

**Partner violence and self-reported pre-exposure prophylaxis (PrEP) interruptions among HIV  
negative partners in HIV serodiscordant couples in Kenya and Uganda.**

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

**Master of Public Health**

**University of Washington**

**2017**

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**Program Authorized to Offer Degree:**

**Department of Global Health**

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Abstract

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**Abstract:**

**Background:** Pre-exposure prophylaxis (PrEP) is effective for HIV prevention among diverse populations and studies of PrEP delivery are investigating ways to deliver PrEP with high adherence. In many settings with high HIV burden, where PrEP is an important intervention, intimate partner violence (IPV) is reported often. We examined the role of IPV to influence interruptions in PrEP use.

**Methods:** We analyzed data from 1,013 serodiscordant heterosexual couples enrolled in a large PrEP demonstration project in Kenya and Uganda, the Partners Demonstration Project. At quarterly study visits, HIV negative participants receiving PrEP self-reported interruptions in their PrEP use and experiences with IPV. The association of IPV and PrEP interruptions was analyzed using multivariate generalized estimating equations.

**Results:** Of 1,013 HIV negative people who used PrEP during the study, 67% were male and the median age was 30 (interquartile range [IQR] 26-36). Interruptions in PrEP use were reported at 328 visits (7.1%

of all visits). The median length of PrEP interruption was 28 days (interquartile range [IQR]: 7-45). At baseline and follow up there were 53 reports of abuse by HIV negative partners, including physical, economic, verbal, or other types of abuse. The frequency of PrEP interruption among people who experienced IPV was 23.8% and those without IPV was 6.9%. The crude odds ratio for PrEP interruption was 3.83 (95% CI 1.8-8.0) and remained significant after adjustment for age, and frequency of intercourse (aOR=2.64, 95% CI 1.17-6.00).

**Conclusion:** IPV was more likely to be reported at visits when PrEP interruptions were also reported, which may have implications for successful adherence to PrEP. Within PrEP delivery, there may be opportunities to assess and intervene on IPV in order to bolster adherence.

**Keywords:** Intimate Partner Violence, Pre-exposure prophylaxis, HIV, adherence, serodiscordant couples, Africa.

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Funding: The Partners Demonstration Project was funded by the Bill & Melinda Gates Foundation (OPP1056051), the National Institute of Mental Health of the US National Institutes of Health (NIH, R01 MH095507) and the United States Agency for International Development (USAID, JAID-OAA-A-12-00023). This work is made possible by the generous support of the American people through USAID; the contents are the responsibility of the authors and do not necessarily reflect the views of USAID, NIH, or the United States Government.

## **Introduction:**

Oral pre-exposure prophylaxis (PrEP) is an effective HIV prevention tool and being rolled out for use in many settings, including Kenya<sup>1,2,3</sup>. In PrEP demonstration projects evaluating delivery models for PrEP, high PrEP adherence has been observed, including among high risk serodiscordant heterosexual couples where an integrated PrEP and ART delivery model reduced HIV incidence by 96%<sup>1</sup>. Demonstration projects in other populations, such as female sex workers, men who have sex with men, adolescents, transgender women, people who inject drugs, are ongoing and investigating delivery strategies to foster high adherence<sup>4</sup>.

In settings with high HIV burden, intimate partner violence has been reported with some frequency in recent Demographic and Health Surveys. Spousal violence in Kenya among those ever-married between 15-49 years of age was reported by 39% of women and 9% of men<sup>5</sup>. In Uganda, spousal violence was reported by 60% of women and 40% of men<sup>6</sup>. In a study in pregnant women in Kenya, 79% of the participants had experienced IPV during pregnancy<sup>7</sup>. Furthermore, intimate partner violence (IPV) has been associated with a higher risk of HIV infection<sup>8,9,10</sup>, including a 55% increased risk of HIV acquisition among women in Uganda<sup>11</sup> and a 11.9% population attributable fraction in a study of South African women.<sup>12</sup> Women living with HIV are also more likely to have experienced partner violence than their HIV-negative female counterparts<sup>13,14,15</sup>.

To our knowledge, only one study to date has examined the potential for IPV to influence adherence to PrEP, finding that experiences with verbal, physical, and economic IPV were associated with low PrEP adherence among heterosexual serodiscordant couples participating in a randomized clinical trial of PrEP efficacy<sup>16</sup>. The objective for our work was to examine whether there is an association between IPV and self-reported interruptions in PrEP use in the context of an open-label demonstration project in order to consider whether there is opportunity within PrEP delivery to screen for IPV and provide intervention for those who experience IPV.

## **Methods:**

### Study Population:

The Partners Demonstration Project was an open-label prospective implementation study at 4 sites in Uganda and Kenya<sup>1</sup>. In brief, pre-exposure prophylaxis (PrEP) was offered to HIV negative partners in high risk serodiscordant heterosexual relationships until antiretroviral treatment was initiated and sustained for at least 6 months by the partner living with HIV<sup>1,17</sup>. During periods when PrEP was dispensed to the HIV negative partners, PrEP uptake, continuation and adherence was high<sup>1</sup>.

### Study procedures:

At enrollment, HIV negative partners had normal kidney function and were not pregnant and partners living with HIV had not yet initiated ART. Following enrollment, HIV negative and participants living with HIV completed quarterly study visits that couples were encouraged to attend together when feasible and desired. At each visit, HIV negative partners were tested for HIV, screened for acute HIV infection based on symptoms, and provided PrEP refills and adherence counseling. Partners living with HIV were monitored for CD4 count and viral load on a 6-monthly basis. Partners living with HIV were advised to initiate ART as soon as they met national ART initiation guidelines and participants chose to access ART at the study clinic or HIV clinic of their choice.

### Data Collection:

Data on demographics, sexual behavior, symptoms, and side effects were collected through standardized interviewer-administered questionnaires in the participant's preferred language. At quarterly visits, participants receiving PrEP were asked to report whether there had been any interruptions in their daily PrEP use during the past 3 months using the following question: "Since the last study visit, was there any period of time when you deliberately decided to take a break from taking PrEP?" If the participant

responded affirmatively, additional questions followed to define the length of the longest PrEP interruption and the reason for the PrEP interruption. Apart from self-report, additional measures of adherence to PrEP medication included pill counts, recordings of pill bottle openings by a medication event monitoring system (MEMS), and quantification of tenofovir in archived plasma for a subset of participants. Annually, scales screening for depression<sup>18</sup> and stigma were administered in addition to the normal quarterly data collection.

#### Intimate partner violence:

At baseline and each study visit, participants were asked if they had been verbally, physically, or economically abused by their study partner in the last three months. Affirmative responses were followed by discussion, in the context of a counselling session, with the study counselor to yield more details, including the type of abuse, and to determine a care plan for the participant. The study staff made great efforts to enquire about social harm in a culturally appropriate manner to foster trust and to encourage disclosure of abuse.

#### Data analysis:

The relationship between experiencing intimate partner violence and reporting a PrEP interruption was examined using a generalized estimating equation (GEE) extension to logistic regression to account for correlation among observations from the same person. A number of demographic, sexual behavior, and medical factors were considered as potential confounders. The final model included adjustment for factors that substantially changed the odds ratio (by 10% or more). Statistical analysis was conducted using STATA version 14.2.

#### Ethics statement:

The study protocol was approved by the University of Washington Human Subjects Division and ethics review committees at each of the study sites. All participants provided written informed consent in English or their local language.

## **Results**

### Participant characteristics:

A total of 1,013 HIV-1 serodiscordant heterosexual couples were enrolled; 67% of the HIV negative partners were male (Table 1). Approximately half of HIV negative women (55%) and men (47%) were age 29 years or younger. Over 95% of couples reported being married to each other and over 97% lived together, with a median length of partnership being nearly 5 years for couples with an HIV-negative woman and 2 years for couples with HIV-negative man. Female participants reported a median of 2 children and male participants reported a median of 1 child. 27% of women and 34% of men reported experiencing stigma. Probable depression was prevalent in 12% of women and 9% of men and 3% of women and 13% of men reported having 3 or more alcoholic drinks per week. At baseline, 1 female participant and 2 male participants reported experiencing abuse from their study partner in the past 3 months.

### Prevalence of self-reported PrEP interruption:

Participant-driven interruptions in PrEP use were reported at a total of 328 visits subsequent to PrEP dispensing (7.1% of all visits). The median length of PrEP interruption was 28 days (interquartile range [IQR]: 7-45). Of the 328 PrEP interruptions reported, 65% were from men (Table 2). The most common reasons reported for an interruption in PrEP use included: breaking up with the study partner living with HIV(27%), experiencing side effects or being fearful of side effects (24.4%), not being at home or having a partner that was not home (17%), running out of pills (7.3%), and getting tired of taking pills (7%).

### Prevalence of IPV:

At baseline and follow up there were 53 reports of intimate partner violence inflicted by the study partner, including physical, economic, verbal, other types of abuse, or combinations of types of abuse (Figure 1). Over 50% of reports described verbal abuse, 25% were physical, and 22% were economic. 52.8% of reports were made by women and 47.2% were made by men. Men and women reported verbal abuse at similar frequencies while the majority of physical abuse reports were made by women.

#### Intimate partner violence and Self-reported PrEP interruption:

PrEP interruptions were reported during 23.8% of visits when IPV was also reported and 6.9% of visits when IPV was not reported (Table 3). The crude odds ratio for PrEP interruption was 3.83 (95% CI=1.8-8.0). After adjusting for age, and frequency of sex, the association between PrEP interruption and IPV remained significant (aOR=2.64, 95% CI= 1.17-6.00). Additional correlates of self-reported PrEP interruption included being married to the study partner (OR= 2.43 95% CI= 1.52-3.90,  $p<0.0001$ ), gastric intestinal discomfort (OR=2.39 95% CI= 1.79-3.19), and having probable depression (OR=2.16 95% CI=1.47-3.18) but these were no longer significant in the multivariate model.

#### **Discussion:**

In this study, participants that reported IPV were significantly more likely to report an interruption in their PrEP use. Participant reports of IPV were rare, but the most common type was verbal abuse, followed by physical and economic abuse. Reports of temporary PrEP interruptions among people who had been dispensed drug were also rare, and they were most often related to partner break up and actual or perceived side effects of the PrEP medication.

Interruptions in PrEP use are important to understand, especially for women. Resumption of PrEP after interruption may coincide with resumption of sexual risk. This is relevant because PrEP resumption may only provide partial protection until PrEP levels return to a steady state.

A recent secondary analysis within a blinded, placebo-controlled PrEP clinical trial examined PrEP adherence and IPV in heterosexual serodiscordant relationships, with results showing women reporting IPV in the past 3 months had increased risk of low adherence by pill count (aRR=1.49 95% CI=1.17-1.89) and plasma tenofovir levels (aRR=1.51, 95% CI=1.06-2.15)<sup>16</sup>. The current open-label study provides data in a context where PrEP use was encouraged to be aligned with HIV risk, and not mandated to be used with unwavering adherence, in contrast to clinical trials. In our study, participants were also encouraged to disclose gaps in PrEP adherence without judgement from study staff or consequence to their research participation so that counseling messages could be tailored to reflect true risk. While there is still likely to be underreporting of IPV and PrEP interruptions in our data, the strength of the correlation that we observed suggests that violence can undermine the use of PrEP and leave people vulnerable to HIV acquisition.

Although women more frequently reported experiencing physical IPV in our study, men also reported experiencing violence, particularly verbal violence. Data to document violence to men are uncommon but it is important to document violence experienced by men, as well as women, and consider the adoption of gender-based interventions. Reports of physical violence were more frequent in women than in men, consistent with the findings of other studies in the region where women were mainly the victims of this type of abuse<sup>19</sup>.

A limitation of our study is the reliance on self-report of IPV events, an inherent limitation of all studies of this nature. Underreporting of IPV could have occurred since there are certain societal expectations and stigma in being the recipient of IPV.<sup>22</sup> Additionally, our questions may not have been sufficiently comprehensive to elicit all reports. We asked about three types of abuse, provided examples, and used a counselling approach when collecting social harm information. However, the examples did not describe every possible experience of abuse and participants might not have been able to recognize their

experience among the listed categories. In addition, IPV is a difficult subject to disclose, especially to study staff, who are much less familiar than close family members and friends.<sup>20,21</sup> In our study, IPV was reported less frequently than the 2014 Kenya Demographic and Health Survey where 39% of women and 9% of men reported IPV and the 2010 Uganda Demographic and Health Survey where 60% of women and 40% of men reported IPV.<sup>5,6</sup> Another limitation is the use of self-reported PrEP interruption as our measure of PrEP adherence. The study used MEMS to capture daily adherence data but we limited this analysis to the self-reported time off PrEP because we wanted to focus on deliberate interruptions that participants recognized as substantial enough to report. Adherence counseling for PrEP in this open-label study focused on PrEP use being aligned with HIV risk, and thus participants were encouraged to feel comfortable describing periods when they did not take their pills. Nonetheless, participants may not have wanted to disclose PrEP interruptions due to social desirability or difficulties with recall. However, we do not expect that there would be a difference in the degree of misreporting among people experiencing IPV and people with no IPV. Future studies should use innovative strategies, including qualitative techniques and motivational interviewing.

The results of this study highlight the potential role for IPV to impact PrEP use and effectiveness through its potential role with PrEP adherence. Adherence support has been recognized as being an important facet of a comprehensive HIV prevention program<sup>23,24</sup>. Within PrEP delivery programs, there may be opportunity to identify people experiencing IPV and dovetail IPV interventions with HIV prevention to people that are using PrEP as an HIV prevention strategy, as had been done in other HIV prevention studies. The SHARE intervention in Uganda, a combination of IPV prevention and HIV services significantly reduced reports of women's physical and sexual IPV and was associated with a lower HIV incidence<sup>25</sup>.

Overcoming the barriers to PrEP adherence faced by young women and men is an important facet for programs delivering oral PrEP for HIV prevention. PrEP delivery provides a valuable opportunity for

health workers to interact with healthy individuals accessing PrEP at established intervals, with opportunities for IPV interventions, which would reduce the onward chance of IPV, HIV risk, and potentially interruptions in PrEP use. Integrating IPV interventions within PrEP delivery will optimize PrEP use and increase the degree to which providers are aware and empowered to intervene on violent situations.

## **Acknowledgements**

We thank the couples who participated in this study for their motivation and dedication and the referral partners, community advisory groups, institutions, and communities that supported this work.

### **Partners Demonstration Project Team**

Coordinating Center (University of Washington) and collaborating investigators (Harvard Medical School, Johns Hopkins University, Massachusetts General Hospital): Jared Baeten (protocol chair), Connie Celum (protocol co-chair), Renee Heffron (project director), Deborah Donnell (statistician), Ruanne Barnabas, Jessica Haberer, Harald Haugen, Craig Hendrix, Lara Kidoguchi, Mark Marzinke, Susan Morrison, Jennifer Morton, Norma Ware, Monique Wyatt

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Data Management was provided by DF/Net Research, Inc. (Seattle, WA). PrEP medication was donated by Gilead Sciences.

**Tables and figures:**

**Table 1.** Participant demographics (At enrollment)

	Female N (%) or Median (IQR) N=334	Male N (%) or Median (IQR) N=679
<b>Age</b>		
18-24	91 (27.25)	116 (17.08)
25-29	93 (27.84)	205 (30.19)
30-34	65 (19.46)	140 (20.62)
35+	85 (25.45)	218 (32.11)
<b>Education (years)</b>		
≤8	210 (62.87)	354 (52.14)
>8	124 (37.13)	325 (47.86)
<b>Sexual Behavior</b>		
Sex acts per month, with study partner	4.50 (3.00-8.00)	6.00 (3.00-12.00)
Number of Sex partners	0 (0-0)	0(0-0)
None	329(98.5)	600(88.4)
1 or more	5 (1.5)	79 (11.6)
<b>Medical History</b>		
Circumcision at enrollment (men)	N/A	462 (68.04)
Effective contraceptive use* (women)	107 (32.04)	N/A
<b>Substance abuse</b>		
Number of alcoholic drinks/week		
0	286 (85.63)	489 (72.02)
1-2	37 (11.08)	97 (14.29)
3 or more	11(3.30)	93 (13.693)
<b>Mental Health</b>		
Probable depression*	39 (11.687)	64 (9.43)
Social support mean **	3.6 (3.20-3.90)	3.7 (3.20-4.00)
Experienced stigma***	90 (26.96)	228 (33.59)
<b>Characteristics of HIV+ partner</b>		
<b>Age</b>		
18-24	292 (43.00)	25 (7.49)
25-29	194 (28.57)	56 (16.77)
30-34	95 (13.99)	71 (21.26)
35+	98 (14.43)	182 (54.49)
<b>CD4 Count (copies/μL)</b>		
≥500	293 (43.15)	127 (38.02)
200-499	292 (43.00)	140 (41.92)
<200	94 (13.84)	67 (20.06)
<b>Viral Load (copies/mL)</b>		
≥50,000	235 (34.61)	196 (58.68)
10,000-49,999	223 (32.84)	78 (23.35)
<10,000	221 (32.55)	60 (17.96)
<b>WHO stage</b>		

Clinical Stage 1	503 (74.08)	205 (61.38)
Clinical Stage 2	176 (25.92)	129 (38.62)
<b>Characteristics of Couple</b>		
Cohabiting	326 (97.60)	657 (96.76)
Married to each other	325 (97.31)	647 (95.29)
<b>Length of Partnership (years)</b>		
<1	46 (14.11)	201 (30.59)
1-5	128 (39.26)	297 (45.21)
>5	152 (46.63)	159 (24.20)
Number of Children	2(1-3)	1 (0-3)
Time discordant (years)	0.08 (0.08-0.58)	0.08 (0-0.17)
Partnerships satisfaction scale	31(27-34)	32 (28-35)
Partner violence experience	1 (0.30)	2(0.29)

\*Effective contraception includes: Oral contraceptive use, IUD, Injectable or implant.

Probable depression measure based on Paros/HSCLD<sup>18</sup>

\*\*Based on Tsai and Broadhead Social Support scale with higher numbers indicating greater satisfaction, maximum score=39<sup>26,27</sup>

\*\*\*Based on the methods described by Kalichman et al. <sup>28</sup>

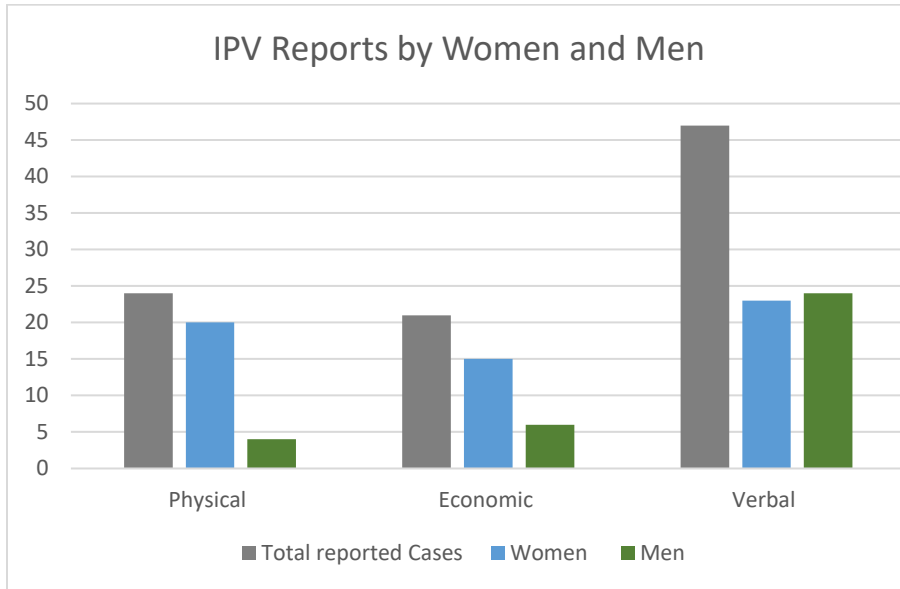
**Table 2.** Prevalence of PrEP interruption following PrEP dispensation

Months since study enrollment	Any self-reported PrEP interruption N (% of all visits)	Self-reported PrEP Interruption >7 days N (% of all visits)
Between enrollment and month 3	55 (8.0)	32 (4.6)
3 months	58 (7.7)	35 (4.6)
6 months	59 (7.6)	44 (5.7)
9 months	50 (7.0)	39 (5.4)
12 months	39 (7.3)	35 (6.5)
15 months	12 (3.0)	10 (2.5)
18 months	25 (7.9)	17 (5.4)
21 months	17 (6.9)	14 (5.4)
24 months	13 (6.7)	9 (4.7)
Total during all follow up	328 (7.8)	235 (5.1)

**Table 3.** Association of reported IPV and PrEP interruption

	<b>N (%) with no self-reported time off PrEP</b>	<b>N (%) with self-reported time off PrEP</b>	<b>OR (95% CI) p-value</b>	<b>Adjusted OR (95% CI) p-value</b>
<b>Partner violence</b>				
Reported IPV	32 (76.2)	10 (26.8)	3.83 (1.8-8.0) p<0.0001	2.64 (1.17-6.00) p=0.02
No IPV report	4,263 (93.1)	315 (6.9)	REF	REF
<b>Sex acts per month with study partner</b>				
0-1	982 (86.75)	150 (13.25)	REF	REF
2-5	1,735 (94.91)	93 (5.09)	0.37 (0.28-0.49) p<0.0001	0.39 (0.30-0.51) p<0.0001
6 or more	1,586 (94.91)	85 (5.09)	0.37 (0.27-0.49) p<0.0001	0.36(0.27-0.49) p<0.0001
<b>Age</b>				
18-24	864 (91.53)	80 (8.47)	REF	REF
25-29	1,239 (92.39)	102 (7.61)	0.88 (0.61-1.26) p=0.48	0.87 (0.60-1.25) p=0.45
30-34	888 (93.77)	59 (6.23)	0.67 (0.43-1.02) p=0.06	0.72 (0.47-1.10) p=0.13
35+	1,312 (93.78)	87 (6.22)	0.66 (0.45-0.95) p=0.03	0.68 (0.47-0.98) p=0.04

**Figure 1:**



\* There was 1 additional case that could not be categorized as economic/verbal/physical

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