

Sexual Behavior, Risk Compensation, and HIV Prevention Strategies Among Participants in the San Francisco PrEP Demonstration Project: A Qualitative Analysis of Counseling Notes

J. Carlo Hojilla¹ · Kimberly A. Koester² · Stephanie E. Cohen^{3,4} · Susan Buchbinder⁵ · Deawodi Ladzekpo⁶ · Tim Matheson⁶ · Albert Y. Liu⁵

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Abstract Pre-exposure prophylaxis (PrEP) is a viable HIV prevention strategy but risk compensation could undermine potential benefits. There are limited data that examine this phenomenon outside of clinical trials. We conducted a qualitative analysis of counseling notes from the San Francisco site of the US PrEP demonstration project to assess how men who have sex with men used PrEP as a prevention strategy and its impact on their sexual practices. Four major themes emerged from our analysis of 130 distinct notes associated with 26 participants. Prevention strategy decision-making was dynamic, often influenced by the context and perceived risk of a sexual encounter. Counselors noted that participants used PrEP in conjunction with other health promotion strategies like condoms, asking about HIV status of their sex partners, and seroadaptation. With few exceptions, existing risk reduction strategies were not abandoned upon initiation of PrEP. Risk-taking behavior was ‘seasonal’ and fluctuations were

influenced by various personal, psychosocial, and health-related factors. PrEP also helped relieve anxiety regarding sex and HIV, particularly among serodiscordant partners. Understanding sexual decision-making and how PrEP is incorporated into existing prevention strategies can help inform future PrEP implementation efforts.

Keywords HIV prevention · Pre-exposure prophylaxis · HIV/AIDS · Men who have sex with men · Risk compensation

Introduction

In 2012, the United States Food and Drug Administration approved the use of the co-formulated drug tenofovir-emtricitabine (TDF-FTC) for oral HIV pre-exposure prophylaxis (PrEP) [1]. This was subsequently followed by the release of clinical practice guidelines for PrEP by the US Public Health Service in 2014 [2]. The premise of PrEP is to provide individuals at risk for HIV with prophylactic antiretroviral medications (ARVs) to lower their risk of HIV acquisition [3]. Several studies have demonstrated that PrEP is efficacious in preventing HIV infection in different populations [4–7], with efficacy estimates ranging from 44 to 75 % when delivered as part of a comprehensive HIV prevention package [8]. PrEP efficacy is highly correlated with adherence [9, 10]. In a substudy of the Pre-exposure Prophylaxis Initiative (iPrEx) trial that evaluated the efficacy of TDF-FTC among men who have sex with men (MSM) and transgender women [4], having detectable drug in the blood was estimated to provide over 90 % protection [10]. These findings suggest that PrEP is a viable biomedical and biobehavioral prevention strategy. However, there is uncertainty as to what impact PrEP might have on

✉ J. Carlo Hojilla
carlo.hojilla@ucsf.edu

¹ Department of Community Health Systems, School of Nursing, University of California, San Francisco, 2 Koret Way, N505, San Francisco, CA 94143, USA

² Center for AIDS Prevention Studies, University of California, San Francisco, San Francisco, CA, USA

³ Disease Prevention and Control, San Francisco Department of Public Health, San Francisco, CA, USA

⁴ Division of Infectious Diseases, University of California, San Francisco, San Francisco, CA, USA

⁵ Bridge HIV, San Francisco Department of Public Health, San Francisco, CA, USA

⁶ San Francisco Department of Public Health, San Francisco, CA, USA

the sexual practices of individuals when offered in an open-label context [11–14].

A key concern is that PrEP might lead users to engage in more risky behaviors through risk compensation, undermining potential benefits [11, 15, 16]. Risk compensation is the increase in risk-taking behaviors triggered by a decrease in perceived risk [17, 18]. Previous studies have noted evidence of risk compensation among participants in vaccine and microbicide trials, as well as in HIV-infected individuals on ARV therapy [19–21]. In contrast, several completed PrEP randomized clinical trials did not show evidence of risk compensation [6, 22–24]. For example, quantitative data from the iPrEx and Partners PrEP studies revealed that condom use increased and diagnosis of sexually transmitted infections (STI) decreased during follow-up [6, 24], and risk practices did not substantially change after unblinding in the Partners PrEP study [25]. Although self-reported condom use and risk practices may be subject to social desirability bias, STI rates provide an objective measure from which to compare participant reports. Outside of clinical trials, there are limited data that explore the impact of PrEP on the sexual practices of users or that offer insight into how PrEP fits in with other strategies for staying HIV negative. To address these gaps in knowledge, we conducted a qualitative analysis of counseling notes from the San Francisco site of the US PrEP Demonstration (Demo) Project. As this study is currently in follow-up (results available in 2015), the purpose of our analysis was to provide an early assessment of how participants incorporated PrEP into their HIV prevention strategy and its potential impact on their sexual practices.

Methods

Parent Study

The Demo Project is a longitudinal, open-label demonstration project conducted in San Francisco, Miami, and Washington D.C. that is currently underway to evaluate PrEP uptake, acceptability, safety, and feasibility among HIV-negative MSM and transgender women. Eligible candidates were recruited from participating HIV/STI clinics or community centers, or were self-referred to the study sites. All participants exhibited evidence of risk for acquiring HIV, including condomless anal sex with two or more male or transgender female partners in the last 12 months. Baseline demographic and risk behavior data were collected from a structured interview conducted at screening. Participants were provided client-centered risk reduction counseling by a counselor or clinician at

enrollment and each subsequent visit, scheduled at 4, 12, 24, 36, and 48 weeks. All study staff conducting the counseling session received training in motivational interviewing techniques. Embedded into each counseling session was a discussion of participants' sexual activities, plans for staying HIV-negative, and medication adherence. Study staff conducting the counseling session used a worksheet with suggested prompts (Fig. 1) and took brief notes regarding the participant's responses. The notes included the counselor's interpretation of the most salient features of the participant's story, as well as issues the counselor wanted to address during follow-up visits. Study staff summarized the conversation, paraphrased responses, and sometimes directly transcribed portions of the participant's response. Transcriptions of verbatim responses were delineated with quotation marks. Participants with mental health, substance use, or social issues (e.g. food or housing insecurity) were referred to a clinic-based social worker or to community resources.

Participant informed consent was obtained as part of the parent study. Counselors were informed of the study's intent to analyze their notes after we had selected an initial sample of participants. Since the counseling notes were already written for these individuals prior to the consenting process, counselors were not primed to potentially embellish or engage more rigorously in either counseling or note writing. An additional set of counseling notes from a group of purposively sampled participants were analyzed after the counselors were consented but no significant differences in documentation were observed between these and the notes collected prior. The study was approved by the University of California, San Francisco Committee on Human Research.

Data Analysis

We analyzed counseling notes from sessions conducted with a sample of participants who had completed at least 24 weeks of follow-up in San Francisco, the largest enrolling site of the US PrEP Demo Project ($N = 300$). We started our review with an initial random selection of 15 participants. An additional 11 participants were then purposively sampled to ensure the individuals included in our review were reflective of the racial and ethnic make-up of the overall San Francisco cohort. Selecting participants who had completed at least 24 weeks of follow-up provided at least four counseling notes from each individual, which allowed us to fully capture participant experiences with PrEP. Since the focus of our study was to provide an early assessment of how PrEP is incorporated as a prevention strategy and what influence it may have on sexual practices, we did not emphasize longitudinal behavioral

PrEP Demo
Follow-Up Visit Counseling Notes

PID:
Counselor:
Visit Date:

Social Harms/Social Benefits (skip at week 4.0 visit):

Since your last visit, have you had any negative experiences that you think are related to taking PrEP or being in The Demo Project (for example, problems with personal relationships, stigma, or discrimination)?

Since your last visit, have you had any positive experiences that you think are related to taking PrEP or being in The Demo Project (for example, improved relationship with a friend or sex-partner)?

Behavior and Activity:

*What has been going on for you sexually?
In what ways has substance use impacted your risk activity?
How does taking PrEP impact your risk activity?*

Pill Taking Experience:

*How has it been taking the PrEP pills?
What has been helpful for you in taking the pills?
What challenges do you experience in taking the pill? (When are you more likely to forget?)
What might help you in taking your pills more regularly?
What keeps you motivated in taking the PrEP pills?
What, if anything, might help make taking PrEP even easier?*

Plan(s) for Staying HIV Negative:

*What I hear you saying is that you currently reduce your risk by.....(and you talked about your desire/plan to also.....).
Have I understood you correctly? (Include taking PrEP as part of the plan for staying negative). What other ideas/plans, if any, do you have for staying HIV negative?*

HIV Testing and Results:

*How are you feeling about getting you HIV test result in a few minutes?
What, if anything, would you like to discuss before I retrieve your results?*

Other Notes/Pending Items (follow-up for future visit):

Fig. 1 Example of counseling worksheet

trends. This information will be more accurately represented with quantitative data that are currently being analyzed.

De-identified copies of counseling notes were systematically coded and analyzed using the Framework Analysis technique [26]. This qualitative analytic strategy is best

sued to thematic analysis carried out by a multidisciplinary team and provided us with the ability to draw descriptive conclusions based on identified themes [26].

The process of data analysis began with open coding to classify all of the data and capture important nuances. Counseling notes were first analyzed within each participant longitudinally and then across participants. The topic headings specified in the counseling notes were used as a guide for the coding classification scheme. Three researchers (JCH, KAK, DL) independently coded the first several transcripts to arrive at a working analytical framework of codes to apply to all subsequent counseling notes. The handwritten counseling notes were manually transcribed verbatim and input into Dedoose (version 4.5), a web-based qualitative data analysis software. A member of the research team not involved in the transcription process validated the accuracy of the data transcription by comparing the handwritten notes to the electronic version. The research team met regularly throughout the coding and analysis process to ensure inter-rater reliability. Codes were compared for agreements between three members of the research team (JCH, KAK, DL); discrepancies were discussed and resolved by consensus. The team read aloud and summarized excerpts coded as Behavior and Activity, Plans for Staying Negative, PrEP Sex Impact, and Sex Practices, among others. We displayed the summarized data in a coded matrix using Microsoft Excel with entries listed by participant and study week. From the spreadsheet, categories were identified. Preliminary themes were then generated through an iterative process that involved repeated analysis of raw data, codes, and categories. The selection of the most salient themes was done through a consensus process with input from JCH, KAK, SEC, and AYL. Preliminary results were then presented to the study counselors for validation.

Results

We examined counseling notes from 130 distinct sessions associated with 26 participants who enrolled between October 2012 and May 2013. We examined between 4 and 6 counseling notes per participant. Participant demographics and baseline risk behaviors are described in Table 1. Participants ranged in age from 21 to 63 years, were all male, and predominantly white; a majority ($n = 19$) reported condomless receptive anal intercourse in the last 3 months at baseline. Counseling notes from two transgender women were excluded because they did not have at least 24 weeks of follow-up. Four themes emerged from our analysis: (1) prevention strategy decision-making is dynamic, (2) PrEP use is part of a larger prevention strategy, (3) sexual risk

Table 1 Sociodemographics and baseline risk behavior characteristics of selected San Francisco Demo Project participants ($n = 26$)

Characteristics	Median (min, max)
Age in years	37 (21, 63)
Number of sex partners in last 3 months ^a	10 (0, 45)
Characteristics	N (%)
Gender	
Male	26 (100)
Race/ethnicity	
White	16 (62)
Hispanic	7 (27)
African-American	2 (8)
Asian	1 (4)
Annual income	
\$0–\$10,999	4 (15)
\$11,000–\$19,999	5 (19)
\$20,000–\$39,999	6 (23)
\$40,000–\$59,999	3 (12)
\$60,000–\$99,999	5 (19)
\$100,000 or more	3 (12)
Education	
Never graduated high school	1 (4)
High school or GED	1 (4)
Some college	6 (23)
College graduate	9 (35)
Any post graduate	9 (35)
In primary relationship with HIV+ partner ^a	8 (31)
Condomless receptive anal intercourse in last 3 months ^a	19 (73)
Alcohol and substance use in last 3 months ^a	
Alcohol	
Once a month or less	5 (19)
≤1–2 times per a week	11 (42)
3 or 4 times a week	3 (12)
≥5 times a week	7 (27)
Poppers	17 (65)
Amphetamine	7 (27)
Cocaine	6 (23)
Crack	1 (4)

Percentages may not add up to 100 % due to rounding

^a Assessed at screening

behavior is ‘seasonal,’ and (4) PrEP alleviates anxiety regarding sex and HIV.

Prevention Strategy Decision-Making is Dynamic

Counselors noted that for most participants ($n = 14$), making decisions about which prevention strategies to

employ was dynamic, often dependent on the context of an encounter with a potential sex partner and the participant's assessment of that potential partner's risk. For encounters perceived as high risk, prevention efforts centered on condom use. A counselor described this sentiment in his notes from a discussion with one participant: "He will independently choose to use condoms if feels the guy gets fucked a lot." An entry from another participant noted,:

Tries to limit going to bathhouses. When he does go, he watches partner put on condom. Uses condom himself when he tops...If partner does not want to have sex using a condom, will let them go down on him, but otherwise no sex.

In partnerships perceived as less risky or with an established level of trust, condom use was less common and prevention efforts centered primarily on a combination of other methods. Serosorting (having sex only with partners who report being HIV-negative) and seropositioning (selecting "less risky" positions—e.g. oral sex or insertive anal sex—with HIV-positive partners) were often mentioned in counseling note entries. One counselor noted his discussion with a participant who preferred condomless anal sex with HIV-positive partners who were on HIV medications and virally suppressed because of a lower perceived risk:

Prefers to bareback with [HIV viral load] undetectable partners who are on top of their health care rather than supposedly HIV negative partners.

Other participants limited their sexual encounters to established partners:

Has been with regular sex partners recently. These are men whose HIV status is negative and he has a certain level of trust for...Has a few regular partners with whom he barebacks, but they trust each other.

PrEP Use is Part of a Larger Prevention Strategy

Men's existing risk reduction strategies, including condom use, negotiated safety (i.e. an agreement between partners regarding their sexual practices within and outside their relationship), seropositioning, and screening for high-risk behaviors (i.e. "party and play" or using methamphetamine and having sex), were not abandoned upon initiation of PrEP. Rather, PrEP complemented these strategies as an adjunct tool that provided additional means of protection. A counselor noted how one participant viewed it as an "extra layer of protection." One counselor's entry on his discussions with a participant on plans for staying HIV negative provides insight into the role of PrEP:

Participant is in an open relationship with primary sexual partner, with whom he has an agreement to use condoms with other sexual partners...Doesn't see PrEP as changing his sexual behavior, but sees it as an 'airbag' for potential exposures...Participant tries to use condoms with all partners, except primary sexual partner with whom he has an agreement to use safer sex practices. Participant sees regular testing through [Demo] Project as important for sexual health. Finally, participant sees PrEP as a small piece of a larger plan for HIV prevention...Currently uses condoms with partners.

This sentiment was echoed in multiple counseling notes across participants and across time points. Although counselors captured fluctuations in participants' risk-taking behaviors over the course of the Demo Project, the use of PrEP in conjunction with other risk reduction strategies remained constant for most participants ($n = 25$).

Participants appeared well informed in their knowledge of HIV transmission and developed well-defined plans for staying HIV-negative. For example, a typical scenario included asking about the HIV status of potential partners, and if negative, when they had last been tested for HIV; or if they were positive, whether they were engaged in care and if their viral load was undetectable. Another participant's plan for staying HIV negative was relayed to the counselor as follows:

Always discusses status prior to sex. If HIV-positive, asks if on meds, in care... Gets checked regularly... Participant limits most sexual partnerships to friends and acquaintances...Prefers oral sex and finds that partners progress from oral sex to anal sex partners gradually and this allows for more time to discuss status, testing, etc.

Counselors noted participants describing the role of PrEP as a "safety net" in situations when judgment may be impaired and usual risk reduction strategies are not followed. For some men, alcohol and illicit drug use triggered loss of inhibition. In discussing how substance use affects risk-taking behaviors with one participant, a counselor noted, "Substance use, going out drinking, impacts risk behavior and so he wants to be on PrEP to be a safeguard for those rare occasions." An entry on a different participant explained, "Participant uses [marijuana], ecstasy, on occasion which can make him less likely to have a conversation around HIV with potential partners. This is why he wants to be on PrEP..." Others reported going to bathhouses or online chat sites as precipitators of risky encounters. One participant expressed that he typically uses condoms with sex partners but at times "gets caught up in the heat of the moment."

Sexual Risk Behavior is “Seasonal”

Risk-taking behaviors were dynamic over the course of the Demo Project, fluctuating between periods of high and low HIV risk. Study counselors captured various personal and psychosocial factors that influenced these seasons of risk. Personal factors included the beginning, opening (i.e. open relationship), closing (i.e. mutually monogamous), and termination of relationships. A counselor described in his notes one participant’s complicated relationship with a former boyfriend:

Ex-boyfriend is back in life, questions leaving current boyfriend. Was in a bottom mood last week. Bare-backed with two partners, one came in him. When [ex-boyfriend] is checking [online site], participant gets upset and wants to react by [bottoming without a condom].

Based on a discussion with the same participant during his follow-up visit, another counselor remarked, “Participant reports increase in sexual behavior/risk for HIV since break-up with ex-boyfriend in the last 3 months.”

Psychosocial factors like substance use and mental health also influenced sexual patterns. A counseling entry from a conversation with one participant noted how he only engages in condomless receptive anal sex when using methamphetamine:

Met partner online, used crystal meth together, then led to [condomless anal sex]. Finds that when he uses, this causes him to switch up his normal behavior—like deciding to bottom without a condom instead of top.

The same participant reported in his 48-week visit that he had entered into a closed relationship and had stopped using methamphetamine. A counselor noted that the participant was “monogamous with HIV-negative boyfriend last 3 months. Plans on taking a break [from PrEP]...”

Another participant who, at his enrollment counseling session, anticipated engaging in more sex once he started using PrEP reported having less sex than he had expected at his 24-week visit. From their discussion, the counselor noted that the participant was feeling depressed and anxious, and had been “less sexually active due to emotional instability within the past 3 months.”

For others, health concerns, like a recent STI diagnosis, led to reconsiderations about their risk-taking behaviors. In a discussion with one participant regarding an STI diagnosis in his 24-week visit, the counselor noted,

[Participant] now has concerns about [condomless anal sex] even with people he knew well...plans to start using condoms more with regular sex partners.

PrEP Alleviates Anxiety Regarding Sex and HIV

Counseling notes from discussions with several participants ($n = 12$) reflected that PrEP relieved ingrained apprehensions surrounding sex and HIV. One participant described his fear of seroconverting and expressed that it was important for him to “feel like I’m taking care of myself.” PrEP provided confidence and “peace of mind” in men’s abilities to explore their sexuality without the fear of becoming HIV infected. A counseling note entry captured one participant’s sense of relief:

[Participant] reported a stronger sense of security in his efforts to stay HIV negative. Participant reported feeling less anxiety surrounding the possibility of becoming HIV positive.

Counseling entries also provided insight into the impact of PrEP on the relationship dynamics of participants in serodiscordant partnerships. Counselors captured how the sense of protection provided by PrEP helped overcome anxieties not just for participants but also for their partners. In a discussion with one participant on his and his HIV-positive partner’s apprehensions, a counselor noted,

[Participant] taking PrEP to ease HIV-positive partner’s anxiety ...and also his own. Decrease in anxiety about HIV, increased closeness and sex with HIV-positive primary partner.

In a number of participants ($n = 10$), comfort with PrEP and confidence in its efficacy has emboldened them to engage in more calculated risk or different sexual practices. A counseling note entry provides perspective into one participant’s experience:

Participant reported having more [condomless anal sex] and more comfortable doing so. Participant attributes his disinhibition to Truvada [TDF-FTC], and having confidence in its efficacy...Participant says that he fully understands the consequences of [condomless anal sex], however, he prefers to take those risks.

Despite this participant describing more episodes of condomless anal sex to the counselor, he reported continued use of other risk reduction strategies. The counselor noted how the participant continued to use condoms in half of his sexual encounters. Another participant with a history of sex addiction described an increase in condomless anal sex and methamphetamine relapse he attributed to using PrEP; this participant was referred to a community support group by the study counselor. Both participants were described by counselors as reporting general adherence PrEP, missing only one or two doses on occasion.

Relief from the paralyzing fear of HIV infection may have contributed to some participants' willingness to expand their experiences and explore sexual roles that they otherwise may not have considered. Counseling entries from a few ($n = 4$) participants noted changing sex roles (e.g. anal insertive to anal receptive, "bottoming" for the first time) over the course of the Demo Project. As an exemplar, one participant who reported being mostly the insertive partner at enrollment was noted by counselors to engage in more receptive anal sex in subsequent visits. When prompted by a counselor, the participant reported that this was partly due to his "heightened sense of safety."

On the other hand, a few ($n = 3$) participants noted that taking a daily pill for prevention was a reminder of the desire to stay HIV-negative and encouraged them to engage in safer sex practices. For example, one counseling note stated, "Participant thought that he would increase his risk, however taking Truvada has been a daily reminder for him to practice safer sex... to try to stay HIV negative." Another noted that he did not want to negate his efforts of taking PrEP every day by putting himself at risk by not using condoms.

Discussion

The goal of our study was to qualitatively analyze the counseling notes of a sample of participants in the San Francisco US PrEP Demo Project to identify major themes related to how participants used PrEP as a prevention strategy and what impact it had on their sex behaviors. Our analysis of a set of longitudinal counseling notes from 26 participants in the San Francisco cohort revealed four major themes.

First, we found that prevention strategy decision-making within a given encounter was largely based on an encounter's context (e.g. bathhouse, online chat site) and an assessment of a potential partner's risk (e.g. unknown versus established partner). This study confirms findings from previous literature that describe the complex strategies that individuals use to reduce risk, and that these strategies vary by partner and context [27–29]. These results provide an understanding of the baseline prevention framework into which PrEP was incorporated among MSM in the Demo Project.

Second, existing risk reduction strategies were not always discarded in the context of PrEP, but rather often shifted to accommodate the incorporation of another prevention tool. Counselors noted that participants utilized PrEP as a complement to existing risk reduction strategies that included condom use, serosorting, seropositioning, and negotiated safety among others. Demo Project participants entered the study with substantial sexual risk for HIV

acquisition, and most viewed PrEP as a risk contingency tool, providing an additional layer of protection against HIV. In particular, PrEP was frequently seen as a safeguard against lapses in judgment triggered by substance use or highly sexually charged contexts. The concept of PrEP as an "additional layer of protection" has also been described among US MSM electing to take PrEP in the iPrEx Open Label Extension [30]. A few participants noted changes in sexual practices (e.g. bottoming for the first time) or drug use (e.g. methamphetamine relapse) associated with PrEP use. Counselors also described decreased condom use in a few participants, although its continued use in perceived high-risk contexts (e.g. anonymous sex in a bathhouse) suggests a more strategic approach. Although emphasis on the use of one prevention strategy shifted for some participants over the course of the Demo Project, most participants consistently used a combination approach to HIV prevention. This is encouraging because an approach utilizing a combination of various prevention strategies is the most likely to make a significant impact on the spread of HIV [31].

Third, risk-taking behavior among participants fluctuated throughout the Demo Project. Following the counseling notes of participants who had completed at least the 24-week follow-up provided us the opportunity to examine temporal changes in behavior. Similar to findings from other studies that assessed reasons for engaging in condomless sex [32, 33], counselors noted that HIV-related sexual decision-making was influenced by various personal, psychosocial, and health-related factors. Personal relationships, substance use, psychological distress, and recent STI diagnoses were some of the elements precipitating changes in risk behavior. Participants went in and out of "seasons of risk" consistent with the sexual risk trajectories of MSM described by Pines and colleagues [34]. Additional research is needed to understand patterns of adherence during fluctuations in risk and to develop strategies and counseling messages for MSM on how to safely start and stop PrEP in the context of changing risk.

Lastly, we found that PrEP provided a sense of relief against ingrained fears surrounding sex and HIV. The negative effects of HIV on sexual pleasure, freedom, and intimacy have been previously explored [35]. In a study of sexual concerns among MSM by Rosser and colleagues [36], participants described how HIV made them fearful of the physical and emotional aspects of sex. Our analyses suggest that PrEP may play a role in alleviating these anxieties and enhancing intimacy, particularly for those in serodiscordant partnerships. For prevention efforts to be effective, they must take into account individual needs, goals, and relationship dynamics to arrive at a suitable balance between HIV risk and intimacy and pleasure [37].

Our findings provide support that PrEP may be a vehicle for achieving this equilibrium.

The frequency and patterns of changes in sexual and drug use behaviors will be evaluated quantitatively in the overall Demo Project cohort upon study completion to include all three sites (San Francisco, Miami and Washington DC). More research is also needed to determine how changes in sexual practices may impact overall risk of HIV/STI acquisition. Depending on these findings, additional risk reduction counseling and sexual behavior monitoring approaches may be useful to help minimize risk compensation with the provision of PrEP.

This study is among the first to explore the role of PrEP as a prevention strategy and the sexual practices of high-risk MSM on PrEP outside of placebo controlled studies. Following each participant's counseling note as they progressed through the Demo Project offered a longitudinal perspective that captured important contextual life events influencing individual behaviors. This formative work provides a framework for understanding sexual decision making among MSM and how these men integrate PrEP into existing prevention strategies. Combined with quantitative longitudinal data on sexual practices and drug use behaviors in the overall PrEP Demo cohort, our qualitative findings will help inform our understanding of why risk compensation happens—which is an essential first step towards developing a respectful, culturally tailored, client-centered PrEP counseling approach.

Our findings have several limitations. First, this was a qualitative study of secondary data collected from counseling notes in an open label PrEP demonstration project. The counseling notes provided a view into the experiences of participants but through the interpretation of the study counselors. Entries documented on the counseling notes were based on the counselor's assessment of which features of the participant's story were most relevant. This limits our ability to directly and fully capture participant experiences. The primary intent of the study counselors' interactions with participants was to provide counseling (informed by motivational interviewing techniques), not to conduct this qualitative study. Therefore, our ability to provide a more in-depth exploration of each participant's story is limited. Future and other ongoing PrEP demonstration studies may benefit from including a qualitative component in order to collect such data. And second, our data may be subject to social desirability bias as participants may have provided responses based on what they perceived would satisfy the study counselors. This may skew how participants responded to questions on sexual activities and HIV prevention strategies. However, this potential limitation might be mitigated by how counselors were trained to foster a non-judgmental counseling environment. Additionally, the repeated interactions between

participant and counselor established trust between both individuals, which allowed organic and candid conversations to emerge. Our analysis was limited to participants from the San Francisco site, and may not be generalizable to PrEP users in other contexts. Future steps will include triangulating our results with the quantitative sexual risk behavior data collected in the PrEP Demo Project. This will allow us to determine if our qualitative findings are congruent with that of the overall cohort across all three sites. Lastly, the role of counseling and regular HIV/STI testing in supporting health promoting behaviors in the PrEP Demo Project is unclear—whether a greater, the same, or lesser degree of risk compensation might have occurred if participants had not received regular counseling and/or regular testing is unknown.

Sexual behavior and prevention decision-making are complex phenomena that should be evaluated in the context of each individual's sexual health goals. Additionally, periods of heightened risk may be driven by personal and psychosocial factors. A holistic approach to prevention that addresses these root issues may be beneficial in reducing HIV risk behaviors. PrEP can serve as an additional layer of protection that is incorporated into existing prevention strategies. In addition to lowering risk among those at substantial risk for HIV acquisition, PrEP may also facilitate intimacy and sexual pleasure among individuals in serodiscordant partnerships and help reduce anxiety around sex and HIV.

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