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User-Identified Gel Characteristics: A Qualitative Exploration of Perceived Product Efficacy of Topical Vaginal Microbicides

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Abstract

Research has demonstrated that certain vaginal gel products—microbicides containing antiretroviral drugs—may reduce HIV infection risk among women. But for vaginal gels to avert HIV and other sexually transmitted infections (STIs), at-risk women must be willing to use them as directed. These products must therefore be “acceptable” to women and an important component of acceptability is users’ perception that the product will work to prevent infection. We sought to understand how women’s perceptions of vaginal gel properties may shape their understanding of product efficacy for HIV and STI prevention. Sixteen women completed two in-depth qualitative interviews (k = 32) to identify the range and types of sensory perceptions they experienced when using two vaginal gels. We identified emergent themes and linkages between users’ sensory perceptions and their beliefs about product efficacy. Users’ predictions about product efficacy for

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preventing infection corresponded to measurable physical properties, including gel volume, location in the vagina, coating behavior, sensation of the gel in the vagina, leakage, and gel changes during coital acts. Although the women described similar sensory experiences (e.g., gel leaked from the vagina), they interpreted these experiences to have varying implications for product efficacy (e.g., leakage was predicted to increase or decrease efficacy). To improve microbicide acceptability, gel developers should investigate and deliberately incorporate properties that influence users' perceptions of efficacy. When a microbicide is approved for use, providers should educate users to anticipate and understand their sensory experiences; improving users' experience can maximize adherence and product effectiveness.

Keywords

Microbicides; HIV; Sexually transmitted infections; Biomedical prevention; Women

Introduction

The HIV/sexually transmitted infections (HIV/STI) prevention field is increasingly focused on biomedical technologies. Topical microbicides remain at the forefront of this work (Abdool Karim et al., 2010; Marrazzo et al., 2012; Padian, Buve, Balkus, Serwadda, & Cates, 2008; Rotheram-Borus, Swendeman, & Chovnick, 2009). Ongoing studies are investigating several microbicide candidates (both vaginal and rectal formulations) (MacGowan, 2010) and mathematical modeling has fostered optimism about population-level impacts and cost-effectiveness of efficacious microbicides (Verguet & Walsh, 2010; Vickerman et al., 2006; Watts & Vickerman, 2001). Even when highly efficacious, however, microbicide effectiveness and public health impact will depend, in part, on actual use and adherence by at-risk individuals (Morrow & Ruiz, 2008). Data from the recent VOICE trial illustrate the vital importance of adherence: most trial participants did not use the vaginal gel products daily as recommended, particularly among young and unmarried women, which contributed to difficulty in demonstrating product efficacy for preventing HIV (Marrazzo et al., 2012). To encourage optimal levels of uptake and adherence, microbicides (including multipurpose technologies) (Thurman, Clark, & Doncel, 2011) must be not only efficacious, but also "acceptable" to potential users (Mantell et al., 2005; Marrazzo et al., 2012; Morrow et al., 2007a, 2007b; Morrow & Ruiz, 2008).

Perceived product efficacy (PPE) is a key feature driving the acceptability of, and potential adherence to, HIV/STI prevention products (Bass, 2002; Greene et al., 2010; Guest et al., 2007; Holmes, Maher, & Rosenthal, 2008; Mantell, Morar, Myer, & Ramjee, 2006b; Saethre & Stadler, 2010). PPE refers to a user's perception of the extent to which a product is capable of producing a desired result. This phenomenon differs from clinical efficacy; instead of reflecting a vaginal microbicide's actual impact on HIV infection and/or STIs, PPE reflects women's beliefs about how the microbicide will alter their own risk of infection. Vaginal microbicides can potentially serve at least three product functions: preventing HIV/STI infection, modifying vaginal moisture or lubrication, and influencing sexual pleasure. We focus here on efficacy for preventing HIV/STIs. Microbicide users are likely to form their own impressions of whether the products are effective for these

purposes. Even if these beliefs do not correspond with clinical efficacy or actual product mechanisms, PPE will affect decisions to use the microbicide, to use it as directed, to continue using it during periods of elevated risk, and to maintain other HIV/STI risk-reduction strategies during use. These behaviors will be crucial components of population-level effectiveness, prompting inquiry into the processes by which potential users will form beliefs about product efficacy.

Previous studies have examined PPE among women in several countries (Bass, 2002; Greene et al., 2010; Guest et al., 2007; Mantell et al., 2006b; Saethre & Stadler, 2010), consistently documenting that users draw conclusions about microbicide efficacy, even if clinical efficacy is unknown. In at least one efficacy study, women expressed strong opinions that a candidate was effective for HIV prevention and other health benefits, despite being told by researchers that the product had no proven efficacy (Bass, 2002; Greene et al., 2010; Guest et al., 2007; Mantell et al., 2006b; Saethre & Stadler, 2010). Women in another study reported conducting their own “tests” to gain more information about product efficacy, such as mixing the gel with semen in a used condom (Saethre & Stadler, 2010).

Prior research has identified various factors that may influence perceived microbicide efficacy, including user characteristics (e.g., perception of personal risk for HIV (Greene et al., 2010) and physical side effects after using the gel (Saethre & Stadler, 2010)). There has been limited inquiry, however, into how women’s perceptions of vaginal microbicide efficacy are related to variations in topical vaginal gel formulation properties. These properties include physicochemical and rheological aspects of gel composition and performance, such as appearance, feel, flow, coating, and dilution effects. Although prior work has suggested that users’ opinions about product efficacy may be tied to microbicides’ physical properties (Holmes et al., 2008; Saethre & Stadler, 2010; Short, Mills, Majkowski, Stanberry, & Rosenthal, 2003; Short, Succop, Ugueto, & Rosenthal, 2007), no study has yet examined the specific user sensory perceptions and experiences, elicited by specific rheological and physicochemical properties, and how they might impact perceived product efficacy or use. These are critically important questions while microbicides are still in development; it is an opportune time to change aspects of product formulation and to prepare appropriate educational strategies to support microbicide users.

The objective of this analysis was to explore relationships between PPE for HIV/STI prevention and the biophysical properties of two different vaginal gel products. We address this knowledge gap through qualitative in-depth interviews, which seek both to understand gel users’ sensory experiences and to explore how women interpret these experiences as indicative of product efficacy.

Method

We report results from the first of a three-stage protocol. The protocol as a whole aimed to produce psychometrically valid scales identifying users’ sensory perceptions and experiences (USPE) of microbicide gels and to consider whether these perceptions would affect users’ willingness to use particular formulations. Results of the complete protocol have been reported elsewhere (Morrow et al., 2013). Here, we discuss emergent results from

Stage 1, which comprised a series of in-depth qualitative interviews exploring USPE while using two different vaginal gels. Qualitative data consisted of individual in-depth interviews. Quantitative data consisted of basic demographic and behavioral information.

Participants

Eligible woman were 18–45 years of age from the greater metropolitan areas surrounding Providence, RI, and Boston, MA. Women over age 45 were not studied due to changes in the vaginal environment that may occur peri- or post-menopause. Eligibility criteria included regular menstrual cycle and vaginal sex with a man (past 12 months). Women were ineligible if they reported an STI diagnosis (prior 12 months); being pregnant or breastfeeding; having a vaginal delivery or other reproductive surgery (prior 3 months); or reporting sensitivity/allergy to nonoxynol-9, latex, or vaginal product constituents. Participants were expected to refrain from vaginal sex for 24 h before each session, to use condoms for vaginal sex within 4 days of a session, and to refrain from douching for 48 h before their first session and throughout the remainder of their participation. Women were compensated for each session.

Potential participants were recruited via print and online advertisements, community-based organizations, and word-of-mouth. They received a brief description of the study, followed by a screening questionnaire via phone. At Session 1, potential participants were provided a detailed explanation of all study procedures and expectations, and all questions were answered. Informed consent was obtained as per applicable guidelines and as approved by site institutional review boards.

Procedure

Qualitative interviews were conducted following participants' use of two vaginal gels selected for their differences (i.e., range) in physicochemical and rheological properties (e.g., viscosity, residual stress, and flow over time). Such property differences manifest in variations in sensations elicited by gel "behavior," allowing a range in user sensory perceptions and experiences. Participants were informed that neither gel was efficacious for HIV/STI prevention.

Participants completed two sessions (1.5–2.5 h each); each included three participant activities and three brief semi-structured qualitative interviews. (1) Participants manipulated the gel in their hands ("in mano") and described, in their own words, their initial impressions of the product, the applicator, and the gel's properties. Product A was HEC (CONRAD, Arlington, VA), which is a moderately viscous, clear gel with low yield stress. Product B was Replens® (Lil' Drug Store Products, Inc., Cedar Rapids, IA), which is of similar viscosity from a lay person's perspective, but is somewhat opaque/cloudy in color with a measurable, palpable yield stress. The clear to opaque/cloudy comparison allowed participants to consider the likely range of topical vaginal gels to be used in microbicide delivery. Some active pharmaceutical ingredients can be loaded into gels and allow for a clear gel color, but others may result in a cloudy or opaque appearance. The range in viscosity and yield stress values for a gel impact initial spreading or coverage of the vaginal vault, as well as the thickness and "feel" of that coverage. These values also impact the

product's propensity toward, and latency of, leaking out of the vaginal vault. Volume and the perception of volume in the vagina are also a function of rheological and biophysical properties of the gels, including their propensity to imbibe water. (2) Participants privately used a standardized prefilled applicator (HTI Comfort Tip: HTI Plastics; Lincoln, NE) to insert 3.5 mL of gel into the vaginal canal. Following application, each participant walked about for 2 min and then described her experience. (3) Participants privately simulated coitus for 30 strokes with a condom-covered (non-lubricated) artificial phallus. Although this procedure is unique among behavioral studies of microbicide acceptability, simulated sex with a phallus is a procedure used in vaginal product formulation development studies, where product rheology is studied. The interviewer guided her through a final interview about her experiences of simulated coitus using the product.

All qualitative interview components were recorded and transcribed verbatim. Interviewers completed standardized reports summarizing salient data. Each participant completed one session for each product, at least 5–7 days apart, with breaks for menstruation. Participants were blinded to product identity and product order was randomized. During interviews at the second product evaluation session, participants were asked to make comparisons between the two products. Thus, at study completion, 32 interviews (each inclusive of *in mano*, application/ambulation, and simulation components) were available for analysis from 16 women who each evaluated 2 products.

Measures

Interviews targeted four primary "dimensions" of USPEs hypothesized to be associated with product acceptability: leakage, application experience, and potential implications for sexual pleasure and covert use. Questions were derived from literature reviews, investigators' prior experience with microbicide acceptability studies, and hypothesized correspondence with the gels' physicochemical and rheological properties. A semi-structured qualitative interview agenda and interviewer training ensured that all interviewers gathered data across the same dimensions. Throughout, participants assessed both positive and negative aspects of product use and experience, and described what they thought the product was "doing" (i.e., product "behavior") that resulted in a specific sensation or experience.

Because the protocol aimed to generate information about user sensory perceptions and experiences of product characteristics and behavior, planned interview agendas did not specifically seek information about perceived product efficacy. As post-session reports were completed, however, it became clear that participants were forming judgments about product efficacy as a function of the felt experience. Interviewers probed for more information when participants mentioned these emergent opinions, as is customary in such interviews. Building on prior work that suggested a relationship between PPE and acceptability, we analyzed these data more closely to understand how users' sensory perceptions impact their judgments of product efficacy. All data collected about PPE were participant-initiated; it was not specifically solicited by interviewers and this type of participant-driven information is considered among the most robust qualitative data. In most cases, women did not make distinctions between HIV and STIs in terms of perceived product efficacy. Most women referred to "STDs" in general (inclusive of HIV and other STIs) or used terms like

"disease," "health," and "protection." Therefore, we did not compare women's perceptions of efficacy specific to HIV versus other STIs.

Based on the 32 interviews with 16 participants, data saturation was obtained for the study's original aims: to identify users' sensory perceptions while using topical vaginal gels, to understand how sensory perceptions would affect potential acceptability, and to develop initial scale items to measure these constructs. Because data on the relationship between sensory perceptions and perceived product efficacy emerged in the context of these more specific discussions and were not part of the original aims, saturation was not expected for the current analysis.

Data Analysis

All transcripts were coded independently by two members of the team, following an iterative development process in which all members of the research team independently reviewed transcripts and developed the final coding structure. Where assigned codes differed, those differences were resolved by discussion and consensus prior to analysis. Because double-coding was used for all transcripts, intercoder reliability was not computed. Data on perceived product efficacy were then analyzed by three reviewers using a framework matrix: a grid juxtaposed cases (i.e., individual participants) with themes, constructs, or questions related to perceived product efficacy. We reviewed each interview in its entirety and entered data in each cell accordingly. We drew on all 32 interviews for these analyses. As anticipated given the rheological and other biophysical properties of the products, we observed differences in each woman's sensory experiences with product A compared to B. We also observed differences among the 16women in the sensory experiences they reported for an individual product. But for this analysis, we focused on ways in which all 16 women interpreted product characteristics and sensory experiences to have a bearing on PPE for HIV/STI prevention, regardless of which product they were discussing. Thematic categories included (non) endorsements of products, toxicity/side effect concerns, perceived efficacy for HIV/STI prevention, potential impact on sexual pleasure, and implications for covert use. The current article reports only analyses on perceived efficacy for HIV/STI prevention. This approach required us to define analytical themes in a highly focused and systematic format, thus allowing an in-depth exploration of the data while maintaining an effective audit trail (Ritchie & Lewis, 2003; Smith & Firth, 2011). Once data were summarized within the framework matrix, we reviewed categories, identified patterns across cases and/or themes, and viewed all the data in relation to products' known physicochemical and rheological properties. This article reports findings related to PPE for preventing HIV and STIs.

Results

Participant characteristics (n = 16; k = 32) are shown in Table 1. Every participant offered at least one unsolicited comment on PPE, whether specific to HIV/STI prevention efficacy (n = 13) or more general statements (n = 3); participants commented with similar frequency on both products. Comments about PPE were more likely to occur in the second interview than in the first, perhaps as a function of participants' opportunity to compare products after both

experiences; the order of product experience did not seem to impact these comparisons. Beyond this observation, further quantification of comment frequency or length is likely uninformative due to differences in participants' comfort and/or verbal ability, as well as the unsolicited nature of these data. Because this is a qualitative study aiming to explore the range of participant experiences, we also did not quantitatively test the association between PPE and the two products. Viewing the data broadly across interviews, however, it appeared that participants were more likely to comment on sensations of product location and coating when referring to Product A: given the rheological and other biophysical properties of Product A, especially in comparison with product B, this was not surprising. What seemed most informative was the participants' ability to compare sensory perceptions once both products had been experienced.

Participants' comments on PPE appeared to be associated with six specific gel characteristics: gel volume, perceived location of the gel within the vaginal environment, perceived coating "behavior" of the gel, sensations ("feel" and physical awareness of the gel), perceptions of gel leakage, and perceptions of changes in gel properties across time. We address each in turn, with illustrative quotations in Table 2. Although each woman's sensory experiences differed between the two products, and although sensory experiences differed across the 16 women, any given woman's comments on PPE reflected a consistent individualized understanding about how product characteristics (e.g., volume, leakage) might influence efficacy. For example, a woman who thought a certain volume of gel determined HIV prevention efficacy with product A expressed the same theory when she was using product B. Our analysis was designed to capture the perceived relationships among product properties, sensory experience and PPE, regardless of which product was being discussed.

Volume

Although participants were not told the specific volume of gel they inserted, *in mano* experiences before insertion may have given them some sense that the volume of gel was identical for both products (i.e., 3.5 mL). That said, participants frequently suggested that "amount" influenced PPE; predominantly, these comments reflected participants' assumptions that a specific amount of gel was necessary to provide protection against HIV/STIs. Participants reported feeling the need to know that all the gel in the applicator was actually inserted into the vagina; some sought confirmation of this by inspecting the empty applicator. Experiences of leakage were met with concern that the correct amount of gel did not remain in the vagina and hence decreased efficacy. Several participants considered putting some of the product within the labia to compensate for a lack of lubrication; however, they also reported concern that using some of the product in this manner would mean that less would be inserted into the vagina, where it would be needed to prevent infection.

Perceived Location of the Product

PPE was also associated with participants' perception of where the product was located in the vagina, basing these perceptions on their sensory experience. Some believed the product's efficacy would be greater if it were located high in the vaginal canal, closer to the

cervix. Others thought efficacy would be best if the product did not move within or come out of the vagina: if it "stayed put" and/or did not leak or drip out of the vagina. These concerns were apparent both as a function of actual leakage experiences following product insertion, and as a function of participants' understanding of the products' properties and potential "behavior" when in the vagina as a function of the *in mano* experience.

Perceptions of Product Coating Behavior

Similar to the impact of perceived location on PPE, some participants noted that they would feel more confident in the product's efficacy if they felt that the product was coating the entirety of their vaginal cavity: The more complete the coating, the better the efficacy. Indeed, one participant even went so far as to state that when she felt the product coating her vagina, it suggested to her that the product would be killing the virus at that moment.

Sensation of the Product in the Vagina

PPE was associated with sensations of the product in the vagina, that is, what, exactly, the product felt like. PPE was higher when participants reported a more "natural" feel of the product in the vagina. It was also associated specifically with a product's lubricating qualities. Participants commented that products that served as lubricants could prevent infection by minimizing injury during sex, regardless of the products' actual anti-microbial pharmaceutics. Whether a "natural" feel is consistent with a lubricating effect was unclear.

Perceptions of Leakage

PPE also seemed to be associated with the experience of leakage, though the range of meaning derived from this experience was particularly broad. First, as noted above, leakage raised concerns that the correct amount of gel needed for prevention of infection would not be available. In addition, some participants reported that leakage after study sessions raised concerns about whether they inserted the product correctly in the first place. Some believed that "thicker" gels would minimize leakage, thereby assuring a correct dose. Interestingly, however, although some interpreted leakage as evidence of reduced efficacy because less was available in the vagina to prevent infection, others interpreted leakage as evidence of increased efficacy because, they surmised, the gel would carry the virus with it out of the vagina and there by prevent infection.

Perceived Changes in the Product During Coital Acts

Finally, some participants noted changes in the way the product looked or felt during and after simulated coitus, which often led to interpretations regarding PPE. For example, some women noted that the product's consistency and/or color changed in the course of the session (e.g., white flecks or clumps of product on the condom after coitus), and they interpreted these changes as evidence of reduced efficacy.

Discussion

As the development of vaginal and rectal microbicides progresses, we must intensify efforts to ensure that these products will be used. Even if microbicides are highly efficacious, consistent and correct use in the context(s) of risk will drive their impact for reducing HIV

and other STIs, and users' experiences will play a leading role. Multiple studies have suggested that users' opinions about product efficacy will shape the reciprocal influences of acceptability, adoption, adherence, and effect. In our formative study, women drew on their sensory perceptions and experiences with a vaginal gel to form beliefs about a product's likely efficacy for preventing HIV and STIs. We found that these beliefs were associated with the product's specific physicochemical properties, including volume, location, coating behavior, sensation of the product in the vagina, leakage, and perceived change during coital acts. Women also drew connections between PPE and predicted user behaviors, noting that positive perceptions of product efficacy would contribute to anxiety reductions and freedom from worry during product use. This study indicates that drug delivery systems, product properties, and users' sensory perceptions interact in ways that may alter the use and, ultimately, effectiveness and public health impact of microbicides. Future studies should explore which specific user sensory perceptions and experiences, elicited by which rheological or other physicochemical properties, impact actual use.

This work is significant for two reasons. First, the physicochemical properties of microbicide products are not fixed; developers can change these properties to better conform to users' expectations. For example, rectal microbicide gel developers have recently reformulated tenofovir-based gel to improve potential acceptability based on preliminary rectal user reports (Anton et al., 2011; Dezzutti et al., 2012). Although some product characteristics may be impossible to modify without diminishing efficacy, others may be more malleable, representing opportunities to improve the user experience, maximize product acceptability, and maximize adherence. By identifying ways in which users interpret their sensory experiences to presume product efficacy, our findings point to specific microbicide properties that merit developers' attention. It will ultimately be the interaction of pharmaceutics, formulation, and user experience, as well as public health policy and advocacy, that will seal the fate of a given microbicide in a given global public health market.

Second, it is clear that there also will be instances in which physicochemical properties cannot be altered to accommodate user preferences, because those properties are critical to efficacy. Where formulation characteristics cannot be modified, understanding the relationship between microbicides' physicochemical characteristics and PPE can allow behavioral scientists to develop education and intervention programs that can prepare users for the specific experiences of using a formulation or device, helping them to cope with or compensate for undesirable product characteristics.

An important strength of this study is our use of emergent data to identify relationships between product characteristics and perceived efficacy for disease prevention. Emergent data are seen as particularly robust because it is participant-driven: participants independently formed and offered their PPE beliefs without prompting from the investigators. Our results align with previous studies indicating that women in vaginal microbicide trials draw conclusions about product efficacy, including beliefs about whether their assigned gel is active or a placebo (Bass, 2002; Greene et al., 2010; Guest et al., 2007; Mantell et al., 2006b; Saethre & Stadler, 2010). We built on these findings, using innovative laboratory-based methods and qualitative interviews to link users' perceptions to gels'

physicochemical and rheological properties. This study offers a novel methodology for investigating linkages between gel properties, users' sensory experiences, and PPE. We are also among the first to propose that women's' perceptions of microbicide efficacy were partially driven by their sensory experiences during product use, which were, in turn, determined by specific product characteristics. Our findings can serve as the beginnings of a fuller conceptual model of perceived product efficacy, which further studies can elaborate and link to actual microbicide user behaviors. Our data may already suggest potential psychological mechanisms by which PPE may influence behavior. In addition to the results presented above, some participants commented that PPE would impact their psychological experience while using a microbicide. Some suggested that using a microbicide with high PPE would provide them with a sense of freedom from worry so they could enjoy sexual encounters. Others wondered whether using an efficacious product would raise their anxiety, with the act of product use reminding them that they were putting themselves at risk for HIV/STI infection. Further research should consider these and other psychological experiences that may link PPE and meaningful user behaviors.

Our findings also had limitations. In keeping with the original scope of this study, the interview agenda did not systematically query participants with respect to perceived product efficacy. Notably, however, all participants did comment on efficacy, lending credibility to these emergent data. While formative qualitative studies such as these tend toward smaller sample sizes, we observed a wide range of participant experiences and efficacy perceptions. The field now needs a systematic study to confirm and expand these findings. The application of our results may be limited to microbicides in vaginal gel formulations; it is not clear whether the relationship between PPE and vaginal gel properties, such as volume and coating, will generalize to other formulations (e.g., films, suppositories), topical rectal formulations, or other delivery devices (e.g., rings, diaphragms).

Our sample was limited to non-pregnant, sexually active, U.S. women of reproductive age. While enrolled women also tended to be formally educated and white, our intended study sample, representing relative equality with respect to age and vaginal delivery history, was met. Although we are unaware of research suggesting that the physical sensations women experience when using vaginal products differ across cultural and geographic borders, women in different settings may have very different interpretations of how sensations reflect product efficacy. Individual and cultural expectations about what constitutes an acceptable user experience may also vary. Thus, our findings may have limited applicability to populations that vary by race/ethnicity, formal education, or other demographic characteristics. We echo calls for microbicide acceptability research to include men and improve the diversity of populations studied (Mantell et al., 2006a, 2006b). Future research should explore ways in which sensory perceptions of microbicide users affect perceived efficacy in a range of populations. Additional studies should also examine whether our findings generalize to users' experiences when they have sex with their partners, compared to simulated sex with the phallus used in the study.

If subsequent studies support the link between product characteristics and PPE, a response by microbicide developers and the public health community is required. In the absence of information about, or a clear understanding of, product efficacy, women will draw their own

conclusions about whether a microbicide prevents HIV and STIs. These conclusions may be driven in part by experiencing the product's rheological properties. Microbicide developers should consider users' sensations and experiences and find a workable balance between the physical properties required for drug efficacy and the properties that will optimize product adoption and adherence. Where the balance favors efficacy (as it should), advocates, public health communities, and providers must prepare users for less-than-optimal sensory experiences, explain how product characteristics influence efficacy, and help users cope with those experiences safely and without jeopardizing effectiveness.

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Table 1

Participant characteristics

Characteristic	*N* (%)
Age	
18–29 years	7 (44)
30–45 years	9 (56)
One or more vaginal deliveries[a]	9 (56)
Ethnicity and race	
Latina/Hispanic	5 (31)
Black	1
White	2
Refused to identify race	2
Non-Latina/Hispanic	11 (69)
Black	3
White	8
Refused to identify race	0
Education	
College or graduate degree	8 (50)
Completed some college	4 (25)
High school diploma or equivalent	3 (19)
<High school	1 (6)
Number of sexual partners, past 12 months	
1	12 (75)
2	3 (19)
3	1 (6)
Living with sexual partner	5 (31)
Using hormonal conception	5 (31)
Ever diagnosed with STI[b] *prior to* the past 12 months	5 (31)

[a] Number of children ranged between 1 and 6

[b] Sexually transmitted infection

Table 2

Illustrative participant quotes

Physical gel characteristic	Participant quote	Perceived relationship: Gel properties and PPE[a]
Volume	"[If it was gonna be for disease prevention], I'd wanna know for certain how much is there."	A specific volume of gel must be present in the vagina for HIV/STI prevention; removing gel from the applicator or vagina will diminish efficacy
	"If I put less…I'm gonna have more probability of catching the virus, right?…My concern would be with this if I clean myself, am I going to lose doses of medication…that actually is gonna be, preventing me of taking in any virus?"	
Perceived location of the product	"[It is good to use an applicator because] I feel more of the gel is gonna get inside of the woman"	The product must be located up inside the vagina, rather than around the outside, in order to be effective
	"The product goes *way* up there some where [where it] waits for germ and bacteria to come"	
	"It feels like it's staying in place, so I mean, I think…that's good"	The product must stay in place where applied in the vagina in order to be effective
Perceptions of product coating behavior	"I think it's just there coating it [the vagina]…protecting me for some reason"	The product forms a barrier between the vaginal wall and infectious agents, so the product is effective when it coats the entirety of the vagina
	"[When you use an applicator,] that way you can put it in from you know, top to bottom….You can insert it in you and as you are pulling it out you can inject it into your vagina"	
	"[During coital activity] it just got moved throughout….It's coated my canal by the movement of the artificial penis"	
Sensation of the product in the vagina	"It just feels like…It's not like prescribed, it's not medicine….It feels like it's part of my own…fluids.…It doesn't smell like alcohol or anything like that, or a hospital, or anything…In other words to meit's like, 'Oh, I know that this is good for me"'	The "natural" feel of the product means that the product is healthy to use and immediately effective
	"I don't feel any different….I don't feel like I've inserted any product or any gel or anything"	The lack of product awareness made it less likely that the product was going to be effective
	"It's, um, a liquid to put in there, and I don't think it does anything"	
	"Once I inserted the product, it felt as if it wasn't there. So I didn't have to wait for anything to happen, like for it to dissolve or anything….So I just checked to make sure, 'okay, did I do this right?' Because I didn't feel anything"	If the user is not confident in her ability to insert the gel properly, she may also feel less confident in its resulting effectiveness
Perceptions of leakage	"[If the product leaked the day after coitus,] I would feel scared when it came out….Like did it work? Was it effective? Did I put it in wrong?….And is it gonna happen like that again if I put it in?"	Leakage threatens product effectiveness, because it diminishes the volume and/or presence of gel available in the vagina for protection against HIV or other STIs
	"[Leakage during application and ambulation] caused me to get nervous…Am I not gonna be putting in the right amount to protect me?"	
	"It doesn't feel like anything's dripping out…It feels like nothing's there…It's so, like, kind of loose"	A lack of leakage promotes the sensation that the product is "natural" and mimics existing vaginal environment. This "natural" sensation is associated with a perception of health and effectiveness
Perceived changes in the product during coital acts	"It's just there….Even though I put water on my hand to rinse it….I just saw stuff in my hands. So probably, in a good way anyway, when you're having sex it's gonna be there…for a while"	The product should resist dilution or absorption during coitus in order to remain effective
	[After seeing white clumps of product on the condom and in her vagina after simulated coitus:] "May be the lubrication clumps with the friction….If this was the real world, I would be worried enough that I wouldn't use it again."	If the product changes color or consistency over the course of coitus, it has reduced effectiveness for the prevention of HIV or STIs. Product

Physical gel characteristic	Participant quote	Perceived relationship: Gel properties and PPE[a]
		effectiveness is linked to consistency and color
	"On the condom it was clear, it's 'cause it was like distributed….The drip was not clear; it was a little um, little milky…Something has changed in the insertion process"	

[a] Users' perceived relationship between gel properties and perceived product efficacy (PPE)