Published in final edited form as:

Arch Sex Behav. 2010 June ; 39(3): 748–760. doi:10.1007/s10508-009-9509-3.

Covert Use, Vaginal Lubrication, and Sexual Pleasure: A Qualitative Study of Urban U.S. Women in a Vaginal Microbicide Clinical Trial

Susie Hoffman, Dr.P.H.^{1,2,6}, Kate M. Morrow, Ph.D.^{3,4}, Joanne E. Mantell, M.S.P.H., Ph.D.¹, Rochelle K. Rosen, Ph.D.³, Alex Carballo-Diéguez, Ph.D.¹, and Fang Gai, M.P.H.⁵

¹ HIV Center for Clinical and Behavioral Studies, New York State Psychiatric Institute and Columbia University, New York, NY

² Department of Epidemiology, Joseph L. Mailman School of Public Health, Columbia University, New York, NY

³ The Miriam Hospital, Providence, RI

⁴ The Warren Alpert Medical School of Brown University, Providence, RI

⁵ Statistical Center for HIV/AIDS Research & Prevention, Fred Hutchinson Cancer Research Center, Seattle, WA

Abstract

Using data from a U.S. clinical safety trial of tenofovir gel, a candidate microbicide, we explored the intersection of sexual pleasure and vaginal lubrication to understand whether and under what circumstances women would use a microbicide gel covertly with primary partners. This study question emerged from acceptability research in diverse settings showing that even though future microbicides are extolled as a disease prevention method that women could use without disclosing to their partners, many women assert they would inform their primary partner. Participants (N = 84), stratified by HIV-status and sexual activity (active vs. abstinent), applied the gel intra-vaginally for 14 days. At completion, quantitative acceptability data were obtained via questionnaire (N = 79) and qualitative data via small group discussions (N = 15 groups, 40 women). Quantitatively, 71% preferred a microbicide that could not be noticed by a sex partner and 86% experienced greater vaginal lubrication during application of the gel. Based on our analysis of the qualitative data, we suggest that women would find it more acceptable to use a microbicide covertly in primary relationships if they believed that the method was truly unnoticeable. Our findings also showed that women's assessment of the possibility of discreet, if not covert, use was strongly related to their perception of how a microbicide's added vaginal lubrication would influence their own and their partner's pleasure, as well as their partner's experience of his sexual performance. A microbicide that increases pleasure for both partners could potentially be used without engendering opposition from primary partners.

Keywords

Sexual pleasure; HIV/STI prevention; vaginal Microbicide; pregnancy prevention

⁶To whom correspondence should be addressed at HIV Center for Clinical and Behavioral Studies, Unit 15, New York State Psychiatric Institute, 1051 Riverside Drive, New York, NY 10032; sh51@columbia.edu, Phone: 212-5433, Fax: 212-543-5260.

INTRODUCTION

The call for female-controlled disease prevention methods emerged in the early 1990s as the HIV epidemic among U.S. women shifted from one in which those who injected drugs predominated to one in which women who were infected through sex with a male partner (often their sole partner) constituted an increasing proportion of HIV-positive women (Centers for Disease Control and Prevention, 1995; Exner, Hoffman, Dworkin, & Ehrhardt, 2003). The HIV epidemic in sub-Saharan Africa, which had always been predominantly heterosexual, also came to be recognized as affecting large numbers of women (Heise & Elias, 1995; Petros-Barvazian & Merson, 1990). Recognition of the changing epidemiology of HIV led to the development of a gendered perspective on women's HIV risk, bringing into focus the ways that gender inequalities in the social and economic spheres (Farmer, Connors, & Simmons, 1996; Zierler & Krieger, 1997) and women's disempowerment in sexual relationships (Amaro, 1995; Gómez & VanOss Marín, 1996; Gupta, Weiss, & Whelan, 1995; Mays & Cochran, 1988) contributed to their susceptibility to HIV. To enhance women's agency in protecting themselves from infection, researchers and activists pressed for female-controlled methods--principally, the female condom, which became available in the U.S. in 1993, and a vaginal microbicide in the form of a topical cream or gel, which is still under development. Female-controlled methods expand options for protection in situations where a man (or woman) does not want to use a condom (Elias & Heise, 1994; Stein, 1990, 1993).

An additional attribute of a microbicide is the possibility to use it covertly. This has been heralded as one of its hallmark characteristics and featured in the effort to promote product research and development (Alliance for Microbicide Development, 2002; Gates, 2006; Population Council and International Family Health, 2001; Rockefeller Foundation Microbicides Initiative, 2002; UNAIDS, 2004). Women, it is argued, would be able to insert the product prior to the initiation of sex without having to negotiate with their partners. Moreover, because a microbicide may not be visible outside the vagina or felt inside it, a partner could be unaware of it before, during, or after sex. Microbicides would thereby increase women's control over protection by enabling them to initiate use (in contrast to the male condom) and to use the method covertly (in contrast to the female condom, which is clearly visible outside the vagina).

Despite the promotion of covert use as one of the most important attributes of microbicides, two relatively consistent findings have emerged across varied settings and types of microbicide "acceptability" studies. One is that although many women value the possibility of using a microbicide covertly, many also say they would inform their primary partners if they were to use one (Bentley et al., 2000, 2004; Coggins et al., 2000; Hammett et al., 2000; Koo, Woodsong, Dalberth, Viswanathan, & Simons-Rudolph, 2005; Mason et al., 2003; Morrow et al., 2003; Weeks et al., 2004). Another consistent finding is that women want products that will not reduce sexual pleasure for themselves and, in particular, for their partners (Elias & Coggins, 2001; Severy & Newcomer, 2005; Woodsong, 2004). These results suggest that gender-based norms for sexual behavior and relationships will affect how women use a microbicide in ways akin to how these norms affect condom use (Mantell et al., 2006; Woodsong, 2004). Many women eschew condoms because men dislike them and women want to please their partners (Logan, Cole, & Leukefeld, 2002). Moreover, requesting condom use in a primary relationship is synonymous with acknowledging risk in the relationship, thereby threatening women's commitment to affirming their primary partnerships as trusting and monogamous (Hirsch, Higgins, Bentley, & Nathanson, 2002; Kline, Kline, & Oken, 1992; O'Leary, 2000; Sobó, 1993, 1995). For these same reasons, women may be averse to secretly using a non-condom STD prevention method in their primary partnerships.

Using data that were collected as part of a HIV Prevention Trials Network (050) Phase I trial, we previously reported on the overall acceptability of a candidate microbicide gel among urban, U.S. women (Rosen et al., 2008) and among the male partners of those assigned to use the gel during vaginal intercourse (Carballo-Diéguez et al., 2007). The primary objectives of that trial were to assess the safety, toxicity, and absorption of 0.3% and 1.0% tenofovir gel (an antiretroviral that inhibits HIV reverse transcriptase) when used vaginally by women at low risk for HIV infection and by HIV-infected women (Mayer et al., 2006). A secondary objective of the study was to assess product acceptability, using both quantitative and qualitative methods. In our earlier report on women, we noted that the majority indicated in a quantitative assessment that they preferred a method that could be used covertly, but many said in small group discussions following completion of the safety trial that they would inform their primary partner if they, themselves, were using a microbicide. We also noted that discourse around covert in these discussion groups was related to women's perceptions of the lubricating or drying qualities of the gel, a theme that was also associated with sexual pleasure.

In this article, we aim to extend previous research on women's interest in using a microbicide covertly by further examining this theme in our data. Crucially, if women find it undesirable or infeasible to use such a product without informing their primary partners, then we need to understand how to make microbicide use acceptable in these relationships, which represent a principal context of HIV infection for women (de Zoysa, Sweat, & Denison, 1996; O'Leary, 2000). To address this issue, we used our qualitative data to examine how tenofovir gel's effect on sexual pleasure and vaginal lubrication intersected to shape women's willingness to use it covertly in different types of partnerships. In the literature to date, the interrelationships among covert use, sexual pleasure, and vaginal lubrication have received much less attention than has each of these aspects of microbicide acceptability alone. Below, we briefly review this literature.

Covert Use

Although many acceptability studies have reported that women would prefer to tell their primary partners if they were using a microbicide, only a few have conducted in-depth analyses to understand women's views concerning covert use. In one study, Ugandan women reported in focus groups where they were shown a variety of available vaginal products (sponge, film, tablets, foams and gel, female condom) that they preferred those they could use without informing partners. However, when actually using the products, covert use dropped from about 40% in the first week to 22% after 10 weeks of use (Green et al., 2001). Some women believed it was their duty to tell their regular partners, whereas others noted that it would be difficult to hide the product applicators. By informing their partners, some sought to avoid the negative repercussions of discovery, and others disclosed because they believed their partners would notice. Overall, one-third of all women reported that their partners felt the product during intercourse.

In another study, U.S. women who either used injection drugs or were the partners of injection drug users met in focus groups to discuss microbicide acceptability (Mason et al., 2003), and 83 participated in a short-term trial, using available foams, gels, and suppositories, after which they were interviewed about their reactions to the products (Hammett et al., 2000; Mason et al., 2003). According to women's reports, more than 80% of partners were aware that women were using the products, most because participants had informed them. Some women informed their partners because they were concerned that vaginal wetness might engender distrust--suspicions that they had a sexually transmitted infection (STI) or had been unfaithful--and others because they believed it was important to involve partners in decisions around protection. Similarly, in a family planning clinic sample of ethnically diverse U.S. adolescent and adult women who were asked to use a vaginal

lubricant during intercourse (Koo et al., 2005), a strong preference to disclose to regular partners emerged in focus group discussions and individual interviews. Women reported that covert use seemed inconsistent with the intimacy and implicit monogamy that define “serious” relationships. By contrast, they believed it was acceptable to use a microbicide without informing a casual or new partner.

Sexual Pleasure

Apart from its ability to be used covertly, a microbicide’s positive or negative effect on sexual pleasure has emerged as an important characteristic related to acceptability (Koo et al., 2005; Mason et al., 2003; Pool et al., 2000; Weeks et al., 2004). Sexual functioning and pleasure are domains that have most often been investigated in the context of men’s dislike of condoms, but increasingly they have been found to influence women’s choice and continued use of contraceptives, including male and female condoms (Higgins & Hirsch, in press; Philpott, Knerr, & Maher, 2006; Severy & Newcomer, 2005). As would be expected, women prefer methods that enhance their pleasure and diminish discomfort, although their perceptions of which characteristics are desirable and which are undesirable vary considerably across cultures, and are influenced by contextual factors, including social class, prevailing gender norms, and relationship characteristics (Higgins & Hirsch, 2007). In a qualitative study of U.S. women, pleasing one’s partner was found to be an important component of sexual pleasure for many and was prioritized over women’s own sexual comfort in some cases (Higgins & Hirsch, in press). In settings besides the U.S., ensuring men’s pleasure has also been shown to be a primary motivation for women’s adoption (or lack thereof) of contraceptive methods, and for the use of a variety of vaginal practices (Scorgie et al., in press; van Andel et al., 2008; van de Wijgert, Mbizvo, Dube, & Mwale, 2001; Woodsong & Alleman, 2008).

Lubrication

Vaginal “wetness” or “dryness” is one characteristic that frequently is modified in order to enhance either women’s or men’s sexual pleasure. A recent study of vaginal practices in KwaZulu-Natal found that women who used vaginal drying agents described them as a necessary strategy for keeping their partner from “straying,” even though they, themselves, might experience discomfort (Scorgie et al., in press). In another South African study, vaginal wetness was identified by some users as an undesirable feature of the injectable contraceptive, Depo Provera (Smit, McFadyen, Zuma, & Preston-Whyte, 2002). In Zimbabwe and Malawi, many men (and some women) reported a strong preference for a dry and tight vagina (Braunstein & van de Wijgert, 2005; Woodsong & Alleman, 2008), and this preference has also been reported in Suriname (van Andel et al., 2008). By contrast, vaginal lubricants increasingly are marketed in the U.S. for the enhancement of both women’s and men’s sexual pleasure (Severy & Newcomer, 2005), although “wetness” may have both positive and negative connotations in various U.S. subcultures (Mason et al., 2003). Not surprisingly, then, women’s assessments of the lubricating or drying qualities of potential microbicides (either trial or surrogate products) are important determinants of whether or not they would find these methods acceptable (Bentley et al., 2000; Morrow et al., 2003).

In the present article, we explored the intersection of sexual pleasure and vaginal lubrication to understand whether and under what circumstances a sample of urban, U.S. women would use a microbicide gel covertly with primary partners. We addressed the following questions: (1) What further can we learn about the disjunction between women’s stated preference for methods that can be used covertly and their assertion that they would inform their primary partner if they were using a microbicide gel? and (2) Are there circumstances under which women would use the microbicide gel without informing a primary partner or characteristics

of microbicide gels that would enable women to use them without informing a primary partner?

METHOD

Participants

Women (N = 84) were recruited in three U.S. cities--New York, Philadelphia, and Providence--through community educational activities, advertisements, fliers on college campuses, clinics, and other locales, and by word-of-mouth. Eligibility criteria included being 18–45 years of age and having regular menstrual cycles or being amenorrheic due to long-acting progestins. For the safety trial, HIV-negative, sexually abstinent study participants were first recruited into cohorts that were stratified by dose of the active ingredient (0.3% and 1.0% strength tenofovir) and frequency of application (once a day versus twice a day). Once the highest practical dose and frequency were established (1.0%, twice a day), subsequent cohorts were stratified by HIV serostatus and sexual abstinence or activity (see Table 1).

Women in sexually abstinent cohorts were required to have been abstinent for 48 hours prior to the study enrollment visit and to refrain from having vaginal, anal, or oral sex until the follow-up visit on the fourteenth day. Women in sexually active cohorts had to be in a mutually monogamous, seroconcordant, heterosexual relationship of at least 3 months duration, have vaginal sex with study-supplied condoms and gel at least twice per week, and refrain from oral and anal sex. All participants underwent a consent process that was approved by local institutional review boards. Detailed inclusion/exclusion criteria are described elsewhere (Mayer, 2006).

The sample for the acceptability analyses included 79 women who completed a quantitative acceptability assessment immediately after 14 days of product use and a subset of 40 women (29 sexually abstinent and 11 sexually active) who participated in one of 15 small group discussions conducted following product use (see Table 1 for number of groups and participants according to HIV-status and sexual activity status). To conduct a discussion group, at least two participants from the same cohort had to be available to participate within six weeks of completing the product trial. This criterion accounted for the fact that only 40 of the 79 women participated in small group discussions.

The mean age of the 79 participants was 36.2 years. The sample was racially, ethnically, and educationally diverse. The demographic characteristics of women who participated in the group discussions were similar to those of all women who completed the quantitative assessment (Table 2). There also were no noteworthy differences in the quantitative acceptability results among women who participated in the qualitative discussions vs. those who did not (data not shown).

Procedure

Participants used 4 grams of the study product intra-vaginally, applied with a pre-filled disposable applicator, for 14 consecutive inter-menstrual days. Participants were assigned to apply the gel vaginally once-a-day (in the morning) or twice-a-day (in the morning and at bedtime). On days when participants in the sexually active cohorts had intercourse, they replaced one of the daily doses with a pre-coital dose, inserted up to two hours prior to intercourse. Male partners were required to wear study-provided condoms during intercourse. Adherence was assessed by daily diaries completed by the participants and by interviewer-administered questionnaire at Day 7 and Day 14.

For the acceptability study, women were assessed quantitatively using an interviewer-administered baseline questionnaire and acceptability questionnaire at Day 14, after completing the safety protocol. Qualitative data were collected via small group discussions, approximately two hours in length, conducted within six weeks of product use and led by two trained, female facilitators, who had prior experience in conducting focus groups. Fifteen small group discussions were conducted, ranging in size from two to five participants (Table 1). All discussions were audiotaped and transcribed. Women received \$25 in compensation for participation in the group interview.

Measures

The quantitative acceptability assessment included questions about women's response to the characteristics of the gel (smell, color, consistency), the effect of the gel on vaginal lubrication, and preference for a microbicide that could be used covertly. Sexually active participants were asked to rate experiences during sex (effect on sexual pleasure, leakage, dryness, stickiness, and wetness).

The small group discussions were guided by a detailed semi-structured topic list, which was developed based on study aims and guides used in earlier studies. Topics relevant to the present analyses included what women thought about a product that could be used without informing partners; under what circumstances and with which types of partners they would disclose or withhold disclosure of gel use; the reasons they had for wanting or not wanting to use a vaginal gel covertly; and whether they believed that this particular gel would allow covert use. Women in sexually active cohorts were also asked about the impact of the gel on sexual functioning, women's and their partner's sexual pleasure, and whether or not women believed their partners were or would be (outside of the trial context) aware of the gel during intercourse.

Data Analysis

Audiotapes of discussion groups were transcribed verbatim in each city by a professional transcriptionist and then reviewed for transcription errors and to remove any personal identifiers. A qualitative data coding scheme was developed based on the topic guide, the study protocol, and prior acceptability research. In this type of analysis, one or more codes were applied to blocks of text that exemplified the respective theme (or code). All coders participated in joint coding and discussion of several transcripts to refine identification and grouping of themes in the coding scheme, develop clear definitions for each code, and add additional codes and subcodes, as necessary. After joint training, two different coders, one from the collection site and one from another site, independently coded each transcript. All six coders had facilitated small group discussions (although not all those who facilitated group discussions participated in coding). Coding pairs then met to review and discuss the code assignments and to reconcile any discrepancies. After consensus was reached, codes for each transcript were entered into QSR NVivo 2 (QSR International, 2002). The members of the coding pairs were rotated to enhance the reliability of coding across transcripts.

To conduct the analysis, we generated coding reports for each of the relevant codes and subcodes. Each coding report was summarized by one investigator and discussed with other investigators to ensure the consistency of interpretations. These summaries described the content of major themes and sub-themes with the aim to understand the range and content of responses to a particular topic, rather than to count the number of participants who commented on each theme. This was a function of the qualitative data collection strategy employed, in which each participant was encouraged by facilitators to engage in the discussion, but was not systematically asked each question. Analysis then focused on what might account for differences in responses and how themes related to each other.

Additionally, data were examined as a function of discussion group characteristics (abstinent vs. sexually active; HIV-negative vs. HIV-positive), and interpreted in light of these characteristics as appropriate. Although approximately half of participants were African-American, we did not conduct analyses separately by race/ethnicity. Discussion groups were not formed on the basis of race/ethnicity and most included participants of more than one racial/ethnic group. Therefore, it would have been of questionable value to try to separate an individual's response from the context of the particular discussion group.

RESULTS

Quantitative Results

In the quantitative acceptability assessment, 56 (71%) women said they would prefer a microbicide that could not be noticed by a sex partner, 15 (19%) said it didn't matter, and 8 (10%) did not prefer a product that was unnoticeable. These percentages did not differ significantly between HIV-negative and HIV-positive women or between sexually abstinent and sexually active women (Rosen et al., 2008). Sixty-eight (86%) women reported increased vaginal lubrication with daily use.

Of 22 participants who used the gel during sexual activity, 10 (46%) agreed strongly or somewhat that the gel "increased my sexual pleasure," 10 (45%) reported no difference, and 2 (9%) disagreed somewhat or strongly (Rosen et al., 2008). When asked about a decrease in their sexual pleasure, the majority reported no decrease or no change. With respect to their partner's pleasure, 11 (50%) agreed strongly or somewhat that the gel "increased my partner's pleasure," 8 (36%) reported no difference, and 3 (14%) disagreed strongly or somewhat with this statement. Four women (19%) agreed strongly or somewhat that the gel decreased a partner's pleasure.

Qualitative Results

The following broad topics emerged from analysis of the small group discussions: (1) women's right to bodily control and decision-making; (2) trust, mutuality, and intimacy in main partnerships (vs. casual partnerships); (3) vaginal lubrication and the possibility of covert use; (4) vaginal lubrication, sexual pleasure, and covert use; and (5) vaginal lubrication, women's arousal, and male sexual performance. There were no substantial differences in themes according to type of group (HIV-negative vs. HIV-positive; sexually active vs. abstinent). However, we have given greater weight in our interpretations about effects on sex to comments in those groups in which women actually used the gel during sex. Common themes were those that emerged in at least the majority of the 15 discussion groups. We use exemplary quotes to illustrate and develop these themes. When a comment is atypical, it is so noted. For each quote, participant number and type of group are shown in brackets.

Women's Right to Bodily Control and Decision-Making—When asked directly what they thought about having a woman-controlled method, participants overwhelmingly affirmed its importance. One woman said "It's just like we got our first vote, [laughing] yes." [#116, Sexually Active, HIV-positive]

Control was variously expressed as personal agency in relation to protection, sexuality, and their bodies, as discussed by these participants:

#138: Yeah. It kind of like give the woman,...it would encourage the woman...to make some decisions about

#137: Yes.

#138: her body and kind of like...encourage her...

#137: Responsibility.

#138: to, responsibility to her own personal body and...go even further than that and say, you know, I started this and I'm gonna begin--, you know, proceed with this... [Sexually Active, HIV-positive]

One woman linked control over protection to control over sexuality more generally:

...like you were saying women that are in situations where they don't control the sexual ...activity itself, or a lot of times when you're in domestic violence situations where he won't use a condom or whatever, and you can't use the female condom and it's like, I won't let you take birth control or something like that; so I think it could be helpful...in helping women in those situations have control over the sexual acts that they...have to perform and stuff like that so. [#50 Sexually Abstinent, HIV-negative]

Women articulated their right to protect themselves, even if a partner did not approve, linking this right to the right not to disclose gel use:

Because you got some people that rejects on you using certain things...and they might not approve. But it's not really up to that person. It's up to you what's best for you...for your own safety.... They ain't got to know that you using it. [#38 Sexually Abstinent, HIV-negative]

...and even if they do tell their partners, the partners don't care! So I think it's important to have this. And even if it was just a birth control product and not an STD product? I mean, there's men out there that don't wanna use condoms. And the women have five, six kids on welfare, you know? So...it could give women control in a lotta different areas. So I think it's important that it can be used discreetly. And I don't oppose someone using it and not tellin' their partner, you know? It's better than not usin' anything. [#100, Sexually Abstinent, HIV-positive]

These women endorsed a woman's right to use a microbicide, including the right not to disclose, if a woman needed to protect herself and could not do so openly. This was believed to be particularly relevant for specific groups of women:

...women that are in abusive relationships, or...women who are sex workers.... I don't necessarily think that you wanna' make the announcement. I think that this is the reason why the availability of this product is so important, so that you could be discreet about it. [#100, Sexually Abstinent, HIV-positive]

Other women identified as needing such a method were those in multiple partnerships:

#38: if you're promiscuous or whatever [she added that she was not]...that should be something that we could have, so the men don't *have* to know.

#51: A secret weapon. [Sexually Abstinent, HIV-negative]

Thus, women constructed their bodily and sexual rights as including the right to use a microbicide and to do so without telling an uncooperative, controlling, or risky partner, or even a casual partner with whom she does not want to share her sexual history.

Mutuality, Trust, and Intimacy in Main Partnerships—Regardless of these expressed rights, women made a distinction between disclosing to regular and one-time or casual partners, most holding that they would tell their regular partners, but that covert use with a casual partner would be acceptable. Women had difficulty imagining that they would ever want to hide microbicide use in primary partnerships, even though they often described men in general as untrustworthy and not taking the need for protection seriously. The following conversation on this topic ensued in one sexually abstinent group, after the facilitator asked about disclosure:

- # 38: well, I'm married so...I've been married for 24 years. And I don't keep anything from him. So me, myself, I would let him know.
- Unidentified Participant: I would tell him after.
- Unidentified Participant: It depends on who it is.
- #46: Yeah, it depends. If it's someone you just met, you might not tell them but if it's someone that, you know, you've been dating for a little while, you can say yeah....
- Unidentified Participant: Yeah, I'm using it. [Sexually Abstinent, HIV-negative]

Women's reasons for wanting to disclose to regular partners were often reflective of their experiences (or expectations) of primary partnerships as open, honest, and trusting. As the speaker above noted, she does not keep any secrets from her long-time partner. Other women spoke in a similar vein, for example, "We tell each other everything, we don't have no secrets". [#137 Sexually active, HIV-positive]. For these women, their desire to disclose reflected beliefs about the nature of intimate sexual relationships, as expressed by this woman:

...when you decide to go to bed with somebody, ...there has to be...something there...you gotta be honest with the person you're givin' yourself to.... You know, this is...you! This is what you're putting inside of you...which is the gel and his penis. So, you know, I feel—regardless—that you should let your partner know.
[#73 Sexually Active, HIV-negative]

Besides being characterized by openness and honesty, primary relationships were described as ones in which "reason" and "doing the right thing", that is, using protection, would prevail, thereby precluding the need for secrecy. Noted one, "if it would help both of you then there should be no problem." [#38 Sexually Abstinent, HIV-negative] Another woman described how she would inform her partner:

"by letting that partner know, you know, that, 'this is what I'm using--it doesn't interfere...with the feelings or...or the sexual intercourse. It doesn't interfere with anything.'" [#24 Sexually Abstinent, HIV-negative]

Because they constructed use of the gel as a neutral act, even as mutually beneficial, these participants did not think a partner would object to its use.

Even though none of the women granted that they would conceal use of a microbicide in their primary partnerships, one woman revealed that she uses contraception without informing her partner, stating, "My husband don't even know that I use...the foam." [#138 Sexually Active, HIV-positive]. Earlier in the discussion, this woman had affirmed that the only situation in which she could imagine not telling her partner would be if there was "something devastating in the relationship," such as physical abuse. Yet, the acknowledgment of her covert use of contraceptive foam flowed naturally in the conversation, without her own recognition of the apparent contradiction [it could also be that, because she's HIV+, the issue is different for the *function* of the product (contraception versus disease prevention...). This discrepancy highlights the importance of evaluating women's statements about what they believe they would, or think they should, do in light of knowledge that they may act differently in real-life circumstances, a challenge we discuss later.

Besides holding that the intimacy that characterizes primary relationships precludes covert use or that the gel was something that reasonable people would want to use, women gave other reasons for wanting to disclose to regular partners. The possibility that the product would have adverse effects for the man prompted a few women to want to disclose:

And I would tell him...because I feel that...who knows? Probably this will go inside the...little opening of the penis. It could give him a great reaction. His penis

might fall off! [group laughter] You never know! [#71 Sexually active, HIV-negative]

Although this woman's concern may have been a consequence of using an investigational product, it is possible that even an approved product would evoke similar concerns for some.

Finally, some women in both sexually abstinent and active groups said they would tell a regular partner they were using a microbicide because he would be likely to know anyway:

- #49: I'm 14 years with my man, so he would know anyway.
 #51: I'm sure he'd know.
 Facilitator: What would he know?
 #49: He would know there was something different.
 #51: Oh God, yea.
 Facilitator: So you're saying he would notice a difference in the response in your body?
 Participants: Right. Mmm-hmm.
 Facilitator: And in lubrication?
 #51: Uh-huh. Definitely.
 #38: He'd say 'Who were you with? Where were you?' [Sexually Abstinent, HIV-negative]

For these participants, "telling" or "not telling" was a moot point, because they believe their partners would be aware, and moreover, might question their fidelity. As the above discussion demonstrates, women's decisions concerning whether or not they would tell a partner were closely related to whether they think a partner would notice they were using a gel and what his reaction would be. As we describe in the section below, women voiced a range of views concerning whether or not partners would be aware of the gel and what they anticipated the consequences of his awareness might be.

Vaginal Lubrication and the Possibility of Covert Use—A consistent theme across all group discussions was that the gel increased vaginal discharge and would (or did) increase lubrication during sex. There were variations in how women felt about the added lubrication and how they thought their partners would--or did--perceive and interpret it. Just as their beliefs about the appropriateness of covert use varied according to partner type, so did women's perceptions about the possibility of covert use.

Many women were sure that a regular partner would notice the added lubrication. Women in the following exchange, although they were in an abstinent cohort, had few doubts that a regular partner would be aware of the gel:

- #49: ...so if you're in a relationship and you don't want the man....to know that you're on this,...he's gonna know 'cause it's all gonna be like...
 Facilitator: And what's he gonna know?
 #49: That you've got something in you.
 #32: Very lubricated.
 Facilitator: Could you pass it off as being very lubricated? [SEVERAL VOICES LOUDLY SAY "NO!!"]
 #32: No woman could be that...
 #51: Imagine being that lubricated and then being excited. You know what I'm sayin'? You're gonna be like water comin' out. [Sexually Abstinent, HIV-negative]

With a new partner, however, some women thought it would be easier to describe the gel as a lubricant, "I think if it was a new partner, yeah, I would use it. I'd just be like, 'Oh, it's lube.' You know, I'd just blow it off like, you know, I'd just make it like that." [#166]

Sexually Active, HIV-positive] Many others believed that new partners would be less aware of a woman's normal level of lubrication, "But if you're like having sex with some random guy or something, then like chances are you won't have sex with him again so he'll just think you're always wet." [#44 Sexually Abstinent, HIV-negative]

The experiences of participants in sexually active cohorts gave greater nuance to the theme that it would be impossible to hide the gel from regular partners but that it might be possible to do so with casual or new partners. What emerged was that their partners' perceptions often stemmed from women's own physical experience of the gel:

Facilitator: Do you think that...this is a product that you could use without a male partner knowing it was there?

#164: In my case, with it being messy, I don't think so.

#166: I think, in my case, because it wasn't that messy, I think I could have explained it away as "Oh, it's just lube" or whatever, you know. [Sexually Active, HIV-negative]

These two women's responses to the physical properties of the gel led them to have different views of the possibility of using it without the knowledge of their partner. One experienced it as too messy to ignore, whereas the other believed it could be "passed off" as a lubricant, even with a primary partner. In fact, the women who thought it was too messy to ignore would not have used it with a new partner either, "because I'd feel too self-conscious" about "the slippery part." [#164 Sexually Active, HIV-positive]

Vaginal Lubrication, Sexual Pleasure, and Covert Use—The women above did not explain to what they attributed the difference in their experience of "messiness". Other women, however, associated differences in their typical levels of vaginal lubrication during sex to different experiences of the gel as well as to different perceptions about the possibility of covert use. One woman, who described herself as typically dry at the beginning of intercourse, reported that even if she had not been in the trial, her partner would have been aware of the gel and, moreover, that his response would probably have been quizzical, even disbelieving:

#73: Like I said earlier, when I have sex with my husband, it's always difficult to go in....Even if I'm already lubricated, self-lubricated.... Okay, so with this gel? You're a lot more lubricated. So, if your partner knows you, he'll know!

Facilitator: And what do you think he would say?

#73: "What the hell is that?" You know, "Why the hell...are you so wet in there? I know you better." [Sexually Active, HIV-negative]

By contrast, another woman noted that although her partner was aware of the gel because she usually is dry during intercourse, the change did not provoke a suspicious or quizzical response because it increased sexual pleasure for both partners:

#81: Yea, because I'm usually dry. You know, I have eczema and, yeah, with it there.

Facilitator: So there's a real, there's a positive, difference?

#81: Yeah, that's probably why it was enjoyable. Uh! [positive tone.] [Sexually Active, HIV-negative]

Because both the woman and her partner experienced an increase in sexual pleasure, the gel was viewed as a sexual stimulant (rather than as a potential disease prophylactic), leading them to want to continue using it after the completion of the trial, regardless of whether or not it was found efficacious.

In contrast to these women, who experienced vaginal dryness during intercourse, another woman described herself as typically being wet before intercourse. As a consequence, she was able to use the gel without her partner being aware of it. Because it was normal for her to be wet at the beginning of intercourse, he did not notice any increase in lubrication:

...I don't think he would know so much. It'll be more...juicier but I don't think he'll know that much. Because I have done it...like...insert the gel at night.... And...we just had sex, 'cause I was in the mood.... And he didn't know no different. He just knew I was excited--I was ready--'cause...if your...body's already tellin' you that you already decided that you want your man...it's gonna be ready automatic! [#116 Sexually Active, HIV-positive]

All of these women were aware of increased lubrication when they had sex with the gel, but the differences in their typical patterns of lubrication, in the meaning of increased vaginal lubrication in the context of their sexual relationship, and in the effect on their sexual pleasure and that of their partners' resulted in different assessments of the possibility of covert use.

Vaginal Lubrication, Women's Arousal, and Male Sexual Performance—As the sexually active woman quoted above noted, vaginal lubrication typically was viewed as a sign of a woman's readiness for sex. Lubrication and arousal, and their relationship to covert use, were themes that were raised in three other discussion groups, albeit among women who had not used the gel during sex:

#58: If I was with a man right now, not only would he not know that I'm using anything, he would just think I was...

#59: And you were totally horny!

#58: Yes. That is what you would be!...I actually was talking to a friend of mine like about it.... He was like, "So what was it like to use it?" And I said, "honestly, the thing is I could use it with a man and what he would think was, 'damn this girl is just wet!'" [Sexually Abstinent, HIV-negative]

This woman experienced the gel as a marker of her own sexual arousal, which also would be arousing to her partner. Other women focused more on the partner's experience of a woman's arousal, "But if a man would touch you down there, he would think oh my God, I really got her excited." [#32 Sexually Abstinent, HIV-negative] In this case, vaginal lubrication was highlighted not only as a sign of a woman's arousal, but also as an indicator of a man's sexual prowess in terms of his ability to excite his partner, a theme that emerged in another group:

Facilitator: Do you think that this is a product that a woman could use without her partner knowing about it...?

#53: If you didn't tell him. Sure, he would probably just think you're wet...

#44: Be real proud of himself.... And also...you know, they're arousing you a lot as you're...

#53: Really wet. [LAUGHTER] [Sexually Abstinent, HIV-negative]

By associating vaginal lubrication with their own sexual arousal and with a man's perception of his sexual abilities, these women were thus suggesting that if a product is seen as enhancing a man's sexual performance, use without disclosure would be relatively easy.

DISCUSSION

In both quantitative and qualitative assessments, these urban, U.S. women embraced the rights-based discourse that has characterized the large-scale international effort to develop an effective woman-controlled STI prevention method. Quantitatively, 71% preferred a method that could be used without informing a partner. In discussions, participants endorsed overwhelmingly women's right to protect themselves, to decide when to use a microbicide, and to refrain from informing their partners, if necessary and possible. They applauded the benefits that women in general could derive from a method that could be used without a partner's knowledge, but as reported by other researchers, they had a strong preference, themselves, to inform a regular partner if they were using a microbicide. Covert use with a one-time or casual partner--someone who did not know them well and might not be honest

with them--was much more acceptable, and many women indicated that in this situation they might not inform a partner.

Also confirming previous reports, we found that women wanted to disclose to their regular partners because of the intimate nature of sexual relationships and their desire to maintain honesty and open communication in their relationships. Some wanted to disclose because they did not think their use of the gel would or should pose a problem because "protection" should be a joint concern. A few would tell because they were concerned about possible side effects for their partner. Finally, many women believed that their primary partner would be aware of the gel, regardless of whether or not they informed him.

We suggest that although many women asserted that they value informing primary partners if they were to use a vaginal microbicide, women's perception that their primary partners would notice a microbicide gel is a more important reason for their caution regarding covert use than may previously have been recognized. For example, one woman revealed that she had previously used contraceptive foam without telling (and without him noticing), shortly after she had stated she would only use a method covertly in extreme circumstances. Another woman described discreet use of the gel during the study period. Thus we found that given the opportunity to circumvent formal disclosure, some women would not be averse to covert use and may adopt a less-than-direct approach, even in their primary partnerships.

Because women in the sexually active cohorts had to be seroconcordant with their male partners, whose consent was also required, this study may have selected for women in stable relationships with good couple communication around sex. Moreover, in research interviews, women may feel it important to affirm socially valued relationship norms that may not guide their behaviors to the degree they suggest. We, therefore, need to temper conclusions based on women's assertions that they would disclose microbicide use to their primary partners with knowledge that people do not always do what they say they would do. The wide-ranging discussions that ensued in the small groups allowed for such an example to emerge--that of a woman who did not disclose contraceptive use to her partner. This situation may not have been reported if the woman had been asked directly about covert use of sexual products.

We also found that women's perceptions concerning the possibility of covert use were shaped by their own experience of the added lubrication and by their typical lubrication patterns during sex. Quantitatively, 86% of women reported increased vaginal lubrication when using the gel. Women described a range of responses to the gel, from unease due to the increase in discharge to a perception of their own sexual arousal (as evidenced by vaginal lubrication) that might also be arousing (and affirming) to a partner. Women who were less bothered by the increase in vaginal lubrication believed the gel would be less noticeable to their partners whereas women who experienced it as "messy" believed a partner would be aware. Women who tended to be dry during intercourse seemed more concerned that a partner would notice than did women who were well-lubricated prior to intercourse.

Among the sexually active women, the large majority reported an increase or no change in their own and their partner's sexual pleasure. In discussions, women who experienced the increase in lubrication as enhancing their own or their partner's sexual pleasure, believed that covert use of the gel would be more feasible, highlighting that even if a partner was aware of the gel, he would not necessarily object to it.

We suggest, therefore, that if a microbicide gel was viewed as an indicator of a woman's sexual excitement and, thus, as an affirmation of her partner's ability to arouse her, it would

be less obtrusive in the sexual experience and would possibly enhance it. In contrast to condoms, which are almost universally viewed as diminishing sexual pleasure, as well as signaling lack of trust and the possibility of infidelity (de Zoysa, Sweat, & Denison, 1996; MacPhail & Campbell, 2000; Misovich, Fisher, & Fisher, 1997; O'Leary, 2000; Sobo, 1993), microbicide gels might be more acceptable to women in primary partnerships precisely because they could be positioned as enhancing her sexual pleasure and her partner's masculine sexual prowess. If women presented the gel to their partners as a sexual enhancement product, rather than as a disease prevention product, they might be able to diminish potential conflict over its use. Therefore, in thinking about what will make microbicides acceptable for use in partnerships that pose significant risk for women to become infected, we propose that discreet use may be a more useful concept than outright covert use. This is similar to the concept of "indirect covert use" (Koo et al., 2005), in which a product is discussed with a partner, but focus is placed on its contraceptive and/or sex-enhancing qualities.

Limitations of this study include the context of the clinical trial setting, in which various restrictions were placed on women and their partners in terms of sexual behavior. In particular, women were using the gel along with condoms during sex. Therefore, except for one woman who acknowledged having intercourse on one occasion with the gel but without a condom, it was not possible for these women (or their partners) to experience what the microbicide would have felt like on its own. Women's perceptions of gel properties reported here may consequently relate to the interaction of condom and gel use. Without condoms, sexually active women may have experienced the gel differently.

The trial protocol also set limits on the number of small group discussions and participants that could be included from each study cohort. As a consequence, only five discussion groups, comprising 11 women, were from sexually active cohorts. Various limitations pertain to all approaches to investigate how women would respond to a product that is still under development (Mantell et al., 2005; Severy & Newcomer, 2005). For example, studies of microbicide acceptability using surrogate products may not require male partners to use a condom, but in these studies the products may seem less "real" than a candidate microbicide. That the main findings of this study accord with those obtained in studies using different strategies to assess acceptability strengthens confidence in their validity. Additionally, the current study had several strengths: participants included women who were low-risk (sexually abstinent or in a monogamous relationship) as well as high-risk (HIV-positive), and some participants (both HIV-negative and HIV-positive) were assigned to use the gel during sexual intercourse. This enabled us to assess the impact of using a candidate microbicide product on both expected and actual sexual functioning and behavior.

The findings reported here suggest that for U.S. women, protection options will be expanded by a product they can insert themselves without the active consent of their partners and that can be described to men as something other than a disease prophylactic. We cannot draw inferences about the ability or willingness of women in other settings to use this product covertly. This study demonstrated that in a cultural setting where "wet" sex is valued and in which some women feel relatively empowered, women can use 4 g of a microbicide gel without incurring outright objection from male partners.

In advocating for microbicides and other woman-initiated prevention methods, it will be important to recognize that some women place less value on their ability to use a gel covertly than on other features of protection products, especially their effects on their own and their partner's sexual pleasure and performance. Notwithstanding this, there are circumstances when women want to be able to use a method covertly; therefore, creating a

microbicide that can be used in this way should remain an important goal to strive for in developing women-initiated prevention methods.

Acknowledgments

This study was supported by the HIV Prevention Trials Network (HPTN) and sponsored by the National Institute of Allergy and Infectious Diseases, National Institute of Child Health and Human Development, National Institute on Drug Abuse, National Institute of Mental Health, and Office of AIDS Research, of the National Institutes of Health, U.S. Department of Health and Human Services (U01-AI-46749, U01-AI-48016, U01-AI-48040, U01-AI-48014, U01-AI-47972, U01-AI-46702 and U01-AI-46745). Study product was supplied by Gilead Sciences, Inc., Foster City, California. Drs. Hoffman, Mantell, and Carballo-Díez were additionally supported by a center grant from the National Institute of Mental Health to the HIV Center for Clinical and Behavioral Studies at New York State Psychiatric Institute and Columbia University (P30-MH43520; Principal Investigator: Anke A. Ehrhardt, Ph.D.). The content of this publication does not necessarily reflect the views or policies of the National Institute of Allergy and Infectious Diseases or the HIV Prevention Trials Network, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. government. We thank Jenny Higgins for insightful comments on earlier drafts. The Acceptability Team acknowledges the important roles played by Teresa Costello and Dana Fry in data collection, and gratefully thanks the women who participated in this study for sharing their experiences.

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Table 1

Participation by Study Cohort in Acceptability Assessments, HIV Prevention Trials Network, phase I trial of tenofovir gel

Cohort	Enrolled in Cohort N = 84	Completed acceptability assessment (quantitative) N = 79	Participated in small group discussion (qualitative) N = 40	Number of discussion groups per cohort N = 15
A ₁₋₄ : Sexually abstinent, HIV-uninfected ^a	48	46	20	7
B: Sexually active, HIV-uninfected	12	11	5	2
C: Sexually abstinent, HIV-infected	12	12	9	3
D: Sexually active, HIV-infected	12	10	6	3

^aThe safety trial design required that “A” cohorts be enrolled sequentially for dose (1.0% vs. 0.3% tenofovir), then frequency of application (once vs. twice daily), with escalation evaluations as per the aims of the safety and toxicity protocol. All doses of gel were 4 grams. Subsequent cohorts applied 1.0% gel twice daily (i.e., the HPDF (highest practical dose frequency)), in the morning and at bedtime. Sexually active participants inserted gel up to 2 hours prior to intercourse, in lieu of one of the other doses.

Table 2

Demographic characteristics of women participating in quantitative and qualitative acceptability assessment

	Completed Follow-Up Acceptability Assessment N = 79	Participated in Small Group Discussion N = 40
Latina	n=15 (19%)	n=10 (25%)
African American	4	3
White	1	1
Other	10	6
Non-Latina	n=64 (81%)	n=30 (70%)
African American	31	15
White	27	13
Asian	2	1
Multiracial ^a	2	0
Other	2	1
Mean age	36.2 years	36.0 years
Highest level of education		
Less than high school	23 (29%)	12 (30%)
High school diploma	24 (30%)	11 (28%)
Some college	17 (22%)	10 (25%)
College degree	12 (15%)	7 (18%)
Some post college	1 (1%)	0
Graduate/professional degree	2 (3%)	0
Type of student		
Full-time student	6 (8%)	3 (8%)
Part-time student	7 (9%)	3 (8%)
Not a student	66 (84%)	34 (85%)
Employment status		
Full-time employment	16 (20%)	6 (15%)
Part-time employment	12 (15%)	6 (15%)
Unemployed	50 (63%)	28 (70%)
Other	1 (1%)	0
Household income		
<\$6,000/year	16 (20%)	10 (25%)
\$6,000–\$11,999/year	35 (44%)	20 (50%)
\$12,000–\$29,999/year	17 (22%)	5 (13%)
\$30,000–\$59,999/year	9 (11%)	4 (10%)
>\$60,000/year	2 (3%)	1 (3%)

^aTwo participants identified themselves as being of more than one race/ethnicity. One participant identified herself as “American Indian Alaska Native, Black/African American,” another identified as “Native Hawaiian/other Pacific Islander, French.”