

## **The Dapivirine Vaginal Ring from the Perspective of Married Men in Uganda**

**Authors:** Anita Kabarambi<sup>1</sup>, Sylvia Kusemererwa<sup>1</sup>, Emily Krogstad<sup>2</sup>, Philippe Mayaud<sup>1,3</sup>, Janet Seeley<sup>1,3</sup>, Joseph Mugisha<sup>1</sup>, Mitzy Gafos<sup>3</sup>

**Institutions:** <sup>1</sup>Medical Research Council / Uganda Virus Research Institute & London School of Hygiene and Tropical Medicine Uganda Research Unit, Entebbe, Uganda

<sup>2</sup>Desmond Tutu HIV Centre, Institute for Infectious Disease and Molecular Medicine, Faculty of Health Sciences, University of Cape Town, South Africa

<sup>3</sup>London School of Hygiene and Tropical Medicine, London, United Kingdom

**Corresponding Author Email Address:** [Anita.kabarambi@mrcuganda.org](mailto:Anita.kabarambi@mrcuganda.org)

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### **Abstract**

Men play a key role in influencing uptake of women's health products such as female condoms and vaginal microbicides, used for family planning and HIV prevention. We explored men's perceptions towards the dapivirine vaginal ring (DVR), a vaginal microbicide, in Kalungu District, rural Southwestern Uganda. Between June and July 2018, we conducted in-depth interviews with ten partners of women participating in the DREAM Study, a Phase IIIb open label extension trial of the DVR. Data were analyzed thematically, drawing on the socio-ecological model theoretical framework. Influencing factors like individual and interpersonal characteristics, perception of HIV risk, lack of knowledge about the DVR, misconceptions, and product characteristics acting at different levels (individual, societal and organizational) affected men's knowledge, attitudes and perceptions towards the DVR which in turn impacted on their willingness to allow their partners to use it. Above all, men wanted to be involved in the decision-making process about the use of the DVR. All the men were happy that there was a new HIV prevention option in the pipeline, and were not concerned about the degree of effectiveness saying it was better than nothing. The use of the DVR in an environment where men expect to make decisions about sex on behalf of women may affect its usage and success. Given this context, women may not always be able to independently choose to use it. If the DVR is approved and rolled out, increased sensitization of men about it will be critical to ensure its uptake.

### **Keywords**

Africa, decision- making, HIV prevention, microbicide ring, socioecological framework

**Word Count:** 6611 of 7500 allowed

## Introduction

Women in sub-Saharan Africa are disproportionately affected by the Human Immunodeficiency Virus (HIV) relative to men, with 67% of new infections occurring among women (UN Women, 2016). Furthermore, women are disproportionately affected by HIV in Uganda. Of the 1 300 000 adults living with HIV, 770 000 (59.23%) are women (UNAIDS, 2018). According to the UNAIDS 2018 report on Uganda, HIV incidence among all people of all ages was 1.4%, with new HIV infections among young women aged 15–24 years accounting for more than double those among young men at 14 000 new infections. Therefore, additional HIV prevention options for women are urgently needed. The dapivirine vaginal ring (DVR), a vaginal microbicide, is an important potential HIV prevention option that will, if licensed, be one of few biomedical HIV prevention products exclusively for women alongside female condoms.

Microbicides are compounds that can be applied inside the vagina or rectum to protect against HIV and sexually transmitted infections (STIs) and can be formulated as vaginal rings, gels, creams, films, or suppositories (WHO, 2019). The DVR contains 25 mg of dapivirine dispersed in a platinum-catalyzed silicone matrix and can be inserted by women themselves every four weeks (Annalene Nel et al., 2016). Findings from two Phase III trials showed that the DVR reduced HIV infections by approximately 30% in women overall (Baeten et al., 2016; Annalene Nel et al., 2016). Both trials together enrolled more than 4,500 women from Uganda, Malawi, Zimbabwe, and South Africa.

Past research shows that men play a key role in women's use and acceptance of women's health products such as family planning methods and use of female condoms (Moore, Beksinska, Rumphs, Festin, & Gollub, 2015; Withers et al., 2015). Male partners' involvement and support is important to many women's consistent use of female-initiated methods (E. T. Montgomery et al., 2011). Like in many other sub-Saharan African settings, men in Uganda continue to dominate decisions on sexual health, especially in rural settings (Kusemererwa et al., 2016). Findings from trials of vaginal microbicides show that men played an influential role in women's use and the acceptability of the products (Lanham et al., 2014). Learnings from microbicide gel trials revealed that although the gel was supposedly 'woman-controlled', men exercised

considerable influence in determining whether and how it was used (C. M. Montgomery et al., 2008). Many women did not want to use vaginal microbicide gel covertly, frequently expressing concerns about the possibility of male partners feeling the product during sex – either because it could potentially negatively impact his sexual experience or because he could become angry or abusive if he discovered she was using it (Hoffman et al., 2010; E. T. Montgomery et al., 2017). Similarly, gender power dynamics affected women’s decision to use or disclose the use of the diaphragm in the context of HIV prevention trials (MacPhail et al., 2009; Sahin-Hodoglugil et al., 2009), with women sharing fears that men would find out they were using the diaphragm and this could lead to social harm (Stadler, Delany-Moretlwe, Palanee, & Rees, 2014).

Although there is limited evidence on how men influence women’s use of the DVR, women from the phase III trials have described similar fears about their partners finding out about them secretly using it, with many not disclosing ring use to their partner or resorting to changing sex positions due to fear that he might feel it (Laborde et al., 2016). While several studies have reported on women’s perceptions of their male partners’ reactions to the DVR (Laborde et al., 2018; E. T. Montgomery et al., 2017), data on men’s perceptions of the DVR are more limited. Consequently, understanding men’s perceptions of the DVR and how they want to be involved in sexual decision-making is crucial for planning the future roll-out of the DVR. In this qualitative study, we explored married Ugandan men’s attitudes and perceptions towards the DVR within the context of a clinical trial.

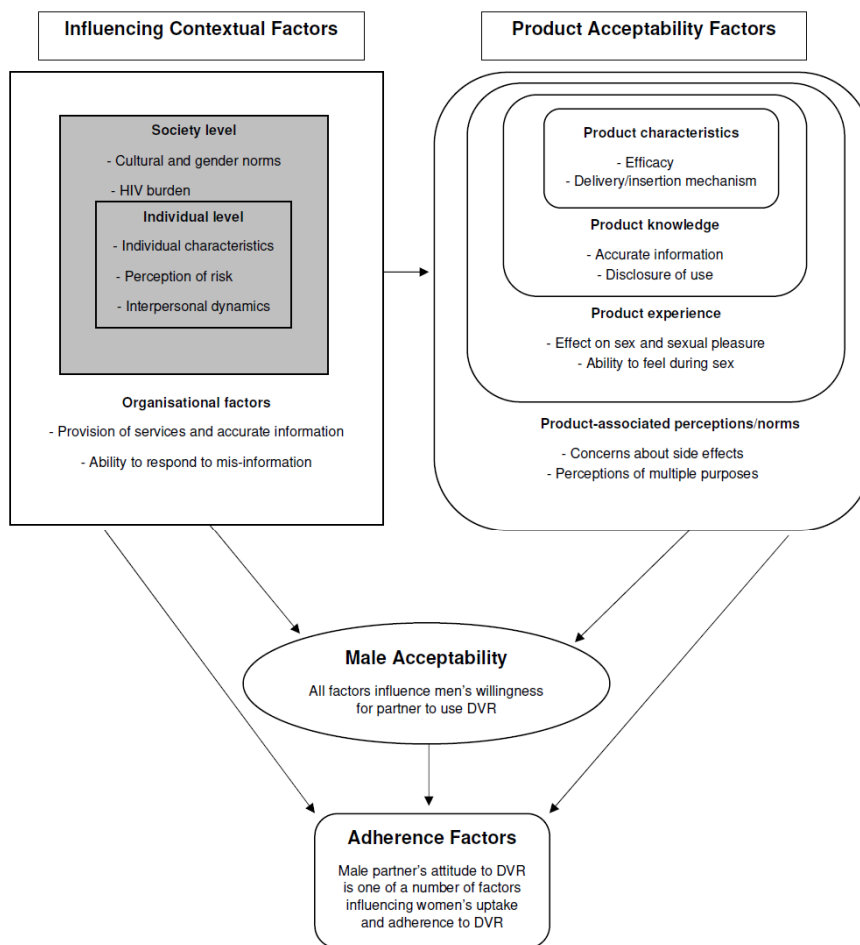
## **Methods**

### ***Conceptual Framework***

We adapted the socioecological model from Mensch et al. that recognises that various influencing contextual factors operate at different levels (individual, societal, organizational) to *influence* product-related attitudes and perceptions (acceptability) and *influence* an individual’s behaviour (adherence to product use) as shown in figure 1 (Mensch, van der Straten, & Katzen, 2012). This model distinguishes between ‘product acceptability’ and ‘product adherence’ in the recognition that ‘acceptability’ is a proximal

determinant of use, and while potentially influencing adherence, will not solely determine it. As such this conceptual framework accounts for the influence of contextual factors on product acceptability and adherence, and the influence of acceptability factors on adherence. This conceptual model allows for the identification of the ways in which acceptability is a factor in product usage and to ascertain which dimensions of acceptability, affect adherence.

Figure 1: Socioecological Model adopted from Mensch 2012.



### ***Study Population and Setting***

This was a qualitative study with ten married men aged between 18 and 45 years, purposively recruited. The men were recruited through their partners who were taking part in the DREAM study, a Phase IIIb open-label extension trial of the DVR (A Nel et al., 2019), whose main objective was to assess continued safety of and adherence to the DVR in healthy HIV-negative women who had taken part in the Phase III trial (IPM027). A list of all the participant identification numbers of women that were taking part in the DREAM study was obtained. Women were randomly selected from this list by selecting every other tenth PID. These were called on phone or approached during their study visit to ask if they had disclosed DVR use to their main male partner. Main male partners were defined as either a husband, regular sex partner or frequent sex partner. We then purposively selected women that had disclosed to their main male partners that they were using the DVR to invite their main male partner to participate in our study. This was done to avoid any social harms in case the partner had not been aware of their partner's use of the DVR. If a woman had not disclosed, they were dropped and others selected. 39% (n=7/18) of women initially contacted had not disclosed fully to their partners that they were using the DVR and were not invited to participate. Of the eleven women who had disclosed DVR use, only one (1) woman refused participation because her main male partner was too busy to attend an interview. For this study, the refusal rate was 9% (n=1/11). All remaining (n=10/18) women agreed to request their husbands to join the study and linked us to their partners for an appointment. All participants were residents in Kalungu district, southwestern Uganda.

### ***Data Collection***

We conducted in-depth interviews (IDIs) using an interview guide that included topics on communication and decision-making dynamics between couples regarding the DVR use, experiences during its use and knowledge about the DVR. We anticipated that saturation of information would be reached after 10-12 IDIs. Saturation was defined as that point when no additional new data was being found. This redundancy indicates that data collection may cease (Faulkner & Trotter, 2017). These interviews were conducted at the time when the greatest number of study participants had used the DVR for at least years.

The interviews were conducted in the local language (Luganda) widely used in the region. Interviews lasted between 45 minutes to one hour. Prior to the interviews, the interview guide was tested during role-plays with two experienced social scientists for the interviewer to get acquainted with the topics and potential probes. The interviews were conducted by the first author (AK), who was accompanied by an experienced social scientist for the first three interviews. All interviews were conducted at a research centre, with audio recordings made using a digital recorder.

### ***Data Management***

Interviews were transcribed directly into English by the first author and independently quality controlled (QC) by another experienced study team member. The first author and QC person were both fluent in English and Luganda. Summaries of interviews were written within one day of conducting the interview.

### ***Data Analysis***

Thematic analysis was used for this study. Transcripts were coded manually by the first author using Excel. A codebook was developed to capture responses relevant to the research questions. The socioecological model informed the coding process. The codes included communication, decision making and gender dynamics about the DVR, experiences during sex and knowledge about the DVR. Relevant transcript excerpts were entered into the spreadsheet, with the rows of the Excel sheet containing each participant, and the codes as columns. Each code was analyzed by column across all ten participants to identify themes.

The interpretation was made through the lenses of the researcher's theoretical assumptions as noted in the conceptual framework.

### ***Ethical Considerations***

Ethical approval was obtained from the local Research Ethics Committees of the Uganda Virus Research Institute Research Ethics Committee (UVRI/REC) and the Uganda National Council for Science and Technology (UNCST), and the London School of Hygiene and Tropical Medicine (LSHTM) Ethics Committee. Domestic violence was

identified as a potential risk for the study. As such, the women provided written consent allowing the research team to contact their male partners and confirming that their partners knew about their use of the DVR. Male partners also provided written informed consent to participate in the study including consent for the audio recording.

## **Findings**

Table 1 shows the characteristics of the men enrolled in this study. We present findings showing how product acceptability factors influenced men's willingness for their partners to use the DVR as an HIV prevention option at the different levels (individual, societal and organizational).



Table 1: Participants characteristics

	Total (%)
Number of men interviewed	10 (100%)
Age, in years	
18-24	1 (10%)
25-29	1 (10%)
30-34	1 (10%)
35-39	3 (30%)
≥40	4 (40%)
Median age, in years	38
Education level	
No school	0 (0%)
Primary school (partial/complete)	4 (40%)
Secondary school (partial/complete)	6 (60%)
University/Tertiary	0 (0%)
Marital Status	
Married	10 (100%)
Number of sexual partners	
One sexual partner	7 (70%)
More than one	3 (30%)
Occupation	
Employed	10 (100%)

## ***Influencing Factors***

### *Individuals' characteristics*

Individuals' characteristics included marital status, financial status, educational background and number of sexual partners among others. This study showed that there were no obvious differences in the views expressed by the men based on their educational background, age and occupation.

### *Perception of risk*

Risk perception can also influence the use of the DVR. This could be risk related to their own behavior risk and or partner behavior and associated risk. Some men were concerned about the reason for their partners bringing an HIV prevention option into the relationship. It led some of them to think that their partners probably did not trust them. It made male partners become more suspicious of their female partners, thinking they may be tempted to be unfaithful. Nine (9) out of the ten (10) men did not perceive themselves as being at risk of HIV. None of the men discussed their own infidelities, and with one exception, none of the men perceived the ring as a method by which their partners were protecting themselves from potential infection from them.

One man said he could withstand any form of discomfort from the DVR as long as he was sure his wife was safe from getting HIV from (an)other partner(s):

*"For me if it is to do with life, I can stand any inconvenience. I told you it is not easy for me to take things for granted especially for HIV prevention. You cannot know how weak a woman's heart can be, so I decided to persevere [meaning that a woman can easily be unfaithful]" (Above 35 years).*

One man, however, was concerned that if a woman was protected from HIV, then she would start having sex with multiple partners as a result:

*"I do not know whether you give them talks to let them know that this ring can protect them in case their partner is not faithful to them. Otherwise,*

*they will think since they cannot get HIV they can have sex with anyone they find” (Below 35 years).*

He, however, went on to say:

*“Despite all the times I tried to spy on my partner, I never caught her with any other man.”*

Two married men who had more than one partner saw the need for their extra partners to use DVR but not for their marital partners. This was because they were not sure of the sexual networks of their extra partners, but believed their marital partner had no other partners.

#### *Interpersonal characteristics*

In this analysis, we focused on the interpersonal characteristics of decision-making dynamics and issues of trust. Decision-making dynamics of men in their homes affected the way they made decisions regarding the use of the DVR. Most (8/10) men described the decision-making processes in their homes as joint with their partner, including decisions about sex. However, with regard to using the DVR, most (9/10) men wanted to make the final decision about their partner’s use of the DVR before she started using it. Some felt that the decision-making process should be a joint one for DVR use. For example, one man below states how he could not understand why a woman would use an HIV prevention option secretly:

*“If you have been making decisions with your partner in other issues, why would someone find it hard to tell me they are using the DVR? I do not think we would be able to live together if she fears me” (Above 35 years).*

Others felt that men would be in a better position than other women to give proper advice about the DVR:

*“You women usually seek advice from fellow women who may be gossipers and end up giving you false advice, which your partner may help you realize if you share with them” (Above 35 years).*

This stems from the societal belief that men need to make a final decision since they are the family head, like one man below who said a woman had no final say in his home:

*“Our culture calls for men being the head. They need to have the final say. For me, a woman has no ‘say’ in my home. I am the one who decides” (Above 35 years).*

Some men said they would not hesitate to stop their partners from using it if they found them using it secretly, as this man stated:

*“I almost opened a case at the police against the research center for involving my partners without my knowledge. I had even stopped them from taking part in the study” (Above 35 years).*

Four men in our study stopped their partners from using the DVR. This was because some feared that the DVR would cause uterine cancer to their partner while others were just angry that they were not included in the decision-making process. However, all these men later accepted their partners to continue using the DVR after getting more information about the study from the research centre. There were no apparent differences in beliefs between the older and younger married men in this study regarding their views about decision-making about the DVR use.

Overall, all the ten men were happy that there was an HIV prevention option that was in the pipeline for women, but wanted to be involved in the decision-making process of whether the women would use the ring.

### ***Product acceptability factors***

#### *Knowledge about the DVR*

A lack of knowledge affected the men’s attitudes and perceptions towards the DVR both at societal and individual levels. Many of them developed misconceptions because of lack of correct information about the ring, with worry about the DVR causing uterine cancer as a primary concern. Four men even stopped their partners from using the DVR because of this concern. Many sought additional information about the ring and the study from the research centre, which they found helpful. The participants who sought

additional information reported that this empowered them to support their partners to use the DVR. Three men reported helping other men in their communities to demystify the rumours that were circulating, stating that their partners had not experienced any issues from the DVR for all the years they used it. All the men were happy that there was a potential new HIV prevention method, but didn't know how much protection their partners were getting from the DVR. Their understanding of its efficacy and protection both for themselves and for their female partners was very limited. Nine of the men assumed the DVR provided 100% protection for their partners and themselves. They cited this as the main reason for allowing their partners to use the DVR. For example, one man commented:

*"I allowed her to use the DVR because I knew she would never get infected with HIV once she had it inserted. If she does not get it [HIV] then I will also be protected from getting it" (Below 35 years).*

This shows how lack of proper knowledge about the DVR shaped their attitudes towards it. All ten men held similar beliefs, saying that they allowed their partners to use the DVR because they knew as long as their partners used it, they would never get infected with HIV. Regarding this overconfidence in the DVR, when asked if they would still support their partners use if it was only 30% effective, all the ten of them said it was better than no protection at all.

Three men also had a misconception that the DVR contained contraceptives, as noted by this respondent:

*"I got worried that she was not conceiving. You know I first heard rumors around the village that our wives would not give birth to children anymore because they had inserted rings in them" (Above 35 years).*

This shows how factors at the societal level affected men's attitudes at an individual level. Other misconceptions were study-related; for example, not having enough information about the study affected some individuals' attitudes towards the DVR. An example is one man who sought to understand how much profit or shares he would receive if the ring was licensed and put on the market. This belief motivated him to

support both his partners to take part in the study as he viewed them as property to give:

*“I have given you two women to take part in the study. If this ring is licensed, what will be my share in this product?” (Above 35 years)*

Another thought that the ring could only be inserted by the study staff and neither he nor his partner could remove it. This was what his partner told him, possibly to avoid a situation where he requested its removal. The majority of men recommended more sensitization targeting men about the DVR as a way of demystifying misconceptions, recognizing how receiving information from the research centre helped them counter misconceptions during the study.

*“If you could bring us training sessions about this ring where we stay and work, this will help our fellow men know about this ring. This is because many of them do not know anything about it” (Above 35 years).*

#### *Characteristics of the DVR*

The characteristics of the DVR shaped men’s perceptions and attitudes towards it mainly at the individual level. Most men (7/10) in this sub-study reported that they did not feel the ring during sex. Three of the ten men reported that they felt the ring before their partners had disclosed to them, while the rest reported that they felt it only because their partners told them they were using it. Some of these men were then curious to see what the DVR looked like, and made their partners remove it for them to see while others went ahead to stop their partners from using it. Among men who reported feeling the DVR, two men reported a positive impact on sexual pleasure and one reported a negative impact. For example, one man said that the ring increased his libido:

*“You know there is a way it [DVR] gives you energy [urge] as a man as it feels like a clock and it arouses you more. It is not bad, where you have been having sex for 30 minutes, you can go to 60 or 70 minutes” (Below 35 years).*

In contrast, another man described a decrease in his partner's libido, negatively impacting his sexual experience:

*“From the time she started using it, her feeling in bed changed, she had reduced appetite for sex. She would not easily get aroused, she would be dry in the vagina and you would be like you are forcing her”. (Above 35 years).*

Despite this feeling, this man let his partner continue using the DVR, saying HIV prevention was better than pleasure. Culturally, the reduced amount of discharge from the vagina during sex in Uganda is often interpreted as lack of interest for sexual intercourse by a woman. Some men did not realize that their partners were using contraceptives nor consider that they were being treated for sexually transmitted infections, all of which may have impacted the presence and amount of vaginal fluids. As such they assumed the change in vaginal fluids during sex was due to the DVR. However, for most (9/10) of the men, feeling the DVR during sex did not bother them at all; it felt normal.

## **Discussion**

In this qualitative study, we found that among married men in Uganda, male partners of women using the DVR were supportive of the DVR as an HIV prevention option. We also found that men want to be told before their partners start using the DVR and be involved in the decision-making process. The majority did not like the idea of women using it secretly. Some had misconceptions about the DVR related to community rumours. Just like reports from women in the Phase III studies of the DVR (Laborde et al., 2018), the majority of men did not feel the ring during sex; however, some of the men felt it during sex before their partners disclosed use. For those that felt it, some liked it since it increased their libido as men; one did not like it as he felt it reduced the libido of his partner. For most, feeling the ring during sex did not bother them as it felt the same as not having the ring inserted.

Consistent with the model conceptualised by Mensch et al. (Mensch et al., 2012), we found that men's knowledge, attitudes and perceptions of the DVR in this study were

shaped by individual, societal, and organisational factors which in turn influenced their willingness to allow their partners to use the DVR.

In this study, men were concerned that the DVR would give autonomy to the women. Even though they described decision-making in their homes as joint, men wanted to make the final decision for their partner to use the DVR, with many opposing its secret use. These findings are similar to those of a microbicide gel study conducted in Zimbabwe where men knew that it was possible for their partners to use the gel secretly, but preferred to be involved in the decision-making process, as secret use would make them angry if they found out (van de Wijgert et al., 1999; Woodsong, 2004). For our study, it was noted that the men also demanded that they should be part of the decision-making process to use the DVR. In another study of family planning in Kenya, men described fearing that women would become more independent if they chose to use contraception, hence challenging their masculinity (Withers et al., 2015). In this study, men expressed similar concerns about women gaining independence if using the DVR.

Previous studies revealed that even if the DVR was designed for autonomous use, some women sought partner approval to use it and lack of male support may be a barrier for its use (Hartmann et al., 2019; Roberts et al., 2019). Although much has been made of the benefits of HIV prevention products that women can use 'covertly,' most of the evidence from microbicide gel studies suggest that women want to discuss gel use with their partners before they use it, especially married women (Woodsong, 2004). Few women in microbicide gel studies viewed the use of the gel as an independent decision (Woodsong, 2004). It should be noted that many of the women in these studies were unmarried, unlike the ones in this particular study that were all married. One study among women in a microbicide study in KwaZulu Natal, South Africa found that it was women least able to negotiate gel use who were more likely to use it secretly (Gafos et al., 2015). In the ASPIRE study of the DVR, a small proportion of women reported keeping ring use secret throughout the study because they were afraid of an angry or suspicious reaction from their partner (E. T. Montgomery et al., 2017). Our own



observations showed that some men who found their partners using the DVR secretly initially stopped them from using it.

Men in this study were pleased there was a new product in the pipeline for HIV prevention for women, regardless of its efficacy levels. There has been similar evidence in other microbicide studies showing how participants do not look at percentages of efficacy; for example, a study of a microbicide gel showed that participants were disappointed that the PRO2000 2% vaginal microbicide gel was being excluded as an HIV prevention option during the discontinuation process, failing to understand that the gel was not effective (Gafos et al., 2011). Similarly, in our study, the female partners may have not fully understood the concept of varying percent efficacy and communicated efficacy to their husbands simply as protection. This could explain why the men assumed 100% efficacy, especially if their female partners did not share the efficacy results in percentage form. In our study, only one man acknowledged that use of the ring could protect their partners from acquiring HIV from them personally, while most men perceived risk to be from someone else. This links to the concern about 'secret use', as men in our study thought that secret use of the ring means that their partners have other partners from whom they think the risk of HIV originates. We also note the issue of monogamy and expectation to be open in marital relationships from the men's point of view. Some of the men regarded themselves as having one partner but did not think this to be the same for their female partners. They said that they were not sure whether their wives were not having sex with other men. They felt that their partners were not in position to disclose such information to them and preferred the fact that they were protected.

Men had further misconceptions about the DVR causing uterine cancer and making their partners infertile. These rumours are consistent with those reported in the literature about microbicide gel and vaginal rings in other sub-Saharan African communities (Chitukuta et al., 2019; Stadler et al., 2014). Such rumours not only affect microbicide studies, but could also have broader implications on uptake of other new health interventions such as vaccinations and contraceptives if not addressed.

### ***Programmatic Implications of findings for roll out of the DVR***

There is need for increased community sensitization and education in order to close the knowledge gap about the DVR. When people have the proper information and knowledge, it will help in the acceptance, uptake, and use of the DVR once licensed. This is key at the individual, community and policy levels. There is also a need to support women to discuss the DVR with their partners if they desire, without reinforcing negative gender inequalities. Men's knowledge of ring use could have implications for adherence (E. T. Montgomery et al., 2017) and intimate partner violence (Stadler et al., 2014), as has been seen in microbicide gel studies. There has been interest in integrating 'female empowerment' training with oral PrEP (pre-exposure prophylaxis) delivery (Celum et al., 2015), and this will be important to explore for the DVR as well. Both women and men need to be included in the design and delivery of programmes without undermining women's decision-making.

The idea that women use the ring to protect from acquiring HIV from their husbands, and yet husbands do not see themselves as the source of risk, is very critical. There is need to support honest dialogue about fidelity and risk among couples to enable them appreciate the need for HIV prevention.

### ***Strengths and Limitations***

This study provides useful insights on Ugandan married men's perspectives on the DVR, as there have been few studies of men's perceptions of the vaginal ring. The use of qualitative data from in-depth interviews among men who have experience with the ring enabled us to get a deeper understanding of men's attitudes and perceptions of the DVR. One major limitation was that of sampling bias: the study was conducted among married men whose partners had disclosed ring use to them. Some women did not consent to have their partners take part in the study because they had not disclosed their ring use to them. Hence, additional studies among men who are not married, those who did not allow their partners to use the ring, didn't know they were using it, or who hadn't used it will be important in order to get unbiased insights of men's attitudes towards the DVR. Another limitation of this study was the small sample size, resulting in

limited representativeness in terms of age ranges, education and socio-professional background.

### **Conclusion**

In this study, the dapivirine vaginal ring was found to be overall acceptable to Ugandan married men as an HIV prevention method for women after receiving information about it. Although several men (n=4/10) initially stopped their partners from using the DVR because they were not told about it, after receiving information about it at the research centre, all men found the DVR to be acceptable for their partners to use. It was evident that men had knowledge gaps on how much protection their partners were getting from it. They also had knowledge gaps on their own HIV risk. Although the DVR could provide a 'female-controlled' option for HIV prevention, this sub-study suggests that its implementation would take place in a highly gendered environment in which women may not always be able to choose to use it independently, especially if men can feel it during sex.

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