



Interest in Pre-exposure Prophylaxis (PrEP) for HIV is Limited Among Women in a General Obstetrics & Gynecology Setting

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Abstract

Pre-exposure prophylaxis (PrEP) is an important tool for reducing the risk of HIV acquisition, but identifying eligible and interested female patients remains difficult. We collected 144 surveys at urban Obstetrics & Gynecology clinics in Louisiana to assess interest in PrEP. Study participants were predominantly African–American (61.8%) and 45.1% had incomes of less than \$20,000 per year. 84.7% of participants estimated their risk of HIV acquisition to be low. Initial interest in PrEP was moderate at 37.5% of the population. Number of partners, condom use, and self-perceived risk of HIV acquisition were associated with initial interest. After receiving more information about side effects and compliance requirements, only four of 144 (7.8% of initially interested, 2.8% of total) women remained interested in using PrEP. Concern about side effects was the major barrier to persistent interest. Further study is needed to determine how best to identify PrEP candidates in Obstetrics & Gynecology settings.

Keywords Pre-exposure prophylaxis · HIV infections · Surveys and questionnaires · Ambulatory care facilities

Introduction

While HIV transmission in the United States has declined significantly from its peak, it is still a major public health problem. In 2017, over 38,000 individuals received a new diagnosis of HIV in the United States. Women represented 19% of the new diagnoses, and 86% of new female cases were attributed to heterosexual contact [1]. Heterosexual African-American women are at a significantly higher risk than other female demographic groups [2]. In addition, the rate of HIV diagnosis is higher in the South than in other US regions [1].

In 2012, the United States Food and Drug Administration (FDA) approved a daily oral combination therapy consisting of tenofovir (TDF) and emtricitabine (FTC) for pre-exposure prophylaxis (PrEP) to prevent HIV transmission in sexually active adults. Approximately 100,000 Americans are

currently taking PrEP for HIV prophylaxis, however, only 7% of these are female [3]. Current indications for PrEP use by the United States Centers for Disease Control and Prevention (CDC) are summarized in Table 1 [4].

In randomized trials, PrEP has been associated with a decreased risk of HIV acquisition in men who have sex with men (MSM), heterosexual couples, and injection drug users. PrEP has been consistently effective in the MSM population, with studies demonstrating a reduced rate of HIV transmission ranging from 44 to >96% [5–7]. In heterosexual women, results of trials have been variable. In the Partners PrEP Study, conducted in East Africa, which enrolled serodiscordant heterosexual couples, risk of HIV acquisition in women was decreased by 71% with TDF alone and 66% with TDF-FTC compared with placebo [8]. Three additional investigations (TDF2, FEM-PrEP, and VOICE) have been conducted among heterosexual African women and have evaluated the benefit of oral TDF-FTC, oral tenofovir alone, or tenofovir vaginal gel [9–11]. PrEP did not prevent HIV acquisition in these trials, however, substantial non-adherence to the study drugs likely played a role in this lack of efficacy. A subsequent analysis demonstrated that in women in whom adherence is at least 75%, oral PrEP is likely to reduce the risk of HIV acquisition by 61% [12].

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Table 1 CDC recommended indications for PrEP use in heterosexually active women

Adult person
Without acute or established HIV infection
Any sex with opposite sex partners in past 6 months
Not in a monogamous partnership with a recently tested HIV-negative partner
AND at least one of the following:
<ul style="list-style-type: none"> • Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection • Is in an ongoing sexual relationship with an HIV-positive partner • A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

An additional explanation for the differential effectiveness between MSM and women is the number of doses of the medication required to achieve therapeutic effect. While two to three doses per week provide sufficient protection in colorectal mucosa, women must take six or seven doses per week to achieve the same concentration of drug in cervicovaginal tissue [13]. Concerns about efficacy and adherence in women may contribute to low rates of PrEP uptake among women.

Additional barriers to the use of PrEP in women may exist among prescribers or potential users of the medication. Lack of awareness among prescribers and patients, cost, and concerns about stigma may exist [14, 15]. It remains a challenge for women's health care providers to efficiently identify women in the general Obstetrics & Gynecology population who would benefit from and would remain interested in PrEP after counseling about its use and side effects. This investigation sought to describe women's interest in PrEP in an urban ambulatory Obstetrics & Gynecology population in the southern United States. It also aimed to identify demographic or behavioral characteristics associated with persistent interest in PrEP after counseling.

Methods

Institutional review board (IRB) approval was obtained from the Tulane University IRB. The requirement for informed consent was waived as no identifying information was collected. An anonymous written questionnaire was administered to attendees of academically-affiliated outpatient general Obstetrics & Gynecology clinics in New Orleans, Louisiana. The questionnaire was developed by the authors for use in this investigation. The study was conducted over the month of August 2018. Inclusion criteria were female sex, age of 18 years or greater, knowledge of spoken and written English, and not having a known diagnosis of HIV.

The study questionnaire was divided into three blocks of questions: demographic, sexual history and PrEP questions. All subjects completed the same demographic and sexual

history questions. The sexual history block included a question about prior knowledge of PrEP, and the source of this information. Following the sexual history block, patients were given a brief written description of PrEP, which explained that PrEP is a once-daily pill that reduces the chances of getting HIV if exposed to the virus through having sex. They were then asked, "Would you consider using PrEP?" If participants responded that they *would* consider using PrEP, they completed a different final block of questions than participants who *would not*.

For women who would consider using PrEP, the final block of questions presented potential barriers to the use of PrEP, and asked if women remained interested in the medication even after learning this information. Potential barriers included: need to use a condom for intercourse, cost, daily adherence, short term side effects (nausea, vomiting, and headache), long term risk of kidney disease, long term risk of decreased bone density and fracture, necessity of seeing a health care practitioner and completing laboratory evaluation four times per year, and necessity of picking up medications monthly at the pharmacy. Participants were then asked if they would be able to discuss PrEP use with their family, friends, or sexual partner.

Condoms are still recommended in PrEP users to reduce the risk of pregnancy, other STIs, and further reduce the risk of HIV acquisition. Since specific rates of kidney disease, decreased bone density, and fracture are not available for women who use PrEP over the long-term, specific rates were not provided. The need to pick up medications monthly was included because many Louisiana insurers have 30-day dispensing limits, even if a 90-day prescription is provided.

For women who would not consider using PrEP, the final block consisted of a list of possible reasons that people might decline PrEP, and participants were asked to mark which of these reasons applied to them. They could select more than one answer. A blank space for free-text answers was also provided.

Univariate analyses were performed to assess associations between demographic and sexual history factors and PrEP questions. Univariate analyses were performed using

Chi squared test or Fisher's exact test when frequencies of responses were low (<5). Women who declined to answer specific questions were removed from the analysis of those questions. Multivariate analyses using logistic regression were performed when significant associations were found in the univariate analysis. Race, age, income, and education were controlled for in multivariate analyses. Two-tailed p-values are reported. p value of <0.05 was considered significant. Statistical analyses were performed using STATA/IC 15.1 (StataCorp LLC, College Station, TX).

Results

One hundred forty-seven women participated in the survey and completed the demographic and sexual history questions. Three survey participants were excluded from the analysis due to incomplete answers to key PrEP questions, leaving 144 surveys for analysis. Age of participants ranged from 18 to >60 years of age (Table 2). Ages across the reproductive spectrum were well-represented. Low income women with a household income of <\$20,000 annually represented 45.1% of the study population (65/144). 34.0% (49/144) of women had an educational attainment of high school or less. 61.8% (89/144) of the study population self-identified as black, 30.6% as white (44/144), and 2.1% as Hispanic/Latina (3/144).

74.3% (107/144) of participants had been sexually active in the last 3 months (Table 3). This was defined as having had any sexual contact (vaginal, digital, oral, or anal) within this time frame. Most participants (82.6%, 119/144) were generally sexually active with men only. The majority reported one sexual partner in the past 12 months (75.0%, 108/144); 7.6% (11/144) had 2–5 partners, and four women (2.8%) reported >5 sexual partners in the past 12 months. Only 1 woman reported ever having had a sexual partner whom she knew to be HIV-positive. 41.0% (59/144) of participants used condoms. For 31.9% (46/144) of the population, condoms were the only contraceptive method used. 28.5% (41/144) of women used hormonal contraception or an IUD. The number of women who had been surgically sterilized or were menopausal was not assessed.

The majority of participants perceived their risk of HIV acquisition to be low (84.7%, 122/144) (Table 4). Only two women considered their risk of HIV acquisition to be high (1.4%). Interestingly, both of the women who considered themselves to be high-risk had been sexually active with only a single partner in the last 12 months. However, when the women who considered themselves to be at medium or high risk of HIV acquisition were combined, there was an association between perceived risk of HIV acquisition and number of partners: 7% (8/116) of women with 0–1 partners

Table 2 Population demographics

	Participants (n = 144)	Percent of total (%)
Age group		
18–24	31	21.5
25–29	26	18.1
30–34	19	13.2
35–39	16	11.1
40–49	29	20.1
50–59	18	12.5
60+	5	3.5
Annual income		
<20 K	65	45.1
20–49 K	43	29.9
50–199 K	21	14.6
≥100 K	4	2.8
Decline	11	7.6
Education		
Less than high school	8	5.6
High school	41	28.5
Some college	41	28.5
Associate degree	15	10.4
Bachelor's degree	14	9.7
Some graduate school	7	4.9
Completed graduate school	17	11.8
Decline	1	0.7
Race/ethnicity		
White	44	30.6
Black	89	61.8
Asian	1	0.7
Hispanic/Latina	3	2.1
Mixed race	2	1.4
Other	3	2.1
Decline	2	1.4

considered themselves to be at medium or high risk of HIV acquisition, while 28% (4/14) of women with two or more partners considered themselves to be at medium or high risk ($p=0.03$, Fisher's exact test). Women who considered themselves medium- or high-risk were also more likely to use condoms: 76.9% (10/13) of medium- or high-risk women used condoms, compared to 37.7% (46/122) of low-risk women ($p<.01$, Fisher's exact test). No other demographic or behavioral factors were associated with self-perception of HIV risk.

43.8% (63/144) of women had heard of PrEP prior to being introduced to it via this survey (Table 4). The majority of these (77.8%, 49/63) had heard of it through radio, television, or other forms of advertising. 11% (7/63) had heard of it from a healthcare provider, and 4.7% (3/63) through

Table 3 Sexual health behaviors

	Participants (n = 144)	Percent of total (%)
Sexually active within 3 months		
Yes	107	74.3
No	33	22.9
Decline	4	2.8
Generally sexually active with		
Men	119	82.6
Women	4	2.8
Both	20	13.9
Decline	1	0.7
Number of partners in last 12 months		
0 partners	15	10.4
1 partner	108	85.4
2–5 partners	11	7.6
> 5 partners	4	2.8
Decline	6	4.2
Contraceptive method use		
Condoms	59	41.0
Hormonal contraception or IUD	41	28.5
Natural family planning or withdrawal	5	3.5
None	46	31.9

Table 4 Findings related to PrEP use

	Participants (n = 144)	Percent of total (%)
Self-perception of HIV acquisition risk		
Low	122	84.7
Medium	11	7.6
High	2	1.4
Decline	9	6.3
Heard of PrEP		
Yes	63	43.8
No	80	55.6
Decline	1	0.7
Consider using PrEP		
Yes	54	37.5
No	90	62.5

their work. No demographic or sexual history factors were associated with having heard of PrEP in univariate analyses.

After a brief introduction, but prior to presentation of the risks, benefits, and procedures for taking PrEP, 37.5% (54/144) of total participants reported they would consider using PrEP (Table 4). Univariate analyses were performed to determine if any demographic or sexual history factors were associated with initial interest in PrEP. Number of partners, condom use, and perceived risk of HIV acquisition

were the only factors associated with interest in PrEP on univariate analyses. 73.3% (11/15) of women with two or more partners, 50.8% (30/59) of women who used condoms, and 84.6% (11/13) of women who considered themselves medium- or high-risk expressed an initial interest in using PrEP. There was no association between initial interest in PrEP and age, income, education, race, sexual activity within 3 months, gender of sexual partners, or use of contraceptive method other than condoms. The significant associations remained significant when age, race, income, and education level were controlled for in the multivariate analysis (Table 5).

Of the 54 women who reported an initial interest in PrEP, 88.9% (48/54) reported that they would feel comfortable discussing PrEP with their Obstetrician/Gynecologist. 44.4% (24/54) would feel comfortable discussing it with their primary care physician. No participants would rather go to another separate physician to discuss PrEP. 81.4% (44/54) would be able to tell their family that they used PrEP, and 87.0% (47/54) would be able to tell their friends about it. 98% (53/54) reported that they could talk about it with their sexual partner. 18.5% (10/54) of respondents were unwilling to spend any money per month on PrEP. 29% (16/54) would spend \$10/month, while 9.3% (5/54) would spend \$100 or more.

It was then assessed how many women who expressed an initial interest were still interested in PrEP after receiving more information regarding its use and side effects. Most women (87.0%, 47/54) remained interested in PrEP even if they still had to use condoms for intercourse. 50% (27/54) remained interested after learning of short-term side effects such as nausea. 66.7% (36/54) remained interested after learning that they would need to see a healthcare provider and get a blood test four times per year. Most women, 90.7% (49/54), were not deterred by the need to go to a pharmacy monthly to pick up medication. 29% (16/54) of women admitted that they would likely not take their prescribed medication every day. Only 16.7% (9/54) remained interested after learning of a possible risk of kidney damage with long term use, and 13.0% (7/54) remained interested after learning of a possible risk of bone loss and fracture.

After being presented with this additional information, only four of the 54 women (7.4%) originally interested in PrEP were still interested and thought they could take the medication every day. These four women ranged in age from 25 to 50. Two were white and two were black. They had varying levels of education and income. They all preferred men as sexual partners, and each had 0–1 sexual partners in the last 12 months. Three used condoms, and two used other forms of contraception. Interestingly, they all considered themselves to be low risk for HIV acquisition, and all would feel comfortable talking to their Obstetrician/Gynecologist about PrEP. No women who considered themselves medium or high risk for

Table 5 Factors associated with initial interest in PrEP

	Would consider PrEP	Would not consider PrEP	Adjusted p-value
Number of sexual partners			
0–1 partner/12 months	41/123 (33.3%)	82/123 (66.7%)	p=0.02
2 or more partners/12 months	11/15 (73.3%)	4/15 (26.7%)	
Condom use			
No	24/85 (28.2%)	61/85 (71.8%)	p=0.03
Yes	30/59 (50.8%)	29/59 (49.2%)	
Perceived risk of HIV acquisition			
Low risk	40/122 (32.8%)	82/122 (67.2%)	p<0.01
Medium–high risk	11/13 (84.6%)	2/13 (15.4%)	

HIV acquisition remained interested in PrEP after receiving additional information.

Each barrier to continued interest in PrEP was evaluated for associations with demographic or sexual history factors. Race was associated with concern about the long-term side effect of kidney disease. 85% (30/35) of black women said they would lose interest in PrEP after learning of this side effect, while 54% (7/13) of white women said they would lose interest ($p=0.04$). There was no racial difference in loss of interest in PrEP for risk of bone loss ($p=0.16$). Age was associated with loss of interest in PrEP after learning that a monthly pharmacy visit might be required. 33% (3/9) of women in the 30–35 year-old age group would decline PrEP for this reason, while 0 women in other age groups would do so ($p=0.04$). No other reasons for losing interest in PrEP were associated with demographic or sexual history factors.

The subset of 90 women who had no interest in PrEP after an initial introduction were questioned regarding their reasons. The most common reason for lack of interest in PrEP was a perception of low risk of HIV acquisition (75.6%, 68/90). Other reasons are listed in Table 6. Women could choose more than one reason for declining PrEP.

Discussion

We examined awareness of and interest in using PrEP in general Obstetrics & Gynecology clinics in a city in the southern United States. Study subjects were predominantly African-American, and a large proportion were low-income.

43.8% of participants in this study had prior knowledge of PrEP. This is higher than in studies of women in other communities, and may be due to highly visible local campaigns by several health organizations that offer PrEP. Among women participating in focus groups in Washington, DC in 2014, 12.8% of women had heard of PrEP [14]. A study in six United States cities in 2015 found that less than 10% of women had heard of PrEP [15]. Among

Table 6 Reasons for lack of interest in PrEP after initial introduction

	Participants (n=90)	Percent of total (%)
Not at risk	68	75.6
Concern regarding side effects	26	28.9
Not wanting to take daily pill	18	20
Concern regarding possible cost	8	8.9
Frequent doctor visits and blood draws	8	8.9
Concern about what people would say	5	5.6

non-transgender women presenting to a Rhode Island sexually transmitted infections clinic in 2016, 17.3% were aware of PrEP [16]. Finally, a survey of women involved in the criminal justice system in 2018 showed that 25% were familiar with PrEP [17].

In other high-risk demographic groups, PrEP awareness varies widely, ranging from 18.2% among black MSM and transgender women in New York City in 2018 [18], to 96.5% among MSM who use amphetamines in Seattle in 2016 [19].

Most participants (84.7%) considered themselves low-risk for acquiring HIV, though only 41.0% used condoms. Women may have underestimated their risk of HIV acquisition, which may have contributed to lower initial or persistent interest in PrEP. A study of college students in Chicago in 2007 showed that nearly half of participants underestimated their risk [20]. Recent data in American women on the topic of perception of HIV risk is not available.

After a brief introduction, 37.5% of the surveyed population considered using PrEP as a biomedical harm reduction tool. Having two or more sexual partners in the last 12 months, using condoms, and self-perceived medium- or high-risk of HIV acquisition were associated with initial interest in PrEP on multivariate analysis. However, after

receiving further information regarding the use and possible side effects of PrEP, only four women (7.4% of interested population, 2.8% of total population) remained interested in PrEP. None of the 13 women that considered themselves to be medium- or high- risk for HIV acquisition remained interested in PrEP. The risk of long term side effects was the most common reason for loss of interest in PrEP among those initially interested.

Other studies conducted in women have shown that the risk of long-term side effects deters potential users from starting PrEP. In focus groups conducted in Washington, DC in 2014, women expressed interest and substantial enthusiasm for PrEP, but they wanted to receive further information about long-term side effects prior to making a decision about whether to use it [14]. In the same study, HIV-positive women who utilized the same or similar medications on a daily basis advised against the daily use of PrEP for their HIV-negative counterparts, due to the side effects that they themselves had experienced [14]. Women participating in focus groups in other US cities as part of another investigation also wanted more information about side effects [15]. Mitigating concerns about side effects will be essential to increasing PrEP uptake among eligible women. More specific information about the frequency and severity of possible side effects may help assuage potential user's fears. Further study is needed in this area.

Compliance represents another barrier to PrEP effectiveness and eligibility. The medication must be taken 6 or 7 days per week to be effective in women. In addition, the CDC recommends counseling and laboratory monitoring every 3 months for patients using PrEP [4]. In this investigation, 29% of women that were initially interested in PrEP admitted that they would not take the medication every day. This is troublesome as actual non-adherence may be higher still. The development of non-daily pharmacologic prevention measures may be necessary to overcome this barrier. In addition, though only 8.9% of women in this population viewed quarterly doctor visits and blood draws as a barrier, loosening this requirement in select patients may increase interest in and adherence to PrEP. There is precedent for less frequent revisits, as individuals with well-controlled HIV now need to meet with their providers only twice a year [21].

Cost was not a major barrier to PrEP in this study. Only 8.9% of participants listed it as a concern. PrEP is covered by most commercial and public insurance plans in Louisiana, and uninsured or under-insured patients can access financial assistance programs through the drug manufacturer or private foundations.

Social stigma surrounding PrEP did not play a large role in this study population. Most women would find it acceptable to discuss PrEP with their Obstetrician/Gynecologist or another health provider. Most felt that they could discuss it with their family, friends, and sexual partners. Other

investigations have found that perceived PrEP-user stereotypes and concern regarding disapproval by others is a major barrier to women using PrEP. In an online survey of Planned Parenthood attendees in Connecticut, 30% of respondents indicated that they would be ashamed to disclose PrEP use [22]. In focus groups in Washington, DC in 2014, women cited expected negative reactions from family, friends, and sexual partners as being a major barrier to PrEP use [23]. It is possible that the relatively higher awareness of PrEP in this study population has lowered the perceived stigma in this group.

An additional important finding is that the large majority of women in this population (88.9%) were comfortable discussing PrEP with their Obstetrician/Gynecologist, as compared to 44.4% of women who would feel comfortable discussing it with another primary care provider. There is currently no established medical "home" for PrEP prescriptions [24]. Though the American College of Obstetrics & Gynecology supports and encourages the prescription of PrEP by Obstetrician/Gynecologists, no published data have described the willingness of this group of physicians to do so [25]. This emphasizes the need for further provider training and research in this area.

This study did have several limitations. The survey used in the study was not validated, was not tested in focus groups prior to implementation, and has not been used in prior studies. Although women with high-risk demographic characteristics were represented, and fewer than half (41.0%) used condoms, the majority of participants were behaviorally low-risk in that only 10.4% reported having two or more partners over the last 12 months. Women were not explicitly categorized as being eligible for PrEP or not, according to CDC guidelines. Prior and recent history of STI, frequency of intercourse without a condom, timing of most recent HIV test, history of unintended pregnancy, gender identity, prior or current intravenous drug use, and information about risk behaviors of participants' sexual partners, all of which could be associated with perceived and actual risk of HIV acquisition, were not assessed. Surgical sterilization and menopause, which could affect condom use, and therefore HIV acquisition risk, were not examined. Participants were not educated on risk factors for HIV as part of the study, and their knowledge of risk factors was not assessed. Improved education regarding risk factors and eligibility for PrEP may have resulted in higher interest in PrEP. Latinas were under-represented because the survey was not offered in Spanish. It is possible that a more detailed discussion of the relatively low risk of side effects to kidney and bone, which concerned study participants, would have allowed more women to remain interested in using PrEP. Future research should address these gaps. Finally, the study was conducted in one urban area in the southern United States and is not necessarily generalizable to other regions.

Conclusion

It remains challenging to identify women in a general Obstetrics & Gynecology population who are good candidates for, and who remain interested in PrEP after counseling. Though general awareness of PrEP was higher than in other populations, and perceptions of stigma were lower, concerns about long-term side effects persisted, and were the main deterrents for continued interest in PrEP after counseling. Participants' underestimation of their own risk of HIV acquisition may also have contributed to the lack of interest. More research is needed to better understand the actual risks associated with long-term PrEP use, and how to best counsel women about their own risks and the risks of medication use. Obstetrician/Gynecologists, due to their established role in discussing sexual history and sexual health with their patients, are well-suited to counsel about and prescribe PrEP. Further training and research into willingness of these providers to be one of the medical "homes" for PrEP is needed.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflicts of interest.

Ethical Approval All procedures performed in this study were in accordance with the ethical standards of the institution and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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