Published in final edited form as:

Cult Health Sex. 2012 ; 14(2): 151–166. doi:10.1080/13691058.2011.630099.

Variations in microbicide gel acceptability among young women in the USA and Puerto Rico

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Abstract

In a multi-site study of vaginal microbicide acceptability conducted with sexually active young women, quantitative assessments revealed significant differences in acceptability by site. Participants in Puerto Rico rated the gel more favourably than mainland US participants in terms of liking the gel and likelihood of future use. To explain these differences, we examined responses to qualitative behavioural assessments. Young women in the mainland USA associated gel leakage with uncomfortable sensations experienced during menstruation, while young women in Puerto Rico had positive associations of gel use with douching. These negative or positive associations affected assessments of the gel's physical qualities. In addition, young women's perceptions of primary partners' support for microbicide use influenced sexual satisfaction with the gel and, ultimately, product acceptability. Finally, geographic HIV risk context contributed to heightened HIV risk perception, which influenced likelihood of future microbicide use, even for women in stated monogamous relationships. Future microbicide acceptability studies should take into account potential differences in acceptability by site such as HIV risk perception based on local HIV prevalence, popularity of vaginal hygiene products in a specific area, and male attitudes in different cultures concerning women's use of HIV protection strategies.

Keywords

microbicide acceptability; USA; Puerto Rico; young women; HIV risk

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Introduction

Over 36 million people are currently infected with HIV worldwide (UNFPA 2010), almost a quarter of whom are between the ages of 15 and 24 years (UNAIDS 2008), with a new infection among youth is estimated to occur every fifteen seconds (Population Services International 2009). Hence, there is an urgent need to develop new HIV-prevention methods, especially some that are acceptable to young people.

Among the prevention methods being studied, topical microbicides, products that may prevent HIV transmission when applied vaginally or rectally, have recently shown some encouraging results. The results of the CAPRISA 004 trial showed that a microbicide gel containing tenofovir applied vaginally decreased the chance of new infections by 39% (Abdool Karim et al. 2010). Microbicides may be especially beneficial to young women. Sixty percent of HIV-infected youth are women, and young women are one of the most vulnerable populations for contracting HIV (World AIDS Campaign 2009). Available HIV prevention methods, such as consistent and proper condom use and mutual monogamy, are not feasible for or acceptable to many young women (Global Campaign for Microbicides 2009), particularly given that these methods are either male-initiated or require a male partner's cooperation. However, microbicide use could be under women's control, thereby fulfilling the need for a female-controlled HIV-prevention option among this population.

A successful microbicide will need to be safe, efficacious and acceptable. Acceptability has been described as 'the voluntary sustained use of a method in the context of alternatives' (Severy and Newcomer 2005: 47). Accurate measurement of microbicide acceptability must include a multifactorial assessment. Morrow and Ruiz (2008) have suggested that microbicide acceptability is affected by the product's physical qualities (i.e., consistency, colour, scent), application and use, as well as contextual factors that vary among individuals. While several studies have focused on vehicle and application-associated factors, little is known about use-associated and contextual factors (Morrow and Ruiz 2008).

Several use-associated and contextual factors have emerged as particularly relevant, including women's prior experience with vaginal products, reactions to a gel's physical qualities, effects of the microbicide on sexual pleasure, partner reaction to the microbicide, and HIV risk perception (Mantell et al. 2005; Severy et al. 2005; Morrow and Ruiz 2008; Greene et al. 2010). As numerous studies have shown, these factors may vary based on local and sociocultural contexts across study sites.

Morrow et al. (2007) found that among adult US women, those with a history of spermicide use were more likely to be willing to use a microbicide than those who had not used spermicides frequently. Furthermore, Severy et al. (2005) noted that vaginal product use varied according to cultural context and Scorgie et al. (2011) found that cultural beliefs about topics such as sexual health and cleanliness inform practices such as vaginal product use.

Braunstein and Van de Wijgert's study (2005) found participants' assessments of the gel's physical qualities, such as consistency and amount of lubrication provided, to be important determinants of acceptability among women in Africa, Asia, Latin America and North America. The authors described how norms and practices regarding vaginal lubrication and cleanliness, which affect assessment of the gel's physical qualities, vary among and within countries and cultures.

Several studies have found women's potential use of a microbicide to be partially dependent on their assessments of the product's effect on sexual pleasure (Rosen et al. 2008; Tanner et

al. 2009; Hoffman et al. 2010). Nevertheless, ideas surrounding behaviours that influence sexual pleasure may also vary based on context (Severy et al. 2005).

Among young women in the USA who have a main partner, perceptions of their partners' assessments of the microbicide have been shown to influence acceptability (Tanner et al. 2010). In addition, research with women in Africa and India has demonstrated that a partner's like or dislike of a microbicide can affect women's acceptability of the product and, moreover, fear of partner's disapproval can influence lack of adherence to product use with a main partner (Greene et al. 2010).

Several studies have also pointed to the need to examine levels of HIV risk perception as they relate to microbicide acceptability (Coggins, Blanchard and Friedland 2000; Severy et al. 2005; Morrow and Ruiz 2008). For example, Bentley et al. (2004) found that acceptability of a candidate microbicide in Africa and Asia was higher in contexts of elevated HIV risk, where people likely have a higher HIV risk perception.

Given that prior research has shown that the abovementioned factors affect microbicide acceptability, in the present study we examined how these factors varied among young women testing a microbicide candidate in diverse geographic contexts, thereby potentially influencing differences in acceptability by site.

Methods

Sample

The data for this study came from a placebo-controlled Phase I microbicide safety and acceptability study with a parallel study exploring acceptability and adherence. The safety and acceptability results comparing women in placebo and microbicide groups have been presented elsewhere (McGowan et al. 2011; Carballo-Diéguez et al. 2011). Participants included 61 young women randomly assigned to use either a microbicide or a placebo gel twice daily for fourteen days, two of whom did not participate in the parallel study (including in-depth interviews), one for lack of time and the second giving no specific reason. The research took place between August 2007 and November 2009 at three sites: Tampa, Florida (29 participants) and Pittsburgh, Pennsylvania (12 participants), both in the mainland USA, and San Juan, Puerto Rico (20 participants). Participants were recruited through media advertisements, flyers, and lists of former research participants who agreed to be contacted in the future. Eligible study candidates were 18 to 24 years old, HIV-negative, non-pregnant, sexually active, and using hormonal contraception or an intrauterine device (IUD). The studies were reviewed and approved by the Institutional Review Boards at all participating institutions.

Quantitative measures

At baseline, we collected information on participant demographics, including age, income, education level, ethnicity/race, employment/student status, and whether participant lived with partner/spouse, parents, or friends. In addition, we assessed sexual behaviour including age at first vaginal sex, lifetime number of male sexual partners, total number of vaginal sex occasions in past ninety days (including number of sex occasions without condoms), and HIV testing history. Our assessment also included history of vaginal product use, such as tampons, cervical caps, female condoms, yeast infection medicines, spermicides and vaginal douches. Upon follow-up participants were asked about product acceptability, including reaction to the gel's physical qualities (overall, consistency, feeling immediately after insertion and 30 minutes after insertion, whether or not they were bothered by leakage), effect of the gel on sexual satisfaction (enjoyment of sex with gel, sexual satisfaction with and without gel), main partner's reaction to the gel, and likelihood of future gel use for

vaginal sex (comparison of rating at baseline and follow-up and if no condoms are used). Acceptability was measured on a 10-point response scale in which 1 was a negative rating and 10 was a positive rating, with a neutral middle range specified (5–6).

Qualitative measures

At follow-up a bilingual research assistant conducted a semi-structured in-depth interview via video teleconference using a guide with open-ended questions and follow-up probes designed to elicit participant feedback on factors influencing gel acceptability and to examine young women's attitudes towards microbicides. The questions focused on participants' history of vaginal product use, reactions to the gel use, the effects of the gel on sexual satisfaction, perceptions of partners' reactions to the gel, perception of HIV risk and likelihood of future microbicide use. The qualitative interviews were audio recorded and transcribed, and the transcripts were verified for accuracy.

Procedure

Participants were instructed to use the assigned study gel twice daily for fourteen days. Although participants were sexually active during the study period, they were not expected to use the gel immediately prior to sex, but rather at regular intervals twice per day. Vaginal applicators pre-filled with either placebo or microbicide gels were distributed to participants upon enrolment, along with panty liners and male condoms. Participants were instructed to use the panty liners to help with possible product leakage and to use male condoms during vaginal sex; they were also asked to refrain from using vaginal douches or other vaginal products during the study and to avoid practicing oral-vaginal sex or penile-anal intercourse. Following the 14-day trial, participants returned to the study site and completed follow-up survey measures, including structured questionnaires administered using Web-based CASI (available in Spanish or English), and an in-depth interview within one day of completion.

Data analysis

The samples from the mainland USA were combined based on similarities identified during initial review of the qualitative data, in which participants from Florida and Pennsylvania described very similar reactions to using the gel during the study and likelihood of using it in the future. Moreover, the sample demographics were alike with around 75% of each sample being white, non-Hispanic and approximately 80% of each sample being students. Finally, due to the small sample sizes ($n=29$ in Florida and $n=12$ in Pennsylvania), combining samples was also more statistically appropriate.

CASI data were analyzed using SPSS Statistics v.17.0 to describe frequencies of demographic variables, sexual behaviour, HIV testing, vaginal product use, and acceptability ratings in our sample. In addition, bivariate analyses were used to identify significant differences between participants at the Puerto Rico site ($n=20$) and those at the mainland US sites ($n=41$), hereafter called USA and Puerto Rico. We used t-tests to compare continuous variables, including sexual behaviour, reactions to gel's physical qualities, sexual satisfaction, main partner's reaction, number of times tested for HIV, and likelihood of future gel use. The number of lifetime sex partners had a skewed distribution, so this variable was rank-transformed prior to t-test analyses. Fisher's exact tests were used to compare categorical variables as appropriate, including participants' history of vaginal product use and demographic information.

A codebook that incorporated categories and themes from the interview guide was developed to analyse qualitative interviews (MacQueen et al. 1998). The codebook included definitions, inclusion and exclusion criteria, and examples. To validate and finalise the codebook, three researchers coded an initial set of three transcripts independently and then

compared the codes to assess concordance. Any discrepancies were discussed until reaching consensus. The codebook was modified where necessary and researchers coded the remaining transcripts using QSR NVivo 8.0 software for qualitative data analysis, comparing coding every fifth transcript to ensure intercoder agreement. Comparisons yielded over 90% agreement consistently. Coding reports were generated for the following codes: history of vaginal product use, reaction to gel use, effect of the gel on sexual satisfaction, main partner's reaction to gel, and likelihood of gel use/perceived HIV risk. Given that a preliminary review of the qualitative data revealed vast differences in the ways in which participants in the USA and those in Puerto Rico described their experiences using the gel and that the quantitative results also demonstrated significant differences between the sites in the USA and in Puerto Rico, we examined the related qualitative themes by location to identify factors contributing to differences in acceptability. Coding reports were analyzed using cross-case and content analysis (Patton 2002), then summarized and discussed by team members. The first author selected quotes that contributed to understanding site variations in acceptability and, when necessary, translated them from Spanish into English.

Results

Quantitative results

Demographics, sexual behaviour, and vaginal product use history—The mean age of respondents was 20 years with no significant differences in age between participants at the US and Puerto Rican sites. In addition, there were no significant differences in average annual income, employment status, or cohabitation status among participants in the USA when compared to those in Puerto Rico. While the majority of respondents (66%) at all sites had a partial college education, US participants were significantly more likely ($p < .05$) to be in school at the time of the study.

The mean age at first vaginal sex was 16 years, with no significant differences between the US and Puerto Rican samples. On average, participants had been with 6 sexual partners in their lifetimes, with no significant differences between participants in the USA and those in Puerto Rico. Among the three sites, most participants (95%) had had only one sexual partner in the past ninety days. There were no significant differences among the sites in the proportion of sex occasions without condoms reported at baseline nor in number of times participants reported having been tested for HIV.

While most participants at all sites (67%) had previous experience using lubricants with vaginal sex, only a few participants in Puerto Rico had used a cervical cap (11% in PR vs. 0% in USA, $p = .10$) and Puerto Rican participants were significantly more likely to have used a vaginal douche than participants in the USA (50% vs. 20%, $p < .05$). Only participants in Puerto Rico ($n=6$) reported having douched in the past three months, ranging from once to six times. These participants reported douching mainly for general hygiene or after menstruation.

Microbicide acceptability—The analysis of product acceptability comparing women in the placebo and microbicide groups showed no significant differences in acceptability by product type (Carballo-Diéguez et al. 2011); therefore, the analysis in this paper focuses on comparison by site of all participants, regardless of study group. Quantitative results indicated several significant differences by location. Most markedly, participants in Puerto Rico reported a higher likelihood of future gel use for vaginal sex than women in the USA ($p < .001$). Compared to US participants' ratings, those of Puerto Rican participants were more positive with regards to gel consistency and feeling after insertion and less negative concerning being bothered by leakage ($p < .01$ for all physical qualities). Sexual satisfaction without the gel was similar in both groups, and women at all sites reported that the gel

interfered somewhat with sexual satisfaction. However, Puerto Rican participants reported significantly less interference of the gel with sexual satisfaction ($p = .012$) and more enjoyment of vaginal sex with the gel than US participants ($p < .001$). Furthermore, Puerto Rican participants rated their partners' reaction to the gel more positively than US participants did ($p < .001$).

Qualitative results

In-depth interviews with participants revealed a variety of opinions on the topics addressed. The qualitative results presented in this section are emblematic of the largest proportion of opinions and were selected to highlight contrasting views on issues in which significant quantitative differences by site were detected, in order to explain those findings more fully.

Vaginal product use—When asked how the microbicide gel compared to other vaginal products used in the past, participants at all sites found similarities and differences. Women indicated that their experiences using tampons, yeast infection creams, lubricants and vaginal douches provided them with a basis of comparison for using the gel, which allowed for a somewhat familiar experience. For example, most participants found the application process to be similar to inserting a tampon, which made it easy for them.

Several participants, both in the USA and in Puerto Rico, compared the gel to lubricants they had used in the past. Some women found using the gel very similar to using a lubricant. A few women found the gel to cause drying of the vaginal area and felt a lubricant would be needed along with the gel. However, most women found that the gel gave them enough (or too much) lubrication, making an additional lubricant unnecessary. Many women described the consistency of the gel as 'thicker and stickier' than a lubricant. Overall, women in Puerto Rico evaluated the consistency more positively than US women. Their contrasting perspectives on the product's comparison to lubricants are illustrated below:

It [the gel] kind of looks the same [as a lubricant], but it was a little more thick. And it was definitely more sticky... I guess when it got inside me, it mixed with my regular fluid, and it just turned into this sticky, gooey white mess. (Jessica, 23 years, USA)

The gel is a little thicker [than a lubricant], but since it goes inside the vagina it is more comfortable. I think it feels better than the lubricant. (Zuleika, 20 years, Puerto Rico)

As discussed above, the quantitative analysis showed that participants in Puerto Rico were significantly more likely than US participants to have ever used douches in the past. The qualitative data gave further evidence of this difference. Many women in Puerto Rico stated they used douches for general vaginal hygiene and, notably, one participant described how she often used a vaginal douche before having sex. When comparing the gel to a douche, a few Puerto Rican participants observed that the gel 'stays inside your vagina' while the douche 'automatically comes out'. Nevertheless, women found the process of inserting a douche comparable to that of inserting the gel. Another participant noted that both the gel and the douche leak out, though the timing may be different:

As soon as I insert [a douche], it comes out. Not the gel. I inserted the gel and after a while, or if I moved around or something, it leaked, it came out. (Monica, 19 years, Puerto Rico)

Hence, participants' familiarity with the feeling of having a substance come out of the vagina and with the process of inserting a douche may have favoured gel acceptability.

Reactions to gel use—Overwhelmingly, participants at the US sites described the gel as ‘gross’ or ‘messy’ and they stated that it made them feel ‘dirty’. When discussing their reactions to the gel, most US participants focused on the discomfort they felt due to the sensation of constant wetness. Several compared this feeling to menstruation, which they associated with feeling ‘unclean’. In addition, use of panty liners during the study reinforced this negative sensation for some participants.

In contrast, participants in Puerto Rico had very favourable reviews of gel use. Interestingly, several women used the words ‘fresh’ or ‘refreshing’, which imply cleanliness, to describe how the gel felt. Others stated that the gel was practically undetectable after insertion, and that they felt no discomfort whatsoever. A few also described gel leakage as similar to the feeling of menstruation. However, they did not consider this to be a negative factor, and it did not affect gel acceptability. The contrasting attitudes of US and Puerto Rican participants are illustrated by the quotes below:

It was like ‘oh, man, I’ve got to put this [gel] in, and it’s going to be all goopy and gross, but I know I have to do it’. (Jessica, 23 years, USA)

[The gel] was comfortable, a pretty nice feeling...rather, like kind of refreshing, you could say. (Maria, 22 years, Puerto Rico)

Hence, while US participants associated gel use with feeling dirty, Puerto Rican participants were more likely to associate it with feeling refreshed.

Effects of gel on sexual pleasure—Participants were sexually active and were instructed to use the gel twice daily during the two weeks of at-home gel use. Based on the quantitative data, women at all sites indicated high sexual satisfaction with their current partner when not using the gel. However, US participants reported significantly less sexual satisfaction and enjoyment than Puerto Rican participants when using the gel. In the qualitative interviews, several US participants complained that the gel was messy during sex, while others said that the gel decreased their desire to have sex. In contrast, the majority of participants in Puerto Rico did not mind using the gel during sex, and some described how the additional lubrication from the gel positively affected their sexual pleasure. The following quotes are representative of typical contrasting responses:

Um, it [the gel] kind of ruined my feelings of having sex, because... I didn’t, it’s not that I didn’t look forward to it as much, but it just didn’t feel like how it normally does. (Jennifer, 20 years, USA)

[The gel] served as a lubricant, and it’s like sometimes I don’t get very stimulated, and before it used to hurt a little. And now it doesn’t. Now I like it, because I can do other things with the gel inside, that don’t hurt me. (Dalisa, 21 years, Puerto Rico)

Partner reaction to gel—US participants reported that their partners often complained about the messiness of using the gel with sex while Puerto Rican participants often reported that their partners liked the lubricating sensation of the gel during sex, as exemplified by the quotes below:

He just thought, again, it was -- that it was messy, that it was runny. When we used the condom, it was all over the condom, and he didn’t like that very much. (Stephanie, 23 years, USA)

I think that [sex with the gel] was easier, and my partner said the same thing. That it felt more comfortable. (Maria, 22 years, Puerto Rico)

In addition, participants described the effects of using the gel on sexual intimacy with their partners:

Before the study, I was just, he was all there, but after the first time, he was just like, after we'd have [sex], he would say, 'Make sure [the gel's] not on my covers, not on me, or on the floor.' I don't know, before he'd be more relaxed and he would think about me afterwards. (Tiffany, 18 years, USA)

Truthfully we grew closer because of the gel...he was very involved as far as being aware of whether or not I inserted it, if it was bothering me, if I felt good. (Carmen, 18 years, Puerto Rico)

Participants at all sites emphasised the impact of their partners' support (or lack of support) during study participation. In the USA, partners' discomfort with the gel often translated into lack of support for study participation. Brittany described how her partner disliked the gel and told her 'Don't do it, just drop out [of the study]'. On the other hand, Amber in the USA explained how having her partner's support made her 'feel more comfortable'. In Puerto Rico, several women described how they sought their partners' support by showing them the paperwork from the study or bringing their partners with them to the first study visit. Women in Puerto Rico also explained that this support helped them while participating in the study. For example, Maritza said of her partner, 'He was like my helper, let's say'. None of the women in Puerto Rico described a lack of partner support for their participation in the study, though a few partners were worried about potential side effects from exposure to the study gel.

HIV risk perception—To determine if HIV risk perception was a factor driving the differences in gel acceptability, we explored women's descriptions of risk for HIV and its relationship to their likelihood of future gel use. Many participants in the USA did not perceive themselves as being at risk for HIV, given their current involvement in monogamous relationships, and this affected their likelihood of using the gel in the future.

I really don't think I would use it just because I don't feel that I'm really at risk... At this point I've been with my boyfriend for four years, I'm not really worried right now. (Nicole, 22 years, USA)

On the other hand, in Puerto Rico a heightened perception of the benefits of HIV prevention affected participants' likelihood of using the gel. They emphasised the positive aspects of disease prevention as a reason to use the gel in the future.

[I would be] quite likely [to use the gel]...because it is going to protect me from AIDS, that's why. (Dalisa, 21 years, Puerto Rico)

In addition, a few participants described friends or relatives who had become infected with HIV in Puerto Rico.

I have a friend who was infected with HIV, and it was because the condom broke and [her partner] was infected, without knowing it. And she became infected as well. (Gabriela, 18 years, Puerto Rico)

I have family members who have HIV, and I wouldn't like for anyone else to become infected. (Adriana, 20 years, Puerto Rico)

Finally, another participant in Puerto Rico made reference to the usefulness of the gel for women 'who have a partner, but who they know is unfaithful...there are many women like that here' (Lucero, 20 years, Puerto Rico). Interestingly, while US participants referred to their own personal risk (or lack thereof), the discourse of women in Puerto Rico centred

more generally on the utility of the microbicide gel for HIV prevention, presenting a perception of societal risk.

Discussion

We aimed to examine differences in microbicide acceptability between young women in different contexts: the USA and Puerto Rico. We considered several factors shown to influence microbicide acceptability: vaginal product use, reaction to gel use, sexual pleasure, partner reaction, and HIV risk perception.

Puerto Rican women's experiences with douching may have positively affected their acceptability of the microbicide due to familiarity with the feeling of inserting a product and having it come out of the vagina and a positive association of intravaginal products with a clean and fresh feeling. In fact, research has suggested that microbicides are acceptable in places where women practice intravaginal cleansing (Montgomery et al. 2010). Women in South Africa testing a microbicide associated the sensation of leakage and increased discharge with the efficacy of the gel in cleansing their vaginas, similar to other vaginal cleansing practices (Stadler and Saethre 2011). Furthermore, our findings are supported by another study in which most Puerto Rican women reported that douching made them feel 'clean' and 'good' (Mason et al. 2003) and they were more likely than women in the USA to say they would use a microbicide (Hammett, Mason, et al. 2000). In addition, a study of vaginal douching practices among Latinas in the USA (primarily of Puerto Rican and Dominican descent) found that women douched both to feel clean and to prevent infections (McKee et al. 2009). Thus, women who douche may associate the act of vaginally inserting a product and allowing it to leak out with being not only clean, but also infection free. Although douching has been shown to alter the vaginal flora and to increase women's risk of bacterial vaginosis and sexually transmitted infections (Cottrell 2010), positive associations of gel use with douching could influence acceptability of the gel by women who douche and facilitate campaigns to promote a successful microbicide candidate (Scorgie et al 2011).

Another potential explanation for women's differing perceptions of the gel in the USA and Puerto Rico may be related to the negative association with menstruation expressed by many US women. The scientific literature indicates that young women in the USA, particularly young white women, often describe menstruation as shameful and even stigmatizing (Johnston-Robledo et al. 2003). In our US sample of mostly young, white women, discomfort related to menstruation may have influenced attitudes towards microbicide use, since participants found similarities between menstruation and gel leakage. In addition, research has demonstrated that in the USA, white women are more likely find suppressing menstruation via continuous contraceptive use acceptable than are women of other ethnicities (Edelman et al. 2007). Hence, the US sample may have more negative associations with sensations similar to menstruation when compared to the Puerto Rican sample. Interestingly, though many Puerto Rican women stated they douched for cleanliness after menstruation, they did not negatively associate gel leakage with feeling dirty during menstruation.

In addition, US women's perception of the gel as messy also translated into reduced sexual pleasure while using the gel. Though some studies of women in the USA have indicated lubrication preferences that would favour microbicide use during vaginal sex (Braunstein and Van de Wijgert 2005; Tanner et al. 2009), in our study we found that US women did not like the consistency of the gel during sex. In contrast, Puerto Rican participants reported fewer negative effects on sexual pleasure, and some found the increased lubrication from the gel to be pleasurable.

Also, participants in Puerto Rico rated their partners' reaction as more favourable than participants in USA. Our results differ from other findings in which men in San Juan, Puerto Rico had negative reactions to microbicides (Hammett, Mason, et al. 2000). However, participants' reports of their main partners' reactions generally paralleled their own perceptions of the gel. Therefore, it is difficult to distinguish whether participants were influenced by their partners' reactions to the gel, or whether they interpreted their partners' reactions to mimic their own. Young women's perceptions of their partners' assessments of a microbicide have been shown to influence their own acceptability and adherence to a product (Tanner et al. 2010; Greene et al. 2010), so it may be that our participants were influenced by their partners' reactions. Almost all of our participants informed their partners of microbicide use, and women from all sites indicated that partner support was an important factor for continued use of the product. Hence, the importance of the partner's reaction to the gel cannot be underestimated, particularly for women with steady partnerships who choose to inform their partners of gel use.

In addition, our qualitative data support the idea that risk perception is higher among our Puerto Rican sample. In fact, the risk contexts in which these young women live are quite different. The overall HIV incidence rate in Puerto Rico is 45.0/100,000, which is twice the estimated US rate of 22.8/100,000 (CDC 2009). Among women in Puerto Rico and the USA, the differences are even more striking, as the HIV incidence rate is 2.5 times higher for women in Puerto Rico (29.8/100,000) than for women in the USA (11.9/100,000) (CDC 2009). Furthermore, HIV incidence rates among white, non-Hispanic women in the USA (majority of our US sample) are even lower (3.8/100,000) than the total rates for women in the USA (CDC 2008). These differing rates may contribute to diverse risk perceptions. Prior research has demonstrated that women who are concerned about HIV infection are more likely to say they would use a microbicide than those who do not prioritize HIV prevention (Hammett, Norton, et al. 2000), which is closely related to risk perception. Therefore, Puerto Rican women may state that they would be more likely to use the microbicide than US women because the risk of contracting HIV is greater where they live. In our sample, women in Puerto Rico tended to focus on societal risk, while those in the USA focused on individual risk. Hence, the difference in risk perception may also be a function of these divergent assessments; nevertheless, in the context of microbicide acceptability it is interesting that respondents in Puerto Rico spontaneously chose to consider societal risk while women in the USA did not.

Our study had some limitations. First, since the study was carried out in locations with different native languages, the behavioural assessments were administered exclusively in English at the US sites and exclusively in Spanish at the Puerto Rico site. Anchors of response scales, such as Extremely Likely or Very Likely, may bring to mind different concepts in different languages. Nevertheless, qualitative data corroborate Puerto Rican participants' more favourable ratings and increased likelihood of using the product. Another limitation of our study is that we had a relatively small convenience sample; hence our findings may not be representative of actual contextual differences, but rather of issues specific to our participants. Furthermore, although our US sample included a few Hispanic/Latino participants, we neither had data on their national background (Puerto Rico vs. other Latin American countries) nor a large enough sample to compare Puerto Rican participants in the USA to those in Puerto Rico in order to explore the influence of local context on participants with similar cultural backgrounds. Finally, participants in our study used the study gel twice daily for a two-week period; they may have had different reactions to gel use had they used it less frequently, over a longer period of time, or only before sex.

Our findings confirm that several important contextual factors impact young women's microbicide acceptability. Women's ideas of vaginal cleanliness, including negative

associations of leakage with menstruation or positive associations with vaginal douches, may affect their perceptions of the gel's physical qualities during and after use. In addition, women who live in places with higher HIV rates may have an increased perception of HIV risk and a greater likelihood of using a microbicide, even if they are in monogamous relationships. Finally, women's perceptions of their primary partner's support for microbicide use may influence product acceptability.

Future research should focus on evaluating, by design, potential differences in acceptability ratings by site in order to determine more precisely the ways in which factors affecting microbicide acceptability vary according to local or cultural context. This requires increased attention to theory in order to guide selection of sites and participant groups. Also, an emic approach to data collection which seeks to obtain acceptability data based on women's experiences using a product within their local and cultural contexts, including how the product fits in with and influences existing socio-cultural practices, will help to ensure that these factors are taken into account (Montgomery 2010). In addition, partner acceptability data should also be collected whenever possible. Ultimately, a careful analysis of site differences will allow for successful development and marketing of microbicide products in various contexts and among diverse populations.

Acknowledgments

This research was sponsored by the US National Institutes of Health (NIH), and co-sponsored by CONRAD and Starpharma Pty Ltd. The studies were designed and implemented by the Microbicide Trials Network (MTN-004, Ian McGowan, PI) and the Adolescent Trials Network (ATN-062, Alex Carballo-Diéguez, PI). The MTN (U01AI068633) has been funded by NIAID, NICHD, and NIMH. MTN-004 and ATN-062 were also funded through NICHD awards to the Adolescent Trials Network (U01HD040533 and U01 HD040474) co-funded by NIMH and NIDA. The study products were provided free of charge by Starpharma Pty Ltd. The Statistical Center was supported by NIAID (U01AI068615). Additional support came from the National Institute of Mental Health to the HIV Center for Clinical and Behavioral Studies at NY State Psychiatric Institute and Columbia University (P30-MH43520; Principal Investigator: Anke A. Ehrhardt). The content is solely the responsibility of the authors and does not necessarily represent the official views of NIH. The authors would like to thank Emily Maynard for her invaluable help with interviewing participants and coding data for this study, Blanca Ortiz-Torres for her thoughtful insights and critiques, and Susie Hoffman, Timothy Frasca, and the participants in the HIV Center writing workshop for their help and guidance during the writing process. In addition, we greatly appreciate the hard work of the study staff at the sites, and are indebted to the study participants for volunteering their time and for their willingness to discuss personal matters with us.

References

- Abdool Karim Q, Abdool Karim SS, Frohlich JA, Grobler AC, Baxter C, Mansoor LE, Kharsany ABM, et al. Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women. *Science*. 2010; 329(no. 5996):1168–74. [PubMed: 20643915]
- Bentley ME, Fullem AM, Tolley EE, Kelly CW, Jogelkar N, Srirak N, Mwafulirwa L, et al. Acceptability of microbicide among women and their partners in a 4-country phase I trial. *American Journal of Public Health*. 2004; 94(no. 7):1159–64. [PubMed: 15226137]
- Braunstein S, Van de Wijgert J. Preferences and practices related to vaginal lubrication: Implications for microbicide acceptability and clinical testing. *Journal of Women's Health*. 2005; 14(no. 5):424–33.
- Carballo-Diéguez A, Giguere R, Dolezal C, Chen BA, Kahn J, Zimet G, Mabrugaña M, et al. "Tell Juliana": Acceptability of the candidate microbicide VivaGel® and two placebo gels among ethnically diverse, sexually active young women participating in a Phase I microbicide study. *AIDS and Behavior*. Aug 24, 2011. [Epub ahead of print], doi: 10.1007/s10461-011-0028-6.
- CDC. Subpopulation estimates from the HIV incidence surveillance system—United States, 2006. *Morbidity and Mortality Weekly Report*. 2008; 57:985–89. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5736a1.htm>. [PubMed: 18784639]

- CDC. Incidence and diagnoses of HIV infection—Puerto Rico, 2006. *Morbidity and Mortality Weekly Report*. 2009; 58:589–91. <http://cdc.gov/mmwr/preview/mmwrhtml/mm5821a3.htm>. [PubMed: 19498337]
- Coggins C, Blanchard K, Friedland B. Men's attitudes towards a potential vaginal microbicide in Zimbabwe, Mexico and the United States. *Reproductive Health Matters*. 2000; 8(no. 15):132–41. [PubMed: 11424261]
- Cottrell BH. An updated review of evidence to discourage douching. *MCN. The American Journal of Maternal Child Nursing*. 2010; 35(no. 2):102–7. [PubMed: 20215951]
- Edelman A, Lew R, Cwiak C, Nichols M, Jensen J. Acceptability of contraceptive-induced amenorrhea in a racially diverse group of US women. *Contraception*. 2007; 75(no. 6):450–3. [PubMed: 17519151]
- Global Campaign for Microbicides. About microbicides 2009. Global Campaign for Microbicides; 2009. http://www.global-campaign.org/about_microbicides.htm
- Greene E, Batona G, Hallad J, Johnson S, Neema S, Tolley EE. Acceptability and adherence of a candidate microbicide gel among high-risk women in Africa and India. *Culture, Health & Sexuality*. 2010; 12(no. 7):739–54.
- Hammett TM, Mason TH, Joanis CL, Foster SE, Harmon P, Robles R, Finlinson H, et al. Acceptability of formulations and application methods for vaginal microbicides among drug-involved women: Results of product trials in three cities. *Sexually Transmitted Diseases*. 2000; 27(no. 2):119–26. [PubMed: 10676980]
- Hammett TM, Norton GD, Mason TH, Langenbahn S, Mayer KH, Robles RR, Feudo R, et al. Drug-involved women as potential users of vaginal microbicides for HIV and STD prevention: A three-city survey. *Journal of Women's Health & Gender-Based Medicine*. 2000; 9(no. 10):1071–80.
- Hoffman S, Morrow KM, Mantell JE, Rosen RK, Carballo-Diéguez A, Gai F. Covert use, vaginal lubrication, and sexual pleasure: A qualitative study of urban U.S. women in a vaginal microbicide clinical trial. *Archives of Sexual Behavior*. 2010; 39(no. 3):748–60. [PubMed: 19636696]
- Johnston-Robledo I, Ball M, Lauter K, Zekoll A. To bleed or not to bleed: Young women's attitudes toward menstrual suppression. *Women & Health*. 2003; 38(no. 3):59–75.
- MacQueen KM, McLellan E, Kay K, Milstein B. Codebook development for team-based qualitative analysis. *Field Methods*. 1998; 10(no. 2):31–6.
- Mantell JE, Myer L, Carballo-Diéguez A, Stein Z, Ramjee G, Morar NS, Harrison PF. Microbicide acceptability research: Current approaches and future directions. *Social Science & Medicine*. 2005; 60(no. 2):319–30. [PubMed: 15522488]
- Mason TH, Foster SE, Finlinson HA, Morrow KM, Rosen R, Vining S, Joanis CL, et al. Perspectives related to the potential use of vaginal microbicides among drug-involved women: Focus groups in three cities in the United States and Puerto Rico. *AIDS and Behavior*. 2003; 7(no. 4):339–51. [PubMed: 14707531]
- McGowan I, Gomez K, Bruder K, Febo I, Chen BA, Richardson BA, Husnik M, et al. Phase 1 randomized trial of the vaginal safety and acceptability of SPL7013 gel (VivaGel) in sexually active young women (MTN-004). *AIDS*. 2011; 25(no. 8):1057–64. [PubMed: 21505316]
- McKee MD, Baquero M, Anderson MR, Alvarez A, Karasz A. Vaginal douching among Latinas: Practices and meaning. *Maternal and Child Health Journal*. 2009; 13(no. 1):98–106. [PubMed: 18297379]
- Montgomery CM, Gafos M, Lees S, Morar NS, Mweemba O, Ssali A, Stadler J, et al. Re-framing microbicide acceptability: Findings from the MDP301 trial. *Culture, Health & Sexuality*. 2010; 12(no. 6):649–62.
- Morrow KM, Fava JL, Rosen RK, Christensen AL, Vargas S, Barroso C. Willingness to use microbicides varies by race/ethnicity, experience with prevention products, and partner type. *Health Psychology*. 2007; 26(no. 6):777–86. [PubMed: 18020851]
- Morrow KM, Ruiz MS. Assessing microbicide acceptability: A comprehensive and integrated approach. *AIDS and Behavior*. 2008; 12(no. 2):272–83. [PubMed: 17592763]
- Patton, MQ. *Qualitative research & evaluation methods*. 3rd edition. Sage; Thousand Oaks: 2002.
- Population Services International. HIV/AIDS statistics. Population Services International; 2009. http://projects.psi.org/site/PageServer?pagename=Statistics_nr

- Rosen RK, Morrow KM, Carballo-Diéguez A, Mantell JE, Hoffman S, Gai F, Maslankowski L, et al. Acceptability of tenofovir gel as a vaginal microbicide among women in a Phase I trial: A mixed-methods study. *Journal of Women's Health*. 2008; 17(no. 3):383–92.
- Scorgie F, Smit JA, Kunene B, Martin-Hilber A, Bekinska M, Chersich MF. Predictors of vaginal practices for sex and hygiene in KwaZulu-Natal, South Africa: findings of a household survey and qualitative inquiry. *Culture, Health & Sexuality*. 2011; 13(no. 4):381–98.
- Severy LJ, Newcomer S. Critical issues in contraceptive and STI acceptability research. *Journal of Social Issues*. 2005; 61(no. 1):45–65.
- Severy LJ, Tolley E, Woodsong C, Guest G. A framework for examining the sustained acceptability of microbicides. *AIDS and Behavior*. 2005; 9(no. 1):121–31. [PubMed: 15812619]
- Stadler J, Saethre E. Blockage and flow: intimate experiences of condoms and microbicides in a South African clinical trial. *Culture, Health & Sexuality*. 2011; 13(no.1):31–44.
- Tanner AE, Fortenberry JD, Zimet GD, Reece M, Graham CA, Murray M. Young women's use of a microbicide surrogate: The complex influence of relationship characteristics and perceived male partners' evaluations. *Archives of Sexual Behavior*. 2010; 39(no. 3):735–47. [PubMed: 19224355]
- Tanner AE, Zimet G, Fortenberry JD, Reece M, Graham C, Murray M. Young women's use of a vaginal microbicide surrogate: The role of individual and contextual factors in acceptability and sexual pleasure. *Journal of Sex Research*. 2009; 46(no. 1):15–23. [PubMed: 19012060]
- UNAIDS. 2008 Report on the Global AIDS Epidemic. UNAIDS; Geneva: 2008.
- UNFPA. AIDS clock. UNFPA; 2010. http://www.unfpa.org/aids_clock
- World AIDS Campaign. Lead the change: Young women, HIV and sexual and reproductive health and rights. World AIDS Campaign; 2009. <http://www.worldaidscampaign.org/en/Constituencies/Youth/Resources/Fact-Sheet-Young-Women-and-HIV>

Table 1

Demographic Information.

	Puerto Rico			USA			t	df	p
	N	M (SD)	N	M (SD)	N	M (SD)			
Age (in years)	20	20.90 (1.71)	41	20.83 (1.66)			-0.16	59	.878
Annual income (in dollars)	16	7,847 (4,977)	40	8,848 (7,240)			0.51	54	.615
	N	%	N	%			Fisher's statistic	df	p
Education level	5	25	1	2			10.72	3	.007
Partial high school/high school graduate									
Partial College	10	50	30	73					
College Graduate	5	25	5	12					
Partial graduate school/graduate school degree	0	0	5	12					
Cohabitation ¹							0.98	1	.408
Lives alone	1	5	4	10					
Lives with partner or spouse	10	50	15	37					
Lives with parents or family	8	40	7	17					
Lives with friends/roommates	1	5	15	37					
Ethnicity/Race ²							38.97	1	<.001
African-American	0	0	5	12					
Asian/Pacific Islander	0	0	2	5					
White/European American	0	0	30	73					
Hispanic/Latina	20	100	4	10					
Employed (Full or Part-time)	10	50	31	76			3.94	1	.080
Student (Full-time)	8	40	30	73			6.19	1	.023

¹ Statistical test = Living with partner/spouse vs. not.

² Statistical test = White/European American vs. Hispanic/Latino.

Table 2

Sexual Behaviour, HIV Testing, and Vaginal Product Use at Baseline

Sexual Behaviour	Puerto Rico				USA			
	N	M (SD)	N	M (SD)	N	M (SD)	t	df p
Age at first vaginal sex (in years)	19	15.79 (2.02)	41	16.10 (1.96)			0.56	58 .577
Lifetime no. of male sex partners (ranked for t-test)	19	5.11 / (4.05)	41	7.15 / (8.80)			0.53	58 .602
Total no. of vaginal sex occasions in past 90 days	17	46.71 (29.99)	37	37.54 (21.92)			-1.27	52 .211
No. of vaginal sex occasions in past 90 days without condoms	17	29.82 (25.43)	37	26.30 (22.84)			-0.51	52 .613
Number of times tested for HIV	20	3.05 (1.15)	41	2.37 (1.96)			-1.44	59 .155
History of Vaginal Product Use	N	%	N	%	Fisher's statistic			
	N	%	N	%	df p			
Tampons	18	90	41	100	4.17	1		.104
Cervical cap	2	11	0	0	4.39	1		.097
Female condoms	1	5	1	2	0.27	1		1.00
Yeast infection medicines	6	30	17	42	0.74	1		.417
Spermicides	2	10	7	17	0.53	1		.704
Vaginal douche	10	50	8	20	5.91	1		.019*
Lubricants with vaginal sex	13	70	27	66	0.10	1		1.00

* Statistically significant at p<.05 level.

/ Median value = 4

Table 3

Attitudes Towards Microbicide Gel.

	Puerto Rico N=20*		USA N=41**		
	M (SD)	M (SD)	t	df	p
Reaction to Gel's Physical Qualities					
Overall ^a	8.35 (1.95)	5.17 (1.90)	-6.09	59	< .001
Consistency ^a	7.75 (2.00)	5.56 (2.61)	-3.31	59	.002
Feeling immediately after insertion ^a	7.50 (2.28)	5.44 (2.09)	-3.51	59	.001
Feeling 30 mins after insertion ^a	6.65 (2.30)	4.88 (2.35)	-2.79	59	.007
Bothered by leakage ^b	5.00 (2.81)	7.51 (2.18)	3.84	59	< .001
Sexual Pleasure					
Enjoyment of vaginal sex with gel ^a	8.32 (1.60)	6.00 (2.72)	-4.03	54	< .001
Sexual satisfaction with gel ^c	8.35 (1.53)	6.37 (2.85)	-3.44	56	.001
Sexual satisfaction without gel ^c	9.53 (0.84)	9.00 (1.51)	-1.41	55	.163
Difference in sexual satisfaction with vs. without the gel	-1.16 (1.46)	-2.63 (2.83)	-2.59	55	.012
Main Partner's Reaction					
Overall reaction to gel ^a	7.25 (1.65)	4.08 (1.87)	-6.39	56	< .001
Likelihood of Future Gel Use (BL)					
Gel for vaginal sex ^d	8.55 (2.40)	6.10 (2.81)	-3.35	59	.001
Likelihood of Future Gel Use (FU)					

		Puerto Rico N=20 [*]		USA N=41 ^{**}		
Reaction to Gel's Physical Qualities		M (SD)	M (SD)	t	df	p
Gel for vaginal sex ^d		9.30 (1.66)	6.59 (2.91)	-4.63	57	< .001
Change in intention BL to FU		0.75 (2.71)	0.49 (2.33)	-0.39	59	.697
Gel when no condoms ^d		9.55 (.76)	7.85 (2.81)	-3.61	51	.001

^a = Likert scale; 1 = Disliked very much, 10 = Liked very much

^b = Likert scale; 1 = Not at all, 10 = Very much

^c = Likert scale; 1 = Not at all, 10 = A lot

^d = Likert scale; 1 = Extremely unlikely, 10 = Extremely likely

^{*} Three variables had missing data for 1 participant

^{**} Five variables had missing data for 3 participants