

A QUALITATIVE STUDY OF OBSTACLES TO DIAPHRAGM AND CONDOM USE IN AN HIV PREVENTION TRIAL IN SUB-SAHARAN AFRICA

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Consistent condom use and the substitution of condoms with potential HIV prevention methods of lower or unknown effectiveness are important concerns in the development of new prevention technologies. This qualitative study explored obstacles to consistent condom use with the diaphragm in MIRA, an HIV prevention trial in South Africa and Zimbabwe. We conducted 26 focus group discussions (FGDs) with 206 women and 7 FGDs and 10 in-depth interviews with 41 male partners of intervention-

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The MIRA trial was funded through Grant 21080 from the Bill and Melinda Gates Foundation.

The authors thank the women and men who participated in the MIRA Social Science study as well as all of the women who participated in the MIRA trial. We are grateful for the contributions of the MIRA team. The principal investigator of the MIRA study was Nancy Padian, trial co-principal investigators and site investigators were Ariane van der Straten, Gita Ramjee, Kelly Blanchard, Tsungai Chipato, and Guy de Bruyn. The MIRA Social Science team included Deborah KacaneK, Kelly Blanchard, Chiweni Chimbwete, Amanda Dennis, Naomi Lince, Sarah Martin, Kate Miller, Tanusha Mudlay, Ethel Qwana, Mthoko Radebe (Ibis Reproductive Health); Neetha Morar, Nonkqubela Bantubani, Victor Dladla, Nolwazi Dlamini, Sibusiso Dumisa, Samanta Edward, Nkosinathi Ngcobo, Prinsloo Ngobeni, Jessica Phillip, Xolani Sithole (HIV Prevention Research Unit, Medical Research Council); Jane Munyoro, Khanyisile Bakam, Beatrice Leballo, Phindile Maesela, Busi Nkala (Perinatal HIV Research Unit, University of the Witwatersrand); Sibongile Mtetwa, Agnes Chidanyika, Rhumbidzai Chiurayi, Audrey Shava (University of Zimbabwe-University of California San Francisco Collaborative Programme); Nuriye Nalan Sahin-Hodoglugil, Elizabeth Montgomery, Jennifer Tuveson, Ariane van der Straten (University of California-San Francisco). Special thanks to Helen Cheng for statistical support. For D. KacaneK most work for this study was conducted at Ibis Reproductive Health. For E. Montgomery, N.N. Sahin-Hodoglugil, 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.

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arm women. The belief that the diaphragm/gel prevented HIV, women's difficulties negotiating condom use, and men's unawareness that using the products together was recommended were obstacles to consistent condom use with the diaphragm/gel. Concerns about protection from HIV and pregnancy, recognition that the diaphragm was not yet proven to prevent HIV or sexually transmitted infections, and the trial context were facilitators. Understanding selective study product use in HIV prevention trials may inform improved adherence counseling and male involvement strategies.

In 2009, 69% of the estimated 2.6 million women, men and children newly infected with HIV worldwide were in Sub-Saharan Africa. In South Africa, young women 15-24 years of age are over three times more likely than young men to be infected with HIV (UNAIDS, 2010). Although condoms are proven methods of HIV prevention, consistent use can be challenging as men may be unwilling to wear condoms, particularly in stable relationships, and women can face significant obstacles to negotiating their use (Buck et al., 2005; MacPhail & Campbell, 2001; Maharaj et al., 2001). Since the early 1990s, research has been under way to promote the female condom and to develop and test new female-initiated methods of HIV/STI prevention, including microbicides, the diaphragm, and other cervical barriers, which held some promise of giving women new tools to protect their health.

Consistent use of condoms and the substitution of condoms with potential HIV prevention methods of lower or unknown effectiveness are two important concerns in clinical trials and policy debates about female-initiated methods of HIV prevention. Promotion of new HIV prevention alternatives to the condom may lead to product substitution, a form of "risk compensation" in which women and men shift from condom use to less effective prevention methods, which could spur an increase in HIV infections (Cassel, Halperin, Shelton, & Stanton, 2006; Orner et al., 2006). Others argue that couples need multiple prevention options, which, if used, could increase the overall proportion of protected sex acts and thus reduce HIV infections (Foss, Vickerman, Heise, & Watts, 2003). Quantitative studies have identified factors associated with acceptability of and adherence to the diaphragm (Behets et al., 2005; Luchters et al., 2007; Okal et al., 2008; van der Straten et al., 2005; van der Straten et al., 2008; van der Straten, Shiboski, 2009) and recent qualitative studies shed light on contextual factors influencing adherence to microbicides used with condoms (C.M. Montgomery et al., 2008). In Zimbabwe, condom use did not decline with the introduction of the diaphragm in a study setting (Posner, van der Straten, Kang, Padian, & Chipato, 2005). However, in one mixed-methods analysis of the same sample, women reported that their male partners did not want to use two barrier products simultaneously (Kang et al., 2007) and some focus group participants in a tenofovir gel trial suggested they would stop using condoms if the tested product prevented HIV (Rosen et al., 2008). Conversely, a mixed method study of a microbicide/diaphragm combination product in South Africa (Guest et al., 2007) showed an increase in condom use over 6 months, attributed to a commitment to the trial procedures, male involvement, and the availability of free condoms. Little is known about the social conditions inhibiting consistent and concurrent use of multiple products and product substitution in a prevention trial context, which requires respondents to use the products over an extended period.

In this article we use qualitative data from the Methods for Improving Reproductive Health in Africa (MIRA) trial to investigate women's and men's perceptions of factors shaping their consistent and inconsistent use of the Ortho all-flex

diaphragm, Replens lubricant gel, and condoms, with particular attention to their accounts of product substitution, defined as using the diaphragm/gel without condoms. The MIRA trial, which tested the effectiveness of the diaphragm for HIV prevention in South Africa and Zimbabwe, was unable to demonstrate any additional protection in the intervention (diaphragm, lubricant gel and condom) arm against HIV infection compared with the control (condoms only) arm (Padian et al., 2007). Furthermore, there was significantly lower condom use at last intercourse in the intervention arm than in the control arm (Padian et al., 2007). A recent analysis showed that 83% of intervention arm women reported at least one act of product substitution (ever using the diaphragm instead of condoms) during their participation in the trial (van der Straten, Cheng et al., 2009).

Using qualitative approaches to understand the motivations and context shaping use of the diaphragm and condoms, as well as product substitution, is critical not only for interpreting the results of the MIRA trial, but for informing future HIV prevention trials where condoms and investigational study products are both intensively promoted. It is also important for the development and rollout of new female-initiated HIV prevention methods (Posner et al., 2005). If proven effective in prevention trials, these methods are likely to confer only partial protection and thus will be promoted in “real life” settings to be used in combination with condoms.

This analysis examines attitudinal, interpersonal, and contextual obstacles to and facilitators of women’s and male partners’ consistent use of condoms alone and concurrently with the diaphragm/gel. Consistent use refers herein to using the products for every act of sexual intercourse, and concurrent use refers to using the diaphragm, gel and condoms at the same time, as was recommended for MIRA intervention-arm participants.

METHODS

STUDY SETTING

The MIRA trial was an open-label multisite, randomized controlled trial conducted with 5,039 sexually active, aged 18-49, HIV-negative women. Participants were enrolled at five clinics in three locations: Johannesburg (Soweto) and Durban (Botha’s Hill and Umkomaas), South Africa; and Harare (Epworth and Chitungwiza), Zimbabwe. Women were randomly assigned to the diaphragm, gel and condoms (intervention) arm or condoms-only (control) arm. Women participating in the MIRA trial were asked to provide written permission for study staff to contact their male partners to invite them to participate in the Social Science Study. Participants were followed up at quarterly clinic visits for up to 24 months and received product adherence and risk reduction counseling; free condoms, including flavored condoms; HIV/ STI testing and treatment of curable sexually transmitted infections (STIs) at each clinic visit. Participants were counseled that they should not use the diaphragm and gel alone for contraception. One year into the trial, staff offered oral contraceptives and Depo-Provera free of charge to interested participants. The methods and primary and secondary results of the MIRA trial are described in detail elsewhere (Padian et al., 2007; Ramjee et al., 2008).

STUDY DESIGN AND SAMPLE

This analysis uses data from the MIRA Social Science Study component, which was conducted with exited participants from all five MIRA clinics, using qualita-

tive research methods, to investigate female participants' and their male partners' experiences with the trial, and perceptions and experiences with the use of the diaphragm, gel, and condoms. The study received ethical approval by the University of California at San Francisco (UCSF) Institutional Review Board Committee on Human Research, the Biomedical Research Ethics Committee of the University of KwaZulu-Natal, the Human Research Ethics Committee of the University of the Witwatersrand, the Medical Research Council of Zimbabwe, the Medicines Control Authority of Zimbabwe, and the Western Institutional Review Board.

We analyzed data from 26 focus group discussions (FGDs) conducted between August 2006 and January 2007 with 206 women, 14 FGDs with exited intervention-arm participants ($n = 105$), and 12 with exited control-arm participants ($n = 101$), as well as 7 FGDs and 10 in-depth interviews (IDIs) with 41 male partners of intervention-arm participants. An average of nine participants were in each FGD (range: 4-12 participants). Women were eligible to participate if they were HIV-negative at their last MIRA trial visit and fewer than nine months had elapsed since that visit. Staff at each site systematically sampled from a list of eligible women to invite participation. The participation rate was 60% for women. Reasons for not participating included employment commitments, relocation out of the area, and lack of interest. To generate a sample of eligible male partner participants, staff at each site compiled a list of women in the intervention arm who had provided permission earlier in the trial for staff to contact their male partners, and who met the eligibility criteria above. A systematic sample of women was selected from this list and their male partners were invited to participate. The participation rate was 14% for men. Staff, particularly at the South Africa sites, experienced challenges recruiting men into FGDs; women had new partners who were not aware of her trial participation and use of the product; several men reported not wanting to discuss personal issues in front of other men, not wanting to come to the MIRA clinic because they perceived it as a women's clinic and did not know men were welcome; other men had relocated (Mtetwa et al., 2007). To address these challenges, in Durban and Johannesburg, we modified the protocol and after ethical approval we conducted IDIs instead of FGDs with men.

DATA COLLECTION

The focus groups and interviews were conducted by trained moderators in Shona in Zimbabwe, isiZulu in Durban, and isiZulu and Sotho in Johannesburg. MIRA Social Science staff received standardized training on the protocol, qualitative interviewing methods, coding and analysis. A moderator and note-taker at each site conducted the 60-90-minute focus groups using a structured discussion guide. The guide topics addressed included acceptability and feasibility of diaphragm, gel, and condom use; adherence to product use; partner dynamics and decisionmaking surrounding the use of study products; covert use of the diaphragm; contraception; and posttrial product use. Prior to starting the discussion, participants signed an informed consent form. All FGD were digitally recorded, transcribed verbatim, and translated into English. Translated texts were reviewed twice for accuracy and clarity; once at the site and again by the coordinating team in the United States.

DATA ANALYSIS

Staff from each site and the U.S. coordinating team together developed, tested, and refined a codebook on themes of acceptability and feasibility of diaphragm, gel and condom use. Each group member applied the initial set of thematic codes to a common transcript, and the codebook was refined through an iterative process in-

cluding adding or modifying code names, categories and definitions, until the group agreed on a common set of codes. To establish coding consistency at the beginning of the coding process, two different coders (one at a site and one from the coordinating team) each coded the same transcript and exchanged their coded transcript. A third person identified the discrepant portions and convened conference calls during which discrepancies were discussed and resolved through consensus and the final codes were entered into Atlas.ti.

Modified grounded theory (Glaser & Strauss, 1967) and thematic analysis approaches informed our coding and analysis strategy. Guided by our research questions, we developed thematic codes, reviewed the cross-site data, identified and summarized important subthemes, and extracted illustrative quotes. Data from women in each arm and from men were analyzed separately to explore emergent themes in each group. Diaphragm and gel use were highly correlated (van der Straten, Shiboski, et al., 2009); thus, in this analysis, the term *diaphragm* refers to the diaphragm and gel together.

In addition to the qualitative analysis we also calculated frequencies of baseline socio-demographic characteristics and behaviors reported at the exit visit by women participants and women whose male partners participated in the Social Science Study, as well as other trial participants who did not enroll in the MIRA Social Science Study using SAS statistical analysis software, Version 9.1.

RESULTS

SAMPLE CHARACTERISTICS

Of the 206 women participating in the qualitative study, nearly half (41%) had greater than high school education, half (51%) were married, and 62% lived with their primary sexual partner (Table 1). At the time of their MIRA trial exit visit, nearly all women (92%) reported having one male sexual partner, 58% reported consistent condom use, and nearly half (46%) reported using condoms for contraceptive purposes since their most recent study visit. Among women in the MIRA Social Science Study who were in the intervention arm ($n = 105$), less than half (41%) reported consistent use of the diaphragm at study exit, and a third reported product substitution in the 3 months prior to their exit visit (data not shown). Characteristics of women who took part in the Social Science Study were similar to the full MIRA trial sample. The 41 women in the intervention arm whose male partners participated in FGDs and IDIs appeared to report higher rates of consistent diaphragm use than other MIRA trial participants (65.8% vs. 52.5%).

INFLUENCES ON INCONSISTENT CONCURRENT PRODUCT USE

Attitudinal, interpersonal, and contextual factors precluded some women and men from using the products concurrently. We did not observe substantive differences in these themes by site. Several participants reported alternating use of the diaphragm with use of the condom for various reasons: Some men reported not knowing they were supposed to use all products together, while others believed there were situations when they did not need to because of low risk perception or a belief that the diaphragm was protective when used alone. Women and men reported inconsistent product use depending on their mutual agreement, their own or their partner's mood, or what products happened to be available at the time. One man in Harare said:

TABLE 1. Sample Characteristics of MIRA Social Science Study Participants and Nonparticipants

Characteristic	Participants in Social Science Study			Trial Participants Not in Social Science Study (<i>n</i> = 4,791)
	Women in Focus Group Discussions (<i>n</i> = 206)	Women Whose Male Partner Participated (<i>n</i> = 41)	Total ^a (<i>n</i> = 243)	
At baseline (screening or enrolment)				
Age ^b				
<24 years	70 (34.2)	14 (34.2)	83 (34.3)	1,847 (38.6)
25-34 years	90 (43.9)	21 (51.2)	109 (45.0)	1,861 (38.8)
>35 years	45 (21.9)	6 (14.6)	50 (20.7)	1,083 (22.6)
Education > high school ^b	85 (41.3)	17 (41.5)	100 (41.2)	2,112 (44.1)
Site ^b				
Harare	80 (38.8)	27 (65.8)	105 (43.2)	2,394 (50)
Durban	91 (44.2)	7 (17.1)	96 (39.5)	1,413 (29.5)
Johannesburg	35 (16.9)	7 (17.1)	42 (17.3)	984 (20.5)
Earned income, past year	95 (46.3)	27 (65.9)	120 (49.2)	2,691 (56.3)
Married ^b	105 (50.9)	30 (73.2)	133 (54.7)	2,837 (59.2)
Living with main partner ^b	128 (62.1)	32 (78.1)	158 (65.0)	3,242 (67.7)
Partner alcohol use during sex	65 (31.7)	17 (41.5)	81 (33.5)	1,711 (35.9)
Knows or suspects partner had other partners	65 (31.6)	11 (26.9)	73 (30.1)	1,479 (31.0)
At exit				
1 male sex partner, past 3 months	177 (92.7)	35 (92.1)	209 (92.9)	3,966 (93.8)
Had at least one new main partner during the study period	68 (33.5)	15 (37.5)	82 (34.3)	1,663 (35.6)
Used condoms, last vaginal sex	147 (76.9)	23 (60.5)	166 (73.8)	3,070 (72.6)
Condom use always, past 3 months	111 (58.1)	28 (73.7)	136 (60.4)	2,505 (59.2)
Contraceptive use (multiple methods allowed) ^b				
Tubal ligation	11 (5.4)	0 (0.0)	11 (4.6)	223 (4.9)
Injectable	60 (29.4)	13 (32.5)	72 (30)	1,208 (26.7)
Combined oral contraceptive pills	40 (20)	9 (22.5)	48 (20)	1,214 (27.0)
Progestin only pills	13 (6.3)	5 (12.5)	18 (7.5)	289 (6.4)
Condom	97 (45.5)	13 (32.5)	108 (45.0)	1,757 (38.8)
Diaphragm	19 (9.3)	3 (7.5)	20 (8.3)	238 (5.3)
Other	2 (1.0)	0 (0.0)	2 (0.8)	82 (1.8)
Believe diaphragm protects from HIV ^b	73 (35.9)	14 (34.2)	86 (35.8)	1306 (32.0)

Notes. ^aTotal is not the sum of the two subgroups because four women who participated in focus group discussions also had male partners who participated. ^bQuestions asked using face-to-face interview. All other questions were asked using audio computer-assisted self-interview.

They go hand in hand. It's 50-50. Some day you use the condom and the other day you use the diaphragm.

Male Partner Study Knowledge and Risk Perception. Some men were unaware that the study recommended using condoms with the diaphragm for every sex act.

I did not understand initially about using the diaphragm and condoms. [I thought] we were supposed to use diaphragm and condoms separately. (man, Harare)

A male participant in Durban said his partner's participation in the study and her reported negative HIV and STI tests at each visit reinforced their perception that their sporadic product use behavior was protective.

We use [diaphragm/gel] at other times and we don't use at other times because we trust each other, because she is in the study, and we can see that there is no disease.

Sexual Pleasure. Experimentation, sexual pleasure, and physical sensation were additional attitudinal and physical factors underlying inconsistent concurrent product use. Some wanted to experiment and see how it felt to use the diaphragm only. They also said that diaphragm use alone enhanced sexual pleasure while using both products at once was “bulky” and precluded a “skin to skin” experience for both men and women.

Why can't we use one [either the diaphragm or the condom]? If you take out the diaphragm, use a condom and if you put on the diaphragm take out the condom. (man, Durban)

Some women in the intervention arm and men resisted using a condom in addition to the diaphragm because they could not conceive of the utility of multiple products in the vagina.

I do not remember that there is somebody who can be able [to] insert the diaphragm and the gel and again . . . another thing on the side . . . The diaphragm and the gel alone in the vagina I do not think that there is another thing you can again use to help on top of that. (woman, intervention arm, Durban)

Men echoed the perception that concurrent use of two barrier methods was cumbersome and interfered with their own or their partner's sexual pleasure.

When we use condoms, she becomes dry after some time and she complains that she is being hurt. (man, Johannesburg)

Men also reported that they themselves disliked condoms because they were uncomfortable, burst, and made sex unpleasurable. One man noted that products used in combination might cause harmful chemical interactions.

These condoms have some oils and . . . if they are the same with the gel and if they are mixed you don't know what will come out which might cause some unknown effects, so as for me, I never used all three [products] at once. (man, Harare)

Determining Product Efficacy. A few women questioned the scientific value of using the products together. If they used the condom together with the diaphragm it would not be possible to determine the efficacy of the diaphragm in preventing HIV.

So, how are you going to know if the diaphragm can prevent the transmission of the HIV virus when we use the diaphragm and the condom together? (woman, intervention arm, Harare)

Another participant said:

What I did not like was the addition of the condoms because we had to know how the diaphragm worked. Because when we used it with a condom, we will not see what worked between them. (woman, intervention arm, Durban)

Diaphragm as Protection From Infection. Some intervention-arm women reported relying solely on the diaphragm for HIV prevention. They believed the diaphragm provided some protection to them but also stated that using all products was optimal.

This is still . . . research to find if it can truly prevent from the virus or if it cannot. So, you just have to keep on using them. But, in my opinion, I think that it works. (woman, intervention arm, Harare)

Women in both study arms described the diaphragm as a reliable method that women could control and use for “their own sake,” to protect themselves consistently on days when their partners were not in the mood for condoms or adamantly refused to use them or when supplies of condoms ran out.

Sexual Violence. Sexual violence was a theme in some women’s descriptions of unpredictable circumstances when diaphragm use without condoms was viewed as a backup method of protection from HIV/ STIs, even though its effectiveness was not yet proven. A few women at the South Africa sites described fears of being raped by strangers and considered the diaphragm a means within women’s control to protect themselves from disease.

Participant F: I prefer the diaphragm and gel 100% because if I get raped I cannot say “use a condom” to him.

Participant D: May I ask you, do you insert the diaphragm every day?

Participant F: As we are sitting here and I am talking to you, it is inside me. At night when I will bathe, it will also bathe. (women, intervention arm, Johannesburg)

Sexual Relationship Factors: Men’s Nonuse and Deceptive Use of Condoms. Women described other unpredictable circumstances in which they worried about condom malfunctions, distrusted men’s use of condoms and favored the diaphragm to protect themselves from HIV and pregnancy. A prominent theme was that condoms were unreliable and men were untrustworthy. For example, some women reported that their male partners surreptitiously tore or pricked holes in condoms to sabotage contraception, or in a few cases, to purposely infect them with HIV.

He does . . . things at times tearing the condom so that you have sex with him thinking that you are protected when you are not. (woman, intervention arm, Harare)

Men’s unwillingness to use condoms, ranging from not being in the mood to blatant refusal to use them, was the most prominent interpersonal influence on use of the diaphragm without condoms, and in the control arm, non-use of condoms in general. One man said:

The condom requires a lot of work, especially for me. When I am tired and in the mood to have sex . . . the condom [is] something that I don’t agree on. (man, Harare)

Men reported that condom use was inappropriate with their wives and primary partners, but more appropriate with “outside” partners. The suggestion or practice of condom use signified distrust, infidelity, and women’s promiscuity. One man stated:

There is no one to trust if you find yourself using condoms on your wife at home and with one from the world [extramarital partner] you do not. That’s impossible. (man, Harare)

Both women and men reported that men’s refusal of condoms was particularly vehement in situations when they returned home after drinking with friends and demanded sex. In those situations, some women reported refusing to have sex, which

sometimes led to fights and violent responses from their partners. Other women were resigned, saying men had more control and the final say in whether, when, and how they had sex.

Nested in discussions about men's refusal to use condoms was the belief that the diaphragm could be a reliable method of protecting women from HIV and pregnancy. One woman in the intervention arm in Harare said:

I used the diaphragm and gel when my husband was refusing to use the condoms so it is better if I protect myself by using the gel and the diaphragm and because he will not be using the condom.

Men from all sites reported that they rarely used condoms with the diaphragm, and suggested that if they refused to use condoms then women should use the diaphragm.

We weren't using them [condoms] a lot. We were now using the diaphragm. (man, Harare)

Men did not dispute the fact that they refused to use condoms and saw the use of the diaphragm as an option which would protect women.

She is supposed to wear a diaphragm. I think that is the safest method because some men can refuse, some may be drunk. One might be having a problem that is bothering him. So if a woman wears a diaphragm, even if she doesn't tell me, she would stay protected. (man, Harare)

Because men often used women's use of the diaphragm as an excuse for not wearing a condom, some women reported using the diaphragm covertly, as a strategy to encourage condom use (Sahin-Hodoglugil et al., 2009).

Interpersonal influences on condom use, including women's ability to negotiate condom use, were dynamic over time. Women and men emphasized that it was the woman's responsibility to protect herself and to educate men about the study products by coaxing men "nicely" to use them during sex.

You should speak to him in a nice way instead of just saying "use"! You should convince him in the way you convince a small child...explaining to him... And remind him of what fate would befall our family and children if we get the virus. (woman, control arm, Harare)

Some women described intermittent setbacks when they used only the diaphragm after initial attempts to negotiate condom use failed, but eventually their partners became more motivated to use condoms.

At times those men I don't know how they think after fully explaining to him and then ask him to put on a condom the way it will have been explained he later refuses. . .he used to agree at times and at times refuse saying, "I can't eat a sweet in a plastic [use a condom]." At that time that's where I used to put on my diaphragm, but now it's okay he is now number one at using condoms and he at times asks where we are going to get more condoms when the study ends. (woman, intervention arm, Harare)

The study environment appeared to motivate male partners to use condoms when they may have never used them previously, by providing condom counseling and free flavored and standard male condoms at MIRA study sites. Participants reported that

the flavored condoms were a novelty that made sex more enjoyable, and offering men a choice of flavors helped women entice men to use condoms.

Although the diaphragm was often viewed as a preferable alternative to condoms, some women and men reported obstacles to consistent diaphragm use in the context of unplanned sex. These included men's impatience to have sex and the belief that taking the time to ensure the diaphragm was inserted properly would be unfeasible or unacceptable.

Trial Context. For some couples, consistent use of the products was not a problem owing to concerns about protection against disease and pregnancy, and recognition that the diaphragm was not yet a proven HIV/STI prevention method. The trial context, including participants' commitment to the trial purpose and procedures also influenced consistent use of the diaphragm, although not necessarily together with condoms. Eagerness to know the results of the study motivated some women and men to use the diaphragm consistently.

We are still investigating what we entered into since the beginning of the study so we will not stop until we get the results. (woman, intervention arm, Harare)

Among women in the control group the perception that using condoms was an obligation to the study staff reinforced women's beliefs that it was possible to negotiate condom use with their partners, yet highlighted the potential for condom use to discontinue when the study ended.

Participant B: Yes, it's possible because we signed a contract 2 years back and he can't refuse.

Participant C: Mine had a problem. There was a time when I was asked to come with him at the clinic for testing. He got tested and his blood was found with no virus. Then he said there was no need for us to use condoms. I reminded him that we must use condoms until the end of the study, and he asked, "So after the study ends, we won't use them, it will be enough right?" (women, control arm, Harare)

DISCUSSION

In this study, selective product use was commonly reported by trial participants in the intervention arm. Factors operating at the individual, partner, and trial context levels played a key role in situations when participants did not use diaphragm and condoms consistently or concurrently. While alternating use of diaphragm and condoms seemed frequent, and overall product substitution was reportedly high, complete abandonment of condoms in favor of the diaphragm during the trial appeared to be rare in this qualitative component of MIRA. A prominent theme underlying use of the diaphragm without condoms was that women and men viewed the diaphragm as a backup HIV prevention method for women when their partners were unwilling to use condoms, rather than as a replacement method for condom use, consistent with prior studies (Buck et al., 2005; van der Straten et al., 2005). We also observed instances in which participants alternated use of the diaphragm and condoms based on their mood and what products happened to be available, suggesting that offering a range of prevention options that suited couple's needs in different situations could potentially increase overall protected sex acts (Foss et al., 2006). The experiences reported here highlight strategies attempted by women who are in relationships in

which they cannot control condom use or the timing of sex and reinforces the urgent need for a diversity of methods that women can use to prevent the spread of HIV infection and, as a backup, when condom use is not possible.

Although most participants understood that the diaphragm was being researched as a potential HIV prevention method, there was simultaneously a pervasive belief that the diaphragm protected women from HIV, a qualitative finding that is consistent with a quantitative analysis of MIRA trial data, which found an association between belief that the diaphragm protected against HIV and product substitution (van der Straten, Cheng, et al., 2009). Qualitative studies of women participating in prevention trials of other female-initiated methods including a microbicide (Mantell, Morar, Myer & Ramjee, 2006) and a diaphragm/microbicide combination (Behets, Van Damme, et al, 2008) also found that participants perceived the investigational product as protective against sexually transmitted diseases (STDs) and HIV infection, respectively, despite the fact that they were aware that efficacy was not yet established. These results underscore the importance of ongoing counseling during clinical trials to ensure that participants recognize that the method being tested is truly under investigation. It is possible that participants' perception of the diaphragm as protective reflected a belief that researchers would only be testing the diaphragm if they were already confident it conferred some protection against HIV/ STDs. On the other hand, the perception of the diaphragm as protective seemed to be less of a misperception and more a belief that took shape within the context of the trial, and it was reinforced for those who continued to test HIV-negative in subsequent follow-up visits. Additionally, women may have viewed the diaphragm as protective because it represented the most reliable and trustworthy method available to them, when their partners were unwilling to use condoms, used them improperly, or sabotaged condom use.

The trial context also contributed to and detracted from perceptions of protection, as well as the ability to use all products consistently. Repeated negative HIV tests may have reinforced the belief that diaphragms were protecting women (in the intervention arm), as has been reported previously (Mantell et al., 2006), and there was also evidence that male partners would be less willing to use condoms after the study was completed. Men's participation and knowledge about trial procedures was largely mediated by women. Our results showed that some partners of intervention-arm women were unaware of the requirement to use diaphragm and condoms concurrently for every act of sex, which likely undermined adherence. In addition, many men reported that they wanted to be more involved in the trial. Increasing communication between study staff and male partners, early in the context of prevention trials, may help to make male partners true stakeholders and enhance adherence to prevention technologies (Mantell, Stein & Susser, 2008; Montgomery et al., 2011).

Despite the fact that participants often viewed the diaphragm favorably, the unpredictability of sex and men's control of the timing of sex made not only consistent condom use but consistent diaphragm use a major challenge for women. Several studies have explored the acceptability and safety of continuous use of cervical barriers as a microbicide delivery mechanism (e.g., once daily removal for cleaning, followed by reinsertion), which might address some of these challenges (Behets, Turner, et al., 2008; Montgomery et al., 2010).

Discrepancies in fertility intentions between some women and their male partners, as well as men's unwillingness to use condoms, including their occasional use of deceptive strategies, were important obstacles to adherence to condom use in both study arms. The lack of congruence between partners in fertility intentions may

need to be addressed in future prevention trials. One way to do this would be to involve male partners early in the process of trial education and product counseling. Involving male partners at the trial outset may improve condom use and facilitate adherence.

Results of this study should be interpreted in light of several limitations. First, these results can not be generalized to all MIRA participants despite the fact that their characteristics were comparable, because the study acceptance rate, particularly among male partners was low. Second, these findings cannot be generalized to people who did not participate in the trial. Third, given that men were particularly difficult to recruit, and the partners of these men appeared to be more adherent to diaphragm use than other participants, it is likely that the experiences of men who were more opposed to diaphragm use are underrepresented.

CONCLUSIONS AND RECOMMENDATIONS

Results from this study highlight that important challenges exist to consistent use of the condom alone or in combination with the diaphragm in this trial population and that product substitution takes many forms and poses significant challenges to evaluation and promotion of female-initiated prevention methods, particularly in open-labeled trials. Gender power dynamics underpin many of the barriers to consistent concurrent product use we identified and continue to pose challenges for reducing women's susceptibility to HIV infection and for investigating and rolling out new HIV prevention methods that women can control. We found that participation in the trial may have given some women more power to negotiate the use of condoms with the diaphragm as per study requirements, but beyond the duration of the trial, women's ability to negotiate condom use was less clear. As suggested by Woodson and Alleman (2008), HIV prevention trials offer important opportunities to launch ancillary studies and interventions to empower women, and irrespective of overt activities, participation in trials may inherently change gender norms or relationship dynamics for participants. Future research should examine these issues more comprehensively. Our results highlight the important role of social contextual factors in inconsistent concurrent product use. These factors include sexual relationship attributes, couple communication, gender power imbalances, and the trial context, as noted in recent conceptual frameworks for examining use and acceptability of microbicides (Simons-Rudolph, Woodson, & Koo, 2008). Consideration of these factors, as well as attitudinal obstacles to concurrent product use, as described here, is important for crafting successful adherence counseling and male partner involvement strategies in future trials of products, which will be promoted in conjunction with male condoms.

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