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Optimizing Content for Pre-Exposure Prophylaxis (PrEP) Counseling for Men who have Sex with Men: Perspectives of PrEP Users and High-risk PrEP Naïve Men

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Abstract

Existing trials of antiretroviral (ARV) medication as chemoprophylaxis against HIV reveal that the degree of protection is primarily dependent on product adherence. However, there is a lack of data on targets for behavioral interventions to improve adherence to ARV as prevention. Information from individuals who have used ARV as pre-exposure prophylaxis (PrEP) can inform behavioral intervention development. Thirty-nine HIV-uninfected MSM at high risk for HIV acquisition participated in one of four semi-structured focus groups. Two of the focus groups consisted of MSM who had been prescribed and used PrEP in the context of a clinical trial; the other two consisted of high-risk MSM who had not previously used PrEP. An in-depth, within-case/across-case content analysis resulted in six descriptive themes potentially salient for a PrEP adherence behavioral intervention: (1) motivations to use PrEP, (2) barriers to PrEP use, (3) facilitators to PrEP use, (4) sexual decision-making in the context of PrEP, (5) prospective PrEP education content, and, (6) perceived effective characteristics of PrEP delivery personnel. Addressing these themes in behavioral interventions in the context of prescribing PrEP may result in the optimal "packaging" public health programs that implement PrEP for high-risk MSM.

Keywords

Pre-exposure Prophylaxis (PrEP); antiretroviral therapy for prevention; ART; HIV Prevention; MSM; adherence

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INTRODUCTION

Pre-exposure prophylaxis (PrEP) to prevent HIV transmission entails the use of daily tenofovir/emtricitabine disoproxil fumurate (TDF-FTC) as a single co-formulated pill. It has recently been approved by the Federal Drug Administration (FDA) to reduce the risk of HIV acquisition among men who have sex with men (MSM) [1], who constitute the majority of prevalent and incident HIV infections in the United States [2]. However, across existing studies of this approach to prevention, adherence appears to be a major factor contributing to the efficacy of PrEP for HIV; two studies in African women found no benefit from PrEP in the setting of poor adherence [3, 4, 5].

The FDA indication for PrEP for MSM was highly influenced by the results of the iPrEx Study, a global, multi-site randomized control efficacy trial, that showed over a three-year period that MSM at high risk for HIV infection assigned to take oral tenofovir-emtricitabine as PrEP reduced their risk of acquiring HIV by 44% compared with those randomized to the placebo [6]. Furthermore, an expanded case-control study among iPrEx participants who seroconverted found that the protective effect exceeded 90% among participants who had detectable levels of study medications in their blood [7]. These results support the need for greater adherence to PrEP to achieve the optimal preventative effect. MSM at risk for acquiring HIV who elect to use PrEP need prevention counseling strategies that teach them to take PrEP on a daily and consistent basis to achieve maximum adherence and the optimal protective effect.

Other studies that have demonstrated PrEP efficacy of PrEP in additional populations also emphasize the need for adequate adherence in order to optimize protection. The TDF2 study, a placebo-controlled trial in young heterosexual men and women in Botswana who used oral PrEP daily reported an efficacy approaching 62% [8]. Plasma drug level analysis revealed that participants in the active drug arm who seroconverted had significantly lower serum levels of detectable study medication in their blood compared with those who did not seroconvert. These findings suggest PrEP adherence that resulted in higher drug levels was associated with protection. Most recently, a study of PrEP in Thai injecting drug users [9] found that daily oral tenofovir was associated with ~50% reduction in HIV incidence compared to placebo. Once again, the level of protection was highly correlated with the detection of study drug in the blood.

The Partners PrEP study [10], a 3-arm placebo controlled trial (TDF only, TDF-FTC, and placebo) conducted with heterosexual discordant couples in East Africa, also demonstrated PrEP efficacy, and reported higher levels of protection among those who were more adherent to the medication. Overall, there was a 67% reduction in HIV acquisition using TDF only compared to placebo, and a 75% reduction with TDF-FTC compared to placebo; moreover, efficacy reached 86% and 90% respectively with detectable serum TDF levels in the active treatment groups [10]. A subset of individuals from the Partners PrEP study participated in an ancillary adherence study [11] in which medications were monitored in real time; participants whose medication adherence levels dropped below 80% were provided adherence counseling using a cognitive-behavioral approach (Life-steps) [12, 13]

adapted from antiretroviral therapy (ART) for treatment to ARV for prevention [14]. In this study, the protective effect of PrEP rose to 100% compared to placebo.

Other PrEP studies designed for heterosexual women have not demonstrated efficacy primarily due to non-adherence. In the FEM-PrEP study [5] of African women, the Data Safety Monitoring Board (DSMB) closed the study early due to increased seroconversions and low drug adherence as measured by infrequent detection in blood. Although participants reported a 95% rate of overall medication adherence, drug was actually detected in fewer than 1/3 of the participants. More recently, the VOICE trial using vaginal gel or study PrEP tablets to protect African women from HIV acquisition also was discontinued by the DSMB, as adherence to study drug was low and seroconversions were high [3,5]. Although successful interventions have been developed to increase adherence to ART for HIV-infected patients [15], evidenced-based interventions for ARV adherence to PrEP are needed. Life-steps [12] is an evidenced-based adherence intervention for ART treatment that utilizes problem-solving and cognitive behavioral therapy to address adherence barriers and to promote adherence facilitators. It was one of the first ART adherence interventions tested in the US [13] and was later adapted and tested in China [14]. It has also been adapted for use in both HPTN 052 [17], a study showing that early ART for the HIV-infected partner was successful in reducing HIV transmissions in serodiscordant couples, and in the AIDS Clinical Trial Group (ACTG) 5175, a multi-site ART treatment trial [18]. With respect to PrEP, the adherence intervention was based on Life-steps [14] in the adherence sub-study for the Partners in PrEP trial [11]. Therefore, we sought to adapt and use this intervention for high-risk MSM who are prescribed PrEP. As part of a sequential intervention development effort to optimally “package” PrEP prescription and counseling, we collected formative data from HIV-uninfected MSM at-risk for HIV acquisition across PrEP-experienced and PrEP-naïve individuals so to identify potentially useful adherence intervention content.

METHODS

Procedures and Participants

To identify the optimal content for a PrEP adherence package for MSM, we conducted four focus groups between October, 2011, and March, 2012, at Fenway Health, which was one of three U.S. sites for the CDC PrEP study [19] and one of the 11 sites of the iPrEx trial [6]. For the first two PrEP-experienced focus groups, we used a purposive sampling method to recruit participants from the PrEP treatment arm in the iPrEx or CDC PrEP studies. The other two focus groups included high-risk MSM, PrEP-naïve volunteers. We used a convenience sampling method to recruit broadly from the community through advertising venue outreach (bar, club, cruising areas) and community outreach and advertising (print, clinic flyers and electronic media). All volunteers underwent a self-report telephone screen to confirm they met participation. PrEP-experienced participants were recruited from subjects who had participated in a prior PrEP clinical trial at Fenway Health. Inclusion criteria for the PrEP naïve participants were: (1) male sex at birth, (2) 18 years or older, (3) HIV-uninfected via self-report, (4) having at least one episode of unprotected anal intercourse in the past three months with a non-monogamous partner or a monogamous

partner who was HIV-infected, and (5) not ever having taken PrEP. The Institutional Review Board at Fenway Health reviewed and approved all study procedures.

Data collection

Informed consent to participate was obtained at the beginning of each focus group via oral explanation of the research, after which participants were given a brief quantitative survey that gathered socio-demographic data which included: age, racial/ethnic identity, education, employment status, annual income, health insurance coverage, sexual identity (e.g., gay, bisexual, straight), current access to a primary care provider, substance use and sexual behavior (focusing on risk of sexual acquisition of HIV) in the prior three months. A focus group coordinator facilitated and audio-recorded all four focus groups; the study coordinator was present for all groups and annotated the session. An Infectious Disease physician also was present for all focus groups to address participant's medical questions pertaining to PrEP use. Participants were compensated $50 for their time.

In collaboration with study staff who worked with participants on the iPrEX study, the Fenway Health Community Advisory Board, deductive question development, and prior research related to medication adherence, we developed a semi-structured interview using probing questions around six major topics. Our open-ended questions assessed participants' adherence beliefs around the efficacy of PrEP, barriers and facilitators of adherence to a daily regimen of PrEP, and sexual decision-making in the context of PrEP use. The 90-minute facilitated discussions of each focus group were recorded using a handheld digital audio recorder and later transcribed by a third-party contractor. All transcripts were checked for errors and corrected before using Atlas.ti (qualitative software program) to manage and code data.

Data analysis

We approached the focus group data using a qualitative descriptive design [20, 21], which provided a contextual framework to explore, analyze and describe findings. A descriptive account of emerging themes was achieved by merging in-depth content analysis [22] with within-case (analysis of each focus group) and across-case (comparing significant statements across focus groups) approaches to data review [23]. The focus group leader and the study coordinator developed a codebook, defined each code and reviewed each transcript line-by-line to identify significant statements. To increase reliability and rigor in our analysis, we used the procedures to insure data trustworthiness outlined by Lincoln and Guba [24]. By establishing credibility (prolonged engagement, persistent observation, peer debriefing), transferability (producing thick descriptions through purposive/convenience sampling), and dependability (auditing study procedures), we created a platform for confirmability, which provides reliable data for researchers to use across studies.

RESULTS

Participants' socio-demographic data are described in Table I. The average ages of the PrEP-experienced and PrEP-naïve participants were 44.4 and 44.1 years, respectively. In the

past three months, the PrEP experienced group reported more number of male sexual partners and more UAI with HIV-infected sexual partners.

Descriptive themes across all participants

The semi-structured interview guide in Table II guided the discussion of significant statements across-groups that supported the six emerging themes presented in Table III, which included (1) motivations to use PrEP, (2) barriers to PrEP use, (3) facilitators to PrEP use, (4) sexual decision-making in the context of PrEP, (5) prospective PrEP education content, and (6), effective characteristics for PrEP delivery personnel. These themes and selected significant supporting statements are discussed below.

Motivations to use PrEP—Participants in the four focus groups reported being highly motivated to use PrEP to protect themselves from HIV acquisition (Quotes 1, 2). Participants generally expressed satisfaction knowing that they were part of a larger group of MSM volunteering to help avert new HIV infections in the community.

Barriers to PrEP use—Participants discussed a number of barriers that might disrupt adherence to PrEP on a daily basis. For all four focus groups, mental health concerns (Quote 3) and substance use/abuse (Quotes 4, 5) predominated the discussion on potential and actual barriers. PrEP-experienced participants described symptoms of depression (e.g., anxiety, insomnia) and alcohol consumption that interfered with their adherence schedule. Other barriers included potential medication costs after study completion (Quote 6), perceived stigma associated with HIV medications use (Quote 7), and apprehension discussing risky sexual behaviors and PrEP use with health care providers (Quote 8).

Facilitators to PrEP use—All four focus groups described strategies to help them adhere to PrEP on a regular basis. Because many participants noted they took medications on a regular basis for other medical concerns, they incorporated individualized approaches, such as daily rituals (Quote 9), anticipatory changes in schedules (Quote 10) or external reminders (Quote 13). In addition, participants suggested other innovative adherence activations that might require a third party, such as phone calls or text messages (Quotes 11 and 12).

Sexual decision-making—Participants generally described concerns that taking PrEP might affect sexual decision-making. The majority of participants suggested that using PrEP could free them from needing to use condoms and still feel protected from HIV (Quotes 14 and 15). Other participants described potential PrEP use in the context of partnerships, specifically feeling protected in seroconcordant relationships (Quote 16) and in non-monogamous, open relationships (Quote 17).

PrEP education information—When asked what topics would be most important for a PrEP adherence counseling package for at-risk MSM, participants in all four focus groups wanted to know how taking PrEP would affect their physical health and the broader MSM community (Quote 18). Participants suggested they needed information on short-term and long-term side effects of PrEP (Quote 19). Another major concern was how participants in

current and prospective PrEP studies would access medication after their research participation ended (Quote 20).

PrEP delivery personnel—Participants recommended that personnel who deliver PrEP, whether in a research or medical context, must be well educated and trained about PrEP use (Quote 21) and must build rapport with the PrEP user (Quote 22). These qualities were essential to an effective adherence package in all focus groups.

DISCUSSION

PrEP-experienced and PrEP-naïve MSM participated in a qualitative study that explored the optimal content for a PrEP adherence intervention. These participants reported high levels of willingness and motivation to use PrEP as an HIV biomedical prevention strategy. Consistent with our results, in a qualitative study of gay and bisexual men in serodiscordant relationships, men saw PrEP as a means to protect oneself from HIV, to reduce the concern and fear of HIV transmission, and to have unprotected sex with reduced chance of infection [25]. We also found that that some participants' motivation might be fueled by their desire to be a part of a larger community. Identifying how motivated participants are to take PrEP daily, how important PrEP is to keeping them safe, and how confident they are in their ability to take PrEP could be included in future PrEP adherence interventions.

Participants noted potential barriers to PrEP adherence that are similar to barriers identified for antiretroviral treatment adherence among HIV-infected patients [26, 27]. These included mental health concerns, substance use and abuse, short and long-term side effects, and stigma and discrimination associated with disclosing PrEP use in the context of risky sexual behaviors. Similarly, studies of PrEP-naïve MSM have found that concerns about side effects, medication costs, access, and perceived stigma and discrimination from peers and health care workers may limit MSM interest in PrEP [25, 28]. At the same time, however, PrEP experienced participants shared how they incorporated PrEP use into their current patterns of taking medications (e.g., using a pill box) and indicated that they would welcome reminders via alarms or text messages on a daily basis. To address barriers and improve adherence to PrEP, participants endorsed the need for behavioral approaches that increase problem-solving skills [29, 30] to help to identify personal barriers and generate alternative solutions.

Because PrEP use is still a novel biomedical prevention technology, additional information is needed to understand risk compensation and sexual decision-making [31]. Generally, both PrEP-naïve and PrEP experienced participants in the current study were concerned that PrEP would affect their sexual decision-making and possibly would lead to an increase in unprotected sexual intercourse. This concern has been raised in previous research studies of PrEP naïve participants [25, 28, 32]. Golub et al. [33] found that approximately 35% of a sample of high-risk MSM (N=180) reported that they would likely decrease condom use if they were taking PrEP. However, sexual risk behaviors actually decreased among MSM enrolled in PrEP clinical trials [10, 14, 34]. In a study of 400 HIV-negative MSM enrolled in a double-blind, placebo-controlled PrEP safety trial, Liu et al. [35] concluded that there was no evidence of sexual risk compensation among American MSM. Marcus et al. [36] found

no evidence of risk compensation in the iPrEx study, but suggested that continued HIV prevention education may be needed for those who engage in sexual risk taking and who are optimistic about PrEP benefits. It is also important to note that in both studies, PrEP had not yet been shown to be effective in decreasing HIV incidence, and participants could not be sure whether they were receiving the placebo or active medication. Thus, the ultimate potential for risk compensation among MSM using PrEP is not fully understood; hence it might be best for clinicians to continue to promote traditional prevention messages (e.g., practice safer-sex and use condom) when providing PrEP to high-risk MSM. Combination prevention approaches that include both behavioral and biomedical interventions might be most effective if they address adherence and include prevention messages [37].

Participants in both the PrEP experienced and naïve groups were concerned about the short- and long-term side effects of PrEP use and the consequences of long-term use in the MSM community. Ongoing trials will report on long-term toxicities as data arrive, but prior studies of tenofovir-containing regimens (primarily as part of a combination regimen for HIV-infected patients) may include renal effects, decreased bone mineral density, gastrointestinal effects, and exacerbation of hepatitis B in patients who do not consistently take the medication [38, 39]. However, in a review of five PrEP efficacy trials, the Forum for Collaborative HIV Research concluded that the side effects did not differ between the placebo and intervention groups [40] Because PrEP interventions for high-risk MSM are relatively new, the implementation process will require provider training to learn how best to counsel potential users and to monitor for side effects, consumer education, and long term monitoring [41].

In the current study, individuals were enrolled on a first-come eligibility basis, which might account for some of the socio-demographic differences in the focus groups (i.e., the higher overall percentage of whites among the PrEP-experienced participants and lower level of income among the PrEP-naïve participants). A stratified sampling technique might yield groups that are more similar. Although these differences could have influenced the results of the study, there appear to be no emerging thematic differences in attitudes and beliefs about PrEP that would differentiate between PrEP-experienced and PrEP-naïve participants. Finally, there seemed to be no salient differences in PrEP use attitudes and beliefs associated with specific socio-demographic characteristics among participants.

As a qualitative study, the findings have some limitations. First, although the four focus groups of PrEP-experienced and PrEP-naïve participants provide relevant data to understand PrEP adherence, the sample was drawn from a northeastern city and included those who self-identified as gay and bisexual men and were engaged in care. Secondly, participants might have provided answers to questions based on peer expectations or dominant voices within the group. This process in focus groups lends itself to group conformance and conflict avoidance [42]. Therefore, these data might be subject to “group think,” and the emerging themes could be biased in that direction. Because PrEP adherence education is currently and primarily an individual-level process, it would have been helpful to have included individual-level data from individual interviews that could triangulate our findings. Lastly, the semi-structured interview guide was developed before focus group implementation and the emerging themes could describe deductive rather than inductive

descriptive results. In a limited 90-minute conversational setting, the study team addressed a core list of questions to identify in-depth targets for ARV behavioral intervention in a timely manner. An inductive, unstructured approach would require the interviewer to have less control and direction over the conversation and to limit probing questions for further exploration.

Despite these limitations, these emerging data provide insight for researchers and clinicians who are developing new PrEP studies and PrEP adherence protocols. The goal of the current study was to identify important content for a PrEP adherence package that can be delivered following a cognitive-behavioral approach. Life-steps [12, 13] has been used in medication adherence interventions for HIV-infected individuals and might serve as a platform for intervention development with HIV-uninfected PrEP users. In addition, use of Life-steps in the Partners PrEP study [11] showed promising increased PrEP adherence. Although it will need to be modified to meet the needs of high-risk HIV-uninfected MSM, some of the basic principles may still apply, including psycho-social education and motivation for taking PrEP, identifying facilitators and problem solving skills for storing and refilling medication, scheduling and keeping PrEP medical appointments, and managing barriers that might interfere with PrEP adherence goals. These steps are consistent with other structured yet tailored approaches to primary HIV prevention that consider individual barriers and facilitators and utilize motivational techniques to achieve the optimal preventative approach. This formative work provides a foundation for us to develop and openly pilot an intervention based on Life-steps [11] to optimally “package” PrEP prescription and adherence counseling.

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References

1. Kashuba ADM, Patterson KB, Dumond JB, Cohen MS. Pre-exposure prophylaxis for HIV prevention: How to predict success. Lancet. 2012; 379:2409–2411. [PubMed: 22153566]
2. Center for Disease Control and Prevention. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention: Division of HIV/AIDS Prevention. 2012. HIV among gay and bisexual men: May 2012 Factsheet.
3. Marrazzo, J.; Ramjee, G.; Nair, G.; Palanee, T.; Mkhize, B.; Nakabiito, C., et al. Pre-exposure Prophylaxis for HIV in Women: Daily Oral Tenofovir, Oral Tenofovir/Emtricitabine, or Vaginal Tenofovir Gel in the VOICE Study (MTN 003). Presented at: 20th Annual Conference on Retroviruses and Opportunist Infections; 2013 Mar 3–6; Atlanta, GA.
4. Muchomba FM, Gearing RE, Simoni JM, El-Bassel N. State of Science of Adherence in PreExposure Prophylaxis and Microbicide Trials. JAIDS. 2012 Epub ahead of print.
5. Van Damme L, Corneli A, Ahmed K, Agot K, Lombaard J, Kapiga S, et al. Preexposure prophylaxis for HIV infection among African women. N Engl J Med. 2012; 367(5):411–22. [PubMed: 22784040]

6. 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. N Engl J Med. 2010; 363(27):2587–99. [PubMed: 21091279]
7. 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; 4(151):151ra125.
8. Thigpen MC, Kebaabetswe PM, Paxton LA, Smith DK, Rose CE, Segolodi TM, et al. Antiretroviralpreexposure prophylaxis for heterosexual HIV transmission in Botswana. N Engl JMed. 2012; 367(5):423–34. [PubMed: 22784038]
9. Choopanya, K.; Martin, M.; Suntharasamai, et al. for the Bangkok Tenofovir Study Group. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomized double-blind, placebo controlled phase 3 trial. Lancet. 2013. published online June 13. http://dx.doi.org/10.1016/S0140-6736(13)61127-7
10. Baeten JM, Donnell D, Ndase P, Mugo NR, Campbell JD, Wangisi J, et al. Antiretroviral prophylaxis for HIV prevention among heterosexual men and women. N Engl J Med. 2012; 367(5):399–410. [PubMed: 22784037]
11. Haberer, J.; Baeten, J.; Celum, C.; Katibira, E.; Ronald, A.; Tumwesigye, E., et al. High adherence among HIV-1 serodiscordant couples in the partners PrEP ancillary adherence study. Presented at: 7th International Conference on HIV Treatment and Prevention Adherence; 2012 Jun 3–5; Miami, FL.
12. Safren SA, Otto MW, Worth JL. Life-Steps: applying cognitive behavioral therapy to HIV medication adherence. Cogn Behav Pract. 1999; 6:332–341.
13. Safren SA, Otto MW, Worth JL, Salomon E, Johnson W, Mayer K, et al. Two strategies to increase adherence to HIV antiretroviral medication: Life-steps and medication monitoring. Behav Res Ther. 2001; 39(10):1151–62. [PubMed: 11579986]
14. Psaros, C.; Haberer, J.; Thomas, K.; Katabira, E.; Ronald, A., et al. Evaluation and process outcomes from an adherence intervention to support HIV pre-exposure prophylaxis (PrEP) adherence in HIV serodiscordant couples in Uganda. Presented at: 7th International Conference on HIV Treatment and Prevention Adherence; 2012 Jun 3–5; Miami, FL.
15. Simoni JM, Amico KR, Smith L, Nelson K. Antiretroviral adherence interventions: Translating research findings to the real world clinic. Curr HIV/AIDS Rep. 2010; 1:44–51. [PubMed: 20425057]
16. Simoni JM, Chen WT, Huh D, Fredriksen-Goldsen KI, Pearson C, Zhao H, et al. A preliminary randomized controlled trial of a nurse-delivered medication adherence intervention among HIV-positive outpatients initiating antiretroviral therapy in Beijing, China. AIDS Behav. 2011; 15(5): 919–29. [PubMed: 20957423]
17. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. 2011; 365(6):493–505. [PubMed: 21767103]
18. Campbell C, Skovdal M, Mupambireyi Z, Madanhire C, Nyamukapa C, Gregson S. Building adherence-competent communities: factors promoting children's adherence to anti-retroviral HIV/AIDS treatment in rural Zimbabwe. Health Place. 2012; 18(2):123–31. [PubMed: 21975285]
19. Grohskopf, L.; Gvetadze, R.; Pathak, S.; O'Hara, B.; Mayer, K.; Liu, A., et al. Phase II Clinical Safety Trial of Tenofovir Disoproxil Fumarate (TDF) for HIV-1 Pre-Exposure Prophylaxis (PrEP) Among U.S. Men who Have Sex with Men (MSM). Presented at: XVIII International AIDS Conference; 2010 Jul 18–23; Vienna, Austria.
20. Sandelowski M. What's in a name? Qualitative description revisited. Res Nurs Health. 2010; 33:77–84. [PubMed: 20014004]
21. Sullivan-Bolyai S, Bova C, Harper D. Developing and refining interventions in persons with health disparities: the use of qualitative description. Nurs Outlook. 2005; 53(3):127–33. [PubMed: 15988449]
22. Miles, MB.; Huberman, AM. An expanded sourcebook: Qualitative data analysis. 2. Thousand Oaks, CA: SAGE; 1994.

23. Ayres L, Kavanaugh K, Knafl KA. Within-case and across-case approaches to qualitative data analysis. Qual Health Res. 2003; 13(6):871–83. [PubMed: 12891720]
24. Lincoln, YS.; Guba, EG. Naturalistic inquiry. Beverly Hills, CA: SAGE; 1985.
25. Brooks RA, Kaplan RL, Lieber E, Landovitz RJ, Lee SJ, Leibowitz Aa. Motivators, concerns, and barriers to adoption of preexposure prophylaxis for HIV prevention among gay and bisexual men in HIV-serodiscordant male relationships. AIDS Care. 2011; 23(9):1136–45. [PubMed: 21476147]
26. Mills EJ, Nachega JB, Bangsberg DR, Singh S, Rachlis B, Wu P, et al. Adherence to HAART: A systematic review of developed and developing nation patient-reported barriers and facilitators. PLoS Med. 2006; 3(11):2039–2064.
27. Mugavero M, Ostermann J, Whetten K, Lesserman J, Swartz M, Thielman N. Barriers to antiretroviral adherence: The importance of depression, abuse, and other traumatic events. AIDS Patient Care STDS. 2006; 20(6):418–428. [PubMed: 16789855]
28. Galea JT, Kinsler JJ, Salazar X, Lee SJ, Giron M, Sayles JN, et al. Acceptability of pre-exposure prophylaxis as an HIV prevention strategy: barriers and facilitators to pre-exposure prophylaxis uptake among at-risk Peruvian populations. Int J STD AIDS. 2011; 22(5):256–62. [PubMed: 21571973]
29. Nezu A, D'Zurilla TJ. An experimental evaluation of the decision-making process in social problem solving. Cognit Ther Res. 1979; 3:269–277.
30. Nezu A, D'Zurilla TJ. Effects of problem definition and formulation on decision-making in the social problem-solving process. Behav Ther. 1981; 12:100–106.
31. Eaton LA, Kalichman S. Risk compensation in HIV prevention: implications for vaccines, microbicides, and other biomedical HIV prevention technologies. Curr HIV/AIDS Rep. 2007; 4(4):165–72. [PubMed: 18366947]
32. Supervie V, García-Lerma JG, Heneine W, Blower S. HIV transmitted drug resistance, and the paradox of preexposure prophylaxis. Proc Natl Acad Sci U S A. 2010; 107(27):12381–6. [PubMed: 20616092]
33. Golub SA, Kowalczyk W, Weinberger CL, Parsons JT. Preexposure prophylaxis and predicted condom use among high-risk men who have sex with men. J Acquir Immune Defic Syndr. 2010; 54(5):548–55. [PubMed: 20512046]
34. Guest G, Shattuck D, Johnson L, Akumatey B, Clarke EE, Chen PL, et al. Changes in sexual risk behavior among participants in a PrEP HIV prevention trial. Sex Transm Dis. 2008; 35(12):1002–8. [PubMed: 19051397]
35. Liu, AY.; Vittinghoff, E.; Chillag, K.; Mayer, K.; Thompson, M.; Grohskopf, L., et al. No evidence of sexual risk compensation among HIV-uninfected men who have sex with men (MSM) participating in a tenofovir pre-exposure prophylaxis (PrEP) trial. Presented at: 6th International AIDS Society Conference on HIV Pathogenesis, Treatment, and Prevention; 2011 Jul 17–20; Rome, Italy.
36. Marcus, J.; Mayer, K.; Guanira, J.; Casapia, M.; Montoya, O.; Chariyalertsak, S., et al. No Evidence of Sexual Risk Compensation in the iPrEx Trial of HIV Pre-exposure Prophylaxis. Poster presented at: 20th Annual Conference on Retroviruses and Opportunistic Infections; 2013 Mar 3–6; Atlanta, GA.
37. Buchbinder SP, Liu A. Pre-exposure prophylaxis and the promise of combination prevention approaches. AIDS Behav. 2011; 15:S72–S79. [PubMed: 21331801]
38. Liu AY, Grant RM, Buchbinder SP. Preexposure prophylaxis for HIV: unproven promise and potential pitfalls. JAMA. 2006; 296:863–865. [PubMed: 16905792]
39. Paxton LA, Hope T, Jaffe HW. Pre-exposure prophylaxis for HIV infection: what if it works? Lancet. 2007; 370:89–93. [PubMed: 17617276]
40. Strobos J, Hauschild B, Miller V. Safety Considerations in the Prevention of Transmission of HIV by Pre-Exposure Prophylaxis (or "PrEP"). Ann Forum Collab HIV Res. 2011; 13(5):1–4.
41. Underhill K, Operario D, Mimiaga MJ, Skeer MR, Mayer KH. Implementation science of pre-exposure prophylaxis: Preparing for public use. Curr HIV/AIDS Rep. 2010; 7:210–219. [PubMed: 20820971]
42. Carey MA. Comment: Concerns in the analysis of focus group data. Qual Health Res. 1995; 5(4): 487–495.

Table I

Descriptive characteristics of PrEP Focus Group Participants (n=39)

	PrEP Experienced Focus Group Participants (n=20)	PrEP Naïve Focus Group Participants (n=19)
Characteristics	**Mean (SD)**	**Mean (SD)**
Age in years	44.37 (6.98)	44.05 (11.00)
Number of Male Sex Partners (past 3 months)	4.88 (9.78)	3.74 (4.7)
UAI (past 3 months)	4.71 (12.10)	4.11 (4.55)
UAI with HIV-infected partners (past 3 months)	2.43 (7.98)	.78 (2.60)
UAI with unknown serostatus partners (past 3 months)	1.29 (2.67)	1.89 (4.34)
Characteristics	N (%)	N (%)
Sexual Orientation		
Heterosexual/straight	1 (5)	2 (10.5)
Homosexual/gay	13 (65)	11 (57.9)
Bisexual	4 (20)	3 (15.8)
Other	1 (5)	3 (15.8)
Refused to answer	1 (5)	0
Racial Group		
Black/African-American	5 (25)	12 (63.2)
American Indian/Alaskan	0	1 (5.3)
White/Caucasian	15 (75)	6 (31.5)
Other	0	0
Hispanic		
Yes	1 (5)	3 (15.8)
No	19 (95)	16 (84.2)
Employment		
Full-time	9 (45)	3 (15.8)
Part-time	4 (20)	2 (10.5)
Unemployed	4 (20)	7 (36.8)
Disabled	3 (15)	6 (31.6)
Other	0	1 (5.3)
Education		
Some high school	1 (5)	0
High school or GED	5 (25)	6 (31.6)
Some college	3 (15)	4 (21.1)
College degree	5 (25)	4 (21.1)
Some graduate work (no degree to date)	2 (10)	2 (10.5)
Graduate/professional	4 (20)	3 (15.8)
Annual Income (before taxes)		
less than $6000	3 (15)	5 (26.3)
$6000 – $11999	2 (10)	6 (31.5)

	PrEP Experienced Focus Group Participants (n=20)	PrEP Naïve Focus Group Participants (n=19)
Characteristics	**Mean (SD)**	**Mean (SD)**
$12000 – $17999	1 (5)	3 (15.8)
$18000 – $23999	2 (10)	1 (5.3)
$24000 – $29999	2 (10)	2 (10.5)
$30000 – $59999	4 (20)	1 (5.3)
$60000 or more	5 (25)	1 (5.3)
Refused to answer	1 (5)	0
Alcohol Use (last 4 months)		
Don't Use	7 (35)	4 (21.1)
Once a month or less	6 (30)	2 (10.5)
About once a week	3 (15)	6 (31.6)
Several times a week	0	7 (36.8)
About once a day	1 (5)	0
Refused to answer	3 (15)	0
Any use	11 (55)	15 (79)
Amphetamine Use (last 4 months)		
Don't Use	15 (75)	16 (84.2)
Once a month or less	1 (5)	2 (10.5)
Not Sure	0	1 (5.3)
Refused to answer	4 (20)	0
Cocaine Use (last 4 months)		
Don't Use	14 (70)	9 (47.4)
Once a month or less	1 (5)	6 (31.5)
About once a week	1 (5)	1 (5.3)
Several times a week	0	2 (10.5)
About once a day	0	1 (5.3)
Refused to answer	4 (20)	0
Poppers Use (last 4 months)		
Don't Use	11 (55)	16 (84.1)
Once a month or less	5 (25)	1 (5.3)
Several times a week	0	1 (5.3)
Not sure	0	1 (5.3)
Refused to answer	4 (20)	0
Health Insurance		
Yes	19 (95)	18 (94.7)
No	0	1 (5.3)
Refused to answer	1 (5)	0
Primary Care Provider		
Yes	18 (90)	18 (94.7)
No	1 (5)	1 (5.3)
Refused to answer	1 (5)	0

Table II

Focus group interview guide

#	Questions	Probes
1.	**PrEP Adherence Content** What topics would be important to discuss?	• How would this content be disseminated? • What type of personnel would be most effective?
2.	**Barriers to PrEP Adherence** What are some of the barriers to taking PrEP on a daily basis?	• Side effects (e.g., nausea, diarrhea) • Mood • Substance use • Economic/occupation/familial concerns
3.	**Facilitators of PrEP Adherence** What do you do to help you remember to take your pills on a regular basis?	• Which novel ways would be acceptable to remind you to take PrEP as prescribed? • PrEP Experienced: What did you do?
4.	**PrEP and Sexual Decision-making** How would taking PrEP affect your sex life?	• How will taking PrEP affect: – Your partner choice? – Type of sex you would/will have (e.g., anal receptive or insertive)? – Types of partners (e.g., anonymous, casual, serodiscordant, etc.)?
5.	**Feasibility and Acceptability of the PrEP Adherence Intervention** How willing do you think MSM at high risk of HIV infection would be to engage in counseling around PrEP adherence and sexual risk?	• Would you prefer to have the same person counsel you about adherence as the person who would provide risk reduction counseling? • Would you prefer to record your adherence using a computer program or with study staff? • What challenges might there be to discuss adherence with study staff?

PrEP = pre-exposure prophylaxis

Table III

Supportive significant statements from focus groups

Emerging Theme	Significant statements	Group
1. Motivation to use PrEP	1. "Not only did I feel like I was potentially doing something beneficial to me, but also because I was helping the larger community."	PE
	2. "I know that I have at risk sex with men and they could possibly be HIV infected, and if there's this drug and I take it every day, it's going to give me a good probability of not getting HIV, then I'm going to take it every day."	PN
2. Barriers to PrEP	3. "I have problems with anxiety and insomnia. When it was at its worst, it was when I couldn't take the medication."	PE
	4. "Drugs and alcohol would be a barrier, as well as side effects from taking PrEP."	PN
	5. "Substance abuse is a barrier. I think if the medication is going to be prescribed to someone, then the prescriber should know if they have substance abuse. So, if you want the medication to work you have to go through substance abuse counseling."	PN
	6. "I think if I had to pay for it at all, I probably wouldn't take it."	PE
	7. "Truvada is a medication for people who are HIV, right? If somebody finds out you're taking Truvada, they're going to think you're HIV."	PN
	8. "Some people aren't "out" to their provider, let alone telling them 'I'm engaged in risky sexual behaviors.' I think those conversations don't happen very often."	PE
3. Facilitators of PrEP	9. "I have a double ritual, which is at night I take the pill out and I put it by the bed, so in the morning, I remember to take it."	PE
	10. "I travel with it, so if I was going to work, I'd put it in a bag with vitamins and have a couple extra, because if I forgot it at home, I would take it at work."	PE
	11. "You could have phone calls, or emails, telling you to take it, just automatically generated on a daily basis."	PN
	12. "A daily text saying, "Have you taken your Truvada today?"	PE
	13. "I would set an alarm on my watch to remember to take it."	PE
4. Sexual decision-making	14. "The first thing that comes to mind when I hear about a pill such as that would be that I could push the condom aside and I can have this pill, so if something goes wrong this is the contraceptive."	PN
	15. "I think it allows you to be less cautious…try it with someone that you probably wouldn't be with normally – be with them rather than wait for the next person that you really want to be with."	PE
	16. "One of my biggest fears is not the sex that I have control of, but the sex I don't have control of, so if my partner is out and about without me, taking risks, and then bringing that home."	PN
	17. "I'm thinking to myself, if I fell in love with somebody who was HIV-positive, and I was a "bottom," that PrEP would be perfect for me. It would allow us to have a little bit less stress around our intimacy. And, I'm not saying we shouldn't still be safe."	PN
5. PrEP education information	18. "I think there needs to be more education about how it (PrEP) affects our health. I read an article and it wasn't clear to me. I wasn't convinced that this really can benefit the community."	PN
	19. "I don't think that there was enough PrEP education on like long-term side effects and like injures to your body, such as osteoporosis and stuff like that."	PE
	20. "PrEP is only available during the study. Beyond the study, we won't receive it. We need to know what to do after the study if we want to continue taking it.	PE
6. PrEP delivery personnel	21. "When you go to the hospital, you might see a doctor that doesn't know anything about AIDS drugs or is not familiar with the type of drug that you're on. You want somebody that would understand the drug and understand its ramifications."	PE
	22. "I have a very strong relationship with my primary care physician, so I think PrEP and the counseling I get from him would be much better received than from a total stranger."	PN

PrEP = pre-exposure prophylaxis; PE = PrEP experienced; PN = PrEP Naïve