

Risk Perception Among HIV Serodiscordant Couples in East Africa Taking Oral PrEP for HIV  
Prevention

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A thesis  
submitted in partial fulfillment of the  
requirements for the degree of

Master of Public Health

University of Washington  
2015

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Program authorized to offer degree:  
Public Health - Epidemiology

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**Abstract**

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Levels of adherence varied across trials for pre-exposure prophylaxis (PrEP) for HIV prevention. One hypothesis for this inconsistency is that low perceived risk of HIV infection drove low adherence in trials where PrEP produced no reduction in risk. Using a mixed methods approach, we explored the level of perceived risk of incident HIV infection in the Partners PrEP Study, in which adherence was generally high. The Partners PrEP Study followed 4747 serodiscordant couples in Kenya and Uganda. A brief cross-sectional survey assessed perceived risk of HIV via questionnaire at 12 months after enrollment. Logistic regression was used to analyze the relationship between perceived risk and demographic variables, sexual behavior, and other objective measures of risk. 3226 couples from the Partners PrEP Study were included in this analysis. Perceived risk was low across the entire study cohort, with only 15.4% of participants reporting high or moderate perceived risk. Participants objectively assessed to be at higher risk

for HIV were more likely to report high perceived risk (OR=1.60, 95%CI: 1.30-1.95,  $p<0.001$ ), but still remained below 20%. In addition, this study also analyzed transcripts from in-depth interviews and focus groups, which were conducted with 68 individuals from 34 mutually-disclosed serodiscordant partnerships at the Thika, Kenya Partners PrEP Study site.

Differences in the perceived risks and benefits of taking PrEP were identified according to participants' serostatus and gender. These differences can be grouped into three major categories: gendered and unequal control over medical decision making in the home; the management of male sexual drives and the interference of traditional prevention strategies with the fulfillment of those drives; and culture-bound definitions of 'women's work. In summary, participants in the Partners PrEP Study reported generally low perceived risk of HIV but had high levels of adherence to PrEP. Perceptions of risk are likely determined by a multi-faceted social and psychological calculus that is too complex for Likert-scale questionnaires to capture in any meaningful way. In interviews, patients articulated complex concerns and interests related to PrEP, which reflected traditional gender roles and gendered power dynamics within the relationship. Successful delivery of PrEP as an HIV prevention strategy for serodiscordant couples should respond to these socio-cultural realities.

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# **Perceived Risk for HIV Infection among Participants in the Partners PrEP Study**

## **Introduction**

The efficacy of pre-exposure prophylaxis (PrEP) for HIV prevention has been evaluated in several clinical trials (1–6). Findings across these trials have been inconsistent, with some studies finding significant HIV protection and others substantially less protection. Two trials, which studied the efficacy of PrEP strategies among heterosexual African women, demonstrated no protective effect (2,4). Analyses done after those two trials were concluded found poor adherence in the study populations (7,8). Across PrEP trials, variations in PrEP adherence between different study populations has been put forward as a likely explanation for the differences in trial outcomes (9,10).

One hypothesis explaining low PrEP adherence in some trials is that such populations had low levels of perceived risk (9), and, as a result, low adherence to PrEP. Investigations to explain the low adherence to PrEP in the two trials that did not show HIV protection have focused considerable attention on perceived risk among the study populations, and developing ways to increase reporting of higher perceived risk has been offered as a strategy to improve PrEP use.

In the Partners PrEP Study, a clinical trial of oral PrEP among heterosexual adults in stable, long-term relationships, adherence was high overall, and PrEP was demonstrated to be efficacious for HIV prevention (1). In the present study, we aimed to describe the perceived risk for acquiring HIV infection in HIV seronegative partners enrolled in the Partners PrEP Study.

## **Methods**

### *The Partners PrEP Study*

Between July 2008 and November 2010, the Partners PrEP Study recruited 4747 heterosexual, mutually-disclosed, HIV-serodiscordant sexual couples from Kenya and Uganda and randomized the HIV uninfected partners to PrEP or placebo, as previously described (1). All couples received HIV testing and counseling as well as individual and couple-based risk-reduction counseling. HIV uninfected men were referred for circumcision services, and HIV infected partners were counseled to begin treatment and referred to local clinics as soon as they met national guidelines for initiating antiretroviral therapy. Use of placebo in the Partners PrEP Study was discontinued prematurely in 2012 after an interim review of HIV incidence found an observed risk reduction of 67% in the tenofovir study arm and 75% in the tenofovir-emtricitabine study arm, each compared to placebo (1).

Seronegative participants were seen at monthly follow-up visits where they were tested for HIV and given 30 days' worth of the appropriate study drug. Plasma samples were taken at the first monthly visit and then on a quarterly basis, and, for a subset of subjects, plasma levels of the study drug were evaluated with methods described previously (11). For this analysis, participants who had plasma tenofovir levels of at least 40ng/mL, a level consistent with high adherence to the daily dosing regimen, at 12 months were considered adherent. For HIV infected partners, CD4 counts and viral load were obtained every six months (1).

For both partners, demographic characteristics, including socio-economic indicators and relationship characteristics, were recorded at enrollment. Sexual behaviors (frequency of unprotected sex with partner, condom use at last sexual encounter with partner, number of new sexual partners, frequency of unprotected sex without partner) were recorded according to self-report at each visit (1).

### *Measurement of perceived HIV risk.*

A cross-sectional analysis was conducted within the Partners PrEP Study cohort in order to measure perceived risk of HIV infection; the survey was implemented part-way through the trial, and thus some subjects, enrolled early into the trial, did not complete the assessment. Data were measured by self-report at the study visit 12 months after enrollment. For the present analysis, couples were included in this study if the seronegative partner and the seropositive partner completed a follow-up assessment at the 12-month visit, including the risk-evaluation questionnaire.

Participants were asked to describe their perceived risk of acquiring HIV from or transmitting HIV to their partner as ‘high,’ ‘moderate,’ ‘low,’ ‘none,’ or ‘I don’t know.’ For the purposes of this analysis, those participants who responded ‘high’ or ‘moderate’ were considered to have higher perceived risk. All other responses (‘low,’ ‘none,’ or ‘I don’t know’) were categorized as lower perceived risk. All participants who gave a response other than ‘I don’t know’ were asked to identify the reasons for their risk beliefs in a fixed response format.

### *Analysis*

Descriptive statistics were generated for perceived risk of infection as well as all relevant demographic and behavioral variables. Univariate logistic regression was used to calculate a crude odds ratio to describe associations between the severity of perceived risk versus demographic and behavioral variables, as well as versus an objective risk scoring measure of risk developed and validated in the study population (12). With the risk scoring tool, a risk score of 5 or higher was considered an indicator of high risk for HIV infection. Variables found to be statistically significant in univariate analysis were included in a multivariate analysis, with the exception of the calculated risk score. This variable was excluded from the multivariate analysis



as this value was calculated using other demographic variables included in the multivariate model. Statistical analysis was conducted with STATA® Data Analysis and Statistical Software version 13 software (College Station, TX).

## **Results**

Of the 4747 seronegative partners enrolled in the Partners PrEP Study, 571 did not complete their 12 month follow-up visit or did not complete the visit concurrently with their partner; 892 completed their 12 month follow-up visit before the risk perception questionnaire was initiated or were not offered the questionnaire; and 58 had seroconverted by 12 months. The remaining 3226 seronegative adults were included in the present analysis: 36.7% (n=1213) were female and the average age was 34.2 years at enrollment. 26.3% (n=850) of participants reported receiving more than 8 years of education, and 70.5% (n=2272) reported having no income. Participants' seropositive partners had an average CD4 count of 512.7 cells/ $\mu$ L, and 9.7% (n=312) had begun ART by 12 months after enrollment. Plasma tenofovir levels were obtained from 441 participants at the 12-month follow-up visit. Of these, 66.7% (n=294) had plasma tenofovir levels of 40ng/mL or higher (Table 1). These characteristics were representative of the Partners PrEP Study cohort as a whole (1).

Of the 3226 participants, 15.4% (n=496) perceived themselves to be at 'high' or 'moderate' risk of HIV infection. However, the majority of the participants reported being at 'low' risk (39.8%, n=1284) or 'no risk' (31.5%, n=1017). A minority (13.3%, n=429) of participants reported 'don't know' for their quantification of perceived risk. Women were slightly more likely than men to respond 'I don't know' when asked to report their perceived risk (17.2% vs. 11.0%, respectively;  $p < 0.001$ ). Otherwise, men and women had comparable degrees of perceived risk (Table 2 and Table 3).

Reported condom use dominated the reasons given by participants for their level of perceived risk. High condom use was identified as a reason for risk beliefs in more than 80% of those who reported being at ‘no risk’ or ‘low’ risk for infection, and low condom use was given as a reason for risk beliefs by 71.2% of participants who reported being at ‘high’ risk for infection. Those who reported themselves to be at ‘moderate’ risk of infection were split on these responses: 37.1% gave high condom use as a reason for their beliefs, and 46.0% gave low condom use as a reason. Additionally, approximately 15.5% of those who reported being at ‘no risk,’ ‘low’ risk, and ‘moderate’ risk, and 5.3% of those who reported ‘high’ risk reported that being on the study drug was a reason for their risk beliefs.

Finally, 22.3% (N=38) of those who responded that they were at ‘high’ risk of infection chose ‘other’ as one of their responses in lieu of the other choices made available by the fixed-response. Of these 38 participants, 25 reported some kind of condom failure or fear of condom failure. Other open-ended responses included the partner’s HIV-positive status, forced unprotected sex, having intercourse while the seropositive partner had an outbreak of genital ulcers, and stopping the study drug for breastfeeding purposes.

In univariate analysis, perceived high risk of HIV infection was correlated with objective measures of HIV risk. Higher risk was reported by 19.7% (n=204) of participants whose risk scoring metric (12) indicated higher risk for infection, compared to 13.3% (n=292) of those whose score indicated lower risk (OR=1.60, 95% CI: 1.30-1.95,  $p<0.001$ ). Reporting unprotected sex within the partnership in the past 30 days was strongly associated with an increased likelihood of reporting higher perceived risk of infection (OR=5.57, 95% CI: 4.49-6.91,  $p<0.001$ ). Participants whose seropositive partners had initiated ART in the previous 12 months were less likely to report perceived high risk for infection (OR=0.70, 95% CI: 0.48-0.99,

p=0.049) than those whose partners had not yet initiated ART. In a multivariate analysis, neither gender nor plasma tenofovir levels (cut off: 40ng/mL) were associated with higher perceived risk. Only unprotected sex within the partnership in the past 30 days remained statistically significant in a multivariate model (Table 4).

## **Discussion**

This is a cross-sectional analysis assessing perceived risk of HIV acquisition in the Partners PrEP Study cohort. This analysis showed that high perceived risk of HIV, as reported in the Partners PrEP Study, is predictive of neither calculated risk of HIV acquisition nor adherence to the daily PrEP regimen. If low perceived risk were sufficient to explain the poor adherence to PrEP observed in other trials, then perceived risk should be higher in the Partners PrEP Study population than in other trials where adherence was low. To the contrary, nearly than 85% of study participants in this survey reported that their perceived their risk of HIV infection was low. The strongest predictor of higher perceived risk was unprotected sex within the partnership in the last 30 days. Those participants with objective measures of higher risk were more likely to report perceived high risk of infection, but still a minority of those at objectively higher risk reported perceiving higher risk. In HIV prevention research, adherence to risk-reduction strategies is often thought of as primarily motivated by perceived risk (13–15). The findings of this study, which show low frequency of reporting of perceived risk in a population that had high adherence to PrEP, contradict this assumption.

These findings are important in light of two earlier studies of PrEP, FEM-PrEP (2) and VOICE (16), both of which recruited heterosexual women and demonstrated little protective effect for oral PrEP in reducing the risk of HIV acquisition. In both of those trials, researchers attributed these study results to low perceived risk among the study participants which, in turn,

led to poor adherence (7–9). Participants in VOICE, where overall adherence was <30%, remarked on the conflict presented by wanting to protect one’s immediate wellbeing and taking powerful drugs with potent side effects (17). In FEM-PrEP, where plasma testing revealed adherence of <25%, three-quarters of participants reported being at ‘low’ risk or ‘no risk’ for incident HIV infection (2).

Both FEM-PrEP and the Partners PrEP Study used a 4-point Likert scale to assess perceived risk of HIV acquisition (no chance, small chance, moderate chance, and high chance in FEM-PrEP, and no risk, low risk, moderate risk, and high risk in the Partners PrEP Study) (7,9), rendering these findings largely comparable. Furthermore, FEM-PrEP asked participants to report their perceived risk of HIV infection during the next four weeks, whereas the Partners PrEP Study asked participants to report their perceived risk in general. Therefore, the protocol followed in the Partners PrEP Study might have been expected to capture a greater frequency of perceived high risk than the FEM-PrEP study protocol. However, perceived risk in the Partners PrEP Study was lower than in FEM-PrEP; 84.6% of the participants in this study reported ‘low’ or ‘no risk’, respectively, compared to 74.8% in the FEM-PrEP study (2). However, adherence in the Partners PrEP Study was much higher than in FEM-PrEP. Over 80% of participants had tenofovir detected in a random sample of blood specimens and approximately 70% had plasma tenofovir levels of >40ng/mL, which is consistent with steady-state dosing (11). Though it has been suggested that low adherence to PrEP in the VOICE and FEM-PrEP trials was a direct result of low levels of perceived risk among study participants (9), higher adherence among the Partners PrEP Study population in conjunction with similarly low levels of perceived risk suggests that perceived risk, as these studies have tried to measure it, is not sufficient to motivate (or de-motivate) adherence to PrEP.

There are a few possible explanations for the incongruence of the relationship between perceived risk and adherence in the results from the Partners PrEP Study. One is that perceived risk for HIV infection may be calculated differently by single and married heterosexual adults or by adults of different ages. For example, qualitative research among a sample of Partners PrEP Study participants found that PrEP adherence may be attributable to partners' desire to maintain their relationship despite their discordance (10). The largely unmarried study population in the FEM-PrEP study may not have benefited from this supportive factor. Furthermore, this study identified significant positive associations with actual risk and unprotected sex with a seropositive partner in the previous 30 days, as well as a statistically significant negative association (although not in the fully adjusted model) with the seropositive partner initiating ART. In contrast, the FEM-PrEP study found significant positive associations with having more than one sexual partner and not knowing whether a sexual partner has other partners at all 3 of their study sites; the number of vaginal sexual partners and not knowing the partner's HIV status at 2 of their 3 study sites; and education levels, recent transactional sex, and recent unprotected vaginal or anal sex at 1 of their 3 study sites (9). Additionally, many couples in the Partners PrEP Study had been romantically involved for many years without transmitting HIV between them. This history could have led them to feel that their risk truly was low.

Another potential explanation is that the measures of perceived risk used by these studies are insufficient to fully capture the depth of one's risk perception. Contemporary social research provides many reasons for suspecting that the brief questionnaires used in these studies were unable to capture meaningful information about perceived risk. Social perceptions of health-related risk encompass possible outcomes which might be viewed deviant, amoral, or otherwise socially undesirable—a distinction that is fundamentally qualitative, not quantitative (18,19).

Therefore, when research protocols aim to quantify individual perceptions of risk through empirical methods (e.g. when study participants are asked to rate their perceived risk on a Likert scale), these complex social dimensions of risk perception are collapsed into a few blunt categories, and the meaning that each participant attributes to concepts such as ‘low’ and ‘moderate’ becomes difficult, if not impossible, to extrapolate.

The interpretation of empirical evidence is rarely, if ever, an exercise of pure reason. Rather, the very process of translating between evidence of risk and an accounting of personal risk is a moral one (20). The perceived plausibility and tolerability of certain risks is often more important than empirical evidence in determining whether some risk will be recognized as valid or true (21). The determination about what even constitutes a risk in the individual imagination is tied to greater social norms and can vary greatly depending on personal experience, public opinion, discourse about that risk, and countless other factors.

Furthermore, it has been well documented that patients in health care settings consider clinical determinations of ‘moderate’ risk to be ambiguous. For example, in a study of healthy individuals undergoing genetic screenings for cancer risks, those individuals who were determined to be at ‘moderate’ risk for developing cancer struggled to comprehend their status and often negotiated with their physicians to be classified into *higher* risk categories. The reason for this behavior was simply that the patients perceived the life trajectories of ‘high risk’ individuals to be more certain—i.e. they were most certainly going to develop cancer (22). The ambiguity of middle-of-the-road risk assessments makes it difficult, if not impossible, to analyze the responses of those who report being at ‘moderate’ risk of HIV infection in this study. Of these 326 participants, 37% reported high levels of condom use as their reason behind this choice and 46% reported that low levels of condom use was their motivation. There is clearly no

singular, meaningful way to interpret the responses of participants who claimed to be at ‘moderate’ risk because the category itself is ambiguous—the term ‘moderate’ bore categorically different meanings for different participants.

Finally, even posing a question about risk has the potential to change or shape the response that is given. For example, research participants are often inclined to provide what they have learned to be the ‘right’ or morally desirable answer when asked about risk or risky behaviors, especially when that research concerns morally charged issues such as HIV and related high-risk behaviors like sexual practices and drug use (23). Study participants may also be inclined to alter their response to avoid association with clinically defined ‘high risk groups’ (drug users, men who have sex with men, sex workers, etc.), as these groups are frequently perceived in the popular imagination as clearly defined ‘types’ of persons who deviate from the social norm and are subject to negative stereotype (24–26). Therefore, participants may be disinclined to report being at high risk not only for reasons of comfort but also for morally loaded reasons about what it means, in the social sense, to be ‘high risk.’ An individual’s response to questions about perceived risk may be useful in building rapport with care givers or in structured counseling efforts such as motivational interviewing (27). However, such questions cannot be used as a direct indicator of perceived risk in the context of PrEP delivery and are unlikely to be informative in determining whether initiating PrEP is appropriate for any given person.

# **Gendered Differences in the Perceived Risks and Benefits of Oral PrEP**

## **Introduction**

By 2012, approximately 1.2 million people in Kenya between 15 and 64 years of age were living with HIV, and an estimated 4.8% of cohabitating married couples were in serodiscordant partnerships, in which one partner is HIV seropositive and the other HIV seronegative, placing nearly 260,000 seronegative spouses at risk for new HIV infection (28). Recent studies have demonstrated that novel biomedical prevention interventions can result in substantial reductions in the risk of HIV transmission between serodiscordant heterosexual partners through early initiation of antiretroviral therapy (ART) for the seropositive partner (29) and pre-exposure prophylaxis (PrEP) for the seronegative partner (1,3).

Sociological research has demonstrated that culturally-constructed gender roles and gendered relationship dynamics can easily overwhelm the intended risk reduction of behavior changes promoted by various HIV prevention interventions (30–34). For example, both the seronegative partner’s belief in treatment efficacy (35) and socially-scripted norms of masculinity (36) have been known to affect adherence to ART within serodiscordant couples. Furthermore, perceived risk of acquiring or transmitting HIV is associated with changes in the frequency of both risky sexual practices (37) and precautionary behaviors (14). Serodiscordant couples in Kenya often display low levels of agreement in their perception of shared risk factors for HIV infection (38). Thus, there is ample reason to suspect that heteronormative gender roles in Kenya will influence the uptake, use, and adherence to novel HIV prevention methods such as PrEP and will do so differentially across genders.

The Partners PrEP Study, a randomized clinical trial of PrEP among 4747 heterosexual, serodiscordant couples in Kenya and Uganda, demonstrated high HIV protection from PrEP and



found high levels of adherence among seronegative participants, of both genders (1). The specific ways in which traditional gender roles helped or hindered patient adherence, as well as the strategies that were used to successfully integrate PrEP into the context of a heterosexual partnership, remain unclear. This study explores the socio-cultural factors that shape heterosexual, HIV serodiscordant partnership members' perceived risks, benefits, and barriers of using oral PrEP and other related HIV prevention strategies (such as condom use).

## **Methods**

This is a qualitative study that explores gendered differences in the perceived risks, benefits, and barriers to using daily, oral PrEP in heterosexual, HIV serodiscordant couples. Participants in this study were in long-term, HIV serodiscordant sexual relationships and were recruited from among the 496 couples enrolled at the Thika, Kenya, site for the Partners PrEP Study clinical trial (7,39). Couples were included into this qualitative sub-study if they were in a stable, sexually active, relationship; if both spouses were at least 18 years old; and if the seropositive partner had not yet initiated ART. For this qualitative sub-study, eligible couples were contacted by phone, and those willing and available to participate were invited to the site for either for focus group discussions (FGDs) or for individual interviews (IDIs). IDI participants were recruited as a couple; FGD participants were recruited individually.

A total of 8 FGDs were conducted: two with only HIV seropositive women, two with only seropositive men, two with only seronegative women, and two with only seronegative men. Twenty IDIs were conducted, during which each individual was interviewed alone, without their study partner present. IDIs and FGDs were led by a couples' HIV counselor and a trained interview assistant. The sessions were conducted in English, Kiswahili, or Kikuyu, according to the preference of participants. Each IDI and FGD followed a semi-structured interview guide.

All IDIs and FGDs were audio recorded. That audio recording was then transcribed and translated into English. All analysis was conducted using English-language translations.

Data were analyzed using MaxQDA version 11 software (Berlin, Germany). Transcripts were analyzed using a modified version of grounded analysis for generating social theory (40). All transcripts were first read and free-coded to identify broad themes and trends. General trends in the data were then discussed with members of the Partners PrEP Study research team. Based upon the research team's expertise in local culture in Thika, as well as the relative "thickness" of the identified trends in the data (41), gendered differences in the experience of HIV-serodiscordant couples was identified as a pattern that merited further exploration. All transcripts were then re-read and re-coded in order to isolate instances in the transcripts in which participants evoked gendered roles, power dynamics, and cultural scripts. The themes presented here were identified during this final stage of analysis.

## **Results**

A sample of 68 participants in the Partners PrEP Study participated in this research. Of these, 33 were HIV seropositive (18 women, 15 men). Participants had an average age of 35.2 years (range: 20-60) and an average CD4 count of 550.9 (range: 261-1164) at the most recent measurement in the study clinic prior to recruitment into the qualitative study. The remaining 35 participants were HIV seronegative (18 women, 15 men), and had an average age of 38.1 years (range: 22-63). The average number of children in households in which the woman was HIV seropositive was 2; in households in which the man was HIV seropositive, the average number of children was 3.

Three distinct themes related to gender roles and gendered differences in responsibility within serodiscordant relationships were identified in the FGD and IDI data. These themes were

(1) gendered power dynamics and control over decision-making in the household; (2) conflicts between risk reduction strategies and male sexual desire; (3) culture-bound definitions of women's work in the household.

*Theme 1: Gendered power dynamics and control over decision-making*

Men and women reported different amounts of personal autonomy and power to make medical decisions in their households. HIV seronegative women overwhelmingly reported that the decision over whether or not each partner would take medication, including ART or PrEP, belonged entirely to their husbands. *“For me, it is my husband who decides.”* One woman indicated that disagreeing with her husband's decisions could result in domestic violence. *“If he agrees to what the doctor tells him, it is ok, but if I tell him...and he doesn't want it, it will result in violence in the home.”*

HIV seropositive men (i.e., the partners of HIV seronegative women) also reported that they have the ultimate authority to make medical decisions for themselves and their spouses. *“Men [will decide], because if the man is taking drugs than my wife will also take them.”* Men often justified this pattern with claims that they were the natural head of the household. One HIV seropositive man reported deceiving his spouse about his HIV status so that she would agree to marry, thus placing him in charge of her. *“I lied to make her come to my home. Even using the drugs, I am the one who will teach her first before I agree to use them. If I accept, she will also accept, but if I refuse, she will also refuse.”*

In female-seropositive couples, women echoed the claims of their male counterparts that medical decisions are usually made by men; however, some indicated that women can find more subtle ways to exert agency over their own personal decisions. *“It is like family planning, when a woman plans to use [contraception] even if the husband refuses, she will still go ahead with the*

*plan. If the man is planning for the pills, she will go for the coil and if you feel it is not good you will go for the injection, because you have already decided.”*

HIV seronegative men largely characterized medical decision-making as a shared process in which each partner takes part. *“The two of you decide [who will take drugs] together.”* Others characterized medical decisions as a choice that individuals have a right to make for themselves *“There is no one who will decide for the other.”* One HIV seronegative man was openly critical of cultural scripts that give men authority over their spouses’ medical decisions. *“According to tradition, most of the time men are the ones who decide, but nowadays, because it is a disease, it is not a ‘must’ for the man to decide. The disease makes you decide that we will do this or that.”*

#### *Theme 2: Conflicts between risk reduction strategies and male sexual desire*

A second theme that emerged from the focus group and interview data was the conflict between risk-reduction strategies, such as using condoms during sexual intercourse, and cultural scripts governing male sexuality. HIV-seropositive women were especially vocal about the poor consequences of these competing interests. The most common complaint was the frequent refusal of HIV seronegative men to use condoms during intercourse. *“He is not using a condom...he refused.”* The management of condom use was also perceived to be essential to the health of the marriage. *“Many men don’t like using [condoms] so we feel if those [PrEP] drugs were available they would assist us because when you have sex with him he doesn’t feel satisfied...if those drugs work, he will not be using the condom and that will assist us through marriage.”*

Many HIV seropositive women also reported that their husbands engaged in risky sexual behavior including regular extra-marital sex. *“A man is a man. He can get out there and whoever he meets will not tell him how she is [if she is HIV-positive].”* One woman also reported forced,

unprotected sex with her husband. *“You have big children, and you spread a sack for the child to lay down there, and you are with your husband. You will not scream because your husband has not put on a condom. You will be forced to give him sex because you fear the embarrassment with the children being around.”*

HIV seronegative men reported dissatisfaction with condoms. *“I don’t want to wear the condom.”* Some also broached the subject of forming new sexual partnerships with women other than their wives. Some posed questions to the researchers about whether they would be able to continue receiving PrEP if they decided to continue the intervention with a different spouse. *“I would like to ask, if I am continuing with [PrEP] and my wife leaves, will it be ok for me to bring my new wife [to this clinic]?”*

In couples with HIV seropositive men, neither partner made reference to struggles with condom use or the need to negotiate male sexuality. One HIV seropositive man suggested that PrEP drugs helped his wife feel comfortable with sex. *“[My wife] can be assisted by [PrEP], because even when you have sex she will have a bit of confidence.”* Also, one HIV seronegative woman made a reference to potential infidelity on the part of her husband. *“You cannot depend on someone 100%. He can slip, or you never know, maybe you have a misunderstanding and he thinks she is doing this because she is negative.”* Overt conflicts between risk reduction strategies and male sexuality, however, were not explicitly referenced by any member of a couple in which the man was HIV infected.

### *Theme 3: Culture-bound Definitions of Women’s Work*

Many conversations with participants referenced gendered divisions of labor in the household. This included the assignment of responsibility for domestic work as well as for the work of seeking medical support and managing the health care of the entire family. HIV

seropositive women made references to the sacrifices that they, as women, make for their families. *“A bigger percentage [of those willing to take medication] will be women, because as you know a woman can sacrifice anything for her family.”* Their spouses, HIV seronegative men, often considered the management of clinic visits and drug regimens to be the responsibility of their wives. *“Normally it is the woman who comes to the clinic.”*

Many HIV seronegative men also expressed frustration with the PrEP regimen and indicated that the burden of taking medication has been thrust upon them by their wives' HIV status. *“You know, she is the one who is sick...If I am not with her, why should I use it? So, let me say that she is the one who is making me use it.”* Some stated that the seropositive woman should carry the pill burden alone. *“[She should take ART in place of me taking PrEP] because she is the one who has the disease.”*

HIV seropositive women were quite vocal on this subject, echoing the observation that their husbands perceive PrEP taking to be burdensome. *“[Men] say they get tired of taking [PrEP drugs]. You may find someone saying ‘Why do I take these drugs...when I am not sick?’”* Others indicated that the burden experienced by partners taking PrEP was not only physical or logistical but also financial. *“Your husband won't agree to buy you food and buy you [PrEP] drugs. You will have put a burden on him and he will chase you.”* Still more referenced the threat of abandonment by their partners, indicating that some HIV seronegative men would rather leave their wives than begin taking PrEP. *“They [men] will say ‘Why am I buying these drugs to take each day? Isn't it better for me to go look for a person who is not sick so that I can stop taking these drugs?’”*

In couples with HIV seropositive men, women spoke at length about the work they must do to care for their children. *“[Women] are the ones who have a bigger responsibility of taking*

*care of children.” They also described the work that they do to manage their spouses’ health care. “Men don’t like to take drugs. When a man leaves in the morning, you will ask him, have you taken your drugs? He even says ‘yes’ when he hasn’t taken them... You feel like you have a big burden in the house, you must check that he has taken them...the burden is on the woman.”*

Multiple women attributed their participation in the Partners PrEP Study to their concern that someone needed to care for their children. *“I just agreed to take [PrEP] because I couldn’t leave [my husband] and I have a child.”*

This pattern appeared almost exclusively in couples with a seropositive woman. Aside from a single participant who commented that his wife needs to be healthy so that she can continue caring for their children after he dies, no HIV seropositive men made reference to the gendered divisions of labor, women’s work in their home. Only one HIV seronegative woman referred to her husband’s refusal to take ART as a regular difficulty for her. None referred to PrEP as burdensome. HIV seropositive men did not refer to ART as a burden at all.

## **Discussion**

This is a qualitative study exploring the socio-cultural factors that shape heterosexual, HIV-serodiscordant couples’ experiences with PrEP for HIV prevention. Analysis of IDI and FGD transcripts revealed differences in the reported risks, benefits, and value of PrEP among study participants according to the gender of the participant as well as the gender of the seropositive spouse. Three major themes were identified among these differences: the gendered power relations and unequal control over medical decision making in the home; the management of male sexual drives and the degree to which prevention strategies interfere with the fulfillment of those drives; and the gendered and unequal division of practical labor, including healthcare-related labor, in the home.

The level of control that male partners claimed over medical and other logistical decisions for the entire household is consistent with findings from other studies, such as a vaginal microbicide trial in Zimbabwe in which male participants “gave permission” to their female partners to participate in clinical research (31). Findings from this interview data, published elsewhere (42), show a similar dynamic in decisions about childbearing; when the man wanted a child more than his wife, the men reported using demanding language such as “she must” and “I will force her.” Though these couples reported that the decision to conceive was mutual, the decision *process* clearly was not. Such intense divisions of power often result in domestic violence against women (43). Other studies have demonstrated that gendered, domestic violence is common in Kenya, and women with HIV are more likely to have experienced domestic abuse than their HIV seronegative peers (44,45). A similar correlation between HIV status and the severity of domestic abuse has also been observed in Uganda (46,47).

The need for women to negotiate men’s sexual desire when adopting HIV prevention strategies is also well documented. Some HIV seropositive women in the Partners PrEP Study reported being forced to have unprotected sex with their husbands by virtue of the fact that any negotiation would wake their children or their neighbors. Even women who gained access to novel, female-initiated prevention methods, such as microbicide gel, during other research trials reported the need to seek consent from their sexual partners in order to use them (32,33,48). These trends indicate men’s culturally-mandated desire to maintain control over sexual behaviors may directly conflict with the behavior change required for risk reduction (such as using condoms), even in instances where the male partner is the one who stands to benefit from that risk reduction strategy.



The threat of physical abuse or the withholding of financial support if unprotected sex is refused has been reported by women in Kenya (49) and in Uganda (50). For this reason, the risk of partner abandonment is generally high among mutually-disclosed couples (50,51) and appears to be higher among female-seropositive couples (52). Data presented here reveal that these tensions, especially those felt by women, can remain high even when the couple's serodiscordant status is being tolerated, even when PrEP adherence is high.

This study also indicates that gendered divisions of labor inform the experiences of women in serodiscordant partnerships. These divisions place the decision-making largely in the hands of the men, but assign the daily management of health-related errands and logistics to the women. Similar divisions of labor have been observed in Zimbabwe, where men adopt a breadwinner role, "taking care of" and "working for" the family. In return, women were expected to be well behaved, to show love and respect by taking care of routine domestic tasks (31). This means that initiating PrEP for the spouse of either gender in a serodiscordant marriage will likely constitute an increased labor burden on the female spouse, regardless of her HIV status.

The perception that oral PrEP is a burden for the male partner is a unique manifestation of the cultural norm that caring for the health of the household is the woman's responsibility. PrEP presents a viable and highly successful HIV-prevention strategy for HIV seronegative men, who, as indicated by their own testimony and their wives' testimony, have low levels of interest in regular condom use, and the Partners PrEP Study showed high adherence to PrEP among men (1). Nevertheless, pill taking is often characterized as burdensome by seronegative men, even when they are taking their pills as part of a daily routine. Complaining about the burden they have acquired through PrEP initiation may allow men to enact power over their spouse or to

counteract the loss of control they may experience due to their spouse's HIV status. The gendered double standard behind these complaints is particularly evident given that concern about the trouble that taking PrEP posed was voiced almost exclusively by members of couples in which the man was seronegative.

The limitations of this qualitative analysis should be considered when interpreting these results. First, participants were recruited only in Thika, Kenya, and the immediately surrounding farming community. These data, therefore, may not be generalizable to other regions. Second, this study drew from a population of couples who were committed to an HIV prevention study and maintaining their relationship despite HIV infection and thus is representative only of couples with these characteristics. For example, there may be reason to suspect that the men in these couples are somehow more tolerant of their wives' HIV serostatus or of the oral PrEP regimen than average. Future research should explore why serodiscordant couples that are staying together manage to stay together. It should investigate what features of their beliefs, living circumstances, or relationships facilitate a healthy and stable relationship, so that those features can be supported among all serodiscordant couples taking PrEP.

## Conclusion

It has been theorized that low levels of perceived risk of HIV infection negatively affects adherence to oral PrEP among heterosexual adults (9). In contrast to this theory, participants in the Partners PrEP Study generally reported low levels of perceived HIV risk while maintaining high adherence to PrEP. This analysis demonstrates that perceived risk (as it is typically measured) is not an informative predictor of adherence. In particular, this study suggests that perceptions of risk are the result of social and psychological processes that are too complex for simple measurement tools (such as single item Likert-scale questions) to capture.

Despite low levels of perceived risk reported via questionnaire, participants in the Partners PrEP Study articulated various social and interpersonal risks related to PrEP in focus groups and interviews. These interpersonal stresses exacerbated (and were exacerbated by) traditional gender roles and marital obligations including, but not limited to, fidelity, sexual relations, childbearing, and household management. This confluence of social pressures is perceived to be more burdensome for women than for men, regardless of the gender of the seronegative spouse.

In sum, the high adherence observed among participants in the Partners PrEP Study shows that neither the stresses reported in interviews nor the low levels of perceived risk recorded in questionnaires were sufficient to deter participants from taking PrEP. For this reason alone, such measurement tools are especially inappropriate for determining someone's eligibility for oral PrEP in a clinical setting. However, the decision of a seronegative partner to initiate PrEP and the lived experience of taking PrEP are nevertheless mediated by myriad social factors that can be identified and reasonably accommodated. Successful delivery of PrEP as an HIV prevention strategy for serodiscordant couples should respond to these socio-cultural realities.

**Table 1: Participant Demographics**

	N	%
<b>Gender</b>		
Female	1213	37.6
<b>Age</b>		
18-25 yrs	343	10.6
25-34 yrs	1650	51.2
35+ yrs	1233	38.2
<b>Income</b>		
Has income	2666	82.6
<b>Education</b>		
>8 yrs	990	30.7
<b>Married or Cohabiting with Partner</b>		
yes	3192	99.0
<b>Number of Children at enrollment</b>		
none	241	7.5
1 or 2	1005	31.2
3 or more	1980	61.4
<b>Unprotected sex in partnership in last 30 days prior to 12-month study visit</b>		
yes	505	15.7
<b>Circumcised (male seronegative partners only)</b>		
fully circumcised	1136	56.6
<b>Plasma viral load of HIV-infected partner at 12 months</b>		
50,000 copies/mL or higher	1160	36.0
10,000-49,999 copies/mL	814	25.2
<10,000 copies/mL	1252	38.8
<b>CD4 Count of HIV infected partner at 12m (n=3197)</b>		
500+ cells/ $\mu$ L	1364	42.7
200-499 cells/ $\mu$ L	1725	54.0
<200 cells/ $\mu$ L	108	3.4
<b>HIV infected partner initiated ART by the 12-month study visit</b>		
yes	312	9.7
<b>Plasma TDF at least 40ng/mL at 12-month study visit (n=441)</b>		
yes	294	66.7

**Table 2: Risk Distributions (Seronegative Partner)**

Perceived risk of HIV transmission	WOMEN (n=1213)		MEN (n=2013)		TOTAL (n=3226)	
	N	%	N	%	N	%
<b>High</b>	80	6.6	90	4.5	170	5.3
<b>Moderate</b>	109	9.0	217	10.8	326	10.1
<b>Low</b>	462	38.1	822	40.8	1284	39.8
<b>No risk</b>	354	29.2	663	32.9	1017	31.5
<b>Don't know</b>	208	17.2	221	11.0	429	13.3

**Table 3: Perceived Risk and Risk Score among Seronegative Partners**

Seronegative Partner	Risk Score		
	Risk Score 5+	Risk Score <5	
Perceived high risk	<b>204</b> [19.7%]	<b>292</b> [13.3%]	496
No perceived high risk	<b>831</b> [80.3%]	<b>1899</b> [86.7%]	2730
	1035 [100%]	2191 [100%]	<b>3226</b>

**Table 4: Factors Related to Self-Reported High Risk of HIV Infection**

Variable	Univariate Analysis		Multivariate Analysis	
	OR (95%CI)	p-value	OR (95%CI)	p-value
<b>Risk Score of 5 or above (unadjusted OR)</b>	<b>1.60 (1.30-1.95)</b>	<b>&lt;0.001</b>		
<b>&lt;25 years old</b>	Ref			
<b>25-34 years</b>	1.15 (0.84-1.59)	0.384		
<b>35 yrs or older</b>	0.85 (0.60-1.19)	0.334		
<b>Female</b>	0.97 (0.80-1.19)	0.801		
<b>8yrs or more of education</b>	1.16 (0.95-1.43)	0.145		
<b>Having any Income</b>	0.87 (0.68-1.11)	0.252		
<b>No children</b>	Ref	--		
<b>1 or 2 children</b>	0.91 (0.62-1.33)	0.625		
<b>3 or more children</b>	0.95 (0.66-1.37)	0.784		
<b>Married or cohabitating</b>	1.37 (0.48-3.90)	0.559		
<b>Unprotected sex w partner in last 30d</b>	<b>5.57 (4.49-6.91)</b>	<b>&lt;0.001</b>	<b>5.54 (4.46-6.87)</b>	<b>&lt;0.001</b>
<b>Unprotected sex w/o partner</b>	1.01 (0.71-1.43)	0.964		
<b>&lt;10,000 copies</b>	Ref	--		
<b>10,000-49,999 copies</b>	1.05 (0.83-1.33)	0.676		
<b>50,000 copies or higher</b>	0.88 (0.66-1.17)	0.377		
<b>Together 2 years or more</b>	1.06 (0.80-1.40)	0.693		
<b>Victim of domestic abuse</b>	2.22 (0.69-7.09)	0.208		
<b>Perpetrator of domestic abuse</b>	1.25 (0.47-3.32)	0.652		
<b>Sex partners outside the partnership</b>	1.08 (0.81-1.44)	0.607		
<b>Index has sex partners outside partnership</b>	1.02 (0.71-1.46)	0.911		
<b>Index had unprotected sex w/ others</b>	1.24 (0.73-2.12)	0.441		
<b>Index on ART (at 12mo)</b>	<b>0.70 (0.48-0.99)</b>	<b>0.049</b>	0.76 (0.52-1.10)	0.148
<b>Index CD4 count 500+</b>	Ref	--		
<b>Index CD4 count 200-499</b>	1.02 (0.84-1.24)	0.861		
<b>Index CD4 count &lt;200</b>	1.11 (0.66-1.88)	0.694		
<b>Plasma TDF level &gt;40ng/mL</b>	0.98 (0.58-1.64)	0.929		

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