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Are Providers PrEPed? A Retrospective Cohort Study Analyzing Retention in Care among Pre-Exposure Prophylaxis (PrEP) Patients

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Abstract

Introduction: PrEP is a novel biomedical prevention tool that has proven to decrease the incidence of HIV acquisition. This once-daily pill consists of tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg and has been shown to decrease the rates of HIV acquisition by 99% in adherent men who have sex with men (MSM). Barriers remain in PrEP implementation, including uncertainty of the most optimal provider for PrEP rollout. The primary outcome of this study retention in care defined as patients attended at least one of two scheduled follow- up visits within 6 months of PrEP initiation.

Setting: This is a single center, retrospective, cohort, chart review conducted at a federally qualified health center in New Orleans and Institutional Review Board approved by Xavier University of Louisiana.

Methods: This study included all individuals initiated on TDF/FTC for PrEP therapy between February 2016 to December 2017 at the clinic and had been issued a PrEP prescription for a minimum of 6 months but no more than 12 months. Retention in care was defined as the patient returning to clinic to follow up with their providers at either the 3 or 6 month visit since PrEP initiation, within a three-week window of the scheduled visit. Adherence was defined as at least 90% self-reported pill completion. Demographic data, adherence rates, number of attended visits, and sexual risk behaviors were collected.

Results: A total of 216 patients were included in the analysis and were prescribed PrEP from 15 health care providers, 9 (60%) of which identified as infectious disease specialists (ID) and 6 (40%) as non-ID specialized Primary Care Providers (PCP). Patients were primarily Caucasian/White (67.6%) and classified as Men who have sex with men (MSM)/bisexual men/transgender women (59.26%). Patient characteristics between the patients in the PCP group and the ID group were comparable however age was significantly different, with slightly younger patients with a mean age of 32.5 years in the PCP group and 35.7 in the ID provider group. Between the two provider types, social behaviors, sexually transmitted infections, risk behaviors, and sexual risk categories were comparable with no differences among the groups. A total of 104 patients (48.14%) returned for both 3-and 6-month follow up, in accordance with the CDC recommendations. In the bivariate model, ID providers were 7.5 times more likely to retain patients in care than PCP (OR=7.5, 95% CI 4.45-12.63). Furthermore, African Americans were 5.56 more likely to be retained in care than Whites (OR=5.56, CI 2.73-11.29). In the multivariable model no factors were associated with increased retention in care including provider types (ID OR=0.88 CI 0.36-2.16).

Conclusions: The finding of this study are consistent with the CDC's recommendations and highlight that PCPs provide similar retention in care outcomes as ID physicians and play a key role in disseminating PrEP to individuals in vulnerable communities.

Keywords

Pre-exposure prophylaxis; Retention in care; Provider type; Primary care physicians; Infectious disease physicians; HIV

Introduction

The HIV/AIDS epidemic has led to significant expansion in viral transmission prevention efforts and practices. Pre-exposure prophylaxis (PrEP) is a novel biomedical prevention tool that has proven to significantly reduce the incidence of HIV acquisition among individuals

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identified as high-risk in both the iPrEX and Partners PrEP trials [1]. This once-daily, pill consists of tenofovir disoproxil fumarate (TDF) 300 mg/emtricitabine (FTC) 200 mg, was FDA approved in July 2012 for HIV prevention [2]. TDF/FTC been shown to reduce the risk of HIV by 99% in men who have sex with men (MSM) with drug levels indicating daily adherence, and a 75% relative risk reduction of HIV acquisition in heterosexual men compared to placebo [1,2]. The benefits of PrEP are promising in curbing the national HIV epidemic; however, there remain barriers among PrEP implementation. One issue that remains underexplored is expanding the roll out of PrEP among non-infectious disease providers [3].

In 2014, the CDC published clinical practice guidelines that were recently updated in 2017 to improve primary care providers (PCP) and Infectious Disease (ID) providers' pharmacovigilance with PrEP. The guideline assists providers in identifying patients at "high risk" of acquiring HIV and groups patients into three categories: MSM, heterosexual adults, and persons who inject drugs (PWID) [4]. Nonetheless, a recent study found that Human Immunodeficiency Virus Providers (HIVP) and medical students' willingness to prescribe PrEP varied among patient types and were not aligned with CDC recommendations [5,6]. In addition to identifying high-risk populations, the guideline emphasizes the importance of monitoring patients every 3 months while on therapy to assess adherence, perform HIV and pregnancy tests, risk reduction counseling, prescription refills, and Sexually Transmitted Infection (STI) testing in symptomatic persons and asymptomatic MSM [4]. Per Hoffman et al 2016, in-depth interviews with 30 clinicians found that the skills for PrEP follow-up including adherence and risk reduction counseling are not routinely practiced by PCPs compared to HIVP [3]. PCPs, on the other hand, were believed to have limited experience in this area but are at the forefront of encountering and managing high-risk patients and thus PCPs could be ideal to target eligble patients who may not be PrEP aware. This dilemma describes the term "purview paradox" and thus the answer to who should prescribe PrEP remains unclear [3]. The paradox is that there is uncertainty among providers of who is to prescribe PrEP since neither PCPs or ID providers believe that it falls within their clinical domains. An established clinical home for PrEP has yet to be defined. Previous research has been focused on interviews; however this study will assess the outcomes of PrEP patients based on provider type to evaluate if PrEP should have a defined home.

Reduced medication adherence and retention in care are significant predictors of increased HIV transmission [7,8]. PrEP medication adherence has been the overarching theme that is correlated with the efficacy of PrEP [1,8-10]. Multiple clinical strategies have been identified to maximize PrEP adherence. Enhanced counseling that incorporates motivational interviewing techniques and dose taking with an activity that is part of the patient's daily routine, are facilitators for PrEP adherence [11,12]. In addition, retention in care may have an equal or greater impact on PrEP effectiveness.

PrEP access remains limited and its widespread use in high-risk populations has yet to be expanded [13-17]. Expanding access can be targeted in many ways, one of which is educating providers. Providers are identified as a barrier to PrEP access [14-16]. Even when no other barriers exist, prescriber bias may be the first hurdle to PrEP therapy [15,16]. Retention in care and adherence remain barriers that influence HIV transmission and are crucial to patient outcomes for PrEP therapy.

With PrEP being a bio-behavioral intervention, healthcare professionals are vital in aiding its widespread use. A main concern of providers is the increased risk compensation patterns that may be associated with PrEP use [16-18]. Prior to FDA approval of PrEP, surveys were conducted to assess sexual behavior changes in patients receiving PrEP therapy and found that patients assumed it could potentially decrease their use of condoms [19-22]. Post-approval it was found that gay and bisexual men using PrEP were more likely to contract an STI after starting therapy [23]. Some suggest that the CDC's recommendations of screening PrEP patients for STI at least biannually for patients who are asymptomatic or quarterly for all MSM patients with or without symptoms, allows for increased detection of STI that may have otherwise been left undiagnosed [24]. Therefore, proper sexual risk counseling as well as providing PrEP follow-up services are critical components of success and may have a significant impact on patient outcomes.

The purpose of this study is to assess retention rates of PrEP patients among ID specialists compared to primary care providers. The Human Resources and Services Administration HIV/AIDS Bureau (HRSA HAB) included "HIV medical visit frequency" as a performance measure for HIV providers in order to maximize patient outcomes. Expanding the provider network for PrEP beyond infectious disease physicians is at the center of health optimization strategies for HIV prevention [7]. Since provider type has been identified as a barrier to PrEP care, it is important to investigate the impact the provider type has on PrEP dissemination in order to maximize its uptake and retention of care in high-risk populations. The primary outcome of this study will explore whether provider specialty impacts patients' retention in PrEP care. This study protocol was approved by Xavier University of Louisiana's local institutional review boards.

Methods

Study design

This retrospective cohort chart review study included all individuals initiated on tenofovir disoproxil fumarate/emtricitabine for PrEP therapy between February 2016 to December 2017 at the clinic and who had been issued a PrEP prescription for a minimum of 6 months but not more than 12 months. One-month post prescription initiation was permitted to allow for any delays in initiation of therapy such as prior authorizations. Patients were then followed at the 3 and 6 month interval. Retention in care was defined as the patient returning to clinic to follow up with their providers at either the 3 or 6 month visit since PrEP initiation, within a three-week window of the scheduled visit. If patients attended their follow up visit 3 weeks after their scheduled appointment they were considered lost to follow up.

Clinical site and eligibility

This study was conducted in a clinic located in New Orleans, Louisiana, which is ranked as the tenth state nationally with new HIV incident cases, per the CDC [25]. This healthcare site is a Federally Qualified Health Center (FQHC) dedicated to serving underserved individuals, in addition to those who are not insured. This site has an embedded dedicated HIV prevention clinic and a general primary care clinic. PrEP was offered to individuals by Infectious Disease (ID) providers and primary care providers (PCP) who are not ID –specialists. ID providers were defined as having credentials, certifications or extensive training and experience (>7 years) related to HIV or infectious disease and include physicians, nurse practitioners and physician assistants. The clinic consists of a dedicated HIV prevention clinic and a general primary care clinic. ID providers encountered patients in the primary care clinic in addition to a dedicated HIV prevention clinic established in February 2016. On the other hand, PCP only encountered patients in primary care clinics.

Patients who presented to the HIV prevention clinic were evaluated for PrEP therapy through a questionnaire that assessed behavioral risk factors. CDC defined risk category(s) included: MSM, heterosexuals with multiple sex partners, or Intravenous Drug Users (IVDU). If eligible for PrEP therapy, patients were then educated on PrEP, counseled on its adherence, and on ways to reduce risky sexual practices. PCP's not affiliated with the prevention clinic utilized the same standardized questionnaire as that of the HIV prevention clinic to assess eligibility for PrEP initiation. Patients were scheduled for 3-month follow-up visits post PrEP initiation per CDC guidelines [4]. Each follow up visit included the same questionnaire to the screening

questionnaire prior to PrEP initiation however also included questions regarding the patient's sexual risk behaviors and adherence to their medication therapy. The primary outcome of this study was defined as retention in care if the patients attend of at least one of two scheduled follow- up visits within 6 months of PrEP initiation [9].

Data collection and measurement

Demographic data was collected for each study participant at baseline and it included age, race/ethnicity, gender identity, insurance type, and provider type. Behavioral data was also collected, which included sexual orientation, number of sexual partners, alcohol use, condom use, prior STD diagnosis, and adherence to medication. All behavioral data was self-reported by the patient and documented in the Electronic Medical Record (EMR). At each follow-up visit the providers would assess any changes in risk compensation patterns including changes in percent condom use and number of sexual partners in the past 3 months. Furthermore, self-reported adherence patterns to PrEP therapy were also collected from each visit. Adherence was defined as at least 90% pill completion [26].

Continuous variables such as total number of sexual partners prior to initiation of PrEP, total number of sexual partners during the first 6 months of PrEP, lowest self-reported percentage use of condoms during sexual intercourse (anal, oral or vaginal) while on PrEP, total number of sexual partners during the first 6 months of PrEP and self-reported PrEP compliance were all reviewed for normality distribution as well as for transformation. Outliers were reviewed for each continuous variable and assessed for inclusion

Statistical analysis plan

Baseline demographic and behavioral data were analyzed using descriptive statistics. For continuous variables, the means and standard deviations were reported and for categorical variables frequency distributions were reported. Two-sample t-tests and Chi-square tests were performed to compare continuous and categorical baseline variables, respectively, by provider type. Simple and multivariable logistic regression analyses were performed to determine which of these variables: recent 6-month history of drug use, alcohol use, sexual orientation, any baseline sexually transmitted infection (chlamydia, gonorrhea or syphilis) or any sexual transmitted infection during PrEP therapy were predictor variables. In order to evaluate predictors of retention in care, both a bivariate and multivariable logistic regression model was performed. Multiple imputation were employed for missing variables. A best fit model for predictor variables was assessed using the Akaike information criterion (AIC) and affirmed with a stepwise regression analysis.

To detect differences at baseline between patients managed by ID providers and PCPs, an alpha of 0.05 was considered significant. All analyses were conducted using Stata IC version 15.

Results

A total of 216 patients were newly prescribed PrEP from February 2016 to December 2017 and had been issued a PrEP prescription for at least 6 months but not more than 12 months. A total of 15 health care providers at the site have been identified for prescribing PrEP, 9 (60%) providers have been identified as infectious disease specialists and 6 (40%) as non-ID specialized PCPs.

Patients were primarily Caucasian/White (67.6%) and classified as Men who have sex with men (MSM)/bisexual men/transgender women (10.29%). When comparing the baseline characteristics between the patients in the PCP group and the ID group, age was significantly different, with slightly younger patients with a mean age of 32.5 years in the PCP group (p=0.04) (Table 1). Between the two provider types, social behaviors, sexually transmitted infections, risk behaviors, and sexual risk categories were comparable with no differences among the groups.

Overall, patients at the clinic had high retention rates with 87.6% of patients following up at least once after PrEP initiation. One-hundred four patients (48.14%) returned for both 3- and 6-month follow up, in accordance with the CDC recommendations. A total of 73 (33.8%) of patients returned to the clinic for the 3-month follow-up, and 13 patients (6.01%) for the 6 month follow-up (without first coming in for the 3-month time frame) (Figure 1). No patients involved in the study sero-converted to HIV positive status after initiation of PrEP.

In the bivariate logistic regression analysis, age was included in our final model since it presented as a statistically significant baseline characteristic difference between the two groups as mentioned previously. In the bivariate analysis, ID providers were 7.5 times more likely to retain patients in care than PCPs (OR=7.5; 95% CI 4.45-12.63). African Americans were 5.56 more likely to be retained in care than Whites (OR=5.56, CI 2.73-11.29). In addition, when analyzing sexual behaviors, serodiscordant couples were most likely to be retained (OR=9.5, CI 4.08-22.03) than their heterosexual counterparts. As per (Table 2), MSM ranked second to serodiscordant couples and were observed to be 7 times more likely to be retained in care than their heterosexual counterparts (OR=7, CI 4.15-11.82). Furthermore, patients with higher risk compensation behaviors, such as increased number of sex partners during PrEP, were also more likely to be retained in care. For each additional sexual partner self reported, the likelihood of being retained in care is 204% (OR=3.04, CI 2.09-4.32).

Based on sexual risk category, although not significant, the serodiscordant couples had slightly greater odds of being retained in care in comparison to other sexual risk behavior categories (OR=1.73, 95% CI 0.43–6.95). Similarly, although not statistically significant, MSM, bisexual men, and transgender women who engaged in sex with men were 1.1 times as likely to be retained in care compared to their cisgender heterosexual male or female counterparts, however this was not statistically significant (95% CI 0.32–3.79). Sexual orientation and gender identity likewise did not predict retention in care in the final analysis. Furthermore, increased sexual risk behaviors and drug utilization were also not predictive of retention in care. Adherence was evaluated in this study, however, since all patients reported >90% compliance with PrEP, this variable was excluded from the multivariable analysis.

In the final analysis, a multivariable model was performed to identify significant predictors of retention in care in the presence of other factors. Overall, no factors were associated with increased retention in care. Provider type was not predictive of retention in care and no difference was observed between the two groups (OR=0.88, 95% CI 0.36–2.16). All variables included in the logistic regression were qualitative confounders of retention in care by provider specialty when combined in the multivariable analysis, although all were individual predictors of being retained in care (Table 2).

Discussion

Provider type and retention in care

Retention in care is a crucial measure when ensuring the

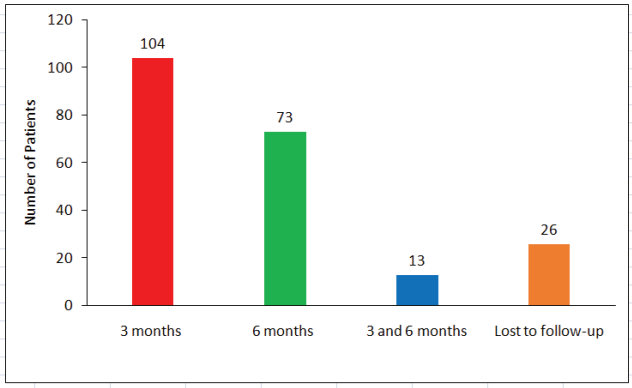

Figure 1: Retention in care among PrEP patients

Patient Demographics	ID Provider (n=135)	Primary Care Physician (n=81)	*p*-value
Age-mean (sd)	35.7 (12.2)	32.5 (8.8%)*	0.04*
Race-n (%)			
White/Caucasian	92 (68.4%)	43 (53.1%)	
African American	30 (22.2%)	29 (35.8%)	0.98
Other	13 (9.63%)	9 (11.1%)	
Social Behaviors-n (%)			
Alcohol Use	92 (68.15%)	47 (58%)	0.15
Illicit Drug Use	38 (28.15%)	25 (30.9%)	0.65
Sexually Transmitted Infection (Chlamydia, Gonorrhea, Syphilis)-n (%)			
Prior to PrEP	26 (19.26%)	22 (27.2%)	0.167
During PrEP	38 (28.15%)	15 (18.5%)	0.12
Risk Behaviors-mean (sd)			
Baseline Number of Sexual Partners	11 (18)	12 (9)	0.87
Number of Sexual Partners 6-months on PrEP	4.7 (6.2)	3.5 (5.9)	0.17
Lowest Reported Percent Condom Use at Baseline	55.4% (31.9%)	53.7% (37.2%)	0.73
Lowest Reported Percent Condom Use on PrEP	38.5% (33.6%)	42.2% (36.5%)	0.45
PrEP Medication Percent Adherence	97% (10.4%)	96% (13.1%)	0.57*
Sexual Risk Behavior			
Heterosexual (MSW†, WSM‡, Bisexual Women, Transgender Men)	14 (10.37%)	11 (13.75%)	0.743
MSM§/Bisexual Men/Transgender Women	82 (60.74%)	46 (57.5%)	
Serodiscordant Couple	39 (28.89%)	23 (28.75%)	

†Men who have sex with women (MSW); ‡Women who have sex with men (WSM); §Men who have sex with men (MSM)

Table 1: Characteristics of patients prescribed PrEP based on provider type

	Univariable		Multivariable	
	Odd Ratio	95% CI	Odd Ratio	95% CI
ID Provider	7.5	(4.45, 12.63)	0.88	(0.36, 2.16)
Age	1.06	(1.05, 1.08)	1.04	0.99, 1.09
Race				
White	1		1	
African American	5.56	(2.73, 11.29)	0.88	(0.32, 2.42)
Other	10.5	(2.46, 44.78)	2.43	(0.47, 12.38)
Risk Compensation Behavior				
Baseline # Sex Partners	1.09	(1.05, 1.14)	0.99	(0.97, 1.01)
Baseline % Condom Use	1.02	(1.01, 1.03)	0.99	(0.97, 1.00)
During PrEP, Number Sex Partners	3.04	(2.09, 4.32)	1.04	(0.94, 1.15)
During PrEP, % Condom Use	1.04	(1.03, 1.05)	1	(0.99, 1.02)
Alcohol Use	8.27	(4.83, 14.13)	1.69	(0.63, 4.53)
Drug Use	5.43	(2.42, 12.16)	0.7	(0.23, 2.11)
Sexually Transmitted Infections				
Baseline STD	15	(4.66, 48.27)	3.03	(0.81, 11.28)
During PrEP STD	16.67	(5.19, 53.43)	2.78	(0.74, 10.24)
Sexual Risk Behavior				
Heterosexual (MSW†, WSM‡, Bisexual Women, Transgender Men)	1		1	
MSM§/Bisexual Men/Transgender Women	7	(4.15, 11.82)	1.1	(0.32, 3.79)
Serodiscordant Couple	9.5	(4.08, 22.03)	1.73	(0.43, 6.95)

†Men who have sex with women (MSW); ‡Women who have sex with men (WSM); §Men who have sex with men (MSM)

Table 2: Factors associated with retention in PrEP care

effectiveness of PrEP. Identifying barriers and facilitators for the continuum of PrEP therapy has yet to be explored. One barrier previously cited by both providers and patients to retention in care is provider type. Patients have identified that obtaining PrEP from a provider other than a PCP facilitates their likelihood to adhere to PrEP therapy [26]. The concern among patients involved an anticipated stigma from their PCP if PrEP was requested due to an established patient-provider relationship [27]. From a provider's perspective, ID clinicians have questioned whether PCPs have sufficient experience or are willing to manage PrEP patients effectively [3,28]. This study is the first, to our knowledge, that compares patient outcomes between different types of PrEP providers. In this study, retention in care was comparable between provider types in the multivariable analysis (ID OR=0.88 CI 0.36-2.16). No significant difference in retention in care outcomes were evident based on provider type in the final model. It is important to note that provider type was not identified as a barrier to retention in care, contrary to what has been proposed in previous studies. Our findings are in support of the CDC's recommendations of expanding PrEP dissemination through PCPs. Both PCP and ID providers can produce similar patient outcomes when prescribing PrEP as our study has identified, and expansion on PrEP uptake is warranted for both groups.

Since the definition of retention in care in this study was less stringent than the CDC's recommendations, allowing patients to be retained as long as they followed up within a 6-month period, more patients were considered retained. One reasoning for this approach is highly attributable to the sites prescribing practices. Numerous prescribers at the clinic provided up to 5 refills on the initial PrEP prescription, which would allow patients to refill their PrEP prescription for up to 6 months after initiation. During the time of data collection for this study, the 2014 CDC guidelines did not have a specific recommendation regarding the number of refills on a PrEP prescription therefore this practice was adopted at the clinic to alleviate transportation and financial barriers for patients in underserved communities such as those in the New Orleans area.

Sexual risk behaviors

Evidence of sexual risk compensation among PrEP users has been an overarching theme in many published studies, however others argue that many patients indicated for PrEP are considered high risk prior to PrEP initiation [29]. Studies suggest sexual risk compensation is a result of patients knowing that PrEP lowers the likelihood of acquiring HIV, therefore, riskier behaviors such as an increase in sexual partners or decreased condom use is observed [30]. Providers are aware of this matter and are less likely to prescribe PrEP due to the possibility of sexual risk compensation among PrEP users [31]. Consistent with previous research, patients' reported condom use after PrEP initiation declined regardless of the provider (8.72% *vs.* 13.3%, PCP *vs.* ID, p=0.56). Conversely, the number of sexual partners among our patients decreased by 0.89% (p=0.29) after PrEP initiation in both provider group. Although not statistically significant, these results emphasize the importance of safer sex and risk reduction counseling being reinforced by providers at each follow-up visit. In addition, our study echoed that both generalists and specialists are equally positioned to provide effective sexual risk counseling as neither group had a statistically significant difference in risk compensation patterns. Highlighting counseling on sustained condom use and STI testing among PrEP patients is crucial to the management of PrEP patient and provider practices.

Adherence

With adherence being necessary for PrEP efficacy, this study explored self-reported adherence rates among patients. Overall, patients involved in the study reported up to 90% adherence to their PrEP prescription in both provider groups. However, as noted in previous studies, over 40% of individuals self-reporting adequate adherence had inadequate dried blood spot drug levels indicative of inadequate adherence [32]. Due to limited access to prescription data, our results may be an overestimation of adherence in this study as patient self reported adherence rates may not always be accurate. In the future, we hope to measure adherence through multiple methods, including blood drug levels, for a more reliable estimation of true adherence [2]. In addition, no patients were diagnosed with HIV during their course of therapy which may suggest that patient adherence was high or that patients were not exposed to HIV positive individuals.

Limitations/future implications

Our study is subject to several limitations. This study was retrospective in nature and conducted at a health clinic in the New Orleans area that allowed for access to a diverse patient population, however, our sample size was limited to patients managed by PCPs. The clinic's health system has historically focused on treating HIV/AIDS patients in the past and expanded its outreach in primary care services. Due to the historical context, there may be a blending of lines between ID providers and PCP's in terms of practice. Future research is warranted to include more patients managed by PCPs and possibly comparing patients at two different sites unassociated with an HIV/AIDS focus. Additionally, most of our secondary outcomes including the number of sexual partners, adherence rates, and percent condom use were based upon self-reporting. Of note, the longitudinal nature of this data did not allow for causality to be determined. Despite the limitations this study offers the following strengths. It is the first of its kind to compare outcomes of PrEP patients based on provider type and our sample was a diverse patient population in terms of age, race, gender and economic status. In addition, this study did not explore differences between clinics and did not include follow up beyond 6 months.

Future research is needed to explore how provider type as well as other patient specific, structural, or social factors may impact retention rates. The need to explore this area further is evident as significant predictors were identified in the bivariate analysis, however, showed no statistically significant difference in the multivariable model. A randomized study based on provider type would be of benefit in the future to add to the growing body of literature on retention of care based on PrEP provider type. Nonetheless, the increased need for PCPs training and adoption of PrEP should be highly encouraged as they seem to provide similar retention in care outcomes as ID specialists.

Conclusions

PrEP dissemination remains limited in high-risk patients and expansion of PrEP nationwide remains a challenge. ID providers have raised concerns that PCPs may not be able to achieve similar outcomes in managing PrEP patients. Based on this study, both provider types achieved similar retention in care outcomes and most patients followed up with their provider at least once during their course of therapy. The findings of this study are consistent with the CDC's recommendations and highlight that PCPs provide similar retention in care outcomes as ID providers and play a key role in disseminating PrEP to individuals in vulnerable communities. Nonetheless, educating PCPs on managing PrEP patients is of utmost importance to achieve these outcomes. The idea of a condensed and comprehensive guideline for all providers caring for PrEP patients may be a necessary to encourage more PCP involvement with PrEP.

Competing Interests

This study has no competing interests.

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