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Pre-Exposure Prophylaxis Accessibility Research and Evaluation (PrEPARE Study)

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Introduction

After 30 years of research, there is still no globally effective HIV vaccine or cure. Men who have sex with men (MSM) currently account for over half of prevalent infections and 63% of incident infections in the United States [1]. In December 2010, the Pre-exposure Prophylaxis Initiative (iPrEx) trial raised new prevention hopes for MSM when it demonstrated the efficacy of once-daily prophylactic tenofovir-emtricitabine (TDF-FTC) at reducing incident HIV infections [2, 3]. Subsequently, the U.S. Food and Drug Administration (FDA) approved TDF-FTC for pre-exposure prophylaxis (PrEP) in adults at high risk for sexually transmitted HIV infection [4]. Other trials have also supported efficacy of PrEP in high-risk heterosexual populations [5, 6]. Recent surveys of high risk MSM have shown that the majority would be in favor of taking daily PrEP to prevent HIV infection if the medication were found to be effective and affordable [7, 8, 9, 10]. One study assessed barriers and facilitators to accessing PrEP by surveying 184 MSM and transgender women in New York City. 55% of those surveyed reported willingness to take PrEP. The major barriers reported were concerns for both long and short term side effects of the medication and free access to PrEP was highly endorsed as a facilitator to PrEP (11).

Despite the data supporting this prophylactic regimen and the MSM population's interest in its use, providers do not widely prescribe PrEP, and patients do not regularly seek it out [10]. Our objective was to identify the real world barriers to receiving PrEP among high-risk MSM when the medication was not subsidized.

Methods

Individuals were recruited during HIV test counseling sessions from 'Early Test' sites in San Diego, California. In brief, the Early Test program offers rapid HIV antibody testing followed by HIV nucleic acid amplification testing (NAAT). This program specifically targets high risk MSM, the population that suffers the greatest incidence of HIV in San Diego, California. Per program procedures, testing clients also receive detailed risk

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assessments [11]. All study staff were provided a standard script for counseling and educating potential subjects on PrEP in general and the objective of the study based on CDC guidelines. Individuals were eligible for the study if they were self-identifying MSM who reported unprotected anal receptive or insertive sex at least once in the previous year. Every MSM Early Test participant that met these criteria was given a program flyer with information on PrEP and the PrEPARE study prior to receiving the HIV test result. The eligible subjects were counseled that the medication would not be subsidized as the purpose of the study was to assess real world barriers to PrEP including cost. Potential subjects were encouraged to reach out to community resources, insurance companies, and pharmaceutical companies for financial assistance.

After counseling and education on the efficacy of PrEP, test clients who then expressed interest were offered participation, which involved a written consent, referral for PrEP to San Diego's Gay Men's Health Clinic, and completion of a survey. Further criteria for study entry and suitability for PrEP were based on the CDC Guidelines including a negative HIV antibody and HIV nucleic acid amplification test (NAAT) result within 14 days of enrollment [4]. At the Gay Men's Health clinic participants received screening for hepatitis B virus (HBV) and other sexually-transmitted infections (STIs). All STIs were treated, and if they were not immune to HBV, subjects were offered vaccination. Participants were then offered a prescription for a 3-month supply of TDF-FTC and required to return to the clinic after 3 months for repeat HIV and STI testing.

From May 18, 2012 to October 31, 2012, a request to complete an online encrypted enrollment survey (supplementary table 1) was sent 1–2 weeks after the initial visit and again at 3 months to determine: whether the subject received a TDF-FTC prescription, if the medication was taken as prescribed, and what barriers existed for those who did not access the regimen.

Given the lack of participation between May 18 to August 8, 2012, the study implemented an additional procedure. From August 8, 2012 to October 31, 2012, a waiver of consent was obtained to ask all eligible individuals who declined study participation at the time of the initial HIV test visit to complete a brief non-enrollment survey to ascertain why they declined to consent (supplementary table 2).

Results

From May 18, 2012 to October 31, 2012, study participation was offered 429 times to 416 unique eligible subjects who were all MSM (Table 1). 68% were white with a median age of 32 (range 18–73 years), consistent with most incident HIV infections in San Diego [12]. Of these individuals, 14 consented for referral to the Gay Men's Health Clinic for PrEP evaluation located 1.5–2 miles from the Early Test sites. Only 2 received and filled a PrEP prescription. This represented less than 0.47% uptake. The two participants who filled and received TDF-FTC prescription both used their private medical insurance and paid \$25 out of pocket co-pays. It is unknown how many other eligible participants also had private medical insurance.

Given the early low uptake of PrEP, after August 8, 2012, study staff conducted a brief non-enrollment survey to assess attitudes about PrEP therapy. Of the 126 potentially eligible MSM asked to fill out the non-enrollment survey, 54 completed the survey. 41% were deterred by presumed long-term side effects, 30% felt that they were not at high risk for HIV infection, 30% did not want to take a daily medication, and 48% felt the drug was too expensive. When asked to indicate the least appealing aspect of the study, the most frequent response was that the drug was too expensive (31%), followed by fears of long term side effects (20%) and low self-perceived risk (20%) (Figure 2). Of these respondents who declined study participation, 7% reported having at least 25 different sex partners and 58% reported at least one unprotected receptive anal sex encounter during the past year (Table 1). In addition, several subjects (n=13) presented for testing multiple times during the five month study period, suggesting that these subjects had some awareness of HIV risk, but declined PrEP nonetheless.

Discussion

Despite standardized education and counseling about HIV transmission and PrEP as an effective prophylactic medication, only 2 of the 416 high-risk MSM who presented for HIV testing and were offered PrEP prescriptions received the medication. Our study revealed that a number of factors deterred these men from accessing and using PrEP as prescribed. About a third of individuals (48%) reported cost as a major barrier, and the only two individuals who eventually accessed PrEP had private medical insurance. It is unclear how many other participants also had private medical insurance and still did not access PrEP. It is also unclear whether participants obtained PrEP through other means outside of this study. The study design was to ascertain barriers to accessing PrEP when the medication is not subsidized. Study participants were encouraged to seek out pharmaceutical assistance through insurance, community resources or pharmaceutical company assistance.

Despite the issue of cost, more individuals reported concerns about potential long-term adverse effects of taking HIV medications (41%) and the idea of taking a daily HIV medication (30%). Although several PrEP studies have reported higher rates of nausea, vomiting and dizziness [5, 3], a major advantage of TDF-FTC use as PrEP has been its favorable safety profile compared to other HIV medications and once-daily dosing [2]. As both our study and another PrEP accessibility study in New York have raised concerns for potential short and long term side effects amongst individuals who might benefit from PrEP, it is clear that further efforts to promote PrEP among high risk MSM should include thorough education about the relative risks and benefits of this medication [11]. In order to alter the risk-benefit ratio for an individual, this education would be more effective if heard from not only test counselors but also healthcare providers, community leaders and peers.

A third of those polled in our study declined PrEP because they did not believe they were at high risk of HIV infection, despite the fact that potential participants were recruited from an HIV testing site and disclosed unprotected sexual activity in the past year. Indeed, over half of individuals reported the highly risky unprotected receptive anal sex as their exposure in the previous 12 months, and 7% of those who declined PrEP reported having at least 25 different sex partners in the same time frame. The disconnect between perceived risk and

actual risk for HIV in our study group strongly suggests that further prevention efforts should be focused on increasing awareness of personal risk of HIV infection and the potential role of PrEP in reducing this risk.

Previous studies have demonstrated great promise in PrEP for HIV prevention in high-risk MSM. While the clinical data is promising, our study identifies certain real-life concerns regarding cost, side-effects, and self-perceived risk, each of which may limit the practical implementation of this regimen. These barriers will need to be addressed before PrEP can be an effective HIV prevention tool among MSM.

Limitations

The study was limited by the small number of non-enrollment questionnaires returned (n=54). The number is relatively small because the non-enrollment questionnaires were offered only during the last three months of the study period. With this sample size, it may be difficult to draw large-scale conclusions about attitudes towards PrEP.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

- Centers for Disease Control and Prevention. [Accessibility verified March, 26 2012] HIV in the United States: At a Glance. 2013 Feb. Available at: <http://www.cdc.gov/hiv/resources/factsheets/us.htm>.
- Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, Vargas L, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *The New England journal of medicine*. 2010; 363(27):2587–2599. [PubMed: 21091279]
- Anderson PL, Glidden DV, Liu A, Buchbinder S, Lama JR, Guanira JV, et al. Emtricitabine-Tenofovir Concentrations and Pre-Exposure Prophylaxis Efficacy in Men Who Have Sex with Men. *Sci Transl Med*. 2012 Sep 12;4(151):151ra125.
- Interim guidance: preexposure prophylaxis for the prevention of HIV infection in men who have sex with men. *MMWR Morb Mortal Wkly Rep*. 2011 Jan 28; 60(3):65–68. [PubMed: 21270743]
- Baeten JM, Donnell D, Ndase P, Mugo NR, Campbell JD, Wangisi J, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med*. 2012 Aug 2; 367(5):399–410. [PubMed: 22784037]
- Thigpen MC, Kebaabetswe PM, Paxton LA, Smith DK, Rose CE, Segolodi TM, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med*. 2012 Aug 2; 367(5):423–434. Epub 2012 Jul 11. [PubMed: 22784038]
- Brooks RA, Landovitz RJ, Kaplan RL, Lieber E, Lee SJ, Barkley TW. Sexual risk behaviors and acceptability of HIV pre-exposure prophylaxis among HIV-negative gay and bisexual men in serodiscordant relationships: A mixed methods study. *AIDS Patient Care STDs*. 2012; 26(2):87–94. [PubMed: 22149764]

8. Aghaizu A, Mercey D, Copas A, Johnson AM, Hart G, Nardone A. Who would use PrEP? Factors associated with intention to use among MSM in London: a community survey. *Sex Transm Infect.* 2012 Sep 26.
9. Mustanski B, Johnson AK, Garofalo R, Ryan D, Birkett M. Perceived Likelihood of Using HIV Preexposure Prophylaxis Medications Among Young Men Who Have Sex with Men. *AIDS Behav.* 2012 Nov 6.
10. Krakower D, Mayer KH. Engaging healthcare providers to implement HIV pre-exposure prophylaxis. *Curr Opin HIV AIDS.* 2012 Nov 7.(6):593–599. [PubMed: 23032736]
11. Golub SA, Gamarel KE, Rendina HJ, Surace A, Lelutiu-Weinberger CL. From efficacy to effectiveness: facilitators and barriers to PrEP acceptability and motivations for adherence among MSM and transgender women in New York City. *AIDS Patient Care STDS.* 2013 Apr; 27(4):248–254. PubMed PMID: 23565928; PubMed Central PMCID: PMC3624632. [PubMed: 23565928]
12. [Accessibility verified December 10, 2012] County of San Diego Health and Human Services Agency Division of Public Health Services Epidemiology and Immunization Services Branch HIV/AIDS Surveillance Program Epidemiology Report 2012. Available at: http://www.sdcountry.ca.gov/hhsa/programs/phs/documents/HAEU_BiAnnual_Report_2012_final.pdf.

Figure 1.
PrEPARE Study Flow Diagram.

Reasons for Subjects Declining Study Participation (n =54)

Figure 2.

Reasons for Subjects Declining Participation in the PrEPARE Study

Table 1

Characteristics of Subjects Offered Participation in the PrEPARE Study

Variables	Total number offered access to PrEP (n=416)	Declined PrEP (n=402)	Filled PrEP prescription (n=2)
Age median (range)	32 (18–73)	32 (18–73)	38 (29–47)
Race and Ethnicity - no. (%)			
Asian	32 (8)	32 (8)	0
Black/African American	27 (6)	25 (6)	0
Native American	11 (3)	10 (2)	0
Pacific Islander	12 (3)	12 (3)	0
White/Caucasian	281 (68)	270 (67)	2
Other or unknown	49 (12)	48 (12)	0
Declined	26 (6)	25 (6)	0
Ethnicity - no. (%)			
Hispanic	113 (27)	108 (27)	1
Non-Hispanic	302 (73)	293 (73)	1
Sexual Risk Factors			
Unprotected sex with a male in the past 12 months - no. (%)	416 (100)	402 (100)	2 (100)
Total # of male partners in past 12 months median (range)*	6 (1–200)	6 (1–200)	4 (3–5)
< 25 partners - no. (%)	346 (92)	334 (92)	2 (100)
25–49 partners - no. (%)	23 (6)	22 (6)	0
50–99 partners - no. (%)	2 (0.5)	2 (0.6)	0
100 or more partners - no. (%)	7 (2)	6 (2)	0
Oral sex with a male in the past 12 months* - no. (%)	373 (99)	359 (99)	2 (100)
Unprotected anal insertive sex in past 12 months*	277 (73)	265 (73)	2 (100)
Unprotected anal receptive sex in past 12 months*	214 (57)	210 (58)	1 (50)
Health Insurance* - no. (%)			
None	106 (28)	100 (27)	0
Medicare	4 (1)	4 (1)	0
Medi-Cal	5 (1)	4 (1)	0
Military	21 (6)	19 (5)	0
Private	241 (64)	236 (65)	2 (100)

* A total of 38 people that were offered study participation were not asked specifically about unprotected oral, anal or insertive sex or health insurance information. Percentages are adjusted based on the total number asked each specific question.