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Educating men about vaginal microbicides: considerations from Kenya

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ABSTRACT

Men desire to be involved in their partner's decision-making about vaginal microbicide use. This coincides with women's desire to inform male partners about their microbicide use. Educating men about microbicides may enhance acceptability and generate critical support for the female participants of microbicide trials. In this multiphase mixed-methods study, we adapted an educational intervention on vaginal microbicides and tested it among men (n = 45) to determine its effect on men's knowledge regarding HIV/STI, vaginal microbicides and microbicide trials. We also conducted focus group discussions (FGDs) with the female partners (K=3, n=43) of the study participants and community representatives (K = 2, n = 24) to obtain their views on male partner microbicide education. We analysed FGD data for key themes using content analysis. HIV and vaginal microbicide knowledge scores increased significantly among men after the educational intervention. Both women and men highly supported male partner microbicide education, in the context of existing gender relations, to increase men's understanding about microbicides, promote adherence and help women gain their partners' trust. Complex gender dynamics should be considered when designing male partner educational interventions to improve acceptability and the use of microbicides and other female-initiated HIV prevention methods.

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Male partners; involvement; vaginal microbicides; education; Kenya

Introduction

Male partner involvement has shown promise in various reproductive and maternal health interventions that typically target women (Akama et al. 2018; Doyle et al. 2018; Ngure et al. 2017). For instance, supportive male participation positively influences pregnant women's uptake of prevention of mother-to-child transmission (PMTCT) of HIV services (Akama et al. 2018) and reduces the rate of mother-to-child transmission of HIV (Aluisio et al. 2016; Oyugi et al. 2017). Similar benefits of male partner involvement have been realised in studies on female-initiated HIV prevention methods, with

male partners playing an important role in their decisions regarding joining the study and use of the investigational product (Doggett et al. 2015; Doyle et al. 2018; Mngadi et al. 2014; Montgomery et al. 2011).

Microbicides are topical products designed to be used in the vagina or rectum to prevent HIV acquisition during sex (Karim, Baxter and Karim 2014; Obiero et al. 2012). Microbicides come in various formulations such as gels, films, capsules, tablets and rings (Shattock and Rosenberg 2012). Vaginal microbicides are designed to be femaleinitiated, thus avoiding the need for male partner consent for use (Karim, Baxter and Karim 2014; Mngadi et al. 2014). Currently, microbicide research focuses on antiretroviral-based products, with the most advanced product being the Dapivirine intravaginal ring which is in the open-label extension phase (Baeten et al. 2016: Buchbinder and Liu 2018; Nel, van Niekerk et al. 2016). Though the Dapivirine intravaginal ring has only shown modest efficacy in reducing HIV incidence during phase III trials (Baeten et al. 2016; Nel, van Niekerk et al. 2016), two ongoing open-label extension studies indicate a higher adherence and effectiveness in the real-world setting (Buchbinder and Liu 2018). Thus, microbicides remain an important tool in the HIV prevention agenda as an alternative form of pre-exposure prophylaxis (PrEP) for women who cannot use oral PrEP for health, social, circumstantial or personal reasons. Qualitative studies indicate that women have a higher preference for long-acting PrEP such as intravaginal rings and implants over short-acting formulations such as pills and gels (Luecke et al. 2016). Vaginal microbicides also provide an opportunity for developing multipurpose prevention technologies (MPTs) that protect against HIV, other STIs and pregnancy, an attractive attribute to many young women (Minnis et al. 2018). Past microbicide trials conducted in Kenya include Nonoxynol-9 phase III trials, phase I trial of Vivagel and phase I/II trials of Dapivirine gel and ring (Nel, Bekker et al. 2016; Obiero et al. 2012).

In sub-Saharan Africa, although vaginal microbicides are generally acceptable to men (Kelly et al. 2015), the majority of them desire that their partners involve them in the decision to use a microbicide (Kelly et al. 2015; Schuler and Bukusi 2017). Women also desire to inform partners of their use of female-initiated methods (Lanham et al. 2014; Montgomery et al. 2017). While vaginal microbicides are designed to be femaleinitiated (Karim, Baxter and Karim 2014; Mngadi et al. 2014), men are crucial to the acceptability of female-initiated HIV prevention methods (Montgomery et al. 2015; Succop et al. 2014).

Gender-transformative interventions, communication skills training and raising awareness among men can promote male involvement in reproductive health, thus leading to improved outcomes (Doyle et al. 2018; Shattuck et al. 2011; Tokhi et al. 2018). Community education, couples-counselling and providing microbicide messaging tailored to the male audience are some of the recommended strategies for male engagement to create a supportive environment for women to use microbicides (Kelly et al. 2015; Lanham et al. 2014).

Recruitment activities carried out during two Dapivirine intravaginal gel and ring phase I/II trials in Kisumu, Kenya between 2009 and 2011 revealed that many women desired to inform their male partners of their trial participation despite the fact that this was not a requirement of the study. This highlighted the need for active engagement of male partners during the conduct of vaginal microbicide trials in this community. Microbicide education to increase male partners' awareness of microbicides and microbicide trials could potentially increase the support for women to use microbicides or take part in research. Thus in 2014, we adapted a vaginal microbicide education tool for male partners from materials used to educate women in past microbicide trials and tested the tool among men living in Kisumu, Kenya. In this paper, we seek to describe the effect of the education sessions on the men's knowledge about microbicides and microbicide trials as well as the perceptions of the female partners and the community regarding vaginal microbicides education for men.

Materials and methods

Adaptation of the educational intervention

In the first part of this study, investigators extracted content from brochures, pamphlets and a teaching aid that were used to sensitise women about microbicides during recruitment activities for the Dapivirine microbicide safety and acceptability trials conducted in Kenya and other sub-Saharan African countries (Nel, Bekker et al. 2016). These educational materials were developed by social scientists working in the International Partnership for Microbicides (IPM) trials in collaboration with the trial investigators and the community engagement teams of the various study sites. The extracted content was incorporated into a visual tool which was presented to community representatives during a two-stage iterative process. The community representatives comprised 12 men and 12 women convenience sampled from a pool of opinion leaders who were well versed with the culture, gender and social aspects of communities in Kisumu. The community representatives' feedback was used to compile a culturally appropriate, colourful visual educational tool tailored for male partner education and involvement in clinical trials. In addition, two single-gender focus group discussions (FGDs) of 12 participants each were carried out with community representatives to obtain their views on the suitability of the microbicide content of the educational tool to a male audience, the best approach for presenting the information, possible barriers and how to address them. Note-taking and digital recording were used to document community representatives' views.

The educational intervention

In the second part of the study, 45 men purposively sampled from social gatherings such as bicycle taxi termini, pubs and community-based groups in Kisumu town were invited to take part in the microbicide education sessions. The eligibility criteria included men older than 18 years whose main sexual partner resided in Kisumu and was aged between 18 and 40 years. The men provided written informed consent to take part in one of three interactive group sessions of 15 men each. The education intervention consisted of two parts, whereby the study staff first presented the educational tool in PowerPoint format and then held an open discussion to respond to the participants' questions or provide additional information as necessary. Each of the educational sessions lasted between one and two hours. This educational intervention

focused on vaginal microbicide trials and vaginal microbicide products that had been or were under development by 2014. The education process focused on the microbicide products that were in the clinical trial phase at the time and left out products that were no longer being researched or that were yet to enter clinical trials. Specific content on microbicides as products included what vaginal microbicides are, their importance, types/formulations of microbicides, antiretroviral-based microbicides, how they are used and some of the side effects to be expected. The trial aspects covered included what microbicide clinical trials are and their importance, eligibility for trial participation, randomisation to various trial arms, HIV prevention during trial participation and role of male partner engagement in trials, among others. The education content also touched on the global and local burden of HIV and effective HIV prevention methods in place. This study was conducted after the completion of phase I/II Dapivirine intravaginal gel and ring trials in Kisumu and was thus not in the context of any ongoing trial.

Pre-and post-educational intervention assessment

Immediately before and after the education session, a structured questionnaire was administered to each man in a face-to-face interview to determine change in three knowledge categories, namely HIV/STI prevention, vaginal microbicides and vaginal microbicide trials.

HIV/STI knowledae

Six questions assessed HIV knowledge before and after the microbicide educational intervention. Two of these questions were open-ended and assessed the respondent's knowledge on how HIV infection can be acquired and prevented. The other four guestions related to HIV sero-discordance, existence of a cure for HIV, STIs as risk factors for HIV transmission and whether women were disproportionately affected by HIV in sub-Saharan Africa. For these questions, the participants could respond 'true', 'false' or 'I don't know' for each item.

Vaginal microbicide knowledge

In this category, three multiple response questions assessed participant's knowledge on what microbicides are, the different forms of microbicides and how microbicides work. A respondent could provide more than one correct response for each of these questions. One question assessed the participant's knowledge on whether there was an approved vaginal microbicide in the market, and another question related to the difference in duration of protection offered by a vaginal ring compared to a vaginal gel. The participant could respond 'true', 'false' or 'I don't know' to these questions. One question assessed whether the respondent knew how long it would take for a microbicide to be developed and approved for marketing.

Vaginal microbicide trials

Five questions assessed the participant's knowledge on eligibility for microbicide trials, importance of attending study clinic visits during the trial, voluntariness during trial participation, condom use during microbicide trials, whether women are encouraged to inform male partners about microbicide trial participation and whether microbicide trials had been conducted in Kenya in the past. The participant could respond 'true', 'false' or 'I don't know' to these questions. Additional multiple response questions focused on the importance of vaginal microbicide trials, randomisation of participants to treatment arms and meaning of a drug under trial.

Focus group discussions with female partners

At the end of the educational sessions, each man was asked to invite his main female partner to the research centre for further information about vaginal microbicide trials. These women participated in three FGDs to obtain their views on male partner education as a way of enhancing women's acceptance of vaginal microbicide trials. Focus group topic guides covered sexual partnerships, the involvement of male partners in reproductive health, male education on microbicides and perceptions of male support for female participation in microbicide trials.

Data analysis

Independent transcriptionists transcribed FGD audio-recordings and translated them into English where necessary. Two analysts coded FGD transcripts to identify and describe salient themes in the data. Data were analysed with content analysis (Miles, Huberman and Saldana 1994). Substantive and conceptual categories were generated through an iterative process of reading the data, generating codes based on the data and scientific literature. Through a recursive analytical process, common and divergent themes were identified and major themes summarised in analytical categories (Straus and Corbin 1990).

For the pre- and post-intervention questionnaires, measures of knowledge fell under three overall categories: HIV/STI prevention, vaginal microbicide products and vaginal microbicide trials. The response to each item in both the pre- and post-intervention questionnaires was analysed separately and then summed up to create a score for each of the three categories and determine if the participant demonstrated comprehension of all required points or not. The final knowledge scores could range from 0 to 1, with '1' indicating all responses in that category were correct, and '0' indicating one or more items in the knowledge category was incorrect. A McNemar's chi-square test was used to determine if changes in the proportion of men who demonstrated comprehension before and after the education session were statistically significant at p < 0.05. All the data were then exported and analysed using STATA I/C version 13 (StataCorp. 2013, College Station, TX, USA).

Ethical approval

The study was approved by the Ethics Review Committee of the Kenya Medical Research Institute (KEMRI) and the University of California, San Francisco, Committee on Human Research, and all participants provided written informed consent.

Results

Demographics of the study population

The 45 men who took part in the group education sessions had a mean age of 30.0 years (SD 5.3). Approximately half of the men had attained a primary school level of education, all men reported to have had a main sexual partner and 91% of them lived with their primary partner (Table 1). Of the 45 women invited by their male partners, 43 (95.6%) visited the research centre and presented their invitation coupons. The mean age of the women was 25 years (SD 4.5). The majority of these women (54%) had attained a primary school level of education, while about one-third of them had attained at least a college level of education. A majority of the women had their own small-scale businesses 21 (48.8%), 10 (23.3%) were students and 10 (23.3%) were unemployed (Table 1). The community representatives were adults drawn from a wide range of professions including healthcare workers, social workers, religious leaders, counsellors, teachers, students, local businessmen and women, and administrative officers. Five of the 24 community representatives had served as community advisory board members in previous vaginal microbicide trials in Kisumu. Individual demographic data for the community representatives were not collected.

Change in knowledge following the educational intervention

In the pre-test questionnaire response categories, the men showed highest baseline levels of knowledge in the HIV/STI section. For instance, at baseline, 43 men (95.6%) said the presence of untreated STIs increased one's chances of HIV infection, while 37 men (82.2%) said that a higher proportion of women than men had HIV in sub-Saharan Africa. The men had much lower levels of baseline knowledge regarding microbicides and microbicide trial participation. In the pre-intervention interview, only 7 men (16%) knew the potential ways in which a microbicide could work, compared to 45 men (100%) after the education session. Similarly, only 13 men (27%) knew treatment groups in a vaginal microbicide clinical trial were determined by randomisation prior to the intervention, compared to 35 men (77%) after the intervention.

Table 1. Demographic characteristics of men who received microbicide education, and their partners.

Demographic characteristics	Male participants (N = 45)	Female partners (N = 43)
Mean age (SD) – years	30.0 (± 5.3)	25 (± 4.5)
Highest education level attained	, , , ,	,
Primary	23 (51.1%)	23 (53.5%)
Vocational post-primary	1 (2.2%)	0 (0%)
High school	8 (17.8%)	6 (14%)
Middle-level college	7 (15.6%)	11 (25.6%)
University	6 (13.3%)	3 (7%)
Occupation		
Unemployed	N/A	4 (11.2%)
Housewife		6 (13.3%)
Employed		2 (4.7%)
Student		10 (23.3%)
Businesswoman		21 (48.8%)
Lives with primary partner	41 (91.1%)	N/A
Mean age of main female partner (SD) – years	25.0 (± 4.3)	N/A

Table 2. Pre- and post-education changes in knowledge levels.

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Knowledge category	Pre-test N = 45 (100%)	Post-test N = 45 (100%)	P-value***	
HIV/STI, n = 45 (100%)				
Correct*	28 (62.2%)	44 (97.8%)	0.001	
Incorrect**	17 (37.8%)	1 (2.2%)		
Vaginal microbicide products, $n = 45$ (100%)				
Correct*	0 (0%)	39 (86.7%)	<0.001	
Incorrect**	45 (100%)	6 (13.3%)		
Vaginal microbicide trials, $n = 45$ (100%)				
Correct*	1 (2.2%)	20 (44.4%)	< 0.001	
Incorrect**	44 (97.8%)	25 (55.6%)	\0.001	

^{*}Proportion of men with all items correct in knowledge category.

However, the education significantly improved the men's knowledge in all areas (Table 2). When combining questionnaire items into a 6-item score, 28 men (62.2%) demonstrated comprehension in all the required points in HIV/STI knowledge at baseline. After the education session, the proportion of men who demonstrated comprehension in all the required points increased significantly for HIV/STI knowledge (97.8%), as well as in the other microbicide categories. Knowledge about microbicides started relatively low, compared to HIV/STI (0% all correct) but then increased to 86.7% all correct in the post-test evaluation. For participation in microbicide trials, the proportion of men with complete knowledge correct was 44% in the post-test (Table 2). All the men who participated in the educational intervention indicated that they would hypothetically support their female partners to participate in microbicide trials and use the products.

Laying the groundwork for microbicide education among men

Qualitative data from the focus group discussions showed an overall environment characterised by financial insecurity, poverty, changing gender roles and economic expectations and concerns about stability of relationships and sexual partnerships. All of these factors seemed to be salient for women and men in terms of how microbicides would be used, men's education about microbicide use and women's participation in microbicide trials. Participants pointed out that health-protective behaviour for HIV prevention often ran in opposition to other important factors, such as maintaining relationships or having children. The gendered nature of relationships, norms about sexual partnerships and fertility and harsh economic realities were seen as important aspects to consider for a microbicide initiative.

Shifting masculinity norms and stability of relationships

A frequent theme that emerged in the qualitative data was the uncertainty and disappointment about men's economic and family responsibilities, and a shifting away from traditional roles, where men had more set and enduring responsibilities, to a time of uncertainty. Gender roles and economic ability played an important part in the unilateral nature of power and decision-making seen in couples. Male community representatives felt that, traditionally, men were the heads of the family and often the breadwinners, and hence were the ultimate decision-makers, including in matters to

^{**}Proportion of men with at least one item incorrect in knowledge category.

^{***}McNemar's chi-square test at significance level of p < 0.05.

do with sex. On the other hand, women were seen as homemakers whose opinion did not matter in decision-making.

A lot of decisions are made by the man in that family. Even if it is coming up with a home, it is the man to make that kind of decision. I think the woman is not allowed to come up with her own decision. But you agree to what the man has said. You only bring an idea. But if it is not accepted by the man, then that idea will not actually be accepted. (Male community representative, FGD)

However, poverty, economic hardship and joblessness contributed to a gradual shift in masculinity norms. Both male and female focus group participants discussed that men, especially vounger-generation men, responded to financial difficulties by becoming less supportive or more dependent on women and retreating into alcohol or idle chat with fellow men in the community.

The men are running away from their responsibilities. They are looking forward to a situation whereby they can be dependent. They come to a house, father a child and then run to the next one where they are not charged with responsibilities. (Male community representative, FGD)

Throughout the focus group discussions, both genders alluded to infidelity as a source of strain in couples' relationships. Infidelity served as a coping mechanism for both men and women in the face of poverty, joblessness and increasing financial difficulties. Both men and women sought extra-marital partners who could meet financial needs that were not met within the couple's relationship.

... For example, if a man finds that he cannot provide for his family he becomes very harsh, he becomes cruel ... you find that the man will start getting extra-marital affairs based on economic grounds. For instance, when a man who cannot provide for his family gets a woman who can give him money, he will start complaining that the wife is useless and so on. This is a loophole for unfaithfulness. (Female community representative, FGD)

In addition, both men and women felt that introduction of a microbicide in a couple would lead to suspicions of infidelity in the female partner.

This also means some people somewhere might not be for it [microbicide]. They might think that it is a ticket for their wives to go and 'do it' with any man knowing that she is not going to be infected. This is also a challenge. (Male community representative, FGD)

Concern over losing one's partner influenced decisions regarding health-protective behaviour. For fear of separation, some women opted not to undergo HIV testing with their partners, even though they knew that it was important.

Some ladies love their boyfriends or husbands so much that they are forced to settle down without taking the [HIV] test. (Female community representative, FGD)

Men's perceptions and reactions to their partner's HIV risks were regarded as important points for consideration in the design of microbicide studies. Likewise, the high value women may place on continuing relationships must be taken into account. Women would find it difficult to participate in microbicide trials or use microbicides privately as this may mean risking losing their relationships or marriage.

I think that they [men] should be involved because if they are not, they will bring problems. It will be very difficult for a woman to use this thing [microbicide]. (Female partner, FGD)

Perceptions on male partner education about vaginal microbicides

Both community representatives and female partners agreed that men were important stakeholders in HIV prevention and that male partners should be involved in microbicide trials as they were also affected by HIV. According to women, men were often to blame for bringing HIV into the couple through their extra-marital partnerships. They felt that some men would thus see microbicides as a beneficial HIV prevention tool for them and their partners.

You find that these *mpango wa kando* [extra-marital partners] will discuss with their sex partners. 'Have you heard about microbicides?' they will keep asking each other and the message will come back to your wife. It means people will go for it. The researchers should therefore find a way of including these men in the education. Men are actually the ones who spread the virus more than women in the society. (Female partner, FGD)

Male partner education was seen as crucial to microbicide trial success by both genders. Male partner education would help increase the men's knowledge about microbicides, promote adherence to microbicides and maintain harmony in the relationships.

My feeling is that it is good to involve men because if you leave it to the women alone, men will feel neglected. Men always tend to be first in everything. They are the head of the house. In any decision, they always want to be the first. When they are involved, they will feel great to participate. They will really support the women because many of them tend to have extra-marital affairs outside. (Male community representative, FGD)

Men felt that educating male partners of female trial participants would remove concerns that microbicides would cause adverse health effects or lead to infidelity, and facilitate ease of disseminating trial outcomes.

If at all there are any side effects, it might affect me, or it might affect my wife. I have to know that my wife is using this microbicide. By the time she is using this microbicide, I have to know whatever side effects might come up. I have to know this microbicide in detail just as much as the wife. (Male community representative, FGD)

Relevant content for a microbicide education tool

Women emphasised that microbicide messaging should be all-inclusive; rather than target the woman, it should focus on the couple, family and nation, to ensure the men did not feel left out. Men felt that microbicide education should promote a sense of ownership among them. In addition, it was important to target men of all ages and at all levels including the health facilities, community and national levels.

I think given the fact that the microbicide is coming in to boost our protection against HIV which is a worldwide/national disaster, maybe I can say in sub-Saharan Africa, it is important to involve all parties. And it is important to understand that all parties understand the essence of promoting the use of microbicides. (Male community representative, FGD)

Both women and men felt that microbicide messaging should be well-designed, concise and in local and culturally appealing language. It should lay emphasis on remaining HIV-negative and staying alive and healthy. Men felt that, at the minimum, microbicide education should include benefits of microbicides, adverse effects of

microbicides, how to use microbicides, how to help women insert the microbicide, reasons for microbicide use and reasons for engaging men in microbicide trials.

I think you should indicate directly the benefit of microbicides and what it is ... Indicate that it is going to help in the prevention of HIV. Men and women have a common interest in the use of microbicides. They are protecting themselves against HIV ... they will be reaping the importance of using microbicides. I would say that there is a big importance there. There is so much that they can get. (Male community representative, FGD)

Both women and men identified women's covert participation in microbicide trials as a challenge because it could lead to discord or violence or divorce in the relationship. Thus, involving and educating the men from the outset would foster trust in relationships.

A woman might join the study without involving the man. The next thing you will hear is that he has given you the woman. 'Where did you go? Okay, go for good'. (Male community representative, FGD)

Other challenges identified included fear of the woman becoming unfaithful and interference with sexual enjoyment, especially for men who preferred dry sex.

Women felt that if male partners were educated on microbicides prior and in good time, they would likely be willing to accompany women to the microbicide trials. Also, if the campaign about male involvement was led by fellow men, and if the men felt that microbicide trials touched on their health, they would be more interested in accompanying women to the trial clinics.

You know when their fellow men are the ones doing that campaign, they will be able to convince them, but if women are the ones doing it, they may not pay much attention to it. They will say that it's only going to favour women so why involve them. (Female partner, FGD)

Discussion

This study demonstrated that both men and women viewed male partner support as essential to women's involvement in microbicide trials, reinforcing the importance of male participation that has been documented in prior research (Montgomery et al. 2015; Venables and Stadler 2012). Educating men about microbicides can enhance their understanding of the importance of microbicide research and help them feel more involved in women's decisions to participate in trials and use microbicides. Data from the educational session with men showed they were willing to be informed on microbicides and that education would likely increase their support for microbicide trial participation by their partners. The results from the qualitative data from female partners revealed, however, that several critical aspects of gender and relationship dynamics needed to be considered in terms of microbicides, including suspicions of infidelity, trust and desires to stay in the relationship. While research studies should strive to offer opportunities for male involvement, the woman who would use the product has to decide in each case if that would be best for her. In many cases, cultivating male support could help to foster a harmonious relationship between partners and create a supportive environment for female study participants to use microbicides, leading to increased study product adherence (Montgomery et al. 2015).

This study showed that microbicide education for men is feasible and can easily be achieved using adapted content from resources already being used to educate women during past or ongoing vaginal microbicide trials. There are several reasons to include men in microbicide education. A male partner educational intervention tool could help address the already documented evidence of men's desire to be involved in decision-making regarding their partners' use of female-initiated reproductive health or HIV-prevention methods (Lanham et al. 2014; Schuler and Bukusi 2017; Tanner 2008). Educating male partners on vaginal microbicides may help generate support for, and reduce the risk of social harm posed to, women participating in microbicide trials, which could result in increased use of vaginal microbicides among disempowered women (Lanham et al. 2014; Montgomery et al. 2015). In this study, men were more likely to be interested in microbicide trial involvement if they were informed about it prior to partner enrolment and through male education. That said, women felt that they would need to use a variety of approaches to win their men's support as seen in past studies (Lanham et al. 2014).

As much as microbicide education for male partners needs to take into account existing gender norms, shifting masculinity norms may provide women with a window of opportunity to exercise more autonomy with respect to reproductive health decision-making. For instance, partners in younger couples, who have similar educational and financial backgrounds, are more likely to discuss reproductive health matters openly and make decisions together (Withers et al. 2015). In addition, economic hardships have thrust more responsibilities onto the women in the recent years, and in many cases the female partner is the sole provider and ultimate decision-maker in the family (Withers et al. 2015). This implicit female partner empowerment could have positive effects in matters such as determining the family size, accessing family planning services and taking protective measures against HIV and STIs. Future microbicide trials need to explore community perceptions regarding changing gender norms, women's empowerment or autonomy in decision-making and the effect it has on couples' relationships and reproductive health access. It is likely that couples may still perceive introduction of microbicides and other HIV prevention tools as a threat to their partnerships. Clinical trials can help improve women's agency to use microbicides through communication programmes that help couples' dialogue about each partner's role in making the woman's trial participation worthwhile (Lanham et al. 2014).

This study revealed that women's uptake of health-protective behaviour was often pitted against the perceived effect on relationship stability. Women were more likely to stay in a relationship and 'make it work' even when their partners' infidelity put them at risk for HIV/STI acquisition. Health-protective decisions were weighed against the risk of losing a partner. Many women felt that they would have to consider the risk of relationship discord or loss if deciding to use a microbicide without informing their partner. On the other hand, disclosure of intended microbicide use or trial participation was perceived by both men and women as an important way to maintain relationship harmony, confirming similar findings from other studies (Kelly et al. 2015; Montgomery et al. 2015). Male partner involvement and education in microbicide trials

could thus benefit from empowering couples to think about what aspects of microbicide use could threaten their relationships and how to address these challenges (Doggett et al. 2015).

While this study does not necessarily advocate using men to mobilise their female partners for microbicide trials due to potential gender-based barriers and risk of coercion, it was interesting to find that men would be willing to relay microbicide messaging to their partners. Past community engagement activities for microbicide trials have often targeted women; however, an all-inclusive approach in which both men and women are educated about microbicides may improve efficiency in mobilising and recruiting vaginal microbicide trial participants. In the context of existing complex partnership dynamics underlying potential vaginal microbicide use in sub-Saharan Africa, it is imperative to introduce vaginal microbicides within the existing gender power structure and partnership dynamics operating in the particular local culture (Doggett et al. 2015; MacPhail et al. 2009).

The effectiveness of microbicides, as with any other PrEP, is dependent on adherence to product use; the higher the adherence, the higher the protection provided by the microbicide (Baeten et al. 2016; Buchbinder and Liu 2018). Many studies in sub-Saharan Africa highlight the influence of partnership dynamics on product adherence (Doggett et al. 2015; Lanham et al. 2014; Schuler and Bukusi 2017), suggesting that male partner engagement may address some of these barriers (Doggett et al. 2015). Lessons from this study can potentially be applied in future microbicide and MPT messaging to enhance male partner support for women to use female-initiated HIV prevention methods without having to worry about negative repercussions from their partners.

Limitations

Firstly, this study did not carry out post-intervention qualitative sessions with the men who were educated, and hence we were not able to determine actual acceptability and perceptions regarding the microbicide education tool and how the men felt the tool could be improved upon. That said, the microbicide education sessions were very well received by the men, and the fact that we had a 95% turn-up of the men's female partners suggests that the education sessions generated high interest in microbicides among the men.

Secondly, a majority of the men and women who took part in this study were married or in otherwise stable relationships, and hence the study findings are more applicable to microbicide use in couples. The study did not specifically recruit young single women who have the highest number of new HIV infections in Kenya and other eastern African countries (Govender et al. 2018). As past studies have shown, women in casual relationships may not feel obliged to tell their partners about microbicides use, and this may influence their decision-making regarding trial participation (Lanham et al. 2014; Schuler and Bukusi 2017). Future studies on male partner engagement for microbicide trials can address this limitation by recruiting men and women in different types of partnerships.

Thirdly, given that this study was not conducted in the context of a larger ongoing microbicide trial, we were not able to assess whether the increase in knowledge about microbicides and microbicide trials translated to actual male partner support for women to participate in trials or use microbicides. In addition, this being a cross-sectional study, we could not assess how long the increase in knowledge among men was sustained. These two limitations will potentially be addressed in future research that aims to validate the education tool for use among men.

Lastly, we focused on vaginal microbicide education only because our target population (young reproductive-age women) was largely heterosexual. The reported prevalence of anal sex is very low in western Kenya where this study was conducted (Kinuthia et al. 2017). As a result, no rectal microbicide trials have been conducted in this population to date.

Conclusion

Men and women propose that male involvement in women's decisions to use microbicides is crucial to the success of microbicide trials. Male partner education is an important way of raising men's awareness of microbicides and the importance of microbicide trials. This heightened awareness could potentially create a supportive environment for women to adhere to microbicide use and to the rigorous trial schedule. Furthermore, engaging men in vaginal microbicide research may help create more gender-equitable relationships, foster relationship harmony and potentially facilitate the marketing of a vaginal microbicide once available. Culturally sensitive microbicide messaging targeting men at all levels of society and addressing the importance of microbicides to both men and women could help mitigate the complex gender and partnership dynamics that underlie potential vaginal microbicide use in many communities in Kenya.

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