



“PrEP just isn’t my priority”: Adherence challenges among women who inject drugs participating in a pre-exposure prophylaxis (PrEP) demonstration project in Philadelphia, PA USA

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ABSTRACT

Pre-exposure prophylaxis (PrEP) has the ability to curb HIV transmission among women if they are highly adherent (e.g. 6/7 weekly doses). In a recent PrEP demonstration project with 95 women who inject drugs (WWID) in Philadelphia, PA, USA, PrEP uptake was high but adherence was low. This qualitative study draws upon the Behavioral Model for Vulnerable Populations (BMVP) to describe how the context of 23 WWID’s lives challenged PrEP adherence using narrative data from in-depth interviews. Content analysis suggests that women’s need to organize their day around predisposing survival needs made it difficult to prioritize PrEP. Adherence was further challenged by dis-enabling structural forces such as entry into institutions that do not provide PrEP (e.g., drug treatment and correctional facilities) and medication diversion to illicit marketplaces. Overtime, women’s perceived need for PrEP was dynamic: in periods they characterized as risky, women considered PrEP highly beneficial and described enhanced motivation to adhere. In periods of low perceived risk, women were less committed to continuing daily PrEP in the context of their competing survival needs. In sum, WWID faced challenges to PrEP adherence that correspond to all of the BMVP domains. To optimize PrEP for WWID, multi-level programs are needed that address the determinants that both increase HIV susceptibility and undermine adherence.

1. Background

In North America, an estimated 2.5 million people have injected drugs in the previous year, 30% (766,000) of whom are women (Degenhardt et al., 2017). While new HIV diagnoses among people who inject drugs (PWID) dropped dramatically from 40% in the 1990s to 6% in 2017 (Centers for Disease Control and Prevention, 2016), injection drug use fueled by the opioid crisis in the United States has been associated with HIV outbreaks in cities and non-urban communities across the country, including Philadelphia where this study takes place (HIV and the Opioid Epidemic, 2018; CDC joins Department of Public Health in investigating HIV cluster among people who inject drugs press

release, 2018; DeMio, 2018; HIV outbreak among homeless people worries health officials, 2018). HIV risk among PWID is increasing along with the surge of illicitly manufactured fentanyl into local drug markets (Frank and Pollack, 2017). Fentanyl is extremely potent (30–50 times more potent than heroin), has rapid onset, and a comparatively short duration of effect as compared to other injected opioids like heroin (Mayer et al., 2018; Somerville et al., 2017). Due to the short duration of its effect, PWID report injecting fentanyl more frequently, increasing the likelihood of HIV exposure through syringe sharing and/or behaviors like commercial sex to procure drugs, which is common among women (Mayer et al., 2018; Somerville et al., 2017; Lambdin et al., 2019; Allen et al., 2020).

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Gendered power inequalities make women who inject drugs (WWID) more vulnerable to HIV than male counterparts (Des Jarlais et al., 2012). Within romantic partnerships, syringe-sharing and condom-use are often perceived as acts of intimacy that demonstrate trust (Shannon et al., 2008; El-Bassel et al., 2010; Amaro, 1995). As a result, women face difficulties negotiating their use within romantic partnerships (Shannon et al., 2008; El-Bassel et al., 2010; Amaro, 1995). WWID also face grave economic insecurity fueled by stigma towards PWID and challenges finding formal employment given the need to inject multiple times daily (Pinkham and Malinowska-Sempruch, 2008). Engagement in commercial sex, a common form of income generation among WWID (Jenness et al., 2011; Rondinelli et al., 2009), is associated with increased risk of traumatic exposures from paying partners, including sexual assault (Shannon et al., 2008; Shannon and Csete, 2010), as well as limited agency to negotiate condom-use (Johnston et al., 2010; Ntumbanzondo et al., 2006; Rao et al., 2003). Taken together, WWID's social and economic marginalization greatly reduces women's autonomy over their HIV risk reduction, highlighting the need for discrete, user-driven HIV prevention options.

Pre-exposure prophylaxis (PrEP) is a user-driven method that effectively reduces HIV risk (Thigpen et al., 2012; Sheth et al., 2016; Choopanya et al., 2013a). PrEP offers several advantages over other HIV prevention strategies for women. Unlike condoms or sterile syringes, women may be able to use PrEP for HIV prevention without their partner's involvement. Additionally, PrEP does not need to be taken at the time of sexual or drug activity for prevention, which may benefit WWID who have little control over when or how sexual or drug encounters occur. One important limitation to PrEP is that for women, adherence to PrEP at the recommended 6–7 pills/weekly is required to achieve prevention-effective drug levels (Thomson et al., 2016). Women participating in PrEP clinical trials experienced challenges with daily adherence due to concerns around product safety, effectiveness and stigma (Corneli et al., 2016; Amico et al., 2017; van der Straten et al., 2014; Velloza et al., 2020; Van Damme et al., 2012). While two randomized control trials of tenofovir disoproxil fumarate (TDF) and tenofovir-emtricitabine (TDF-FTC) as PrEP with high adherence demonstrated efficacy among women and PWID (Thomson et al., 2016; Baeten et al., 2012; Choopanya et al., 2013b), trials of these same drugs did not demonstrate efficacy in other trials among women due to low adherence and were closed for futility (Thomson et al., 2016; Van Damme et al., 2012; Murrain et al., 2015).

Despite PrEP's advantages, WWID have been underrepresented in all phases of PrEP research. This has led to nominal PrEP uptake among WWID (Mera Giler et al., 2017; Glick et al., 2019a; Smith et al., 2018), and as a consequence, little is known about real-world adherence challenges WWID face when taking PrEP (Mera Giler et al., 2017; Glick et al., 2019b). A few studies have explored hypothetical barriers to PrEP adherence among PWID samples that include WWID, and have found that participants perceive many barriers to taking daily PrEP (Allen et al., 2019; Biello et al., 2018; Footer et al., 2019). While these participants were not taking PrEP, they recalled previous challenges taking daily medication to inform their perceptions (Allen et al., 2019; Biello et al., 2018; Footer et al., 2019). The most commonly described barrier related to how competing needs of addiction severity and housing instability would make it difficult to remember to take PrEP daily (Allen et al., 2019; Biello et al., 2018; Footer et al., 2019). Additionally, some PWID expressed concerns that PrEP-use could be interrupted by incarceration, which disconnects individuals from regular sources of medication and social services (Biello et al., 2018). While these studies provide important insight, findings are limited by their use of hypothetical scenarios, which may not reflect barriers WWID face in the real-world. Understanding barriers WWID experienced after accepting a PrEP prescription could help inform implementation research and the development of interventions to promote PrEP adherence in this vulnerable population.

We recently concluded the first community-based PrEP

demonstration project designed for WWID (henceforth called Project Sexual Health Equity [SHE]) (Felsler et al., 2020; Roth et al., 2021). Among 95 women enrolled and educated about PrEP within the syringe services program (SSP), 69/95 initiated PrEP. Despite initial interest, adherence was consistently low, with only 12/69 having detectable levels of Tenofovir in urine at any point over follow-up. Given WWID would benefit from PrEP, and that daily pills remain the only commercially available PrEP formulation in the US, we explored the research question, "How does the context of WWID's lives challenge their ability to adhere to daily PrEP?"

Our approach to addressing this question was guided by the Gelberg-Andersen Behavioral Model for Vulnerable Populations (BMVP) (Gelberg et al., 2000), which was developed to explain why marginalized individuals are disposed to use health services, and to identify factors that enable or inhibit access to care. With its focus on vulnerable populations, BMVP accounts for the context of access to care, along with the social, economic and public policy environments that influence access (Gelberg et al., 2000). The three components to the model are: 1) Predisposing factors that exist prior to an illness that place individuals in a vulnerable position with respect to their ability to receive care, such as substance use and homelessness; 2) Enabling factors that are individual, programmatic and societal supports and barriers to health care access. Together they may be viewed on a continuum, with positive levels of the factor indicating a support and lower, negative levels of a factor indicating a barrier; and 3) Need factors, such as perceived health needs within the population. BMVP has been used extensively to identify the domains that determine healthcare access, including medication adherence, among vulnerable female populations (Gelberg et al., 2000; Victor et al., 2018; Oser et al., 2016; Spori, 2012; Bazargan et al., 2004; Shamburger-Rousseau, 2013; Ackerson and Gretebeck, 2007; Gonzalez et al., 2012; Bazzi et al., 2019; Holtzman et al., 2015; Matthews et al., 2020).

2. Methods

2.1. Participants and setting

Participants in Project SHE were cisgender women, 18 years or older, reported injection drug use within the last 30 days, and qualified for PrEP based on the 2017 Centers for Disease Control and Prevention guidelines (Centers for Disease Control and Prevention, 2017). To be eligible for the present analysis, participants had to be enrolled in Project SHE and accept a PrEP prescription from the study's prescribing provider. Participants were recruited in-person by study staff as participants presented for a follow up visit which occurred 12- and 24-weeks after baseline (hereafter referred to as "first FU" and "second FU"). Participants were sequentially enrolled until saturation, the point in the analysis of data that sampling more data would not lead to more information related to research questions (Mason, 2010), had been reached. Saturation was assessed both in terms of code and meaning saturation (Hennink et al., 2017). Active self-reflection was used to recognize when code saturation had begun: this involved recognizing when during codebook development that no new codes were being added and that the codebook structure had stabilized. This occurred after 18 interviews. However, participants continued to be recruited until a comprehensive understanding of adherence barriers was reached, which speaks to meaning saturation. In total, code and meaning saturation was reached after 23 interviews.

2.2. Data collection

Qualitative data collection occurred between July 2018 and August 2019. Two female interviewers conducted qualitative interviews using a semi-structured guide. Interviews were conducted in a private space at the SSP, were audio recorded using a digital recorder, and lasted 1 h. The guide was designed to explore factors that may impact PrEP adherence,

gleaned from literature of barriers and facilitators to PrEP uptake and adherence among MSM (Young et al., 2014; Smith et al., 2012), PWID (Escudero et al., 2015), and women (Smith et al., 2012; Auerbach et al., 2015), as well as BVMP for theoretical drivers of healthcare utilization. Areas of inquiry and sample questions from the interview-guide are presented in Table 1. Following the interview, participants received a \$20 cash incentive. Participants provided written informed consent during their baseline visit, and the protocol was approved by the institutional review boards at Drexel University and Prevention Point Philadelphia.

2.3. Data analysis

Audio recordings were transcribed verbatim, anonymized, and managed using NVivo (Bazeley and Jackson, 2013). Content analysis was used to identify themes regarding barriers to PrEP adherence (Erlingsson and Brysiewicz, 2017). The objective of content analysis is to systematically transform large amounts of text into a highly organized summary of key results (Erlingsson and Brysiewicz, 2017). The analysis of the first interview formed the basis of an evolving coding system and provided direction for exploration in future interviews. This recursive and cyclical coding allowed for concurrent data collection and analysis. First, a-priori codes corresponding to BMVP domains in the interview guides were developed for the first codebook iteration. Transcripts were read to gain an understanding of how participants experienced adhering (or not) to PrEP. Codes reflecting unanticipated themes from interviews were added to the codebook. Codes that related to the same issue were sorted into categories. One of the final stages of content analysis is to identify connections among the categories, or themes. At this stage, we used BMVP to organize and frame major themes. Data analysis ended once new themes failed to emerge and it was concluded that saturation was reached. We present below major themes that emerged from our data, organized using BMVP. Quotations are identified using participants' self-selected pseudonyms and adherence levels via urinalysis at first and second FU visits.

Table 1
Interview guide areas of inquiry for in-depth interviews.

BMVP Construct	Domain	Exemplar interview question	Follow Up
<i>Predisposing Factors</i>	Substance use disorder	Tell me a little bit about what your daily drug use looks like	
	Housing	Please describe your housing situation	Are there any ways that your housing impacts your ability to take PrEP everyday?
<i>Enabling Factors</i>	Exploration of barriers	Describe any situations where you missed taking some of your PrEP pills	
	Medication Diversion	We have heard that some participants are approached by pharmacies to sell their prescription. Can you tell me why you think this may be happening?	
<i>Need Factors</i>	HIV Risk	How vulnerable do you think you are to HIV?	<i>If little risk:</i> What are the things you do to keep yourself at low risk for HIV? <i>If risk is perceived:</i> Tell me about what puts you at risk for HIV
	Perceived need for PrEP	Can you talk to me about why you accepted a PrEP prescription?	

3. Results

3.1. Predisposing factors: the context of women's daily survival needs took precedence over taking daily PrEP

To understand participants' PrEP adherence, it is necessary to first examine the context of participants' daily lives, particularly the role of predisposing factors. The main organizing force of women's day-to-day lives was the need to meet basic survival needs stemming from the intersection of opioid use disorder, economic insecurity, and housing instability. Participants injected fentanyl on average 4.6 times every day to stave off painful opioid withdrawal symptoms (see Table 2): *You're only high for a short period. You're sick again in literally 3 h and you have to use again. You have to keep buying more [drugs]. It's a very expensive and time-consuming habit* (Farrah, nonadherent at first and second FU). How women would acquire money to maintain their opioid habit was a constant concern, given that most earned less than \$10,000/year: *Everyday, everyone out here pretty much is worried about getting their next dollar to get well or to get high. I have been out for days with no money, being like, 'Oh my god where is my next dollar coming from'* (Sunday, non-adherent at first FU and lost to follow up at second FU)? Intertwined with opioid use disorder and economic insecurity was housing instability, which was experienced by 16/23 participants. Homeless women commonly described avoiding sleep as much as possible: *A lot of us girls on the street, we are up for so many days because we are afraid to sleep*

Table 2
Socio-demographics and PrEP adherence among qualitative subset (n = 23).

	Qualitative Subset (N = 23) N(%)
Age mean (±std)	36.1 (±7.4)
Income	
\$0–4,999	10 (43.5)
\$5,000–9,999	4 (17.4)
≥\$10,000	9 (39.1)
Insurance Type	
Public Insurance	21 (91.2)
Private Insurance	1 (4.4)
No insurance	1 (4.4)
Race	
NH White	16 (69.6)
NH Black	3 (13.0)
NH Other Race ^a	0 (0.0)
Hispanic Ethnicity	4 (17.4)
Currently Homeless	16 (69.6)
Spends most time in SEP neighborhood	17 (73.9)
10 or more arrests in lifetime	11 (47.8)
Daily injection drug use ^b	17 (73.9)
Mean number of injections per day (±std)	4.6 (3.1)
Inconsistent condom use ^b	17 (73.9)
Transactional sex ^b	15 (65.2)
Self-perceived HIV risk very/extremely likely	11 (47.8)
PrEP Adherence	
12 Week Self-Report	N = 23
Non-adherent	4 (17.4)
Inconsistent	7 (30.4)
Adherent	12 (52.2)
12 Week Urinalysis	N = 18 ^c
Non-adherent	13 (72.2)
Inconsistent	4 (22.2)
Adherent	1 (5.6)
24 Week Self-Report	N = 18
Non-adherent	5 (27.7)
Inconsistent	7 (40.0)
Adherent	6 (33.3)
24-Week Urinalysis	N = 12 ^d
Non-adherent	10 (83.4)
Inconsistent	1 (8.3)
Adherent	1 (8.3)

^a Includes Asian, Pacific Islander, Native Hawaiian, and mixed race.
^b Within last 6 months.
^c Does not add to 23 due to missing urinalysis data.
^d Does not add to 18 due to missing urinalysis data.

because it is so common that men attack you in your sleep. You even gotta protect yourself in your sleep (B, nonadherent at first and second FU). Women also had to be on constant high alert to protect personal belongings, which many carried with them at all times to prevent them from being stolen: *Everything I own I lug around from place to place. I get scared because stuff gets stolen all the time. It's happened twice in this past week. All my stuff is gone* (Adrianna, inconsistent adherence at first FU, nonadherent at second FU).

By positioning PrEP in the wider context of women's daily lives and survival needs, it is possible to identify the predisposing factors that challenged their ability to prioritize daily PrEP:

I don't think it was my first priority to take [PrEP] on a daily basis. I'm a dope fiend, so my priority is to get dope ... Living while homeless in an active addiction—especially as a woman—PrEP just isn't my priority. My priority is to get well. My second is to get my ass washed. My last thought is PrEP (Sunday, not-adherent at first FU and lost to follow up at second FU).

Because PrEP ranked relatively low compared to other basic needs, women had trouble remembering to take it every day:

It just always skips my mind [to take PrEP] ... I wake up and gotta get my morning bag, then I'm out there trickin', then I'm looking for a cup of coffee. Do you get it? I just forget about it. There's just never time to get my thoughts together to remember about PrEP (Prepper, inconsistent adherence at first FU, lost to follow up at second FU)

Additionally, women who did not have stable housing often described how the lack of safe pill storage led to pills being lost or stolen:

Being homeless makes [taking PrEP] harder cuz everything keeps getting stolen ... it's not like I live in an apartment and can just put it in my medicine cabinet ... I gotta hide stuff. I had my bag where all my clothes were, and the [PrEP] pills were, because I try not to carry around a lot of stuff on me. I went back there the one night and my stuff was thrown all over the place. It was like somebody dumped them out and they were all over the ground (Tina, not-adherent at first FU, lost to follow up at second FU)

As points of comparison to living on the street, living in homeless shelters or their own apartments offered women safer and more reliable storage for pills, which facilitated more consistent PrEP use. For example, one participant who adhered to PrEP based on urinalysis attributes her adherence to her ability to safely store PrEP within her own apartment:

I have a better [adherence] outcome cuz I have a home ... If I put [PrEP] down it's gonna be there. If you're livin' on the street, you sit your bag down on the ground, somebody runs off with it, or you forget it, or you just can't carry it (Sprinkles, adherent at first FU, missing adherence data at second FU).

Three participants transitioned from living on the streets to living in homeless shelters over the course of the study. The increased security of living in a shelter freed up time to remember to take PrEP:

[Taking PrEP] is easier now in the shelter because I'm less stressed. I have more of a daily routine. I'm not running around worrying about where I'm gonna sleep. The last thing I was worried about was taking a pill everyday ... so I really wasn't taking it that much until I got to the shelter, then I was taking it more (JJ, nonadherent at first FU, inconsistent adherence at second FU)

Another critical predisposing factor was women's low medication-taking self-efficacy. Women commonly used words like "irresponsible" and "forgetful" to describe themselves. Many attributed low PrEP adherence to the belief that PWID are generally unable to commit to daily responsibilities, such as taking daily medication: *You know, people*

like drug addicts, we aren't good at doing things on a consistent basis more or less. So I can't say that I'm gonna take a pill every day even if it's gonna save my life (Farrah, nonadherent at first and second FU). Similarly: *Unfortunately I'm just not responsible enough to wake up every morning to take a pill. You think it is the easiest thing to do. It's like brushing your teeth, right? But I just can't do it* (Bizz, nonadherent at first and second FU). Taken together, women's low self-efficacy and their need to prioritize daily survival challenged participants' ability to take daily PrEP. While many attributed their lack of PrEP adherence to being irresponsible, their narratives reveal that they are highly motivated and responsible for attending to their daily survival needs. However, the challenges of daily survival made prioritizing daily PrEP nearly impossible.

Enabling Factors: Structural Factors Challenged PrEP Adherence.

Adherence was also impacted by structural dis-enabling forces, such as the black market for prescription drugs as well as participation in institutions (e.g., drug treatment or carceral facilities) that do not support PrEP continuation. First, women's dire economic situation was exploited by predatory pharmacies who were willing to purchase PrEP, a medication worth \$2,000 a month at the time of the study (Luthra and Gorman, 2018), for a fraction of that cost. PrEP diversion became a viable and relatively safe income generating activity: *Kensington is a big drug market. [Selling prescriptions] is just another way for someone to make money* (Bizz, nonadherent at first and second FU). It was rumored by multiple participants that women frequently sold their paper PrEP prescription to local pharmacies: *I feel like a rat for telling you guys this ... There is a pharmacy offering like \$100 if we brought the script to them, not the pills, but the script. So instead of getting the PrEP medication, they're selling the prescription to them* (Tina, nonadherent at first FU, lost to follow up by second FU). The sale of prescriptions to pharmacies was not unique to PrEP; participants reported pharmacies purchased a variety of high-demand medical technologies: *[Pharmacies] are buying everything. Like, Latuda—a once-a-day medication for bi-polar. They're buying it for \$1500 bucks ... You can sell diabetic test strips, a whole bunch of stuff ... I know like four pharmacies that do it* (Mel, nonadherent at first and second FU). Due to the weight of their need to generate income for daily survival, selling PrEP prescriptions outweighed the value of taking PrEP for some women: *People in the study sell their PrEP meds to pharmacies all the time because ... they need that money right now. Medicine doesn't help you right now* (Kate, nonadherent at first and second FU).

Further, participants described a total lack of support for PrEP continuation from institutions they chose (e.g., drug treatment) or were forced (e.g., jail) to participate in. Some women described that these institutions refused to provide them with PrEP because of the facility's policies:

I wanted to take [PrEP] when I was in jail, and they wouldn't give it to me because they said I didn't have [HIV] ... I woulda took it. But they said that it's an expensive medication. And if I don't have [HIV], then the jail didn't want to cover it. And I told them that I was in a study, and it—that wasn't good enough (Mama, nonadherent at first and second FU)

Other women described challenges remembering to bring their PrEP pills as they moved between the community and in-patient opioid treatment centers:

[I was taking PrEP] maybe a couple weeks, and then I missed a little bit because I was in [New] Jersey for about a month for [inpatient drug treatment] and didn't bring my PrEP ... And then I came back and I started taking [PrEP] again and once again I went out to Jersey to kick the habit and then I started to get high again ... But that's why there were times when I would miss it and then I would get back on it (Little, inconsistent first and second FU).

Predisposing factors within the context of women's daily lives, such as poverty and addiction, directly challenged their ability to adhere to PrEP. However, this context also made them vulnerable to dis-enabling factors in the form of structural obstacles that further challenged daily

adherence.

Need Factors: Women's Perceived Need for PrEP Fluctuated with their Drug Use and HIV Risk Perception.

In BMVP, perceived health needs often determine whether or not individuals engage in care. In the context of our study, participants' perception of their need for PrEP was complex and dynamic, changing greatly over time, which influenced adherence. Because of the longitudinal nature of the study, we observed many transitions in women's lives, including going from periods of drug use to abstinence. When women were in periods of active drug use, their need to generate income corresponded to engaging in behavior that elevated their HIV risk, such as engaging in transactional sex: *If I got no money to get no dope ... I'm gonna look out for a [transactional sex client]. I've had 3, 4, 5, [clients] in a day ... It is exhausting* (Kate, nonadherent at first and second FU). Within the intersection of poverty and transactional sex, some women were unable to negotiate condom use:

I've slept with a couple guys without [condoms] ... Shit happens and sometimes you're desperate ... It's not that you want to do it ... it's just—When you're sick, you're sick. And the money sounds right. But then after you are like, 'What did I do?' (Anonymous, nonadherent at first FU, lost to follow-up second FU)

Participants who were experiencing periods of high perceived risk were more motivated to take PrEP consistently. For example, one participant described that a recent sexual assault while engaging in transactional sex heightened her perceived HIV risk and made her increase her PrEP use: *I was taking [PrEP] on and off but now I don't plan on ever stopping PrEP. As long as there's HIV out here, and there's asshole mother fuckers that do what they did to me, I will always take it* (JJ, nonadherent at first FU, inconsistent at second FU). Similarly, the only two participants who adhered to PrEP discussed still feeling at consistently high risk for HIV: *I know I should take [PrEP]. I think it's a very good idea. I still see this one [transactional sex client], and I use condoms, but the condom could break. I just think it's safe if I just stay on the [PrEP] medication as much as I can* (Sprinkles, adherent at first FU, missing adherence data at second FU).

When women stopped using drugs over the course of the study, their perceived need for PrEP often decreased:

I stopped taking PrEP cuz I stopped doing drugs. When I stopped doing drugs, I didn't feel like I had to have sex for money or anything like that. Getting on suboxone changed my risk. I'm not doing drugs. I'm not going out chasing the drugs, not caring what I'm doing. I'm actually caring what I'm doing now (Gem, inconsistent at first FU, nonadherent second FU).

Similarly: *I actually ran out [of PrEP] when I was in rehab. But even if I hadn't, I woulda stopped taking them because at that point I'm thinking with a clear mind, 'I'm healthy now. I'm not putting myself at risk. Why take this pill everyday?'* (Sunday, nonadherent at first FU, loss to follow up second FU). Awareness of how HIV risk fluctuates lead to some participants stockpiling PrEP to use during future periods of HIV risk:

I started [PrEP] at first but then decided I was gonna start saving them to have a supply for when I felt more at risk. I wanted to have my stash for if I were to become more in my habit and I were in the street, whatever the case may be. So that I had them when I become at risk [for HIV] (Anonymous, inconsistent at first FU, nonadherent at second FU)

Women's perceptions of their HIV risk were complex and fluctuated with periods of drug use and abstinence. The dynamic nature of perceived HIV risk and subsequent perceived need for PrEP made it difficult for women to remain motivated to take daily HIV prevention medication.

4. Discussion

Drawing from the first PrEP demonstration study for WWID, we utilized BMVP to explore how the context of women's lives challenged adherence to daily PrEP. Most participants in this sample were living in a state of grave economic insecurity and were homeless. Having nowhere safe to sleep or store medications, both predisposing factors, impeded adherence in two ways: first, it increased social and physical vulnerability which led to a state of near constant stress which challenged their ability to prioritize PrEP. Second, it made them susceptible to schemes to quickly generate income such as selling PrEP prescriptions to predatory pharmacies for a nominal fee, a form of prescription drug diversion. One lesson that clearly emerged from our data is the need to address the syndemic nature of women's HIV risk that also challenged adherence.

Women's medication-taking self-efficacy also emerged as a barrier to PrEP adherence. Self-efficacy is a construct derived from Bandura's social-cognitive theory that considers individuals' perceptions of their own capabilities as playing a key role in behavior change (Bandura, 1989). The importance of medication-taking self-efficacy for adherence is supported by vast literature (Bazzi et al., 2019; Strecher et al., 1986; Hyde et al., 2008; Mize et al., 2002; Li et al., 2017; Waldrop-Valverde et al., 2013). For example, in their study of people who use drugs in Florida, Waldrop-Valverde et al. (2014) reported that self-efficacy for taking antiretroviral therapy (ART) was significantly predictive of dose adherence and number of days adherent over a 6-month follow up period (Waldrop-Valverde et al., 2013). In our study, self-efficacy may have been conditioned by internalized stigma, which involves endorsing negative beliefs associated with socially devalued characteristics, such as history of substance use, and applying them to the self (Earnshaw et al., 2015). This was evinced by participants' negative descriptions of PWID (e.g. as being irresponsible) as explanations for low adherence. The relationship between internalized stigma and medication-taking self-efficacy, and their combined affect on medication adherence, has been described by others (Turan et al., 1999). It is important to note that we did not explicitly measure stigma, but found internalized stigma emerged from the data. Given the literature that describes how other stigma mechanisms, such as anticipated and experienced stigma (Earnshaw et al., 2013), also negatively impact PrEP use (Velloza et al., 2020; Calabrese and Underhill, 2015), an area for future research is how various sources and intersections of stigma, as well as self-efficacy, influence PrEP adherence among WWID.

Our data suggest there is an active street market for PrEP involving patients and pharmacies, which emerged as a barrier to adherence. Our study is not the first to document the diversion of ART to illicit marketplaces in exchange for money (Surratt et al., 2013; Buttram, 2018; Kurtz and Buttram, 2016; Kurtz et al., 2014; Kuo et al., 2020; Associated Press, 1995; Surratt and Kurtz, 2013). However, ours is the first that we know of to uncover diversion of PrEP prescribed to PWID. Participants in our study described diversion occurring with local pharmacies in a medication fraud schema previously described by Inciardi et al. (2007) (Inciardi et al., 2007). Namely, patients fill their prescriptions through Medicaid at local "mom and pop" pharmacies, then sell the medication back to the pharmacy for a fraction of the retail value. The medication is then resold by the pharmacy for profit or full Medicaid reimbursement (Inciardi et al., 2007). A dearth of regulation in pharmaceutical pricing and patent laws has resulted in the high cost of ART, making them highly profitable in the illicit marketplace (Lieberman et al., 2020). Small independent pharmacies may participate in diversion to stay competitive in a market dominated by large-chain pharmacies (Boseley and Carroll, 2002). While WWID may participate in medication diversion due to economic hardship, the patient is almost always lowest on the diversion chain, benefitting the least financially (Inciardi et al., 2007). Women in our study reported receiving \$100-\$200 for their prescription while this medication carried a list price of up to \$2000 at the time of our study (Luthra and Gorman, 2018). While clinicians should be aware of the market for PrEP, and the potential for such

markets to challenge adherence, care must be taken not to restrict patients' supplies, such as under-prescribing PrEP to PWID out of fear of medication diversion, which has been found in other studies (Kuo et al., 2020; Campbell et al., 2018).

WWID in this sample (and in other studies (Sawyer and Wagner, 2020; National Institute on Drug Abuse, 2018; Substance Abuse and Mental Health Services Administration, 2019)) had frequent contact with criminal justice and drug treatment systems, neither of which were reported to support PrEP continuation. With the case of incarceration, the Medicaid Inmate Exclusion Policy forces most detainees off the Medicaid roles at entry (Department of Health & Human Services, 2016). This policy has been shown to lead to long-lasting Medicaid coverage gaps after reentry (Mallik-Kane and Visser, 2008) and decreased rates of filling prescriptions (Banerjee et al., 2010). While people retain insurance coverage when receiving inpatient drug treatment, PrEP-use may be interrupted by policies requiring preapproval of outside medications (Vertava Health, 2021), and substance use treatment providers may be less likely to prescribe PrEP to patients due to providers' low PrEP awareness and concerns about costs necessary to prescribe and monitor PrEP use (Biello et al., 2018; Spector et al., 2015). Therefore, guidance and policy are needed to ensure continuity of PrEP care on entry and exit from custodial settings.

Finally, PrEP adherence was influenced by fluctuations in perceived HIV risk and subsequent need for PrEP. When participants felt at risk for HIV, they were motivated to take PrEP, though they still struggled to adhere given predisposing and dis-enabling factors. When women perceived they were at low risk for acquiring HIV, such as during periods of abstinence from drug use, they discontinued PrEP. Others have cited this phenomena as seasons of risk (Elsesser et al., 2016). Although women's HIV risk may be objectively lower during periods of abstinence, PWID risk relapse, making PrEP persistence important for long-term harm reduction. Additionally, individuals interested in re-starting PrEP during periods of high perceived HIV risk will need to be supported by staff who know how to safely re-start individuals on PrEP, which may include getting re-tested for HIV to ensure they remain PrEP-eligible.

BMVP provided a valuable framework for identifying predisposing, enabling, and need-related factors that challenged adherence. Utilizing all three components of the theory was critical for identifying how factors directly contributed to non-adherence, as well as understanding bidirectional processes through which predisposing factors heightened vulnerability to enabling factors, and outweighed motivations to adhere during periods of perceived need. There are three conceptual points related to BMVP to be noted. First, although we used the established categories of BMVP and grouped substance use under predisposing factors, a social construction perspective to substance use would maintain that the negative impact of drug use on medication adherence is shaped by judgmental and punitive social policies and practices (Hansen et al., 2014; Pickard et al., 2018) and are not individual predisposing characteristics. For example, people with substance use disorder who have more social capital most likely would not experience the same adherence challenges that result from being homeless. Therefore, from a social construction perspective, characteristics related to substance use would be categorized under enabling domains, which we recommend researchers consider in future work guided by BMVP. Second, the concept of self-efficacy is considered a predisposing factor. While participants in this study explicitly discussed self-efficacy as it relates to their ability to take daily medication, it is possible to interpret that self-efficacy, and more broadly "power," permeate all BMVP components: For example, within enabling factors, women lacked power in accessing PrEP while incarcerated, despite requesting it. Related to need, economic insecurity challenged their ability to negotiate condom use with paying partners, which increased their perceived need for PrEP. Despite this, the myriad of competing needs left many powerless to adhere. Therefore, interventions seeking to improve PrEP adherence among vulnerable women will need to address power. While we believe

BMVP allowed us to identify these power constructs because it is a model for vulnerable populations and often applied to women, other theories that explicitly measure these constructs, such as Theory of Gender and Power (Wingood and DiClemente, 2000), could be a complementary model for future research. Lastly, individuals' perceptions of their HIV risk and subsequent need for PrEP fluctuated over the course of the study, suggesting that the "need" BMVP component would benefit from measures that capture the nuance of how perceptions of risk change over time.

Study findings must be interpreted within the limitations of the design of a small, exploratory, qualitative study. Participants in this study were recruited during participation in a longitudinal demonstration project at an established SSP, so they represent a group of WWID who were retained long enough to initiate PrEP and be recruited for an interview. WWID who were lost to follow-up may have different perceptions about PrEP and face a different set of challenges to adherence. This also suggests that findings can only be interpreted as adherence challenges when PrEP is offered at an SSP, as opposed to other medical settings. Given that our Project SHE demonstration study (Roth et al., 2021), as well as others (Walters et al., 2017, 2020), have identified the role SSPs can play in increasing access to PrEP for PWID, implementation science research is needed to identify the resources SSPs will need to scale up PrEP prescription and adherence support. Lastly, adherence was categorized based on tenofovir urinalysis results, which only report on past 48-h adherence. This may be an insufficient recall period to understand true adherence patterns. Future studies should include specimen with a longer lookback such as dried blood spots or hair.

Despite these limitations, findings have multiple implications for practice and policy. Women's unstable lives made it difficult for them to prioritize taking daily PrEP and vulnerable to predatory pharmacies. Structural and/or financial interventions, such as permanent supportive housing and income assistance via contingency management would be novel interventions that support women establish routines and decreases their need to divert to illegal marketplaces for income generation. For example, Housing First, an approach that offers low-barrier housing and case management services to PWID (Pathways to Housing PA, 2018), has been associated with improved adherence to a variety of medications for participants (Pathways to Housing PA, 2018; Rezanoff et al., 2017; Hawk and Davis, 2012) and could also improve PrEP adherence. Additionally, offering storage lockers for WWID to safeguard medication and other personal belongings may also be a quick solution to improve sense of security and decrease loss of medication. Strategies to improve access to PrEP while in carceral or inpatient drug treatment programs could include staff education about PrEP and advocacy around ending Medicaid Inmate Exclusion Policy to allow for federal Medicaid funds to pay for preventative care during incarceration. Related to women's struggles with prioritizing daily PrEP, continuing PrEP while incarcerated or in substance treatment, and dynamic perceived need for PrEP, having long-acting forms of PrEP available to WWID that confer longer periods of HIV prevention also removes the challenge of remembering to take daily medication or persisting on it while in incarceration or drug treatment settings. Clinical studies are assessing efficacy of once-monthly oral PrEP (Medicine NUSNLo, 2020), subdermal implants (Matthews et al., 2019) and injectables (Landovitz et al., 2020), and studies show that these forms of PrEP are acceptable among PWID (Shrestha et al., 2019; Biello et al., 2019; Beymer et al., 2019). Providing multiple PrEP modality options and supporting women as they decide which modality best responds to their real-world adherence challenges may improve PrEP adherence and decrease HIV transmission among this vulnerable population (Bailey et al., 2017).

Taken together, findings from this analysis present some of the first data to examine PrEP adherence among WWID enrolled in a demonstration project. We found that women face multi-level challenges to PrEP adherence. WWID struggled daily to survive in the context of poverty, housing instability and opiate addiction, which made it nearly impossible to take daily PrEP. Assisting WWID with basic needs (safety

and security in housing and related resources), consistent access to PrEP in jails and drug treatment programs and offering alternatives to daily oral PrEP are potential strategies to optimize HIV prevention through PrEP in this vulnerable population.

Author statement

Marisa Felsher: conceptualisation, Methodology, Software, Formal analysis, Data curation, Investigation, writing (original draft), writing (review and editing), Project administration; Eliza Ziegler: Methodology, Formal analysis, Data curation, writing (original draft), writing (review and editing); K. Rivet Amico: writing (original draft); Adam Carrico: writing (original draft); Jennie Coleman: writing (original draft); Alexis Roth: conceptualisation, Methodology, Formal analysis, Investigation, Resources, Data curation, writing (original draft), writing (review and editing), Supervision, Project administration, funding acquisition.

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