



Published in final edited form as:

Contraception. 2015 December ; 92(6): 596–601. doi:10.1016/j.contraception.2015.08.007.

Meaning-making matters in product design: Users' sensory perceptions and experience evaluations of long-acting vaginal gels and intravaginal rings

Rochelle K. Rosen^{a,b}, Jacob J. van den Berg^{a,c}, Sara E. Vargas^{a,c}, Natali Senocak^a, Julia G. Shaw^a, Robert W. Buckheit Jr.^d, Kelley Alison Smith^a, and Kate Morrow Guthrie^{a,b,c}

Rochelle K. Rosen: rrosen@lifespan.org; Jacob J. van den Berg: jvandenberglifespan.org; Sara E. Vargas: svargas@lifespan.org; Natali Senocak: natalisenocak@gmail.com; Julia G. Shaw: julia.shaw@gmail.com; Robert W. Buckheit: rbuckheit@imquestbio.com; Kelley Alison Smith: ksmith20@lifespan.org; Kate Morrow Guthrie: kmorrow@lifespan.org

^aCenters for Behavioral and Preventive Medicine, The Miriam Hospital, Coro West, Suite 309, 164 Summit Avenue, Providence, RI 02906 USA

^bDepartment of Behavioral and Social Sciences, Brown School of Public Health, Providence, RI 02906 USA

^cDepartment of Psychiatry and Human Behavior, The Warren Alpert Medical School of Brown University, Providence, RI

^dImQuest BioSciences, Inc., 7340 Executive Way, Suite R, Frederick, MD 21704 USA

Abstract

Objective—Users' sensory perceptions and experiences (USPEs) of intravaginal products can inform acceptability and adherence. Focusing on the meanings women derive from formulation/device characteristics facilitates developers' design iterations toward optimizing user experience. We investigated how users of long acting gels and intravaginal rings (IVRs) impute meaning to characteristics that may affect future product use.

Study Design—Focus groups were conducted with contraceptive IVR and vaginal lubricant users. Current perceptibility science and historical theory on the cultural acceptability of fertility regulating methods informed the analysis.

Results—21 IVR users and 29 lubricant users attended focus groups in which they manipulated products in their hands and discussed reactions to product characteristics. Participants used prior product experiences, and sensory perceptions of prototype manipulations, to inform meanings about product properties and performance for pregnancy, disease prevention, comfort, and perceived efficacy. The meanings derived from product characteristics depended on why the product would be used; a characteristic deemed problematic in one risk context may be considered preferable in another.

Corresponding author: Rochelle K. Rosen: rrosen@lifespan.org.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Conclusions—Intravaginal product users create narratives that ascribe influence or causality to product characteristics. These meanings, whether correct or incorrect biologically, will shape vaginal product acceptability, use, and effectiveness.

Implications—Long-acting, and sustained-release, drug delivery systems will be part of the multipurpose prevention continuum. Developers must consider how sensory experiences and culturally salient assumptions shape the meanings users make of product design characteristics. Those meanings will ultimately impact use and effectiveness.

Keywords

multipurpose prevention technologies; microbicides, meaning-making; STI-prevention; intravaginal ring; vaginal gel

Introduction

Each year, millions of women across the globe face unmet needs for family planning, negative maternal and child outcomes of unplanned pregnancies, and/or sexually transmitted infections (STIs, including HIV) [1–3]. There is a need for contraception, STI prevention, and multipurpose prevention technologies (MPTs) women will effectively use. MPTs are products being developed as single or multidrug formulations or devices used for sexual and/or reproductive health. They could include contraceptive agents, as well as STI prevention [4] in combination.

“Long-acting gels” (LAGs) and sustained-release intravaginal rings (IVRs) are two possible MPT drug delivery systems (DDS). LAGs would protect across several days with coitally-independent dosing. IVRs would provide sustained delivery of active pharmaceutical ingredients, or drugs, ranging from three weeks to one year [5, 6]. Such DDS are already under investigation: A dapivirine IVR (for HIV prevention) is currently in Phase III clinical trials [6, 7] and several vaginal gels have already been investigated as microbicide delivery systems. [8–13]

Product acceptability and adherence are critical in the development of vaginal DDS [8, 14]. In the CAPRISA004 trial (1% TVF gel delivered in 2 peri-coital doses within a 24-hour period), adherence support was rigorous; those with use rates of 80% or more had HIV infection rates reduced by 54%. Subsequent studies, however, have had difficulty replicating those effects. In the VOICE trial, the same vaginal gel prescribed daily did not reduce HIV infections [15]; poor adherence levels obviated product effectiveness. Most recently, the FACTS 001 trial, using the same dosing regimen as CAPRISA004, also had a protective effect only among high adherers; presence of TVF in genital fluid (evidence of recent gel use, and, presumably high adherence) was associated with a 52% reduction in HIV rates. However, most trial participants were less able to use the gel as prescribed, leading to an inability to claim overall effectiveness[16]. Clearly, the consistent and correct use of prevention products is essential to their effectiveness. Formulations or devices that deliver drug over extended periods of time may have fewer user demands regarding dosing. Reduced user demands could lead to greater adherence and thus increase effectiveness.

We investigated women's perceptions about IVRs and LAGs as DDS for prevention technologies. In this paper we characterize key rheological, biophysical, and mechanical properties of LAGs and IVRs that elicit specific user sensory perceptions and experiences (USPEs), hypothesizing that those sensations and experiences shape acceptability and the willingness of women to effectively use them. We also consider the importance of that meaning-making process, and the implications of those derived meanings, on product adherence and perceived product efficacy. We present qualitative data illustrating how contraceptive IVR and vaginal lubricant users form associations, attributions, and opinions about characteristics of prototype rings and gels, to identify USPEs most relevant for preclinical user-centered product design and iteration. The meaning-making process is illustrated with participant comments.

Although it has recently flourished in health-related research [17–21], meaning-making has been an existing, if underused, acceptability-related construct for decades. It is defined as a process of making mental representations of possible relationships between concepts or things [22]. In microbicide and MPT research, meaning-making refers to the meanings and opinions participants derive from sensory perceptions and experiences of product characteristics. Examples include how users' understanding of product efficacy is informed by product characteristics [12, 23, 24]. Similar studies also detailed user narratives about product use [25–27], including how perceived product efficacy shapes a woman's willingness to use vaginal microbicides [23, 28, 29].

In 1973, John Marshall considered the cultural acceptability of fertility regulating methods (FRM), arguing that potential adopters saw FRM, not as material objects, but “as a cluster of perceived attributes” or “phenomenological qualities” [30, 31]. He divided these into three groups: 1) perceived inherent attributes, 2) perceived associational attributes, and, 3) perceived effects. Each comes with specific cultural meaning(s) including an evaluation of what is good or bad, desirable or undesirable. Inherent attributes determine when and how a product is used, and how effective it is. Associational attributes include assumptions about when the product should be used (e.g., for intercourse with specific partners) or how it is obtained. Finally, effects are what happens with product use (e.g., weight gain, promiscuity in Marshall's research; HIV prevention, pregnancy prevention, sensations associated with sexual pleasure in this study) [32]. In the discussion, we return to Marshall's classification system and consider implications for meaning-making about MPT drug delivery systems.

Methods

We recruited participants from the northeastern United States via community-based organizations, advertisements, and word of mouth. Recruitment materials invited current and recent vaginal ring and lubricant users to provide researchers with their opinions about designing products women want to use. Eligibility criteria included: 18–45 years of age, regular menstrual cycle, vaginal sex with a man (past 12 months), and use of either an IVR or vaginal lubricant (past 12 months).

Participants completed a brief written demographic and sexual/reproductive health history questionnaire. They were compensated US\$30 for and reimbursed US\$10 toward

transportation or child care. The study was reviewed and approved by the appropriate human subject research protection boards; participants provided written informed consent.

IVR group participants evaluated four prototype rings of varying materials and dimensions. LAG group participant evaluated three gels with varying rheological and other biophysical properties. Demonstrated products exhibited a range of properties affecting user perceptions: rings differed in cylinder diameter (4mm vs. 5mm) and materials (Tecoflex EG-85A vs. Tecoflex EG-93A); each gel (PreSeed[®], Replens[®] and KY Jelly[®]) had different rheological and other biophysical characteristics that impact “feel” and gel behavior (e.g., lubricity, spreading). The order of product presentation was randomized in each group.

Participants began by discussing prior product experience and, if relevant, any reasons for discontinuing use. Participants manipulated study products (either rings or gels) one at a time, following a protocol that guided them through a series of maneuvers. Products were evaluated only based on this manipulation; no intravaginal insertion of products occurred. For example, IVR participants were asked to note size and perceived weight, and to hold the rings as they would for vaginal insertion. Gel participants were directed to, for example, turn their palm sideways and observe product movement, rub the product between their thumb and fingers, and rub it between their palms. After manipulation, participants discussed sensations experienced and attitudes about specific characteristics of the prototypes (see Table 1).

Analysis

Focus groups were audio recorded and transcribed verbatim. Notes describing participants’ hand movements, any unique manipulation techniques, and non-verbal communications were added to transcripts during cleaning. Transcripts were coded by two trained independent coders using both *a priori* codes drawn from the research agendas, and codes that emerged from the data. Coding was compared, discrepancies resolved, and final codes entered into NVivo software [33].

Specific details regarding methodology of the study, as well as more comprehensive presentations of user evaluations of specific product properties, can be found elsewhere [34, 35]. This thematic analysis focuses on user narratives about meaning-making. We restrict our results to a few selected characteristics to convey the importance of how product properties elicit meaning for users.

Results

Four focus groups were conducted with 21 women who used an IVR within the last year. Additionally, four focus groups were conducted with 29 women who used a vaginal lubricant within the last year. Selected participant characteristics are summarized in Table 2. About half of lubricant users and two-thirds of ring users reported current use. Overall, participants used meaning-making to explain how specific product characteristics interact with aspects of their bodies and lives, which we illustrate with representative quotes. Quotes are identified with a participant number, age range, and vaginal delivery category.

Intravaginal Rings

What participants perceive as flexibility or pliability is a function of ring materials, and both ring and cylinder diameters. Participants indicated that ring flexibility and pliability would have implications for comfort during insertion and for retention of the ring, and that the ring's size would affect drug delivery and efficacy. Softer rings were expected to be more comfortable during insertion and daily wear, and more pleasurable during intercourse, for example: *"It's too strong, it's too not flexible, it just feels like this hard ring, that seems like it would be irritating"* (ppt#34: 30–45 yrs, no vaginal delivery). Participants referenced their own bodies in meaning-making to explain how stiffness and flexibility interacted with their body to impact comfort and awareness of a ring: *"It's just not the shape of me"* (ppt#42: 30–45 yrs, no vaginal delivery). Some participants said that a larger ring (i.e., overall ring diameter), or a larger cylinder diameter, would be necessary to deliver more drug for longer-term (>30 days) sustained release STI or pregnancy prevention, or for MPT rings. Additionally, a larger cylinder or ring was perceived as more durable by some.

Ring appearance also played a role in meaning-making. The appearance of the cylinder surface prompted consideration of whether a device was porous enough to allow drugs to pass into a user's body. While users may not have fully understood that material porosity is only one in several ring design metrics influencing drug delivery, this interchange explains the participant's meaning-making process:

Ppt 40: Does the texture of the ring change after, like, a three week exposure to [the body]?

Facilitator: It shouldn't, but I don't know the real answer to that question....

Ppt 40: I may be way overthinking this, but perceptually, because of the matte feel of [my contraceptive ring], I feel confident that it's leaching contraception.

Because of the glossy finish on this [prototype ring], it doesn't—I don't react to it as though it's going to leach. So my reaction is that I wonder, is the glossiness going to come off—so the chemical can—

Ppt 41: Like a gel coat on a pill or something?

Ppt 40: Exactly. Intellectually, I would understand if it didn't, but perceptually.

Facilitator: And would that make you feel differently about using it?

Ppt 40: Only in that I would identify a greater sense of security in a non-glossy finish.

(ppt#40: 18–29 yrs, no vaginal delivery; ppt 41: 18–29 yrs; no vaginal delivery)

Some participants' expressed concerns about wearing a ring for several months. Several women endorsed this sentiment: *"I think if it was switched out with the [same] frequency [as menstruation], it wouldn't bother me....I would be more concerned about the plastic over a long-term in a body, with the mucus and stuff, as opposed to the physical, it physically being there"* (ppt#41: 18–29 yrs, no vaginal delivery). Several participants drew on the concept of their natural menstrual cycles to explain their concerns with a long-term contraceptive product: *"I kinda like the natural cycle of the 28 days. I just feel like it's a really natural*

thing to get your period once a month. Um, so I wouldn't really go for the three month deal" (ppt#38: 30–45 yrs, no vaginal delivery). Another participant echoed this thinking, particularly with respect to an MPT product: *"...I like that the [contraceptive ring] follows the sort of natural menstrual cycle, I think if you're gonna combine another, you know HIV protection, something, with the same birth control, I think it would be good to stick to that pattern"* (ppt# 43: 18–29 yrs, no vaginal delivery). Participants indicate in these quotes that they like the familiarity and reassurance that a natural menstrual cycle provides.

Long-Acting Gels

Meaning-making about gels that deliver long-acting drugs included beliefs about the association between a gel's rheological and other biophysical properties and the product's protective efficacy. Therefore, meaning-making conflated the delivery system with the drug being delivered. Although less viscous (i.e., "thinner") gels were generally preferred for lubricant use, highly viscous, sticky, or bioadhesive gels were seen by some as more likely to prevent HIV or STDs: *"when I think of what it's going to be used for, I want it to be thick and I want it to stay there [another participant nodded affirmatively] (ppt#19: 18–29 yrs, 2+ vaginal deliveries). Some participants specifically indicated that they wanted a stickier, more adherent product for HIV prevention [34]: "It was hard to get off [my hands] and it was really sticky and thick. I feel like it would really, it would be a better barrier"* (ppt#29: 30–45 yrs, no vaginal delivery); and, *"[it would] have to be a little thicker [two other participants nodded affirmatively] because you want it to adhere"* (ppt#15: 30–45 yrs; no vaginal deliveries). While stickiness is a characteristic that many considered less desirable in a sexual lubricant, it was deemed appropriate in the context of STI/HIV protection because it meant the product would stay in the body longer and therefore offer better protection.

Implications and Discussion

In the current study, meaning-making refers to a cognitive process whereby participants attempt to explain the sensory experiences elicited by how a product feels and behaves in their bodies. Meaning-making about the materials and mechanical properties of intravaginal rings, and the rheological and biophysical properties of gels evaluated in this study fell into three distinct categories: 1) perceived product characteristics and descriptions of how they would work as prevention products, 2) perceived effects of those characteristics on the body or for the user, and 3) willingness to alter ideal characteristics of current products to accomplish the targeted prevention goals.

Often, participants' presumptions about how the body and the drug delivery system work and interact are not correct. For example, among the meanings made were: (1) a larger device or volume is needed to attain more protection, (2) how products "look" (e.g., shiny ring surfaces) indicate how well a product will deliver drug, (3) sticky products adhere to vaginal walls and, therefore, provide better protection. In fact, a sticky feel and bioadhesion are not necessarily one in the same, product appearance is not necessarily related to drug delivery, and drug efficacy is determined by factors beyond drug volume. Even when these narratives are not correct, however, such meanings could impact decision-making and

adherence behavior. Meaning-making will affect product use and could potentially alter product effectiveness.

Meaning-making was frequently based on experiences with other products and participants' presumptions of what a product might feel like and/or how it would behave in the vagina. These, along with desired effects for prevention products, shaped our participants' assumptions about new products. Intentionally exploring participants' explanations and attributions regarding various drug delivery system characteristics gives insight into the meaning-making processes influenced by formulation and device perceptibility and used to evaluate product acceptability and use.

These data regarding users' meaning-making about pregnancy and disease prevention products map perfectly onto Marshall's tripartite model for FRM. Perceived inherent attributes are based on sensory perceptions and experiences of the user as she interacts with the product's biophysical, rheological and/or mechanical properties and performance: a gel is sticky, not sticky or somewhat sticky; a ring's surface appearance is judged somewhere along the shiny-to-matte continuum; ring materials are, to one degree or another, hard or soft. Perceived associational attributes represent how those characteristics are assumed to interact with the body: a gel's stickiness is perceived to influence its adhesive qualities, having implications for effectiveness; drug delivery depends on the porosity of the ring surface; the hard-soft continuum impacts durability, comfort, and pleasure. Perceived effect may vary based on the desired product indication (pregnancy, STI, or HIV prevention, or some combination) and include perceived product efficacy, e.g., a user's assumption that because of its characteristics, a given product is likely to be more or less effective [29]. The valence and balance of each of these elements is critical to understanding how meaning is made, ultimately impacting product acceptability and use.

Marshall argued in 1973 that the acceptability of fertility regulating methods could be predicted, and even strategically controlled, if researchers understood users' perceived attributes, meanings, and cultural settings. The same will be true of microbicides and MPTs: if we better understand the meanings users ascribe to potential products, early in the development process, we can better tailor those products to users' needs. Incorporating users' perceptibility evaluations into product design will allow developers to make decisions that engender better uptake, education and marketing.

There are a number of study elements that should be considered. We enrolled vaginal product users in order to inform development of products that will be acceptable to future users. Our recruitment did not seek to represent a particular segment of future prevention product users (e.g., young women; women in serodiscordant couples). The study findings here may only be applicable to those populations similar to sexually-active women of reproductive age (18–45 years). We did not directly consult male partners. Although we sought to demonstrate a variety of product properties, participants could only extrapolate to other possible product characteristics from the gel and ring prototypes evaluated here (or that they had previously experienced). We acknowledge that both more properties and combinations of properties need to be fully explored to elucidate clarity for product development. We also recognize that the domains of meaning-making will likely vary in

different cultural contexts, and thus we do not offer conclusions here regarding which products or characteristics are most preferred by whom or for which indication. We do, however, believe that identifying those domains in one population is beneficial because it can inform the introduction of products and the investigation of meaning-making about them in other environments.

The meanings users make of perceptible vaginal product characteristics will be directly relevant to perceived effectiveness, acceptability, and willingness to use, whether or not they reflect developers' intentions. A central challenge is to understand not *whether* women make meaning of product experiences, but rather *how* that meaning is made, *upon what sensory perceptions and experiences meaning is based*, and if there are strong population-based or cultural assumptions about sexual pleasure, disease prevention, contraception, or ethno-theories about the body that connect these experiences and influence women's choices. Our findings suggest that meaning is made based on a variety of information, including product characteristics, individual phenomenological experiences, relevant prior product use experiences, and cultural factors that shape sexual experience and understandings of how the body should function or feel. Product developers need to be aware of meaning-making to maximize effective use and, ultimately, STI and pregnancy prevention.

Acknowledgements

The authors would like to acknowledge the Project MAPLE Study Team, including Patrick Kiser, David Katz, Karen Buckheit, Lara Thompson, Dana Bregman, Judith Fabian, Shwetha Ugoankar, Todd Johnson, and Ryan Teller.

We gratefully acknowledge the contributions made by the participants in this study who shared their opinions and experiences. This project was supported by the National Institute of Allergy and Infectious Diseases (NIAID) U19AI077289 (Buckheit, PI: Morrow, Project 3 Lead Investigator), the National Institute of Child Health and Human Development (NICHD) K24 HD062645 (Morrow, PI), NIAID P30 AI042853 (Carpenter, PI: van den Berg, post-doctoral fellow) through the Lifespan/Tufts/Brown Center for AIDS Research, and the generous donation of PreSeed. The content is solely the responsibility of the authors and does not represent the views of the NIAID, NICHD, or the National Institutes of Health. NIAID and NICHD had no involvement in the study design, nor in the collection, analysis and interpretation of data.

References

1. World Health Organization. Global Health Observatory (GHO): HIV/AIDS; 2015.
2. World Health Organization. Global Health Observatory (GHO): Sexually Transmitted Infections (STIs); 2015.
3. Singh S, Sedgh G, Hussain R. Unintended pregnancy: worldwide levels, trends, and outcomes. *Stud Fam Plann.* 2010; 41:241–250. [PubMed: 21465725]
4. CAMI. CAMI Health [Website]. 2014
5. Johansson E, Sitruk-Ware R. New delivery systems in contraception: vaginal rings. *Am J Obstet Gynecol.* 2004; 190:54–59.
6. International Partnership for Microbicides. The Ring Study. 2002–2011
7. Microbicide Trials Network. Fact Sheet: Two Phase III Sister Studies of a Microbicide Ring to Prevent HIV: The Ring Study and ASPIRE. 2014
8. Mantell J, Myer L, Carballo-Diequez A, et al. Microbicide acceptability research: current approaches and future directions. *Soc Sci Med.* 2005; 60:319–330. [PubMed: 15522488]
9. Bentley M, Morrow K, Fullem A, et al. Acceptability of a novel vaginal microbicide during a safety trial among low-risk women. *Fam Plann Perspect.* 2000:184–188. [PubMed: 10942354]

10. Van Damme L, Wright A, Depraetere K, et al. A phase I study of a novel potential intravaginal microbicide, PRO 2000, in healthy sexually inactive women. *Sex Transm Infect.* 2000; 76:126–130. [PubMed: 10858715]
11. Morrow K, Rosen R, Richter L, et al. The acceptability of an investigational vaginal microbicide, PRO 2000 Gel, among women in a phase I clinical trial. *J Womens Health (Larchmt).* 2003; 12:655–666. [PubMed: 14583106]
12. Rosen R, Morrow K, Carballo-Diéguez A, et al. Acceptability of tenofovir gel as a vaginal microbicide among women in a phase I trial: a mixed-methods study. *J Womens Health (Larchmt).* 2008; 17:383–392. [PubMed: 18328009]
13. Abdool Karim Q, Abdool Karim SS, Frohlich JA, et al. Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women. *Science.* 2010; 329:1168–1174. [PubMed: 20643915]
14. Morrow KM, Ruiz MS. Assessing microbicide acceptability: a comprehensive and integrated approach. *AIDS and Behavior.* 2008; 12:272–283. [PubMed: 17592763]
15. Marrazzo, J.; Ramjee, G.; Nair, G.; Palanee, T.; Mkhize, B.; Nakabiito, C. Pre-exposure prophylaxis for HIV in women: daily oral Tenofovir, oral Tenofovir/Emtricitabine, or vaginal Tenofovir gel in the Voice study (MTN 003). 20th Conference on retroviruses and opportunistic infections Atlanta; USA. March 2013;
16. CONRAD. HIV prevention study does not confirm pericoital tenofovir gel effectiveness - Protection observed in small group of women who used the product consistently [Press Release]. 2015
17. Kernan W, Lepore S. Searching for and making meaning after breast cancer: prevalence, patterns, and negative affect. *Soc Sci Med.* 2009; 68:1176–1182. [PubMed: 19157667]
18. la Cour P, Hvidt N. Research on meaning-making and health in secular society: Secular, spiritual and religious existential orientations. *Soc Sci Med.* 2010; 71:1292–1299. [PubMed: 20691529]
19. Stuckey H, Tisdell E. The role of creative expression in diabetes: An exploration into the meaning-making process. *Qual Health Res.* 2010; 20:42–56. [PubMed: 19926796]
20. Park C, Edmondson D, Fenster J, Blank T. Meaning making and psychological adjustment following cancer: The mediating roles of growth, life meaning, and restored just-world beliefs. *J Consult Clin Psychol.* 2008; 76:863. [PubMed: 18837603]
21. Park C. Making sense of the meaning literature: an integrative review of meaning making and its effects on adjustment to stressful life events. *Psychol Bull.* 2010; 136:257. [PubMed: 20192563]
22. Baumeister, R. The Guilford Press; 1991. Meanings of life.
23. Morrow, K.; Rosen, R.; Vargas, S.; Barroso, C.; Kiser, P.; Katz, D. User-Identified vaginal gel characteristics: A qualitative exploration of perceived product efficacy. International Microbicides Conference; Pittsburgh, PA, USA. 2010.
24. Mantell JE, Morar NS, Myer L, Ramjee G. “We have our protector”: Misperceptions of protection against HIV among participants in a microbicide efficacy trial. *American journal of public health.* 2006; 96:1073. [PubMed: 16670239]
25. Stadler J, Saethre E. Blockage and flow: intimate experiences of condoms and microbicides in a South African clinical trial. *Cult Health Sex.* 2011; 13:31–44. [PubMed: 20960355]
26. Coast E. Wasting semen: Context and condom use among the Maasai. *Cult Health Sex.* 2007; 9:387–401. [PubMed: 17612958]
27. Montgomery C, Gafos M, Lees S, et al. Re-framing microbicide acceptability: findings from the MDP301 trial. *Cult Health Sex.* 2010; 12:649–662. [PubMed: 20397079]
28. Morrow KM, Underhill K, van den Berg JJ, Vargas S, Rosen RK, Katz DF. User-Identified Gel Characteristics: A Qualitative Exploration of Perceived Product Efficacy of Topical Vaginal Microbicides. *Arch Sex Behav.* 2014
29. Morrow KM, Fava JL, Rosen RK, et al. Designing preclinical perceptibility measures to evaluate topical vaginal gel formulations: relating user sensory perceptions and experiences to formulation properties. *AIDS Res Hum Retroviruses.* 2014; 30:78–91. [PubMed: 24180360]
30. Marshall J. Fertility regulating methods: cultural acceptability for potential adopters. World Health Organization (WHO), Expanded Programme of Research, Development and Research Training. 1973:99–113.

31. Marshall J. Acceptability of fertility regulating methods: designing technology to fit people. *Prev Med.* 1977; 6:65–73. [PubMed: 850682]
32. Marshall, J. Fertility regulating methods: Cultural acceptability for potential adopters. In: Duncan, GW., editor. *Fertility Control Methods*. New York: Academic Press; 1973. p. 125-132.
33. QSR. NVivo qualitative data analysis software. In: 9 QIPLV. , editor. 2010.
34. van den Berg J, Rosen R, Bregman D, et al. "Set it and forget it": women's perceptions and opinions of long-acting topical vaginal gels. *AIDS Behav.* 2014; 18:862–870. [PubMed: 24248674]
35. Morrow KM, Hendrix C. Acceptability of Different Dosage Forms. Invited oral presentation to the CONRAD Trends. Microbicide Formulations Workshop conference January 25–26, 2010 Arlington, VA, USA As cited in *Clinical Evaluation of Microbicide Formulations*. Antiviral Research. 2010; 88(suppl):S40–S46. [PubMed: 21109067]

Table 1

Key content areas for focus group discussions

Ring Groups:

- 1 Prior ring use and experiences, including:
 - a. History of, and reasons for, ring use; including product likes and dislikes and reasons for discontinuation, if applicable
 - b. Insertion and removal; expulsion experience(s): when, how and with whom used
 - c. Partner attitudes, effect on intercourse, sexual pleasure, comfort, etc.
- 2 “Manipulation of first prototype ring
 - a. Observe size, weight, ring and cylinder dimensions (diameter, circumference)
 - b. Hold as for insertion and removal; squeeze between thumb and first two fingers, additional movements at will
- 3 Discussion of first prototype ring
 - a. Specific characteristics (size, flexibility, comfort, awareness, etc.)
 - b. Discussion of specific biomechanical properties and performance features
 - c. Long-term use
 - d. Willingness to use
 - e. Possible effects on intercourse: awareness of ring by self/partner, sexual pleasure
 - f. Potential for covert use
 - g. Phenomenology (i.e. what the ring feels like to the user)
- 4 Repeat manipulation and discussion of next 3 rings
- 5 Comparison of properties of all 4 rings

Gel groups

- 1 Prior gel/lubricant use and experiences, including
 - a. History of, and reasons for, gel/lube use; including product likes and dislikes and reasons for discontinuation, if applicable
 - b. Application/insertion: when, how and with whom used
 - c. Partner attitudes, effect on intercourse, sexual pleasure, comfort, etc.
- 2 “Manipulation of first gel
 - a. Observe color, characteristics, amount, weight, smell
 - b. Move between fingers, over palm, invert hand, separate fingers, etc.
- 3 Discussion of first gel
 - a. Specific characteristics (look, feel, likely application, awareness, leakage, etc.),
 - b. Discussion of different rheological properties
 - c. Long-acting product
 - d. Willingness to use
 - e. Possible effects on intercourse: e.g., lubrication, desiccation, sexual pleasure
 - f. Potential for covert use
 - g. Phenomenology (i.e. what the gel feels like to the user)
- 4 Repeat manipulation and discussion of next 2 gels
- 5 Comparison of properties of all 3 gels

Table 2

Demographic Characteristics and Sexual/Reproductive Histories of Sample

| Product: | Gel (N=29) | | Ring (N=21) | |
|---|------------|-------|-------------|-------|
| | Mean | SD | Mean | SD |
| Age | 31.5 | 7.0 | 28.2 | 6.0 |
| Number of Male Vaginal Sex Partners (past 12 months; ring n = 20) | 1.6 | 1.4 | 1.9 | 1.7 |
| | n | % | n | % |
| Ethnicity | | | | |
| Hispanic/Latina | 2 | 6.9 | 1 | 4.8 |
| Race | | | | |
| Black/African American | 2 | 6.9 | 2 | 9.5 |
| Caucasian/White | 18 | 62.1 | 14 | 66.7 |
| Asian | 2 | 6.9 | 3 | 14.3 |
| Multiracial | 4 | 13.8 | 1 | 4.7 |
| Other or Did Not Identify by Race | 3 | 10.3 | 1 | 4.8 |
| Education | | | | |
| Less than high school and high | 4 | 13.8 | 0 | 0.0 |
| Beyond high school | 25 | 86.2 | 21 | 100.0 |
| Current Marital Status | | | | |
| Never been married | 15 | 51.7 | 13 | 61.9 |
| Married | 10 | 34.5 | 7 | 33.3 |
| Separated or Divorced | 4 | 13.8 | 1 | 4.8 |
| Household Income (annual) | | | | |
| <\$15,000 | 8 | 27.6 | 3 | 14.3 |
| \$15,000–\$35,999 | 10 | 34.5 | 6 | 28.6 |
| >\$36,000 | 10 | 34.5 | 11 | 52.4 |
| Not reported | 1 | 3.4 | 1 | 4.8 |
| Sexual History | | | | |
| Oral sex (past 12 months) | 23 | 79.3 | 18 | 85.7 |
| Anal sex (past 12 months) | 6 | 20.7 | 5 | 23.8 |
| Most Recent Sexual Partner | | | | |
| Main | 25 | 86 | 17 | 81 |
| Non-Main | 4 | 14 | 4 | 19 |
| Vaginal Product History | | | | |
| Vaginal medication | 23 | 79.3 | 17 | 81 |
| Vaginal douche | 12 | 41.4 | 3 | 14.3 |
| Vaginal lubricants | 29 | 100.0 | 16 | 76.2 |
| Spermicides | 9 | 31.0 | 2 | 9.52 |
| Desiccants | 2 | 6.9 | 1 | 4.8 |
| Intravaginal rings | 7 | 24.1 | 21 | 100.0 |
| Hormonal Contraceptive Use | | | | |

| Product: | Gel (N=29) | | Ring (N=21) | |
|------------------------------|------------|------|-------------|------|
| | Mean | SD | Mean | SD |
| Currently Using | 13 | 45 | 14 | 67 |
| Number of vaginal deliveries | | | | |
| 0 | 23 | 79.3 | 17 | 81.0 |
| 1 or more | 6 | 20.6 | 4 | 19.1 |

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript