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Pre-exposure prophylaxis prescribing and retention in care among heterosexual women at a community-based comprehensive sexual health clinic

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Abstract

In the United States, heterosexual women account for 20% of new HIV infections. As a user-controlled HIV prevention method, pre-exposure prophylaxis (PrEP) has substantial potential to reduce new infections among women. However, among women, PrEP is vastly underutilized. To guide efforts to increase women-at-risk's PrEP use, we sought to describe the characteristics of women prescribed PrEP as well as their retention in PrEP care. We conducted a chart review of women who received care at a comprehensive sexual health clinic within a large urban health care system. Referral sources included the health care system's clinics and HIV testing program, as well as local community-based organizations. From 1 December 2014 to 5 August 2016, 554 women received care at the clinic. During this period, 21 heterosexual women (3.8%) received at least one prescription for daily oral PrEP. For women prescribed PrEP, median age was 35 years old (range: 20–52). The majority (66.7%) were either Latina or non-Latina Black and most (81.2%) had public health insurance. The most common PrEP indication was being in a known sero-discordant partnership (85.7%). Of women in such partnerships, 83.3% reported their male partner was currently taking antiretroviral medications (ARVs) and 16.7% reported trying to conceive with their partner (not mutually exclusive). Of women with ARV-using partners, 66.7% reported that their partners were virally suppressed. Retention in PrEP care at three months was 61.1% and, at six months, 37.5%. Further study is necessary to expand PrEP to women whose risk factors extend beyond being in a known sero-discordant partnership, and to understand the reasons for the observed drop-off in PrEP care visits in real-world settings.

Keywords

HIV; primary prevention; women; antiretroviral agents; PrEP

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Disclosure statement

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Introduction

Pre-exposure prophylaxis (PrEP) represents an innovative HIV prevention strategy, particularly for heterosexual women. Unlike most other HIV prevention methods, PrEP is user-controlled, and, thus, its use does not require the cooperation or participation of a male partner. However, despite its known efficacy in heterosexual couples (Baeten et al., 2012; Thigpen et al., 2012), PrEP remains vastly underutilized among women (Mera et al., 2016). The Centers for Disease Control and Prevention (CDC) estimate that about 500,000 heterosexual women in the United States (U.S.) are eligible for PrEP (Smith et al., 2015). However, data accounting for 80% of the U.S. retail pharmacies that have prescribed daily oral PrEP indicate about 19,000 women have received a PrEP prescription (Mera et al., 2016).

Elucidating the characteristics of heterosexual women prescribed PrEP in clinical practice is essential for developing effective strategies to increase PrEP use among this key population. However, there are no published studies specifically focused on PrEP prescribing to non-pregnant U.S. women in a real-world clinical setting. Therefore, among women prescribed PrEP, we examined socio-demographic and clinical characteristics as well as retention in PrEP care.

Methods

Clinical site and eligibility

We conducted a retrospective chart review of women who received care at a community-based comprehensive sexual health clinic. The clinic is part of large integrated health care system in the Bronx, a region of New York City with a high HIV prevalence (New York City Department of Health and Mental Hygiene, 2014). The clinic, which opened in late 2014, provides PrEP, post-exposure prophylaxis, and screening and treatment for sexually transmitted infections. The clinic's PrEP referral sources include the health care system's HIV clinic (i.e., HIV-negative individuals in sero-discordant partnerships), hospital-based HIV testing program, affiliated community-based clinics, and local community-based organizations. In New York State, through a combination of health insurance coverage, a State-sponsored PrEP assistance program, and a pharmaceutical-sponsored drug assistance program, there is nearly universal coverage for PrEP clinical visits, lab tests, and medication (Gilead Sciences; New York State Department of Health). Institutional Review Board at the Albert Einstein College of Medicine approved the study.

Using the electronic medical record (EMR), we identified all HIV-negative women who received care at the clinic from 1 December 2014 to 5 August 2016. Using the clinic's PrEP registry, which includes all patients prescribed emtricitabine/tenofovir disoproxil fumarate for PrEP, we identified all women who self-reported heterosexual contact, as documented in the EMR.

Data collection and measures

Using the EMR, we collected data on age, race/ethnicity, insurance status, referral source, PrEP indication, dates of clinic visits, and HIV test results of women prescribed PrEP.

Retention in PrEP care

As there is no gold standard for assessing retention in PrEP care, we used a measure consistent with national PrEP guidelines' recommended clinic visit schedule (i.e., every three months) and another recent publication to assess retention at three and six months after the index PrEP visit (Chan et al., 2016; Centers for Disease Control and Prevention, 2014). The EMR contains clinic visit and prescription data for all clinical encounters within our health care system. Retention at three and six months was defined as having any PrEP care-related clinic visit or phone note (i.e., EMR note documenting correspondence by phone between patient and health care provider related to PrEP care) between two and four months and five and seven months, respectively, after the index visit. Retention at three and six months were assessed only for those women with sufficient follow-up time from the index visit. Retention was not defined by maintenance of medication.

Results

From 1 December 2015 to 5 August 2016, 554 HIV-negative women received care at the clinic. Among 21 women (3.8%) prescribed PrEP, median age was 35 years old, and most were either Latina or non-Latina Black and had public health insurance (Table 1). We did not find a significant difference by age, race/ethnicity, or insurance status between women prescribed PrEP and those who were not (data not shown). About one-quarter of women prescribed PrEP were referred from the HIV clinic; there were no documented referrals from community-based organizations.

The most common indication for PrEP was being in a known sero-discordant partnership (85.7%) (Table 1). Of women in such partnerships, 83.3% reported their partner was currently taking antiretroviral medications (ARVs) and 16.7% reported trying to conceive with their partner (not mutually exclusive). Of women with ARV-using partners, 66.7% self-reported their partners had an undetectable HIV viral load. For all women prescribed PrEP, retention in care at three months was 61.1% and, at six months, 37.5%. No HIV seroconversions were identified.

Discussion

This is the first study to describe characteristics and retention in care among non-pregnant U.S. women prescribed PrEP. We found that most women were in known sero-discordant relationships with ARV-using partners, most of whom were reported to be virally suppressed. Less than two-thirds of women were retained in PrEP care at three months and only about one-third at six months.

Patient- and provider-level factors may explain why most women prescribed PrEP were in known sero-discordant partnerships. This finding, similar to that of a study of U.S. women at high risk for HIV before, during, and after pregnancy, may suggest that PrEP appeals to women with an identifiable HIV risk (e.g., known HIV-positive partner). However, many women at high risk may perceive themselves to be at low risk because they have one male partner; however, the HIV status of that partner is often unknown (Blackstock et al., 2015; Hader, Smith, Moore, & Holmberg, 2001). Low perceived risk of HIV has been identified as

a potential barrier to PrEP uptake among women (Garfinkel, Alexander, McDonald-Mosley, Willie, & Decker, 2016). Similarly, for providers, a woman being in sero-discordant partnership may be an easily recognizable HIV risk factor. Because often partner's risk behaviors and community HIV prevalence place women at increased risk in addition to her individual risk behaviors, providers may find it challenging to identify women at substantial risk for HIV infection (Adimora et al., 2006; Doherty, Schoenbach, & Adimora, 2009).

That most women on PrEP were in known sero-discordant partnerships suggests PrEP providers may not be reaching women at highest risk. Although treatment-as-prevention is an effective HIV prevention strategy, it is not known what additional prevention benefit PrEP provides when one's partner is durably suppressed (Cohen et al., 2016; Rodger et al., 2016). The CDC's PrEP guidance offers no specific recommendations about PrEP use in this context. However, while most women reported their partners had undetectable viral loads, we do not know whether their partners, in fact, were virally suppressed and for how long. A recent study in our health care system indicated frequent missed opportunities for identifying persons engaged in care who are at high HIV risk, a disproportionate number of whom are heterosexual women (Cossarini, Ginsberg, Anastos, & Felsen, 2016). Taken together, these findings suggest "inreach" is needed to identify women-at-risk in care as well as outreach to those with other HIV risk exposures (e.g., inconsistent condom use with partner of unknown HIV status, etc.).

While we found a drop-off in visit attendance after PrEP initiation, identifying an optimal retention threshold is challenging. One study found that women took PrEP for a median of seven months, suggesting at least 50% were retained in care at six months (Seidman et al., 2016). However, many of these women were pregnant or breastfeeding which may have affected their decisions about continuing PrEP. A study of men who have sex with men found retention in PrEP care at three and six months to be 72% and 57%, respectively, higher than our study's estimates (Chan et al., 2016). Another found that women were more likely to discontinue PrEP compared with men (Marcus et al., 2016). As cost and lack of insurance coverage have been suggested as barriers to PrEP use, we would have expected greater retention among women as PrEP coverage is nearly universal in our sample.

Our study has several limitations. First, we do not know how many women seen at the clinic may have been truly eligible for PrEP. Given the care setting, we suspect that many more than our sample were PrEP eligible, which mirrors national trends. Second, we obtained data via chart review. Data from regular clinical care may not have been systematically recorded, and, therefore, may be missing certain clinical information. Third, our findings may be specific to sexual health clinics with relatively high background HIV prevalence in regions with near-universal coverage for PrEP and, therefore, not generalizable to other health care settings or geographic locations where PrEP is not covered. Lastly, we do not know to what extent women were adherent to PrEP or the exact timing or reasons for PrEP discontinuation (e.g., no longer in a known sero-discordant partnership).

At a community-based comprehensive sexual health clinic, we found that of the few women prescribed PrEP, most were in known sero-discordant relationships with ARV-using partners. We observed a substantial drop-off in clinical visits after PrEP initiation. Given PrEP's

promise as a novel and effective HIV prevention strategy, initiatives to increase PrEP use among women should consider strategies to reach different categories of women-at-risk as well as elucidate the reasons why women may not be retained in PrEP care.

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Table 1

Socio-demographic characteristics and retention in PrEP care among women prescribed PrEP (n = 21).

Age, median, range	35 (20–52)
Race/ethnicity, n (%)	
Non-Latina Black	6 (28.6%)
Latina	8 (38.1%)
Other/not documented	7 (33.3%)
Insurance	
Public (i.e., Medicaid)	17 (81.2%)
Private	4 (19.0%)
Referral source	
HIV clinic	6 (28.6%)
HIV testing and counseling program	2 (9.5%)
Affiliated clinic within the health care system	3 (14.3%)
Unaffiliated clinic	3 (14.3%)
Sought PrEP	3 (21.1%)
Sought PEP and transitioned to PEP	2 (9.5%)
Sought STI testing	2 (9.5%)
PrEP indication	
Sero-discordant partnership	18/21 (85.7%)
Partner on antiretrovirals ^a	15/18 (83.3%)
Partner on antiretrovirals with undetectable viral load ^b	10/15 (66.7%)
Trying to conceive with partner ^a	3/18 (16.7%)
Partner with suspected or known concurrency	2/21 (9.5%)
Multiple male partners	1/21 (4.8%)
Proportion retained in PrEP care	
At 3-month visit ^c	11/18 (61.1%)
At 6-month visit ^c	6/16 (37.5%)

^aDenominator is of those in sero-discordant partnerships.^bDenominator is of those with a male partner on antiretrovirals.^cDenominator includes only those with sufficient follow-up time from PrEP initiation.