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Barriers and Facilitators to Oral PrEP Use Among Transgender Women in New York City

Christine Tagliaferri Rael[1], **Michelle Martinez**[2,4], **Rebecca Giguere**[1], **Walter Bockting**[2], **Caitlin MacCrate**[2,3], **Will Mellman**[2], **Pablo Valente**[2,4], **George J. Greene**[5], **Susan Sherman**[6], **Katherine H.A. Footer**[6], **Richard T. D'Aquila**[5], and **Alex Carballo-Diéguez**[1]

[1]HIV Center for Clinical and Behavioral Studies at the New York State Psychiatric Institute and Columbia University, New York, NY

[2]Program for the Study of LGBT Health at the New York State Psychiatric Institute / Columbia Psychiatry and the Columbia University School of Nursing, New York, NY

[3]CUNY School of Public Health, New York, NY

[4]Columbia University Mailman School of Public Health, New York, NY

[5]Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago. IL

[6]Johns Hopkins Bloomberg School of Public Health, Department of Behavior and Society, Baltimore, MD

[7]Division of Infectious Diseases, Department of Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL

Abstract

Transgender women may face a disparate risk for HIV/AIDS compared to other groups. In 2012, Truvada was approved for daily use as HIV pre-exposure prophylaxis (PrEP). However, there is a dearth of research about barriers and facilitators to PrEP in transgender women. This paper will shed light on transgender women living in New York City's perceived and actual challenges to using PrEP and potential strategies to overcome them. After completing an initial screening process, four 90-minute focus groups were completed with N=18 transgender women. Participants were asked what they like and dislike about PrEP. Participants identified the following barriers: uncomfortable side effects, difficulty taking pills, stigma, exclusion of transgender women in advertising, and lack of research on transgender women and PrEP. Facilitators included: reducing

Christine Tagliaferri Rael, 1051 Riverside Dr., New York, NY 10032, T: 646-774-6967, F: 646-774-6955, Cr2857@cumc.columbia.edu.

Compliance with Ethical Standards

Conflicts of Interest

All authors declare that they have no conflicts of interest.

Ethical Approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the Institutional Review Board, Human Subjects Committee of the New York State Psychiatric Institute and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

pill size, increasing the types of available HIV prevention products, and conducting scientific studies to evaluate PrEP in transgender women.

Introduction

In 2012 a fixed dose formulation of tenofovir dipivoxil and emtricitabine (Truvada) was approved for daily use as HIV pre-exposure prophylaxis (PrEP) in the United States (U.S.) (1). Though this method of HIV prevention, called oral PrEP here, is highly efficacious, its initiation and consistent use remains low in some population segments, such as transgender women (e.g., individuals who were assigned male at birth but identify as women)(2–4). This is concerning, since PrEP has the potential to mitigate the high prevalence of transgender women living with HIV in the U.S. (~22%) (5). In New York City (NYC), addressing HIV in this group is especially urgent. Specifically, NYC transgender women have the highest percentage of newly identified HIV-reactive test results (20%) of any group (6). There is a dearth of research about barriers to and facilitators of oral PrEP in this population. Research to understand this topic is urgently needed to inform, 1) interventions to promote oral PrEP use (7), and 2) the development of new PrEP products in the HIV prevention pipeline (8). The work presented in this paper will shed light on NYC transgender women's perceived barriers to using PrEP and strategies to overcome them.

We reviewed the literature on transgender women and oral PrEP use and/or acceptability using several scholarly databases including Pubmed, GoogleScholar, and a large University library catalogue. We found that with the exception of one study (7), all research on this topic grouped transgender women with gay and bisexual men. This is an issue for several reasons. First, transgender women's healthcare needs, HIV risk profile, and barriers to HIV prevention and treatment are distinct from gay and bisexual men (9–11). Therefore, transgender women are highly likely to have different challenges related to biomedical HIV prevention product use than these men, making extrapolation from gay and bisexual men-only studies inappropriate (7, 12–14). Second, to our knowledge, only one study that has examined gay and bisexual men and transgender women as one demographic has recruited a sufficient number of transgender women to power a separate, transgender-focused analysis (3, 4, 15, 16). However, this transgender-focused sub-study was unable to draw meaningful conclusions about PrEP in this population, primarily because of low adherence (4). This leads to challenges in designing oral PrEP interventions tailored for transgender women that address their specific PrEP-related needs.

Equally important to informing proposed and ongoing oral PrEP interventions, is informing the development of new products in the HIV prevention pipeline. Several daily (e.g., oral Cabotegravir), event-based (e.g., products used with receptive anal or vaginal intercourse; TDF pills, topical substances), and long-acting (e.g., PrEP injections, subdermal PrEP implants) HIV prevention strategies are currently in development (17–20). As potential future HIV prevention products move through the development process, it is important to their future implementation to understand transgender women's perceptions of and past experiences with oral PrEP (8).

Methods

This study was conducted in collaboration with, 1) *Project AFFIRM*, a longitudinal study of transgender identity development, and 2) Sustained Long-Acting Prevention against HIV (SLAP-HIV), which aims to develop and conduct a phase I clinical trial of a long-acting biomedical HIV prevention product. All work was approved by the Institutional Review Board, Human Subjects Committee of the New York State Psychiatric Institute. To gain an overall sense of how oral PrEP is perceived among transgender women, focus group discussions were used.

Participants and procedures

Participants were self-identified transgender women, at least 18 years old, HIV-negative (self-report), living in NYC, who reported receptive anal or vaginal intercourse in the last three months. Data were collected from September 2016-February 2017.

All participants were recruited through a convenience sample of 160 diverse transgender women contained in *Project AFFIRM's* database, who had previously agreed to be contacted about future research studies. To ensure a diverse sample, especially in terms of age and race/ethnicity, *AFFIRM* recruits transgender women into their database through a purposive, venue-based approach across a variety of settings (offline and online; e.g., bars, pride events, online social forums). Specifically, *Project AFFIRM* identifies locations and venues frequented by transgender individuals using ethnographic research methods. Locations that yield high proportions of transgender racial/ethnic minorities are particularly targeted, to ensure adequate inclusion in the sample.

Those who fulfilled eligibility criteria and had given consent to be contacted for other studies were invited to our research offices and underwent a new consent process, before completing a brief interviewer-administered, tablet-based survey in English or Spanish. The survey included the following topics: demographics, PrEP knowledge, and access to healthcare. Immediately following the survey, participants (N=28) were asked to take a rapid oral HIV test (OrSure Advance®) to verify seronegativity. Individuals who had a negative HIV test were invited to participate in one of four focus groups, which took place at a medical center in New York City at a later date. All participants were compensated $50 for their time and travel expenses.

Four focus groups were completed with N=18 participants (Group 1: n=3; Group 2: n=5; Group 3: n=7; Group 4: n=3) in English (Groups 1-3) or Spanish (Group 4), depending on participants' language preference. Focus groups took approximately 90 minutes to complete and were co-led by the first author and a trained research assistant. Discussions focused on perceived barriers and facilitators to oral PrEP. Participants who completed focus groups were compensated $50 (in addition to the $50 received for the surveys).

Measures

Focus group discussions were divided into two parts. Part 1 focused on understanding participants' existing knowledge about oral PrEP. Specifically, focus group attendees were asked the following question: "What have you heard about PrEP or Truvada?" During the

ensuing discussion, participants were probed about the following topics: where they had heard the information they shared about oral PrEP; how they liked oral PrEP if they had used it; what things they had heard from friends or other people in the transgender community about oral PrEP. At the beginning of Part 2, participants were given a detailed explanation of oral PrEP (e.g., dosing schedule, cost, potential side-effects, how to access PrEP), and were encouraged to ask clarifying questions until none remained. This was intended to ensure that all respondents had accurate information about this topic. Additionally, participants were given a written summary of this information they could refer back to if necessary during the subsequent discussions.

Next, participants were asked what they liked and disliked about oral PrEP; respondents were encouraged to focus on specific likes and dislikes that could be unique to transgender women. Lastly, participants were asked to respond to the following question: “If you had the chance to tell the scientists who developed this product what they could do to make it better for transgender women, what would you tell them?”

Data Analysis

Descriptive statistics were calculated for: (1) the sample overall (e.g., all participants who completed the tablet-based survey), and (2) the focus group participants. Audiotapes of focus group discussions were transcribed. Since both coders were bilingual, Spanish language transcripts were coded in Spanish. However, examples of text presented in this manuscript were translated to English by the coders. Transcripts were coded using Dedoose. Codes were identified by the first author and a research assistant, trained in qualitative methods, using a multilayered strategy. First, a list of *a priori* codes, or codes developed in advance by the research team (21), was generated based on topics addressed by the focus group guide. Coders also planned to analyze the text to identify *in vivo* codes, or experiences described by participants that characterized their perceptions of oral PrEP (22) *In vivo* codes were created by noting overlapping themes in the transcripts, developing code definitions that summarized these themes, and discussing code definitions to ensure consensus between coders. Themes represented by *a priori* and *in vivo* codes were intended to characterize the presumed meanings underlying the respondents’ answers (23). To ensure that themes represented data in a consistent way, the first author and the research assistant worked separately to identify codes.

During the analysis phase, coders examined themes alongside the data examples they were intended to represent. Comparisons of text assigned to *a priori* and *in vivo* codes were made after the each pass through the data and inconsistencies were discussed until agreement was reached. *A priori* codes that were absent from or poorly represented by the text were eliminated. Coders also discussed the *in vivo* codes they identified and examples of quotes illustrating these themes. This was to ensure that codes were similarly assigned to text samples between the coders. Next, coders reexamined the data for an all-inclusive assessment of possible themes and met for the last time to discuss *a priori* and *in vivo* codes, ensure consensus, and verify that example quotes illustrated the intended themes. It was determined that eight distinct themes emerged from the data and language originating from the participants themselves was used to name them.

Results

Of the N=28 individuals who completed quantitative, 27 were eligible to participate in focus groups. Of those, 18 participated. Table 1 summarizes the characteristics of transgender women who completed quantitative surveys and focus groups. Of the participants who completed quantitative surveys, nearly all (n=26; 96.3%) had heard of oral PrEP prior to participating in this study. However, less than one-quarter of respondents (n=6; 22.2%) had previously or currently used this product.

Barriers

"It was a month and a half of misery"

Participants worried about the uncomfortable side effects associated with PrEP use. Respondents were particularly concerned about stomach pain and nausea. Some participants, who had previously used oral PrEP, reported severe abdominal discomfort. Other transgender women in our focus groups who had not used PrEP anticipated similar events upon medication initiation. One former PrEP user described how regularly occurring abdominal distress interfered with her normal daily functioning.

> "And it felt like my stomach was going in, but this, everyday I took it at 5 o'clock. It don't matter where I was, I was bending down like, "Oh my God. I got to hurry up and get home." But it's not… I didn't have to use the bathroom or anything. It made my stomach went completely hollow…" (Focus Group 2)

Still, some participants were aware that side effects, including nausea and abdominal distress, should lessen over time with consistent PrEP use. Most respondents who had used oral PrEP were willing to continue to take medication for some period of time, provided that side effects would soon lessen. One participant explained that initially, oral PrEP use was uncomfortable. However, after awhile, her body became accustomed to the new medication and the side effects disappeared.

> "…the reason why I decided to get on PrEP, I actually was one of the girls to be asked to be on PrEP. I was doing sex work, so that was my main reason why I wanted to be on PrEP. Just so that I can have that extra security. That extra protection. First week of me taking it, a lot of people did not suffer side effects. But I did, and they were very uncomfortable. There were these uncomfortable feelings. Uncomfortable pains in my body that I had to - that my body had to get used to. But once my body got adjusted to the medication, the side effects went away, and it was just a matter of taking them daily." (Focus Group 3)

However, this was not true in all cases. Some transgender women in our groups explained that if side effects were prolonged or became too severe, they would be unwilling to continue with medication. One participant who had previously used PrEP recounted how the severity and duration of her PrEP-related discomfort led her to discontinue use.

> "…it was a month and a half of misery. I spent every single day sick and miserable. I was constantly nauseous, debilitatingly nauseous at some points, and when I switched from PEP (to prevent HIV infection from a recent exposure) to PrEP, I

> noticed that I… not only did the nausea get worse, but I also developed a constant, and I mean literally from the moment I woke up until the moment I went to bed, sore throat. My throat was sore from… as if I had strep. It felt like strep throat, and I also got lock jaw. Like, my jaw joint would seize and I couldn't open my mouth more than that without physically grabbing my jaw and forcing it open and cracking the joint in the process. After about two weeks of that, I'm like, 'I can't do this anymore. I can't,' and so I just stopped taking them, and three days later, my stomach was fine, my jaw was fine, my throat was fine." (Focus Group 2)

"I don't like taking pills…"

Many participants reported anticipated or actual difficulty taking oral PrEP pills. Three major themes emerged, including participants' aversion to the large pill size, pill fatigue (e.g., difficulty taking pills because of the constant stress and/or monotony associated with constant pill swallowing), and a general dislike of all pills. In particular, participants feared that the large size of oral PrEP pills would be difficult or uncomfortable to swallow. In fact, several transgender women in our groups who had not used PrEP reported that the large pills were a deterrent to medication uptake. However, of the few participants who had used oral PrEP, none cited pill size as a reason for discontinuation. One respondent explained how she believed she would be unable to take PrEP pills because she would have difficulty swallowing them.

> "I think the way it is now, it wouldn't agree with me or I wouldn't like it. Ok, I'm talking about how the pill is sized. If you can make it a little smaller, I feel like a lot of people would opt for – you wouldn't have the case where girls say, 'Yeah that's big and it's not going to go down'" (Focus Group 4)

Participants also reported pill fatigue. Specifically, some transgender women in our groups felt that adding another oral tablet to the sometimes already complicated medication regimen that many transgender women have was unappealing. Respondents explained that it is not uncommon for transgender women to take multiple medications for body feminization or to treat illness. One participant reported that while taking one pill a day does not seem like a lot, it could be challenging for her, since she already must keep track of several other medications.

> "…I don't like the idea of having another pill to keep track of. That's part of what I like about it and what I don't like. I mean, I do like that it's just one pill. That's it. But I also don't like how it would be another pill to add to all the other pills I take." (Focus Group 1)

Other participants reported a general dislike of all pills. That is, some participants did not like the idea of taking any pills, regardless of their intended purpose. For example, some transgender women in our groups explained that they were, "not a pill person" and/or "just don't like taking pills". One respondent explained that she feels overwhelmed by taking pills, including oral PrEP. *"Well it's that – ok I think that I don't like it [oral PrEP] because I don't like taking pills. It just drives me crazy." (Focus Group 4)* Additionally, other respondents reported a history of difficulty taking pills for other purposes. In fact, one participant revealed that she is inconsistent with her feminizing hormone therapy regimen,

which is a priority for many transgender women, because she dislikes taking pills. *"I'm very much on and off on my hormones because I just hate taking pills. I do. You know what I'm saying?" (Focus Group 2)*

"Yeah, there's a lot of stigma…"

Some participants felt that oral PrEP use is stigmatizing and noted an explicit bias against transgender women who take PrEP. Some transgender women in our focus groups worried that they would be mistakenly identified as HIV-positive. This was problematic for respondents in our groups, since there is a great deal of prejudice in the transgender community against transgender women living with HIV. One participant recounted a story where one of her transgender friends, who is also a sex worker, was confronted by a client after he found PrEP tablets in her purse.

> "…I have a friend, she was a sex worker, and she had the [PrEP] pills. She told me that one of her clients, while she was in the bathroom, he was looking through her stuff. He, like, panicked almost, thinking that he had something because he thought that those pills meant that she had HIV. Yeah. He was like, 'Oh, no, you have HIV. What are those pills?'" (Focus Group 3)

Other participants reported that oral PrEP use implies promiscuity in some cases. Respondents felt that there was pressure not to disclose oral PrEP use, since this could cause others to assume they were engaging in risky sex. One former PrEP user explained how disclosing her use of this medication led others to think she was having sex with multiple partners. *"…And people automatically, like, people assumed I was sleeping around. And I'm being blunt. I was like, 'No, no, no. I just, I like to be safe.'" (Focus Group 1)*

"It's not marketed to us…"

Participants felt excluded by marketing campaigns for oral PrEP, since they believed that PrEP was mainly advertised to gay men, which was off-putting to them. Specifically, transgender women in our groups felt that by tailoring the majority of print and other ads to gay and bisexual men, it implied that PrEP is a product mainly intended for use by this group. This was difficult, since participants felt that their female gender is central to their individual identity. Taking a product meant for use by gay and bisexual men was perceived as an affront to that identity and a significant barrier to use. One participant explained that she found the idea of using PrEP challenging, since she interpreted this product to be masculine, which was undesirable.

> "I'm trying to choose my words carefully, but with society at large, a lot of people don't think of transwomen as women. They think of us as men who are trying to be women. And so that sort of knowledge, for me, it's this thought of PrEP as something that's for gay men. It can get kind of personal. It's psychological in a sense. I know at least - how do I put this? It's just the idea of taking something that isn't really marketed towards transwomen can be off-putting, you know?" (Focus Group 1)

Still, participants acknowledged that some PrEP advertising is tailored for transgender women. Specifically, respondents in our groups reported that they had seen oral PrEP ads on

the subway that feature transgender women. Despite this, most participants felt that these ads were an addendum to gay and bisexual men-focused campaigns, since comparatively, there were far fewer transgender women -focused ads. One participant describes how she and her friends felt upset by the dearth of transgender-focused PrEP marketing materials.

> "…I haven't seen it marketed a lot for transwomen. I've seen some subway stuff. Some subway ads that, you know, of transwomen on them as well. But for the most part it seems like very much like a gay men thing and I know that bothers a lot of trans people that I've talked to." (Focus Group 1)

"You can't expect someone to be full on your PrEP wagon if you haven't…researched it…"

Participants overwhelmingly felt that there was little research to support the use of oral PrEP by transgender women. Specifically, respondents in our groups highlighted a need for greater understanding of clinical factors that differentiate transgender women from other groups, particularly gay and bisexual men. This was especially true with respect to cross-sex hormone use. Participants worried that the use of feminizing hormones and other gender-affirming medications in combination with PrEP could produce unanticipated and potentially harmful, health outcomes. One participant articulated the need to conduct biomedical HIV prevention research with transgender women separately from GBM, since work that has combined these groups has failed to capture data about the unique clinical aspects of transgender women, such as feminizing hormone therapy.

> "Like, if you look at sexual behavior, if you have sex with men, it's kind of looked at and researched the same with transwomen. But if you look at it from a medical standpoint and you're like, 'We're on hormones and this is a whole other level of healthcare that has to be taken into account when you prescribe PrEP.' And I don't know if it's researched enough…" (Focus Group 1)

Participants in our groups also reported that the dearth of research about transgender women and oral PrEP has left uncertainty about the effect that HIV prevention medication has on feminizing hormone levels. That is, participants worried that using oral PrEP could cause feminizing hormone therapy to become less effective, since there are no data to show this is not the case. All respondents reported they would be unwilling to take HIV prevention medications if interference with hormone serum concentrations were possible. One participant described how, for her, non-interference with hormone levels is the most important attribute of HIV prevention medications. *"As long as it doesn't prevent…yeah, your [hormone] levels - whatever. As long as it doesn't interfere, that's all that should matter." (Focus Group 3)*

Facilitators

"I would want a smaller pill. That would make me want to take it more"

Almost all participants endorsed the idea that reducing the size of oral PrEP pills would increase their willingness to take medication. Several respondents suggested that pill producers should simply manufacture a smaller tablet. One participant reported that in order for her to want to use oral PrEP, there must be a smaller pill available. *"…if this is the size of the pill then I would want a smaller pill. That would make me want to take it more."*

(Focus Group 3) Alternatively, another respondent suggested that taking two smaller pills is preferable to the single large one that is currently on the market.

> "…I think that it might be way more effective, or not more effective necessarily, that's the wrong word. But way more comfortable to say take two pills that are half the size as opposed to one that's a horse pill." (Focus Group 2)

"…People want to try the new methods…"

While a small minority of participants expressed skepticism about biomedical HIV prevention, the majority of transgender women in our groups endorsed support for this approach. However, not every participant preferred oral tablets. Participants explained that a variety of HIV prevention methods are necessary, since different people have different needs and preferences. One participant explained that although oral PrEP tablets are feasible for some, the development of alternative biomedical HIV prevention methods is necessary for others who cannot or will not take pills.

> "…Up until now all we had was the pill, and that's fine for those of use who want to continue taking pills. Fine. But other people want to try new the methods that they're making that are coming to the market soon. To be able to keep preventing HIV and presenting people with the best HIV prevention option of their choice." (Focus Group 4)

"We need to know what this pill does to our bodies…"

Because transgender women are different than gay and bisexual men, participants in our groups suggested that product developers conduct trials to evaluate the effects of PrEP on transgender women. Participants in our groups felt that this was especially important, given inconclusive data about cross-interactions between HIV prevention medications and gender affirming hormones. One participant described how she would want to know how different types of hormones interact with HIV prevention medications.

> "I'd like to know how it would - how it's going to interact with my hormones. Specifically. Specifically. Like, how is it going to interact with someone who takes hormones orally? How is it going to interact with someone who takes hormones through injections? Or patches. How - you know?" (Focus Group 1)

Discussion

This study identified barriers and facilitators to oral PrEP use among HIV-negative transgender women living in New York City. Our findings suggest that transgender women experience barriers associated with oral PrEP common to other at-risk groups and barriers specific to transgender women.

Participants in this study reported concern about medication side effects, particularly prolonged abdominal discomfort. These concerns were not unfounded, since temporary, PrEP-associated side effects, otherwise known as "start-up syndrome", are well documented (24). For example, in clinical trials, participants randomized to receive pills containing active PrEP drug reported abdominal pain (5-19%) (25–28), flatulence (8%) (29), and vomiting

(4-8%) (26, 28, 30). On average, after three months, most symptoms resolved (24). However, evidence from our study showed that symptom duration at start-up may be too long for some PrEP users. Specifically, some participants reported discontinuing medication long before three months, citing intolerable PrEP side effects as a major contributor. Others reported that they would be unwilling to use oral PrEP if severe and prolonged side effects were likely. To address issues associated with “start-up syndrome” in the short term, clinicians should consider providing new PrEP users with strategies or medications to treat its associated conditions. That is, when first prescribing oral PrEP, providers should discuss the potential side effects and provide new users with a clear plan on how to address these problems, and/or medications to lessen discomfort. In the long term, it is necessary to develop new PrEP strategies with fewer and less severe side effects.

Participants reported difficulty taking pills. Specifically, transgender women in our study reported disliking the large size of oral PrEP pills, pill fatigue, and a general aversion to taking any kind of pills. The large size of oral PrEP pills has been noted by participants in other studies (31). Transgender women in our focus groups worried about gagging on pills and felt concerned that they would be difficult or uncomfortable to swallow. Reducing the size of PrEP tablets was identified as a facilitator to medication use. Alternatively, some participants endorsed the idea of taking two smaller pills rather than one large one.

Additionally, participants reported pill fatigue, or frustration related to adding an additional medication to their existing daily regimens. Pill fatigue has long been a barrier to the use of daily antiretroviral medications (32). On the other hand, some participants reported a dislike for taking pills of any kind. Convincing healthy individuals to adhere to a daily pill to prevent HIV infection is often difficult (33). Thus, long-acting HIV prevention strategies that are not administered orally could help to address challenges with daily pill use and dislike for pills (33, 34). Evidence from the contraceptive literature supports this assertion. Specifically, this work shows that strategies requiring daily adherence (e.g., pills) are less effective at preventing pregnancy than long-acting methods (e.g., implants, injections) (35). Additionally, women who use long-acting forms of contraception are less likely to discontinue medication use after 24-months than women who use oral tablets (36). Clinical trials of long-acting PrEP injections are in progress and enrolling transgender women (37). Injectable PrEP may be especially acceptable to transgender women, given their familiarity with injectable hormones (38).

Participants reported stigma against transgender women who use oral PrEP. Specifically, respondents in our groups worried that they would be mistakenly believed to be HIV-positive or perceived to be promiscuous. HIV is stigmatized in the transgender community (39) and in general (40). Participants may fear additional judgment by friends, family members, partners, or others close to them if they were thought to be living with HIV. This may be particularly complicated for transgender women, since HIV-related stigma would presumably be layered upon other types of stigma, such as transphobia (e.g., intense dislike or prejudice against transgender people). Stigma related to HIV may be amplified even further for individuals who engage in sex work, since HIV-status is sometimes used against transgender women sex workers in this context (7). Moreover, the relationship between oral PrEP use and perceived promiscuity is well documented (41). That is, PrEP is perceived by

some to be an HIV prevention measure for individuals who wish to have “risky” sex or sex with multiple partners. Like with other groups, this stereotype is harmful and may further marginalize transgender women.

Transgender women in our focus groups felt excluded by gay and bisexual men-focused advertisements for oral PrEP. Specifically, participants felt that because the majority of print ads for PrEP in NYC are tailored to gay and bisexual men, it is a product primarily intended to be used by this group. This was true even though participants acknowledged the existence of some transgender women-focused PrEP ads. This finding is not unique to NYC. Other research about transgender women in San Francisco found that these women perceived PrEP to be mainly for high socioeconomic status gay men (7). Interestingly, all but one respondent in our focus groups had heard of oral PrEP prior to participating in this study. This is contrary to other work, which found that “lack of knowledge” about PrEP is a barrier to uptake in transgender women (7, 42). Thus, our findings may mean that in NYC, ad campaigns are successful in communicating the existence of PrEP, but fail to convince transgender women that this product is appropriate for them. Altering existing PrEP marketing strategies to be more trans-inclusive is necessary. However, the scope of our research did not allow us to identify ways to make PrEP advertisements more transgender women-friendly, which should be noted as a limitation.

Participants were concerned about the dearth of transgender women-focused PrEP research studies. Specifically, respondents in our groups reported reluctance to use oral PrEP, since little is known about the effect this medication could have on transgender women, particularly with respect to cross-sex hormone use. For transgender women in our study, the continued safety and effectiveness of hormones were a priority. Though existing research shows that cross-interactions between feminizing hormones and PrEP are unlikely (4), no empirical data are available to demonstrate this is the case. Future clinical trials of PrEP medications should consider, 1) monitoring transgender women’s hormone levels during the course of trials, and 2) assessing any impact of PrEP on the beneficial effects of feminizing hormones, since transgender women often prioritize hormones over other forms of healthcare (7, 43). To this end, it is imperative that future trials treat transgender women as a group separate from gay and bisexual men. Transgender women have different concerns related to medications and are a clinically, socially, and behaviorally distinct group.

Though we did not question participants about their experiences participating in research, it is likely that our findings could be applicable in this domain also. That is, when transgender women-specific PrEP-related concerns are left unaddressed in clinical trials, medication adherence (4) and subsequent medication uptake when products go to market could be affected. A study of transgender women’s participation in HIV vaccine research reported that ensuring all clinical trials personnel receive transgender cultural competency training, creating trans-friendly environments, developing true partnerships with trans-friendly organizations and providers, providing transgender women participants with trials materials that address trans-specific concerns (e.g., hormones), and collecting/tracking data on trans-specific issues (e.g., hormone levels) could have positive implications for enrollment, retention, and adherence (39). Specifically, these changes may help transgender women to overcome issues that provoke discomfort and/or disengagement in healthcare settings,

including mistrust of the medical community, absence of trans-friendly care providers with an adequate understanding of transgender medicine, and conscious or unconscious transphobia among clinic staff/providers (7, 11, 39).

In contrast to findings from other work (15, 42, 44), the cost of oral PrEP and "access to PrEP" were not identified as barriers to product use in our study. This could be because most focus group participants were covered by public or private health insurance, and likely felt that PrEP would be included in their prescription benefit. In our study, all participants reported having access to a health clinic. In addition, many participants used feminizing hormones to affirm their gender identity, prescribed by a licensed professional. This indicates that in addition to insurance coverage, a substantial portion of our respondents have access to a healthcare provider who is familiar with transgender health and is likely willing to prescribe PrEP. Other studies have shown that among transgender women who have access to a trans-competent healthcare provider, individuals saw few barriers in requesting a prescription for HIV prevention medications (7). It is important to note that our sample is diverse in terms of education and income, indicating that insurance coverage is not isolated to high socioeconomic status individuals. This is possible because in NYC, the Department of Health, public health clinics, and other community-based organizations proactively outreach to city residents to enroll qualifying individuals in healthcare plans, including Medicaid.

Limitations

This study took place in New York City, and some findings may not be applicable to other regions of the U.S. For example, access to PrEP, health insurance coverage, access to trans-competent healthcare providers, and knowledge of PrEP in this context is likely higher than in other parts of the country. However, given the low uptake of HIV prevention medication in transgender women, the issues raised by participants may be paradigmatic and thus warrant further exploration. Discussions about PrEP could have influenced other participants' likelihood of taking this medication. Specifically, it is possible that those who had a favorable or unfavorable opinion of PrEP could have swayed the attitudes of other respondents on this topic. Lastly, we were unable to ascribe specific quotes to individual speakers.

Conclusions

Despite these limitations, we feel that findings are relevant, given the dearth of research on transgender women and PrEP. Specifically, results of this work can be used to inform future outreach campaigns on PrEP access. For example, the NYC Department of Health's innovative #PlaySure campaign encourages New Yorkers, including transgender women, to identify and use the HIV prevention strategy or combination of strategies that works best for them (e.g., oral PrEP, condoms, HIV treatment as prevention) (45). Using targeted messaging (e.g., sex-positive print advertisements that feature diverse couples and individuals), innovative strategies to ensure that sexually active people have consistent access to tools that facilitate safer sex (e.g., small carry cases to transport condoms, lube, and oral PrEP or anti-retroviral pills, called the #PlaySure kit), and conveniently located

access points for sexual health services, the #PlaySure campaign aims to stop the spread of HIV and other STIs in vulnerable groups (46). Future #PlaySure campaigns might focus on overcoming transgender women's misconceptions about PrEP, stigma related to PrEP medications, and could feature more transgender individuals in print and online materials.

Additionally, findings could be integrated into future or ongoing PrEP trials. For instance, some injection studies are currently enrolling participants, including transgender women, in clinical PrEP trials in New York City. Based on our work, trials could consider adding clinical outcome measures to study how medications affect gender affirming hormones.

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Table I

Characteristics of the Overall Sample and Focus Group Participants[a]

Participant Characteristics	Overall Sample (N = 28)[b]		Focus Group Participants (n = 18)[c]	
	n (%)	Median [Range]	*n* (%)	Median [Range]
Age (years)		32.3 [18-52]		29.9 [18-52]
Average weekly income before taxes ($US)		$300.00 [$40-$1,500]		$300.00 [$40-$1,200]
Education				
High school graduate/GED	6 (22.2%)		4 (25.0%)	
Some college/technical school	8 (29.6%)		4 (25.0%)	
College graduate	4 (14.8%)		3 (18.8%)	
Race				
Other/More than one race	18 (66.7%)		11 (64.7%)	
Black/African American	5 (18.5%)		4 (23.5%)	
White	4 (14.8%)		3 (17.6%)	
Native Hawaiian/Pacific Islander	2 (7.4%)		0 (0.0%)	
American Indian/Alaska Native	2 (7.4%)		1 (5.9%)	
Hispanic/Latina Ethnicity (yes)	21 (77.8%)		12 (70.6%)	
Covered by health insurance (yes)				
Public insurance (e.g., Medicaid)	17 (63.0%)		14 (82.4%)	
Private insurance	4 (14.8%)		3 (17.6%)	
Participant reports access to a health clinic (yes)	25 (92.6%)		17 (100.0%)	
Use feminizing hormones (yes)	24 (88.9%)		15 (88.2%)	
Of participants who use hormones, *only* uses hormones prescribed by a licensed professional (yes)[b]	18 (75.0%)		12 (80.0%)	
Rapid oral HIV test result (negative)	27 (100.0%)		17 (100.0%)	
Heard of oral PrEP prior to involvement in the study (yes)	26 (96.3%)		17 (100.0%)	
Previously or currently using oral PrEP (yes)	6 (22.2%)		4 (23.6%)	

[a] Not all participants responded to each question category

[b] One participant survey was spontaneously dropped from the secure data system, so data from N = 27 overall and n = 17 focus group participants are included in the table.

[c] Percentages do not add up to 100% for the total column N, since the sample is dependent on the number of participants who use hormones for their gender transition, which is < the total column N.