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Achieving the Optimal Vaginal State: Using Vaginal Products and Study Gels in Uganda, Zimbabwe, and South Africa

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ABSTRACT

Preferences and practices related to the vaginal condition have implications for the use of vaginal HIV prevention products. The authors used qualitative methods to explore narratives relating to the vaginal state amongst women in South Africa, Uganda, and Zimbabwe who had previously participated in a biomedical HIV prevention trial. They investigated women's behaviors related to optimizing the vaginal state, experiences and perceptions of the gel's effect on the vaginal state and on penile-vaginal intercourse, women's narratives on male partner perceptions, and how preferences relating to the vaginal state may have interfered with gel use.

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Reproductive health; women; HIV/AIDS; HIV prevention; qualitative studies; vagina

Introduction

Practices, perceptions, and norms relating to sex and the body are complex and vary across cultures, societies, and relationships. Important to consider in developing HIV prevention products designed for vaginal use are sociocultural norms and preferences relating to sex, hygiene, and genitalia, in the contexts for which their use is intended (Hilber et al., 2012; Severy & Newcomer, 2005). Preferences relating to the vaginal state, including optimal levels of lubrication, warmth, and tightness during sex, are central to the acceptability of prospective HIV prevention products designed for vaginal use (Gafos et al., 2010). Central to any discussions of vaginal state preferences is the socially constructed nature of conceptualizations of the perfect or ideal vagina/vaginal state (Ogbo & Leye, 2016). The notion of a perfect vagina, implies the notion of the "imperfect but perfectible vagina" (Braun & Kitzinger, 2001). The way in which women experience their vaginas is influenced by broader sociocultural norms and systems of meaning (Braun & Kitzinger, 2001).

The term *vaginal practices* refers to a range of behaviors women engage in to modify and manage the condition of their vulvo-vaginal area, to achieve an

optimal state. Motivations for vaginal practices are diverse and include beauty, hygiene, health, dyadic relationship maintenance, as well as physical sensation and partner sensation during sex (Hull et al., 2011). In communities where women regularly engage in vaginal practices, HIV prevention products requiring vaginal insertion may interfere with existing practices. In the early stages of developing a vaginal microbicide gel, researchers were concerned about barriers to acceptability in areas of sub-Saharan Africa in which vaginal drying practices had been documented (Braunstein & Van de Wijgert, 2005). Early studies found, however, that although some women complained that gels were messy, the lubricating properties of the product were regarded in a positive manner (Montgomery et al., 2010).

Yet, findings from our research published in an earlier paper showed that amongst a range of eight modes of delivery for biomedical HIV prevention products (cervical barrier, implants, injectables, oral tablets, vaginal gel, vaginal film, vaginal ring, and vaginal suppository), gels did not rank highly in product preference ratings (Luecke et al., 2016). Women perceived gels to create uncomfortable sensations of being wet

and leaky. Other vaginal products are currently being developed, such as rings, films and suppositories (www.ipmglobal.org/our-work/our-products). In trials testing vaginal products, greater attention needs to be paid to the way in which their properties and the actual physical sensations produced by their use, impact user experience (Morrow et al., 2014b).

Greater insight is needed into the ways in which the use of vaginal HIV prevention products, particularly in sub-Saharan Africa, might be influenced by preferences and practices around the vaginal state including conditions of lubrication, hygiene, tightness, and temperature (Braunstein & Van de Wijgert, 2005; Gafos et al., 2014; Montgomery et al., 2010). Preferences related to the optimal vaginal state have implications for women's own feelings of comfort and perceptions of hygiene, overall and during sex, and their sexual partners' perceptions of the same. It is critical to assess (1) how the use of such a product would fit into existing practices and preferences relating to sex and genital hygiene maintenance; (2) the ways in which potential end users of a product perceive its effects on the body and sex, and the sensation of using it; and (3) how vaginal state preferences may influence women's disclosure of using a vaginal HIV prevention product.

The findings presented in this article come from VOICE-D, a qualitative ancillary study to the VOICE HIV prevention trial, conducted among former participants in South Africa, Uganda and Zimbabwe. We examined women's narratives on vaginal state preferences, vaginal practices they engaged in, and their experiences and perceptions of the vaginal study gel provided in VOICE. Our goal is to improve understanding of how preferences relating to the optimal vaginal state may interfere with women's ability and willingness to use vaginal products.

Methods

The VOICE/MTN-003 trial, conducted 2009–2012, enrolled 5,029 women from Zimbabwe, Uganda, and South Africa and was the first trial to evaluate the effectiveness of daily, noncoitally dependent use of an antiretroviral-based microbicide, as well as daily oral tenofovir tablets, for the prevention of HIV (Marrazzo et al., 2015). Women in the two gel arms ($n = 2,010$) were randomly assigned a daily regimen of either 1% tenofovir vaginal gel ($n = 1,007$) or a placebo gel with

no active ingredient ($n = 1,003$). Participants were asked to insert their assigned vaginal gel using a plastic applicator at approximately the same time each day. Testing of the vaginal gel was stopped early (November 2011) due to futility (Marrazzo et al., 2015). During VOICE, participants were instructed not to insert any non-study products into their vaginas for the trial's duration. Participants were asked to report insertion of any products or materials into their vaginas for cleansing purposes, as well as any substances they might have inserted into their vagina at times other than during menses in the prior three months.

VOICE-D/MTN-003D was a follow-up study conducted 2012–2014 after the completion of VOICE. Qualitative research methods were used to investigate product-related perceptions and experiences of former VOICE participants. Semi-structured in-depth interviews and focus group discussions were conducted in participants' language of preference (Zulu, Luganda, Shona, or English) by trained female interviewers. Data collection took place in two stages involving 171 women: 47 in Durban (South Africa), 65 in Chitungwiza (Zimbabwe), and 59 in Kampala (Uganda). Of the 171 participants, 88 were in Stage 1 (including participants on active or placebo products) and 83 were in Stage 2 (limited to former participants on active products); 44 were in both stages. In the second stage, women were presented with results of their tenofovir blood plasma levels during the VOICE trial, a biological indicator of their recent adherence to study product use (van der Straten et al., 2015). All participants completed a demographic survey. Ethical approval was obtained from Institutional Review Boards and Ethics Committees at each of the study sites in Zimbabwe, Uganda, and South Africa and collaborating institutions in the United States and South Africa.

Audio recordings of in-depth interviews and focus group discussions were transcribed verbatim into their original language, reviewed by site interviewers, translated into English, and reviewed by an international team to ensure accuracy, clarity, and completeness. Qualitative data were analyzed using an inductive approach; a codebook was iteratively developed reflecting the study's key objectives and emerging themes. Data were coded and thematically analyzed using the NVivo 10 software package (QSR International, London) by a team of four analysts; $\geq 80\%$ inter-coder reliability was established and verified on $\sim 10\%$ of the transcripts throughout the coding process. Data presented in this article were primarily

coded with a combination of the following codes (parent nodes in CAPITALS; child nodes in parentheses): EFFECT (cleanses, lubricates, tightens); SEX (vaginal sex); STUDY PRODUCTS (gel). Participant demographic characteristics collected via an interviewer-administered questionnaire are presented, as are quarterly self-reports of non-menstrual vaginal practices collected via audio-computer assisted self-interview reporting.

Results

Table 1 presents demographic characteristics of the VOICE-D sample from both data collection stages combined. In the table are also presented self-reported data from VOICE-D participants on vaginal practices including cleansing and the insertion of paper and tissue/absorbing materials into the vagina at two time points during the VOICE trial (baseline and product use end visit).

Data in Table 1 show that cleansing the vagina with water was very common across all three countries, reported by 64% of women (gel and tablet combined) at both time points. Cleansing with soap-like substances was fairly common, especially amongst South African women (47% at baseline). Cleansing the vagina with soap reportedly decreased over time for women in South Africa and Uganda, but increased amongst Zimbabwean women (11% to 14%). Women's reporting of inserting some kind of material (paper, tissue, rags, wool, or cotton) into their vagina for nonmenstrual management purposes (menstrual management data was assessed separately and is not shown) decreased amongst all women except Zimbabweans in the gel arms (increasing from 23% to 48%). Overall reporting of vaginal practices decreased between the two time points across the three sites, although we cannot be certain whether the decline in reporting is an indicator of a change in behavior. Notably, there was little overall difference in vaginal practices between women in the gel and tablet arms, suggesting that use of study gel did not impact on vaginal practices (or reporting thereof).

The following section presents qualitative data collected in both stages of VOICE-D, providing in-depth exploration of practices that women engage in to achieve desired vaginal states, the perceived effects of the study gel on the vaginal state and on sexual intercourse, and challenges relating to daily application of the gel. Direct quotations (translated) from

participants are presented in italics, followed by brackets providing details of the participant's nationality, whether she was in the gel or tablet arm of VOICE, using a placebo or active drug product, and the data collection stage the quote comes from.

Vaginal practices

Women listed products and substances in many forms and consistencies (e.g. powders, liquids, teabags, tablets and creams) used in a variety of ways (e.g. ingesting, dissolving under the tongue, smoking, douching, applying topically, wiping against and inserting into the vagina), to cleanse or modify the vaginal state.

Vaginal practices for sex

Participants described a range of practices women engage in prior to sexual intercourse, including cleansing/douching, and the use of products to tighten or dry out the vagina. Women, particularly those from South Africa, listed local products used by women to tighten or close the vagina (*iyavalana* in Zulu):

People wash (their vaginas) a lot ... they use many things ... Zulu things (traditional products) ... 'Izigezo' ('cleansers') ... to bring together the vagina... so that it can be tight... like 'muti' (traditional medicine). (South African, active tablet, Stage 1).

Pre-coital cleansing was described by participants in all three countries, involving the use of cold water, either on its own or in conjunction with a soap or detergent substance. The high reporting of cleansing with water and/or soap as seen in Table 1 may have been pre-coital rather than for general hygiene, however this detail was not captured during VOICE. Douching with cold water prior to sex was described as a way of tightening the vagina. Notably, bathing the vagina in cold water was also cited as a way to counteract the perceived loosening effects of the gel on the vagina.

It (vagina) becomes too open, then my husband complains ... that it is now too open ... it feels too open like soon after delivery (child birth) ... if you put your fingers inside (vagina) ... if you had put the gel, all the fingers could fit as it would be open ... But if you bathe with cold water it would close up... I bathed with cold water in the evening... then it (vagina) would close. (Zimbabwean, placebo gel, Stage 1)

One cited motivation for tightening the vagina was masking infidelity. Women described the use of

Table 1. Demographic Characteristics of VOICE-D Participants and Quarterly Reporting of Nonmenstrual Vaginal Practices During VOICE Participation.

Demographic characteristic	All sites (n = 171)	South Africa (n = 47)	Uganda (n = 59)	Zimbabwe (n = 65)
Mean age (range)	26 (18–38)	24.3 (18–38)	26.6 (19–37)	26.6 (18–38)
Number sero-converted during VOICE (per cent)	16 (9%)	9 (19%)	4 (7%)	3 (5%)
Enrolled in tablet arms of VOICE	87 (51%)	23 (49%)	30 (51%)	34 (52%)
Enrolled in gel arms of VOICE	84 (49%)	24 (51%)	29 (49%)	31 (48%)
Relationship/sexual partners				
Currently married	84 (49%)	0	26 (44%)	58 (89%)
Has current primary sex partner or married	165 (96%)	47 (100%)	53 (90%)	65 (100%)
Mean number of sexual partners in lifetime (range)**	11 (1–99)	3 (1–15)	26 (2–99)	2 (1–35)
Exchanged sex for money/goods/gifts/shelter/drugs in past year	14 (8%)	0	13 (22%)	1 (2%)
VOICE Baseline (ever in past 3 months)				
Gel arms	n = 84	n = 24	n = 29	n = 31
Tablet arms	n = 87	n = 23	n = 30	n = 34
Inserted soap into vagina	41 (24%)	22 (47%)	12 (20%)	7 (11%)
Gel	24 (29%)	15 (63%)	7 (24%)	2 (6%)
Tablet	17 (20%)	7 (30%)	5 (17%)	5 (15%)
Cleansed vagina with water only	109 (64%)	26 (55%)	36 (61%)	47 (72%)
Gel	52 (62%)	15 (63%)	16 (55%)	21 (68%)
Tablet	57 (66%)	11 (48%)	20 (67%)	26 (76%)
Inserted paper/tissue/rags/wool/cotton into vagina (non-menstrual purpose)	44 (26%)	9 (19%)	19 (32%)	16 (25%)
Gel	21 (25%)	5 (21%)	9 (31%)	7 (23%)
Tablet	23 (26%)	4 (17%)	10 (33%)	9 (26%)
VOICE Product use end visit (ever in past 3 months)				
	All sites (n = 159)	South Africa (n = 40)	Uganda (n = 56)	Zimbabwe (n = 63)
Gel arms	n = 80	n = 21	n = 28	n = 31
Tablet arms	n = 79	n = 19	n = 28	n = 32
Inserted soap into vagina	25 (16%)	9 (23%)	7 (13%)	9 (14%)
Gel	12 (15%)	7 (33%)	3 (11%)	2 (6%)
Tablet	13 (6%)	2 (11%)	4 (14%)	7 (22%)
Cleansed vagina with water only	101 (64%)	20 (50%)	36 (64%)	45 (71%)
Gel	47 (59%)	9 (43%)	18 (64%)	20 (65%)
Tablet	54 (68%)	11 (58%)	18 (64%)	25 (78%)
Inserted paper/tissue/rags/wool/cotton into vagina (nonmenstrual purpose)	29 (18%)	2 (5%)	15 (27%)	12 (19%)
Gel	15 (19%)	1 (5%)	8 (29%)	15 (48%)
Tablet	14 (18%)	1 (5%)	7 (25%)	6 (19%)

* Data captured during VOICE trial duration for Stage 1 and Stage 2 VOICE-D participants combined.

**If more than 99 lifetime sex partners, a value of 99 was recorded (not a truly continuous variable).

certain substances ingested or drunk with the purpose of tightening the vagina to hide their engagement in penile-vaginal sex with multiple partners.

If you want to hide something from your boyfriend, then you should drink it (vaginal practices product) and it will tighten you ... After you've taken it, you should go and clean yourself otherwise your boyfriend will notice something and beat you then tell you that you are a slut. (South African, active tablet, Stage 1)

Women described the use of specific vaginal cleansing products between sex partners, to mask their infidelity.

When you sleep with a man, he can't just go in (penetrate the vagina) ... if you'd been sleeping with another man, your partner's penis gets stuck ... It doesn't go in easily ... it doesn't just slip in ... There are powders ... the product for washing is a green solid product ... it can be ground ... it looks like sugar ... Women use the products when they have left one partner and gone to another one ... (otherwise) the main partner can feel a difference

from since he last had sex. (South African, active tablet, Stage 1)

The theme of optimal vaginal lubrication was prominent in women's narratives of vaginal practices. Although some women reported using products to dry out their vaginas, others used products to lubricate their vaginas for sex:

(Snuff tobacco) helps make you dry and enjoy sex ... The vagina gets dry instead of being wet ... You don't have to hear that noise (sound of penis penetrating wet vagina). (South African, active gel, Stage 1).

Effects of gel on sex

Some of the women in both stages of VOICE-D shared their positive perceptions of the effects of the gel, including narratives relating to the way in which the gel gave them a 'high sex urge', and increased their desire for, and enjoyment of sex. The perceived positive effects of the gel on women's libido was described as beneficial for the maintenance of sexual relationships, enhancing male partner sexual satisfaction.

Increased libido and desire for sex was partly ascribed to increased vaginal lubrication, making sex easier:

(The gel) increased our libido ... libido was very good because our vaginas were slippery (laughs) ... It was very smooth ... the vagina was slippery ... excellent for love-making. (Ugandan, active gel, Stage 1).

Women also described positive perceptions of the way in which the gel made them feel ‘hot’ (sexy), and feminine.

(Gel) was good for me ... It made me “hot” (sexy) ... just right... a real “lady” ... I liked my gel very much ... it made a difference ... I used to feel it ... It makes me hot, burn ... mmm ... I felt “hotter” after I had applied it ... when having sex ... I was excelling. (South African, active gel, Stage 1)

In addition to making women themselves feel “hot,” women explained that their male partners would also tell them that they were hot and sexy after applying the gel:

(Gel) treated me well. He (sex partner) also said that there was a difference... He said that I was hot (sexy)... It made me hot. (South African, active gel, Stage 1).

Tightening

Vaginal tightness from gel use emerged as a common theme in the qualitative data. Participants from all the study communities in both stages of data collection spoke positively of the tightening/narrowing effect on the vagina. South African women likened the tightening effects of the gel to traditional herbal products (izigezo) used for the same purpose. Referring to the tightening effects of the gel on the vagina, many of the participants used terminology relating to being “virginal”; describing the sensation created by the gel like having sex “for the first time,” as if you were “losing your virginity again;”

(The gel) puts tissues together, tighter ... I would feel ‘hot’ ... at the same time my vagina would be tighter. (South African, active gel, Stage 1).

Vaginal tightening, and being virginal was described as a desirable effect of the gel, particularly for ensuring male partner pleasure; for this reason, some women explained that they would time their use of the gel around anticipated sex.

My partner said that it made me (vagina) tight when we were sleeping together. He was happy when I was using

the gel ... When I was no longer using the gel he asked me why I had stopped ... He said that he could feel a difference (with the gel) ... as if it was his first time sleeping with me (virgin-like). (South African, active gel, Stage 1)

Some women said that although their partners reacted positively to the effects of the gel on their vaginas, they did not disclose that gel use had caused this change, instead ascribing it to the effects of common vaginal practices.

“The boy” (partner) said that I was hot at that time ... (the gel) closed me up (tightened the vagina) ... He asked why I was closed up all of a sudden ... I would say that that was maybe because I had washed with cold water ... he liked it... he was happy. (South African, active gel, high adherence, Stage 1)

The positively regarded ‘tightening’ effect of the gel may have resulted in some women using the gel more frequently than instructed.

When you sleep with (partner) after (using gel for a few days), it feels as if you are doing it (having sex) for the first time ... the vaginal walls come together and it feels as if you are sleeping with a man for the first time ... some people used to overdose the product and maybe use it twice a day because it had the benefit of making the vagina feel tighter. (South African, active gel, Stage 1)

Despite being instructed to use the gel daily at the same time, in both study stages women spoke of their own coitally-dependent (application before/at coitus) use of the study gel.

(Gel) was helping me a lot ... if you have inserted this thing it was firming (vaginal muscles) and made one feel like a virgin ... I was using it (gel) to be a virgin ... if my man was coming over ... when I was expecting a visitor I would start inserting it. (South African, active gel, Stage 2)

It was suggested that the study gel had a similar effect on other vaginal practices’ products described above and could be used for the same purpose of hiding infidelity. Perceptions that the gel tightened the vagina and “firmed everything back to the original form” meant that after having sex with a secondary partner, one’s primary partner would be unable to detect the infidelity.

Widening/loosening

Concurrent (and in contrast) to narratives of the tightening effect of the gel, some women described a “loosening/widening” effect on the vagina; narratives on widening

came mostly from Zimbabwean women. One participant in the tablet arm who found penile-vaginal penetration uncomfortable described her desire to use the vaginal study gel for its widening effects:

My private part (vagina) was too tight ... I wanted to use the gel so that it can loosen it up a bit ... It was even difficult to have sex (without gel) ... That's why I wanted the gel. (Zimbabwean, active tablet, Stage 1).

Other women regarded the widening effect negatively, commenting that it made the vagina “too wide/open,” reducing the friction of penile penetration.

(After using gel) there was no joy (no sex) ... he (partner) would complain because during sex he would just go in (penetrate the vagina) and it would be the end, the vagina will no longer be tight ... you are now like someone in labour, the vagina will be too open. (Zimbabwean, placebo gel, Stage 1)

Where the widening effect of the gel was negatively perceived, other vaginal practices and products could counter the widening:

A certain salt is being sold ... if you are using gel, and for some reason, your vagina expands, you could then use the salt ... your vagina would (return to normal) ... so I also bought the salt. (Zimbabwean, active gel, Stage 2).

Lubrication

Some of the participants believed that the study gel had the effect of making a woman produce more vaginal fluid, eliciting contrasting reactions amongst women, and demonstrating the diversity of preferences related to optimal vaginal lubrication. Positive narratives on the lubricating effects of the gel came from women in both VOICE-D stages, including comments alluding to the use of gel negating the necessity of engaging in foreplay (romance), as the gel would lubricate the vagina sufficiently to prevent discomfort during penile-vaginal penetration.

I liked it (gel) ... whenever I inserted it, it would remain there (in the vagina) and during intercourse I would not have any difficulty because I would be well lubricated because of the gel ... I enjoyed using it ... every time I would have sex with my husband, he didn't have to romance me (foreplay), my vaginal fluids would just flow like water. (Ugandan, active gel, Stage 2)

Women in both study stages stated that the lubricating properties of the study gel made vaginal

sex easier, more comfortable and thus more enjoyable, especially for those with previous experiences of vaginal dryness, painful intercourse, and low libido.

The good thing about that gel is that if a person didn't really have vaginal fluids, you would be able to get them ... it (gel) would create them ... it would make one feel lubricated ... Every time you put it (gel) there (in vagina) it would make you feel comfortable. (Ugandan, active gel, Stage 1)

It used to be so painful to have sexual intercourse without using the gel. So the gel was making it easier for me ... The gel's lubrication would help me out. (Zimbabwean, active gel, Stage 2)

Some of the women described how the gel helped to prevent tissue trauma and abrasions (described as bruises) occurring in the vagina as a result of penile-penetration, and thus protected against HIV infection. A few of the participants who disclosed selling sex said that the gel was beneficial to their trade and meant they did not have to purchase sexual-lubricant.

Reports of partner perceptions of the lubricating effect of the gel on the vagina were mixed. Some women said that prior to using the gel their male partners had complained about vaginal dryness. Similar to the non-disclosure about the tightening of the vagina caused by the gel, some women chose not to disclose the cause of the vaginal lubrication.

I started having a lot of vaginal fluids (vaginal fluid) ... my husband asked me ... “How come nowadays you are like this (have a lot of vaginal fluids)?” I told him that I take a lot of millet porridge nowadays, because I did not want to let him know what I was involved (the study) ... Before I was dry (vaginally), now ... I had a lot of vaginal fluids ... he was wondering why, in a good way. (Ugandan, placebo gel, Stage 1)

In contrast to positive narratives of the gel's lubricating effect, there were women in both study stages who regarded the increased vaginal lubrication caused by the gel negatively, expressing disgust, embarrassment and discomfort at the excess wetness. Women explained that when the vagina becomes too lubricated, sexual pleasure is adversely affected:

If you were over-lubricated in your vagina, the sexual pleasure would diminish ... your vagina would be too wet ... from the over-lubrication of the gel. (Zimbabwean, active gel, Stage 2).

Women described situations in which after applying the study gel, they would feel disgusted and embarrassed about the wetness of their vaginas; partners would also complain about the levels of lubrication:

(Our) husbands would be affected by the gel during sexual intercourse... It would feel like the vagina becomes too wet... husbands would complain. (Zimbabwean, active gel, Stage 1).

At times, male sex partners reacted to the increased vaginal lubrication with disgust and anger, occasionally leading to physical violence.

When I was sleeping with my man ... I would just get wet (because of the gel) ... I was embarrassed ... he would get angry ... he can be crazy ... He would ask how he's supposed to sleep with me then (when vagina is so wet)... It would get really bad ... it became a big problem ... he would just slap me ... He just said that he doesn't like it ... that maybe I'm doing something to him or there's something (disease) I'm giving to him. (South African, active gel, Stage 1)

Respondents in all three countries used terms relating to the gel being slippery, citing this as a negative characteristic making sex unpleasant for the male partner.

The gel made it difficult to have sex due to its slipperiness ... most men don't like this ... they want there (vagina) to be dry. So we ended up not using the products ... It was too wet and slippery. It wasn't okay. (Focus group discussion, Zimbabwe, active gel, Stage 2)

Using the gel concurrently with a male condom (as instructed by study staff) enhanced slipperiness and reduced pleasure.

At times if you insert your gel ... he (husband) would end up frustrated and just gives up because it was difficult. It was too slippery and he would just withdraw ... It was even more difficult with a condom because already it's slippery ... we keep on trying like that but in the end he will just give up on the sex ... He will be frustrated and give up. (Focus group discussion, Zimbabwe, active gel, Stage 2)

In addition to decreased friction caused by the gel, other factors such as gel texture and the sound of squelching with penile-penetration were cited as reasons for negative partner reactions to the gel:

It made a funny sound there (vagina) during sex (squelching) ... My husband would ask "what you have

been using?" ... when I had this (vaginal squelching sound) ... he said it wasn't okay. (focus group discussion, Zimbabwe, active gel, Stage 2).

Women expressed concern relationship security would be jeopardised if male partners lost interest, and abandoned them in search of other sexual partners.

That is why in the end we gave up (using gel) ... Because you can't let your husband leave you, you will be abandoned ... The slipperiness ... that is the main reason we stopped using gel ... Our husbands ... were going to end up leaving us to stay at their small house (with mistress). (Focus group discussion, Zimbabwe, active gel, Stage 2)

Drying

Women described how the lubrication of the vagina by the study gel was short-lived, resulting in what was described as dryness/itchiness. A few of the participants who enjoyed the lubricating properties of the gel for the purposes of sexual intercourse, described how after initially lubricating the vagina, if sexual intercourse was prolonged, the vagina would get dry/itchy. The short-lived lubricating effects of the gel could be problematic in sexual encounters, particularly if male partners desired another round of sex, as women were instructed to only apply the gel once a day; this proved particularly challenging for women who chose not to disclose gel use to sex partners.

If your privates (vagina) dried ... it was a problem ... if he (man) went for another round of sex, you would find yourself (vagina) dried up ... I would just let it be because it was not allowed to use the gel a second time ... we were supposed to apply it once in a day ... I would remain like that (dry vagina) ... sometimes he would first finish the sex ... he would say in astonishment "Before you were like this (dry)... now you are well lubricated!" ... when I would get dry, he would ask "why are you not well lubricated anymore?" ... I would say that I also do not know why ... when I was with my husband during the first round of sex, I would have vaginal fluids but when we went for a second round of sex, I would get dry. (Ugandan, active gel, Stage 1)

Disclosure of gel use in the context of sexual relationships

Gel use and the effects of the gel had implications for fidelity, communication and disclosure within sexual relationships. Women recounted situations in which their male partners became aggressive as a result of

their vaginal state, making accusations regarding presumed infidelity:

When I visited him (male partner), he would find my vagina wet ... he'll shout at me, asking who I had been sleeping with. (South African, active gel, Stage 1).

Other women worried about the appearance of the gel in the vagina after application, concerned about the potential reactions of their partners, having to explain what the gel was and thus disclose their study participation.

When I looked at how the gel was like ... (I was worried) he (partner) would ask me what's going on with me ... the gel looks "slimy" ... it wouldn't be okay for me to have sex after applying the gel down there ... he was going to have a big problem and I was going to have to explain ... We were going to fight since I hadn't told him and only left him to find out about it (gel) by himself when having (sex). (South African, active gel, Stage 1)

Even when women's partners reacted positively to the gel's effects, women were reluctant to disclose to their male partners the real reason behind the positive changes in their vaginal state.

(My partner) he felt it (gel) too, he used to comment about how nice it felt and I did not want to tell him why it felt like that ... I would have been a fool if I told him... Whether he was (enjoying) or not ... I was enjoying the nice time (sex) (giggling). (South African, active gel, Stage 1)

Timing and modification of gel use

The volume of gel in each applicator was described as excessive; some sex workers, who found it difficult to carry several applicators around, would insert a small amount of gel from the same applicator prior to sex with each client. The excessive volume of gel was a general concern amongst participants, not only among sex workers. Women likened the sensation of the gel oozing out to having wet oneself. To mitigate the uncomfortable feeling of wetness, women would not use the full amount of gel in each applicator.

Instead of using all the gel in the applicator ... I didn't use it all ... I only used half of it ... (otherwise) I would feel like a lot water was coming out there (vagina), as a result I would use a little. (Zimbabwean, active gel, Stage 2).

Women explained that the timing of gel application was critical in order to avoid negative reactions from male partners. Some said that to counteract the excessive lubrication caused by the gel, they would insert it

in the morning, and wash the gel out of their vaginas before sex:

I would wash in the evening (after inserting gel) and by the time we would have sex in the night, it (vagina) would not be too wet. (focus group discussion, Zimbabwean, active gel, Stage 2).

Washing out the gel soon after application was also described as a way to mitigate its perceived physical side effects, including stinging, itchiness and rashes, causing the onset of menstruation, making urine smell foul, and causing the production of excessive vaginal discharge.

Discussion

Our findings illustrate that amongst these women from South Africa, Uganda, and Zimbabwe, preferences related to the optimal vaginal state, are heterogeneous, nuanced, and complex. Participants' perspectives on the effects of the VOICE study gel on the vaginal state and on penile-vaginal intercourse were varying and often contrasting; perceived effects included widening, loosening, tightening, cleansing, drying, and lubricating. Women's assertions about the positive effects of the gel may have questionable credibility given the low level of gel use in VOICE (Marazzo, 2015). Nevertheless, the positive narratives are informative because they illustrate preferences around the desirable vaginal state, rather than a state affected by use of the vaginal gel.

In VOICE, there was high self-reporting of engagement in some type of vaginal practice. Although the quantitative data indicate that overall vaginal practices declined over the study period, it is not clear whether practices actually changed or whether participants were reluctant to report since they had received instructions from study staff not to engage in some of these practices. Despite the reported decrease in vaginal practices over the study period, the qualitative data suggest that women continued to engage in various practices, some of which seem to have been specifically geared at counteracting the undesirable effects of the gel.

Women in VOICE-D described a range of practices and products used to modify the vaginal state: products were eaten, drunk, smoked, ingested, inserted into the vagina, topically applied, and used for douching. Much of the literature on vaginal practices in sub-Saharan Africa is related to vaginal drying (Gafos et al., 2010; Hilber et al., 2010; Runganga, Pitts, &

McMaster, 1992; Scorgie et al., 2009, 2011). Motivations for engaging in vaginal practices described by VOICE-D participants included drying, cleansing, tightening, warming, lubricating, and making one hot (sexy). Vaginal hygiene is important to women; reported prevalence of vaginal cleansing by participants in VOICE was high (Table 1), and VOICE-D participants described a range of cleansing products. Discourse on the desirability of a warm vagina has been previously documented in South Africa (Ndinda, Uzodike, Chimbwete, & Mgeyane, 2011; Scorgie et al., 2009). Women from Zulu-speaking communities listed products traditionally used to tighten/close (*uzovaleka*, *iyabuyela*, *iyavalana*) the vagina. Male preferences for friction-enhanced dry sex in sub-Saharan Africa have been well documented, and similar narratives around the desirability of vaginal tightness, often associated with being virginal have been previously described (Hilber et al., 2010; Ndinda et al., 2011; Runganga et al., 1992).

Literature on vaginal practices in sub-Saharan Africa suggests that the vaginal state is closely interlinked with women's sexuality (Scorgie et al., 2009). The primacy accorded to male sexual pleasure was evident in VOICE-D participants' narratives, and many of the reasons women gave for choosing to engage in vaginal practices, as well as use or not use the gel, were related to male sexual satisfaction. A common theme emerging from the data was that the gel negatively impacted the sexual pleasure of male partners, jeopardizing relationship security. Some women in VOICE-D described negative reactions that male partners had to the additional vaginal lubrication caused by the gel, at times partners would get frustrated and even violent. Notably, some women said that the lubricating properties of the gel resulted in less physical pain and vaginal tissue damage during sex. This illustrates the conflicting sexual scripts between male preferences for dry frictional sex with women's motivation to avoid painful sex (Duby et al., 2015).

In contrast to narratives relating to negative perceptions of the gel's effects on the vagina, women listed ways in which the gel had beneficial effects on their own and their partners' sexual pleasure, and on their vaginal state; these included lubricating/drying, tightening/loosening/widening, increasing sexual comfort, and increasing libido. Contrary to other accounts of partners' displeasure at the increased lubrication caused by the study gel, and literature on male preference for dry

sex in sub-Saharan Africa, some women in VOICE-D described the vaginal lubrication by the gel as a positive attribute, commenting that prior to using the gel their partners had complained about vaginal dryness.

Aside from implications for the sexual relationship context, the effects of the gel on the vagina also caused disgust and embarrassment to women themselves. Participants complained about the excessive volume of gel in each applicator, causing gel to leak out, wetting underwear. User challenges relating to gel consistency, leakage, and vaginal gels being 'messy to use' have been cited elsewhere (Morrow et al., 2014a). Optimal lubrication appears to be central to women's preferences relating to the vaginal state; the wetness/dryness of the vagina is one characteristic frequently modified in order to enhance sexual pleasure (Hoffman et al., 2010). The interaction of a vaginal product with lubrication will be central to women's willingness to use it. It is critical to consider the centrality of optimal and 'normal' vaginal lubrication to a woman's sense of health and sexuality; when vaginal secretions are perceived to be abnormal or irregular, women and their male partners make associations of disease, poor hygiene, infidelity and promiscuity (Mason et al., 2003).

To mitigate the unpleasant effects of the gel on the vagina, women in VOICE reported modifying gel regimes by not inserting the full amount in each applicator, only partially inserting, or not inserting the gel far enough into the vagina (van der Straten et al., 2015). In addition, women described situations in which they would apply gel in the mornings, and wash it out before sex or before it oozed out. Reasons for this included the unpleasant discharge sensation, to avoid perceived side effects, and to avoid excessive lubrication in case a male partner wanted sex. If women were washing the gel out soon after application, and/or not using the full amount of gel in each applicator, and/or not inserting the gel far enough into the vaginal canal, there may have been insufficient drug to protect against HIV acquisition during intercourse.

Despite prior research indicating that women in sub-Saharan Africa are likely to feel comfortable inserting products into the vagina because of existing vaginal practices, (Braunstein & Van de Wijgert, 2005), several VOICE-D participants expressed fear of inserting a foreign product into their vaginas. Women in a recent study in the

United States also shared the perception that any foreign substance, such as a vaginal gel, would be invasive (van den Berg et al., 2014). One contradiction emerging from our findings relates to women's reported reluctance to insert study gels into their vaginas; however at the same time a high reported prevalence of vaginal practices involving the insertion of "culturally approved" products into the vagina. Further exploration of the reasons behind this seeming inconsistency is warranted.

Given that women ascribed contrasting effects to the gel, such as tightening and loosening, drying and lubricating, it may be that the explanations about the gel and its effects are more a reflection of women's concerns with their vaginal state and how gel may alter it rather than about the actual physical effects of gel on the vagina. In addition, this may also reflect the wide range of baseline 'natural' states of women's vaginas. It is not clear whether social desirability bias caused women to detail positive attributes of the gel, describing what an ideal vaginal product would do, or their actual experiences of using the gel. If the former is the case, we may not be able to ascribe these positive properties to the study gel itself, but could instead assume that these state-altering properties are those desirable for a vaginal product. Even with questionable credibility, these narratives provide useful insight into perceptions and preferences related to valued vaginal states, particularly in the sexual context. However, it is important to note that positive narratives of the gel's effects were apparent in both stages of VOICE-D; arguably women in Stage 2, who were presented with results of a biological marker of their adherence to study product use, may have had less incentive to give positive feedback due to social desirability (van der Straten et al., 2015). Notably, individual narratives were fairly consistent across both stages; women did not appear to change their opinions of the gel.

Limitations to this research include social desirability bias mentioned above, and the variability of women's narratives, calling into question their credibility. In addition, we have presented women's views, and their perspectives on male partners' reactions to the effects of the study gel, without speaking directly to men themselves. Lastly, the opinions expressed and experiences described in these findings reflect those of the sample

interviewed, and may not be representative of women in their communities.

Recommendations

Changes to the vaginal state inevitably caused by a vaginal microbicide must be proactively acknowledged and discussed with potential gel users and their sexual partners, who will be conscious of changes in the vaginal state. Women need to be provided with the skills to disclose vaginal product use, or, where necessary, supported in their efforts to hide product use without minimizing its effect. Positively perceived attributes of vaginal gels can be capitalized on, including sex-positive counselling about enhanced lubrication and pleasure. Negative attributes should be mitigated; for example, minimizing dose size where possible, and recommending insertion at times of day where the negative effects of usage, such as leakage, are less problematic. Other options include developing forms of delivery that are less voluminous and leaky, and using other formulations that are not semisolids (gels) such as fast dissolving tablets, films, or rings.

Understanding vaginal practices, and the individual, relationship, and local contexts in which they occur is critical for the development of any topical HIV prevention product used by women. Our findings have implications for future vaginal products, providing insight into preferences relating to the vaginal state, prevalence of, and motivations for, women engaging in vaginal practices, as well as how these may have interfered with gel use. Lessons from this research on users' perceptions of how gel affected the vaginal state, and how gel use fits in with existing vaginal practices, should inform the development of vaginal products for the prevention of HIV.

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