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Feasibility of Short-Term PrEP Uptake for Men Who Have Sex With Men With Episodic Periods of Increased HIV Risk

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Abstract

Background: Pre-exposure prophylaxis (PrEP) with emtricitabine/tenofovir disoproxil fumarate is efficacious in reducing HIV acquisition. For some gay, bisexual, and other men who have sex with men (MSM), daily ongoing PrEP may be unsuitable for use as a long-term prevention strategy because of episodic risk, cost issues, or concerns about the biological consequences of medication.

Setting: This study evaluated the feasibility of short-term, fixed-interval episodic PrEP (Epi-PrEP) for use among vacationing MSM. We describe the feasibility of implementing a clinic-based Epi-PrEP pilot program for 48 MSM who reported occasional condomless sex and anticipated a defined high-risk time.

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Methods: This was a nonrandomized naturalistic study of an observational clinical intervention. The primary outcome assessed was adherence, as measured by self-report and plasma tenofovir levels.

Results: Of 54 MSM who enrolled in the study, 48 completed the 3-month visit. The majority (93.7%) had tenofovir concentrations consistent with daily use on returning from vacation. Almost 3/4 reported condomless sex during vacation, and about 1/3 reported recreational drug use. During the 3-month follow-up, 1 participant had become HIV-infected because of a lapse in continued access to the PrEP after study. Although adverse events were common, none were serious. More than 70% of participants indicated an interest in daily ongoing PrEP use.

Conclusions: Epi-PrEP was well tolerated by at risk MSM in this study, with high levels of medication adherence. Many participants felt the experience of initiating PrEP while on vacation could be a means for transition to long-term PrEP use.

Keywords

HIV; MSM; pre-exposure prophylaxis; adherence

INTRODUCTION

Pre-exposure prophylaxis (PrEP) with emtricitabine/tenofovir disoproxil fumarate (F/TDF) has been shown to be highly effective in reducing HIV transmission and has the potential to dramatically enhance HIV prevention efforts if correctly used.[1] PrEP has been approved in the United States for daily use to prevent HIV transmission in at risk men who have sex with men (MSM),[2] transgender people, and heterosexuals. Although promising, questions remain regarding how to best implement PrEP in different community contexts and how individual preferences and risk profiles inform use patterns.

For some MSM, daily ongoing PrEP may be unsuitable for use as a long-term prevention strategy because of, for example, primarily episodic risk, cost issues, and concerns about the biological consequences of long-term medication use. Several studies have begun to explore alternative dosing strategies such as event-driven dosing.[3–6] Another potential alternative might be the strategic use of PrEP for discrete periods of high risk, such as travel away from familiar sociosexual networks at “home.”[7–9] Travel-related increased risk, associated with the liminal space of vacations (eg, fewer responsibilities and the desire for adventure) combined with “time out behavior” (fewer inhibitions and more substance use), has been described elsewhere.[10–13] In a recent study, a quarter of MSM participants reported condomless anal sex with a new male partner while on vacation.[8] It is not known whether nonadherence could be greater during these more risky periods, impacting PrEP effectiveness than when used on a chronic basis.[14,15]

To better understand these issues and address a potential high-risk period for MSM, the current study evaluated the feasibility of short-term, fixed-interval episodic PrEP (Epi-PrEP) with brief adherence counseling intervention. Specifically, we describe the feasibility of implementing a clinic-based Epi-PrEP pilot project for MSM who reported occasional unprotected sex and who anticipated a defined high-risk time during the study period (ie,

vacation). The primary outcome assessed was adherence, as measured by self-report and plasma tenofovir concentrations assessed during the high-risk period. We hypothesized that the Epi-PrEP intervention would be feasible for delivery, acceptable among participants, and result in high levels of PrEP adherence among those receiving the intervention.

METHODS

Epi-PrEP Intervention

Eligible participants consented to participate in an open-label study of F/TDF. This was a nonrandomized naturalistic study of an observational clinical intervention. Given the efficacy evidence of daily long-term PrEP[1,16] and the specific research questions not involving PrEP efficacy, an arm that withheld PrEP was not deemed justified for the present study. At least 2 weeks before vacation, participants were evaluated by a medical professional, and if medically indicated (see below), they were prescribed a 30-day supply of F/TDF (Truvada) and instructed to adhere to daily dosing starting 7 days before the trip departure date, during the specified trip period, and 7 days after the trip. A 7-day lead-in period was performed to ensure participants reached steady-state drug concentrations.[17] This was based on an iPrEx pharmacodynamic modeling study and TFV-DP pharmacokinetics in healthy volunteers.[18–20] The 7-day trial was based on less well-informed primary data but provides a conservative buffer of 1 week to prevent persistent HIV from replicating after sexual exposure before drug concentrations fell.

Participants also received a single session cognitive behavioral therapy–based adherence intervention before PrEP initiation. This brief intervention, based on the previously evaluated intervention Life-Steps,[21–23] included the following elements: (1) psychosocial assessment (10 minutes, including health status, substance use, partnerships and sexual behavior, and expected sexual behavior on vacation); (2) PrEP psycho-education (10 minutes, including adherence education, potential medication side effects, possible impact of substance use on adherence, and pill sharing); and (3) motivational interviewing to make an adherence plan (10 minutes, including pros/cons of maintaining PrEP adherence and not adhering to PrEP, identifying potential adherence barriers and solutions, and self-rating of adherence motivation). The intervention was delivered by either a study nurse or PhD level investigator.

Participants and Recruitment

To be eligible, participants had to: (1) self-identify as cisgender MSM; (2) be 18 years of age or older; (3) report, within the past 12 months or during a recent vacation, condomless insertive or receptive anal sex with 2 or more men or any transactional sex with a man; (4) have identified an upcoming period of episodic risk (ie, vacation) lasting 5–14 days during which they anticipated having at least 1 high-risk sexual event; (5) be able to understand English; and (6) be willing and able to provide informed consent. Exclusion criteria included the following: (1) being HIV-positive; (2) having a glomerular filtration rate, < 60 mL/min, (3) being Hepatitis B surface antigen–positive, (4) having symptoms suggestive of acute HIV seroconversion at screening or enrollment; (5) having used PrEP or PEP within the previous 3 months (so as to decrease possible confounding associated with adherence-

related habit formation of experienced users); (6) being currently enrolled in another study involving medications, investigational drug, or medical devices; or (7) having other conditions (based on the opinion of an investigator or designee) that would preclude informed consent, make the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with study procedures.

Participants were recruited in Boston, MA, and Pittsburgh, PA, using passive community–based recruitment methods including flyers/posters distributed at community locations, electronic advertisements placed on social networking apps (eg, Facebook, Scruff, and Craigslist), provider referrals, and word of mouth. Interested men were asked to call or email to learn more about the study and complete a phone screening to assess initial eligibility.

Study Visits and Data Collection

Eligible men from the initial phone screening were scheduled for informed consent and a clinical screening visit. The baseline study/clinical visit, completed at least 2 weeks before the trip, included a full assessment battery, safety laboratory assessments, STI/HIV screening, and online behavioral survey. The enrollment study visit, completed at least 1 week before the trip, included a review of laboratories from the baseline visit, dispensation of 30-day supply of F/TDF, and adherence counseling. The postvacation study/clinical visit, completed 1–3 days after the trip, included a blood draw for plasma tenofovir measurement, referral to STI screening if symptomatic, safety laboratories, and online behavioral interview and self-assessment of PrEP adherence. Finally, the 3-month follow-up study/clinical visit included serum creatinine determination, HIV-antibody screening, referral to STI testing if symptomatic, and online behavioral interview.

Quantitative self-report measures were completed using Qualtrics on a tablet during the visit or within a few days before or after the visit. Medical data were collected at each visit and recorded in participant study records. All study procedures were conducted by trained research staff in a private area within a health research institution. Participants received $25.00 for each study visit. In addition, all study-related screening/laboratories and 30-day supply of F/TDF (Truvada, donated by Gilead Sciences) were provided free of cost to participants.

PrEP Adherence

PrEP adherence, the primary study outcome, was collected within 1–2 days after the trip and included both self-report and blood draw to determine tenofovir concentrations in plasma. Plasma adherence levels were determined using previously described methods and metrics.[17] Based on DOT studies, using a 90% sensitivity threshold, tenofovir concentrations ≥35.5 ng/mL are associated with daily adherence; tenofovir concentrations between 4.2 ng/mL and 35.4 ng/mL are associated with 4 pills/week. Self-reported adherence was measured using 2 questions. First, participants were asked to rate their ability to take PrEP on a daily basis using a 5-point Likert scale ranging from excellent to poor based on a measure validate for antiretroviral therapy treatment adherence.[24] Separate questions were asked for the periods before and during vacation. Second, participants were then asked to indicate if they took their PrEP medication on each of the days before the vacation (eg, prevacation day 1 = yes,

no, do not know, or N/A; prevacation day 2; prevacation day 3; etc.) and on each day during vacation. For each of the days during vacation, they were also asked if they had condomless sex and if they used any nonprescription drugs.

Safety Assessments

Safety laboratory and behavioral assessments were collected at baseline, after the trip, and at 3 months.

Statistical Analysis

All analyses were completed in SPSS.v.26 (IBM, Armonk, NY). Frequencies were first generated to describe the overall sample. Comparisons by site and biologically measured adherence were completed using χ^2 and *t* tests.

Ethical Approval

The study received ethical approval from the Institutional Review Boards of the University of Pittsburgh (PRO15060504) and the Fenway Institute (IRB00000858).

RESULTS

Study Participants

Between January 2016 and April 2017, 66 of 243 participants prescreened as eligible; of those, 56 were screened during the initial clinical visit of whom 55 were eligible. In total, 54 participants were enrolled in Pittsburgh, PA, and Boston, MA, of whom 48 completed the postvacation visit (Table 1) and 42 completed the 3-month follow-up visit (n = 39 completed all surveys). The final follow-up was completed in August 2017. Participants were all cisgender men and mostly white (72.2%) and had a mean age of 39 years (range 24–64); 83.3% identified as gay, and 68.5% were employed full-time. Baseline STI screening identified: 1 case of syphilis, 2 cases of rectal gonorrhea, 1 case of rectal *Chlamydia trachomatis*, and 1 case of genitourinary *C. trachomatis*. A total of 5 participants (9.3%) reported not accessing the needed health care in the past 12 months because of affordability issues.

PrEP Use and Adherence

PrEP adherence is described in Table 2. The majority were adherent, with 91.5% having tenofovir drug concentrations consistent with daily use and 93.6% having drug levels consistent with protection (4 pills a week or greater) for the week before the postvacation study visit. There were no significant demographic differences between the adherent and nonadherent groups (data not shown). Self-reported adherence was high, 95.8% reported their ability to take daily PrEP as excellent or very good. Most (85.4%) self-reported missing no doses, 6 reported missing 2 or fewer doses, and 1 reported missing 6 doses. Most (66.7%) reported that maintaining high levels of adherence was not difficult while on vacation (Table2). The primary barriers to PrEP use reported (Table 2) were having an inconsistent schedule (27.1%), not always returning to the place they were staying (10.4%), being too

busy (8.3%), alcohol use (8.3%), being in an unfamiliar environment (6.3%), and drug use (2.1%).

More than two-thirds (71.4%) of participants reported being likely or very likely to remain on PrEP; 3 participants reported that they were unlikely to continue. Almost half (48.7%) reported being likely/very likely to continue using PrEP episodically and 60.1% to use PrEP consistently (data not shown). Most participants (69.0%) preferred obtaining future PrEP through their primary health care provider, but a proportion (16.7%) preferred a location separate from their main provider.

Side effects were generally mild and self-limited; none were greater than grade 2, and none were reported at the 3-month follow-up visit. Fifteen participants reported a total of 16 side effects, the most common being diarrhea (n = 4), flatulence (n = 3), and nausea (n = 4). None of these adverse events led to product discontinuation; however, 1 of the 3 participants who had less than protective drug levels also reported nausea.

One participant became HIV-infected after his participation in the study (more than 2 months after his postvacation visit) due to a lapse in insurance coverage for ongoing PrEP use despite it being indicated, due to a job change, and due to moving to another city with fewer PrEP access options for the underinsured. There were no other seroconversions.

Vacation Behaviors

Participant vacations lasted for a mean of 9 days (range 5–16 days). Most (76.1%) of the samples reported condomless anal sex during vacation (Table 3). More than three-fourths (76.1%) reported condomless sex and almost a third (31.2%) reported some recreational drug use while on vacation (Table 3). All those who reported condomless anal sex also reported being adherent to PrEP except 1 participant who reported less than daily PrEP use and condomless sex on 8 days. This participant remained HIV-negative at the final clinical visit. Condomless sex was fairly consistent over the course of the study (Table 4). The proportion of participants who reported never/rarely using condoms for insertive anal sex decreased slightly from 46.1% at baseline, 43.6% after the trip, and 38.4% at 3 months and increased slightly during vacation for receptive anal sex with 30.8% at baseline, 33.4% at after the trip, and 30.8% at 3 months. Of the 3 people with tenofovir levels that were less than protective, none reported drug use.

DISCUSSION

Although the first study demonstrating the efficacy of tenofovir-based PrEP in decreasing HIV acquisition in MSM was reported in 2010,[1] uptake has been limited.[25–27] Some MSM may not use PrEP because they perceive it to be appropriate for those who are consistently engaging in condomless sex. However, previous studies have suggested that some MSM may have “seasons of risk,” (ie, periods when chemoprophylaxis would be warranted).[8] The intent of the current study was to evaluate whether vacation periods could provide an optimal environment for constructive habit development (ie, good adherence) or whether the lack of a usual daily routine and increased time for leisure, might be associated with challenges to PrEP adherence in the context of heightened risk. There was a high level of

adherence in this study of high-risk MSM on short-term, fixed-interval Epi-PrEP. Nearly all participants (93.6%) had drug levels consistent with protection (4 pills/wk or greater) during the week before their postvacation visit. Interestingly, there was also high agreement of biological and self-reported adherence, perhaps suggesting that MSM may be able to correctly assess their level of adherence during short-term PrEP use. Our initial hypothesis that varying levels of adherence might be reported was somewhat supported because not all participants reported perfect adherence. However, there were no significant demographic or behavior differences between groups. These findings contrast with other studies that show varying rates of adherence for both long-term and event-driven PrEP use.[14,15]

Most (70%) men indicated an interest in continuing PrEP after vacation. This highlights the utility of vacation PrEP as a potential pathway to the uptake of continuous ongoing PrEP. For some, an episodic use period may provide an opportunity to try it out and get comfortable before integrating it into their daily life. It also suggests that Epi-PrEP may be a preferred option for some MSM, given that 30% did not want to enroll in continuous PrEP care after the vacation. This highlights the importance of discussing and providing multiple methods of PrEP use and multiple points of entry into PrEP care to best suit individual risk profiles, needs, accesses, and preferences.

There remain many challenges in understanding PrEP persistence over time, including the tension between individually-driven dosing and expectations of perfect adherence over long periods.[28–32] After participation in this study, 1 participant subsequently became HIV infected after a lapse in PrEP access associated with his loss of health insurance and moving to a new city with limited free/low-cost PrEP access opportunities. This underscores the importance of continuity of care across health systems/providers and the need to prioritize sustainable low-threshold access to affordable PrEP to improve community-based PrEP dissemination.[31,33–35] Continued access to PrEP for participants of research/demonstration projects is an ethical concern that warrants serious consideration because the field continues to move forward.

There are several limitations of these findings to consider. This was a research study with several components and participants had to be highly motivated to enroll; there were several interactions with the study staff including the Life-Steps adherence counseling; and participants knew they were going to be assessed on return from the vacation, all who may have impacted on adherence. Medication and laboratory test results were provided freely, which may have been a contributing factor for some men, for whom PrEP may have been otherwise difficult to access, to participate, thereby, impacting the composition of the sample. However, we intentionally chose 2 different kinds of cities (eg, location, population, size of MSM community, and PrEP access programs); the final sample was small, highly educated, mostly white, and mostly gay-identified and cannot, therefore, be generalized to the other MSM populations and in particular communities with low-PrEP uptake including black MSM, young MSM, and under resourced individuals (eg, low SES, access to sustainable health care and PrEP providers). Moving forward, a more real-world design, that oversamples higher-need communities, is necessary to better determine what supports are necessary to understand how Epi-PrEP may best be implemented in specific communities with low-PrEP uptake.

For some, daily PrEP may not be the best option for use as a long-term prevention strategy, not only because of the episodic nature of risk but also because of cost issues and concerns about the biological consequences of long-term medication use. Initiating PrEP for episodic risk events such as vacation periods may be an effective opportunity for MSM to acclimate to PrEP (eg, adjusting to side effects) without the demands of the usual day-to-day or to experiment with PrEP for a shorter time before considering a longer-term adoption. The success of this strategy will depend on the ability of high-risk MSM to predict periods of contextually-driven heightened risk and to be adherent to Epi-PrEP regimens during these time-limited episodic high-risk phases. Future research should include how individual risk or individual preference can drive the most appropriate dosing strategy (eg, on demand, daily, and episodic).

CONCLUSIONS

These findings suggest that gay, bisexual, and other MSM can be adherent to short-term, fixed-interval episodic F/TDF for PrEP during high-risk vacation times. Time-limited dosing strategies may be a realistic, feasible, acceptable, and useful option for some high-risk MSM whose behaviors are episodic but nonrandom. Furthermore, initiating Epi-PrEP on vacation may, for some, also provide a pathway to the uptake of long-term PrEP use. Understanding different PrEP use patterns is essential for providing effective PrEP interventions. Access to low cost and sustainable PrEP access is a social justice issue that must be considered in both research and community-based public health programs designed to increase PrEP uptake and effective use over time.

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TABLE 1.

Epi-PrEP Study Sample Characteristics (N = 54)

		Biologic Adherence (n = 47)*	
		Less than Protective (n = 3)	Protective (n = 44)
	Total (N = 54) n (%)	n	n
Enrolled			
Pittsburgh	23 (42.6)	2	20
Boston	31 (57.4)	1	24
Age			
Mean	39	39	40
SD	11.9	17.7	12.0
Race			
Black	7 (13.0)	1	5
White	39 (72.2)	1	32
Multiracial and others	8 (14.8)	1	7
Ethnicity			
Latino	6(11.1)	0	6
Sexual orientation			
Gay	45 (83.3)	3	36
Bisexual/p ansexual	9 (16.7)	0	8
Education			
No college	3 (5.6)	0	3
Any college	51 (94.4)	3	41
Income			
<40,000	25 (46.3)	2	20
40,000–99,000	19 (35.2)	0	15
>99,000	10 (18.5)	1	9
Problems accessing medical care (past 12 mo)†			
Yes	5 (9.3)	0	5
No	49 (90.7)	3	39

*There were no statistical differences between less than protective and protective.

†Participants were asked during the past 12 months was there any time when you needed medical care but did not get it because you could not afford it?

TABLE 2.

Adherence While on Vacation (N = 48), Epi-PrEP Study, 2016–2017

Adherence Measure	n (%)
Tenofovir concentration (n=47) *	
7 doses/wk; ≥ 35.5 ng/mL	43 (91.5)
≥4 doses/wk; 4.2–34.4 ng/mL	1 (2.1)
≥2 doses/wk; 2.5–4.1 ng/mL	3 (6.4)
≥1 dose/wk; 0.5–2.4 ng/mL	0 (0.0)
Missed doses (self-report)	
0 missed doses	41 (85.4)
1 missed dose	3 (6.3)
2 missed doses	3 (6.3)
6 missed doses	1 (2.1)
Overall (self-report)	
Excellent	34 (70.8)
Very good	12 (25.0)
Good	1 (2.1)
Poor	1 (2.1)
Reported barriers to adherence †	
It was not difficult	32 (66.7)
Having an inconsistent schedule	13 (27.1)
Not always staying at the place I was staying	5 (10.4)
Too busy	4 (8.3)
Alcohol use	4 (8.3)
Being in an unfamiliar environment	3 (6.3)
Drug use	1 (2.1)

* One participant did not have drug measurements.

† Participants could choose multiple barriers.

TABLE 3.

Vacation Behaviors, Epi-PrEP Study, 2016–2017 (N = 48)

	n (%)
Vacation days (n=47) *	8.98 (3.01)
Condomless sex †	
No days	11 (23.9)
≤24% days	11 (23.9)
25%–49% days	11 (23.9)
50%–74% days	8 (17.4)
75%–99% days	1 (2.2)
Every day	4 (8.7)
Male sex partners (bottomed, receptive anal sex)	
0	26 (54.2)
1	9 (18.8)
2–9	11 (22.9)
10+	2 (4.2)
Male sex partners (topped, insertive anal sex)	
0	18 (37.5)
1	6 (12.5)
2	21 (43.8)
10+	3 (6.3)
Female sex partners	
0	44 (91.7)
1	3 (6.3)
2	1 (2.1)
Drug use ‡	
No days	33 (68.8)
≤24% days	6 (12.5)
25%–49% days	3 (6.3)
50%–74% days	1 (2.1)
75%–99% days	2 (4.2)
Every day	3 (6.3)

* Only collected for those who completed post-trip assessment; mean vacation days and SD reported.

† n = 46, 2 participants did not report vacation end date.

‡ Did you use any nonprescription drugs.

TABLE 4.

Behavior Change From Baseline to 3-Month Visit, Epi-PrEP Study, 2016–2017 (N = 39)

Condom Use with Male Partners	Baseline (%)	Post-trip (%)	3 Month (%)
Insertive anal sex			
Never/rarely	46.1	43.6	38.4
About half the time	15.4	10.3	17.9
Always/most of the time	30.8	10.3	23.1
No insertive anal sex	7.7	35.9	20.5
Receptive anal sex			
Never/rarely	30.8	33.4	30.8
About half the time	15.4	5.1	5.1
Always/most of the time	17.9	7.7	10.3
No receptive anal sex	35.9	53.8	53.8