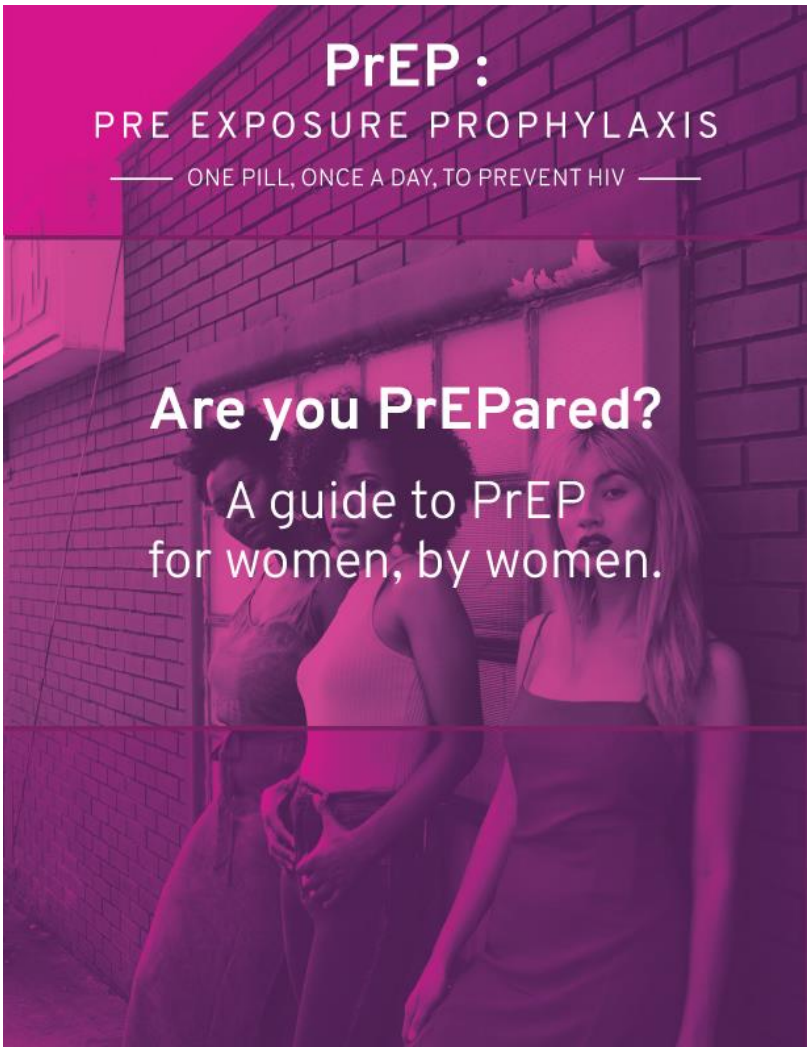
Project Sexual Health Equity

Report of Study Results



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A Report Submitted to Community Partners
at
Prevention Point Philadelphia

Background

HIV is a persistent and increasing public health problem among persons who inject drugs (PWID) in the United States (US). Until recently, the incidence of HIV in PWID was low, falling from about 40% in 1990 to 6% in 2017[1]. However, in the last few years, multiple US cities have reported HIV outbreaks among PWID[2,3] including Philadelphia where a 115% increase in new HIV cases was observed from 2016 to 2018[4]. A major driver is the increasing prevalence of fentanyl, which requires more frequent injection to stave off painful withdrawal symptoms, compared to longer acting opioids like heroin[5].

In particular, women who inject drugs (WWID) are at elevated risk for HIV. Although the absolute number of new HIV cases attributed to injection drug use were higher among men who inject drugs[1], a recent nationally representative study estimated that WWID were 40% more likely to have a new HIV diagnosis[2]. Research has demonstrated that gender is an important factor for understanding the differences in HIV acquisition among PWID[3,4]. WWID often report more frequent syringe sharing and inconsistent condom use which introduces greater opportunities for HIV exposure compared to male counterparts[3,4]. In part, WWID's risk is shaped by having to negotiate prevention methods (e.g., condoms or new syringes) with male partners, which has been shown to impede their use[6-8]. Thus, innovative, WWID-controlled strategies are needed to reduce the risk of HIV acquisition in this population.

One such method is the once daily medication called pre-exposure prophylaxis, or PrEP. PrEP has been shown to reduce HIV infection by up to 74% in PWID[9]. Since 2014, the Centers for Disease Control and Prevention (CDC) has recommended PrEP for HIV prevention in PWID and women[10]. While PrEP could be a useful HIV risk reduction tool for PWID, and WWID in particular, PrEP awareness and uptake is low in this population[11,12]. However, studies show that once PWID are educated about PrEP, many find it to be an acceptable HIV prevention method[11,12].

Syringe services programs (SSPs) could play a key role in increasing PrEP awareness and uptake among PWID. SSPs are a potential access point for many PWID who would benefit from and are clinically eligible for PrEP. Further, some SSPs, such as Prevention Point Philadelphia (PPP), already provide prescription medications and long-term monitoring for other conditions such as buprenorphine for opioid dependence[13]. In fact, Hepatitis B vaccine completion rates[14], buprenorphine maintenance[13], and anti-retroviral medication adherence[15] have all been higher among PWID receiving care in a SSP compared to traditional medical settings. Therefore, PrEP may be a natural extension of what is already being done in these settings with great success. Because of this, PrEP interventions delivered in a SSP may be more likely to be acceptable and increase retention. However, research has yet to assess the acceptability and feasibility of SSP-delivered PrEP care for WWID.

This report details the methods and main outcomes of Project Sexual Health Equity (SHE), one of the first PrEP community demonstration projects in the United States for PWID. The goal of Project SHE was to assess facilitators and barriers to PrEP initiation when offered to WWID at Prevention Point.

Methods

Subjects

Participants were cisgender women, 18 years and older who attended PPP's weekly women's drop-in program on Tuesday nights. Eligible participants reported injection drug use in the last 30 days and at least one other HIV risk factor according to CDC PrEP prescribing guidelines[*16]. Women who were pregnant, had a positive HIV test, or were already receiving PrEP care, were excluded from the study and referred for care elsewhere.

Data Collection

Eligible, consenting participants completed an initial study visit and were followed for up to six months. At each visit, surveys were completed with a trained research assistant. Surveys asked questions about demographics, mental and physical health, HIV-risk behaviors (such as syringe/paraphernalia sharing, inconsistent condom use, etc.), and PrEP knowledge and attitudes. PPP phlebotomists collected specimens to assess clinical eligibility for PrEP (HIV, hepatitis B, and renal function), and participants self-collected samples to screen for sexually transmitted infections, pregnancy, and PrEP adherence (among those choosing to take the

[*] Other risk factors were transactional sex, inconsistent condom use with partners who are men who have sex with men or PWID; bacterial STI diagnosis; syringe sharing; or recent opioid agonist treatment.

medication). Participants also met with the study's medical provider who took a health history and provided individualized PrEP and adherence counseling.

Participants who wanted PrEP were given the option of having Philadelphia Pharmacy manage their medication with pick-up during study visits or taking a paper prescription to fill at the pharmacy of their choice. Participants were also offered prescriptions for naloxone and birth control. At their final visit, participants were asked about their experiences participating in the study and future PrEP preferences. Study medical providers referred participants who wished to continue PrEP to another provider. In addition to the PrEP-related study visits, a subset of women participated in qualitative interviews. Interviews assessed their perceptions of HIV risk, ability to access and adhere to PrEP, as well as their care experience.

Results

Study Participants

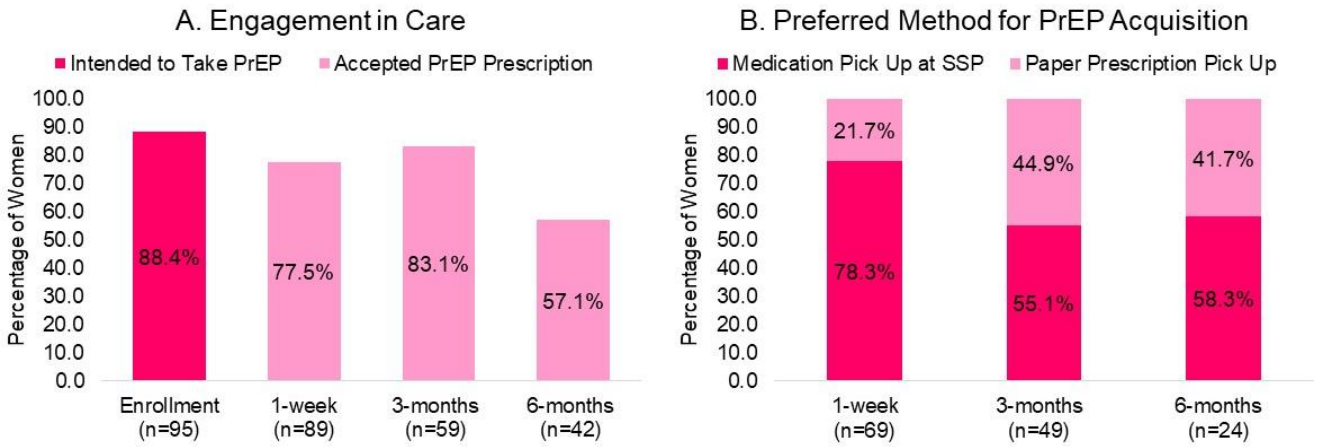
Between April 2018 and October 2019, we enrolled and followed 95 WWID. The sample was mostly white with average age of 36. Most were homeless, earned less than $4,999 a year, and had public insurance. Most reported HIV risk behaviors (e.g., polydrug use, high number of injections per day, transactional sex, condomless sex, and high number of sexual partners). However, less than half of women perceived themselves likely or highly likely to acquire HIV. Just over half were aware of PrEP prior to enrollment.

STI Incidence and Testing Preferences

Over the course of the study, 25/95 (26.3%) screened positive for gonorrhea/chlamydia (GC/CT) at least once. By study visit: 17.9% (17/95) screened positive at baseline, and 18.3% (11/60) and 9.5% (4/42) screened positive at second and third follow up visits, respectively. Of those ever diagnosed (n=25)[†], most (64.3%, n=18) screened GC/CT positive once, and 28% (n=7) screened for CT/GC at two visits. No participant screened CT/GC positive at all three visits. Among the positive STI screens, nearly half (48.5%) of infections would have been missed if only genital screening was performed. This shows the need for multi-site screening for this population. At each time point, the majority of participants received appropriate treatment. Treatment rates improved when a small incentive of $5 was provided to come in for results and treatment. The majority of participants (62%) indicated that PPP would be their preferred location for future STI testing.

Engagement in the PrEP Care Cascade

Engagement in the PrEP care cascade[‡17] and preferred method for acquiring PrEP among WWID are displayed in Figure 1 below.



At baseline, 84/95 (88%) intended to take PrEP. Approximately 80% of participants accepted a PrEP prescription at 1-week and 3-months. However, acceptance decreased to 57% at 6-months (Figure 1A). Women who chose to take PrEP were more likely to report inconsistent condom use, more frequent use of the

[†] N= refers to sample size

[‡] The PrEP care cascade is a framework for identifying gaps in the care continuum, involving a series of steps that includes 1) a medical evaluation for PrEP eligibility, 2) initiating PrEP, and 3) retention in PrEP services.

SSP, and recent sexual assault as compared to those that did not initiate PrEP. During qualitative interviews with participants, women revealed that sources of risk beyond their control (i.e. sexual assault or accidental needlesticks) contributed greatly to their perceived HIV risk and drove their decision to initiate PrEP:

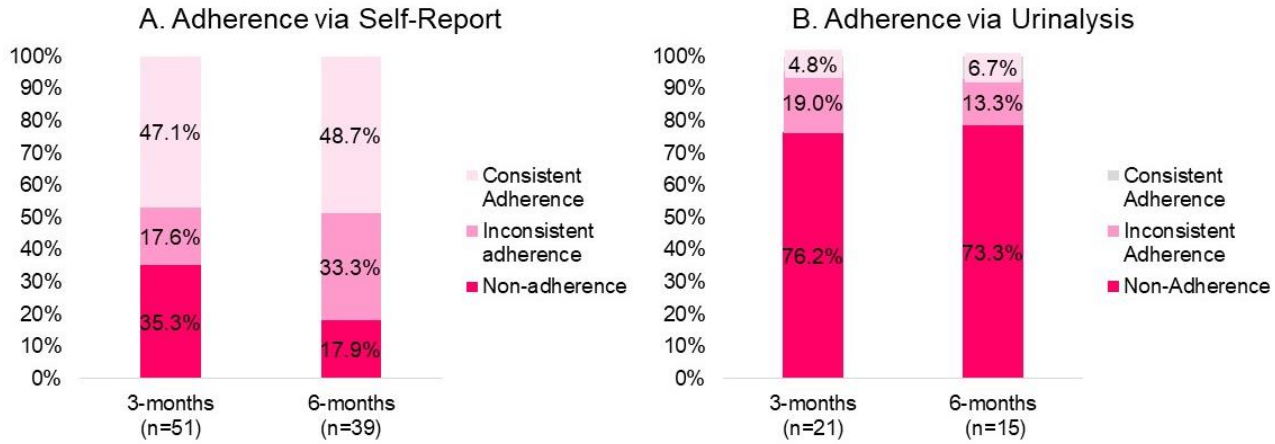
> *"I work— street [sex] work, so yeah [I'm] very vulnerable to HIV...Just the fact I've gotten raped a few times, that impacted my decision [to get on PrEP]"*

At every study visit, most women preferred to pick up PrEP at the SSP instead of filling a paper prescription elsewhere (Figure 1B). Women preferred the ease of picking up prescriptions at PPP and reported predatory practices from outside pharmacies:

> *"I'm getting [PrEP] through you guys…because I'm hearing a lot of people [are] selling the prescriptions to the pharmacies….And I don't wanna do that….Because I wanna take …like I might have a bad day one day and not pick it up and wanna sell it"*

Adherence

Project SHE also measured participant's PrEP adherence. As shown in Figure 2, most women reported partial or complete adherence at 3-months and 6-months (2A). However, self-report adherence did not match urinalysis adherence results.



Urine testing for tenofovir levels indicated that over 70% of women who reported complete PrEP adherence were actually non-adherent (2B). In qualitative interviews, women reported multiple barriers to adherence. These included housing instability, predatory pharmacy practices, and changing HIV risk perception. The following quote highlights the many adherence challenges participants face:

> *"[Being homeless] makes [taking PrEP] harder, cuz everything keeps getting stolen, like. You know, it's not like I live in an apartment and can just put it in my medicine cabinet or in the kitchen cabinet…Like I gotta—I hide stuff, I try to move it every like four days, or so, so it's not in the same spot for too long."*

Acceptability and Satisfaction

The vast majority of women (35 of 36) reported they were mostly or very satisfied with the services received, that most or all of their programmatic needs had been met (n=35/36) and that they prefer to receive future PrEP care at the SSP (32/36). One participant summarizes why we believe the project was so acceptable:

> *"It's just very easy [getting PrEP at Prevention Point]. I come here anyway…I'm already comfortable here. I trust the staff. So, if I were to have any issues, whereas before like with some things I might just be like, 'ah whatever,' like I might actually speak up for myself, if something bad happened. And it's because it's Prevention Point. If it were somewhere else, I might be hesitant to do that."*

Summary and Recommendations

WWID face unique HIV risks because of the difficulty they often face using other harm reduction methods with male sex and drug use partners. Despite their increased risk for HIV, research within this population is scarce. There has been limited evaluation of PrEP for PWID and no published trials specific to WWID. Our findings highlight that WWID actively engaged in PrEP care when it was offered within a SSP, a setting they regularly access and trust. Most women adopted PrEP one week after being offered a prescription. This shows that using SSPs is an acceptable and feasible way to offer PrEP to WWID.

Despite viewing PrEP as an important HIV prevention tool, not all WWID initiated PrEP. For these women, additional supports to assist with barriers and access to post-exposure prophylaxis (PEP) may be needed. Although initiation and retention in care was high, adherence to PrEP was low. This is troubling because higher levels of PrEP adherence are needed to effectively protect WWID from vaginal or parenteral HIV exposure[18]. Given that high adherence is necessary for WWID, additional supports to help increase adherence are needed.

Recommendations:

1. WWID viewed PrEP as an important HIV prevention tool and prefer to access PrEP through PPP. High retention in care demonstrates that providing PrEP at PPP was feasible and acceptable to WWID. We recommend the development of a PrEP program with long-term follow-up for PPP clients.
2. Adherence to PrEP in this group was low so additional supports are needed. Participants suggested having a safe place to store medications, such as a medication locker or daily medication management at PPP, might increase adherence.
3. While the study removed many barriers to care, many women still experienced barriers to PrEP initiation. Going forward keep supports to decrease drop-off between accepting the prescription and initiating PrEP might include PrEP navigation to provide support during those challenging first days of starting a new medical routine.
4. High prevalence of STI indicates the need for increased access to testing and treatment for WWID. Since a high proportion of infections would have been missed if only genital screening was offered, we recommend multisite STI screening for this population and incentivizing returning for results to increase treatment rates among persons screening positive. Offering regular screening at PPP will likely increase case finding.

Team Accomplishments

- Designed PrEP educational materials tailored to WWID and made these publicly available in English and Spanish.
- Shared findings with Prevention Point Staff at staff meetings, developed this final report, and disseminated scientific findings at conferences and via academic journals including 4 presentations and one manuscript on PrEP initiation that is under its second review.
- Ongoing development of manuscripts including: a methods paper detailing the implementation of the study, a quantitative paper examining predictors of PrEP initiation, a quantitative paper examining retention in care, and a mixed-methods paper examining adherence.

Team members

Team members included: **Dr. Alexis Roth**, Assistant Professor at Drexel's School of Public Health, Principal Investigator. **Dr. Barbara Van Der Pol,** Professor at University of Alabama Birmingham School of Medicine, Co-Investigator. **Dr. Doug Krakower, Dr. K. Rivet Amico, and Dr. Scarlett Bellamy** consulted on the project. **Sam Sitrin** and **Jose Benitez, MSW**, at Prevention Point Philadelphia were champions of this project. Other PPP staff who were instrumental in conducting Project SHE included **Elby Katumkeeryil, Kayla Madden, Blue Lorano, Jade McKnight, Jennie Coleman, Krystal Santiago, and Ms. Terrie Hawkins**. Research assistants to the project were **Brogan Piecara, MPH** and **Marisa Felsher, ABD** who helped design, implement and manage different aspects of the study, and **Brenna Aredas, MPH, Bolutife Odeniyi, and Eliza Ziegler, MPH. Rachel Fox, PA** was Project SHE's physician assistant and additional medical support and oversight was provided by **Dr. Alicia Tucker** and **Dr. Annette Gadegbeku**. Community Research Partners included **Project SAFE, Philadelphia Public Health Laboratory, Philadelphia Department of Disease Control, STD Control Program, Philadelphia FIGHT, and Philadelphia Pharmacy. We'd like to thank the study participants and community advisory board without whom, Project SHE would not have been possible.**

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