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Population-Level Effectiveness of HIV Pre-exposure Prophylaxis Among MSM and Transgender Persons With Bacterial Sexually Transmitted Infections

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Background: Pre-exposure prophylaxis (PrEP) is highly efficacious, but its effectiveness may be limited by poor adherence or discontinuation. Our objective was to estimate the effectiveness of real-world PrEP use in a population at increased risk of HIV infection.

Setting: King County, Washington.

Methods: We conducted a retrospective cohort study using sexually transmitted infection (STI) partner services (PS) interview data collected January 2014–August 2018 in King County, Washington, USA. During PS interviews, men who have sex with men and transgender persons who have sex with men were asked if they were taking PrEP. We linked STI PS data to HIV surveillance data to estimate HIV incidence among self-reported PrEP users vs. nonusers using Cox proportional hazards regression, adjusting for age, race/ethnicity, and calendar year.

Results: Among 4368 individuals, 1206 (28%) were taking PrEP at the time of the PS interview. The median observation time was 14 months (interquartile range 6–23 months). Five (0.4%) of 1206 PrEP users and 97 (3%) of 2162 PrEP nonusers were subsequently diagnosed with HIV ($P < 0.001$). HIV incidence was lower among PrEP users than nonusers [0.17 vs. 1.86 cases per 100 person-years, adjusted hazards ratio 0.21 (95% confidence interval: 0.08 to 0.58)]. Latinx ethnicity, Native Hawaiian/Pacific Islander ethnicity, gonorrhea, and syphilis were also independently associated with higher HIV risk.

Conclusions: Self-reported PrEP use was associated with a 79% reduction in HIV incidence among men who have sex with men and transgender persons who have sex with men with STIs in King County.

Key Words: HIV, PrEP, MSM, TGSM, STD

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INTRODUCTION

HIV pre-exposure prophylaxis (PrEP) is highly efficacious in preventing HIV infection, but suboptimal adherence and retention on PrEP may limit the effectiveness of the intervention in practice. Among men who have sex with men (MSM) and transgender women prescribed PrEP in geographically diverse US cities, a significant proportion never started PrEP and approximately 30%–50% discontinued it within a year of starting.[1–4] The reasons why patients abandon PrEP are not well understood, but discontinuation is associated with higher copayments, lower levels of education, substance abuse, younger age, and black race.[1,5,6] Insofar as PrEP discontinuation occurs disproportionately among those more vulnerable to HIV infection, suboptimal PrEP retention threatens to compound racial/ethnic disparities in PrEP uptake and further exacerbate HIV health inequities.[7]

Although PrEP discontinuation is common, the extent to which it impacts the population-level effectiveness of PrEP is not clear. To date, relatively few studies have evaluated the effectiveness of PrEP in real-world practice (ie, nonresearch settings). One of the first such studies in the United States, from the Kaiser Permanente Northern California health system, reported no new HIV infections with 388 person-years of PrEP use, although those who discontinued PrEP were administratively censored.[8] However, subsequent studies of the Kaiser PrEP program reported 2 new HIV infections with 850 person-years of PrEP use, both in individuals who lost insurance coverage, and when the analysis was further broadened to include the patients who did not start PrEP after eligibility assessment or who discontinued it, 22 new infections [incidence rate 1.1 per 100 person-years, 95%

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confidence interval (CI): 0.7 to 1.7] were diagnosed.[5,9] A similar study of patients prescribed PrEP in the US Veterans Health Administration and in a cohort in Montreal, Canada, reported HIV incidence rates of 0.8 cases per 100 person-years and 3.9 cases per 100 person-years, respectively, with most infections among individuals who discontinued PrEP.[10,11] However, neither of these studies compared HIV incidence with control populations. Among a cohort of MSM on PrEP in Sydney, Australia, the HIV incidence was approximately 0.05 per 100 person-years; compared with a historical control group of MSM monitored before the program implementation, implementation of PrEP was associated with a 31.5% reduction in recent HIV infections.[12] A case–control study in the San Francisco sexually transmitted infection (STI) clinic found that patients who reported having ever used PrEP at the time of their first clinic visit had 76% lower odds of subsequent HIV diagnosis compared with those who had not ever used PrEP.[13] Together, these studies suggest that PrEP is effective, but the level of effectiveness is difficult to quantify and the impact of PrEP discontinuation on the population-level effectiveness remains unclear.

The objective of this study was to estimate the effectiveness of real-world PrEP use among persons at highest risk of HIV in King County, Washington. We used public health STI and HIV data to identify MSM and transgender persons who have sex with men (TGSM) who were diagnosed with a bacterial STI and compared the subsequent incidence of HIV among individuals who reported taking PrEP to the incidence among those who reported not taking PrEP at the time of their STI diagnoses.

METHODS

We conducted a retrospective cohort study using King County, WA, STI partner services (PS) interview data collected January 1, 2014, to August 31, 2018.

STI Case Investigations and Partner Services Interviews

We identified MSM and TGSM with STI who were and were not taking PrEP at the time of the STI PS interview by self-report and matched those data to HIV surveillance data to identify persons who were subsequently diagnosed with HIV infection. Disease intervention specialists (DIS) began asking all individuals interviewed for PS if they were taking PrEP at the time of their STI diagnosis in 2014.[14] Throughout the study period, the Public Health Seattle and King County PS protocol was for DIS to investigate all cases of syphilis to determine the stage of infection and attempt to interview all individuals with early syphilis (primary, secondary, or early latent). Before April 2016, DIS also investigated and attempted to contact all MSM and TGSM diagnosed with gonorrhea or chlamydia. After April 2016, interviews were limited to HIV-negative MSM and TGSM with rectal or urethral gonorrhea or untreated chlamydia. During the study period, all individuals diagnosed with HIV were asked about current or past PrEP use at the time of their HIV diagnosis. PrEP users who had a diagnosis of HIV were subsequently contacted by DIS to assess their PrEP adherence at time of diagnosis.

Data Sources

We used the PS interview data from the Washington State Public Health Information Management System (PHIMS), data on PrEP from a supplemental PS database and HIV diagnosis data from the Enhanced HIV/AIDS Reporting System. These data sets are routinely matched using a deterministic algorithm based on name, date of birth, and sex.[15,16] The matching is performed weekly, and case matches are indicated in the PHIMS database available to DIS conducting case investigations and PS interviews. Race/ethnicity is collected at the time of case reporting. We used information obtained from the PS interview to define the gender of sex partners, anal sex with men, and methamphetamine use in the past year, as methamphetamine use is predictive of HIV acquisition among MSM.[17,18] Each participant's first PS interview was used in this analysis to determine the PrEP status and start time of observation. We did not include information obtained about PrEP use obtained in subsequent PS interviews for those who had more than 1 case during the analysis period.

Population

The study population included MSM and TGSM diagnosed with gonorrhea, chlamydia, or syphilis of any stage who were interviewed for PS. MSM were defined as any male-identified persons who reported having sex with men as both cisgender and transgender men have comparable HIV risk.[19] Transgender persons other than transgender men were defined on the basis of self-identified transgender identity in the PS interview or discordance between assigned sex at birth and current gender identity, using a 2-step gender identity process.[20] We assumed that self-reported PrEP use was accurate based on previous research, and that those without an indication of PrEP use were not on PrEP.[21] We excluded persons diagnosed with HIV within 14 days of their PS interview.

Analyses

Descriptive statistics were used to characterize the study population. χ^2 and 2-sample t tests with equal variance were used to compare characteristics of PrEP users and non-PrEP users. The Fisher exact test was used to compare characteristics of HIV-positive PrEP users and nonusers. Analyses were conducted using Stata 15, College Station, TX.

We calculated the proportion of individuals who acquired HIV among those taking PrEP and not taking PrEP at the time of the first PS interview in the analysis period. We did not attempt to define PrEP discontinuation among the group reporting PrEP use because our primary intent was to analyze the impact of real-world PrEP use, which includes periodic discontinuation for many individuals. Moreover, we did not have systematically collected data about PrEP use

over time because this information was only available for individuals who had a subsequent sexually transmitted disease (STD) diagnosis and interview. We used Cox proportional hazards regression to calculate the risk of HIV diagnosis among PrEP users and non-PrEP users. The proportional hazards assumption was tested with respect to PrEP status and other variables included in multivariate analysis. Adjusted regression models included variables with a P value of <0.20 in bivariate comparisons, including individuals with missing data in some fields. The variables included in the adjusted models included PrEP use, race/ethnicity, age, STD, and year of HIV diagnosis. We included the year of diagnosis in the model to adjust for the secular trend of decreased HIV incidence among MSM in King County over the analysis period.[22] We categorized all variables for tests of association with PrEP use and HIV acquisition. MSM and TGSM entered the study cohort at their first PS interview for a bacterial STI on or after January 1, 2014. The observation time ended for each individual on the date of HIV diagnosis or August 31, 2018. The analysis did not incorporate updates to subjects' PrEP use status based on information obtained after the initial STD PS interview.

RESULTS

Demographics

The study population included 4368 individuals [4313 (98%) cisgender men, 17 (0.40%) transgender men, 31 (<1%) transgender women, and 7 (<1%) TGSM] (Table 1). There were 667 (16%) cases of syphilis, 2616 (60%) cases of gonorrhea, and 1255 (24%) cases of chlamydia. Among the 139 persons who did not report anal sex, 20 (14%) had rectal infections. Forty-six percent of study subjects were between the ages of 20 and 29 years. Sixty-eight percent were white, 7% were black, and 18% were Latinx. The majority (96% of those with complete data) reported anal sex in the past year. A total of 1206 persons (28%) reported taking PrEP, and 3162 (72%) had no indication of PrEP use (N = 1234 missing a response) at the time of the STD PS interview. PrEP use varied by race/ethnicity, with PrEP users more likely to be white, and PrEP nonusers more likely to be black ($P < 0.001$). Only 4% of individuals reported methamphetamine use, 49 (4%) among PrEP users and 131 (5%) among nonusers ($P = 0.90$).

HIV Diagnoses by PrEP Status

The median period of observation was 14 months [interquartile range (IQR) 6–23 months]. Five (0.4%) of 1206 people who reported PrEP use at the time of their STI diagnoses and 97 (3%) of 2162 persons who were not using PrEP at the time of their STI diagnoses were subsequently diagnosed with HIV infection (Table 2, $P < 0.001$). As shown in Figure 1 and Table 3, the HIV incidence was lower among PrEP users than nonusers (1.86 vs. 0.17 cases per 100 person-years) with an adjusted hazard ratio (aHR) of 0.21 (95% CI: 0.08 to 0.58). The median time to HIV acquisition was 17 months among PrEP users and 35 months among PrEP nonusers ($P < 0.001$).

All 5 PrEP users who were diagnosed with HIV after their STI PS interview were white MSM who reported discontinuing PrEP before their HIV diagnosis, none of whom took PrEP for longer than 12 months. Among the 97 individuals who were not taking PrEP at the time of their STI diagnosis and later acquired HIV, 61% (N = 59) were white, 33% were Latinx (N = 32), 6% were black (N = 6), and 5% were Asian (N = 5) (Table 2). Latinx ethnicity [aHR 2.27 (95% CI: 1.38 to 3.74)] and Native Hawaiian/Pacific Islander ethnicity were associated with higher HIV incidence [Table 3, aHR 2.84 (95% CI: 1.13 to 7.12)]. Syphilis [aHR 2.85 (95% CI: 1.49 to 5.44)] and gonorrhea diagnoses were associated

TABLE 1. Characteristics of Men and Transgender Persons Who Have Sex With Men Diagnosed With Syphilis, Gonorrhea, or Chlamydia at the Time of the PS Interview, by PrEP Status at the Time of the Interview (N = 4368)

Variables Total N = 4368	Total N (%)	On PrEP (N = 1206)	Not on PrEP (N = 3162)	*P*
Age				<0.001
<20	162 (4)	15 (1)	147 (5)	
20–29	2027 (46)	441 (36)	1586 (50)	
30–39	1297 (30)	460 (39)	837 (26)	
40–49	519 (12)	183 (15)	336 (11)	
50+	363 (8)	107 (9)	256 (8)	
Race				<0.001
White	2959 (68)	897 (74)	2062 (65)	
Black	316 (7)	63 (5)	253 (8)	
AI/AN	37 (1)	9 (1)	28 (1)	
Asian	384 (9)	81 (7)	303 (10)	
Native Hawaiian/PI	78 (1)	13 (1)	65 (2)	
Other	417 (10)	103 (9)	314 (10)	
Multiracial	177 (4)	40 (3)	137 (4)	
Ethnicity				0.66
Latinx	803 (18)	214 (18)	589 (19)	
Non-Latinx	3511 (81)	979 (81)	2532 (80)	
Missing	54 (1)	13 (1)	41 (1)	
Gender				0.98
Cis or trans male	4330 (100)	1195 (100)	3135 (100)	
Transgender female	31 (<1)	9 (<1)	22 (<1)	
NB/GQ/other	7 (<1)	2 (<1)	5 (<1)	
STI diagnosis				
Syphilis	667 (15)	223 (19)	444 (14)	<0.001
Gonorrhea	2675 (61)	790 (66)	1885 (60)	<0.001
Chlamydia	1608 (37)	385 (32)	1223 (39)	<0.001
Anal sex with men, past year				<0.001
Yes	3532 (81)	1010 (84)	2522 (80)	
No	139 (3)	9 (0)	130 (4)	
Missing	697 (16)	187 (16)	510 (16)	
Methamphetamine use, past year				0.90
Yes	180 (4)	49 (4)	131 (5)	
No	3771 (94)	1052 (94)	2719 (94)	
Missing	63 (2)	19 (2)	44 (2)	

AI/AN, American Indian/Alaska Native; GQ, gender queer; NB, nonbinary; NH/PI, Native Hawaiian/Pacific Islander; STI, sexually transmitted infection.

TABLE 2. New HIV Diagnoses Among Men and Transgender Persons Who Have Sex With Men Diagnosed With Syphilis, Gonorrhea, or Chlamydia, by PrEP Status at the Time of the STI PS Interview (N = 4368)

Variables Total N = 102 HIV-Positive Individuals	On PrEP (N = 5)	Not on PrEP (N = 97)	*P*
Age			0.44
<20	0 (0)	9 (9)	
20–29	2 (40)	48 (50)	
30–39	2 (40)	20 (21)	
40–49	0 (0)	12 (12)	
50+	1 (20)	8 (8)	
Race			0.13
White	5 (100)	59 (62)	
Black	0 (0)	9 (9)	
AI/AN	0 (0)	0 (0)	
Asian	0 (0)	5 (5)	
Native Hawaiian/PI	0 (0)	5 (5)	
Other	0 (0)	13 (13)	
Multiracial	0 (0)	6 (6)	
Ethnicity			0.66
Latinx		30 (31)	
Non-Latinx	0 (0)	64 (66)	
Missing	5 (100)	3 (3)	
Gender			—
Cis or trans male	5 (100)	97 (100)	
Transgender female	0 (0)	0 (0)	
NB/GQ/other	0 (0)	0 (0)	
STI diagnosis			
Syphilis	2 (40)	18 (19)	0.24
Gonorrhea	3 (60)	64 (66)	0.80
Chlamydia	1 (20)	37 (38)	0.42
Anal sex with men, past year			—
Yes	3 (100)	85 (100)	
No	0 (0)	0 (0)	
Missing	2	12	
Methamphetamine use, past year			0.75
Yes	1 (20)	14 (15)	
No	4 (80)	78 (83)	
Missing	0 (0)	2 (2)	

AI/AN, American Indian/Alaska Native; Cis, cisgender; GQ, gender queer; NB, nonbinary; NH/PI, Native Hawaiian/Pacific Islander; STI, sexually transmitted infections; Trans, transgender.

with higher HIV incidence [aHR 2.05 (95% CI: 1.22 to 3.46)]. Black race [aHR 1.21 (95% CI: 0.59 to 2.45)] and age <20 years [aHR 1.85 (95% CI: 0.72 to 4.80)] were associated with higher HIV incidence, although these were not statistically significant.

DISCUSSION

In this population-based study of MSM and TGSM who were diagnosed with a bacterial STI in King County during 2014–18, PrEP reduced HIV incidence by 79% among MSM and TGSM with STIs in King County compared with nonusers, with HIV diagnosis rates of 0.17 and 1.86 cases per 100 person-years, respectively. All the individuals taking PrEP who later acquired HIV had discontinued PrEP before their HIV diagnosis. PrEP use at the time of the STI PS interview differed by race, and among those not taking PrEP, HIV diagnosis was associated with Latinx and Native Hawaiian/Pacific Islander race/ethnicity, syphilis, and gonorrhea.

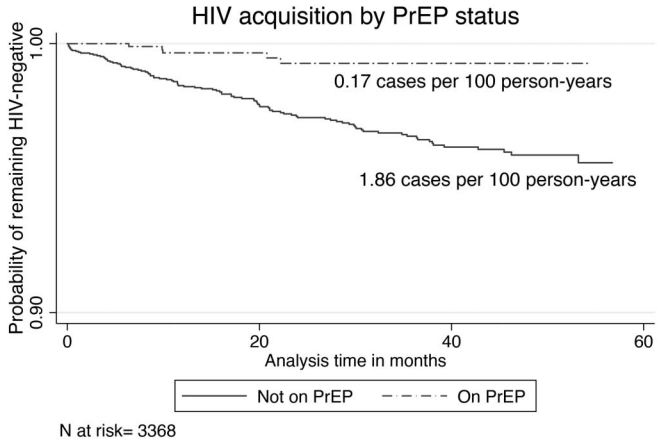

FIGURE 1. Kaplan–Meier curve of HIV acquisition by PrEP status. *aHR, adjusted hazard ratio with respect to race/ethnicity, age, and bacterial STI diagnosis.

Our study builds on previous analyses of PrEP effectiveness. As in the studies conducted in the Kaiser health care system, Montreal, and Sydney described above, all the new HIV infections in our study occurred in individuals who had discontinued PrEP. We found a similar level of PrEP effectiveness (79%) to that observed in the PROUD randomized controlled trials of PrEP effectiveness in the United Kingdom (86%), which compared HIV incidence in an immediate start PrEP cohort compared with a deferred treatment cohort. This consistency in our findings is remarkable in light of the much higher HIV incidence in that population (1.2 cases per 100 person-years in the immediate PrEP group; 9 per 100 person-years in the deferred PrEP group) than in our study population.[23] Together with previous studies, our findings demonstrate that PrEP remains highly effective at preventing HIV in the real-world setting, even in the context of premature PrEP discontinuation.

Although our study suggests that PrEP as it is currently being used in King County, WA, is highly effective in preventing HIV, we observed 5 seroconversions in PrEP users, all of whom had discontinued PrEP. This finding underscores the importance of supporting PrEP retention as seroconversions during PrEP interruptions have also been demonstrated in other studies.[5,9] As we continue to scale-up PrEP, we need to expand our focus on measuring uptake to include continued PrEP use over time. Although myriad factors can lead to PrEP discontinuation, the field needs a better understanding of why people discontinue PrEP and what interventions can effectively increase the duration of PrEP use.[24] An important part of this endeavor will be to

TABLE 3. Cox Models Examining HIV Acquisition by PrEP Status

Variable	Incidence Rate Per 100 Person-Years (N)	Unadjusted Hazard Ratios (95% CI)	Adjusted Hazard Ratio (95% CI)
PrEP status			
Not taking PrEP	1.86 (97)	Reference	Reference
Taking PrEP	0.17 (5)	0.20 (0.08 to 0.48)	0.21 (0.08 to 0.58)
Race/ethnicity			
White	0.09 (64)	Reference	Reference
Black	0.12 (9)	1.38 (0.67 to 2.77)	1.21 (0.59 to 2.45)
Latinx	0.16 (30)	1.98 (1.29 to 3.04)	2.27 (1.38 to 3.74)
AI/AN	0 (0)	—	—
Asian	0.06 (5)	0.66 (0.27 to 1.64)	0.77 (0.30 to 1.94)
NH/PI	0.23 (5)	2.88 (1.16 to 7.16)	2.84 (1.13 to 7.12)
Other	0.13 (13)	1.50 (0.83 to 2.72)	0.77 (0.38 to 1.52)
Multiracial	0.14 (6)	1.65 (0.71 to 3.81)	1.35 (0.58 to 3.16)
Age			
<20	0.22 (9)	2.35 (0.93 to 5.93)	1.85 (0.72 to 4.80)
20–29	0.09 (50)	0.97 (0.48 to 1.98)	0.80 (0.39 to 1.66)
30–39	0.07 (22)	0.70 (0.32 to 1.52)	0.61 (0.28 to 1.36)
40–49	0.10 (12)	0.93 (0.39 to 2.20)	0.88 (0.37 to 2.10)
50+	0.10 (9)	Reference	Reference
80			
Gender			
Cis or trans male	0.10 (102)	Reference	Reference
Trans female	—	—	—
NB/GQ/other	—	—	—
STI diagnosis			
Syphilis	0.15 (20)	2.58 (1.37 to 4.85)	2.85 (1.49 to 5.44)
Gonorrhea	0.11 (62)	1.87 (1.12 to 3.14)	2.05 (1.22 to 3.46)
Chlamydia	0.05 (19)	Reference	Reference
Anal sex with men, past year			
Yes		Reference	Reference
No		—	—
Missing		—	—
Methamphetamine use, past year			
Yes		1.05 (0.99 to 1.02)	—
No		Reference	Reference
Year of HIV diagnosis			
2014		Reference	Reference
2015		0.67 (0.42 to 1.06)	0.80 (0.48 to 1.23)
2016		0.36 (0.18 to 0.71)	0.38 (0.19 to 0.77)
2017		0.60 (0.30 to 1.19)	0.64 (0.32 to 1.30)
2018		—	—

AI/AN, American Indian/Alaska Native; Cis, cisgender; GQ, gender queer; NB, nonbinary; NH/PI, Native Hawaiian/Pacific Islander; STI, sexually transmitted infection; Trans, transgender.

differentiate premature discontinuation from appropriate discontinuation based on a true decrease in HIV risk, since some patients discontinue PrEP because they perceive or know that their HIV risk has decreased.[25–27]

The racial/ethnic disparities that we observed in PrEP use among MSM/TGSM with bacterial STIs and in HIV diagnosis among persons not on PrEP are troubling. It is notable that none of the racial/ethnic minority individuals in our study population who were taking PrEP seroconverted, though this population was relatively small. These results reflect national data demonstrating that most PrEP users are white and that PrEP access and awareness is still an issue for many black and Latinx individuals who could benefit from PrEP.[28] Although we also observed an increase in seroconversion among Native Hawaiians/Pacific Islanders, they represented only 1% of the study population, thus magnifying the impact of any seroconversions among this group. Ongoing and more intensive efforts are needed to eliminate racial/ethnic disparities in PrEP use, and dedicated efforts are needed to engage and retain racial/ethnic minority MSM and

TGSM, particularly among those with Latinx ethnicity as this is a rapidly growing population.[29,30]

The key strength of our study is that it was a county-wide, population-based study of PrEP effectiveness among MSM and TGSM with bacterial STIs, a population at high risk of HIV infection. As such, it encompassed various health systems and included individuals with private insurance, public insurance, and no insurance. However, this study included only 1 county and only persons interviewed for purposes of STD PS and may not be generalizable to other areas in the United States or other populations. We did not examine PrEP use as a time-dependent covariate because we only had data pertaining to PrEP use and PrEP nonuse without uniform access to dates of PrEP start or discontinuation, and in addition, using STI surveillance data to determine PrEP use subsequent to the initial encounter would have introduced an ascertainment bias. Because our intent was to evaluate the effectiveness of real-world PrEP use, including periods of discontinuation, we do not view missing data on PrEP persistence as a major limitation. Our decision to examine PrEP use at only the first STI PS interview during the analysis period means that we did not account for individuals who were not taking PrEP at the time of first interview, but later started it. This undoubtedly led to some degree of misclassification, but does not substantially detract from our primary finding because neglecting this change would lead to underestimation of PrEP effectiveness. Thus, it is reasonable to consider the 79% a lower level estimate of effectiveness. Among the 5 PrEP users who later acquired HIV, we were able to confirm PrEP discontinuation prior to HIV diagnosis. We were missing some data on PrEP use among the STI PS interview, which could have affected our findings, but this is also an expected feature of using public health program data. In addition, it is possible that we missed some HIV acquisitions that were not diagnosed during the analysis period. Although our cohort self-reported PrEP use or lack thereof, we do not believe this to be a limitation based on previous studies which demonstrate self-report to be corelative with dried blood spot PrEP drug levels.[13]

Our study demonstrates that PrEP is highly effective with real-world use, even in the setting of PrEP discontinuation. Although the observation that some persons who discontinued PrEP subsequently acquired HIV highlights the need to improve, our finding that PrEP is over 79% effective is encouraging and should foster additional momentum to expand PrEP access and use.

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