

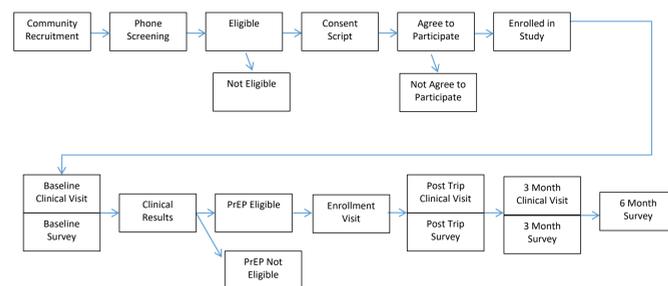
Introduction

- TDF/FTC Pre-Exposure Prophylaxis (PrEP) has been shown to be highly effective at reducing HIV transmission.¹
- Although PrEP was approved for daily use to prevent HIV transmission in at risk men gay, bisexual, and other men who have sex with men (MSM), some may have discrete periods of high risk (e.g. vacations),^{2,3,4} and this use has not been previously evaluated.
- This study evaluated the feasibility of short term, fixed interval episodic PrEP (Epi-PrEP).

Methods and Materials

- Participants agreed and consented to participate in an open label study of TDF/FTC plus a focused behavioral intervention. See Figure 1 for study flow.

Figure 1. Study Flow



- Community-based recruitment methods (e.g. flyers, app-based, word of mouth) were used to recruit participants in both Boston and Pittsburgh (Figure 2).
- Inclusion criteria: (1) born male who has sex with men; (2) 18 or older; (3) condomless anal sex with 2 or more men or any transactional sex with a man within the past 12-months; (4) upcoming period of episodic risk away (i.e. vacation) from their home city (5-14 days) during which they anticipate having at least 1 high-risk sexual event; and (5) able and willing to provide informed consent.

Methods and Materials

- At least 2-weeks prior to vacation they were given a 30-day supply of TDF/FTC and instructed to adhere to daily dosing starting 7-days prior to vacation through 7-days post vacation. Study drug was provided by Gilead Sciences, Inc.
- Participants also received a single session cognitive behavioral therapy—based adherence intervention.⁵
- Adherence was assessed via self-report and plasma TFV concentration levels - using 90% sensitivity thresholds - within 3-days post-vacation⁶.
- Safety labs and behavioral assessments were collected at baseline, post-trip, and at 3-months.

Figure 2. Study Recruitment Flyers



Table 1. Epi-PrEP Study Sample Characteristics (N=54)

		n
Enrolled	Pittsburgh	23
	Boston	31
Age	Mean (SD)	39 (11.85)
Race/Ethnicity	Black	7
	White	39
	Multi-racial & others	8
	Latino	6
Education	No college	3
	Any College	31
Income	<40K	25
	40K-99K	19
	>99K	10
Vacation Days	Mean (SD)	8.98 (3.01)

Results

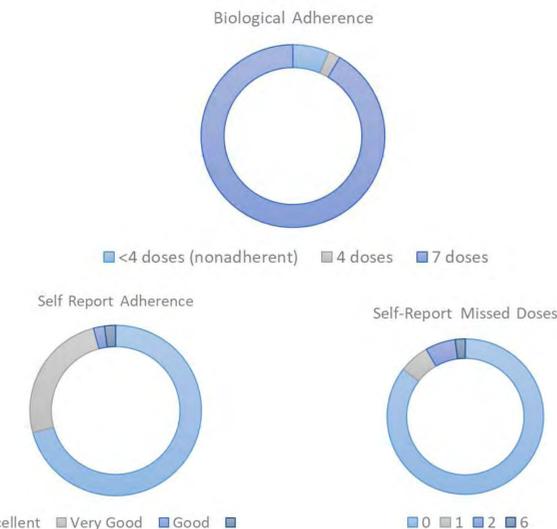
Sample

- 54 participants were enrolled in Boston and Pittsburgh, of which 48 completed the post-vacation visit (Table 1).
- Participants were mostly white (72.2%), had a mean age of 39 (range 24-64), 83.3% identified as gay, and 68.5% were employed full-time.

PrEP Adherence

- Only 3 individuals (6.3%) had drug levels below protective levels (<4 daily doses during the week).
- There was high concordance between biological markers and self-reported adherence (Figure 3)
 - 95.8% reporting their ability to take daily PrEP as excellent or very good
 - 6 participants reported missing 2 or fewer doses
 - 1 participant reported missing 6 of 7 doses.

Figure 3. Vacation Adherence



Results

Vacation Behaviors

- Participant vacations lasted a mean of 9 days (range 5-16)
- Of the 3 people with less than protective levels of drug, none reported drug use.
- 77% of the sample reported condomless anal sex during 1 to 14 of their vacation days.
- All who reported condomless anal sex were adherent except 1 who reported partial PrEP use and condomless sex on 8 days.

Post Study PrEP

- 55.5% of participants reported being likely or very likely to remain on PrEP after the study.

HIV Seroconversion

- 1 participant became HIV-infected 2+ months after vacation due to a lapse in insurance to cover ongoing PrEP (move and job change); after 3 months of follow-up there were no other seroconversions.

Discussion

- These findings suggest that most MSM can be adherent to short-term fixed-interval episodic 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 non-random.
- Initiating Epi-PrEP on vacation may, for some, provide a helpful way to initiate long term PrEP.
- Understanding PrEP use patterns is essential for providing effective PrEP interventions.

Funding: NIMH R34-MH104083-03 (Co-PIs: Stall, Mayer)

Contact: James E Egan, University of Pittsburgh, jameserinegan@pitt.edu

Citations

- Grant, R.M., et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med*. 2010. 363(27):2587-99.
- Coffas, G.N., et al. Drug use and sexual risk behavior among gay and bisexual men who attend circuit parties: a venue-based comparison. *J Acquir Immune Defic Syndr*. 2001. 28(4): p. 375-9.
- Ellesser, S.A., et al. Seasons of risk: anticipated behavior on vacation and interest in episodic antiretroviral pre-exposure prophylaxis (PrEP) among a large national sample of U.S. men who have sex with men (MSM). *Aids and Beh*. 2016. 20(7):1400-7.
- Stack, C., et al. Sexual Behavior Patterns and PrEP Dosing Preferences in a Large Sample of North American Men Who Have Sex With Men. *JAIDS*. 2016. 71(1):94-101.
- Adherence intervention based on: Saloner, S.A., et al. Two strategies to increase adherence to HIV antiretroviral medication: Life-Steps and medication monitoring. *Behav Res Ther*. 2001. 39(10):1151-62.
- Hendrix, C., et al. Tenofovir-Emtricitabine Directly Observed Dosing: 100% Adherence Concentrations (HPTN 066), in Conference on Retroviruses and Opportunistic Infections. 2014: Boston, MA.