31,32). In the case of PrEP, accessibility may be affected by barriers such as distance to travel to the clinic, poor interpersonal communication with healthcare providers, stigma, discrimination, and insufficient knowledge (33). Universal access to healthcare is a critical determinant of health; as such, access to PrEP for high-risk population groups including FSWs remains critically important. This is particularly relevant in South Africa, because not only is sex work illegal, but FSWs are also a group particularly vulnerable to discrimination and violent clients (34). In a study conducted in two South African districts, Shamu et al. (35) reported that awareness was an important barrier to access to PrEP by the study participants.

The acceptability of an intervention is defined as the degree to which people administering or receiving the intervention consider it to be appropriate based on anticipated or emotional responses to it (36,37). Acceptability has become a key consideration (37) in the successful design, evaluation and implementation of healthcare interventions, including prevention programmes such as PrEP (30). Just like accessibility, PrEP acceptability is affected by social and cultural factors. If an intervention is considered acceptable, patients are more likely to adhere to and derive benefit from a particular treatment or intervention in support of its overall effectiveness (30,38). A South African study in which a high level (98%) (20) of acceptability of oral PrEP among FSWs was reported, demonstrated that the potential acceptability of PrEP was motivated by awareness and understanding of PrEP. A study in Jamaica by Logie et al. (39) reported high PrEP acceptability among sex workers, also that exposure to sexual violence and client violence were associated, in a multivariable analysis, with high levels of acceptability.

Data regarding PrEP acceptability and accessibility in South Africa could help to understand more of the implementation of PrEP and the extent to which introducing new, long-acting modalities of administration of PrEP could help improve uptake and continuation, thereby containing the spread of the HIV infection. This study aimed to explore the accessibility and acceptability of various PrEP modalities among FSWs who visit the Wits RHI Sex Worker Clinic in Salt River and its mobile clinic in Cape Town, South Africa. The specific objectives were (i) to assess the level of accessibility of oral PrEP, currently available at the clinic; (ii) to assess the acceptability of alternative modalities of PrEP (DVP VR and CAB LA); and (iii) to describe the barriers and facilitators to access and acceptability of various PrEP modalities. In our knowledge, no previous study has explored acceptability of new PrEP modalities among FSW in the City of Cape Town

Methods

Study setting

This study was conducted at the Wits RHI Sex Worker Clinic in Salt River, Cape Town, South Africa (hereinafter called "the Salt River SW Clinic"). Cape Town is the second largest metropolitan area in South Africa after Johannesburg, with a high concentration of FSWs living with HIV in the greater metropolitan area (40).

Wits RHI is a renowned African research institute, with its headquarters in Johannesburg. It addresses some of the greatest public health concerns affecting the region, including HIV and its related challenges, sexual and reproductive health, and vaccine availability (41). The Wits RHI Key Populations (KPs) programme is funded by the United States Agency for International Development (USAID).

The Wits RHI Sex Worker Clinic programme provides health services to the FSW key populations (KPs). It operates in the Cape Town Metro area with a fixed clinic and a mobile wellness clinic service in places that FSWs frequent. The programme offers HIV counselling and testing, ART, screening for sexually transmitted infection (STIs) and tuberculosis (TB), distribution of condoms including the provision of health information on correct and consistent use, and PrEP. It has been offering oral PrEP to HIV-negative FSWs by health care providers (professional nurses) as part of a government-led programme since 2016. The programme also advocates the rights of KPs so that those who are referred for other help or treatment are provided with support in a non-judgmental environment.

The Wits RHI Sex Worker Clinic in Salt River was chosen for this study because of the well-established oral PrEP programme and the possibility of accessing an adequate number of FSWs.

Participants and procedures

Population and sample

In this cross-sectional study, the study population comprised women who earn a living from sex work in the metropolitan area of Cape Town. We recruited the study sample from all Cape Metro sub-districts that correspond to the catchment area of the Wits RHI Sex Worker Clinic. Consecutive sampling was used to recruit participants (42). Inclusion criteria were: HIV-negative; aged 18 years or older; self-identified as FSW; and either on oral PrEP or PrEP naïve. We excluded FSWs who were HIV-positive, and male or transgender subjects. Participation in the study was voluntary, and the choice to participate or not was independent of their care at the clinic.

All FSWs aged at least 18 years old presenting at the clinic during the study period were provided by the clinic nurse with study flyers and invited to participate in the study. Consenting participants were screened for HIV infection and those who tested negative were formally enrolled into the study after signing an informed consent form.

Considering acceptability as the main outcome of the study, the sample size was calculated based on a worst-case scenario of 50% of respondents answering “Yes, probably” or “Yes, definitely” to the relevant items of the questionnaire. By assuming an acceptable margin of error d = ±0.10 and a 95% confidence level, we calculated a minimum sample size of 97, increased to 100 to allow for incomplete responses. Data collection was interrupted when the desired sample size was reached.

Data collection tools

A semi-structured questionnaire was used for data collection. It consisted of eight sections: demographic information; view on health and the risk of HIV infection; contraception; sexual behaviour with both clients and main partner; preferred HIV prevention method; accessibility, and barriers to PrEP; PrEP acceptability and perception with long-acting HIV.

The questionnaire was drawn from similar questionnaires used in previous studies (43,44) and adjusted to suit the objectives and research questions of this study. A pre-test of the questionnaire was conducted among 10 voluntary participants at the sites to ensure that the questions were easily understood. As a result of the feedback from the participants, minor modifications were made to the draft questionnaire. We added two new items inquiring about awareness of new PrEP modalities and potential barriers to their use if they were made available. The final questionnaire is available as Supplementary Material 1.

Measures

Socio-demographic data

The socio-demographic variables considered in this study include age (years), marital status (married/cohabiting, single/divorced/widowed), population group as per Statistics South Africa categorisation (Black African, White, Coloured and Indian) (45) and the highest educational level attained (primary, secondary or college/technical school). A questionnaire item investigated whether sex work was the primary or a secondary source of income.

Risk of infection perception

The following question was asked to the participants: "*Referring to your past and present sexual practices, what do you think is your level of risk of getting infected with HIV?*" The question was meant to assess an individual's perception of her risk of contracting HIV. The responses were categorised as follows: no risk, low risk, some risk, high risk, or prefer not to say.

Sexual behaviour

The sexual behaviour measure included behaviours with clients and with the main partner (if applicable). Sexual behaviour with clients focused on the approximated number of clients per month each participant was likely to have, and the frequency of condom use. On sexual behaviour with the main partner, we asked if the main partner was aware of the participant's sex work, if the participant was aware of the main partner's HIV status, and the frequency of condom use. Main partner, in this study, was defined as a sexual partner the relationship with whom was considered, by the participant, the most important relative to other sexual relationships.

Oral PrEP awareness

PrEP awareness was determined by asking all participants if they had been aware of oral PrEP before the information they received within the scope of this study.

Accessibility to oral PrEP

Eleven questions were asked to investigate the level of accessibility of oral PrEP. A score of 1 was given if the response indicated easy access, or otherwise a 0 was given. The 11 questions are

provided as Supplementary Material 1. A total oral PrEP accessibility score was calculated as the number of items with score equal to 1.

PrEP acceptability

PrEP acceptability was measured by examining the intention to use it if it were free of charge, and willingness to pay for it. Twenty-eight questions were asked to rate PrEP acceptability. A score of 1 was given for a "definitely no" response, 2 for a "no" response, 3 for a "yes" response and 4 for a "definitely yes" response. The 28 questions are provided as Supplementary Material 1. A total PrEP acceptability score was calculated as the sum of the 28 scores.

Preference for PrEP modality

In comparison to the current oral pill, participants were asked to choose their preference if the alternative modalities were to be made available free of charge or for a certain fee. The new modalities included the long-acting cabotegravir injectable and dapivirine vaginal ring.

Facilitators and barriers to PrEP use

Open-ended questions were used to elicit information on challenges related to accessing oral PrEP. Participants were asked to list their likely reasons for not being willing to use the dapivirine vaginal ring or the long-acting cabotegravir injectable even if they were to be offered free of charge.

Data collection and processing

Data were collected via face-to-face interviews by the researcher and a research assistant. The face-to-face interviews in this study allowed the researcher to capture verbal and non-verbal cues

such as discomfort and enthusiasm with questions. Data were collected for three months between 25 October 2021 and 14 January 2022. The research assistant was trained on data collection procedures to ensure the accuracy and reliability of data. To ensure the privacy of study participants and the confidentiality of data, a private room was used during data collection and no identification data, such as name or national identification number, was asked or recorded. Participants were identified by unique study identification numbers.

Screening for inclusion criteria, including an HIV test, and request of preliminary consent to study participation were done by the clinic nurse. Eligible participants were then referred to the researcher to administer the informed consent and the questionnaire. The administration of the questionnaire took an average of 20 minutes. To avoid missing data, the questionnaires were filled in in the presence of the researcher who verified that all questions were responded to, before the departure of each participant. After administration of the questionnaire, a R100 food voucher was given to each participant for appreciation of their time in the study**.**

Data was entered and stored using REDCap (46), and access was limited to the PI. Data was exported to Microsoft Excel for cleaning and coding, and subsequently to the STATA statistical software version 16 (47) for analysis.

Statistical analysis

Categorical variables were summarised using frequencies and proportions, and continuous variables by median and interquartile range.

We first used univariate logistic regression to test the association between current oral PrEP uptake status and all potential predictors. We then used Poisson regression models (both univariate and

multivariate) for the analysis of the PrEP accessibility score, and linear regression (both univariate and multivariate) models for the analysis of oral PrEP acceptability total score.

In all cases, we considered site of interview (fixed or mobile service), age, marital status, highest level of education, ethnicity, sex work as source of income (primary or secondary) and previous STI treatment as potential predictors. All significant predictors (at the 20% significance level) in the univariate models were used to build the multivariate model, using stepwise forward regression. The variable age was kept in the multivariate model as a known potential confounder.

Results

Study participants characteristics

As shown in Table 1, 84% of the 100 participants obtained services from the mobile clinic and 16% from the fixed clinic because they did not want to waste time visiting fixed clinic hence most participants preferred services very closer to them or their working places. A high proportion (88%) of FSWs indicated that sex work was their primary source of income. Fifty-nine percent of the participants were above 30 years old, and their median age was 32.6 years (IQR =11.7). Of all participants, 74% had obtained secondary education. Only 22% were married or cohabiting, and the remaining 78% were single or separated.

Only 2% indicated that they had no risk of HIV infection, while 97% said that they were at risk and only 1% preferred to not say what their HIV risk perception was. Of the 56 participants who had a main partner, 64.3% (36/56) knew their main partner's HIV status, 37.5% (21/56) never used condoms with their main partner and a mere 14.29% (8/56) used condoms regularly with their main partner.

PrEP oral uptake was very low at 33% (95%, CI: 24% – 43%). Eighty-seven percent heard of PrEP before being introduced to this study. Of the 87 FSWs who had knowledge of PrEP before this study, 71.3% (62/87) knew where to pick up PrEP.

Out of 100 FSWs, 57% reported previous experience with long-acting drugs like contraceptive injections, and 71% were willing to use a long-acting cabotegravir injectable HIV prevention method.

Table 1: Characteristics of study participants

Variable	Level	Frequency	Percentage
Categorical variables			
Site of data collection	Clinic	16	16.0
	Mobile clinic	84	84.0
Age category	≤30 years	41	41.0
	> 30 years	59	59.0
Marital status	Single/Separated	78	78.0
	Married/Cohabiting	22	22.0
Highest level of education	Primary school	19	19.0
	Secondary school	74	74.0
	College/Technical school	7	7.0
Population Group	Black	50	50.0
	White	8	8.0
	Coloured	40	40.0
	Indian/Asian	2	2.0
Sex working as source of income	Primary	88	88.0
	Secondary	12	12.0
Previous STI treatment	No	14	14.0
	Yes	85	85.0
	Preferred not to say	1	1.0
HIV risk perception	I have no risk	2	2.0
	I have low risk	11	11.0
	I have some risk	15	15.0
	I have high risk	71	71.0
	Preferred not to say	1	1.0
Number of sex partners in past 30 days	5-10	6	6.0
	11-15	18	18.0
	More than 15	73	73.0
	Preferred not to say	3	3.0
Frequency of condom use	Sometimes	8	8.0
	Most of the time	16	16.0
	Always	75	75.0
	Prefer not to say	1	1.0
Has a main partner	Yes	56	56.0
	No	40	40.0
	Prefer not to say	4	4.0
Is partner aware that you are selling sex? *	Yes	22	39.3
	No	34	60.7
Aware of partner HIV status*	Yes	36	64.3
	No	20	35.7
Partner HIV status**	Positive	4	11.1
	Negative	32	88.9
Condom use with main partner	Never	21	37.5
	Sometimes	7	12.5
	Most of the time	8	14.3
	Prefer not to say	20	35.7
Ever heard about PrEP before today	Yes	87	87.0

	No	13	13.0
Knows where to pick PrEP***	Yes	62	71.3
	No	25	28.7

Table 1: Characteristics of study participants (cont'd)

Variable	Level	Frequency	Percentage
Experience upon arrival at clinic or mobile clinic	Excellent	18	18.0
	Good	60	60.0
	Fair	21	21.0
	Bad	1	1.0
Rate the treatment you got upon arrival at clinic or mobile clinic	Excellent	10	10.0
	Good	58	58.0
	Fair	27	27.0
	Bad	5	5.0
Nurse used language understood by participant	Yes	85	85.0
	No	6	6.0
	Not sure	9	9.0
PrEP always available at the clinic	Yes	43	43.0
	No	17	17.0
	Not sure	40	40.0
Experienced discrimination at the clinic	Yes	27	27.0
	No	59	59.0
	Not sure	14	14.0
Well educated about PrEP by the nurse	Yes	88	88.0
	No	5	5.0
	Not sure	7	7.0
Transport to the clinic	Walk	61	61.0
	Tax	39	39.0
Time taken to be served at the clinic	Less than 20 minutes	64	64.0
	20-40 minutes	17	17.0
	41-60 minutes	7	7.0
	More than 1 hour	12	12.0
Comfortable with waiting time	Yes	41	41.0
	No	46	46.0
	Not sure	13	13.0
Experience with long-acting drugs like contraceptive injection	Yes	57	57.0
	No	43	43.0
Willing to use a long-acting HIV prevention method	Yes	71	71.0
	No	29	29.0
Currently on oral PrEP	Yes	33	33.0
	No	67	67.0
Continuous variables			
	Median	**IQR**	
Age (Years)	32.6		11.7
Accessibility score	8		2
Acceptability score	83		16.5

*Question only asked to participants who reported having a "main partner"
** Question only asked to participants who knew partner's status

*** Question only asked to participants who heard about PrEP before

Oral PrEP uptake

Table 2 describes the distribution of the independent variables by oral PrEP uptake status.

Partner awareness of sex work (p-value=0.037), use of condom with the main partner (p-value=0.036), knowledge of where to pick oral PrEP medication (p-value=0.020), oral PrEP availability at the clinic (p-value=0.014) and experience with long-acting drugs like contraceptive injection (p-value <0.001) were significantly associated with oral PrEP uptake status.

Participants whose main partners were not aware of their sex work had a 70% (OR = 0.3, 95% CI: 0.1-0.9) decrease in odds of being on oral PrEP relative to the group whose main partners were aware of their sex work. FSWs who sometimes used condoms with their main partner had an 80% (OR = 0.2, 95% CI: 0.0-0.9) decrease in odds of being on oral PrEP relative to the group who never used condoms with the main partner. FSWs who did not know where to pick oral PrEP had 80% (OR = 0.2, 95% CI: 0.1-0.8) decrease in odds of being on oral PrEP relative to those who knew where to pick oral PrEP. Participants who reported oral PrEP was not always available at the clinic had 70% (OR = 0.3, 95% CI: 0.1-0.8) decrease in odds of being on oral PrEP relative to participants who reported that oral PrEP was always available at the clinic. FSWs who had no previous experience with long-acting drugs like contraceptive injection were 5.4 times odds to be on oral PrEP of those who had previous experience (OR = 5.4, 95% CI: 2.2-13.4). Though with weak evidence (p-value = 0.509), participants in the 30 years and older age group had 1.3 times the odds of being on oral PrEP relative to those in the younger age group.

Table 2: Factors associated with PrEP uptake among female sex workers*

Variable	Level	On PrEP, n (%)	Not on PrEP, n (%)	OR (95% CI)	P-value
Total		33 (33)	67 (67)		
Site of data collection	Clinic	5 (31)	11 (69)	1	
	Mobile clinic	28 (33)	56 (67)	1.1 (0.3-0.5)	0.871
Age category	≤30 years	12 (29)	29 (71)	1	
	> 30 years	21 (36)	38 (64)	1.3(0.6-3.2)	0.509
Has a main partner	Yes	21 (37)	35 (63)	1	
	No	12 (30)	28 (70)	0.7(0.3-1.7)	0.446
Marital status	Single/Separated	23 (29)	55 (71)	1	
	Married/Cohabiting	10 (45)	12 (55)	2.0(0.8-5.3)	0.164
Highest level of education	Primary school	5 (26)	14 (74)	1	
	Secondary school	27 (36)	47 (64)	1.6(0.5-5.0)	0.408
	College/Technical school	1(14)	6(86)	0.5(0.0-4.9)	0.525
Population Group	Black	18 (36)	32 (64)	1	
	Non-Black	15 (30)	35 (70)	0.8(0.3-1.8)	0.524
Sex working as source of income	Primary	29 (33)	59 (67)	1	
	Secondary	4 (33)	8(67)	1.0(0.3-3.7)	0.979
Previous STI treatment	No	6 (43)	8 (57)	1	
	Yes	27 (32)	58 (68)	0.6(0.2-2.0)	0.417
HIV risk perception	I have no risk	1 (50)	1 (50)	1	
	I have low risk	6 (55)	5 (45)	1.2(0.1-24.4)	0.906
	I have some risk	1 (7)	14 (93)	0.1(0.0-2.2)	0.132
	I have high risk	24 (34)	47 (66)	0.5(0.0-8.5)	0.640
Number of sex partners in past 30 days	5-10	1 (17)	5 (83)	1	
	11-15	6 (33)	12 (67)	2.5(0.2-6.5)	0.447
	More than 15	25 (34)	48 (66)	2.6(0.3-3.5)	0.394
	Preferred not to say	1 (33)	2 (67)	2.5(0.1-2.6)	0.577
Frequency condom use	Sometimes	3 (37.5)	5 (62.5)	1	
	Most of the time	5 (31)	11 (69)	0.8(0.1-4.5)	0.760
	Always	24 (32)	51 (68)	0.8(0.2-3.6)	0.753
Is partner aware that you are selling sex? **	Yes	12 (55)	10 (45)	1	
	No	9 (26)	25 (74)	0.3(0.1-0.9)	**0.037**
Aware of partner HIV status**	Yes	16 (44)	20 (56)	1	
	No	5 (25)	15 (75)	0.4(0.1-1.4)	0.155
Partner HIV status***	Positive	2 (50)	2 (50)	1	
	Negative	14 (44)	18 (56)	0.8(0.1-6.2)	0.813
Condom use with main partner	Never	19 (46)	22 (54)	1	
	Sometimes	2 (13)	13 (87)	0.2(0.0-0.9)	**0.036**
Ever heard about PrEP before today	Yes	31 (36)	56 (64)	1	
	No	2 (15)	11 (85)	0.3(0.1-1.6)	0.164
Knowing where to pick PrEP****	Yes	27 (44)	35 (56)	1	
	No	4 (16)	21 (64)	0.2(0.1-0.8)	**0.020**
Experience upon arrival at clinic or mobile clinic	Excellent	9 (50)	9 (50)	1	
	Good	18 (30)	42 (70)	0.4(0.1-1.3)	0.123
	Fair	5 (24)	16 (76)	0.3(0.1-1.2)	0.095
	Bad	1 (100)	0(0)		

Table 2. Factors associated with PrEP uptake among female sex workers (cont'd)

Variable	Level	On PrEP, n (%)	Not on PrEP, n (%)	OR (95% CI)	P-value
Rate of treatment received upon arrival at clinic or mobile clinic	Excellent	3 (30)	7 (70)	1	
	Good	17 (29)	41(71)	1.0(0.2-4.2)	0.965
	Fair	10 (37)	17 (63)	1.4(0.3-6.5)	0.691
	Bad	3 (60)	2 (40)	3.5 (0.4-33.0)	0.274
Nurse used language understood by participant	Yes	29 (34)	56 (66)	1	
	No	2 (33)	4 (67)	1.0(0.2-5.6)	0.969
	Not sure	2 (22)	7 (78)	0.6(0.1-2.8)	0.476
PrEP always available at clinic	Yes	20 (47)	23 (53)	1	
	No	13 (23)	44 (77)	0.3(0.1-0.8)	**0.014**
Experienced discrimination at clinic	Yes	12 (44)	15 (56)	1	
	No	18 (31)	41 (69)	0.5(0.2-1.4)	0.211
	Not sure	3 (21)	11 (79)	0.3(0.1-1.5)	0.156
Well educated about PrEP by nurse	Yes	27 (31)	61 (69)	1	
	No	3 (60)	2 (40)	3.4(0.5-1.5)	0.195
	Not sure	3 (43)	4 (57)	1.7(0.4-8.1)	0.509
Transport to the clinic	Walk	22 (36)	39 (64)	1	
	Tax	11 (28)	28 (72)	0.7(0.3-1.7)	0.416
Time taken at the clinic	Less than 20 minutes	23 (36)	41 (64)	1	
	20-40 minutes	8 (47)	9 (53)	1.6(0.5-4.7)	0.404
	41-60 minutes	1 (14)	6 (86)	0.3(0.0-2.6)	0.275
	More than 1 hour	1 (8)	11 (92)	0.2 (0.0-.3)	0.091
Comfortable with waiting time	Yes	17 (41)	24 (59)	1	
	No	14 (30)	32 (70)	0.6 (0.3-.5)	0.285
	Not sure	2 (15)	11 (85)	0.3 (0.1-.3)	0.102
Experience with long-acting drugs like contraceptive injection	Yes	10 (18)	47 (82)	1	
	No	23 (53)	20 (47)	5.4 (2.2-13.4)	<0.001
Willing to use a long-acting HIV prevention method	Yes	27 (38)	44 (62)	1	
	No	6 (21)	23 (79)	0.4 (0.2-.2)	0.100

* Odds ratios (OR) and p-values from univariate logistic regression
** Question only asked to participants who reported having a "main partner"
*** Question only asked to participants who knew partner's status
**** Question only asked to participants who heard about PrEP before

Accessibility of oral PrEP

As shown in Table 3, the only factor which showed a significant relationship with the accessibility score at the 5% significance level (p-value < 0.001) was sex work as a primary or secondary source of income. Both in the univariate model and in the multivariate model adjusted for age group, the accessibility score was higher among FSW with sex work as a primary source of income. In the multivariate analysis, accessibility of oral PrEP was lower among FSWs for whom sex work was

their secondary source of income compared to those for whom sex work was a primary source of income (aIRR for accessibility score = 0.8, 95% CI: 0.7 – 0.9).

Table 3: Factors associated with accessibility score for oral PrEP among female sex workers*

Factor	Level	Univariate		Multivariate	
		IRR (95% CI)	P-value	IRR (95% CI)	P-value
Site	Clinic	1			
	Mobile clinic	1.0 (0.9-1.1)	0.462		
Age (years)		1.0(1.0 –1.0)	0.902	1.0(1.0 – .005)	<0.875
Marital status	Single/Separated	1			
	Married/Cohabiting	1.0(0.9 –1.1)	0.707		
Highest level of education	Primary school	1			
	Secondary school	1.0(0.9–1.1)	0.799		
	College/Technical school	0.9(0.8–1.1)	0.243		
Population Group	Black	1			
	Non-Black	1.0(1.0– 1.1)	0.305		
Sex work as source of income	Primary	1			
	Secondary	0.8(0.7 – 0.9)	**<0.001**	0.8(0.7–0.9)	<0.001
Previous STI treatment	No	1			
	Yes	1(0.9 – 1.1)	0.952		
	Prefer not to say	0.9(0.6 – 1.3)	0.523		
Experience with long-acting drugs like contraceptive injection	Yes	1			
	No	1.0(0.9 – 1.1)	0.943		

* Incidence rate ratios (IRR) and p-values from univariate and multivariate Poisson regression models.

Acceptability of alternative PrEP modalities

Age, marital status, level of education and previous treatment for STIs were significantly associated with the acceptability score in the univariate analyses, as shown in Table 4.

In the multivariate model, one year increase in age was associated with a significant reduction by 0.4 points in the acceptability score (95% CI: -0.0; 0.0, p-value=0.041), and having had previous STI treatment or refusing to answer the question were both predictors of lower acceptability scores (-5.1 points, 95% CI: -14.9; -4.6 and -43.2 points, 95%CI -78.2; -8.2 respectively).

Table 4: Factors associated with acceptability score for alternative PrEP modalities among female sex workers*

Factor	Level	Univariate		Multivariate	
		Coefficient	P-value	Coefficient	P-value
Site	Clinic	1			
	Mobile clinic	0.8(-8.9 – 10.4)	0.874		
Age (in years)		-0.4(-0.9 – -0.0)	**0.041**	-0.4(-0.8 – -0.0)	0.043
Marital status	Single/Separated	1			
	Married/Cohabiting	8.6(0.3 – 16.9)	**0.043**		
Highest level of education	Primary school	1			
	Secondary school	2.9(-5.9 – 11.8)	0.511		
	College/Technical school	-14.2(-29 – 0.6)	**0.060**		
Population Group	Black	1			
	Non-Black	-3.8(-10.8 – 3.2)	0.288		
Sex working as source of income	Primary	1			
	Secondary	-5.2(-16.5 – 5.5)	0.334		
Previous STI treatment	No	1		1	
	Yes	-5.3(-15.2 – 4.6)	0.294	-5.1(-14.9– 4.6)	0.016
	Prefer not to say	-44.1(-79.7 – -8.5)	**0.016**	-43.2(-78.2 – -8.2)	0.043
Experience with long-acting drugs like contraceptive injection	Yes	1			
	No	-0.8 (-7.9 – 6.4)	0.834		

***Linear regression coefficients and p-values from univariate and multivariate models.**

Of the 71 participants who were ready to take long-acting HIV prevention methods, 29 mentioned that the oral pill can be easily forgotten hence their preference for long-acting methods. Twenty-six participants, without giving a comparative reason against oral PrEP, stated that they preferred the long-acting injectable cabotegravir. The remaining 16 gave other reasons ("*to protect myself from HIV", "it gives me privacy as compared to the pill", "prefer long-acting injectable cabotegravir than dapivirine vaginal ring"*) for preferring long-acting HIV prevention methods.

Out of the 19 participants who were not willing to use the dapivirine vaginal ring if it was to be made available, one participant preferred the injection, three feared the side effects, six were not willing to be on PrEP, four preferred the condom, one preferred the pill and four would not take

something they were not sure of. Lastly, out of the 22 FSWs who would not take the long-acting cabotegravir injectable if it was to be made available, four feared side effects, two preferred the dapivirine vaginal ring, four preferred condoms, four did not prefer the injection, two preferred the oral pill and lastly six did not want to be on PrEP.

Barriers and facilitators of PrEP

The analysis of the responses to the open-ended items investigating facilitators and barriers of PrEP use highlighted long waiting times (72%), availability problems (27%) and side effects (38%), limited privacy (31%) and nurse unavailability (44%) as the main barriers. It took long for most participants to initiate PrEP due to eligibility processes involved and the nurse(s) responsible for PrEP initiation were not always available. The development of side effects after taking oral PrEP and limited privacy associated with oral PrEP daily assumption could expose FSWs to stigmatisation in their communities or households.

The risk of HIV infection was stated by 97% participants as a personal facilitator to PrEP uptake. In addition, the institutional PrEP uptake facilitators included availability (43%) and cost (71%).

Discussion

Despite the high level of awareness of oral PrEP found among the FSWs enrolled in this study, we reported a low uptake (33%). This agrees with the results of another South African study by Pillay et al. (12), which reported a 37% oral PrEP uptake rate among FSWs. In Uganda, a study by Witte et al. (4) concluded that despite endorsing PrEP, many women engaging in sex work remained reluctant to use it. This study reported that only 11% (36/322) of HIV-negative women who engaged in sex work were enrolled on PrEP. A multinational (South Africa, Uganda, and Zimbabwe) randomised placebo-controlled trial by Marrazzo et al. (48) reported that non-adherence to daily oral tablets by participants was a challenge to successful oral PrEP uptake. These findings suggest the need to motivate FSWs not only to take PrEP but also to adhere to treatment.

Partner awareness of sex work, condom use with main partner, knowledge of where to pick oral PrEP medication, oral PrEP availability at clinic and experience with long-acting drugs like contraceptive injection were found to be associated with the oral PrEP uptake status in this study. We reported that condom use by FSWs who had main sex partners was very low relative to FSWs without main sex partners. Similar findings were reported by Pillay et al. (12) where condom use was reported to be lower in the group of FSWs with main partners as compared to the group of FSWs with casual partners. However, the same study went on to report that FSWs who were on oral PrEP preferred to use both oral PrEP and condoms with main partners and clients simultaneously without difficulties.

These findings were similar to the report by Muhumuza et al. (49) where PrEP uptake was associated to personal and environmental factors to be considered for a successful roll-out. The

personal factors included PrEP awareness whereas environmental factors included PrEP availability at clinics. We reported that FSWs whose partners were aware of their sex work were more likely to taking oral PrEP relative to FSWs whose partners were not aware of their sex work. However, a qualitative study in South Africa by Beesham et al. (43) reported an instance where a participant was forced by the partner to dispose the PrEP tablets. We also reported on factors that showed a difference in accessibility level scores before and after adjusting for other covariates. The difference in accessibility level scores was reported between the FSWs who took sex work as a primary source of income and FSWs who took sex work as a secondary source of income, both before and after adjusting for age.

Alternative PrEP modalities in this study were rated acceptable by 71% FSWs, with a similar finding being reported by Tolley et al. (50) where more than 75% of 136 women (100 African and 36 from the USA) from a general population rated the new modalities as acceptable. We also found that an increase in age was associated with a decrease in acceptability level of alternative PrEP. Our findings concurred with a study in Uganda by Witte et al. (4), who reported that older women who had spent more time in sex work were more difficult to target to change behaviour.

We reported on reasons why 71% of FSWs in this study preferred long-acting HIV prevention methods than oral PrEP. One of the reasons mentioned in this study was that the pill ensures less privacy relative to the long-acting injectable cabotegravir and dapivirine vaginal ring. A qualitative multinational study by Scorgie et al. (51) reported that it was not easy for young women to disclose their oral PrEP uptake even to family members. This is in agreement to our finding that in general women, including FSWs, require privacy when taking PrEP. We reported that FSWs in this study, due to the limited of privacy associated with oral PrEP, were exposed to stigmatisation in their places of residence.

We found that that FSWs preferred a PrEP modality that did not take away their privacy and that did not expose them to side effects. A similar report was given by Jackson-Gibson et al. (19) finding that the barriers to PrEP uptake included side effects and community stigma against PrEP. Bekker et al. (14) listed some of the side effects associated with oral PrEP which include nausea and headaches occurring in around 10% of PrEP users. It is an individual's decision to use PrEP and an individual will choose a PrEP modality that is appropriate and that is used under non-stigmatising environments.

We reported on both personal and institutional PrEP uptake facilitators which included risk to HIV infection and availability and cost of PrEP, respectively. Our findings were similar to a study by Muhumuza et al. in Uganda where personal, community and structural facilitators were reported (49).

Strengths and limitations

This study is based on a small sample size, and only allowed for limited precision in the estimates, and limited power in the regression analyses (52). A larger sample size might have produced more precise estimates and lead to the identification of further factors associated with accessibility and acceptability. The findings of this study cannot be generalised, since data was collected from one health facility. Biased sample was possible given the consecutive sampling that was done but more importantly, sex workers getting care elsewhere and not from a dedicated clinic or not regularly attending health care were not represented and this would affect the representativity and generalizability of the results

Conclusion and recommendations

Oral PrEP uptake among FSWs is currently low. Limited privacy, long waiting times and side effects were the main barriers associated with oral PrEP, suggesting the need to handle them in order to improve PrEP uptake. New methods like the long-acting injectable cabotegravir are not taken daily and hence attract less risk of forgetting, also allowing for more privacy than the oral pill. However, some FSWs feared the unknown side effects associated with inserting the dapivirine vaginal ring.

This study provides valuable lessons for an effective and successful introduction of new PrEP modalities broadly. PrEP should be accessible and the need to remove barriers to PrEP uptake are some of the lessons derived from this study. The new modalities were reported to be highly acceptable and preferable among FSWs. There is need to improve awareness and remove stigmatisation. We recommend the availability of service points and health education to counter PrEP myths and address the fear of side effects.

Declarations

Ethics approval and consent to participate

This study was approved by the Research Ethics Committee of Stellenbosch University (Reference number: S21/07/132), was given permission by the Western Cape Government Department of Health in South Africa (Reference number: 9802) and The Witwatersrand Reproductive Health and HIV Institute facilitated access to potential study participants. All participants voluntarily consented to participate by signing and returning the consent form to the research.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated during the current study are available from the corresponding author on reasonable request.

Competing interests

Authors have no competing interests to declare.

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Author Contribution

RTM: Principal investigator, developed the research question, developed protocol, collected data, cleaned data, analysed data, and interpreted the results and did the study write up.

AC: Supervisor, reviewed the protocol, reviewed the analysis and the study write up.

NH: Co- supervisor, reviewed the protocol, reviewed the data collection tool, reviewed the write up, was the contact person at Wits Reproductive Health and HIV Institute, University of the Witwatersrand, Johannesburg, South Africa.

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List of Abbreviations

ART	Antiretroviral therapy
CAB LA	Long-acting cabotegravir injectable
DPV VR	Dapivirine vaginal ring
FDA	Food and Drug Administration
FSWs	Female Sex Workers
HICs	High-income countries
HIV	Human Immunodeficiency Virus
IPM	International Partnership for Microbicides
KPs	Key populations
LMICs	Low and middle-income countries
MSM	Men who have sex with men
PrEP	Pre-exposure prophylaxis
STDs	Sexually transmitted diseases
STI	Sexually transmitted infections
TB	Tuberculosis
UNAIDS	United Nations Programme on HIV and AIDS
USA	United States of America

WHO World Health Organisation

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Supplementary Materials

Supplementary Material 1: Questionnaire

Participant questionnaire

Project title: Acceptability and accessibility of Pre-Exposure Prophylaxis modalities for HIV prevention (oral daily PrEP, dapivirine vaginal ring and long acting cabotegravir injectable) among female sex workers in Cape Town, South Africa: A cross-sectional study

Principal investigator: Rachel Mbuyamba Contact number: +27789508234

Questionnaire number			
Name of site:	**Clinic**	**Mobile unit**	
Date			

Thank you for taking the part in this survey. The questionnaire will be completely anonymous, meaning that we will not use your real name. In this first section, we will ask you some questions about your background. This information will help us to better understand your background. If you feel uncomfortable to answer any personal question, you have the option to mark "Prefer not to say".

1. **How old are you?** ……Years

2. **What is your marital status?**
   - ☐ Single, never married
   - ☐ Committed, but not living together
   - ☐ Married or living together like a married couple
   - ☐ Divorced or separated
   - ☐ Widowed
   - ☐ Prefer not to say

3. **What is the highest level of education you have completed?**
   - ☐ No school/ Unfinished primary
   - ☐ Primary school
   - ☐ High School
   - ☐ Matric
   - ☐ College/ Technical school
   - ☐ University degree
   - ☐ Prefer not to say

4. **Is sex work your primary, secondary or partial form of income?**
   - ☐ Primary
   - ☐ Secondary

- ☐ Partial
- ☐ Prefer not to say.

5. **What is your ethnicity?**
   - ☐ Black African
   - ☐ White
   - ☐ Mixed ancestry
   - ☐ Indian/Asian
   - ☐ Other; specify……

The next section includes questions about your view on health, how you perceive your risk of HIV infection, your sexual practices, and your opinion about PrEP prevention methods. These questions will help us understand why people would prefer some HIV- PrEP prevention methods over others. If you feel uncomfortable to answer any personal question, you have an option to tick "Prefer not to say".

YOUR VIEW ON HEALTH AND THE RISK OF HIV INFECTION

6. **Have you ever been treated for a sexually transmitted infection? (frequency of STI in last year)**

- ☐ Yes 1 to 5 times
- ☐ 5 to 10 times
- ☐ More than 10 times
- ☐ No
- ☐ Prefer not to say

7. **Referring to your past and present sexual practices, what do you think is your level of risk of getting infected with HIV?**

- ☐ I feel that I have NO risk
- ☐ I feel that I have LOW risk
- ☐ I feel that I have SOME risk
- ☐ I feel that I have HIGH risk
- ☐ Prefer not to say

CONTRACEPTION

8. **What contraception method(s) do you use? (Multiple answers if applicable)**

- ☐ None
- ☐ Male condom
- ☐ Female condom
- ☐ Pill
- ☐ Implant
- ☐ Injection
- ☐ Morning after pill
- ☐ Intrauterine Device (IUD)
- ☐ Sterilization
- ☐ Other, specify _____

SEXUAL BEHAVIOR: CLIENTS

9. How many sexual encounters have you had in the past 30 days?

- ☐ <5
- ☐ 5-10
- ☐ 11-15
- ☐ More than 15
- ☐ Prefer not to say

10. How often do you use condoms when having sex with clients?

- ☐ Never
- ☐ Sometimes
- ☐ Most of the times
- ☐ Always
- ☐ Prefer not to say

SEXUAL BEHAVIOR: PARTNER (IF APPLICABLE)

11. Apart from your sex work clients, do you have a personal sexual partner?

- ☐ Yes
- ☐ No
- ☐ Prefer not to say

12. If you have a personal sexual partner, does he/she know that you practice sex work?

- ☐ Yes
- ☐ No
- ☐ Prefer not to say

13. Do you know the HIV status of your personal sexual partner?

- ☐ Yes
- ☐ No
- ☐ Prefer not to say
- ☐ N/A

14. If yes, what is his/her HIV status?

- ☐ Positive
- ☐ Negative
- ☐ Prefer not to say
- ☐ N/A

15. How often do you use condoms when having sex with your personal sexual partner?

- ☐ Never
- ☐ Sometimes
- ☐ Most of the times
- ☐ Always
- ☐ Prefer not to say

☐ N/A

PREFERRED HIV PREVENTION METHOD

16.Have you heard about PrEP before today?

☐ Yes
☐ No

17.What prevention methods do you use at present in order to reduce your risk of getting infected with HIV? (Multiple answers if applicable)

☐ Male condoms
☐ Female condoms
☐ Pre-Exposure Prophylaxis (PrEP)
☐ Post Exposure Prophylaxis (PEP)
☐
☐ Reduce number of occasional partners
☐
☐ Treatment of sexually transmitted infections
☐ Not sharing syringes, razors and needles
☐ Other, please specify: ……

ACCESSIBILITY AND BARRIERS TO PrEP

. 18.Which PrEP modalities are you aware of?

☐ Oral daily PrEP (a pill)
☐ Dapivirine vaginal ring
☐ Long-acting cabotegravir injectable
☐ Other: Specify…….
☐ None

19. Do you know where to get these different types of preventive medication if you need them?

☐ Yes
☐ No

20. At your first arrival at the clinic, fwhat was your experience like?

☐ Excellent
☐ Good
☐ Fair
☐ Bad
☐ Prefer not to say

21. Do you feel that you were treated with dignity and respect at the clinic?

☐ Excellent
☐ Good
☐ Fair
☐ Bad
☐ Prefer not to say

22. Did the nurse speak to you in a language that you could understand and ask questions?

- ☐ Yes
- ☐ No
- ☐ Not sure

23. Is PrEP always available at the clinic?

- ☐ Yes
- ☐ No
- ☐ Not sure

24. Have you experienced any discrimination at the clinic?

- ☐ Yes
- ☐ No
- ☐ Not sure

25. Do you think that this information provided useful ?

- ☐ Yes
- ☐ No
- ☐ Not sure

26How did you travel from your home to the clinic of mobile van

- ☐ Walk
- ☐ Taxi
- ☐ Cycle
- ☐ Train

27 If the answer in 26 is not WALK, the how long did it take you to the clinic or mobile van?

- ☐ Less than 20 min
- ☐ 20-40 min
- ☐ 41-60 min
- ☐ More than hour

28 If the answer in 26 is not WALK, how much did it cost you to pay transport?

- ☐ Less than R30
- ☐ R31-100
- ☐ More than R 100

29. Are you comfortable with this waiting time for the services ?

- ☐ Yes
- ☐ No
- ☐ Not sure

30. List the challenges that you are facing to access PrEP

……

……

……

……

PREP ACCEPTABILITY

The next questions are focused on your opinion about PrEP, in order to understand what characteristics and circumstances are important for different people if they decide to take PrEP or not. We also want to understand what type of support would be needed if someone decided to take PrEP.

31. Please rate based on your opinion the following questions, from 1 to 4, where with 1 you do not agree at all and 4 you fully agree.

1. **No, definitely not**
2. **No, probably not**
3. **Yes, probably**
4. **Yes, definitely**

	1	2	3	4
31b. (i) Would you use PrEP if it was provided at no cost to you (free of charge)?	O	O	O	O
31b. (ii) Would you use PrEP if you had to pay for it (not free of charge)?	O	O	O	O
31c. Would you use PrEP even if you have to take it for several days/weeks before you are adequately protected?	O	O	O	O
31d. Would you take PrEP if it caused mild side-effects at the beginning (nausea, diarrhea, tiredness)?	O	O	O	O
31e. Would you take PrEP knowing that you still have to use condoms?	O	O	O	O
31f. Would you take PrEP if you have to do an HIV test regularly (every 3-6 months)?	O	O	O	O
31g. Would you take PrEP if you were in a relationship with an HIV-positive partner?	O	O	O	O
31h. Would you take PrEP if you were in a relationship with a partner whose HIV status is unknown?	O	O	O	O
31h (ii) Would you continue to use PrEP even you are not working?	O	O	O	O

The following statements list various circumstances that might influence the decision to take or not PrEP. Please answer as if the statements apply to you.

32. Please rate the following statements based on your opinion, from 1 to 4, where with 1 you do not agree at all and 4 you fully agree.

1. **No, definitely not**
2. **No, probably not**
3. **Yes, probably**
4. **Yes, definitely**

	1	2	3	4
32a. I would use PrEP because it would make me feel safer, giving me extra protection from acquiring HIV	○	○	○	○
32b. If I am to use PrEP, I would take PrEP daily to ensure it protects me from getting HIV (ensure effectiveness)	○	○	○	○
32c. I would use PrEP if people who are important to me would recommend that I use PrEP	○	○	○	○
32d. I would take PrEP if my partner encourages me to take PrEP	○	○	○	○
32e. I would use PrEP if my partner does not want to use condoms	○	○	○	○
32f. I worry about long term effects of PrEP on my body/health	○	○	○	○
32g. If I was taking PrEP I would be afraid that some people may think I have HIV	○	○	○	○
32h. If I was taking PrEP I would be afraid that some people may think my partner has HIV	○	○	○	○
32i. I think it is disrespectful for my partner if I take PrEP	○	○	○	○
32j. I think it is embarrassing if other people find out I use PrEP	○	○	○	○
32k. I would use PrEP if I would be able to pick up pills at a private place (my privacy is assured)	○	○	○	○
32l. I would use PrEP even if I have to attend a medical check-up every 3-6 months	○	○	○	○
32m. I can take a pill every day for several months without forgetting	○	○	○	○

32n. If I take PrEP,I would need support to remember taking it every day	○	○	○	○
32o. I would take PrEP daily if I receive text/SMS support	○	○	○	○
32p. I would take PrEP daily if I receive one-to-one counselling and support for not forgetting the pill	○	○	○	○
32q. I would take PrEP daily if I have access to group support from peers	○	○	○	○

To summarise, we would like to ask you again about your willingness to take PrEP

The vaginal ring is a small soft plastic ring that women can place in their vagina and releases Dapivirine. Long-acting injectable cabotegravir (CAB LA) is another of the antiretroviral drugs for PrEP in HIV-uninfected women.

33. Do you have experience of any long-acting drugs like the contraceptive injection?

- ☐ Yes
- ☐ No

34. Would you consider a long-acting HIV prevention method?

- ☐ Yes
- ☐ No

35. Why? ……..

36. Are you currently taking oral PrEP (pill)

- ☐ Yes
- ☐ No
- ☐ Prefer not to say

37. Please rate based on your opinion the following statements, from 1 to 4, where with 1 you do not agree at all and 4 you fully agree.

1. **No, definitely not**
2. **No, probably not**
3. **Yes, probably**
4. **Yes, definitely**

	1	**2**	**3**	**4**
37a. If the Dapivirine vaginal ring becomes available, do you think you would use it over the pill?	○	○	○	○

37b. If the long-acting cabotegravir injectable becomes available, do you think you would use it over the pill?	O	O	O	O
37c. Would you be willing to take PrEP in general?	O	O	O	O
37d. Would you be willing to use PrEP if Wits RHI offers it to you at no cost in that place as part of a study?	O	O	O	O

38. If your response to 36a is 1 or 2, what may keep you from using the dapivirine vaginal ring?

……

39. If your response to 36c is 1 or 2, what may deter you from using the long-acting cabotegravir injectable?

……

Supplementary Material 2: Ethical Approval

UNIVERSITEIT STELLENBOSCH UNIVERSITY

Approval Notice

New Application

19/10/2021

Project ID :16751

HREC Reference No: S21/07/132

Project Title: HIV-PrEP Female Sex workers Wits protocol

Dear Miss RT Mbuyamba

The **Response to Modifications** received on 11/10/2021 08:43 was reviewed by members of **Health Research Ethics Committee** via **expedited** review procedures on 19/10/2021 and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Date: 19 October 2021

Protocol Expiry Date: 18 October 2022

Please remember to use your Project ID 16751 and Ethics Reference Number S21/07/132 on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review

Translation of the informed consent document(s) to the language(s) applicable to your study participants should now be submitted to the HREC.

Please note you can submit your progress report through the online ethics application process, available at: Links Application Form Direct Link and the application should be submitted to the HREC before the year has expired. Please see *Forms and Instructions* on our HREC website (www.sun.ac.za/healthresearchethics) for guidance on how to submit a progress report.

The HREC will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Please note that for studies involving the use of questionnaires, the final copy should be uploaded on Infonetica.

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility, permission must still be obtained from the relevant authorities (Western Cape Departement of Health and/or City Health) to conduct the research as stated in the protocol. Please consult the Western Cape Government website for access to the online Health Research Approval Process, see: https://www.westerncape.gov.za/general-publication/health-research-approval-process. Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and instructions, please visit: Forms and Instructions on our HREC website https://applyethics.sun.ac.za/ProjectView/Index/16751

If you have any questions or need further assistance, please contact the HREC office at 021 938 9677.

Yours sincerely,

Miss EL Rohland
Health Research Ethics Committee 1 (HREC 1)

National Health Research Ethics Council (NHREC) Registration Number:

REC-130408-012 (HREC1)▪REC-230208-010 (HREC2)

Page 1 of 2

Federal Wide Assurance Number: 00001372
Office of Human Research Protections (OHRP) Institutional Review Board (IRB) Number:
IRB0005240 (HREC1)▪IRB0005239 (HREC2)

The Health Research Ethics Committee (HREC) complies with the SA National Health Act No. 61 of 2003 as it pertains to health research. The HREC abides by the ethical norms and principles for research, established by theWorld Medical Association (2013). Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects;the South African Department of Health (2006). Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (2nd edition); as well as the Department of Health (2015). Ethics in Health Research: Principles, Processes andStructures (2nd edition).

The Health Research Ethics Committee reviews research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research (United States Code of Federal Regulations Title 45 Part 46); and/or clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services.

Supplementary Material 3a: Access authorisation, WHI

July 07, 2021

To whom it may concern,

RE: Acceptability and Accessibility of Pre-Exposure Prophylaxis modalities for HIV Prevention (Dapivirine Vaginal Ring, Long Acting Cabotegravir Injectable and Oral PrEP) among Female Sex Workers in Cape Town, South Africa: A Cross-Sectional Study

This letter serves to confirm that University of Witwatersrand Reproductive Health and HIV Institute (Wits RHI) will facilitate access to the potential study participants for the above-mentioned study through our Key Populations Programme site in Salt River, Cape Town.

Final ethics approval from the University of Stellenbosch and permission from the Western Cape Government Department of Health is required prior to initiation of any study activities.

Yours Sincerely,

NAOMI HILL
Programme Head and Chief of Party, Wits RHI Key Populations Programme

University of the Witwatersrand
WITS RHI

Tel +27 11 358 5300 | Hillbrow Health Precinct, 22 Esselen Street, Hillbrow, 2001, Johannesburg, South Africa | www.wrhi.ac.za

Wits RHI is an Institute of the University of the Witwatersrand and a WHO Collaborating Centre

Supplementary Material 3b: Access authorisation, City of Cape Town

CITY OF CAPE TOWN
ISIXEKO SASEKAPA
STAD KAAPSTAD

CITY HEALTH

Dr Natacha Berkowitz
Epidemiologist: City Health

T: 021 400 6864 F: 021 421 4894
E: Natacha.Berkowitz@capetown.gov.za

Ref: 9802 2022-06-29

RE:
Acceptability and accessibility of pre-exposure prophylaxis modalities for HIV prevention (dapivirine vaginal ring, long-acting cabotegravir injectable and oral daily PrEP) among female sex workers in Cape Town, South Africa: A cross-sectional study

Dear Dr Rachel Mbuyamba

Your research request has been approved as per your protocol. However, we note that this application was sent post collection of data. Please ensure that the stipulations below are adhered to.

Please refer to the subsequent pages for the approval of any facilities or focus areas requested. Approval comments on any proposed impact on City Health resources are also provided.

Northern & Western:

Contact Person: Dr Andile Zimba (Area North Manager)

Tel/Cell: 021 980 1230/084 627 2425

Email: Andile.Zimba@capetown.gov.za

Please note the following:

1. All individual patient information obtained must be kept confidential.
2. Access to the clinic and its patients must be arranged with the relevant Manager such that normal activities are not disrupted.
3. A copy of the final report must be uploaded to https://web1.capetown.gov.za/web1/mars/ProjectClosure/UploadReport/0/9802, within 6 months of its completion and feedback must also be given to the clinics involved.
4. Your project has been given an ID Number (9802). Please use this in any future correspondence with us.
5. No monetary incentives to be paid to clients on the City Health premises
6. If this research gives rise to a publication , please submit a draft before publication for City Health comment and include a disclaimer in the publication that "the research findings and recommendations do not represent an official view of the City of Cape Town "
7. As the research is approved as per submitted protocol, any changes to the protocol need to be submitted and approved by City Health prior to implementation.
8. We are currently not approving research for joint authority facilities (Dirkie Uys, Durbanville, Heideveld, Kasselsvlei, Nolungile, Nyanga, Parow, Ravensmead, Scottsdene) as they are in the process of being consolidated into one authority.

Thank you for your co-operation and please contact me if you require any further information or assistance.

Kind Regards
Dr Natacha Berkowitz Epidemiologist: City Health