

An Evaluation of Intravaginal Rings as a Potential HIV Prevention Device in Urban Kenya: Behaviors and Attitudes That Might Influence Uptake within a High-Risk Population

Donna Jo Smith, M.A.,¹ Sabina Wakasiaka, M.P.H.,³ Tina Dan My Hoang, MSPH,¹
Job Joab Bwayo, MBChB, Ph.D.,^{3*} Carlos del Rio, M.D.,^{1,2} and Frances H. Priddy, M.P.H., M.D.¹

Abstract

Purpose: We sought to assess the potential acceptability of intravaginal rings (IVRs) as an HIV prevention method among at-risk women and men.

Methods: We conducted a qualitative assessment of initial attitudes toward IVRs, current HIV prevention methods, and common behavioral practices among female sex workers (FSWs) and men who frequent FSWs in Mukuru, an urban slum community in Nairobi, Kenya. Nineteen women and 21 men took part in six focus group discussions.

Results: Most participants, both male and female, responded positively to the concept of an IVR as a device for delivering microbicides. Women particularly liked the convenience offered by its slow-release capacity. Some female respondents raised concerns about whether male customers would discover the ring and respond negatively, whereas others thought it unlikely that their clients would feel the ring. Focus groups conducted with male clients of FSWs suggested that many would be enthusiastic about women, and particularly sex workers, using a microbicide ring, but that women's fears about negative responses to covert use were well founded. Overall, this high-risk population of FSWs and male clients in Nairobi was very open to the IVR as a potential HIV prevention device.

Conclusion: Themes that emerged from the focus groups highlight the importance of understanding attitudes toward IVRs as well as cultural practices that may impact IVR use in high-risk populations when pursuing clinical development of this potential HIV prevention device.

Introduction

WOMEN NOW ACCOUNT FOR 46% of adult HIV-1 infections worldwide and 57% of adult infections in sub-Saharan Africa.¹ As HIV increasingly affects women, a safe, effective, acceptable, female-controlled method of HIV prevention is urgently needed to decrease heterosexual HIV transmission. Vaginal microbicides, which could be applied topically by women, are in development, with 12 products in clinical trials and 4 in phase II/IIB or phase III trials.² Topical microbicides have several limitations as HIV prevention methods, however. Most are short acting and require application prior to each act of intercourse or at least daily; some

microbicides are also spermicides, posing problems for women desiring fertility. Topical gels may have undesirable local effects, such as excessive moisture. Sexual partners could notice the additional lubrication and, thus, the microbicide, raising issues of fidelity and trust.^{3,4} In addition, none of the topical microbicide candidates tested to date in efficacy trials have demonstrated effectiveness.^{5,6}

To address many of these limitations of topical microbicides, intravaginal rings (IVRs) containing microbicidal compounds also are under development for HIV prevention. Originally developed and licensed to deliver reproductive hormones for contraception and hormone replacement therapy (HRT), IVRs are flexible, silicone rings approximately

¹Department of Medicine, Division of Infectious Diseases, Emory University School of Medicine, and ²Department of Global Health, Rollins School of Public Health, Emory Center for AIDS Research, Atlanta, Georgia.

³Kenya AIDS Vaccine Initiative, Department of Medical Microbiology, University of Nairobi, Kenya.

*Deceased.

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2–3 inches in diameter, designed to be inserted into the vagina and placed near the cervix (Fig. 1). IVRs could offer several biological and acceptability benefits over topical HIV microbicides currently in development. In trials, microbicide creams, gels, suppositories, or films have decreased intravaginal retention over time after application. In contrast, IVRs would provide a more steady concentration of the HIV microbicide at a local level,⁷ ensuring topical coverage of the vaginal epithelium and possibly the submucosal lymph tissues and regional lymph nodes, which are also thought to be targets of HIV infection. An IVR could be left in place for 3–12 months, including during menses and sexual activity,⁸ but could also be removed and reinserted by the woman if necessary, for example, when changing to a new IVR or if pregnancy occurred. Such long-acting IVRs could eliminate daily dosing and likely increase adherence and, therefore, effectiveness. Equally important, IVRs have the potential to be a more private form of HIV prevention than topical microbicides in that they are unlikely to cause noticeable changes in vaginal moisture or discharge, and they may go unnoticed by the male partner during sexual activity.⁹ Furthermore, HIV prevention methods that can be used discreetly or covertly by women may allow them to protect themselves from exposure to HIV infection in situations where gender inequality reduces women's ability to request condom use or abstinence.

In three controlled studies, IVRs for contraception and HRT were found to be highly acceptable among users in developed countries.^{9–11} However, no acceptability data exist on IVRs for women in developing countries, particularly among women who find it difficult to negotiate condom use. Acceptability in this population could be influenced by a variety of factors, including fear of side effects from a foreign device, concerns that the technology will interfere with fertility, apprehension about its effect on sexual pleasure, and worry that sexual partners will act punitively if they are aware of the device. Current research on topical microbicides in developing countries indicates that varying genital practices and sexual preferences can influence acceptability.¹² For



FIG. 1. Intravaginal ring. Courtesy of Karl Malcolm.

example, a study in Rwanda found a marked preference for lubrication during sex among both Rwandan men and women,¹³ whereas in Kenya, Zambia, South Africa, and Zimbabwe, researchers found a preference for dry sex.^{4,14–16} To begin to address this gap in the literature on IVR use in developing countries, we conducted focus groups with at-risk women and men in Nairobi, Kenya, assessing initial impressions of the IVR itself and characterizing risk behaviors and cultural practices that might influence IVR uptake.

Materials and Methods

Study setting

The investigation was conducted prior to a larger planned study of IVR use in women at risk for HIV in Mukuru, a slum area in Nairobi, Kenya, with a high prevalence of HIV and commercial sex work. We have been conducting community health education and HIV testing in preparation for potential clinical trials of HIV microbicides or vaccines in Mukuru for the past 3 years. Mukuru's population is estimated at 365,000. Average income is far below the poverty line, with unemployment and underemployment very high, and education levels very low.¹⁷ HIV prevalence in 2003 was 11.9% for women and 9% for men.¹⁸

Study procedures

In preparation for the focus groups, we held a series of community meetings with local administrators and village elders both to provide them with background information about microbicide research and development and to attain community support for the study. Simultaneously, field workers mapped Mukuru and identified key points for recruitment, such as bars and brothels, within which we established contact with female sex workers (FSWs) and their male clients. Willing at-risk participants were invited to attend presentations at the study site to learn more about the study and participate in HIV testing and counseling. Eligible women and men were HIV-negative, aged 18–50, residents of the Mukuru slum area, and reported exchanging sex for money, or *vice versa*, at least three times in the past month. Because microbicidal IVRs are primarily indicated for HIV-negative women, we decided to limit participants to those who were at risk for HIV infection. Those who tested HIV-positive during the screening process were counseled and provided support to receive further evaluation and management at Kenyatta Hospital Comprehensive Care Centre. Individuals who tested HIV-negative were invited to attend one-on-one information sessions at the study site, a local Mukuru community health clinic. Written, informed consent was obtained from participants, and a trained interviewer administered a short questionnaire to all participants covering sociodemographic and risk characteristics as well as confirming eligibility criteria.

Three male focus groups and three female focus groups were conducted between June and September of 2006, with each group comprising 6–7 members for a total of 19 HIV-negative FSWs and 21 HIV-negative male clients (Table 1). Female participants were between the ages of 19 and 44 (average age 28), and male participants were between 20 and 64 years old (average age 33). Most of the female respondents were Catholic ($n = 13$), single ($n = 13$), and had completed primary school ($n = 16$). Most of the men identified

TABLE 1. KEY DEMOGRAPHICS, MUKURU FSW AND MALE CLIENTS FOCUS GROUPS

	Women (n = 19)	Men (n = 21)
Education levels		
No formal schooling	1 (5%)	0
Primary school, 6 years or less	16 (84%)	13 (62%)
Secondary school, 12–6 years	2 (11%)	8 (38%)
Current marital status		
Single	13 (69%)	12 (57%)
Married	0	6 (29%)
Widowed	1 (5%)	0
Divorced/separated	5 (26%)	3 (14%)
No. of dependents		
0	0	9 (43%)
1–2	10 (53%)	4 (19%)
3–4	7 (36%)	6 (29%)
>5	2 (11%)	2 (9%)
STIs diagnosed in last year		
Yes	9 (47%)	7 (33%)
No	10 (53%)	14 (67%)
Average no. of sex partners per day		
1–2	0	12 (57%)
3–4	11 (58%)	7 (33%)
>4	8 (42%)	2 (10%)
Usually engages in vaginal sex with casual partners		
Yes	19 (100%)	21 (100%)
No	0	0
Usually engages in oral sex with casual partners		
Yes	9 (47%)	7 (33%)
No	10 (53%)	14 (67%)
Usually engages in anal sex with casual partners		
Yes	11 (58%)	4 (19%)
No	8 (42%)	17 (81%)
Condom use with casual partners ^a		
Always (100% of the time)	2 (11%)	5 (28%)
Sometimes (about 50% of the time)	12 (63%)	3 (17%)
Rarely (20% of the time or less)	4 (21%)	7 (38%)
Never	1 (5%)	3 (17%)

^aThree male respondents did not answer this question.

as Catholic ($n = 9$) or reported no religion ($n = 9$); most men were also single ($n = 12$), and some had completed secondary school ($n = 8$). All of the women identified their occupation as sex worker. The men reported a variety of occupations, including laborer ($n = 6$), minibus driver or worker ($n = 4$), and builder or painter ($n = 4$). Most focus group participants reported having more than one partner per day, and a higher proportion of male respondents reported always using male condoms with casual partners than did female respondents (5 of 21 vs. 2 of 9).

Study instruments

Informed consent documents, sociodemographic questionnaires, and focus group guides were designed in English and translated to Kiswahili, the local language. Study instruments were pretested among female commercial sex workers and male clients from Mukuru-Kware, a section of Mukuru in which the population has characteristics similar to those of participants in the focus groups.

Before directly assessing attitudes toward the IVR, men and women were asked about related topics, including HIV risk

perceptions and prevention methods, family planning preferences, and common sexual practices, designed to provide important social and cultural context to their responses about the ring itself. Female participants were also asked additional questions about common intravaginal behaviors, such as douching. Focus group guides included information on microbicide drugs, explaining to respondents that these drugs are being developed to protect against exposure to HIV and that IVRs have been approved for family planning and are being considered as a way to deliver microbicides but are not yet available for this purpose. Participants were shown a sample IVR and asked about first impressions regarding size and appearance. Men and women were also asked for their thoughts on IVR self-insertion, use during sex, acceptability among sexual partners, and potential of covert use. The study was approved by the Ethics Board of Kenyatta National Hospital and Emory University's Institutional Review Board.

Data analysis

Focus group facilitators worked as a team to transcribe and translate the data from Kiswahili into English, provid-

ing important contextual depth to this process of cross-language analysis.¹⁹ English translations were then entered into NVivo 7, a qualitative data analysis software from QSR International (651 Doncaster Road, Doncaster, Victoria 3108, Australia). A group of four co-authors defined a coding schema that closely followed the structure of the focus group guide initially. Through an iterative process, other themes that emerged as significant but that were not specifically asked about in the guides were also coded. After reading all the transcripts and reviewing coding summaries, the co-authors determined key themes and variables for further analysis and reporting.

Results

Focus group data include not only responses to the IVR itself but also more general data about common sexual behaviors and cultural beliefs, included because they provide a framework for the participant's perspectives on the ring and have the potential to influence IVR acceptability and uptake. These broader themes comprise responses to questions focused on HIV stigma, risk perceptions, attitudes toward prevention methods such as condoms, and common sexual behaviors and practices among this high-risk population in Mukuru, Kenya. Discussions about the IVR covered both physical characteristics and logistics of use as well as possible side effects. Major themes in the data include behaviors that may affect ring use, such as douching, gendered attitudes toward sexual pleasure, and concerns regarding the success of covert use.

Attitudes toward HIV and HIV prevention methods

These focus groups suggest that the stigma associated with HIV remains strong in participant communities. Statements such as these below were common in all focus groups, illustrating the emotional and economic tensions created in families struggling to care for loved ones with AIDS, as well as the fears of abandonment generated by an HIV-positive status:

R: You really suffer and our beloved forsake us because of AIDS. (*Women's FG2*)

R: It also brings war. Your husband begins to say that you are the one who brought it (HIV). People start fighting, accusing each other of bringing the problem. Your husband runs away. (*Women's FG3*)

Although HIV was perceived as an immediate threat by male and female focus group participants, this sense was expressed most strongly by the women. As single mothers and sole breadwinners for their children, they were acutely aware of the double-bind created by the fact that the means they use to feed their children also places them at high risk of contracting HIV.

R: We are at risk of getting HIV because you know people like us, we are single parents. We have children. I am jobless and I have a child who depends on me. . . . I [also] have my sister's child who was left orphaned. . . . They depend on me. . . . Now, the risk is that the method I use to fend for them, I could easily get infected

with HIV. You know HIV is like an accident. I could meet someone who is able to assist me, so I have sex with him. I'm after money, you see? When having sex, some refuse to use condoms for protection . . . and since you are after money—you know—it is very much risky. It is very risky. (*Women's FG2*)

The above respondent's description of HIV as an occupational hazard succinctly illustrates the social and economic circumstances in which she and many other sex workers labor.

When asked for their thoughts on the effectiveness of condoms as a method of HIV protection, men and women argued strongly that condoms were inadequate. Female participants acknowledged that men who care about protecting their wives or themselves or men who want to make sure that they do not have children outside of their marriages are often willing to use condoms, but these clients were presented as being a distinct minority. Both men and women described condoms as an ineffective means of protection, primarily because men often demand flesh-to-flesh sex, as supported by the much-repeated adage that one "cannot eat sweets in wrappers." As this male client of FSWs simply states:

R: They [condoms] are good, but you won't feel the same during sex; there is no maximum enjoyment. (*Men's FG2*)

Women in each of the focus groups felt that they could not oppose such attitudes, because their financial needs were so pressing.

R: This is someone who is just using you. . . . You are not an important person to him. . . . You're after the money in his pocket. That person doesn't want you to use a condom. If you tell him to use it, he says no. He says, "If you want us to use this, I can get somebody else, since it appears you are not interested in money." You see? (*Women's FG2*)

A theme that arose spontaneously in all the women's groups is a belief that some HIV-positive men covertly pierce condoms in order to intentionally infect others.

R: Condoms are good, but it all depends on the person you are with because some can pierce the condom with their nails. So you will think that you are protected when you are not. Even a small hole on the condom spoils the whole of it. It is a preventive measure but not very effective. (*Women's FG1*)

R: Eeh . . . or sometimes he tells you that he has worn it. . . . You know he is infected and wants to spread it to you. Now you know he will pierce it down there and you will get infected. They don't help. (*Women's FG2*)

This frequently expressed view suggests women's sense of the fragility of condoms as a means of HIV protection and a sense of powerlessness experienced by some FSWs in their sexual encounters.

Male responses to questions regarding condoms as an HIV prevention device paralleled those of female participants in terms of their beliefs that condoms are inadequate, although

this perspective was not as strongly voiced by men as by women.

R1: Condoms may have holes.

R2: Condoms may burst if the trip is long—if one prolongs the sex act. . . .

R5: Condoms may get pierced by a needle. Condoms may also get expired. You can't use expired flour. (*Men's FG1*)

Interestingly, one male respondent described the belief propagated by some herbalists that using condoms sap one's sexual strength.

R: Herbalists sell some traditional medicines called triberia. They encourage clients to use this for HIV prevention instead of using condoms. They tell clients that a condom finishes one's strength. Triberia is said to increase sexual strength. (*Men's FG1*)

Although it is difficult to ascertain from these focus groups the prevalence of this notion that condoms affect virility, among herbalists or in the broader community, such perspectives could have a significant impact on both condom use and on the uptake and effective use of other HIV prevention devices.

Overall, both male and female respondents expressed much frustration with condoms as a primary method of HIV protection. Women in particular voiced a need for alternative methods of HIV protection, as the following respondent reveals.

R: We just use them[condoms] for prevention, but we still get infected. That is why we need another method for prevention, so that we don't use condoms. One that will be in our body system. (*Women's FG1*)

Common sexual and intravaginal practices

When asked to identify common sexual practices in their community, female participants reported vaginal sex as the most frequent sex act they engage in with their clients. Significantly, in all three women's focus groups, women acknowledged the cultural taboos against anal sex, but their comments suggested that it is not necessarily an uncommon practice.

R6: Penile vaginal sex was used by our forefathers from the beginning. . . . If you practice dog styles [anal sex], you can't go to heaven.

R5: Money is money.

R6: May God forgive us, since we are in business. Otherwise, it's not a normal practice. (*Women's FG2*)

Several women reported a preference for oral or anal sex during menstruation or when vaginal sex might be painful or simply as a response to a customer's request.

R5: There are different styles. Now if the front [vagina] has become a problem, you will have to use a different style.

R2: But with me, even if I feel pain, I will persevere so as to get the money. Let me suffer after you have left.

R6: I would rather have anal sex. What's wrong? [Gen-

eral laughter]. There are many parts that one can use. The mouth, the anus . . . (*Women's FG2*)

Male respondents echoed women's views that vaginal sex is their most common sexual act, even as they confirmed that oral and anal sex are familiar sexual activities. Interestingly, dialogue from one male focus group describes their engagement in anal sex as situational.

Moderator (M): Which sexual acts are common in this community: penile/vaginal sex, oral sex or anal sex?

R3: It all depends on where you are; when I have sex along the corridors of a pub, I will always go for anal sex because it takes a shorter time.

R2: If we are on a drinking spree, she will sit on me and I will enter wherever she wants me to.

M: Where for example?

R2: In the anus or vagina. But if we are doing it in my house, I can go for oral sex because I would have enough time for her. (*Men's FG2*)

These male respondents' frank dialogue illustrates a social context where drinking sprees and a lack of private space strongly influence their risky sexual behavior.

Female respondents were also asked to describe their douching habits, as such practices could possibly interfere with microbicide effectiveness. Women described using various common household products for douching. In all of the focus groups, women most commonly mentioned douching with lemon or salt water, but some also said they used detergent, soda ash, and Coca Cola. These products were used frequently, preferably after every client.

M: Do women in your community use any preparations or products to clean or tighten the vagina?

R5: We were being deceived to use lemon.

R1: Bathing with warm water mixed with salt.

R6: You place a piece of cloth this way and that (demonstrating) and then you become a vajo (slang word for virgin).

[*Unanimous laughter*]

M: What does the piece of cloth have?

R3: Lemon, water mixed with salt and . . . (*Women's FG2*)

R: First of all, it [douching] keeps away bad smell, since you are meeting many people. Secondly, it prevents against infections. Third, it makes you be the very very one like you were created. (*Women's FG1*)

In each of the women's focus groups, respondents described their frequent douching as an effort to protect themselves from sexually transmitted infections, to clean and tighten the vagina, and to reduce vaginal lubrication—all of which they saw as necessary to protect their business.

Impressions of the intravaginal ring

After receiving background information on microbicides and handling a prototype of the IVR, several women in each of the women's focus groups voiced first impressions of the ring as too large, both in circumference and thickness, and its texture as too hard, whereas others emphasized that the size was not a problem.

R5: The size is the biggest problem.

R6: She screams to express that it is big [parenthetical remark of one focus group participant to another].

R4: The size is very big.

R6: It will hurt us the first day but once we get used to it. (*Women's FG3*)

Male respondents' first impressions of the ring were also varied, with some finding it big and others not.

M: What is your first impression of the device?

R5: It is big.

R7: No, it is not big. The head of a baby is bigger and yet it passes through the woman's vagina.

R1: It is okay. (*Men's FG3*)

Some female participants suggested that the rings should come in a variety of sizes to accommodate women's preferences.

Despite some concerns about the size of the ring, most women thought that given proper instruction, they could easily insert the ring themselves. A few respondents voiced their preference for a trained medical professional to insert the ring the first time and to instruct them on proper insertion.

R: I feel the doctor should insert it for me. I may insert it badly and it may bring problems to me. (*Women's FG2*)

R: If we are educated, we can insert it. Because if we can insert the female condom, even this one, if educated, we could insert it. (*Women's FG3*)

Women also discussed the acceptability of ring use during menstruation; a few women observed that the ring might be dislodged by a heavy menstrual flow or perhaps feel uncomfortable to use during periods, but most did not seem to think that wearing the ring during menstruation would be a problem:

R3: Yes. When you have periods, you will be very uncomfortable to have it in.

R5: In my opinion, periods don't last long. And once you are through with them, this ring will get clean again.

R3: I will remove it and return it. (*Women's FG2*)

R3: During menstrual period, maybe it may come out when you go to urinate.

R6: It can't come out. This thing is placed far. (*Women's FG2*)

When asked for their thoughts on duration of use, most women found the IVR's long-acting formulation appealing because of the convenience of not having to worry about HIV prevention for several months. In all the women's focus groups, female respondents reported that their preferred length of use for the ring would be 3 months to 1 year, which is similar to the duration of their preferred method of birth control, or injectable hormones.

R: One year is good because once you insert it, you forget about it for a long time knowing that you are safe. You rest your head from worrying about HIV. (*Women's FG3*)

However, some women were apprehensive about leaving the ring in the vagina for extended periods of time and the resulting effect on vaginal hygiene. A small group of both men and women thought the ring would require washing or changing between each encounter with different men.

R2: It depends on how the ring is made. If it has been made in a way that it will not collect dirt, then why remove it?

R1: But if it will be used for six or seven clients, then you must change.

R4: It is supposed to be changed. (*Women's FG1*)

R: The problem is that all men who will be having sex with her will leave all their sperm particles on the ring, and you won't tell who was there before you. It should be washed. (*Men's FG3*)

Men and women in each focus group asked pertinent questions about the ring's potential side effects and, in particular, its effect on vaginal hygiene. A few men and women also wondered how the ring might affect fertility. One woman voiced her concern that the IVR might have negative effects similar to those she associated with the IUD:

R: Won't this thing bring problems to your body? If the coils [IUD] cause you to get wounds in the stomach, what about this? Have you seen someone who has used the coil? You hear that they have problems. When it is removed, she has cancer. (*Women's FG3*)

Although a few men expressed concerns about potential negative side effects, for most, the ring's capacity to prevent HIV seemed to outweigh their fears, as the following dialogue suggests.

R3: If she will be comfortable, then I would be comfortable too.

R6: I would be comfortable.

M: Why?

R6: Because it is a preventive measure for both of us.

R5: If it is prevention against HIV, I will surely be comfortable.

R7: As long as it assures me safety, I would be fine with it.

M: Do you have any safety concerns about this device?

R2: I feel I might touch it during intercourse.

R4: It could have some side effects on both of you. (*Men's FG2*)

When women were asked to compare a hypothetical microbicide cream (that would be applied topically) to the IVR for HIV prevention, most preferred the ring because of its convenience and duration of use. As the women observed, applying a microbicide cream or gel before each sexual encounter is impractical for FSWs.

R: If I meet a client at Pipeline [neighboring community], will I run back to get the cream? No. (*Women's FG3*)

R: If it [the IVR] is inserted inside, even if you meet someone, you will not worry about whether or not he will wear a condom because you are already protected. (*Women's FG3*)

Most men also favored the microbicide ring over a microbicide cream or gel; many of them feared the cream/gel might create excess vaginal lubrication, thus curtailing their sexual pleasure.

R2: It [microbicide cream] might make the vagina wet.

R4: It will reduce friction . . .

R1: . . . and that will curtail the sexual pleasure. The vagina would not be in its natural state. (*Men's FG2*)

As these comments indicate, the effect of the ring on sexual pleasure was of prime concern to male respondents. Some men hypothesized that ring use would make women feel uncomfortable and lead them to stop sexual intercourse, whereas others voiced concern that if they felt the ring during intercourse, it would decrease their sexual pleasure.

R3: If it is not deeply inserted, it would definitely affect the sexual pleasure.

R2: It is true that it would affect the sexual pleasure, especially if you reach it during sexual intercourse. (*Men's FG2*)

When female participants were asked to consider how the ring might affect their sexual pleasure, a few women thought that it would not diminish their pleasure, and one even speculated that it might increase pleasure. However, by far most female respondents in each focus group made clear that their sexual encounters with clients were about business, not pleasure:

M: So it will affect the sexual pleasure?

R3: Eehhhh . . . [Yes].

M: Okay.

R6: You know we are talking and we haven't tried using the ring. Maybe if you use it, the sexual pleasure will increase. . . . Maybe if we use it, we will have more warmth [unanimous laughter] (*Women's FG2*)

M: And would it affect one's sexual pleasure?

R4: It won't affect. Even if it affected the pleasure, I am here for money. . . .

R: You know as a woman, I don't care about pleasure. All I want is money. (*Women's FG1*)

In each focus group, women redirected the discussion about the ring's effect on their own sexual pleasure to the ring's effect on their male customers, expressing the fear that their clients might feel the ring and respond negatively, thus affecting the women's livelihoods.

As related to the conversation on sexual pleasure, the ring's potential for covert use raised many questions for female respondents, primarily around whether or not they felt covert use would be successful. Several women doubted that men would notice the ring, and still others thought that if men did notice the ring, they might appreciate the protection. In each women's focus group, however, a clear theme emerged in which women voiced concerns that clients who felt the ring during intercourse might accuse them of witchcraft, respond violently, or, most importantly to the women, refuse payment, as the following dialogue reveals:

M: If these partners give a woman money or other goods in exchange for sex, do you think that her use of a microbicide ring would affect their willingness to do so?

R1: Obviously it will decrease because if he touches things like those, you will never see [him] come back.

R6: And he will make you lose customers.

R1: He will spread everywhere that you are like this or that, and there are things you are using.

R3: He will make you lose customers. He will spoil your market.

R5: He will say you are using witchcraft. . . .

R4: There are those who will understand and there are those who will not understand. . . .

R1: He must have varied thoughts.

R6: It should be inserted in such a way that the man will not reach it. (*Women's FG2*)

Although some men did not seem to be bothered by the potential of covert use, particularly by sex workers, several men in each focus group insisted that they had a right to know if a woman was wearing a microbicide ring.

M: How would you feel if your partner used the device without your knowledge?

R3 and R4 simultaneously: That is worse.

R4: It's like going to your house and meeting a snake on the table waiting to attack.

R2: She must inform me before using the device.

R4: Your sexual urge will fade off when you notice the device. (*Men's FG3*)

A few male respondents asserted that nonpayment would be an appropriate response if a sex worker did not inform them that she was using a ring.

R1: If she placed it wrongly and I pushed it inside, she will start making noise. And it is at this point that I will evade paying.

M: Mmh . . .

R2: If you reach the ring, she will feel uncomfortable and ask you to stop the sexual act. And thus I won't pay because I had not gotten satisfied.

R7: If carelessly placed, no one will pay her. (*Men's FG3*)

Overall, men's responses to the issue of covert use suggest that the women's fears of negative repercussions are well founded.

Notwithstanding their fears about their client's responses to covert use, several women observed that they should be able to wear a ring to protect themselves, with or without their partners' permission or knowledge.

R7: This should be your secret; you don't need to tell him that it is in. You would be protecting yourself from those who want to infect you. . . .

R5: So this means when you use this thing, it is your secret. It's not for your client to know what's going on. (*Women's FG1*)

Discussion

The results of our focus groups with FSWs and male clients in Mukuru, Kenya, provide the first acceptability findings of

an IVR designed specifically for use as a hypothetical HIV prevention device. Our respondents were generally open to the potential of a microbicide IVR and voiced a strong desire for the development of more prevention tools. Some of the issues raised in the focus group are paralleled in the literature on topical microbicides, such as concerns regarding lubrication and covert use, but the results also introduce new findings that might be of particular interest to researchers and designers of microbicide IVRs as they move through the developmental process.

Positive aspects

The high-risk women who participated in these focus groups confirmed the well-documented male preference for skin-to-skin contact during sexual intercourse and appreciated the potential for an IVR to provide protection against HIV when their clients refuse to use condoms. In comparing topical creams, gels, and condoms with the IVR as a means of HIV protection, FSWs found the IVRs long-lasting formulation especially appealing because their working conditions are often not conducive to the preparation and planning involved in successfully using a topical microbicide, nor would the IVR's use inhibit the spontaneity desired in sexual encounters.^{8,20} Furthermore, given the preference for dry sex within some communities in Kenya and sub-Saharan African, the fact that the IVR is unlikely to create additional lubrication during sex might raise its appeal in communities and provide another potential advantage.^{4,14}

Design questions and adverse effect concerns

Women and men in Mukuru raised a number of questions and concerns about the microbicide ring that could be addressed in product design and early clinical studies. Some male and female respondents' first impressions of the prototype ring were that it was too large for easy insertion or that its size and texture might cause discomfort during sexual intercourse; several women suggested that the ring should be made in a variety of sizes rather than have it assumed that one size fits all. Both men and women voiced concerns about how leaving the ring inserted for extended periods of time might affect vaginal hygiene. Reproductive safety has been cited as a key factor in acceptability of other HIV prevention methods,²¹ and a few respondents did raise concerns about risks of decreased fertility or risk to a fetus during pregnancy, although these concerns were not major themes. Several respondents observed, however, that they would prefer a ring designed to protect against unwanted pregnancy as well as HIV. It was also observed that they would prefer a ring that could protect men from HIV if the female user was HIV-infected. Development of IVRs with HIV prevention, contraceptive, and STI prevention properties either in a single drug or combinations of drugs has been proposed, but current products entering clinical trials focus on HIV-specific microbicide activity.⁸ The effect of IVR use on HIV prevention for the male partner of HIV-infected females is an important question that is being addressed in topical microbicide development and should be included in development plans for IVRs.

Behavioral factors impacting IVR use

The results of these focus groups suggest that although anal sex might be somewhat stigmatized, it is not necessarily uncommon within this high-risk population in urban Kenya. Brody and Potterat²² have argued that unsuspected and unreported penile-anal intercourse has played a larger role in fueling the HIV epidemic in Africa than previously assumed. In order to provide clear information about anal sex risk to future IVR users, researchers should assess protection against infection from anal sex by collecting data on anal sex frequency among trial participants in clinical trials of IVRs.

The effects of vaginal douching in this high-risk population also need to be further assessed during IVR clinical development, given the hypothesized link between frequent douching and increased prevalence of HIV.²³ Specifically, the potential for interactions between microbicide IVRs and a wide range of douching products should be evaluated prior to large-scale clinical trials, as it is unknown if IVRs exposed to acidic or abrasive materials may have faster rates of degradation, different rates of drug excretion, or potential for chemical interactions. Women who douche frequently may experience a higher rate of adverse events with IVR use, such as pain, mucosal abrasions, and potential increase of STIs and HIV. In light of historic and recent topical microbicide efficacy trials showing increased rates of HIV transmission with microbicide use, these factors will need careful attention in preclinical and early clinical studies.^{24,25}

Discussions about the ring's effect on sexual gratification indicate a marked gender disparity, most likely influenced by the commercial nature of the participants' sexual interactions. Male respondents were clearly interested in the potential effects of an IVR on their own sexual pleasure, whereas female respondents in this population found it difficult to discuss the effects of the ring in terms of their own satisfaction, instead focusing their responses on how they imagined the ring would affect the sexual pleasure of their male clients. Both men and women hypothesize that the ring could interrupt a man's sexual pleasure and, therefore, affect compensation. As with the condom, which hinders skin to skin contact, ring uptake may decrease if it interferes with sexual pleasure or even if there is the perception that it would interfere with sexual pleasure. FSWs might be reluctant to use a microbicide IVR if they thought it would jeopardize their livelihoods. IVR developers should continue to assess these attitudes during clinical testing and be prepared to address them during introduction of the device.

Concerns about covert use

Microbicides, whether delivered topically or through an IVR, have been heralded as a way to address the pervasive gender imbalance and power inequities that many women face by providing them with a tool for HIV prevention that they could control themselves. Yet initial studies of microbicide acceptability among married women have indicated that, for some, covert use of a microbicide might raise trust issues as vexing as those experienced in negotiations of condom use. A Ugandan study found that women in their pre-trial microbicide focus groups believed surreptitious use of

a microbicide was advantageous, but they did not manage to sustain covert use over time, primarily because they feared negative repercussions.²⁶

Our results suggest that covert use might be as challenging for some FSWs as it is for some married women. Although these high-risk female participants' opinions were quite diverse on whether their male clients would detect an IVR during sex, particularly in the setting of alcohol use, some voiced fears that covert use might backfire, leading to negative repercussions, such as accusations of witchcraft, gossip that drives away potential customers, or even physical violence. Findings from the men's focus groups suggest that men are more likely to approve of FSWs using IVRs than they are of their wives using IVRs, but men also voiced a strong belief that they have a right to be informed should any sexual partner use an IVR. Several noted that they would avoid paying or respond with anger if they discovered an FSW using a ring without their consent. Significantly, in trials of contraceptive IVRs, albeit in a non-FSW population, a substantial proportion of regular male partners did report feeling the IVR during sex—about 29% in one study,⁹ so the women's fears around the potential failure of covert use might be substantiated. Nevertheless, several women asserted that women have the right to use an HIV prevention method covertly.

Limitations

This study has several limitations. Our small, targeted sample of high-risk women and male clients of FSWs in Mukuru, Kenya, is not representative of the larger, general Kenyan population, although our results might be useful for similar high-risk groups within Kenya and sub-Saharan Africa. It is also noteworthy that unbiased opinions may be difficult to collect from this study population; the very presence of a research group may have led these women and men to have a less critical eye, particularly if they feel they may stand to benefit by responding positively about a product. To counter this, we offered no compensation for participation beyond reimbursement for transportation and time, and we tried to minimize the potential for less critical responses by repeatedly emphasizing how important their honest opinions would be to successful product development, even if negative. Researching a hypothetical product has inherent challenges. The men and women in this study expressed their opinions without having had the opportunity to use the IVR. The characteristics identified as desirable or of concern based on these first impressions could dissipate upon actual use, presuming effective microbicide products emerge from clinical trials.⁸ Similarly, important desirable or questionable product acceptability characteristics may only be identified during actual product use in clinical trials. It is also worth considering the inherent challenges of cross-language data collection and analysis.¹⁹ We attempted to mitigate these challenges by using highly skilled researchers equally fluent in Kiswahili and English and experienced in addressing such cross-language issues, who both facilitated the focus groups and transcribed and translated the focus group data, thus providing the important advantage of social context to the process of translation.

Conclusions

This qualitative research study presents initial findings for acceptability of the IVR among FSW and male clients in an urban African setting, who were receptive to the IVR as a potential HIV prevention device. This investigation among a high-risk population in a developing country indicates that in addition to concerns about side effects and safety, acceptability may also be influenced by sexual behavior, intravaginal practices, and pleasure seeking. Practices such as douching and preferences for dry sex may play a role in decision making, negotiation, and uptake of such a device. IVRs were conceptualized as a tool that would primarily appeal to women, providing them with greater autonomy to protect themselves from HIV, yet the assumption that women will be able to use IVRs covertly will need careful exploration in clinical trial settings, with close attention to the safety of vulnerable populations, such as FSWs.²⁶ Furthermore, it is important that acceptability studies include men in order to identify their major concerns about IVR use and address them proactively.²⁰

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Address reprint requests to:
 Donna Jo Smith, M.A.
 Institute of Public Health
 Georgia State University
 PO Box 3995
 Atlanta GA 30302

E-mail: donnajsmith@gsu.edu