

## **Intimate Partner Violence and Condom and Diaphragm Non-Adherence among Women in an HIV Prevention Trial in Southern Africa**

Deborah Kacanek, Sc.D.,<sup>1</sup> Alan Bostrom, Ph.D.,<sup>2</sup> Elizabeth T. Montgomery, M.P.H., Ph.D.,<sup>3</sup>

Gita Ramjee, Ph.D.,<sup>4</sup> Guy de Bruyn, MBBCh, M.P.H.,<sup>5</sup> Kelly Blanchard, S.M.,<sup>6</sup>

Amelia Rock, S.M.,<sup>7</sup> Sibongile Mtetwa, M.S.,<sup>8</sup>

Ariane van der Straten, M.P.H., Ph.D.,<sup>2,3</sup> and the MIRA Team

<sup>1</sup>Department of Biostatistics Harvard School of Public Health, Boston, MA; <sup>2</sup>Department of  
Medicine, Center for AIDS Prevention Studies, University of California San Francisco, San  
Francisco, CA; <sup>3</sup>RTI International, Women's Global Health Imperative, San Francisco, CA;  
<sup>4</sup>Medical Research Council, Durban, South Africa; <sup>5</sup>Sanofi Pasteur, Pittsburgh, PA; <sup>6</sup>Ibis  
Reproductive Health, Cambridge, MA; <sup>7</sup>JSI Research and Training Institute, Washington, DC;  
<sup>8</sup>University of Zimbabwe, Harare, Zimbabwe

Corresponding Author: Deborah Kacanek, Sc.D.

Center for Biostatistics in AIDS Research

Harvard School of Public Health

665 Huntington Ave.

Boston, MA 02115

dkacanek@sdac.harvard.edu; tel:617-432-2833; fax:617-432-3163

These data were presented at the XVIII International AIDS Conference, Vienna Austria, 2010.

**Conflicts of Interest and Source of Funding:** Bill and Melinda Gates Foundation (#21802).

No conflicts of interest declared.

**Running Head:** Intimate Partner Violence and Non-Adherence

## ABSTRACT

**Background:** We longitudinally examined the effect of intimate partner violence (IPV) on condom and diaphragm non-adherence among women in the Methods for Improving Reproductive Health in Africa (MIRA) study, a phase III HIV prevention trial in southern Africa.

**Methods:** Recent IPV (fear of violence, emotional abuse, physical violence or forced sex, in past 3 months), condom non-adherence and diaphragm non-adherence were assessed at baseline, 12 month and exit visits (up to 24 months). The association between IPV and a) condom non-adherence or b) diaphragm non-adherence across visits was modeled using Generalized Estimating Equations (GEE) adjusting for potential confounders.

**Results:** Of 4505 participants, 55% reported recent IPV during their trial participation. Women reported fearing violence (41%), emotional abuse (38%), being physically assaulted (16%), and forced sex (15%) by their regular male partner. IPV was associated with condom non-adherence in both study arms (adjusted odds ratio (AOR) 1.41, 95% confidence interval (CI) 1.24-1.61 (control arm) and AOR 1.47, 95% CI 1.28-1.69, (intervention arm)) and with diaphragm non-adherence (AOR 1.24, 95% CI 1.06-1.45) adjusting for age, study sites, number of sex partners, and knowledge of male partner infidelity. Modeling effects of each form of IPV separately on non-adherence outcomes yielded similar results.

**Conclusions:** Prevalence of recent IPV was high and associated with condom and diaphragm non-adherence during the trial. Counseling in prevention trials should proactively address IPV, for its own sake, and in product and risk-reduction counseling. Strategies to encourage men's positive involvement in product use and prevent IPV perpetration should be considered.

**Keywords:** Intimate partner violence, gender, HIV infection, adherence, longitudinal analysis, condom use, gel

ACCEPTED

## INTRODUCTION

Intimate partner violence (IPV) and HIV infection are pervasive and intersecting epidemics which pose significant threats to women's survival worldwide. In a 10-country survey of women, lifetime prevalence of physical or sexual IPV ranged from 15% to 71%.<sup>1</sup> In Sub-Saharan Africa, over half of HIV infections are in women, and in South Africa young women are three times more likely to be infected with HIV infection than young men.<sup>2,3</sup> The prevalence of IPV in South Africa and Zimbabwe is particularly high.<sup>4-6</sup> Rooted in gender power imbalances within intimate partner relationships<sup>7,8</sup> and inequitable gender norms at the societal level, women's experiences of emotional, physical and sexual violence by a male intimate partner, as well as male perpetration of IPV, have been associated with inconsistent condom use, multiple sexual partners, sexually transmitted diseases and HIV infection.<sup>9-13</sup> Women who experience IPV may be unsuccessful in their efforts to negotiate condoms, or be less likely to refuse sex or to suggest the use of condoms because they fear violence.<sup>7,14,15</sup>

Female-initiated methods of HIV prevention, including the female condom, diaphragms, other barrier methods, and microbicides have the potential to give women more options to protect their health when they are unable to negotiate condom use since some of these methods may be used without their partner's knowledge, or may not necessitate their partner's active cooperation. Adherence to methods with proven effectiveness (including the male and female condoms) is critical to averting HIV transmission. Optimizing adherent use of female-initiated prevention methods in HIV prevention trials is also crucial to determining the effectiveness of the method under investigation in preventing HIV infection.<sup>16</sup> Although female-initiated methods of HIV prevention are needed to increase women's options and autonomy over sexual decision

making, their real-world effectiveness may be compromised for women experiencing IPV. Experiences of IPV may also pose challenges to women's consistent use of female-initiated methods of HIV prevention.<sup>17</sup>

Most studies linking IPV to inconsistent condom use have been cross sectional. A few studies have explored longitudinal relationships of IPV to inconsistent condom use in the US<sup>18</sup> and incident HIV infection in South Africa<sup>19</sup> and Uganda.<sup>20</sup> In the context of HIV prevention trials, which require sustained high levels of adherence to study products and longer-term follow up (i.e. 12-36 months), it is important to identify factors contributing to and impeding sustained adherence. Indeed, greater adherence has also been associated with greater effectiveness of oral PrEP and microbicides<sup>21, 22</sup> in preventing HIV transmission. The inability of several prevention trials to establish efficacy or effectiveness has been attributed, in part, to lower-than-anticipated adherence.<sup>23-25</sup> We therefore examined the relationship of longitudinal patterns of IPV to condom and diaphragm self-reported non-adherence among women participating in the Methods for Improving Reproductive Health in Africa (MIRA) study. Understanding whether women who fear or experience IPV can consistently use the diaphragm as a potential female-initiated HIV prevention method, or whether women who use the diaphragm experience greater IPV is critical for evaluating its overall effectiveness and public health benefit. To address gaps in prior studies,<sup>18-20</sup> the current study sought to account for the time varying nature of exposure to IPV, examined multiple forms of IPV including fear of violence, and investigated its relationship to diaphragm as well as condom non-adherence in a large sample of women in Southern Africa.

## **METHODS**

The MIRA trial was an open-label multisite, randomized controlled trial of the diaphragm and gel for prevention of heterosexual HIV acquisition, which enrolled and followed 5039 sexually active, 18-49 year-old, HIV-negative women from 2003-2006 at five clinics in Johannesburg (Soweto) and Durban (Botha's Hill and Umkomaas), South Africa and Harare (Epworth and Chitungwiza), Zimbabwe. Women were randomly assigned in a 1:1 ratio to the intervention (diaphragm, lubricant gel and condoms) arm or control (condoms-only) arm. Participants were followed up at quarterly clinic visits for up to 24 months, and received product adherence and risk reduction counseling, free male condoms, HIV/ STI testing and treatment of curable STIs at each clinic visit. The methods and results of the MIRA trial are described in detail elsewhere.<sup>26,27</sup> The study protocol was reviewed and approved by Institutional Review Boards (IRBs) at the participating sites and at the University of California, San Francisco. Counseling staff at each site were equipped with referrals to local support organizations that addressed IPV.

Women completed an audio computer-assisted survey interview (ACASI) in their native language at their baseline visit and at each quarterly study visit. The ACASI collected information on sexual behavior and current and previous use of the diaphragm, gel and condoms. Study investigators added questions on intimate partner violence to the ACASI interview one year after study enrollment began, and IPV was assessed at women's baseline, twelve month, and exit visits thereafter.

### **Analysis Sample**

Of the 5039 women in the MIRA trial, 4505 women (2244 in the intervention arm, and 2261 in the control arm) had available data on IPV during a baseline, 12-month or exit visit and

condom use data at one or more follow up visits (n=9547 person-visits). Visit intervals after seroconversion for women who acquired HIV were censored from this analysis because the team expected that this would affect their subsequent product use. Exit visits occurred between 12 and 24 months of participation. When an exit visit occurred at 12 months it was classified in this analysis as a 12 month visit rather than an exit visit.

## Measures

### *Intimate Partner Violence*

We measured four forms of recent fear or experience of IPV using questions adapted from a diaphragm acceptability study in Zimbabwe<sup>28</sup> and informed by a gender-based violence study in South Africa.<sup>8</sup> Questions referred to IPV by the woman's "regular partner" (defined as "the person you had sex with most often. This may be your husband, your boyfriend or your casual partner.") during the three months prior to the interview. Fear of violence was defined as a "yes" response to at least one of the following two questions: "In the last 3 months have you ever been afraid that your regular partner might shout or scream at you?" or "In the last 3 months have you ever been afraid that your regular partner might shove, hit, slap, kick or otherwise physically harm you?." We defined emotional abuse as a "yes" response to the question "In the last 3 months has your regular partner emotionally or verbally hurt you in some way, such as insult you, yell at you, humiliate or swear at you?" We defined forced sex as responding yes to "In the last 3 months, has your regular partner either physically or verbally forced you to have sex?" and we defined physical violence as a "yes" response to at least one of the following two questions: "In the last 3 months, has your regular partner shoved, hit, slapped, kicked or otherwise physically hurt you?" and "Has your regular partner used, or threatened you with a

weapon, such as a gun or knife?” We classified women as experiencing IPV, defined as “Any fear or experience of intimate partner violence” if they reported experiencing at least one form of violence at that study visit, and no violence if they did not report experiencing any form of violence by an intimate partner.

### *Condom Adherence and Diaphragm Adherence*

Self-reported adherence information on the two outcomes, condom non-adherence and diaphragm non-adherence, was collected via ACASI at each visit for the prior 3 months. To be consistent with an earlier MIRA study<sup>29</sup> condom and diaphragm non-adherence were individually defined as did not *always* use the product since the last visit or did not use the product at the most recent sexual intercourse. Because women were given the diaphragm at enrollment, and IPV was measured at only baseline, 12 months and exit, only diaphragm non-adherence at the 12 month and exit visits was investigated in this analysis.

### *Covariates*

We examined the association of baseline covariates that were associated with IPV and condom and diaphragm non-adherence in prior studies and were potential confounders of the relationship between IPV and non-adherence. Covariates of interest covered women’s socio-demographic and study related characteristics (age, site, study arm, educational attainment, whether the woman earned an income, marital status, cohabitation with her partner), women’s sexual risk behaviors (number of recent sex partners, receiving money in exchange for sex), and women’s report of male partner characteristics (knowledge or suspicion that the male partner had other sex partners, age difference with the partner, partner being away from home greater than 1



month out of the year, partner alcohol use before sex, partner HIV status, and partner employment). Covariates associated with both the outcome and the violence indicator at a level of  $p < 0.1$  were included in multivariable regression models.

## Data Analysis

We conducted all data analyses using SAS 9.1 (Cary, NC). First, to describe the sample and identify correlates of IPV, baseline characteristics were compared between women who reported IPV at least once during the study period versus those who did not report experiencing IPV, and differences were tested using  $\chi^2$  tests for categorical variables. We then calculated the prevalence of each form of IPV and any IPV at each visit, summarized it in a plot, and tested for differences in the prevalence of IPV across visits using  $\chi^2$  tests. Next, we calculated frequencies of condom and diaphragm non-adherence at each visit, and tested differences in the frequency of condom and diaphragm adherence across visits using  $\chi^2$  tests. Because the prevalence of condom non-adherence at each visit differed by arm after enrollment, all analyses and models of condom non-adherence were stratified and presented by arm.

The longitudinal relationship of IPV exposure to a) condom non-adherence and b) diaphragm non-adherence was modeled using Generalized Estimating Equations (GEE) based on binomially distributed data and a logit link. The working correlation was an exchangeable correlation structure which assumed equal correlations between all pairs of observations from the same subject. The unadjusted models included categorical time (visit), a time-varying dichotomous IPV indicator and an IPV\*time interaction. In cases where the p-value for the interaction of IPV and time was  $> 0.2$ , the interaction term was dropped and models included only time and IPV. Multivariable models adjusted for the baseline covariates that were identified

as potential confounders. Results of the models are reported as odds ratios with 95% confidence intervals. Separate unadjusted and adjusted models were fit for each type of violence as well as the “Any IPV” indicator and an indicator of “Any physical or sexual IPV.”

The multivariable models which used the “Any IPV” indicator for the IPV exposure were then used to generate and plot estimated probabilities of non-adherence for combinations of violence and visit.

Finally, we investigated the association between the pattern of IPV exposure from enrollment to the 12 month visit and condom non-adherence and diaphragm non-adherence at the 12 month visit, by restricting analyses to the 1924 participants who answered questions about IPV at both the baseline and 12 month visits (950 in the diaphragm and gel arm, and 974 in the condom arm). Condom non-adherence in each arm and diaphragm non-adherence at the 12 month visit were modeled using logistic regression. The predictor was the individual’s pattern of IPV exposure (any vs. none) from baseline to month 12. These categories were: Persisting (Yes at baseline and month 12), Incident (No at baseline and Yes at month 12), Remitting (Yes at baseline and No at month 12), and None (No at baseline and month 12), the reference category. Multivariable (adjusted) logistic regression models adjusted for baseline covariates that were associated with each violence pattern and the non-adherence outcomes at 12 months at  $p < 0.1$ .

## RESULTS

Overall, 52% of the 4505 women were from the Harare site, 30% from the Durban site, and 18% from the Johannesburg site. Nearly half (44%) had completed high school. The majority of women was married (60.7%), lived with a regular male partner (69.1%) and had one sex partner over the past three months (91.9%) (Table 1).

### **Prevalence and correlates of IPV**

Among the 4505 women, 757 (16.8%) provided information on IPV at one visit, 2465 (54.7%) at two visits, and 1283 (28.5%) at three visits. Over half of the women (54.6%) reported IPV in the three months prior to enrollment or prior to at least one follow-up visit (Table 1). Specifically, 1841 (40.8%) reported fearing violence by their male partner, 1730 (38.4%) reported that their male partner emotionally abused them, 729 (16.2%) reported that their male partner had physically assaulted them, and 668 (14.8%) reported that their male partner had forced them to have sex in the three months prior to the interview (data not shown in table).

In bivariate analyses, women who reported fearing or experiencing IPV versus those reporting no IPV were more frequently from the Johannesburg site and less frequently from the Durban site, more likely to have earned an income, to have had more than one sex partner in the past three months, and to have had sex in exchange for money or drugs (Table 1). Women fearing or experiencing IPV more frequently had a male partner who was away from home at least one month out of the year, who they knew or suspected had sex with other partners, who had sex under the influence of alcohol or drugs, and who was HIV-positive or of unknown HIV status. Age group, education, marital status, living with the male partner, HIV seroconversion, and partner employment were not associated with reports of IPV prior to enrollment or during followup.

The proportion of women reporting any IPV, overall and by type of IPV was highest at the baseline visit, and was lower at subsequent visits (Figure 1). For example, the proportion of women who feared that their partner would be violent toward them in the past three months declined from 36% at the baseline visit, to 24% at month 12, and 23% at exit ( $p < 0.0001$ ). The

prevalence of physical violence ( $p < 0.0001$ ) and forced sex ( $p = 0.03$ ) differed modestly over time (Figure 1).

### **Prevalence of Condom and Diaphragm Non-adherence**

Condom non-adherence was reported at 2339/4797 (48.8%) of person visits among women in the control arm and 3040/4750 (64.0%) of person visits among women in the intervention arm. The proportion reporting condom non-adherence was similar in the two arms at baseline and diverged during follow-up as previously reported;<sup>23</sup> the proportion non-adherent decreased from 69.7% at baseline to 40.8% at 12 months and 43.6% at exit in the control arm ( $p < 0.0001$ ) and from 72.1% at baseline to 62.7% at 12 months and 60.2% at exit in the intervention arm ( $p < 0.0001$ ) (data not shown in tables).

Women reported diaphragm non-adherence at 1974/3599 (54.8%) of the intervention arm 12 month or exit visits (baseline visit not included). The proportion reporting diaphragm non-adherence was similar at the 12 month (54.3%) and exit (55.3%) visits ( $p = 0.771$ ) (data not shown in tables).

### **IPV and Condom and Diaphragm Non-Adherence: Unadjusted and Adjusted Results**

Table 2 presents unadjusted and multivariable (adjusted) models of IPV and condom non-adherence by arm, and diaphragm non-adherence, with separate models for each form of IPV. In unadjusted and adjusted models, IPV predicted higher odds of condom non-adherence over the trial period in both arms and diaphragm non-adherence in the intervention arm (Table 2). In adjusted models, the association between IPV and condom non-adherence (adjusted odds ratio AOR 1.41, 95% confidence interval (CI) 1.24-1.61 (control arm) and AOR 1.47, 95% CI 1.28-

1.69, (intervention arm)) and with diaphragm non-adherence remained (AOR 1.24, 95% CI 1.06-1.45) adjusting for age, study sites, number of sex partners, and knowledge of male partner infidelity.

Figures 2a-2c show the association between IPV and the probability of condom (2a-2b) and diaphragm (2c) non-adherence at the three study time points, as estimated by the multivariable models. The estimated probability of condom non-adherence declined over time in both arms and it was higher when women reported IPV than when women reported no IPV, controlling for age, site, number of sex partners, and partner infidelity (Figure 2a-c). Among women in the control arm, the effect of IPV on reported condom non-adherence differed over time (p-value for IPV\*visit interaction=0.0008); there was no association between IPV and condom non-adherence at baseline and a positive association at 12 months and at exit. Although the probability of diaphragm non-adherence did not appear to change from the 12 month to exit visit, it was higher when women reported IPV, relative to when women did not report IPV (Figure 2c).

### **IPV Pattern and Condom and Diaphragm Adherence: Unadjusted and Adjusted Results**

Among the 1924 women who answered questions about IPV at both baseline and 12 month visits, 23.9% reported persisting IPV, 10.4% reported incident IPV, 25.2% reported remitting IPV and 40.4% reported no IPV at both visits (Table 3). In multivariable models, women in the control arm who experienced persisting IPV (AOR 2.2, 95% CI 1.54-3.1) and incident IPV (AOR 1.69, 95% CI 1.08-2.6) had higher odds of reporting condom non-adherence at month 12 compared to women with no IPV prior to both their baseline and month 12 visits. Remitting IPV was associated with condom non-adherence at follow-up in unadjusted models,

but not in adjusted models. In the intervention arm, only women experiencing persisting IPV (AOR 1.53, 95% CI 1.06-2.2) had higher odds of condom non-adherence relative to women with no IPV prior to both visits. Women experiencing persisting IPV (AOR 2.0, 95% CI 1.39-2.9) and remitting IPV (AOR 1.51, 95% CI 1.07-2.1) had higher odds of diaphragm non-adherence at 12 months relative to women with no IPV at both visits (Table 3).

## DISCUSSION

Women in the MIRA trial reported high rates of recent IPV and the association between IPV and diaphragm and condom non-adherence persisted over the trial period. Modeling the effects of each form of IPV on non-adherence yielded similar results. The similar OR estimates for different types of IPV underscore that IPV and not just one particular form of IPV is associated with condom and diaphragm non-adherence. These results suggest that IPV is likely to impede adherence to HIV prevention interventions, even those that are specifically designed to give women greater control over protecting their sexual health.

The prevalence of various forms of recent IPV reported by women in the MIRA trial was high and similar to that found in other studies with women in South Africa and Zimbabwe. For example a DHS survey in Zimbabwe found 25% of women reported physical violence and 12% forced sex in a current relationship.<sup>6</sup> We also observed a drop after the baseline visit in prevalence of some forms of IPV, particularly fear of violence and verbal abuse, which may have been attributable to several potential factors. It may be that once women began to participate in the trial they were less likely to report intimate partner violence out of a desire to provide socially desirable responses. ACASI was used to collect IPV data to minimize social desirability bias. Alternatively, women may have felt a sense of safety and support as a result of their participation in the trial and their interactions with staff that reduced their fear of and threats by a

male partner. A third possible explanation is that women who experienced IPV were less likely to be retained in the study and were lost to follow up or withdrew without completing a closing visit, however we did not observe differences by IPV exposure in the proportion completing a closing visit.

This longitudinal study found that when women reported fearing or experiencing IPV they had greater odds of diaphragm non-adherence, relative to when women did not report IPV, consistent with an earlier study in Zimbabwe.<sup>28</sup> Additionally, there was a tendency toward greater associations with diaphragm non-adherence for women experiencing persisting IPV and persisting emotional abuse relative to no IPV. Yet, we also found that persisting and remitting forced sex were associated with condom non-adherence but not diaphragm non-adherence. It could be that non-use of condoms was a strategy for some women to mitigate further experiences of forced sex; the lack of an association with diaphragm non-adherence may suggest that for some women the diaphragm was an alternative option that was acceptable to their male partner or that women were able to use covertly or discreetly, regardless of whether they had experienced forced sex. A study of sex workers in Madagascar found that women who reported experiencing IPV upon requesting that their partner use a condom were more adherent than those with no IPV exposure to a gel-diaphragm combination product.<sup>29</sup> A study of product substitution (use of the diaphragm instead of condom) in MIRA found that women who experienced IPV at baseline had nearly 2.0 greater odds of reporting using a diaphragm instead of a condom.<sup>30</sup> It may be that there are subgroups of women who experience IPV who are able to use the diaphragm when condom use is not possible, yet others for whom even consistent diaphragm use is not possible in the face of IPV.

There are some limitations to this study. Results from this study are not generalizable to women who did not participate in the trial. All data are self-reported, however since both non-adherence and IPV are sensitive behaviors, it is likely that those who reported it actually had experienced it. Despite these limitations, this study has several important strengths, which include the large sample of women, the longitudinal design within a randomized trial, and the comprehensive examination of multiple types and patterns (e.g., persisting, incident, remitting) of IPV exposure in relation to both condom and diaphragm non-adherence.

Results from this study have implications for the effective prevention of HIV infection in women and for implementation of HIV prevention trials. Clinical trials should provide support and protection to women who experience IPV, and address IPV as part of study counseling. In addition, since the associations we observed between IPV and condom and diaphragm non-adherence may be key pathways through which IPV may heighten HIV risk, interventions and policies that explicitly address IPV and links to HIV infection risk are urgently needed. In South Africa, structural interventions aiming to shift inequitable gender norms, roles and expectations and improve women's economic empowerment have shown promise in reducing IPV rates, but yielded mixed results regarding HIV-related risk. For example, the IMAGE study, a community level microcredit and gender awareness intervention showed a decline in IPV prevalence<sup>31</sup> but no effect on HIV incidence. Similarly, Stepping Stones,<sup>32</sup> a gender-transformative intervention to build more gender equitable relationships between young men and women, showed a reduction in IPV prevalence and HSV-2 incidence but not HIV. These approaches that prevent men's perpetration of IPV and reduce HIV risk by altering inequitable gender norms that condone men's use of violence to assert power and control over women,<sup>33,34</sup> are critically important, as are interventions that promote men's positive involvement in product use<sup>35</sup>. Research that identifies



multilevel determinants<sup>34</sup> of men's perpetration of IPV<sup>13</sup> and evaluates interventions targeting young men and women should be a high priority.

ACCEPTED

## **ACKNOWLEDGEMENTS**

We would like to thank the women who participated in this study and the staff at the study sites. For D. Kacanek most work for this study was conducted at Ibis Reproductive Health. For E. Montgomery and A. van der Straten most work for this study was conducted at the University of California San Francisco Department of Obstetrics, Gynecology and Reproductive Sciences. For G. de Bruyn, all work for this study was conducted at University of the Witwatersrand, Perinatal HIV Research Unit, Johannesburg. The MIRA Trial was funded by a grant from the Bill and Melinda Gates Foundation (#21802).

### **Author Contributions:**

DK is the primary author who designed the study and led the writing. AB was primarily responsible for conducting the statistical analysis of the data. DK, ETM, GDB, GR, KB, AR, SM, AVS were involved in the conduct of the MIRA protocol. All authors contributed to interpretation of the results and to drafting and editing the manuscript. All authors have approved the final manuscript.

**REFERENCES**

1. Garcia-Moreno C, Jansen HA, Ellsberg M, et al. Prevalence of intimate partner violence: Findings from the WHO multi-country study on women's health and domestic violence. *The Lancet* 2006; 368(9543): 1260-9.
2. Gouws E, Stanecki KA, Lyster R, et al. The epidemiology of HIV infection among young people aged 15-24 years in southern Africa. *AIDS* 2008;22(Suppl 4):S5-16.
3. Shisana O, Rehle T, Simbayi LC, et al. *South African national HIV prevalence, incidence, behavior and communication survey 2008: A turning tide among teenagers?* Capetown: HSRC Press; 2009.
4. Jewkes R, Penn-Kakana L, Levin J, et al. Prevalence of emotional, physical and sexual abuse of women in three South African provinces. *S Afr Med J* 2001; 91(5):421-8.
5. Dunkle KL, Jewkes RK, Brown HC, et al. Prevalence and patterns of gender-based violence and revictimization among women attending antenatal clinics in Soweto, South Africa. *Am J Epidemiol* 2004; 160(3): 230-239.
6. Hindin MJ, Kishor S, Ansara DL. *Intimate partner violence among couples in 10 DHS countries: predictors and health outcomes*. DHS Analytic Studies No. 18. USAID 2008.
7. Blanc AK. The effect of power in sexual relationships on sexual and reproductive health: an

- examination of the evidence. *Stud Fam Plann* 2001;32(3):189-213.
8. Jewkes R, Levin J, Penn-Kekana L. Risk factors for domestic violence: findings from a South African cross-sectional study. *Soc Sci Med* 2002; 55:1603-1617.
  9. Maman SJ, Campbell J, Sweat MD, et al. The intersections of HIV and violence: directions for future research and interventions. *Soc Sci Med* 2000; 50:459-478.
  10. Dunkle KL, Jewkes RK, Brown HC, et al. Gender-based violence, relationship power, and risk of HIV infection in women attending antenatal clinics in South Africa. *The Lancet* 2004; 363: 1415-1421.
  11. Speizer IS, Pettifor A, Cummings S, et al. Sexual violence and reproductive health outcomes among South African female youths: A contextual analysis. *Am J Public Health* 2009; 99(Supp 2): S425-31.
  12. Frye V, Ompad D, Chan C, et al. Intimate partner violence perpetration and condom use-related factors: Association with heterosexual men's consistent condom use. *AIDS Behav* 2011; 15(1):153-62.
  13. Decker MR, Seage G, Hemenway D, et al. Intimate partner violence perpetration, standard and gendered STI/HIV risk behavior, and STI/HIV diagnosis among a clinic-based sample of men. *Sex Transm Dis* 2009; 85:555-560.

14. Amaro H. Love, sex, and power. Considering women's realities in HIV prevention. *Am Psychol* 1995;50(6):437-447.
15. Heise LL, Elias C. Transforming AIDS prevention to meet women's needs: a focus on developing countries. *Soc Sci Med* 1995;40(7):931-943.
16. Tolley EE, Harrison PF, Goetghebeur E, et al. Adherence and its measurement in phase 2/3 microbicide trials. *AIDS Behav* 2010; 14(5):1124-36.
17. Saul J, Moore J, Murphy ST, et al. Relationship violence and women's reactions to male-and female-controlled HIV prevention methods. *AIDS Behav* 2004; 8(2): 207-214.
18. El-Bassel N, Gilbert L, Wu E et al. HIV and intimate partner violence among methadone-maintained women in New York City. *Soc Sci Med* 2005; 61:171-83.
19. Jewkes RK, Dunkle K, Nduna M, Shai N. Intimate partner violence, relationship power inequity, and incidence of HIV infection in young women in South Africa: a cohort study. *Lancet* 2010;376:41-48.
20. Kouyoumdjian FG, Calzavara LM, Bondy SJ et al. Intimate partner violence is associated with incident HIV infection in women in Uganda. *AIDS* 2013; 27:1331-1338.
21. Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. 2010. *N Engl J Med* 363(27):2587-99.

22. Abdool Karim QA, Abdool Karim SS, Frohlich JA, et al. Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women. *Science* 2010;329(5996):1168-74.
23. Institute of Medicine. 2008. *Methodological challenges in biomedical HIV prevention trials*. Washington, DC: The National Academies Press.
24. Weiss HA, Wasserheit JN, Barnabus RV, et al. Persisting with prevention: the importance of adherence for HIV prevention. *Emerg Themes Epidemiol* 2008. 5(8).
25. van der Straten A, Van Damme L, Haberer JE, et al. Unraveling the divergent results of pre-exposure prophylaxis trials for HIV prevention. *AIDS* 2012; 26(7):F13-19.
26. Padian NS, van der Straten A, Ramjee G, et al. Diaphragm and lubricant gel for prevention of HIV acquisition in southern African women: A randomized controlled trial. *The Lancet* 2007;370:251-61.
27. Ramjee G, van der Straten A, Chipato T, et al. The diaphragm and lubricant gel for prevention of cervical sexually transmitted infections: results of a randomized controlled trial. *PLOS One* 2008; 3(10):e3448.

28. van der Straten A, Kang MS, Posner SF, et al. Predictors of diaphragm use as a potential sexually transmitted disease/HIV prevention method in Zimbabwe. *Sex Transm Dis* 2005; 32(1):64-71.
29. Turner AN, van Damme K, Jamieson D, et al. Predictors of adherent use of diaphragms and microbicide gel in a four-arm, randomized pilot study among female sex workers in Madagascar. *Sex Transm Dis* 2009;36(4):249-257.
30. van der Straten A, Cheng H, Moore J, et al. The use of the diaphragm instead of condoms in a phase III diaphragm trial. *AIDS Behav* 2009;13:564-72.
31. Pronyk P, Hargreaves JR, Kim JC, et al. Effect of a structural intervention for the prevention of intimate partner violence and HIV in rural South Africa: A cluster randomized trial. *The Lancet* 2006; 368: 1973-1983.
32. Jewkes R, Nduna M, Levin J, et al. Impact of Stepping Stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: Cluster randomised controlled trial. *BMJ* 2008;337:a506.
33. Dunkle KL, Jewkes R. Effective HIV programming requires gender transformative work with men. *Sex Transm Infect* 2007; 83(3): 173-4.
34. Krishnan S, Dunbar MS, Minnis AM, et al. Poverty, gender inequities, and women's risk for human immunodeficiency virus/AIDS. *Ann NY Acad Sci* 2008; 1136:101-10.

35. Montgomery ET, van der Straten A, Chidanyika A, et al. The importance of male partner involvement for women's acceptability and adherence to female-initiated HIV prevention methods in Zimbabwe. *AIDS Behav* 2011, 15(5): 959-969.

ACCEPTED



## Figure Legends

Figure 1: Prevalence of recent intimate partner violence among women in the MIRA study.

IPV=Intimate Partner Violence

Figures 2a-2c: Estimated probabilities of condom non-adherence in the control arm (a) condom non-adherence in the intervention arm (b) and diaphragm non-adherence in the intervention arm (c) for visits with and without intimate partner violence, based on GEE models. Models adjusted for age, site, number of sex partners, and partner infidelity. Error bars represent 95% confidence intervals. IPV=intimate partner violence, GEE=generalized estimating equations.

ACCEPTED

**Table 1: Baseline characteristics of 4505 women enrolled in the MIRA study**

Characteristic	All (N=4505)	Intimate Partner Violence (N=2448)	No Intimate Partner Violence (N=2057)	P-value
<b>Socio-Demographic Characteristics</b>				
<b>Study Arm</b>				
Intervention	2244 (49.8)	1190 (48.6)	1054 (51.2)	0.08
Control	2261 (50.2)	1258 (51.4)	1003 (48.8)	
<b>Site</b>				
Harare	2325 (51.6)	1256 (51.3)	1069 (52.0)	0.0001
Durban	1351 (30.0)	632 (25.8)	719 (35.0)	
Johannesburg	829 (18.4)	560 (22.9)	269 (13.1)	
<b>Age</b>				
<=24	1654 (39.0)	932 (40.0)	722 (37.7)	0.30
25-34	1702 (40.1)	915 (39.3)	787 (41.1)	
>=35	885 (20.9)	481 (20.7)	404 (21.1)	
Education >High School	1996 (44.2)	1108 (45.3)	884 (43.0)	0.16
Earned income	2408 (56.8)	1357 (58.3)	1051 (55.0)	0.03
Currently married	2736 (60.7)	1482 (60.5)	1254 (61.0)	0.78
Lived with partner	3110 (69.1)	1704(69.6)	1406 (68.5)	0.35
<b># partners last 3 months</b>				
1	4141 (91.9)	2180 (89.0)	1961 (95.3)	0.0001
2 or more	364 (8.1)	268 (11.0)	96 (4.7)	
Exchanged sex for money, food, drugs, shelter	238 (5.3)	163 (6.7)	75 (3.6)	0.0001
HIV seroconversion during the trial	88 (2.0)	52 (2.1)	36 (1.8)	0.33
<b>Completed closing visit</b>				
Yes	4368 (97.0)	2369 (96.8)	1999 (97.2)	0.2
No	137 (3.0)	79 (3.2)	58 (2.8)	
<b>Number of visits reporting IPV</b>				
1	--	1476 (60.3)	--	
2	--	778 (31.8)	--	
3	--	194 (7.9)	--	
<b>Partner Characteristics</b>				
<b>Partner older</b>				
<5 years	1986 (48.7)	1065 (47.5)	921 (50.1)	0.18
5-9 years	1470 (36.0)	836 (37.3)	634 (34.5)	
10+ years	625 (15.3)	341 (15.2)	284 (15.4)	
Partner away > 1 month	1249 (29.6)	743 (32.0)	506 (26.6)	0.0001
<b>Partner infidelity</b>				
Knows/suspects	1340 (29.7)	938 (38.3)	402 (19.5)	0.0001
No	1201 (26.7)	528 (21.6)	673 (32.7)	
Don't know	1964 (43.6)	982 (40.1)	982 (47.7)	

Characteristic	All (N=4505)	Intimate Partner Violence (N=2448)	No Intimate Partner Violence (N=2057)	P-value
Partner had sex under influence of alcohol or drugs	1539 (36.5)	981 (42.2)	1539 (29.4)	0.0001
Partner HIV+				
Yes	134 (3.2)	81 (3.5)	53 (2.8)	
No	3048 (71.9)	1604 (68.9)	1444 (75.6)	
Don't know	1055 (24.9)	642 (27.6)	413 (21.6)	0.0001
Partner employment				
Employed	3312 (78.2)	1816 (78.0)	1496 (78.3)	
Unemployed	762 (18.0)	413 (17.7)	349 (18.3)	
Student	88 (2.1)	51 (2.2)	37 (1.9)	
Other/Don't know	75 (1.8)	47 (2.0)	28 (1.5)	0.41

Intimate Partner Violence defined in this table as any fear or experience of intimate partner violence reported at  $\geq 1$  visit. All values shown represent numbers (%) unless otherwise stated.

Data missing for 173 participants for income, 313 participants for partner age, 186 participants for partner away, 173 participants for partner employment, 175 participants for partner had sex under influence of alcohol or drugs, 173 participants for whether partner had HIV infection.

**Table 2: Effect of Exposure to IPV on Each Non-Adherence Outcome: GEE Results<sup>1</sup>**

IPV Indicator	Condom non-adherence in control arm		Condom non-adherence in intervention arm		Diaphragm non-adherence	
	OR (95% CI)	aOR (95% CI) <sup>2</sup>	OR (95% CI)	aOR (95% CI) <sup>2</sup>	OR (95% CI)	aOR (95% CI) <sup>2</sup>
Any IPV (vs. none)	1.47 (1.29-1.65)	1.41 (1.24-1.61)	1.43 (1.25-1.63)	1.47 (1.28-1.69)	1.31 (1.13-1.50)	1.24 (1.06-1.45)
Fear of Violence (vs. none)	1.49 (1.3-1.71)	1.45 (1.26-1.68)	1.36 (1.18-1.57)	1.37 (1.18-1.59)	1.41 (1.20-1.66)	1.28 (1.07-1.53)
Emotional Abuse (vs. none)	1.40 (1.22-1.60)	1.34 (1.16-1.54)	1.29 (1.11-1.49)	1.34 (1.16-1.54)	1.31 (1.12-1.55)	1.31 (1.09-1.56)
Physical Violence (vs. none)	1.44 (1.18-1.76)	1.39 (1.13-1.70)	1.65 (1.33-2.04)	1.66 (1.33-2.08)	1.47 (1.16-1.86)	1.26 (0.97-1.64)
Forced Sex (vs. none)	2.15 (1.74-2.66)	1.99 (1.59-2.48)	1.55 (1.22-1.96)	1.56 (1.22-1.99)	1.30 (1.01-1.68)	1.35 (1.02-1.78)
Any physical or sexual IPV (vs. none)	1.75 (1.48-2.07)	1.66 (1.39-1.98)	1.60 (1.34-1.92)	1.66 (1.39-1.98)	1.36 (1.12-1.65)	1.28 (1.03-1.58)

IPV=Intimate partner violence, OR=Odds Ratio (unadjusted), aOR=adjusted Odds Ratio, CI=Confidence Interval, GEE=Generalized estimating equations

<sup>1</sup>Separate models fit for each of the six IPV types and indicators

<sup>2</sup>Adjusted models controlled for age, site, number of sex partners, male partner infidelity

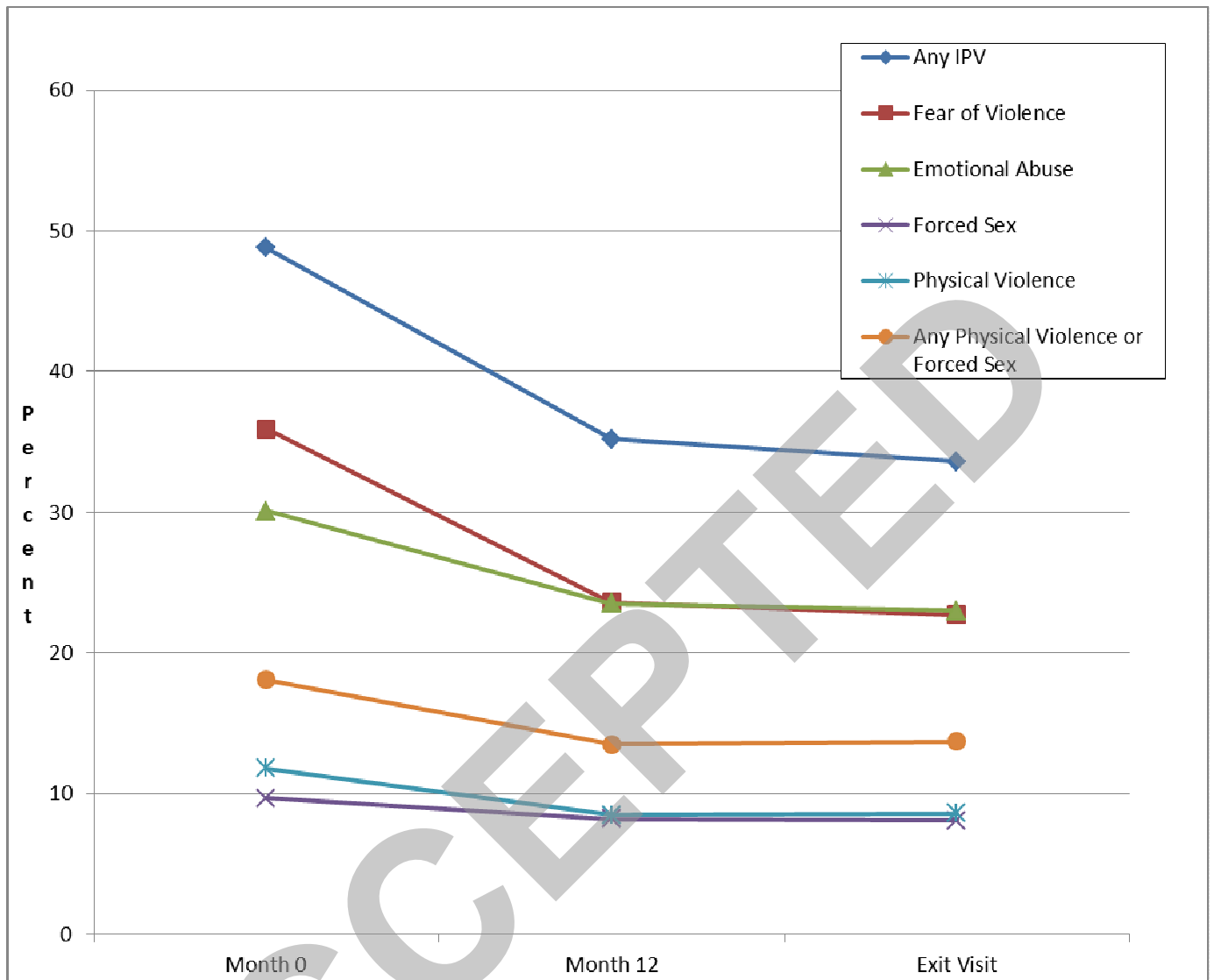
**Table 3: Effect of change in IPV exposure from baseline to 12 months and condom and diaphragm non-adherence at 12 months**

	Condom non-adherence in control arm		Condom non-adherence in intervention arm		Diaphragm non-adherence	
	OR (95% CI)	aOR(95% CI)	OR (95% CI)	aOR(95% CI)	OR (95% CI)	aOR(95%CI)
<b>Any IPV</b>						
Persisting	2.33(1.67-3.22)	2.2 (1.54-3.1)	1.54 (1.09-2.17)	1.53 (1.06-2.2)	2.17(1.56-3.12)	2.0 (1.39-2.9)
Incident	1.75 (1.15-2.7)	1.69(1.08-2.6)	1.25 (0.77-2.0)	1.2 (0.74-1.95)	1.45 (0.90-2.27)	1.42 (0.88-1.3)
Remitting	1.47 (1.06-2.04)	1.38 (0.99-1.94)	0.95 (0.68-1.33)	0.99 (0.7-1.39)	1.61 (1.16-2.27)	1.51 (1.07-2.1)
None	1.00	1.00	1.00	1.00	1.00	1.00
<b>Fear of Violence</b>						
Persisting	2.08 (1.41-3.03)	1.88 (1.25-2.8)	1.23 (0.81-1.89)	1.22 (0.79-1.89)	1.64 (1.09-2.5)	1.38 (0.9-2.1)
Incident	2.08 (1.37-3.12)	2.0 (1.32-2.1)	1.61 (1.01- 2.63)	1.61 (0.99-2.6)	2.04 (1.27-3.23 )	1.98 (1.23-3.2)
Remitting	1.79 (1.28-2.44)	1.67(1.2-2.3)	1.09 (0.79-1.51)	1.15 (0.82-1.6)	1.72 (1.23-2.38)	1.55 (1.11-2.2)
None	1.00	1.00	1.00		1.00	1.00
<b>Emotional Abuse</b>						
Persisting	2.08(1.41-3.03)	2.0 (1.37-3.1)	1.45 (0.94-2.27)	1.36 (0.87-2.1)	2.33 (1.47-3.70)	2.3 (1.43-3.7)
Incident	1.39 (0.91-2.13)	1.25 (0.80-1.95)	1.49 (0.92-2.38)	1.4 (0.86-2.3)	1.41 (0.89-2.22)	1.34 (0.83-2.2)
Remitting	1.09 (0.77-1.52)	1.02 (0.72-1.46)	1.19 (0.83-1.72)	1.2 (0.82-1.74)	1.18 (0.83-2.87)	1.09 (0.76-2.58)
None	1.00	1.00	1.00	1.00	1.00	1.00
<b>Physical Violence</b>						
Persisting	2.08 (0.88-5.0)	1.73 (0.72-4.2)	1.32 (0.59-2.94)	1.33 (0.59-3.0)	2.70 (1.08-6.67)	2.4 (0.97-6.1)
Incident	1.25 (0.72-2.17)	1.12 (0.64-1.98)	2.0 (1.09-3.85)	1.97 (1.01-3.8)	1.15 (0.65-2.04)	1.05 (0.58-1.91)
Remitting	1.41 (0.92-2.17)	1.37 (0.88-2.1)	1.05 (0.66-1.67)	1.07 (0.67-1.70)	1.37 (0.87-2.17)	1.26 (0.78-2.0)
None	1.00	1.00	1.00	1.00	1.00	1.00
<b>Forced Sex</b>						
Persisting	4.35 (1.79-10.0)	3.9 (1.6-9.6)	4.35 (1.27-14.3)	4.1 (1.21-14.0)	2.08 (0.82-5.26)	2.1 (0.82-5.5)
Incident	1.64 (0.93-1.86)	1.53 (0.58-2.8)	2.08 (1.01-4.35)	1.94 (0.94-4.0)	1.67 ( 0.86-3.23)	1.8 (0.93-3.6)
Remitting	1.75 (1.06-2.86)	1.71 (1.03-2.8)	1.45 (0.85-2.5)	1.36 (0.8-2.3)	1.37 (0.82-2.27)	1.3 (0.79-2.3)
None	1.00	1.00	1.00	1.00	1.00	1.00

Physical Violence  
or Forced sex

Persisting	2.69 (1.45-4.98)	2.4 (1.25- 4.5)	2.16 (1.14-4.08)	2.2 (1.14-2.1)	2.29 (1.23-4.25)	2.1 (1.11-3.9)
Incident	1.62 (1.01-2.59)	1.48 (0.91-2.4)	1.84 (1.04-3.25)	1.74 (0.97-2.3)	1.31 (0.77-2.20)	1.28 (0.75-2.2)
Remitting	1.60 (1.10-2.34)	1.53 (1.04-2.3)	1.19 (0.80-1.77)	1.13 (0.75-1.7)	1.34 (0.90-1.99)	1.32 (0.88-1.9)
None	1.00	1.00	1.00	1.00	1.00	1.00

IPV=Intimate partner violence, OR=Odds Ratio, aOR=adjusted Odds Ratio, CI=Confidence Interval; <sup>1</sup>Separate models fit for change from baseline to 12 months in exposure to each of the six IPV types and indicators; <sup>2</sup>Adjusted models controlled for age, site, number of sex partners, male partner infidelity at baseline.



**Figure 1. Prevalence of Recent Intimate Partner Violence Among Women in the MIRA Study.** IPV=Intimate Partner Violence

Figure 2 (a)

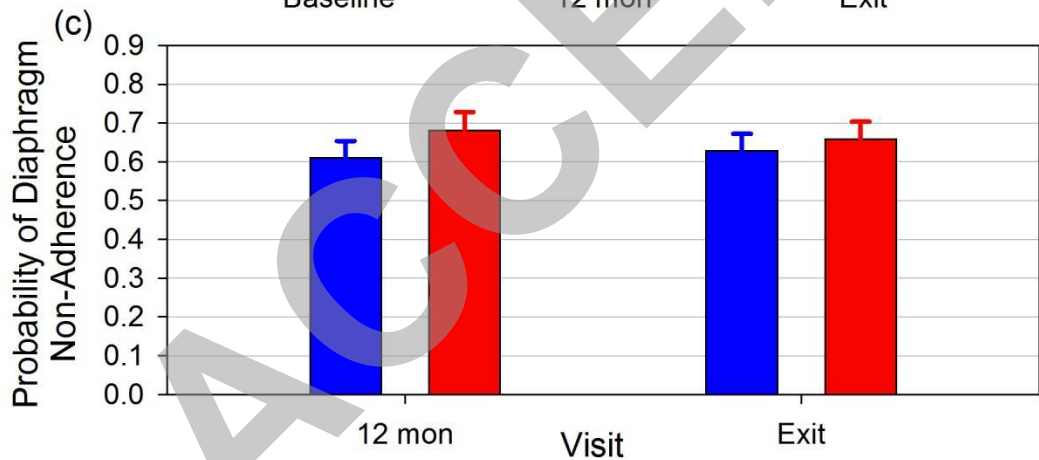
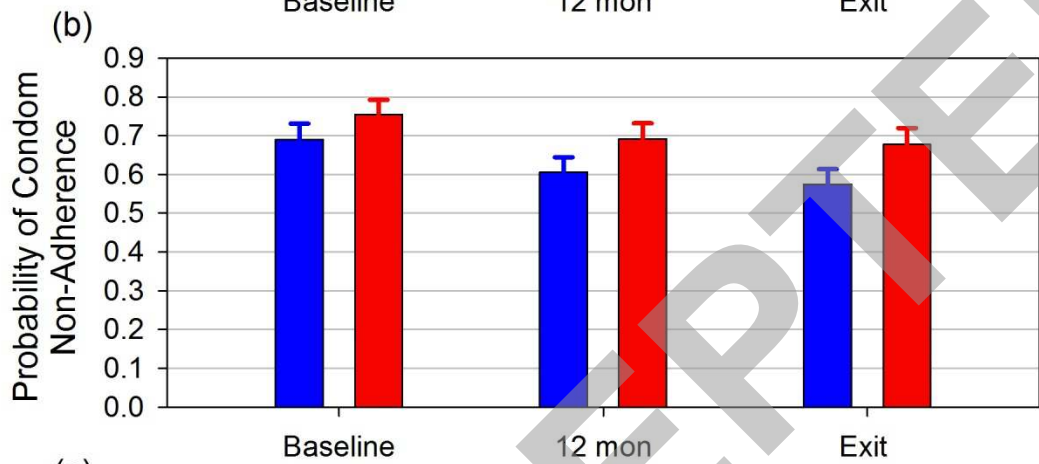
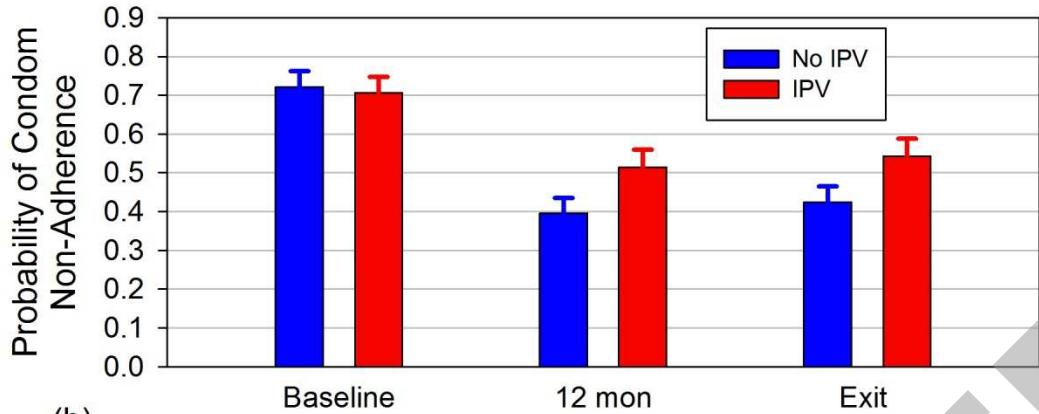


Fig. 2a-2c: Estimated probabilities of condom non-adherence in the control arm (a) condom non-adherence in the intervention arm (b) and diaphragm non-adherence in the intervention arm (c) for visits with and without intimate partner violence, based on GEE models. Models adjusted for age, site, number of sex partners, and partner infidelity. Error bars represent 95% confidence intervals. IPV=intimate partner violence, GEE=generalized estimating equations.