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Exploring new and existing PrEP modalities among female sex workers and women who inject drugs in a U.S. city

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Abstract

This study explored the attitudes and preferences of female sex workers (FSW) (n=12) and women who inject drugs (WWID) (n=16) to existing (e.g., pill) and new (e.g., injection, implant) Pre-Exposure Prophylaxis (PrEP) modalities, in Baltimore, Maryland, USA. This study reports on seven focus groups conducted between December 2016 and April 2017. Results found participant familiarity with existing delivery methods (i.e., pill) can shape initial preferences, suggesting that clinician education on new modalities should draw upon other medications as points of comparison (e.g., contraceptive implant). Effect duration of the injectable and implant modalities emerged as a key positive attribute, particularly in the context of women's broader structural vulnerability (e.g., homelessness). Potential barriers to uptake of new product types included agency (e.g., control around side effects) and perceptibility issues, including awareness of the user and third parties. The study revealed a tension between the desire for self-regulation of medical regimens versus the realities of participant's day-to-day instabilities, which pointed to the potential benefits of long-acting PrEP delivery methods among underserved at-risk populations. Clinician education and structural interventions that provide an enabling environment for uptake and adherence emerged as key to the future success of PrEP across all modalities among these vulnerable populations.

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Keywords

HIV; female sex workers; female injection drug users; PrEP; delivery systems

Introduction

Understanding the HIV epidemic among women and removing barriers to harm reduction approaches requires greater understanding of the role of sex work and drug use within this population. In the U.S., numbers of newly diagnosed HIV cases among women have declined, yet women still made up 19% of newly diagnosed cases (7,402 of the 39,513) in 2015. Overall 86% of HIV cases among women were attributed to heterosexual sex, and 13% were attributed to injection drug use(Auerbach, Kinsky, Brown, & Charles, 2015). A national behavioral HIV analysis of high-risk heterosexual women (N=4,722) found 18% of women traded sex and that HIV prevalence was 4.1% compared to 2.5% among non-traders(Brantley, Footer, Lim, Kerrigan, & Sherman, 2017). Parenteral exposure (i.e., frequency of multi-person needle sharing) is not the only driver of HIV acquisition amongst people who inject drugs (PWID) (Celentano, Latimore, & Mehta, 2008). Research has emphasized the role of sexual transmission through unprotected sex in facilitating HIV amongst PWID, including women who inject drugs (WWID) (N. El-Bassel, Witte, Wada, Gilbert, & Wallace, 2001; Spittal et al., 2002; Strathdee & Sherman, 2003). With elevated HIV risk amongst these overlapping populations, FSW and WWID should be high priority for pre-exposure prophylaxis (PrEP) in the U.S. The CDC estimate that 468,000 women are PrEP eligible (Aaron & Cohan, 2013), yet a 2014 study of at-risk women from six U.S. cities reported PrEP awareness below 10% (Auerbach et al., 2015). Studies in other contexts suggest a strong interest in PrEP among both WWID (Bazzi, Yotebieng, Agot, Rota, & Syvertsen, 2017; Eisingerich et al., 2012) and FSW (Reza-Paul et al., 2016). Amongst high risk populations of women, barriers to PrEP acceptability and adherence can include individual (e.g., risk perceptions), interpersonal (e.g., partner support), and structural factors (e.g., stigma) (Auerbach et al., 2015; Baral, Strömdahl, & Beyrer, 2012; Callahan et al., 2015; Van Damme et al., 2012).

To date, data on acceptability of parenteral PrEP (i.e., injectable, implant) among at risk populations is largely absent globally, including in the U.S. A multi-country study looking at the acceptability of PrEP among a number of user groups (including PWID) found route of administration as the most important attribute(Eisingerich et al., 2012). Long-lasting alternatives to oral PrEP are hypothesized to potentially reduce users' likelihood of sharing, selling, or forgetting to take PrEP (Eisingerich et al., 2012). The current development of long-acting forms of PrEP offers a potentially exciting advancement in the field of HIV prevention, particularly for those who face challenges around an oral daily regimen.

In this study of FSW and WWID from Baltimore City, Maryland, USA we explored knowledge and PrEP awareness, alongside participants' attitudes and preferences towards three different PrEP delivery methods (i.e., PrEP pill, PrEP implant, PrEP injection). We aimed to better understand the acceptability and feasibility of adherence around different product types among these similar yet distinct populations.

Methodology

Setting

Data was collected in Baltimore City, Maryland, U.S. where street-based sex work and injecting drug use are prevalent. Street-based sex work is frequently characterized in this setting by co-occurring structural risks (e.g., homelessness, violence, poverty)(Decker, Pearson, Illangasekare, Clark, & Sherman, 2013; Kurtz, Surratt, Kiley, & Inciardi, 2005). WWID share similar vulnerabilities as FSW in the city, given women's frequent reliance on sex work to support injection drug use(Latkin et al., 1994; Tobin, Kuramoto, Davey-Rothwell, & Latkin, 2011). Despite this convergence, it was decided to conduct separate focus groups to better unpack the role of distinct risk factors for each population.

Population

The study sample was recruited through distribution of recruitment cards from two sources in Baltimore City. The first was an ongoing cohort study of street-based FSW (the SAPPHIRE Study) and second was the City Health Department's needle exchange program (NEP). For the FSW participants, women were eligible if they were aged over 15 years, HIV negative, sold or traded oral, vaginal or anal sex for money, for things like food, drugs, or favors and picked up clients on the street or a public place in the past three months. The SAPPHIRE Study was an observational study and although women received social service referrals, they were not specifically provided with PrEP information. For WWID, women had to be aged over 18 years, reported injecting drugs and sexual activity in the last 6 months and be HIV-negative. The WWID group were not asked about participation in sex work. Eligible participants who provided informed consent completed a demographic and risk behavior survey and participated in a 45–90 minute audio recorded focus group session. Groups ranged in size from 3–7 participants. Focus groups were held in community-based organizations and facilitated by 2–3 trained staff. All participants received a $45 Visa gift card. Ethical approval was obtained from the Johns Hopkins Bloomberg School of Public Health Institutional Review Board.

Focus group procedures and format

Prior to the focus group, participants completed a demographic and risk behavior questionnaire. Participants were guided through a power-point presentation accompanied by videos and handouts on the different PrEP products that would be the subject of the session: the Truvada pill, a PrEP injection (in development) and a PrEP implant (in development). The presentation included information on dosage, frequency, mode of administration and side-effects. The focus group guide elicited participants' HIV risk perceptions and HIV prevention practices, basic awareness and understanding of PrEP, as well as exploring participants' likes and dislikes around different delivery methods (e.g., side effects, frequency of dosing, perceptibility).

Analysis

Transcribed focus groups and notes were reviewed by the research team (KF, SS, SG) to develop a provisional codebook. Analysis was both inductive and deductive, with first-level

codes drawn from the interview guide, but with addition and refinement based off emergent codes observed in the text (Fereday & Muir-Cochrane, 2006). The final codebook was applied across focus groups using Microsoft Word macros, a computer-assisted method for text analysis, whereby text is coded in Microsoft Word and exported to excel for higher order analysis and memo writing (La Pelle, 2004). Final codes were analyzed by the research team for recurrent and emergent themes, and memos were used to highlight contradictions and patterns across focus groups. The current analysis focuses on FSW and WWID attitudes and opinions towards three types of PrEP delivery method (i.e., pill, injectable, implant) and correspond to existing and emergent categories.

Results

A total of 28 women participated in the focus groups (n=12 FSW and n=16 WWID). Demographic characteristics of focus group participants are shown in Table I. Awareness of PrEP was low amongst both groups, with 80% of FSW never having heard of PrEP compared to 69% of WWID. Key findings from this study were that participants: (1) recognized the importance of harm reduction strategies (e.g., sexual health) and the benefits of PrEP, despite engaging in high risk practices; (2) considered competing factors with respect to perceived convenience and ease of use of different PrEP products; (3) had distinct ideas about how new PrEP routes of delivery might affect uptake (e.g., agency around side effects and perceptibility issues distinct to FSW and WWID); (4) identified socio-structural obstacles as barriers to uptake and adherence and (5) explored structural level intervention components that could shift the burden from the individual in order to support PrEP uptake and adherence, irrespective of product type.

> *HIV Risk Perceptions and Sexual Health* - "You're always scared of getting it [HIV] you know?" *(FG 3, WWID)*

Across FSWs and WWID, knowledge of PrEP was very low. Women were concerned about the risks of HIV due either to personal experiences of risk (e.g., condomless sex) or having family or friends who had contracted HIV. For FSW, risk from clients who did not want to use condoms represented one of the major occupational challenges. As this group explained:

> Participant 1: I have had them [clients] refuse [condoms]
>
> Participant 2: Some try to be sneaky
>
> Participant 3: (Pulls off condom gesture) They try to pull them off and I'm like "uh"
>
> Participant 1: So extra protections
>
> Participant 2: If they [the clients] don't have them [condoms], I always like to have a female condom.
>
> (FG 5, FSWs)

For WWID there was less focus on the sexual risks of HIV. Some women mentioned that sex wasn't a high priority in their lives. As these women discussed:

> Participant 1: Most of the time, us, we ain't having sex, sex is the last thing on our mind.

> Participant 2: It wasn't like – it wasn't a lot of sexual activity going on - basically almost none.
>
> (FG 2, WWID)

The majority of WWID considered themselves in serious relationships and therefore less concerned about condom use with intimate partners. Instead WWID considered the greatest risk to be associated with unsafe injection practices, and discussed harm reduction strategies they adopted to minimize risk.

All groups spoke of receiving regular HIV testing through clinics (including City Health Department mobile clinics) or other outreach and were interested in PrEP as an additional form of HIV protection. In particular, women recognized that there were often constraints on their ability to minimize risk. As one participant put it:

> Participant 2: There's a lot of girls … I mean we try to use condoms, but there's times you just don't. *(FG 7, FSW)*

Barriers and facilitators to acceptability/uptake and hypothetical adherence— A number of potential product attributes that could act as barriers or facilitators to PrEP product uptake, acceptability and adherence were pre-identified by the research team and explored through the structured format of the focus group guide.

> *Perceived ease of use and convenience* - "It's like if it ain't convenient for them [WWID], and your life ain't that important when you're high, you're not going to take it [PrEP pill]." *(FG 4, FSW)*

Overall, all women used birth control or other drug regimens (e.g., medications for mental health) as their point of comparison when talking about a daily pill regimen. In particular, women with existing pill regimens felt that adding an additional pill would be the most convenient for them. However, both groups recognized that for less stable women, in particular women getting high or with no permanent place to stay, a daily pill regimen could be challenging. As this focus group participant explained:

> Participant 3: I mean the pill's hard – having to remember to take it every day. We're on the street. I don't have stable living environment. It's hard for me. I lose stuff all the time, and I have stuff stolen or things happen to my stuff. It would just be hard for me in the environment to take a pill every day.
>
> (FG 7, FSW)

For these reasons the longer lasting delivery methods (i.e., injection or implant) offered a greater level of convenience and ease of use, simply in terms of not having to worry about daily adherence. As this focus group discussed:

> Participant 1: I like this [injection] better because you don't have to take it every day. Like my birth control, I feel like this is easier, it is constantly there. I don't take the chance of not remembering.
>
> Participant 4: I feel the same. The ones you stick in are better because you don't have to worry about taking it every day.

Participant 3: I had the birth control rod too, so I think that would be better [the implant option].

(FG 6, FSW)

As illustrated above, convenience and ease of use were closely related to frequency of administration, with women preferring less frequent delivery methods. Across both groups the preference was for a longer lasting injectable (6 month vs 3 month), while one of the most attractive aspects of the implant was its long lasting duration (12 months), although some WWID had concerns about forgetting to go back for renewed protection.

Agency around side effects and unique complications- " You can't get rid of it [injection], you can't remove the medicine." *(FG 5, FSW)*

Most women recognized that side effects are always a risk factor with taking a medication, and although discussed as a concern, it was not critical to the acceptability of any product type. However, there was considerable anxiety that with the new delivery methods (i.e., injection and implant) women would have less control over potential side effects. In contrast to the pill, both delivery methods were perceived as reducing women's agency over their bodies.

Participant 3: With the injection, once they put it in, you're stuck. If you have the side effect there's no reversing it. Like if you have the pill you can stop taking it or the implant you can get it taken out, but with the injection you're just stuck.

(FG 6, FSW)

Among both groups there were concerns about potential interactions with other medication regimens (e.g., medications for depression, Hepatitis C Virus). In particular for WWID, this centered on questions around whether PrEP would interact with methadone or suboxone treatment. Infection and associated care was an additional major concern for WWID with respect to the implant.

Participant 1: And then I guess just infection if you mess with it.

Participant 2: Yeah, that would probably be a big one for us too is infection. Like how soon after you get it is it possible for infection? Like I said, we're bad at taking care of ourselves. If it's an open wound and it gets infected –

Participant 1: Abscesses – how does it react with abscesses?

(FG 3, WWID)

Population specific perceptibility concerns - "Geeking is a side effect, when you're tweaking out, you're paranoid, and would be freaked out by an implant." *(FG 1, WWID)*

Perceptibility concerns were less frequent among the FSW groups, with a few participants voicing potential benefits associated with having a visible implant.

Participant 2: The only thing that would be good with that [the implant] is the Johns will know you don't have HIV. That's the only thing that would be positive about

that. When you get in the car, they'll ask you, let me see your arms, your hands, do you have diseases or drugs? They believe whatever you say.

(FG 4, FSW)

In contrast WWID had a mixture of perceptibility concerns, including concern around scarring and marking, with even more pressing concerns related to paranoia while high.

Participant 2: Because we're all on a bunch of drugs … I go on a crack binge – I'm going to be honest – we get really paranoid. And you have something foreign in your body … I don't know.

Participant 1: Then you get to picking at it and all that.

(FG 3, WWID)

An additional perceptibility concern surrounded visibility to family and intimate partners. Women across groups generally did not have concerns about those close to them knowing, although they raised the injectable as a good option for those who wanted to hide it from their intimate partners.

Socio-structural barriers to PrEP uptake and adherence—It was notable that women often expressed an individual preference for the PrEP pill, alongside affirming a hypothetical ability to adhere, including seeing a medical provider for refills. However, this repeatedly conflicted with descriptions of the realities within their and other women's lives. Access to medical providers emerged as problematic, particularly among WWID.

Interviewer: Do any of you take medication regularly?

Participant 1: I'm supposed to.

Interviewer: What gets in the way?

Participant 1: I haven't seen my shrink because I'm getting high – haven't been to the dentist, or doctor. After my son, I got the rod in my arm for the birth control because I figured it was easier than the pill."

(FG 2, WWID)

Day to day structural vulnerabilities in women's lives were commonly raised with respect to potential barriers to pill adherence.

Participant 4: A lot are homeless or in and out of prison.

Participant 1: Yeah, a lot are homeless and can't keep their things, I lost everything several times when I was homeless.

Participant 4: It's important, whether they are in a shelter or an abandonment.

Participant 1: People that don't have insurance, that would be a big issue.

(FG 5, FSW)

Shifting the burden around uptake and adherence—Women volunteered unprompted ideas around how to potentially incentivize PrEP uptake and adherence. In the

context of longer acting delivery methods, women discussed the importance of reminders or incentives.

> Focus group facilitator: Do you think people will forget if it's too long?
>
> Participant 4: Addicts are like "today", you know what I mean? We all remembered [to come to the focus group] because there's an incentive. We're getting something, you know what I mean?
>
> Participant 2: That's how addicts are. Am I getting something out of this? Something we can touch and something we can use, you know?
>
> (FG 3, WWID)

In addition, women felt that treatment needed to come to them.

> Participant 3: Like if they have a medical truck … they could bring it to the people instead of having to go in to see the doctor. Having it the neighborhoods, we're more likely to take it and stay on it…"
>
> (FG 4, FSW)

For WWID, another suggestion focused on integrating PrEP provision into drug programs, for instance, making PrEP available at methadone clinics. In particular, women were very conscious of the need for practical solutions to assist with structural barriers to adherence around the pill form of PrEP.

> Participant 2: They need to put some lockers up or something for street walkers where they keep their medication at, and they'd be able to take it and lock it back up – like you've got the mailbox and stuff like that.
>
> (FG 7, FSW)

Discussion

In this study we explored FSW's and WWID's willingness to use three different formulations of PrEP, only one of which (the PrEP pill, Truvada) is currently available. Findings support other studies among at-risk populations that point to long-acting systemic delivery methods as being a good alternative option to daily adherence regimens (Strauss et al., 2017). Product acceptability and hypothetical adherence was rooted in participants' positionality as women, street-based sex workers and injecting drug users, with participants drawing on these overlapping identities and corresponding vulnerabilities throughout the focus group discussions.

Results found participant familiarity with existing delivery methods (i.e., pill) can shape initial preferences, suggesting that clinician education on new modalities should draw upon other medications as points of comparison (e.g., contraceptive implant.).The lack of sexual HIV risk perception among WWID supports a dual need for investment in sexual health risk education alongside promoting PrEP awareness. This supports previous work that integration of PrEP with other prevention services (e.g., HIV risk reduction, condom provision, adherence counselling) is key to effectiveness (Eisingerich et al., 2012).

Results reveal preferences which are important for product development, but also have policy implications for supporting PrEP use among high-risk women. Familiarity with mode of delivery and frequency of product administration emerged as a key factors influencing perceptions around convenience and ease of use, with a preference for the longer lasting formations. An important finding involved WWID views on the implant option, with concerns around drug use associated paranoia and self-care considerations with respect to infection. Interventions involving women's use of long-lasting contraception formulations (Rose, Lawton, & Brown, 2010) point to the importance of addressing potential deterrents to PrEP uptake and use through health provider education and patient counselling.

Across groups, women's ability to exercise individual agency over treatment emerged as key, but conflicted with the reality of women's day-to-day life and socio-structural environment. Structural vulnerability is a useful conceptual lens to unpack socio-structural factors that can constrain and require groups/individuals to renegotiate their agency (McNeil et al., 2015). Existing literature indicates key barriers to healthcare access and utilization among these populations (e.g., healthcare related stigma, insurance) which could counter uptake and adherence to existing and new PrEP modalities(Nabila El-Bassel, Wechsberg, & Shaw, 2012; Lazarus et al., 2012). In this study, the individual and socio-structural world of daily drug use and related issues such as healthcare access, homelessness and incarceration raised important barriers to uptake and adherence to a daily pill regimen. ART adherence studies among PWID have found suboptimal adherence, suggesting integrated services to address socio-structural barriers can support real-world adherence (Bachireddy et al., 2014) (McNeil et al., 2016). Participant input on how to overcome barriers to uptake and adherence across highlights the importance of integrating population knowledge into the design and delivery of interventions.

Previous literature from trials on PrEP (oral and vaginal) adherence among women, have pointed to the importance of contrasting risk-perceptions, culture, community and structures as promoting and inhibiting correct product use [Amico 2013]. This study contributes to the need for more behavioral data to unpack these socio-structural dynamics in the context of new and existing PrEP products.

Limitations

The study has a number of limitations. WWID were sampled from the Baltimore NEP and may therefore be more stable in terms of accessing services. In addition, while the study set out to look at two distinct populations, in the context of Baltimore there is overlap between FSW and WWID experiences. Recognizing that this may not be the case elsewhere, the groups were interviewed separately to help generalizability, although findings may not be representative of non-urban areas.

Conclusions

FSW and WWID represent two important groups at high risk for HIV, for whom a focus on PrEP as a key HIV prevention strategy has been absent. This study adds to the nascent literature in the U.S. context on women's awareness and preferences around existing and

new delivery methods. Moving forward, this study highlights that variation in individual product preference supports the development of a range of PrEP delivery methods. However, attention should be given to health provider education around facilitators and barriers to product uptake, alongside the importance of supporting structural interventions to promote uptake and adherence.

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Table I.

Characteristics of Focus Groups with Women Who Inject Drugs

Participant Characteristics of Women who Inject Drugs	Group 1 (n=7)	Group 2 (n=4)	Group 3 (n=5)	Total (N = 16)
Mean Age	45	52	33	43
Race, n (%)				
White	5 (71)	0 (0)	5 (100)	10 (62)
Black/African American	2 (29)	4 (0)	0 (0)	6 (38)
More than one/Other	0 (0)	0 (0)	0 (0)	0 (0)
Relationship Status, n (%)				
Serious	4 (57)	2 (50)	4 (80)	10 (63)
Casual	0 (0)	1 (25)	0 (0)	1 (6)
None	3 (43)	1 (25)	1 (20)	5 (31)
Sex Partners, Median	1	2	1	2
Condomless Acts, (%)[a]	43%	42%	60%	49%
PrEP Familiarity, n (%)				
Don’t know much	5 (71)	2 (50)	4 (80)	11 (69)
Know a little bit	2 (29)	1 (25)	0 (0)	3 (19)
Know a fair amount	0 (0)	1 (25)	0 (0)	1 (6)
Know a lot	0 (0)	0 (0)	1 (20)	1 (6)

[a]The proportion of women who reported having at least one act of condomless sex in the prior 6 months

Table II.

Characteristics of Focus Groups with Female Sex Workers

Participant Characteristics of Female Sex Workers	Group 4 (n = 6)	Group 5 (n = 3)	Group 6 (n = 3)	Group 7 (n = 3)	Total (N = 15)
Mean Age	25	49	34	41	36
Race, n (%)					
White	6 (100)	3 (100)	1 (33)	2 (67)	12 (80)
Black/African American	0 (0)	0 (0)	2 (67)	1 (33)	3 (20)
More than one/Other	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Relationship Status, n (%)					
Serious	4 (80)	2 (67)	0 (0)	0 (0)	6 (55)
Casual	0 (0)	0 (0)	1 (33)	0 (0)	1 (9)
None	1 (20)	1 (33)	2 (67)	3 (100)	7 (64)
Sex Partners, Median	10	50	10	4	10
Condomless Acts, (%) *a)*	10%	35%	13%	16%	17%
PrEP Familiarity, n (%)					
Don’t know much	5 (83)	3 (100)	2 (67)	2 (67)	12 (80)
Know a little bit	1 (17)	0 (0)	1 (33)	0 (0)	2 (13)
Know a fair amount	0 (0)	0 (0)	0 (0)	1 (33)	1 (7)
Know a lot	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

a) The proportion of women who reported having at least one act of condomless sex in the prior 6 months