

What's Love Got to Do With It? Explaining Adherence to Oral Antiretroviral Pre-Exposure Prophylaxis for HIV-Serodiscordant Couples

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Objective: Adherence may be the “Achilles heel” of pre-exposure prophylaxis (PrEP), a promising biomedical approach to HIV prevention. This article presents an explanation of PrEP adherence for African serodiscordant couples derived from qualitative data.

Design: Explaining quantitative findings is one way qualitative investigation contributes to research in medicine and public health. This qualitative interview study was nested in the Partners PrEP Study, a phase III randomized trial evaluating oral tenofovir and emtricitabine/tenofovir PrEP to prevent HIV acquisition by HIV-uninfected partners in serodiscordant heterosexual couples.

Methods: In-depth qualitative interviews were provided by 60 Partners PrEP Study participants in Uganda. Interviews used open-ended questions eliciting information on adherence experiences, barriers, and facilitators. An inductive approach informed by grounded theory methodology was used to analyze study data.

Results: The proposed explanation may be summarized as follows. Serodiscordance destabilizes couples, as the HIV-negative partner reacts with anger, fear, and sadness to the implication of infidelity represented by HIV infection. A “discordance dilemma” ensues, as the desire to avoid acquiring HIV and the advantages of preserving the relationship become competing priorities. PrEP is

seen as a solution—a means of safeguarding health without ending the relationship. PrEP users benefit from the support of partners, who reinforce adherence. Where discord in the relationship persists, adherence suffers.

Conclusions: PrEP adherence in serodiscordant couples may be understood as a function of the desire to reduce risk although preserving a partnered relationship. PrEP use in stable couples may be associated with improved adherence and thus, greater effectiveness.

Key Words: adherence, HIV prevention, HIV-serodiscordant couples, HIV acquisition, pre-exposure prophylaxis, PrEP

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INTRODUCTION

Biomedical approaches to HIV prevention offer new possibilities for slowing the AIDS epidemic. One promising strategy is pre-exposure prophylaxis (PrEP). “PrEP” refers to taking antiretroviral medications before HIV exposure, using oral pill or topical vaginal gel formulations, by uninfected persons as a means of preventing HIV acquisition.

Efficacy of PrEP in differing formulations and populations has been investigated across multiple clinical trials.^{1–9} Results have varied widely, with reported rates of reduction in HIV transmission ranging from 0% to 73%.⁹ Two trials have been discontinued—in full or in part—for futility.^{5,6,8} The highest efficacy rates to date have been seen in the Partners PrEP Study. Partners PrEP is an investigation of PrEP efficacy in heterosexual African serodiscordant couples and parent to this research. Reported efficacy rates are 62% (for daily oral tenofovir) and 73% (for daily oral emtricitabine/tenofovir).⁹

Accurate evaluation of PrEP efficacy requires precise adherence measurement. The Partners PrEP Study included monthly assessment of medication adherence using clinic-based pill counts. Electronic medication monitoring (via MEMS caps) and home-based unannounced pill counts were conducted in a substudy of 1152 participants from 3 sites. A preliminary report based on objective adherence measures indicated excellent adherence in the substudy. The Haberer et al¹⁰ report of median unannounced pill count adherence at 99.1% (interquartile range: 97.2–100) and median electronic monitoring adherence at 101.9% (interquartile range: 97.4–104.7) is

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consistent with the clinic-based pill count adherence of 97% recently reported for the full trial [greater than 100% MEMS adherence typically results from extra openings without dosing (ie “curiosity events”), although extra dosing and/or pill sharing could contribute as well].⁹ These adherence data, combined with high PrEP efficacy, suggest most Partners PrEP Study participants achieved high adherence to study drug.

We conducted a qualitative interview study using a subset of Partners PrEP Study HIV-uninfected participants randomized to PrEP or placebo and their HIV-positive partners to identify influences on adherence. Our goal was to understand PrEP adherence in stable HIV-serodiscordant couples.

METHODS

Partners PrEP Study Overview

The Partners PrEP Study is a phase III, double-blind, 3-arm, randomized, placebo-controlled trial evaluating safety and effectiveness of once-daily oral tenofovir disoproxil fumarate and coformulated emtricitabine/tenofovir disoproxil fumarate PrEP for preventing HIV acquisition by uninfected partners in 4758 stable HIV-serodiscordant heterosexual couples in Kenya and Uganda (ClinicalTrials.gov NCT00557245). HIV-negative partners were randomized 1:1:1 to receive a once-daily oral dose of tenofovir PrEP, emtricitabine/tenofovir disoproxil fumarate PrEP, or matching placebo. Eligible HIV-positive partners received antiretroviral therapy (ART). Couples also received free condoms and monthly risk reduction counseling.

Qualitative Study Site

Qualitative interview study participants were recruited from the Kabwohe Clinical Research Centre (KCRC), a Partners PrEP Study site in rural southwestern Uganda. KCRC followed 531 Partners PrEP Study couples.

Sampling

Partners PrEP Study participants were HIV-serodiscordant couples in stable relationships. At KCRC, stable relationships were partnerships in which couples (1) were married and/or cohabiting with no plans to separate; (2) were sexually active; and (3) had children or intended to have children together.

The qualitative study used a purposeful sampling strategy. Purposeful sampling is a qualitative strategy aimed at systematic representation of a variety of relevant perspectives on a topic of inquiry.¹¹ Here, the purposeful sample included study product users, termed “PrEP participants,” and their HIV-positive partners. PrEP participants were sampled across a range of adherence rates obtained through unannounced pill counts. Low (<80%) adherers were oversampled. HIV-positive partners were a convenience sample.

Recruitment

Potential qualitative study participants were approached by research assistants during routine follow-up visits. The research assistants described the research and extended an

invitation to participate. Those who agreed were scheduled for an interview appointment.

The study was approved by the Partners Health Care Human Research Committee, Boston, MA; the Human Subjects Division of the University of Washington, Seattle, WA; and the Uganda National Council on Science and Technology, Kampala, Uganda. Written informed consent was obtained from all participants.

Data Collection

Data were collected through in-depth in-person interviews. Interviews consisted of open-ended questions designed to elicit detailed information on adherence influences. Questions addressed the following topics: (1) experiences of taking study pills; (2) descriptions of specific missed doses; (3) descriptions of specific longer adherence lapses; (4) impact of serodiscordance on the coupled relationship. Interviews were conducted by trained Ugandan interviewers in private locations (where conversations could not be overheard) in a local language (Runyankole or Rukiga). They were audio-recorded with permission and averaged about an hour in length. Data reported here were collected and analyzed before Partners PrEP Study efficacy results were revealed.

Data Preparation

After each interview, interviewers produced a complete transcript in English from local language audio recordings. Each transcript was reviewed for quality. Additions and corrections to transcripts were made as indicated by the quality review.

Data Analysis

Data analysis aimed at developing an explanation of PrEP adherence for serodiscordant couples taking part in the Partners PrEP Study. An inductive approach informed by grounded theory methodology^{12,13} was used in which explanation was derived from systematic review, reduction, and interpretation of data. First, individual interview transcripts were reviewed for content on adherence influences. Data were then reduced through a 2-step analytic process. In step 1, written case narratives were produced from each transcript. The narratives assembled the transcript material into a coherent “adherence narrative” for each interviewee. Interview quotes illustrating the narratives were included.

General categories representing “types of adherence influence” were extracted from the narratives in data reduction step 2. The categories were used to construct matrices of adherence influences. Data corresponding to each type of influence were entered into the matrices. The completed matrices revealed recurring patterns or “themes” in the data. Themes were assembled into an explanatory logic to account for PrEP adherence. The explanation was developed by the first author and independently confirmed by the second author.

RESULTS

Participant Characteristics

Forty-five PrEP participants and 15 partners (n = 60) were interviewed. Almost 60% (58%) were men. Mean and

median age for the sample was 35 years (range: 22–51). Mean length of Partners PrEP Study participation was 15 months (median: 13.5 months). All interviewees described themselves as married and living with their partners at enrollment [Ugandan couples who live together for a period of time may refer to themselves as married. These marriages may or may not reflect unions formalized by religious or traditional ceremonies and/or explicit agreements between families (signified by payment of “bride price”). To avoid misrepresentation, we have omitted references to “marriage” from the text, in favor of more general terms such as “partner,” “partnered relationship,” and “couple.”]. Mean duration of the partnered relationship was 9.8 years. Eighty percent had children with their partners.

Explanation of PrEP Adherence

Results are organized to present the explanation of PrEP adherence inductively derived from the qualitative data. Citations from the interview transcripts are included to illustrate and verify key points.

The “Discordance Dilemma”

Discovery that one partner was HIV-positive although the other was not created a crisis for serodiscordant couples in this study sample. HIV-negative partners felt hurt, angry, and betrayed by the evidence of infidelity infection represents and threatened by the prospect of their partner’s imminent illness and premature death. Infected partners, for their part, feared “dying alone.” Tensions developed, sometimes escalating into violence. Some relationships came close to fracturing under the strain.

For these interviewees, discovery of serodiscordance meant preserving health and staying together suddenly seemed incompatible. Avoiding HIV infection was paramount, but seemed impossible for HIV-negative partners, especially women. Long-term condom use was an unrealistic alternative, as condoms were considered expensive, inconvenient, uncomfortable, and inconsistent with the desire to have children. This is the “discordance dilemma,” characterized this way by 1 participant as follows:

“I feel stuck. I love my wife. I want to have sex. I don’t like condoms. I don’t want to get infected, either... It’s not easy. It’s difficult. It’s a dilemma.”

The Meaning of PrEP: Hope and Opportunity

Couples struggling with the discordance dilemma saw PrEP as a “way out”. They understood the drugs were part of research and that the research was designed to determine whether PrEP “works”. However, even the hope of efficacy, when consistent condom use was unlikely, sufficed to prevent separation as a means of avoiding HIV.

“If it wasn’t for this research, I wouldn’t be with my wife after discovering she is HIV-positive. All my hopes are in this research, because I don’t have any other protection. I can’t say I will keep using condoms all the time... When this research ends, I will know whether the drugs work or not.”

I will then see whether to go ahead and build a family with my wife.”

“I wanted to stay married to my partner because we fell in love. What happened, happened. I found myself negative when she is positive. I still want to be with my wife. So when the doctor told us about this study, I saw it as an opportunity. You never know, it might work!”

PrEP, like ART for treatment, represents access to a valuable resource for rural Ugandans living with HIV/AIDS. Introduction of a valuable resource into a situation of resource scarcity is viewed as opportunity. People respond with determination to capitalize on the opportunity as a way of improving their lives. Thus interviewees willingly traveled long distances, under difficult conditions, every month, to keep follow-up appointments and replenish pill supplies. When necessary, they supplemented the study travel stipend with their own funds rather than renege on the opportunity offered by PrEP.

Determination to capitalize on a valuable resource contributed to adherence. Most interviewees understood PrEP dosing requirements and developed strategies for taking doses correctly. They arranged for reliable reminders—radio programs aired at dosing time, cell phone alarms—and selected dosing times compatible with work schedules. The considerable effort devoted to devising adherence support strategies reflects interviewees’ high levels of commitment.

“I feel so motivated to come [to clinic] every month. I have a feeling [these pills] will help me in the future. Can they give you drugs for swallowing and you hesitate? No way!”

Over time, commitments to keeping clinic appointments and taking study pills as prescribed were reinforced by a subjective sense of benefit. Some interviewees reported feeling healthier since enrolling in the research, attributing it to the pills they were now regularly taking.

“For the time I have been taking them, I have not fallen sick with malaria. I used to fall sick, but nowadays I no longer fall sick. So if I stop taking them, even for two days, won’t these frequent fevers attack me again?”

In addition to individually devised adherence strategies, PrEP participants benefitted from others’ support—both for adherence and for persisting in the research. Support came principally from 2 sources.

Family members supported adherence, typically by providing daily reminders of dosing times. Children sometimes performed this function; more often it was HIV-positive partners. Although some partners seemed uninvolved, others appeared concerned and attentive to the task of ensuring continued good health through correct use of study pills.

“[My husband reminds me] to take my drugs the moment the time is up. Even before the radio mentions the time, he quickly reminds me that I need to

swallow my drugs. If he knows I am travelling somewhere, he tells me to carry my drugs. He doesn't want me to leave my drugs behind."

Partners could go to considerable lengths to support adherence. Some directly observed daily study drug doses or carried out their own pill counts. If partners were also taking medication (ART or cotrimoxazole as prophylaxis against opportunistic infections), they might match their own dosing schedules to their spouse's, as a way of promoting adherence (for both). Men reported "helping with housework" as a form of adherence support. HIV-positive partners' commitments to succeeding at prevention through PrEP is reflected in their efforts to prevent missed doses at the expense of their own comfort and convenience. The following illustrates:

"One time she [PrEP participant] lost her maternal uncle. She left home [to travel to the funeral] without the drugs, but I was lucky to discover she hadn't boarded a car yet. So I hired a [motorcycle taxi] and rushed them to her on the road before she could leave."

The second source of support cited by interviewees was Partners PrEP Study counselors. Interviewees turned to counselors with questions about adherence. They consulted them about concerns related to study procedures, the temptation to drop out, and relationship problems. Not infrequently, the interviews suggested interventions by study counselors had been instrumental in averting separation.

"I wanted to chase away my first wife, actually divorce her. But when I sat with the counselors, they advised me and gave me some options, and my heart settled... The counselors care about us so much."

"We tested and were told that my husband is positive while I am negative. I wanted to leave the relationship and ...go back to my home. That is when we were taken to Kabwohe. There, we found other health workers who gave us advice about how we should live together. They taught us all that and I became strong."

Relationship Discord and Adherence

Although some couples managed to repair the damage created by the discovery of serodiscordance, others lived with continuing discord. Tension and quarreling persisted—over suspected infidelities, condom use, and other threats to the relationship. Sex became less frequent; some individuals began a second relationship. At some point, one or the other partner might "give up" and make a decision to separate.

Interventions by family elders or study counselors succeeded in helping some couples avoid separation. But serodiscordance distanced many partners, who might remain together but lead largely independent lives.

The new distance weakened solidarity. Some individuals taking study drugs complained of lack of cooperation

from partners in their efforts to avoid acquiring HIV. Complaints ranged from perceived indifference to active opposition. One woman cited her husband's unwillingness to invest resources in her health and well-being—even refusing her, as she put it, "a cup of milk for me to remain strong." For others, the sense of betrayal occasioned by learning of HIV serodiscordance evolved into distrust, and then suspicion, of partners' "sinister motives," that is, intent to deliberately transmit the infection to avoid "dying alone."

"Whenever he [gets home late], I get so angry suspecting he was with other women. Because he knows I am negative, I start suspecting that maybe he has a sinister motive of wanting to infect me."

[At a certain point] "I saw that he has a sinister motive. It's because he is infected and I am not. He thinks he is going to die and leave me behind. Because he's always saying, 'This world is nothing. We are going to leave everything behind. Even if you feel proud [not to be HIV-positive], you are also going to die.'"

"One time she said to me, 'I will not die alone. I won't die and you survive.'"

For some, experiencing the partner as unco-operative contributed to adherence lapses. Given the effort required to keep follow-up appointments and the burden of daily pill taking, without cooperation from partners, some individuals taking study drugs lost sight of the "point", temporarily "giving up".

"I began to suspect he is seeing other women... is he sleeping with other women so he can acquire more infection and pass it on to me? [This makes me] so angry that I feel it's useless to keep taking this medicine. Because of that, I decided to leave it."

Adherence lapses typically ended when Partners PrEP Study staff reached out, renewing connections to the research and to counselors, who encouraged resumption of participation.

DISCUSSION

This qualitative analysis suggests relationship dynamics have a major impact on adherence in a double-blind placebo-controlled efficacy trial of PrEP among HIV-serodiscordant couples in Uganda. Near-perfect adherence is motivated by a desire to avoid HIV infection while preserving the partnered relationship and reducing reliance on condoms. Support from HIV-positive partners and family members reinforces adherence efforts of individuals, facilitating adherence success. Discord in the relationship detracts from that success.

Understanding why serodiscordant couples wish to stay together, despite damage done to the relationship by the introduction of HIV, is important in explaining how the

desire to preserve partnerships motivates PrEP adherence. Cultural factors shed some light on this. For example, marriage is highly culturally valued, socially expected, and considered a permanently binding commitment. Divorce is discouraged by local Christian churches. Once married, a move to separate by either partner will likely meet with objections from family and friends who may intercede to try to keep the couple together.

Children also reinforce partnered relationships. A desire for children brings men and women together and shared children strengthen determination to overcome or endure interpersonal difficulties. Children are an investment in the future and an important source of social standing in the community, without which individuals remain marginalized.

Economic circumstances also play a role in keeping couples together. Where people are very poor, as in this setting, 2 individuals working together to generate income have a higher standard of living than 1 person alone. Partnering improves life prospects in settings of resource scarcity. Separation is economically disadvantageous, especially for women. Because women cannot own property, separation leaves them with no viable option but to return to their parents, who must then refund the dowry received from the partner's family.

Gender is a critical analytic dimension for future research on PrEP. The question of how gender may impact efficacy has yet to be definitively answered. Clinical trial data evaluating PrEP for HIV prevention in women have yielded mixed results,^{3,8,9,14,15} for which behavioral and pharmacological explanations have been offered.^{16,17} We might expect differences in adherence to oral PrEP for men and women, given persisting gender inequalities in parts of Africa. However, to date, neither quantitative nor qualitative analyses of Partners PrEP Study adherence data have revealed gender variation.¹⁰

Interviewees taking study pills clearly preferred PrEP to condoms as protection against HIV transmission. They hoped that by proving efficacious PrEP would ultimately eliminate the need to rely on condoms for prevention. Condoms were unpopular for various reasons, including inconvenience, reduced sexual pleasure, discomfort, perceived cost, and inconsistency with fertility desire. Despite obstacles, most interviewees reported consistent condom use. Strong encouragement from study counselors and distribution of free condoms during clinic visits contributed to this, as did a sense of vulnerability to HIV infection.

The qualitative data suggest the desire to avoid infection although preserving a partnered relationship, reinforced by culture and economic circumstances, plays a central role in explaining near-perfect adherence observed in the Partners PrEP Study. Even before evidence of efficacy was reported, the "hope" of protection against HIV transmission without reliance on condoms motivated Partners PrEP Study product users to adhere. Whether the same explanation will apply in nonresearch "real-world" settings is not yet known. Clinical trials provide supports in the form of counseling, outreach, and financial incentives that likely help improve adherence. Accumulating evidence of efficacy may have a similar effect. Ascertaining levels, patterns and antecedents of adherence in

routine clinical settings will be critical for future demonstration projects.

A distinguishing feature of the Partners PrEP Study is the recruitment of stable couples, whereas other PrEP trials have recruited individuals. PrEP adherence outside partnered relationships presents several challenges. Single individuals and men who have sex with men may be socially and economically vulnerable. They may not know the serostatus of their sexual partner(s) and may not include them in their adherence efforts. PrEP users who have not disclosed their HIV status may conceal pills and avoid dosing in front of their sexual partners, to avoid the impression of taking medications to treat HIV infection. Partnered relationships provide potential support for PrEP adherence.

Our goal has been early generation of an explanation of PrEP adherence in heterosexual HIV-serodiscordant couples in the Partners PrEP Study. We have set out deliberately to understand adherence in the PrEP testing-and-approval process, so that early insights can inform subsequent investigation and ultimately, "real world" implementation of PrEP.

This work has the following limitations. The explanation presented here necessarily reflects the contextual particularities of a single small geographic location: rural southwest Uganda. The clinical trial environment includes intensive adherence counseling and other supports, which will be not be readily available to individuals outside research contexts. The explanation is not intended to be immediately generalizable. Rather, the intent is to generate an initial account of PrEP adherence among HIV-serodiscordant couples for validation, refinement, and/or revision through subsequent research. Ultimately, the result of this iterative process will be a social model of adherence to PrEP and other user-dependent prevention strategies. The model will inform continuing efforts to optimize biomedical prevention tools to curtail the spread of HIV.

CONCLUSIONS

PrEP adherence for HIV-serodiscordant couples may be understood as a function of a couple's determination to resolve the discordance dilemma. The use of PrEP in the context of partnered relationships may be associated with improved adherence and thus, greater PrEP effectiveness.

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