Exploring Feasibility and Acceptability of HIV Pre-Exposure Prophylaxis for Female Sex Workers, Men Who Have Sex with Men, Male Sex Workers, and Transgender Women in a Selected District of Nepal

STUDY REPORT

Study Approvals:
Nepal Health Research Council (NHRC): 238/2018
Protection of Human Subject Committee (PHSC), FHI 360: 1178158
Department of Drug Administration (DDA) Nepal, August 2018

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LINKAGES
Across the Continuum of HIV Services for Key Populations

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Contents

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Abbreviations

AHF	AIDS Healthcare Foundation
AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral
CBO	Community-based organization
CBS	Community-based supporter
DDA	Department of Drug Administration
FDA	Food and Drug Administration
FSGMN	Federation of Sexual and Gender Minorities in Nepal
FSW	Female sex workers
HA	Health assistant
HBsAg	Hepatitis B surface antigen
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HTC	HIV testing and counseling
IA	Implementing agency
IBBS	Integrated Behavioral and Biological Surveillance
ID	Identity document
JMMS	Jagriti Mahila Maha Sangh
KP	Key population
LINKAGES	Linkages across the Continuum of HIV Services for Key Populations Affected by HIV
MSM	Men who have sex with men
MSW	Male sex worker
NCASC	National Centre for AIDS and STD Control
NCS	Nari Chetana Samaj
NGO	Nongovernmental organization
NHRC	Nepal Health Research Council
NPHL	National Public Health Laboratory
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PHSC	Protection of Human Subjects Committee
PI	Principal investigator
PLHIV	People living with HIV
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
RPR	Rapid plasma reagin
SACTS	STD/AIDS Counseling and Training Service
SPARSHA	Society for Positive Atmosphere and Related Support to HIV and AIDS
SPSS	Statistical Package for Social Sciences
SSI	Semi-structured interview
STI	Sexually transmitted infection
Trans	Transgender
UIC	Unique identifier code
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

Study Summary

Title: Exploring the feasibility and acceptability of HIV pre-exposure prophylaxis for female sex workers, men who have sex with men, male sex workers, and transgender women in a selected district of Nepal

Study Duration: November 2018–June 2019. Study participants were followed for three months (90 days) after initiation of pre-exposure prophylaxis (PrEP).

Study Approvals:

Nepal Health Research Council (NHRC): 238/2018

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Design: This was a clinical study with a prospective cohort design. The study used a mixed-methods approach, incorporating quantitative clinical data collection with study participants, and qualitative interviews with study participants, service providers, and government officials. Quantitative data were collected by using data collection forms developed for the HIV pre-exposure prophylaxis (PrEP) demonstration study during initial and follow-up visits at the LINKAGES Nepal community clinic. Qualitative data were collected through semi-structured interviews (SSIs) with key population (KP) study participants, health care providers, and government officials.

Sample Size and Populations: The sample was comprised of a total of 104 individuals consisting of 26 female sex workers (FSWs), 26 men who have sex with men (MSM), 25 male sex workers (MSWs), and 27 transgender (trans) women 18 years of age or older who had been diagnosed HIV negative in the LINKAGES Nepal community clinic and found eligible as per the HIV risk profile, clinical characteristics, and other inclusion criteria.

Objectives:

1. To assess the feasibility of PrEP implementation among FSWs, MSM, MSWs, and trans women in Nepal
2. To assess the acceptability of PrEP among FSWs, MSM, MSWs, and trans women in Nepal
3. To identify programmatic and individual-level determinants of PrEP uptake, adherence, and retention
4. To monitor sexual risk behaviors, side effects, and toxicities (tolerability) of the ARV drugs used for PrEP
5. To monitor clinical outcomes, including the rates of sexually transmitted infections (STIs), seroconversions, and pregnancy

Study Sites: Lalitpur district of Nepal, where LINKAGES Nepal works with FSWs, MSM, MSWs, and trans women to provide HIV prevention, care, support, and treatment services

Study Management: The study was implemented by LINKAGES Nepal, STD/AIDS Counseling and Training Center (SACTS), Parichaya Samaj, and Nari Chetna Samaj, in collaboration with the National Center for AIDS and STD Control (NCASC) and the National Public Health Laboratory (NPHL), Ministry of Health and Population (MOHP), with funding from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development (USAID).

Major Findings:

1. The majority of the participants (93 percent) accepted PrEP, ranging from 100 percent among FSWs and trans women to 86 percent in MSWs. None of the participants who initiated and completed PrEP for 90 days seroconverted during follow-up or at the end of the 90-day period. Qualitative findings also support acceptance of PrEP among key population (KP) members, service providers, and policymakers. The majority of participants who completed the three-month course of PrEP and some of the participants who discontinued considered PrEP to be trustworthy, and they expressed interest in using PrEP in the future. The majority said that the program should be expanded to other places and areas of the country.
2. PrEP was provided using existing service structures with minimal training and supervision. The existing staff were found capable of providing high-quality services using the current government supply system, and the majority of the clients completed retention for 90 days without any extra expenditure. Based on the qualitative findings of beneficiaries, service providers, and policymakers, PrEP provision is feasible as part of the existing HIV program for KPs in Nepal.
3. Of the total 104 KP members initiated on PrEP, 64 percent continued PrEP for a total of 90 days. These were the participants who visited the clinic every month for three months, collected their supply at the end of the first and second months, and participated in all laboratory investigations conducted at the end of each of the three months. Continuation was 27 percent among FSWs, 77 percent for MSM, 88 percent for MSWs, and 67 percent for trans women. Retention on PrEP among FSWs was comparatively low; some of the reasons for discontinuation identified during the qualitative interviews were side effects, mobility of sex workers, and fear of disclosure.
4. The majority of the participants experienced some side effects—the most common being headache, dizziness, nausea, vomiting, pain in the abdomen, diarrhea, and lethargy—which were the reasons for discontinuation. Some participants found the size of the pill too large to swallow or the smell of the medicine unpleasant, or they did not like the color.
5. The most common reason given by the participants for not disclosing their PrEP use was stigma related to HIV and sexual orientation.
6. There was not much change in condom use among the participants prior to and after completing the 90-day course of PrEP. However, condom use among MSM participants was comparatively low in comparison to other KP participants. There was no increase in reactive

syphilis results. There was no increase in serum creatinine level compared to baseline. None of the FSWs completing the 90 days of PrEP had a positive pregnancy result, indicating that PrEP was used as additional method of prevention.

Recommendations:

1. **Coordinate with NCASC and NPHL to roll out PrEP across the country among KP members at substantial risk of HIV**, given that PrEP is already an accepted method of HIV prevention recommended by the World Health Organization (WHO), as well as this study's finding that PrEP is acceptable among KPs in Nepal. PrEP also presents an opportunity to promote HIV testing, access to sexually transmitted infection (STI) diagnosis, and HIV and STI treatment services.
2. **Integrate PrEP into the existing HIV program for KPs, which includes HIV testing, STI services and treatment, and care and support services** for KPs and people at high risk of HIV infection. PrEP is also worth considering for all people at substantial risk of HIV, including HIV-negative partners of HIV-positive clients.
3. As continuation of PrEP was found to be low among FSWs, **counseling with FSWs who will be initiating PrEP should include an especial focus on adherence to and continuation of PrEP**. Counseling should address the possible side effects and coping approaches. A special counseling package including components of motivational interviewing to address barriers should be prepared and implemented during rollout.
4. **Develop informational materials highlighting PrEP, its importance, side effects with coping strategies, implementation modalities, and availability**. Share these informational materials with people at substantial risk of HIV using the means of communication that would reach the largest number of people.
5. **Use an individual or one-on-one educational approach for informing clients about side effects**, their duration, what should be done at home to cope with side effects, and how PrEP can be continued while managing these side effects. This should form an integral part of client education during follow-up visits. Pills with a pleasing color and taste and packaged attractively could increase continuation.
6. **Counseling on PrEP disclosure should form part of any future rollout**. Along with disclosure counseling, sensitization on HIV and sexual orientation should be provided by service providers and within the community.
7. Given that PrEP is an additional method of HIV prevention to be used along with condoms, **PrEP counseling with KPs should focus on the importance of using condoms in tandem with PrEP.** In fact, stressing the importance of condoms during PrEP use should be a standard part of the counseling package for all KPs and include a focus on the benefits for family planning and STI prevention.

1. Introduction

The Linkages across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES) Nepal project focuses on the introduction of innovative approaches and technologies to improve and expand access to HIV prevention and treatment services. Among these approaches, pre-exposure prophylaxis (PrEP) for HIV is a complementary intervention in combination prevention to reach those who are not using the traditional methods of HIV prevention, including condoms and behavior change approaches.

HIV continues to disproportionately affect vulnerable or key populations (KPs), such as men who have sex with men (MSM), male sex workers (MSWs), people who inject drugs (PWID), female sex workers (FSWs), transgender (trans) people, and adolescent girls and young women more broadly (UNAIDS, 2016). UNAIDS estimates that 40 percent to 50 percent of all new HIV infections among adults worldwide occur among these KPs and their sex partners (amfAR, 2016). In 2016, young women ages 15–24 accounted for 20 percent of new infections globally and 25 percent in sub-Saharan Africa (UNAIDS, 2016).

Nepal continues to face a concentrated HIV epidemic, and HIV transmission is largely driven by selected KPs, which includes FSWs, clients of FSWs, MSM, MSWs, trans people, and PWID (NCASC, 2019). The 2018 national HIV infection survey estimates that approximately 29,944 people (including 1,296 children) in Nepal are infected with HIV, with an estimated overall adult HIV prevalence of 0.14 percent. The estimates also show that 25 percent of total infections are distributed among KPs—PWID (3 percent), MSM and trans people (9 percent), clients of sex workers (9 percent), MSWs (2 percent), and FSWs (2 percent) (NCASC, 2019). The Integrated Biological and Behavioral Surveillance (IBBS) surveys indicate that HIV prevalence among KPs has mostly either stabilized or decreased in some groups. The HIV epidemic in Nepal is largely driven by infections among KPs, and heterosexual transmission is dominant (around 85 percent) (NCASC, 2019). According to the national KP size estimation 2016, the population size of FSWs was 49,000, 60,300 MSM, 18,300 MSWs, and 21,500 trans people. As per the recent IBBS surveys, HIV prevalence among FSWs was 2.2 in percent in Kathmandu valley in 2017 and 0.7 percent in Terai highway districts in 2018. Similarly, HIV prevalence in 2017 among MSM, MSWs, and trans people in Kathmandu valley and Pokhara was 6.2 percent and 2.2 percent, respectively, and 8.2 percent in Terai highway districts in 2018. The HIV prevalence among truckers (proxy for clients of FSWs) was 0.3 percent in 2016 (NCASC, 2016).

1.1 LINKAGES Nepal and Pre-Exposure Prophylaxis Demonstration Study

LINKAGES Nepal (October 2016–September, 2020) is part of the global LINKAGES project funded by the U.S. Agency for International Development (USAID) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and implemented by FHI 360 in partnership with Pact, Intra-Health International, and the University of North Carolina at Chapel Hill. The project aims to accelerate the ability of governments, KP organizations, and private sector providers to use evidence-based approaches to plan and implement comprehensive and sustainable services that reduce HIV transmission among KPs and extend the lives of those living with HIV.

LINKAGES Nepal is building upon its learning and experiences from more than two decades of work conducted with the support of USAID. The project is designed to support global goals in controlling the epidemic and achieving an AIDS-free generation, while aligning with the Government of Nepal's priorities, the National HIV Strategic Plan 2016–2021, and USAID Nepal's Country Development Cooperation Strategy. Furthermore, it aims to build the human capital of a healthier and well-nourished population. LINKAGES Nepal provides the continuum of HIV prevention, care, and treatment services among FSWs, clients of FSWs, and people living with HIV (PLHIV) in 19 project districts, and MSM, MSWs, and trans people in five project districts of Nepal. In the context of Nepal, the trans people reached by LINKAGES to date are trans women. The project works in close collaboration with the Government of Nepal, local nongovernmental organization (NGO) partners, and national networks of KPs and PLHIV and their community-based organizations (CBOs).

LINKAGES Nepal has introduced innovative ideas, approaches, and technologies to improve and expand access to HIV prevention, testing, and treatment services. PrEP is an additional potential option and complementary approach to prevent HIV transmission among KP members at higher risk of HIV infection, particularly FSWs, MSM, MSWs , and trans women. PrEP entails the use of an antiretroviral (ARV) medication to prevent the acquisition of HIV infection when taken by uninfected individuals. PrEP may either be taken orally, using an ARV also taken as treatment of HIV infection (tenofovir plus emtricitabine) among those living with HIV, or topically as a vaginal gel containing tenofovir. Oral PrEP is highly effective in preventing HIV acquisition. Where PrEP has been implemented alongside HIV testing and antiretroviral therapy (ART) services, population-level reductions in HIV incidence among MSM have been reported in high-income settings, including the United States, Australia, and the United Kingdom. However, similar trends are not yet observed in lower- and middle-income countries (LMICs) (WHO, 2019).

1.2 Rationale for the Study

Over the past seven years, the field of HIV prevention and treatment has made great strides in producing evidence to support new interventions based on the provision of ARVs to HIV-negative individuals and people living with HIV. A recent systematic review of all oral PrEP efficacy data showed that PrEP can be almost as effective as correct and consistent condom use (Fonner et al, 2016). Following the positive results of most of the recent PrEP safety and efficacy studies, a number of national regulatory bodies, starting with the U.S. Food and Drug Administration (FDA), approved the combination ARV pill tenofovir plus emtricitabine (Truvada®) for use as oral PrEP (FDA, 2012).

These approvals have been supported with a series of guidance and recommendation documents from the World Health Organization (WHO), the most recent of which has recommended PrEP for any individual at "substantial risk" of HIV (WHO, 2016). The original definition of substantial risk, which was based on a modeling study suggesting that individuals from any geographical area with 3 percent or greater incidence would benefit from PrEP, has since been augmented to take a more nuanced, individualized approach whereby providers and individuals can determine whether risk is substantial on a case-by-case basis. In 2019, WHO recommended event-driven PrEP for MSM (WHO, 2019).

While oral PrEP does confer significant protection for those with high adherence, questions regarding who will use it, how, when, and why, and whether a given health system can effectively deliver PrEP as a prevention intervention, remain at the forefront of in-country policy-making agendas. Requirements for PrEP implementation include an uninterrupted supply of PrEP drugs to health facilities, PrEP prescription accompanied by education on its use, community follow-up of PrEP users to encourage maintaining adherence to PrEP, and supervision and monitoring of PrEP implementation through recording and reporting.

To date, several demonstration projects have been completed and/or are ongoing with a variety of KPs. Thailand is a leader in PrEP implementation in the Asia Pacific region, featuring a variety of demonstration and research projects (Phanuphak, 2017). Similarly, demonstration projects are ongoing in Vietnam (Green, 2017), Australia (Grulich, 2017), and the Philippines (Project PrEPPY, 2017). Cambodia and Indonesia have also planned PrEP demonstrations. That being said, we are still far behind in the achievement of providing PrEP to 3 million individuals at high risk of infection by 2020 (UNAIDS, 2016). As per PrEP Watch and the Global PrEP tracker, 75 countries are listed as having conducted activities related to PrEP (AVAC, 2019).

According to a recent IBBS survey in Kathmandu, consistent condom use among FSWs with their most recent client is 85 percent, and 62 percent with regular non-paying sex partners (NCASC, IBBS, 2017). Nearly three-quarters of MSM and trans people reported always using condoms during anal sex with non-paying male sex partners in the previous month (NCASC, IBBS, 2017). According to the most recent data received from NCASC in Nepal, nearly 45 percent of individuals living with HIV do not know their HIV status, and only 72 percent of identified PLHIV are enrolled in ART (NCASC, 2017). Considering this context of HIV prevention and treatment, additional approaches besides condoms and ART—such as PrEP—are needed.

Since PrEP is not currently being prescribed in Nepal, LINKAGES Nepal conducted a demonstration study to assess the feasibility and acceptability of PrEP use in the country. PrEP is included in the *National HIV Testing and Treatment Guidelines 2017*, but it has not yet been implemented, as the acceptability of PrEP among KP members and the feasibility of implementation are not yet known. The findings of this study are expected to inform government decision making on the inclusion of PrEP as an additional method of HIV prevention in Nepal.

1.3 LINKAGES Programmatic Activities and Key Partners of Demonstration Study

LINKAGES Nepal works alongside local nongovernmental organizations (NGOs), KP-led CBOs, and national networks of KPs and PLHIV to provide HIV prevention education and referrals in the community, HIV testing and counseling (HTC) services, and sexually transmitted infection (STI) treatment services as part of standard care. LINKAGES Nepal refers and links KP members found living with HIV to government-run service sites for antiretroviral therapy (ART).

For this study, LINKAGES Nepal collaborated with the Nari Chetana Samaj (NCS) prevention services for FSWs and clients of FSWS, and the Parichaya Samaj (PS) prevention services for MSM, MSWs, and trans women. These organizations work in the area of demand generation for PrEP among KPs in the community by informing them of the availability of PrEP in Lagankhel clinic and referring KP individuals for HIV testing and STI services. Trained community-based supporters are mobilized to generate demand for HTC and STI services, HIV prevention

education, condom and lubricant promotion and distribution, and support of PLHIV for ART adherence and retention. They also follow up with KPs regarding their adherence and retention practices.

LINKAGES Nepal partners STD/AIDS Counseling and Training Services (SACTS) is a standard service provider for HTC, STI check-ups, HIV case management and referral, gender-based violence (GBV) screening and referral, and condom and lubricant promotion and distribution to KP individuals referred from the community, as well as those who attend the clinic on their own. Trained health assistants (HAs) provide these services in the clinic.

National Centre for AIDS and STD Control (NCASC) is the overall national coordinating body for HIV and STI-related programming and services in the country and is responsible for the development of the national strategy, program implementation guidelines, training curricula, and other documents necessary for implementing HIV-related activities in the country. It is also the body responsible for managing logistical supplies of HIV and STI test kits reagents, ARVs, and drugs for treating STIs. NCASC must authorize the implementation of all HIV-related activities introduced in the country. NCASC was one of the key stakeholders whose support was instrumental in getting ethical approval for the study from Nepal Health Research Council (NHRC), approval for the use of generic combined tenofovir and emtricitabine for PrEP from the Department of Drug Administration (DDA) of the Ministry of Health and Population (MOHP), supplying the generic fixed-dose combination tenofovir and emtricitabine, and monitoring the study closely.

The National Public Health Laboratory (NPHL) is the overall national coordinating body for laboratory-related services in the country. It is responsible for the development of policies, national guidelines, and training curricula, and other documents necessary for the implementation of HIV laboratory services in the country. NPHL is also the national reference laboratory in the country to conduct medical laboratory investigations. During the study, NPHL conducted baseline and follow-up investigations (serum creatinine, hepatitis B antibody, hepatitis C antigen, and pregnancy tests) for PrEP participants. NPHL also monitored the study and provided technical support for the laboratory.

The Federation of Sexual and Gender Minorities Nepal (FSGMN) is an umbrella organization working for lesbian, gay, bisexual, transgender, and intersex people in Nepal. As a partner of LINKAGES Nepal, FSGMN in this study supported Parichaya Samaj for demand generation of PrEP among MSM, MSWs, and trans women in Lalitpur.

Jagriti Mahila Maha Sangh (JMMS) is an organization working for sex workers in Nepal. The organization mobilizes its CBOs to support LINKAGES Nepal implementing agencies for HIV prevention, care, and support services among FSWs in the districts. For this demonstration study, JMMS supported NCS for demand generation of PrEP among FSWs in Lalitpur.

1.4 Study Goal and Objectives

The goal of this PrEP demonstration study was to measure the feasibility, acceptability, and uptake of PrEP among those who were eligible and offered PrEP.

The objectives were:

1. To assess the feasibility of PrEP implementation among FSWs, MSM, MSWs, and trans women in Nepal
2. To assess the acceptability of PrEP among FSWs, MSM, MSWs, and trans women in Nepal
3. To identify programmatic and individual-level determinants of PrEP uptake, adherence, and retention
4. To monitor sexual risk behaviors, side effects, and toxicities (tolerability) of the ARV drugs used for PrEP
5. To monitor clinical outcomes, including the rates of STIs, seroconversions, and pregnancy.

2. Methodology

2.1 Study Design

This was a mixed-methods descriptive study with a prospective cohort design. Clinical quantitative data were collected from the study's PrEP participants, and qualitative semi-structured interviews (SSIs) were conducted with PrEP participants, service providers, and government officials.

Details of the methods and analysis used to address each objective are listed in Table 1.

Table 1. Objectives, data collection methods, analysis, and data sources

Objectives	Data Collection Methods	Analysis	Data Sources
To assess the feasibility of PrEP implementation among FSWs, MSM, MSWs, and trans women in Nepal	• SSIs with PrEP participants • SSIs with providers	• Thematic analysis of transcripts from SSIs	• SSI question guides
To assess the acceptability of PrEP among FSWs, MSM, MSWs, and trans women in Nepal	• Clinical records related to uptake • SSIs with PrEP participants	• Analysis of clinical records • Thematic analysis of SSI transcripts	• SSI question guide • PrEP eligibility screening form, participant initial and follow-up forms
To identify programmatic and individual-level determinants of PrEP uptake, adherence, and retention	• Clinical data on delivery of PrEP in clinic settings based on PrEP participant forms	• PrEP participant records	• PrEP participant initial and follow-up records
To monitor sexual risk behaviors, and side effects and toxicities (tolerability) of the ARV drugs used for PrEP	• Clinical data from PrEP participant follow-up forms	• Review of client follow-up forms • Analysis of adverse event forms	• PrEP participant initial and follow-up record forms • Adverse event report form

Objectives	Data Collection Methods	Analysis	Data Sources
To monitor clinical outcomes, including the rates of STIs, seroconversions, and pregnancy	• Clinical data from PrEP participant clinic forms	• Review of PrEP participant initial and follow-up forms	• PrEP participant initial and follow-up record form

2.2 Study Setting

This demonstration study assessed the feasibility and acceptability of oral PrEP as an additional HIV prevention method in Nepal at a single operational city clinic run by LINKAGES Nepal. The clinic was a static/fixed, standalone, NGO-run entity in the urban setting of Lalitpur district that provided HTC, STI case management, and referral for HIV treatment services for FSWs, client of FSWs, MSM, MSWs, and trans women.

Within the Lalitpur district, LINKAGES Nepal also operated mobile clinics at strategic locations to provide HTC services to FSWs and clients of FSWs, MSM, MSWs, and trans women. Community-based supporters (CBS) of implementing agencies working on prevention in the district conducted outreach education sessions for HIV prevention and referrals among FSWs, clients of FSWs, MSM, MSWs, and trans women.

As part of this demonstration study, the CBS conducted demand generation for PrEP during their regular outreach education sessions by informing the KP members of the availability of PrEP at the city clinic in Lagankhel. They also briefed them on eligibility and asked FSWs, MSM, MSWs, and trans women 18 years of age or older to visit the clinic if they were interested in taking PrEP. They followed up and provided support for adherence and retention to the study's PrEP participants. However, they did not perform eligibility assessments for PrEP during outreach.

2.3 Study Populations

2.3.1 Quantitative

The target populations were FSWs, MSM, MSWs, and trans women living in Lalitpur district who met the following eligibility criteria:

1. Self-identified as an FSW, man who has sex with men, MSW, or trans woman. Sex worker (male and female) was defined as a man or woman who exchanged sex for money, valuables, drugs, or favors.
2. Resident of Lalitpur district within catchment area who could be reached and followed up by community outreach in Lalitpur district
3. 18 years of age or older
4. Willing and expressing commitment to adhere daily to oral PrEP, and to be available for three months of the PrEP course

5. Understood the purpose of the demonstration study and was willing to provide written consent to participate in the study, including participation in clinical tests and specimen collection
6. Willing to provide consent to give access to test results (HIV, rapid plasma reagin [RPR], serum creatinine, hepatitis B, hepatitis C, and pregnancy)
7. Willing and able to come to the project clinic as scheduled and to take part in all project procedures
8. Known anti-HIV, HBsAg, anti-HCV negative
9. At high risk for HIV infection, defined as having had one or more of the following during the previous six months:
    a. Sexual partner with HIV who was not virally suppressed or had no evidence of viral suppression
    b. Condom-less anal or vaginal or neo-vaginal intercourse with a partner who was HIV positive or of unknown HIV serostatus
    c. One or more STIs (e.g., urethral discharge syndrome, anorectal syndrome, genital ulcer disease syndrome, or RPR reactive)
    d. Exchanged (received or gave) sex for money, valuables, drugs, or favors
    e. Used drugs for sexual pleasure (including erectile dysfunction drugs)

2.3.2 Qualitative

A proportion of the FSWs, MSM, MSWs, and trans women who received PrEP were offered and invited to participate in an SSI (see Section 2.5 Sample Size for numbers of participants). These SSI participants included those who had completed the 90-day course of PrEP and those who had stopped PrEP at any point during the study period.

Anyone who initiated PrEP and discontinued by not picking up their pills at the next pill pick-up date or who did not report for final testing was considered a PrEP **discontinuer**.

Anyone who reported to the community clinic for monthly pill pick-up and also participated in final laboratory testing was considered as having **completed** PrEP.

Additionally, service providers and clinical staff (project coordinator, HAs, laboratory assistant) at the study site, CBS, and government staff involved in monitoring were also invited to participate in SSIs.

2.4 Recruitment of Participants

2.4.1 Quantitative

Individuals who screened eligible to enroll in the PrEP demonstration study were invited to enroll and asked to sign a consent form prior to their inclusion in the study.

Recruitment was conducted from three groups of individuals accessing HTC services in Lalitpur district:

- KP members referred from the community by CBS for HTC in the SACTS clinic who tested HIV negative were invited to participate in eligibility screening for the PrEP demonstration study.
- KP members testing HIV negative in mobile HTC clinics in Lalitpur district who were identified as interested in PrEP were referred to SACTS clinic and invited to participate in eligibility screening for the PrEP demonstration study.
- KP members directly accessing HTC services in SACTS clinic Lagankhel who were diagnosed HIV negative and were interested in PrEP were invited to participate in eligibility screening for the PrEP demonstration study.

According to the standard services provided to KP individuals, upon entering the clinic—whether static or mobile—the registration clerk entered the client in the general register, provided a unique identifier code (UIC), and prepared a file for HTC and STI case management services.

The client then received counseling for the HIV testing and STI examination and management. During the post-test counseling, the HA informed the client about PrEP and offered it to clients with negative HIV test results.

If the client was interested in participating in the study, the HA explained the procedures, the lab tests to be performed, the duration and nature of the demonstration study, and the possibility of continuation after the demonstration study concluded. The HA also asked for written consent for eligibility screening. If the client provided consent, the HA conducted eligibility screening and referred sample collection of laboratory tests. Samples were then collected for serum creatinine, hepatitis B and C, syphilis screening, and pregnancy (females only) at the same clinic where eligibility screening was conducted. Those samples were transferred to the NPHL for testing, and the results were received the next day. However, the participants were asked to return in two days for results. Those found eligible and who provided their consent were invited to enroll in the PrEP demonstration study.

During enrollment, participants were assigned a study identification number, which was linked to their current UIC used for programmatic work. A separate PrEP register was maintained at the clinic recording the name of the participant, their UIC, contact address, telephone number, and any social media handles such as on Viber, Messenger, and imo. This register was kept with the HA. The HA sought participants' permission for follow-up using the contact number they specified and/or by CBS in the community. Participants were then introduced to the CBS assigned to them.

PrEP participants were to be recruited within 90 days or until the number of participants enrolled reached 100—whichever occurred first. The maximum course of PrEP for each participant was 90 days in this demonstration study.

LINKAGES Nepal did not deny services to any FSWs, MSM, MSWs, or trans women who declined to enroll in the study or were deemed ineligible during screening. Instead, they were provided with routine services depending on the service delivery point's capacity and the beneficiary's needs. Although PrEP was not available to non-study PrEP participants, all other existing non-research or standard services were available.

Follow-up and Measures to Minimize Loss to Follow-up

Follow-up for adherence to PrEP was part of the demonstration study. To ensure the study participants continued PrEP and were retained in the study, the following measures were taken:

1. With the participant's permission, the HA collected the study participant's telephone number and/or social media contact, including Viber/Messenger/imo, during registration. The HA also sought permission for the CBS to follow up through calls or visits, if calls were not received.
2. The HA verified that the telephone number was active by dialing the number on site prior to providing the PrEP drug.
3. The HA also provided contact information to the study participant in the event that the participant should have any questions. The contact information provided was the official number of Lagankhel clinic, and clients were informed that the number was answered during work hours.
4. Participants were contacted by the method of their choice to remind them of their scheduled appointments to pick up their pills. This could include SMS, telephone, or use of Viber/Messenger/imo at two weeks, one week, and one day before their scheduled appointment at the clinic.
5. If the participant did not present on the regular pill pick-up date, the HA called the participant daily for two days with a reminder to pick up the pills. If participants did not present within two days of receiving the call or could not be contacted by phone or Viber/Messenger/imo within the following two days, the HA requested that the CBS assigned to the study participant make a field visit and remind participants of the need to pick up their pills.
6. Upon the HA's request, the CBS followed up with the study participants daily through one-on-one interaction for three consecutive days, during which time the participant's privacy was accorded the utmost priority. To ensure privacy, the CBS met study participants at a place and time convenient for them.
7. Given the relatively short project duration and follow-up time, loss to follow-up was defined as participants missing one study visit within seven days of the scheduled visit after the follow-up from the HA and CBS. With participants' prior permission, reasonable efforts were made to contact participants by phone or Viber/Messenger/imo to learn reasons for missed visits. Any participant who was recorded as lost to follow-up

was not re-enrolled in the study. If participants were contacted and decided not to return, they were asked if they were willing to participate in a brief exit interview to understand the reasons for dropout and to ensure that there were no safety concerns.

2.4.2 Qualitative

PrEP participants for the SSIs were recruited from the pool of PrEP participants from the clinical component. HAs contacted participants via phone or Viber/Messenger/imo and asked them to participate after ensuring they met the age requirements and were members of KPs (FSWs, MSM, MSWs, and trans women). They included those who completed the 90-day PrEP course and those who discontinued during the study (see Section 2.3.2). The selected participants who did not answer the phone were met in person by the CBS at the place where they had previously been regularly contacted for outreach education.

A maximum of 48 participants providing consent were included in the SSIs (24 who had completed the 90-day course of PrEP and all discontinuers up to a maximum of six from each KP group who had discontinued PrEP, regardless of the reason). All service providers (project coordinator, HA, five CBS) and government officials (two from NPHL, two from NCASC) who were interested in participating in the SSIs were interviewed.

2.5 Sample Size

2.5.1 Quantitative

This study recruited 104 participants (26 FSWs, 26 MSM, 25 MSWs, and 27 trans women) to receive PrEP drugs in the demonstration study. The sample size was based on logistical limitations and the availability of the PrEP drug from the national supply.

2.5.2 Qualitative

The sample size for qualitative SSIs was determined based on the recommendation for at least six individuals in one subgroup (Morse, 1994). However, we were unable to reach this minimum number in some subgroups, particularly among those who had discontinued PrEP. A total of 39 KP individuals were interviewed, of whom 23 had completed the PrEP course and the remaining 16 had discontinued PrEP (Table 2).

Table 2. Number of SSI participants

Groups	Number of SSI Participants		
	Completed PrEP Course	Discontinued PrEP	Total
FSWs	5	4	**9**
MSM	6	4	**10**
MSWs	6	2	**8**
Trans women	6	6	**12**
Total KP participants	**23**	**16**	**39**

A total of 14 SSIs with health care workers, project management staff, and government officials were conducted. All service providers and government officials involved in the study for services or monitoring visits were included in the SSIs.

2.6 Data Collection

2.6.1 Data Collection Tools and Process

2.6.1.1 Quantitative

Several quantitative instruments were used for data collection (Table 3). Has registered clients as participants of the PrEP demonstration study and completed the initial history and examination form for PrEP, which included all details necessary for study participation, including the baseline results test (HIV antibody, syphilis screening, hepatitis B and C screening, and a pregnancy test [for FSWs]). The initiation history and examination form also included the names of the PrEP medicines and total doses, along with follow-up dates. During the follow-up visit, the HA filled out the follow-up history and examination forms, which included the results of routine follow-up tests (HIV antibody, syphilis screening, pregnancy [for FSWs]), adherence-related information, details of any side effects, prescribed PrEP medicines with total doses, and the next follow-up date, if applicable. Any adverse events were recorded and reported separately.

A research assistant then entered the data (eligibility form, initial form, follow-up form) into the system. This was done at the FHI 360 office to ensure confidentiality of the files and in the data collection process.

Table 3. Quantitative data collection tools

No.	Tools	Description
1.	PrEP Eligiblity Screening Form	Documented the eligiblity of the client to join the PrEP study
2.	PrEP Initial History and Examination Form	Primary data source, contained all the details of the study participant's medical history and results of baseline testing, details of the PrEP education provided, date of initiation, and the drugs used and filled at PrEP initiation
3.	PrEP Follow-up Form	Primary data source, captured PrEP procedures/services provided during each clinical visit. Contained details on adherence, including pill count, side effects, STI examination records, and test results (HIV test, STI screening, and pregnancy test [for FSWs only]), details of education provided during follow-up, record of pills refilled during follow-up meeting.
4.	PrEP Register	Register of study participants at the clinic and their IDs
5.	Adverse Events Reporting Form	Documented any adverse effects from services/medication provided at the clinic

2.6.1.2 Qualitative

Qualitative data were collected through SSIs with the PrEP participants, clinical service providers, staff supporting PrEP implementation, and government officials. The SSIs covered the following domains:

1. Likes, dislikes, and concerns about PrEP/the intervention
2. Knowledge of PrEP
3. Preferred means of communication, including the reasons (telephone, in person by CBS, in person at clinics, written information)
4. Like, dislikes, and follow-up in the community and in the clinic
5. Factors to be addressed prior to development of PrEP policies
6. Challenges/barriers faced by FSWs, MSM, MSWs, and trans women before/during PrEP enrollment
7. Major barriers and difficulties faced during implementation
8. Challenges for implementation
9. Suggestions for addressing challenges and barriers
10. Ideal PrEP model for Nepal

Interview guides developed a priori were used for qualitative data collection. These were developed in collaboration with NCASC and NPHL, were pretested, revised accordingly, and then finalized.

SSIs were conducted by a trained consultant with expertise in qualitative interviewing who was hired specifically for the PrEP demonstration study. Interviews were conducted at one of the LINKAGES Nepal project sites or at a convenient site chosen by the participant as a safe and private location. Interviews were conducted in Nepali. Written notes were taken during the interview, translated, and entered into an electronic file. No audio recording was done during the interview.

All of the information collected in the qualitative interviews was transcribed, translated, and kept in a separate file in a secure location at the FHI 360 Nepal country office. The forms will be kept secure for five years after the completion of the study, after which time they will be destroyed.

2.6.2. Training for the Researchers

2.6.2.1 Quantitative

The HAs and all other staff underwent a five-day training to implement the quantitative component of the PrEP demonstration study. They were trained on an approved curriculum in research ethics, the FHI 360 code of conduct, and study procedures, including ways of obtaining informed consent, maintaining privacy and confidentiality, and proper completion and storage of study documents.

At the end of the training, a brief pretest was conducted to ensure that the data collectors were using appropriate procedures and to check whether the forms functioned as intended. This pretest was in the form of role-play, with LINKAGES staff acting as KP members in various scenarios (e.g., meeting study participant in the community, introducing the study, obtaining informed consent, using standard operating procedures, and explaining the use of PrEP as an additional method of HIV prevention).

2.6.2.2 Qualitative

Consultants hired by LINKAGES Nepal conducted all SSIs. LINKAGES Nepal provided orientation to the consultants on the study, study partners, and populations, as well as the sensitive nature of the study and issues specific to KPs. The consultants also completed FHI 360's online Research Ethics Training and signed a confidentiality agreement. The consultants interviewed three KP individuals (FSWs, MSM, MSWs, or trans women) as part of the pretest. All participants were required to give their consent for participating in the pretest.

After the pretest, the interview guides were revised and finalized in close consultation with FHI 360 Nepal and the FHI 360 HQ team. Paper-based transcripts were stored in a safe location and electronic files were stored in a password-protected computer at the FHI 360 Nepal country office.

2.7 Data Management

2.7.1 Quantitative Data Management

The quantitative data generated from this demonstration were stored electronically. They were entered in a password-protected Statistical Package for Social Sciences (SPSS) database. All information related to the study participants, PrEP regimen, testing records, initial data, and follow-up information was collected by the HA using PrEP initial and follow-up record forms. Information on the identity of the study participants was kept in a PrEP register. All forms, including the PrEP register, were kept in the Lagankhel city clinic in a secured location which only the designated HA could access.

At the end of the three-month study, the implementing agency shared the participants' files with the technical specialist of LINKAGES Nepal for review and analysis. LINKAGES Nepal technical specialists were responsible for keeping these documents secure. A consultant performed data entry with the support of monitoring and evaluation staff at LINKAGES Nepal.

2.7.2 Qualitative Data Management

All qualitative data were transcribed and translated by the consultant who conducted the interviews. Any handwritten field notes taken during data collection were typed and entered as electronic files. Each transcript was given an identifying archival number for later reference. Password-protected electronic copies of all transcripts were kept by LINKAGES Nepal staff.

The LINKAGES Nepal office is responsible for storing the hard copies of the informed consent documents, interview guides, and notes in a locked cabinet inside a secured storeroom for five years after the conclusion of the study.

2.8 Data Analysis

Quantitative data from PrEP participants and qualitative data from PrEP participants, clinical service providers, staff supporting PrEP implementation, and government officials were collected and analyzed as described below. Results are presented together for the different study populations, except where variation among the populations was observed.

The research consultant analyzed the quantitative data, including means and frequencies, using SPSS (Statistical Package for Social Sciences).

All qualitative data were in textual format and analyzed using NVivo 12 software. LINKAGES Nepal staff and the consultant led the analysis, with input and support from the FHI 360/LINKAGES HQ team. A codebook was developed a priori and modified after the pretest. Data were analyzed using deductive codes generated from the data collection instruments, as well as emergent inductive codes created from the data. Once the initial set of transcripts was coded by members of the study team, conference calls were held with the FHI 360 headquarters team to discuss the patterns and trends in data. This provided an opportunity to adjust the qualitative data analysis approach. Approximately 20 percent of the transcripts were double-coded to ensure inter-coder reliability. Study staff produced code reports and created memos that summarized the themes and included supporting quotes.

2.9 Limitations

The PrEP study population may not be representative of the total populations of FSWs, MSM, MSWs, and trans women since the number of participants able to be recruited was limited due to logistical issues. We also relied on self-reported measures for risk behavior, adherence, and side effects, which may not always be accurate. We could not measure the PrEP drug level in the blood because of the lack of a testing facility. Also, close data collection and monitoring of participants within the context of this study might not reflect how the PrEP participants used PrEP in real-life situations. We were not able to enroll all KP members who were eligible and willing to participate due to a limited supply of the PrEP drug.

Despite these limitations, results from this study will be used to inform the future use of PrEP, help policymakers think through implementing PrEP programs, and develop hypotheses for further studies.

3. Results

3.1. Quantitative Results: Key Populations

3.1.1 Uptake of PrEP

A total of 144 KP individuals were screened for potential PrEP use, 112 of whom were found eligible (78 percent) on the basis of HIV risk, clinical criteria, and study requirements. Of these 112, 104 KP individuals (93 percent) accepted to initiate PrEP. All eligible FSWs and trans women (100%) accepted PrEP, compared to 86 percent of MSWs and 87 percent of MSM (Table 4).

Table 4. Eligibility and uptake of PrEP by key population

Key Population	Screened	Eligible %	Accepted %
FSWs	31	26 (84%)	26 (100%)
MSM	48	30 (63%)	26 (87%)
MSWs	37	29 (78%)	25 (86%)
Trans women	28	27(96%)	27 (100%)
Total	**144**	**112 (78%)**	**104 (93%)**

Participants who were eligible but did not accept to **take** PrEP cited fear of side effects and an inability to align their daily routine with the PrEP delivery schedule, while other participants did not present for enrollment and were not able to be reached by the study team.

3.1.2 Retention on PrEP

Of the total 104 KP participants who accepted and initiated PrEP, 67 (64 percent) completed a 90-day course: 22 MSWs (88 percent), 20 MSM (77 percent), 18 trans women (67 percent), and seven FSWs (27 percent). Of the total 37 participants who discontinued, 16 discontinued PrEP before the end of their first month of follow-up, 12 before their second month of follow-up, and five participants discontinued PrEP before their third-month follow-up appointment date. Among the 37 KP participants who did not complete PrEP for the full period, 25 stopped without providing any reason, and the remaining 12 discontinued due to various mild side effects after taking a few pills. The percentage of PrEP completion was higher among MSWs (88 percent) than MSM (77 percent) and trans women (67 percent). For details refer to Table 5.

Table 5. Retention on PrEP by key population

Key Population	Initiated PrEP	Retention on PrEP			% Who Completed 3 Months (90-Day Course) of PrEP
		Up to 1 Month	Up to 2 Months	Up to 3 Months	
FSWs	26	17	7	7	27
MSM	26	23	22	20	77
MSWs	25	24	24	22	88
Trans women	27	24	19	18	67
Total	**104**	**88**	**72**	**67**	**64**
	Retention rate	**85**	**69**	**64**	

As most clients who discontinued were at substantial risk of HIV, these clients were followed up in the community and provided other means of HIV prevention, including condoms and condom-compatible lubricants.

3.1.2 Age of Participants

The mean age of participants who initiated PrEP was 26 years (FSWs 26.2 years, MSM 24.4 years, MSWs 24.8 years, trans women 29.1 years). The median age of study participants was 24 years (FSWs 25 years, MSM 21.5 years, MSWs 20 years, trans women 29 years).

The mean age of participants who completed the 90-day course of PrEP was 26.3 years, and 26 years for those who discontinued. Similarly, the median age of those who completed PrEP was 24 years, while it was 23 years for discontinuers. For details, refer to Table 6.

Table 6. Age groups of participants according to PrEP initiation and retention status

Study Participants	FSWs		MSM		MSWs		Trans Women		Total	
	N	%	N	%	N	%	N	%	N	%
Initiated PrEP										
18–24 years	12	46%	16	62%	16	64%	13	48%	57	55%
25–34 years	11	42%	7	27%	5	20%	8	30%	31	30%
35–44 years	2	8%	2	8%	3	12%	4	15%	11	11%
45 years and older	1	4%	1	4%	1	4%	2	7%	5	5%
Total	**26**	**25%**	**26**	**25%**	**25**	**24%**	**27**	**26%**	**104**	**100%**
Median age	25		21.5		20		29		24	

Study Participants	FSWs		MSM		MSWs		Trans Women		Total	
	N	%	N	%	N	%	N	%	N	%
Completed PrEP										
18–24 years	1	14%	12	63%	15	71%	8	47%	36	56%
25–34 years	5	71%	5	26%	4	19%	7	41%	21	33%
35–44 years	1	14%	2	11%	2	10%	2	12%	7	11%
45 years and older	0	0%	1	5%	1	5%	1	6%	3	5%
Total	**7**	**11%**	**19**	**30%**	**21**	**33%**	**17**	**27%**	**64**	**100%**
Median age	26		22.5		20		29.5		24	
Discontinued PrEP										
18–24 years	11	58%	4	67%	1	33%	5	56%	21	57%
25–34 years	6	32%	2	33%	1	33%	1	11%	10	27%
35–44 years	1	5%	0	0%	1	33%	2	22%	4	11%
45 years and older	1	5%	0	0%	0	0%	1	11%	2	5%
Total	**19**	**51%**	**6**	**16%**	**3**	**8%**	**9**	**24%**	**37**	**100%**
Median age	23		20		25		24		23	

3.1.4 Condom Use at Last Sex

More than four out of five KPs (84 percent) who initiated PrEP reported using a condom during their last sexual contact before the time of initial recruitment. Similarly, 85 percent of those who completed PrEP used a condom during their last sexual contact. Among those who discontinued PrEP, condom use for the last sexual contact declared at the last recorded follow-up was 81 percent. For details refer to Table 7.

Table 7. KP participants who reported using condoms at last sex

Participants	FSWs		MSM		MSWs		TG Women		Total	
	N	%	N	%	N	%	N	%	N	%
Who initiated PrEP	23	88%	14	54%	23	92%	27	100%	87	84%
Who completed PrEP	5	71%	18	90%	18	82%	16	89%	57	85%
Who discontinued PrEP	15	79%	5	84%	3	100%	7	78%	30	81%

There was no observed difference in reported condom use prior to and following participation in the PrEP study.

3.1.5 Results of Follow-up Testing

HIV seroconversion: None of the study participants tested HIV positive on the HIV antibody test conducted at 30 days, 60 days, and 90 days during the PrEP study.

Other follow-up test results: Twelve key population participants with a rapid plasma reagin (RPR) reactive result were considered reactive for syphilis at baseline (initial phase). All of these participants were treated for syphilis. The study found that one man who has sex with men (5 percent of the MSM participants) and one trans woman (6 percent of the total trans women participants) had an RPR reactive result during screening on the third-month follow-up visit. There was no increase in serum creatinine level compared to baseline. All had results within the normal range of 0.5 to 1.4 mg/dL. None of the FSWs completing the first-, second-, and third-month follow-up visits had a positive pregnancy result.

3.2. Qualitative Results: Key Populations

3.2.1 PrEP Decision Making

During the SSIs, PrEP participants were asked, "Tell me about your decision to start using oral PrEP." Of the 39 PrEP participants who were interviewed, most (22) described deciding to use PrEP to ensure their own safety because of their high-risk behaviors like multiple sex partners, unsafe sexual practices, or both. Five of these participants also mentioned that their unsafe sexual practices were due to their clients' refusal to use condoms. For example:

> *As you know, I am an MSM and I have more than one sexual partner. So, to prevent myself from HIV/AIDS, I decided to take PrEP.* – MSW, continuer

> *I work as a sex worker, and I need to have multiple partners. But the problem is: some of them do not prefer a condom. You know, clients are not always the same. Some of them want sex without a condom, some are drunk, and sometimes the condom breaks during intercourse.* – MSW, discontinuer

Similarly, five participants reported that they decided to use PrEP after they obtained counseling on the importance of PrEP for HIV prevention from health care providers. Another five participants said that they were motivated to use PrEP after their friends provided them with information about the utility of PrEP for HIV prevention. Two participants reported starting to use PrEP because their sexual partners were diagnosed HIV positive.

> *Actually, I was in a relationship with one guy, and since he was recently diagnosed HIV positive, I was worried and panicked because we were in relationship for a long period of time. Staff from* [name of organization] *supported me, and he suggested that I take PrEP.* – Trans woman, discontinuer

One participant said he had used PrEP because he was getting such an expensive medication free of charge. Another said he had decided to use PrEP after he learned that his friends were suffering from various STIs.

3.2.2 PrEP Disclosure

Of the 39 participants who were interviewed, 15 respondents said they disclosed their PrEP use to friends, a spouse, or a partner. The majority (13) said that they disclosed it because they either worked or lived with the person, or their friends were also using PrEP. Most who

disclosed said that their friends, spouse, or partners supported their PrEP use by reminding them to take the medicine on time.

> *We used to talk about the medicine. We also encouraged each other to take the medicine. One of our friends tried to discontinue the medicine but we did group counseling, and he continued*. – Trans woman, discontinuer

> *We used to take our medicines together. In case one forgot, the other reminded. It was easy for both of us to be taking the same medicine at the same time.* – MSW, completed

> *I had communicated about my PrEP intake with my friends in the community, who could understand me… sometimes it's easy to share feelings in a group. When I shared my experiences with my friends, they also shared their feelings. I mentioned that I benefited from PrEP and asked about their experience, too.* – Trans woman, completed

However, two participants said that their friends were not supportive of their PrEP use, as evidenced in this quote:

> *They usually teased me, saying I am different than them, since I was the only one in group who took medicine.* – FSW, discontinuer

When probed further and asked if their family members knew if they were taking PrEP, nine participants stated that they had not told family members and would never disclose their PrEP use to family members in the future.

The most common reason given by the participants for not disclosing their PrEP use to family, friends, or anyone else was the stigma related to HIV and PrEP use. Most said they feared people might automatically think they were HIV positive or at risk of getting HIV if they knew they were taking PrEP. Many also felt that it was a personal decision, and they did not have to disclose their PrEP use to anyone.

> *I will not share with anyone… People are nosy and they interfere. They may suppose that the medicine I am having is for AIDS, which is not true.* – FSW, discontinuer

Another participant, an FSW, feared that disclosure might affect her work and that her clients would stop seeing her, as she might be perceived as being at high risk for HIV.

> *If they* [clients] *knew that I am having multiple sexual relations and I am at risk of getting HIV, they will not keep relations with me, and I will be jobless. That not only affects my life, but my children also. And you know, people see and behave differently when they come to know about my work and my risky behavior.* – FSW, completed

Another reason why participants chose not to disclose their PrEP use was because of stigma associated with sexual orientation (two MSM, two MSWs, four trans women). All said they had not disclosed their sexual orientation to anyone in their family. Reasons included not wanting to lose respect from their family members, they felt their family would abandon them, it would bring shame, or it would hurt their family's feelings.

> *Because I am scared my family might ignore me. I love my children and wouldn't be able to tolerate if they ignored me because of my sexual orientation.* – MSM, discontinuer

It is really difficult to disclose that I am taking medicine for HIV/ AIDS. She [my mother] *will probably ask for the reasons and I may have to tell her everything. If she knows about my sexual behavior, she will never forgive me… Because you know, sex and HIV are still understood as a "bad disease."* – MSW, completed

In addition, several participants mentioned that if they disclosed their PrEP use, people would think of them in a negative manner or would start gossiping about them:

People would see, think, and behave negatively toward us, if they knew we are third gender. For me, it's better not to share rather than giving more explanation. To share why I need to take PrEP, I need to share everything that happened to me including my sexual orientation and how I am at risk of having HIV. So, I don't want to share with anyone. – Trans woman, discontinuer

My husband might take this negatively. If my son comes to know about having a pill for HIV, what will I say to him? I live in a joint family. I need to be very conscious.
– FSW, completed

My friends and family members may not understand about my PrEP, and they may discriminate. – MSM, completed

3.2.3 Challenges Faced by Participants

Challenges described in this section were responses to the question, "What have been your biggest challenges using PrEP?" This section does not include reports of challenges with side effects, as these are described in the next section.

Twelve PrEP participants of the 39 interviewed mentioned challenges. The most common challenge (50 percent) was storage of the pills. PrEP participants said that they often found it difficult to hide the pills from others at home since they had not disclosed their PrEP use to anyone at their place of residence. To address the challenge, they said that they either carried the medicines with them at all times in a bag, put the medicines in a different bottle, or removed its label so that no one could tell they were using PrEP medicines.

I think the biggest challenge for me is to hide the medicine, as I haven't told anyone about my PrEP use. I live with my children and I need to be very conscious on that. I need to keep medicine away from reach of children. And my sister-in law also frequently visits me. I need to hide medicine from her as well. – FSW, completed

Yes, I stay with my family, and you know, in family everything is shared. We share rooms and cupboards as well. Therefore, initially it was difficult to hide the medicine, so I kept the pouch in an old bag in the corner of cupboard so that no one could see it.
– Trans woman, completed

I have empty bottle of vitamins and I transferred my PrEP medicine to that bottle so that if someone sees the bottle of medicine, they will think I am taking vitamins, not PrEP.
– FSW, completed

Four participants stated that taking the pills every day, especially at the same time each day, was a challenge.

> *Fixing the schedule was difficult.* [Name] *told me that I need to take the pill at fixed times. If today I took medicine at 6:00 a.m., then the next day also I should take it at the same time. Fixing a time to take the medicine was difficult because sometimes when I go for nights out, I usually sleep longer the next day.* – Trans woman, discontinuer

Three participants mentioned that swallowing the pills was a challenge because of the large size of the pill and because the taste of the pill was not pleasant. However, two of them said that they gradually adjusted to the size and taste of the PrEP pills.

> *The medicine is quite big in size, sometimes it was difficult to swallow. The color and taste of medicine was also not good.* – Trans woman, discontinuer

> *The size of the medicine is quite big, so it was difficult for a few days to swallow. When I saw the medicine for the first time, I was frightened. How can I take this big tablet? However, I got used to it later.* – MSW, completed

3.2.4 Side Effects and PrEP Discontinuation

The majority of the participants (34 out of 39) said they experienced some sort of side effect while taking PrEP pills. The most common side effects were headache, dizziness, nausea, vomiting, abdominal pain, diarrhea, and lethargy. A few participants also mentioned developing a rash on their body, having mood swings, or feeling irritable. Many stated that the side effects lasted an average of two days to about 15 days after starting the pills. Only two clients said they did not experience any side effects.

When asked if they had heard about any side effects experienced by other people taking PrEP, 15 participants replied yes. They said that they had heard people complaining of headache, dizziness, nausea, vomiting, abdominal pain, diarrhea, and rash. Another seven participants said they had not heard about any side effects.

Participants were also asked what they did to manage side effects. Among those who experienced them, 11 said they either sought advice from the service providers via phone or went to the clinic to consult the same provider. Among those, seven PrEP participants said they stopped taking PrEP after discussing the side effects they were experiencing with the service provider. For example:

> *Yes, I went to clinic to report side effects. He* [the service provider] *suggested that I report if the side effects got worse and said I could stop taking the medicine any time I wanted to discontinue*. – Trans woman, discontinuer

> *I called the clinic, they told me that sometimes simple side effects are expected and if that doesn't subside, I need to consult the clinic. I called the clinic, and they told me if I am not comfortable and do not want to continue the medicine, I can stop anytime. I just needed to visit the clinic and inform them. But I was busy in my own work and couldn't go to the clinic.* – MSM, discontinuer

The participants who continued PrEP and had side effects said that they consulted service providers, who counseled them and assured them that the side effects would decrease over time.

> *As I mentioned earlier, I felt uneasy for the first 10 to 15 days. The size of the medicine is quite big, so it was difficult to swallow. I had abdominal pain, nausea, and dizziness during the first month. I asked* [name], *and he assured me that it will be normal after few days.* – MSW, completed

A few other participants did not consult providers when they had side effects. They described the side effects as minor resolving in one to two weeks.

Two participants discontinued PrEP on their own, without seeking any advice from anyone or talking to PrEP providers at the clinic. As one participant explained:

> *As I told you, I have a busy schedule. I need to work a lot. I didn't have time to consult a service provider. I stopped taking medicine on my own. Once I stopped taking medicines, all of the side effects subsided.* – FSW, discontinuer

Three other participants mentioned that taking medicines for gastritis or drinking plenty of water had relieved their side effects.

Among the participants who discontinued PrEP, eight said that the main reason for their discontinuation was the side effects they experienced while taking the pills. Most took the pills for at least 20 to 30 days before they discontinued its use.

> *As I said earlier, after taking the medicine I felt uneasy for two to three days. I suffered from abdominal pain, body ache, back pain, and uneasiness in the throat. My condition became worse after taking these pills, so I decided to discontinue this medicine.*
> – FSW, discontinuer

One of the participants added that using PrEP with alcohol made it even worse:

> *Let me tell you frankly, I drink alcohol, and my family is not happy with my habit. When I started taking this medicine* [PrEP], *I became disoriented, and sometimes I felt drowsy. So, I discontinued. My family was worried about my behavior and thought it's because of heavy drinking habit or some black magic. I could not tell them, nor did my symptoms resolve. So finally I decided to discontinue this medicine.* – MSM, discontinuer

Another six participants said they forgot to take the pills with them when traveling and missed taking PrEP for more than seven days in a row. They were advised by their providers that they could not continue taking PrEP if they had missed their dose for more than seven consecutive days. Two mentioned that if the pills had been available in other pharmacies, they would have bought them and continued taking PrEP.

> *As I told you, I needed to go to Biratnagar for official work. I didn't have time to take medicine with me. When I got back, I talked with* [name], *and he told me that they are not allowed to give medicine after I discontinued for more than seven days. So, I had to stop taking this medicine.* – MSM, discontinuer

> *I was in a rush when I received the call from my family and learned that my father had passed away. I headed towards Nepalgunj without thinking anything. I forgot*

everything, even medicine. I came back here after 15 days and asked [name] *to continue the medicine. He told me that this is a demonstration project, and they are not allowed to give medicine to those who miss their dose for more than a week.* – Trans woman, discontinuer

Two respondents stated that they were not at high risk and had stopped taking PrEP because they thought it was unnecessary.

> *For the last four months, I have been in a relationship and haven't kept any other sexual relations. I am faithful toward him. So, I discontinued the medicine. If I am not having risky behavior, it's pointless to take PrEP.* – MSW, discontinuer

3.2.5 Perceptions on Service Provision

3.2.5.1 Satisfaction with the Service

Satisfaction of the KP participants was assessed by asking them, "How did you find the service in the SACTS facility?" The majority of participants (38) said that they were satisfied with the services they received, and none were dissatisfied. Participants were especially happy with the friendliness of the staff and the confidentiality with which their information was kept.

> *I am happy with the service I received. They are very good and friendly. They always provide service maintaining our privacy. They provide medicine free of cost, even blood test.* – FSW, completed

> *I am very happy with the service I receive from SACTS. First, they are very friendly, and they never discriminate against me despite knowing that I do sex work.* – FSW, completed

> *I am satisfied with the services provided by this facility. They are good. They called us and described in brief about the drug and its usefulness for people like me who are in risk of getting HIV. They also informed me about the possible side effects with taking medicine and gave me their number in case I needed to consult with them. So, their service is good.* – MSM, completed

> *I am satisfied with the service they provide. They are conscious about the privacy of the client, which is very good. I am sure that the things I shared with people in clinic will never be disclosed. That gave me confidence to share my personal matter including the problems that I could never share with my family. I regard this* [name of organization] *to be my family.* – MSW, discontinuer

> *I am satisfied with the service received from the clinic: they provided free condoms, a free HIV screening test, and free medicine. I think the cost of medicine is high, and if we needed to purchase it, we couldn't afford to. We are getting everything free. Because of these services, we are safe.* – Trans woman, completed

However, one participant mentioned that it would have been better if there had been a female doctor with whom to share her problems, as it would have been more comfortable:

> *I am happy with the services I received. But sometimes it's awkward to talk with the doctor, because he is male. If the organization could manage a female doctor, it would be better.* – FSW, discontinuer

3.2.5.2 Information Provided by Service Provider

Understanding the Information

Participants were asked, "Was it easy to understand the information provided by the health care worker?" Most (32) said that the information was easy for them to understand, as the instructions were very simple and clear.

> *Yes, they instructed me clearly. They even made me clear about the side effects of the medicine and the dose to be taken.* – MSM, completed

> *Yes, the information provided was easy to understand. He said that I need to take the medicine daily for three months. Minor side effects are normal, and if side effects become severe, I need to contact him immediately.* – FSW, completed

> *Yes, they provided the instructions very clearly and even told me that PrEP is not 100 percent preventive, so we should use a condom even though we are taking PrEP.*
> – Trans woman, completed

One participant also mentioned that although the information was easy to understand, it was difficult to comply with those instructions.

> *Although the instructions were easy to understand, they were difficult to follow because we needed to take the medicines on time and to be conscious about time.*
> – MSM, discontinuer

Similarly, another participant mentioned that even if the information was easy to understand, it was incomplete.

> *Yes, the information provided was easy to understand. But the information was incomplete. They talked very little about the side effects of the medicine.*
> – MSM, discontinuer

3.2.5.3 Interactions with Community-based Supporters (CBS)

Follow-up and Support from CBS

When participants were asked, "What is your thinking about the follow-up and support you received through CBS in the community?" 35 participants responded. Participants mentioned that they were getting follow-up through phone calls regularly. They were happy about being asked about side-effects and adherence of medicines.

> *I got frequent calls from CBS and the clinic regarding the regularity of medicine. They used to call me to collect medicine before the completion of the month. She used to call three to four days before I finished the medicine.* – FSW, completed

> [Name] *used to call me twice a week. She frequently asked me about how I was doing and any side-effects I had. On the phone, they always motivated me to take the medicine daily.* – FSW, completed

> *In my view, follow-up is a good practice. They are concerned about me and call to ensure my well-being, so it is a good practice. I am happy with this.* – MSM, completed

Of the 35 participants who discussed CBS support, 17 mentioned that the follow-up was adequate for them.

> *Yes, the follow up was enough. They usually call me twice a week. That's good; it reflects that they are worried about my health.* – MSW, completed

> *Yes, they used to call me twice a week. When I was busy, I requested them to call me on my convenient time and they always did so. When they needed to make a call, they called me at a given time.* – MSW, completed

None of the participants mentioned that the support they received was inadequate.

3.2.6 Recommendation for Improvements

Participants were asked, "Are there any areas where you would like to see improvement in PrEP delivery?" Among 21 participants who responded to this question, more than half (11) recommended changing the color, size, and taste of the medicine. They felt that the size of the medicine was too large for them to swallow, a white color instead of dark green would have been preferable, and the smell of the medicine was not good.

> *Everything is good, but it would be better if you could change the size, color, and taste of the medicine.* – Trans woman, discontinuer

> *The color of the medicine* [dark green] *is not good, and we have to take the medicine for too long to complete its dose to minimize the risk of HIV.* – MSM, completed

Similarly, three participants recommended that it would have been better if the total duration of taking the medicine was shorter, as they were bothered by the idea of taking medicine regularly for three months.

> *It is not comfortable to take medicine every day regularly for a long time. So, it would be better if we could take this medicine for few days or for a shorter a period of time.*
> – MSM, completed

Likewise, three participants also mentioned that it would have been better to reduce the side effects of the medicine.

> *It would be better if we could better manage the side effects of the medicine*.
> – Trans woman, discontinuer

One participant suggested managing the travel cost of the participants. Another wished not to use condoms while taking PrEP, as the condom itself is protective, and the effectiveness of medicine would not be known.

> *My suggestion is that if we take medicine, then it would be better if we didn't need to use condoms, or if we use condoms, we need not take the medicine. If we must do both the things, then what's the use of taking the medicine?* – FSW, completed

Likewise, another participant wished to have a medicine that works lifelong instead of only the duration of taking the medicine.

> *It would be good if this medicine worked lifelong. It's only effective if we are taking it. This medicine only prevents from HIV, so it would be good if it works for STI prevention*

also. It would be better if this medicine had long-term effect rather than just three months. – MSM, discontinuer

One participant recommended expanding the program to other parts of the country as well, since there are many people who need it.

Six participants found that everything was fine and that there was no need for changes.

3.2.7 Trust in PrEP

Among the participants who were asked "Do you think PrEP is trustworthy?", the majority of those who completed the 90-day course (15) said that PrEP was trustworthy, as did four participants who discontinued PrEP. A few (completed: 1, discontinued: 2) said PrEP was not trustworthy, while 10 participants (completed: 3, discontinued: 7) were not sure.

Among the participants who were asked if they would recommend PrEP to others, 26 responded yes (completed: 19, discontinued: 7); only three said they would not recommend it (completed: 1, discontinued: 2), while seven participants were not sure (completed: 1, discontinued: 6).

Participants were also asked if they would use PrEP in the future. Eighteen participants (completed: 15, discontinued: 3) said that they would use PrEP in the future, four said they would not (completed: 1, discontinued: 3), and two participants who discontinued PrEP said they were not sure.

Table 8. Views and perceptions of participants who completed or discontinued PrEP

	Completed PrEP for 90-day Study Period	Discontinued PrEP before 90-day Study Period
PrEP is trustworthy		
Yes	15 (79%)	5 (36%)
No	1 (5%)	2 (14%)
Not sure	3 (16%)	7 (50%)
Would recommend PrEP to others		
Yes	19 (90%)	7 (47%)
No	1 (5%)	2 (13%)
Not sure	1 (5%)	6 (40%)
Would use PrEP in future		
Yes	15 (94%)	3 (38%)
No	1 (6%)	3 (38%)
Not sure	0	2 (25%)

Participants reported that PrEP is trustworthy, as it prevents HIV transmission, protects them if the condom breaks during sex, and is used in other countries as well. The reasons mentioned by participants who did not trust PrEP were that one must use a condom along with PrEP, it does not provide long-term protection, and it has many side effects.

Table 9 provides the explanations participants gave when answering the questions of whether PrEP was trustworthy, if they would use PrEP in the future, or if they would recommend it to others.

Table 9. Trust in PrEP

Trust in PrEP	Illustrative Quotes
Yes	
PrEP prevents HIV transmission (20 of 39)	*PrEP is trustworthy. My status is HIV negative due to the use of this medicine.* – FSW, completed *Yes, of course, I am taking this medicine and it has worked for me. I am satisfied with PrEP and I also have full trust in this drug that this will help me.* – MSM, completed
Protects if condom tears during sex (20 of 39)	*Even in unsafe sex or if condom breaks, PrEP can prevent from HIV. It does not mean that we should have unsafe sex after taking PrEP, but in exceptional conditions like tearing of condom, PrEP is helpful.* – MSW, completed *I trust that the medicine protects me. I want to share one incident. Two months back I was having sex using condom with my client, and during intercourse the condom ruptured. Unlike other times, I wasn't worried because I was taking PrEP, and it protects me. If I was not taking the medicine, there was chance of getting HIV.* – Trans woman, completed *I think it is trustworthy. Condoms are also not 100 percent effective, there is a chance of tearing, so PrEP is very useful in this context. It minimizes risk of having HIV. It is useful for people having risky behavior.* – Trans, completed
PrEP is used in other countries as well (20 of 39)	*I think this program is already implemented in other countries, so I thought it is trustworthy. I also checked Google and found that the drug company is international.* – Trans woman, completed *I trust in PrEP because it's effective for prevention of HIV/ AIDS. It has been successfully used by different countries.* – MSM, discontinuer
PrEP use is not dependent on others, unlike condoms (20 of 39)	*To use a condom, we need to convince another person: he may not use condom or refuse to use. Because of that we may be at risk. Our safety is in another's hands, they need to use a condom. When I take this medicine, safety is in my hands, I can be safe taking the pill. I can protect myself and do not need to depend on others.* – FSW, completed

Trust in PrEP	Illustrative Quotes
No	
Need to use condom along with PrEP	*I don't think the medicine is trustworthy, because while having medicine also we need to use a condom.* – Trans woman, discontinuer *We don't suffer from AIDS immediately after having unsafe sex. It takes six months to one year. Even after taking PrEP medicine, we have to use a condom, so how can I say that's its trustworthy? The doctor of* [name] *hospital has told me to use a condom even if I take the medicine. He should have told me that I don't need to use a condom after taking the medicine or I don't have to take the medicine after using condom. By doing both, how can I trust this medicine?* – FSW, completed
Does not provide long-term protection; many side effects	*And this medicine works till* [as long as] *we take it. No lifetime protection or not even work for a year. Furthermore, it has many side effects.* – Trans woman, discontinuer
Only 50 percent trustworthy	*For me, it's only 50 percent trustworthy. Neither I will take nor suggest anyone to take this medicine.* – Trans woman, discontinuer
Not sure	
PrEP is not 100 percent effective	*I am not sure whether this medicine works 100 percent or not. While taking PrEP I wanted to have sex without condom with my boyfriends, but I was not fully assured that PrEP will work 100 percent. So, I have to use a condom even though I don't want to use one.* – Trans woman, completed *I can rate it 80 percent effective… It's not as trustworthy as a condom. I didn't feel as safe as using a condom.* – Trans woman, discontinuer
PrEP has many side effects	*I am not sure, but I think it's 20 to 25 percent trustworthy. I think so, because it has lots of side effects.* – FSW, discontinuer *No medicine is 100 percent effective. But this medicine has lots of side effects. So, I doubt its potentiality.* – MSW, discontinuer
PrEP is an experimental drug	*It might be trustworthy for others but not for me. The medicine made us sick rather cure us. Have you heard of the syringe scandal these days? People prick needles to healthy people with the syringe used for HIV-positive people. I felt same, I was given medicine to make me sick and do some study on me.* – Trans woman, discontinuer
PrEP is very new to Nepal	*As this program is implemented for the first time in Nepal, I am not sure whether to trust it fully or not.* – MSM, completed

When participants were asked whether they would recommend PrEP to others, most (26 of 39) said that they would (Table 10).

Table 10. Recommending PrEP to others

Recommendation	Illustrative Quotes
Will recommend PrEP	
If they are at high risk	*I have told many friends that PrEP helps us to protect from HIV, so people like us who are involved in risky behavior should take this medicine.* – MSM, completed *It depends upon my friends and their sexual activity, and how many sexual partners they have. If they have risky behavior obviously, I will suggest PrEP to them.* – MSM, discontinuer
Prevents HIV	*I recommend my friends to take PrEP, as it's useful for prevention.* – FSW, discontinuer *Of course, I will recommend this medicine to my other friends as well, because when we are having this medicine it prevents us from HIV if we have unprotected sex.* – MSW, completed *To date, I haven't shared with anyone. I would like to suggest taking medicine to my friends. We have only two options to be healthy, either we need to leave risky behavior or need to take PrEP.* – MSW, completed
Will NOT recommend	
PrEP has many side effects	*No, because I suffered a lot from the side effects of the medicine. It makes mood shift, nausea, vomiting a lot. So I will never suggest to anyone, not even to an enemy.* – Trans woman, discontinuer
Stigma related to HIV and sexual orientation	*I have not told any of my friends about it, because they will not understand about it. There is stigma regarding HIV and different sexes such as MSM, MSWs, FSWs, so I will not suggest* [it to] *anyone. I am working in* [name] *so as a* [title], *I will consult other people, but due to stigma I will not suggest it to friends.* – MSM, completed
Not sure	
People are not educated	*Most of the people who are involved in this work are uneducated. It's difficult to make them understand.* – FSW, discontinuer
Might have side effects	*I am not sure, because he might face side effects like mine.* – MSW, discontinuer
Not sure if PrEP works	*I am not 100 percent sure that this medicine works. Because we need to use a condom even after taking this medicine.* – Trans woman, discontinuer

When participants were asked whether they would take PrEP in the future, most (18 of 39) described being involved in risky behavior, and since PrEP prevents HIV, they will use PrEP in the future if it is available.

Table 11. Use PrEP in future

Future Use of PrEP	Illustrative Quotes
Yes	
They are at high risk/involved in risky behavior	*I will also continue this in the future, as I am always in a risk group.* – FSW, completed *Yes, I will, because I trust this medicine, and I think this is the best medicine for me as my sexual behavior is sometimes risky.* – MSM, completed
Prevents HIV	*I have also planned to take this medicine later if it will be available. Because this is a good medicine for me as it helps to prevent from AIDS.* – MSM, completed *I think that this medicine will surely help to make me safe. HIV will not transmit from my partner to me if they have HIV.* – MSM, completed
Had no side effects	*As I did not have any side effects of PrEP, I am ready to repeat PrEP in the future.* – MSM, completed
No	
PrEP is not 100 percent effective/does not offer lifelong protection	*Even we take medicine, we have to use condoms to protect ourselves from AIDS, so why waste time here? I have already taken PrEP for three months, so I will not repeat it again. It would be better if this three-month course can be helpful for preventing us from HIV lifelong. I cannot take this medicine for lifelong.* – FSW, completed *For me, it's only 50 percent trustworthy. I will neither take nor suggest anyone to take this medicine.* – Trans woman, discontinuer
PrEP has many side effects	*It's difficult to take the medicine. It has lots of side effects.* – FSW, discontinuer
Not sure	
Use only if PrEP has no side effects	*I will repeat it if only there are no side effects.* – FSW, discontinuer

3.2.8 Perceptions on PrEP Rollout

Participants were asked, "What recommendations would you make for this program to be expanded to other areas in Nepal?" Among the 36 participants who responded to this question, the majority (30) said that the program should be expanded to other places and areas of the country. Among those who recommended expansion of the program, six respondents said that the program should be focused on major cities such as Pokhara and Biratnagar, whereas four participants suggested expanding the program to target rural and remote places, as people lack access to resources and information in such places.

> *This program should be expanded in villages and rural parts of Nepal. People of urban areas are educated and smart. They have adequate knowledge on the prevention of HIV, but people in rural areas are totally unaware of it. So, rural areas should be the focus for program expansion.* – FSW, discontinuer

Likewise, six participants said that the expanded program should mainly focus on key and high-risk populations.

> *Counseling is the major aspect of continuation of PrEP, and it should be strong. Different groups such as trans people, MSM, MSWs, and FSWs should be identified first, and PrEP should be focused on them rather than the general public.* – MSM, completed

> *I think this program should reach other places of Nepal as well. We need to target trans people, MSM, FSWs, and wives of migrants. Because these groups are always at risk of getting of HIV.* – Trans woman, discontinuer

Two participants recommended that the program target adolescents and college students, as they are at high risk of unprotected sex.

> *I think we need to target people who practice unprotected sex, especially college-going students, because they have high chances of having unprotected sex.*
> – MSW, discontinuer

However, two participants were not sure whether the program should be expanded to other areas, and two other participants were dissatisfied with the program and hence would not recommend expansion to other places.

> *I wouldn't recommend this program to be expanded in other areas of Nepal. Instead of giving positive message in the community, it will provide bad information about HIV and its treatment.* – Trans woman, discontinuer

> *I don't think this program is effective. The medicine does not work.* – MSM, discontinuer

3.3. Qualitative Result: Service Providers

3.3.1 Role of Participants

Service providers were asked, "How were you involved in this study? What was your individual role?" Of the 10 service providers who responded to this question, six CBS said that their role was to provide counseling to KP individuals on benefits, inform them about the possible side effects of PrEP, and encourage KP individuals to use PrEP.

My main role was to find out the high-risk group or KPs and identify those who were having risk behaviors, make them aware them of HIV and STIs. If they were doubtful on their HIV status, I counseled them and brought them to the clinic for an HIV test. At the same time, I informed them about PrEP availability in the clinic and counseled them to start PrEP. – CBS

Similarly, the role of two program coordinators was to follow up on the activities of CBS, observe screening tests, keep records, prepare reports, and coordinate and communicate with other staff. The role of one laboratory person was to conduct HIV testing and collect samples for RPR, serum creatinine, and hepatitis B and C. One health assistant said that his role was to provide adequate information and counseling to study participants on using PrEP.

3.3.2 Training

Ten participants were asked, "What do you think about the training you received?" Everyone said that they found the training on PrEP useful and effective. Many said that they did not know about PrEP until the time of the training and that they were excited to learn about PrEP.

The training was good. I learned about PrEP. When I first learned about PrEP, I was excited because this medicine can prevent HIV and save the lives of many people who are at risk of contracting HIV. – CBS

One participant said he was initially concerned about the side effects. However, during the course of the training, they were informed about all the side effects and how to manage them and told that they could contact the doctor, if necessary.

I found the training good. At first, I was afraid, because we need to give medicine to clients. That medicine might have side effects—how can I motivate them to take medicine? What if they have severe side effects and damage their kidney or anything like that...? If a client gets sick, or a client dies, I will be responsible for that. I had that sense of fear but [the trainer] *clarified everything. He taught us how to tackle each situation and assured us that if we have any problem while working, we can contact him directly; that gave us a sense of support. Otherwise, it's difficult to motivate anyone to take medicine.* – CBS

Another respondent said they learned that PrEP only protects against HIV but not STIs and pregnancy and that they should still use condoms along with taking PrEP, as directed.

Training was good. From that training I came to know that this medicine only works for HIV, it does not prevent STI and pregnancy. For that, they should use condom. – CBS

One laboratory technician stated that after learning about PrEP for the first time, they felt it would be challenging for the clients to take the medicines every day, as well as to come to the clinic monthly and give a blood sample.

As a lab technician, my main role is to collect samples. In the training, I learned about PrEP for the first time. Initially, I found it challenging because clients must take it daily. They need to visit the clinic monthly and need to give a blood sample. – Lab technician

When asked the most useful aspect of the training, most said that they found the content of the training useful, but only a few provided detail. One CBS explained being clear on when the

PrEP drugs come into effect after starting them and how counseling was an important aspect of providing PrEP.

> *Most of the time, we think that medicine works soon after intake, but* [name] *told me that this medicine starts working only after a week of intake. We need to convey that while counseling, because PrEP is different than other medicines. Other medicine starts working soon after intake, but PrEP starts working only after a week.* – CBS

Another respondent said that the training helped her understand the eligibility criteria for PrEP clients, and that it was very helpful as an implementer of the program.

> *Such type of training is essential for us because we are the implementers of this program. It guided us on eligibility—whom to include and whom to exclude in the demonstration project. We should have enough information to deal with each situation. I learned how to measure creatinine level in this training. I also learned how we can develop demand generation of PrEP in the field.* – Program coordinator

Participants were also asked if the training provided was sufficient. Eight participants said that they would have liked for the training to be extended for a few more days, and they suggested providing more information about the side effects of PrEP and more focus on counseling. One of them also said it would have been better if they could have seen the PrEP pills during the training. The remaining two respondents said that the training was enough.

3.3.3 Providing Oral PrEP

3.3.3.1 Difficulties Experienced While Providing PrEP

Service providers were asked, "Did you find it difficult to offer PrEP to clients?" Of the nine service providers who responded to this question, eight said that they faced difficulties either during counseling or after the clients faced side effects.

> *I used to get phone calls at midnight because most of the clients take medicines at night. Some of them would have their side effects at midnight. They used to call me and complain of headache or vomiting. Some of them even told me that I gave them poison, to get revenge on them. I called them and arranged a meeting with* [name] *so that they got better counseling and understood the medicine better.* – CBS

> *It was difficult to one make them understand about PrEP, two to bring them here to the clinic, three to get them ready for the blood test, and four to make them ready to take medicine. Above all, the most difficult task was to convince them to continue the full course.* – CBS

3.3.3.2 Challenges While Providing PrEP

The most common challenges were tracking participants and following them up as they used fake names and numbers, counseling them and making them ready for PrEP use, providing complete information (including about side effects), and collecting blood samples twice.

> *Clients promise us to be here for screening test. We wait for them at the clinic, but they do not come. When we call them, they make lots of excuses.* – Program coordinator

It was difficult to make our client understand about PrEP. Because this medicine is new, limited people know about it. It's obvious that everyone thinks twice to try new things, especially if that's medicine. – Health assistant

Collecting Medicines on Time

When service providers were asked whether the clients collected their medicines on time, the service providers noted that they needed to make frequent phone calls to remind the clients. Even after that, clients were not willing to come to get medicines on time. They generally came before seven days of finishing their medicines. Some clients requested the medicines to be delivered to their homes.

We need to make frequent phone calls to remind them that their medicine is getting over and they need to come to clinic to refill. Most of them request us to bring the medicine to their place. – CBS

Most of them were reluctant to visit the clinic. Most of the time, KP members stay at home and go out only at around 5 to 6 p.m., because of the fear of disclosure. So, I requested Mr. [name of staff] *to stay at the office even after office time was over to provide services for them. Some of the clients visited our clinic even after 7 p.m. to receive the service.* – Program coordinator

Out of the 10 users, eight do not come on time. We call them weekly and remind them, but they hardly follow us and only come to clinic after three to four days of finishing their medicine, but they usually come before seven days. – Health assistant

Remaining HIV Negative

When service providers were asked, "Did clients remain HIV negative on PrEP?" all 10 service providers said that clients did remain HIV negative after PrEP.

We haven't recorded any cases that were positive in between or after PrEP.
– Program coordinator

Stigma as a Challenge

Service providers were also asked whether they considered stigma as a challenge. All service providers mentioned that stigma related to sexual behavior, sexual orientation, and HIV was a challenge for bringing clients to the clinic and getting participants ready for PrEP.

Participants have an inferiority complex about visiting the clinic. Some felt awkward and are afraid that their status might get disclosed, though we tried our best not to do so. So, most of the participants requested that we bring the medicine to their place. They wanted to have medicine but were reluctant to visit the clinic. – CBS

Yes, sex workers are always hidden in the community. There is stigma related to their work, and they are reluctant to visit the clinic. They kept changing their name, home, and phone number. – CBS

3.3.4 Side Effects

Provider's Concerns about Side Effects

Service providers' concerns about side effects were also investigated in the study. They mentioned that some side effects such as nausea, vomiting, dizziness, lethargy, and diarrhea were common and not to be worried about. They also added that counseling was a must for side effects. CBS also suggested that clients consult the clinic in case of side effects.

> *I used to say that these side effects are normal and will disappear after certain time. They don't need to worry about that.* – Lab technician

Client's Concerns about Side Effects

Service providers were asked about client's experiences regarding the side effects of the medicine. The 10 service providers said that most of the clients complained about some level of side effects, the most frequently reported being nausea, vomiting, dizziness, and diarrhea. Service providers also counseled the clients, saying that these side effects were short term and would disappear after a certain time.

> *Some of the clients who had side effects like dizziness, lethargy, and vomiting, they scolded us. They thought we didn't provide them good-quality medicine. Some of them called me and used vulgar words and said that they have side effects because the quality of medicine was not good.* – CBS

> *Most of the clients complain of nausea, vomiting, abdominal pain, and dizziness.* – CBS

> *Out of 10, seven clients complained that they have some side effects. Some clients even discontinued the dose because of side effects.* – CBS

3.3.5 Adherence

All the service providers were asked, "What were your PrEP clients' challenges for taking the pill every day?" Some said that their clients were sex workers who often had an unstable routine, either working at night or traveling frequently. One added that it was difficult to make them understand about PrEP, as most were illiterate.

> *Most of them are sex workers. They stay up late at night, and during the day they sleep for the whole day. It was difficult for them to fix a time for taking medicine.* – CBS

> *Most of the KP* [individuals] *are mobile and they don't stay in same place; they don't carry the same name and number also. Their working, sleeping, and eating time is not fixed. But they need to take medicine at a fixed time. Fixing the time is the main difficulty in the daily intake of medicine. And most of them are uneducated, so it is difficult to make them understand.* – CBS

> *Some FSWs told that they take medicine at night. I doubt them, because most of them drink alcohol, and might forget to take medicine.* – CBS

One participant talked about the size and the smell of the pills as a challenge for continuation of PrEP. They described how the clients complained about the size and the smell of the pills.

> *They complained that the size of the tablet is big, making it difficult for participants to swallow. The color of the medicine is not good and should be either white or pink. Also,*

they said that the taste of medicine is not good; it should be in chocolate flavor. Also, the smell is bad. It should smell good and needs to be aromatic. – Health assistant

Another participant, who was a program coordinator, said that one of the main challenges they had heard from the clients was that they needed to visit the clinic regularly and give blood samples.

Some of them used to say it's boring and irritating to take medicine daily, to give blood test monthly, and to come to the clinic to receive the medicine. – Program coordinator

One CBS mentioned that the clients kept asking them why they needed to use condoms while taking PrEP, and that they were very hard to convince in the beginning.

It's really difficult to convince that while taking medicine, they also need to use a condom. They questioned me a lot, saying if they must use a condom, why take PrEP? Initially they were in a dilemma about whether to use a condom or not, but later I convinced them to use condoms. – CBS

Among the participants who were asked how they counseled clients on taking PrEP every day, most said they explained to the clients how PrEP protects them against HIV and that they need to take the medicine every day at the same time.

I used to say that medicine only works if it is taken daily in a fixed time. They should not miss any dose. And if they miss any dose, they should not take a double dose. Based on the situation, I also told them about PEP [post-exposure prophylaxis]*. For taking PEP, they need to come to the clinic within 72 hours of risk activities.* – CBS

One CBS said that he explained to participants by saying that PrEP "allows them to be safe and to have control" over protection, unlike condoms, which are usually negotiated by their clients (for sex workers).

I suggest them to continue the medicine. The provided medicine is good for prevention of HIV, as they are always at risk of getting HIV. Using condom is not sometimes in their hand, they need to convince their costumer [client], *and if they refuse to use, the FSW will be at risk. But taking medicine is in their hands, they can take medicine and save themselves from HIV.* – CBS

Another service provider described how the clients did not trust them in the beginning since they had never heard about PrEP and how it can protect them against HIV.

It's difficult to convince them at first. They keep on questioning and do not trust us, because to date, they haven't heard about the medicine that could prevent HIV. They ask the question that if the medicine is effective, why they need to use a condom. But later, when we keep on talking about PrEP and its benefit, they started listening to us. – CBS

One CBS said that they even suggested that their clients set up an alarm on their phone to remind them to take the medicine.

When asked about the frequency of counseling, all the CBS said that they counseled the clients two to three times per week on average.

The health assistants said that they counseled the clients when they came to the clinic to collect PrEP. The counseling sessions typically lasted 30 to 45 minutes.

All the service providers except the lab technician were asked if the counseling provided to participants was sufficient, and all said that it was.

> *I think the provided counseling was enough, because we used multiple counseling models. We keep on telling them the benefits of PrEP until they fully understood the benefits and risks of taking PrEP.* – Program coordinator

3.3.6 PrEP Integration

Service Delivery

When service providers were asked, "What made PrEP services successful?" most (9) said that multiple services like counseling, laboratory tests, and medicine distribution done in a coordination with multiple levels of staff was the reason behind the success of PrEP. They also mentioned that maintaining confidentiality and providing respect to individual clients was a strong reason why PrEP services ran smoothly.

> *The counseling, services, and free screening test all worked for the success of this program. On top of that, the "one-door system" that we adopted was effective. In this system, unlike other clinics, clients need not go to different departments for services. They get counseling, a screening test, and medicine from the same place.*
> – Program coordinator

One community-based supporter also mentioned that CBS played the most important role in the success of PrEP, since the most challenging part of bringing clients to the clinic was done by CBS staff.

> *I think the central role is played by CBS because they are the ones who bring the clients. CBS has close relationship with clients; most of them are here because of our personal relationship. Our* [name] *has also played an important role in counseling and bringing clients for the service. The privacy we maintained also helped immensely for the success of this program.* – CBS

Clients

Service providers were also asked what worked well in the PrEP study to bring clients to the PrEP service facility. They responded that equal treatment of all participants and counseling were the factors that worked. Moreover, one service provider also mentioned that increasing awareness about HIV and its transmission also made the service easier.

> *All categories of clients were equally treated. The follow-up that we did worked well.*
> – CBS

> *These days, compared to earlier, people are aware of HIV, its prevention, and transmission. That could be the reason people accepted this medicine and, consequently, we were able to meet our target*. – CBS

Two service providers also mentioned that comparatively high levels of knowledge and awareness among MSM and trans people versus FSWs made PrEP counseling and acceptance

among these participants easy. Furthermore, one service provider also mentioned that it was easier to work with trans people because of their higher level of knowledge and awareness.

> *MSM and trans people have better knowledge about HIV and PrEP compared to FSWs. They are more conscious about their health. So, our drop rate is also less in MSM and trans people.* – Health assistant

Improvements Needed

Service providers were asked, "What improvements are needed for providing PrEP?" Two out of 10 service providers suggested arranging the travel cost for clients, as clients were unwilling to leave their work and come voluntarily. Another two service providers recommended using mass media for publicity. One service provider suggested providing PrEP to wives of HIV-positive men.

> *I think we can even include HIV-negative females whose husbands are positive. So, it's better to change the criteria of giving medicine. In this program we have included only those females who openly said that they are a sex worker.* – CBS

One of the program coordinators suggested shortening the information on the counseling and consent forms.

Feasibility of Rolling Out PrEP

Service providers were also asked, "How could PrEP be integrated into existing services?" Four service providers strongly believed that integrating PrEP with regular health service provision would increase service utilization by the target population.

> *Yes, it will be better if we could integrate PrEP in regular HIV programs. But for the success of the program, PrEP should be given by organizations like ours.* – CBS

> *I think it's better to integrate the services so that they can get all services from the same place and program. For example, if we conduct a health camp just for HIV, people may not come, but if we included blood pressure, sugar, thyroid test also, the number of beneficiaries will increase.* – CBS

> *So, for rollout we need to focus on high-risk populations and their partner. From the part of planner and implementer it is not difficult.* – Government official

All service providers and government officials mentioned the need for PrEP rollout and ensuring its feasibility.

> *One of the major questions here is whether PrEP is a demand of KP individuals or not… I don't think we are clear enough on this. So, what I can say now is that there is global evidence on PrEP working well, so we adopted that and went for demonstration. From our point of view it is needed, but we don't know whether it is the need of KP members or not.* – Government official

> *I think it's difficult to go directly to the general population. So, for the rollout, we need to focus on high-risk populations and their partners.* – Government official

> *Beyond these four groups, we can include PWID and migrants as well. The main challenge is the acceptability of the program. If the demonstration shows high acceptability, then we have to go for rollout and it is feasible, too.* – Government official

4. Conclusions and Recommendations

1. The majority of the participants (93 percent) accepted PrEP, ranging from 100 percent among the FSWs and trans women to 86 percent among MSWs. None of the participants who initiated and completed PrEP for 90 days seroconverted during follow-up or at the end of the 90-day period. Qualitative findings also support the acceptance of PrEP among KPs and was supported by service providers and policymakers as well. The majority of participants who had completed the 90-day course and some of the participants who discontinued, considered PrEP trustworthy and committed to using PrEP in future. The majority said that the program should be expanded to other places and areas of the country.

   Recommendation: Since it is already an accepted method of HIV prevention and recommended by WHO, based on the finding that PrEP is acceptable among KPs in Nepal, coordinate with NCASC and NPHL to roll out PrEP across the country among KPs at substantial risk of HIV. PrEP also presents an opportunity to promote HIV testing uptake, and to access to STI diagnosis and treatment services. Integrate PrEP with existing HIV programs that include HIV testing, STI services, and treatment and care support services for KP individuals and people at high risk of HIV. It is worth considering the inclusion of all at substantial risk of HIV, including HIV-negative partners of HIV-positive clients.

2. PrEP was provided using the existing service structure with minimal training and supervision. The existing staff were capable of providing high-quality services using the current government supply system. The majority of PrEP participants continued PrEP for 90 days without any extra expenditure for implementation. Also, based on the qualitative findings among beneficiaries, service providers, and policymakers, PrEP is feasible if provided as part of existing HIV programs for KPs in Nepal.

   Recommendation: Provide PrEP as part of existing HIV programs for KPs that include HIV testing, STI services, and treatment and care support services for both KPs and people at high risk of HIV. PrEP also presents an opportunity to promote HIV testing uptake and access to STI diagnosis and treatment services. PrEP is worth considering for all at substantial risk of HIV, including HIV-negative partners of HIV-positive clients.

3. Of the total 104 KP individuals initiated on PrEP, 64 percent continued on it for a total of 90 days. These were the participants who visited the clinic every month for three months, collected the supply of the drug at the end of first and second months, and participated in all laboratory investigations conducted at the end of the first, second, and third months. Continuation was 27 percent for FSWs, 77 percent for MSM, 88 percent for MSWs, and 67 percent for trans women. Retention on PrEP among FSWs was comparatively low. Side effects, the mobility of sex workers, and disclosure were some of the reasons for discontinuation identified during the qualitative interviews.

   Recommendation: As continuation of PrEP was found to be low among FSWs, especial focus should be given to adherence and continuation of PrEP within this group. Counseling

should address the possible side effects and coping approaches. A special counseling package with components of motivational interviewing to address barriers should be prepared and implemented during rollout. Informational materials should be developed highlighting PrEP, its importance, side effects with coping strategies, implementation modalities, and its availability. These should then be shared with people at substantial risk of HIV using the means of communication that would reach the largest mass possible.

4. The majority of the participants experienced some type of side effect—headache, dizziness, nausea, vomiting, abdominal pain, diarrhea, and lethargy—which were the reasons for discontinuation. Some of the participants felt that the size of the pill was too large to swallow, the smell of the medicine unpleasant, and the color displeasing.

   Recommendation: Use an individual or one-on-one educational approach for informing PrEP users about side effects, how long these last, what should be done at home to cope with the side effects, and how PrEP can be continued while managing these side effects. This should be part of client education during follow-up. If possible, attractive packaging of the pill and giving the pills a pleasant color and taste could increase continuation.

5. The most common reason given by the participants for not disclosing their PrEP use was stigma related to HIV and sexual orientation.

   Recommendation: Counseling on PrEP disclosure should be part of a future rollout. Along with disclosure counseling, sensitization on HIV and sexual orientation for service providers and in the targeted community should be included in the package.

6. There was not much change in condom use among the participants before participation and after completing the 90-day course of PrEP. However, condom use among MSM participants was lower than among other KP participants. There was no increase in syphilis reactive result or serum creatinine level compared to baseline, and none of the FSWs completing the study had a positive pregnancy result. This also indicates that PrEP was used as additional method of prevention.

   Recommendation: Given that PrEP is an additional method of HIV prevention to be used along with condoms, counseling with KPs on PrEP should focus on the importance of using condoms in tandem with PrEP. In fact, the importance of condom use during PrEP use should be a part of the counseling package for all KPs and include a focus on the benefits for family planning and STI prevention.

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