

“We Have Our Protector”: Misperceptions of Protection Against HIV Among Participants in a Microbicide Efficacy Trial

Joanne E. Mantell, MS, MSPH, PhD, Neetha S. Morar, MMedSc, Landon Myer, MA, MPhil, PhD, and Gita Ramjee, MSc, PhD

The urgent need for vaginal microbicides and other new HIV prevention technologies is widely recognized.^{1,2} In many settings, women have difficulty negotiating condom use with their partners because of socio-economic and gender inequalities, in turn increasing their vulnerability to HIV and other sexually transmitted infections (STIs). To help address this need, a number of different microbicial products are being evaluated as possible methods of HIV prevention.³

Women's beliefs and attitudes about vaginal microbicides will strongly influence their acceptance of a product and, in turn, the product's impact on risk of HIV infection. Even if it is only partially protective against HIV, a vaginal microbicide used consistently and correctly during every sexual encounter may be more protective than inconsistent condom use.⁴ A recent review indicated that more than half of microbicide acceptability studies were based on surrogate product use,⁵ reflecting the limited number of candidates being tested in large-scale clinical trials. As a result, there are few insights into beliefs about microbicides among women who have used test products.

Examining the perspectives of high-risk women who have participated in trials of candidate microbicides is likely to reveal perceptions of product acceptability, efficacy, and use that have not emerged in research based on surrogate products. Through focus groups conducted after the end of a trial, we investigated participants' beliefs, attitudes, and experiences regarding the use of a candidate microbicide.

METHODS

Study Context and Population

Focus group participants were recruited from a cohort of 198 HIV-negative female

Objectives. We examined perceptions of the effectiveness and acceptability of a candidate microbicide among 94 South African female sex workers who had participated in a phase 3 microbicide trial for HIV prevention.

Methods. Sixteen focus groups were conducted in 2001, 12 to 15 months after participants were informed that the candidate microbicide had been determined to be ineffective in preventing HIV and other sexually transmitted infections (STIs).

Results. Participants clearly indicated that they understood the experimental nature of the candidate microbicide, and they recognized that they had been informed after the trial that the product was ineffective. Nevertheless, most continued to believe that the candidate microbicide helped prevent HIV and other STIs, alleviated reproductive tract pain and STI symptoms, and helped to clean the vagina.

Conclusions. These findings underscore the importance of understanding women's perceptions of the efficacy of candidate microbicides and the rationale for these beliefs. These issues need to be addressed in counseling throughout microbicide trials for HIV prevention. These results also demonstrate how desperate many women at high risk of HIV infection may be for new HIV prevention technologies. (*Am J Public Health.* 2006;96:1073–1077. doi:10.2105/AJPH.2004.047514)

sex workers at truck stops in the KwaZulu-Natal Midlands who had participated at the Durban, South Africa, site of a randomized placebo-controlled COL-1492 phase 3 trial completed in 2000. At screening for the trial, the women received gynecological examinations; were tested for pregnancy, HIV, candidiasis, chlamydia, trichomoniasis, gonorrhea, syphilis, and genital ulcer disease; were treated if found to be infected with an STI; and were offered pre- and posttest HIV counseling.⁶ HIV-positive women were referred for ongoing counseling and medical care.

Within a 28-day period, HIV-negative women were asked to return to the research center; if they met eligibility criteria, they were asked to consent to be enrolled in the trial. To be eligible for enrollment at the South African trial site, a woman had to be aged 16 years or older and willing and able to give informed consent and to adhere to the study protocol, and must not be a user of intravenous drugs or intravaginal spermicides other than the study drug, pregnant and not intending to become pregnant in the

next 6 months, and allergic to latex or any ingredient in the study gel.⁶

Once enrolled, the women were randomly assigned to receive either COL-1492 (a nonoxynol-9 vaginal gel) or the placebo (Replens, a vaginal moisturizer). They were told that nonoxynol-9 was a gel used as a spermicide that was being tested for HIV prevention, and that Replens was a gel used as a vaginal moisturizer that looked like nonoxynol-9 but did not have nonoxynol-9 in it. At enrollment, all participants received gynecological examinations; were tested for pregnancy, HIV, and syphilis; and received pre- and posttest HIV counseling and STI treatment if needed.

At monthly follow-up visits, the women completed questionnaires on sexual practices, adherence to instructions on product use, product acceptability, and condom use. They underwent a gynecological examination, were tested for HIV and syphilis, and were given unlubricated male condoms and the gel. They also were counseled about the risk of STIs, ways of practicing safer sex, and the need to

use a condom for every act of sexual intercourse. Curable STIs were treated throughout the study by a physician and nurses. Participants' understanding of informed consent and study procedures was assessed and reinforced regularly during follow-up. Counseling was conducted in a group setting, followed by one-to-one sessions in a private room with trained HIV counselors.

Before eligibility screening for the trial, an HIV/STI education workshop was conducted with each group of potential participants. Community liaison persons—sex workers elected by their peers and employed by the South African Medical Research Council—talked to the women about informed consent, placebos, and randomization. However, 3 months after enrollment, most of the women incorrectly believed that both the experimental and placebo gels had a protective effect against HIV and other STIs.⁷

This trial was terminated once the study end points were reached. The final analysis suggested a slightly higher incidence of HIV infection among women using the nonoxynol-9 product compared with users of the placebo.⁶ At the end of the trial, participants were counseled to stop using the gel, and in November 2000, the women (in groups of 10) were informed in isiZulu, the primary local language, that the gel was not effective in preventing HIV or other STIs. A small proportion indicated they were disappointed with these results.

Posttrial Focus Group Sample and Data Collection Procedures

Twelve to 15 months after participants were told of the COL-1492 trial results, we conducted 16 focus groups to explore group norms and behaviors about product acceptability with a convenience sample of 94 trial participants (we were able to locate 100 of the 198 trial participants, and only 6% of the trial participants located refused to participate in the focus groups). These women were HIV-negative at the time of trial enrollment; whether they seroconverted after the end of the trial was unknown. The trial participants spoke isiZulu and were migrants from rural areas in KwaZulu-Natal Province. Their average age was 25 years and their average education level was sixth grade.

At baseline, these women reported a low rate of condom use with clients and an even lower rate with regular partners.⁸ Focus group participants reported an average of 18.5 sexual partners each week (range, 5–60). Comparison of the 94 focus-group participants and the 198 trial participants revealed no systematic differences in their demographic characteristics, sexual activity, and condom use.

Two community liaison persons recruited trial participants for the focus groups by telephone or at the truck stops. Most of the trial participants who did not participate in the focus groups had moved for better employment opportunities. Participants were given a small transportation allowance for their participation. The median number of participants per focus group was 6, and in most cases the groups comprised women from several truck stops. Discussions were conducted in isiZulu.

Each focus group was facilitated by a female researcher who held a master's degree in the social sciences; she was supported by an observer who took notes. The facilitators were trained in key microbicide issues and qualitative interviewing techniques. The focus groups were audiotaped and subsequently translated and transcribed into English by bilingual Zulu- and English-speaking staff. None of the study team members who had been involved in the COL-1492 microbicide trial conducted the focus groups or participated in data analysis.

We used a semistructured focus group interview guide to elicit participants' experiences during the trial and their attitudes and intentions about gel use. Participants were asked how they felt about participating in the trial and then were asked a series of open-ended questions about (1) product and applicator characteristics; (2) sexual behaviors, cultural values, and practices; (3) disclosure of microbicide use to clients and steady partners; (4) effects on sexual enjoyment; and (5) understanding of the trial's objectives and outcome.

Data Analysis

We used a grounded theory approach to allow for inductive analysis of data reduction, coding, and convergence.^{9,10} Data analysis was directed to the salient themes that emerged from the focus group discussions.

Transcripts of each focus group were reviewed and coded independently by 2 of the researchers; neither of these individuals conducted the focus groups. Transcripts were coded first on paper and later with a standardized computer software package (NUD*IST N'Vivo, QSR International, Doncaster, Victoria, Australia) to facilitate systematic organization of the data. Similarities and differences between themes and the interrelationship of these themes were compared across the focus groups. The researchers discussed discrepancies in codes and reached consensus about them to enhance accurate interpretation of the data.

RESULTS

The most striking and consistent finding across all 16 focus groups was that beliefs about the gel's acceptability were closely tied to perceptions of its effectiveness. Despite the fact that participants clearly indicated that they understood the experimental nature of the study gel and that they had been informed that the gel had no HIV/STI prevention efficacy, the women believed that the gel provided prophylaxis against HIV and other STIs, alleviated reproductive tract pain and STI symptoms, and rid their bodies of "dirt" and helped to cleanse their vaginas.

Prophylaxis Against Infection

The women uniformly attributed protective effects to the gel and believed that it prevented STIs. Some felt protected because they did not contract an STI, even after having sex with an infected client; this proved to them that the gel worked:

I had sex with him not knowing that he had an STI. . . . He told me after having been to the doctor. I was protected because I did not get anything.

Similarly, remaining free of HIV infection was viewed as an indication of the gel's protective effect:

When I used this gel, I got help. I was happy because my blood was tested [for HIV]. . . . They gave me the results and there was no problem with the result.

Others hoped that the gel would be effective in preventing HIV infection:

I like the gel because I told myself that it was going to protect me. I liked it and wanted to use it and ensure that it protects me. It will protect me from sexually transmitted infections and it was said that it might cure this killer disease. I even told myself that the disease won't get me.

Some of the women reported that because they felt protected by the gel, they experienced a sense of psychological freedom that resulted in increased sexual pleasure. None said they believed that the gel protected them from pregnancy.

The gel took on added significance as a protective device in light of the fact that many women reported that some of their clients and partners did not want to use condoms. Some women were concerned about the condom's effectiveness and viewed the gel as providing better protection. Others believed that in the case of condom breakage, the gel would protect them:

Even if it [the condom] bursts, we don't have any problems. We have our protector.

At trial baseline, only 17% of the women reported that they were protected by condoms in more than 50% of the sex acts they engaged in.⁶ One woman told her clients who refused to use condoms that she was using the gel; she indicated that these men felt protected by the gel.

Belief in the gel's efficacy was further reinforced by the economic pressures on the women and their concerns about losing clients:

You try to force a person to use a condom but when you see this person really doesn't want to use it and is going to the next person who will sleep with him without a condom, and the money he has is a lot, you just think that you have your gel, and you take the money.

One woman who knew that her main partner had other female partners convinced him to accept the gel by telling him that it protected against HIV transmission.

Alleviation of Symptoms

With few exceptions, the women felt that the gel reduced uterine, bladder, abdominal, and menstrual pain; ameliorated rashes; and diminished vaginal wetness and discharge, despite the lack of scientific evidence that the

experimental gel actually had such curative properties. The cessation of vaginal discharge, dissipation of vaginal odors, and nonoccurrence of genital sores were cited as evidence of the gel's efficacy.

A handful of the women stated that they took various medications to cure their vaginal discharge. One woman reported that after being told by a medical provider that she had an STI, she realized that use of the gel alone did not protect her from infection. However, she believed that gel use combined with STI treatment was curative.

Some women reported that their health problems had reemerged after the trial when they no longer had access to the gel. This led them to believe that if they still had the gel, they would not experience pain and discharge. The gel was seen by some as a product that energized them, prevented fatigue, and made them healthier. The changing color of the gel after insertion, its increased thickness, and reduction of foul vaginal odors also shaped participants' beliefs about the product's effectiveness. The altered color of vaginal discharge after sex was attributed to the gel's cleansing the vagina and womb:

Before I used the gel I did not know that I had dirt in the womb because sometimes I used a condom and sometimes I didn't. So when the gel came, I started using it. There was a difference. Before when I had sex without a condom, I was forced to go to the clinic so they could give me something to clean [my womb]. So when the gel came, I stopped going to the clinic.

Whereas many of the women believed that the "dirt" came from their own bodies, some attributed dirt and disease to their male clients.

Understanding of the Trial's Objectives

Despite their beliefs in the gel's efficacy, the majority of the participants understood the purpose of the trial. Most were aware that the candidate microbicide might not protect them from HIV, and some mentioned that they were told of the need for concurrent condom use. Women in all of the focus groups said they knew that the gel was being evaluated and that some participants were given the nonoxynol-9 gel while others were given a placebo:

We were told that we could use the gel but it was not the real gel and that it was being tested.

They said it was still being tested. No one knew exactly if it could protect.

The participants' disappointment upon learning that the gel had been found ineffective was another indicator of their understanding of the trial:

We felt good and had hope when we were using the gel, but we felt bad when we heard it was not successful.

However, there was evident tension in the difference between participants' understanding of the candidate gel and their emotional responses. In all of the focus groups, participants said that they would prefer to have been given the gel with the "active ingredient" during the trial and that they wanted an effective microbicide to be available immediately; they did not want to wait for product efficacy to be demonstrated in a trial.

DISCUSSION

These focus group findings provide important insights into participants' perceptions about the efficacy and acceptability of a candidate microbicide that they used during a phase 3 microbicide trial. Even though the participants had been told that the nonoxynol-9 gel conferred no HIV/STI protection, they still hoped that the gel was effective and believed that it was an important alternative to condoms. These hopes and beliefs were also reported by participants in semistructured individual interviews conducted after the focus groups. Some of the women used this belief in the gel's effectiveness to negotiate gel use with their clients.

Participants' belief in the gel's efficacy may have stemmed from their strong desire for a method that they could initiate to protect themselves against HIV and other STIs, a theme that appears in other microbicide research.¹¹ Eagerness to use a product not known to be effective also has been reported in women in Botswana¹² and gay men in the United States.¹³

Our finding that women viewed the gel as effective in "removing dirt" and providing vaginal "cleansing" is not surprising, given the widespread belief across cultures that

women's bodies are dirty or in need of cleaning.^{14–17} Postcoital vaginal douching for hygiene and STI prevention has been reported among South African women in other studies, including studies of sex workers.^{18–20} Beliefs about the gel's effectiveness may have been reinforced by participants' observation that the gel changed color after sexual intercourse. Future research should consider the ways in which beliefs about the body and vaginal cleansing intersect with hopes for product effectiveness and acceptability.

In this poverty-stricken community rife with AIDS, these sex workers' hopes of avoiding a stigmatized and life-threatening disease, of being "clean," and retaining their clients may have influenced their views of the gel's effectiveness. This finding is complemented by the results of a study of the male clients and steady partners of these women, who believed that the trial products had a cleansing effect on their penises and helped to heal genital sores.²¹

Although it may have been the STI treatment provided during the trial that eliminated their discharge and pain, participants nevertheless attributed this relief of symptoms to the gel. This phenomenon will require close attention in future trials. Participants' persistent belief in the effectiveness of the trial microbicide, despite their having been told that it was ineffective, may have contributed to a decreased reliance on condoms for HIV prevention. Such behavior changes within the context of a microbicide efficacy trial could, paradoxically, increase participants' risk of HIV infection. Because consistent condom use was low at trial baseline and use with clients increased during the trial,⁸ there is no evidence that participants' positive beliefs about the gel led to their abandonment of the male condom. However, even if there had been a reduction in the levels of condom use, women who use an effective microbicide in a sufficient proportion of non-condom-protected acts of vaginal intercourse may not be at greater risk for HIV when consistency of condom use is low.²²

Several methodological limitations must be noted in interpreting these findings. First, these self-reported data, collected from a self-selected (volunteer) sample of sex workers 12 to 15 months after their participation in a

microbicide trial, are not necessarily representative of all women who might use a vaginal microbicide. However, the general situation of our study participants is probably very similar to the situation of sex workers and women at high risk of HIV infection in other resource-limited settings. Second, our participants' statements were subject to retrospective reconstruction of their individual trial experiences 12 to 15 months after the trial, and participants may have under- or overreported their feelings about the candidate microbicide and condom use.

Third, in focus groups, participants' responses may be influenced by peer group dynamics. However, participants in each of our focus groups expressed similar beliefs, and the potential for diffusion across communities of female sex workers was minimal owing to the substantial geographic distances between truck stops. This convergence of themes contributes to our confidence in the validity of our results. We used systematic and rigorous procedures to minimize the bias that is always a possibility in the analysis of qualitative data. Fourth, we do not know whether participants' HIV serostatus (which was known to the participants, although not to the researchers, at the time the focus groups were conducted) and their disappointment about the trial's results affected their focus group responses. Finally, because trial and focus group study staff were not interviewed, we cannot determine whether their attitudes influenced participants' responses to the gel.

These qualitative data from women who used a candidate microbicide may indicate some of the challenges that can be anticipated in future HIV prevention trials and posttrial product marketing. To fully assess the implications of microbicide use for behavioral change, researchers conducting clinical trials of microbicides need to evaluate more fully participants' perceptions of HIV/STI risk, their condom negotiation strategies, and their condom use. In our study, it appeared that the trial consent process worked relatively well in that participants were aware that the gel was being tested and that it might not work. On the other hand, participants were so keen to have an effective product that they could control that they falsely attributed benefits to the product. However, this

"optimistic bias" about the efficacy of a new investigational product may be promising in terms of the speed with which a new type of biomedical intervention related to sexual behavior (which has been difficult to change) might be accepted.

In trials currently under way,²³ researchers have conducted intensive community education about microbicides before trial implementation and recruitment. This may help not only to mitigate erroneous beliefs about the candidate product but to increase awareness of the need for effective HIV prevention. Initial intensive counseling, followed by "booster" educational sessions—a strategy employed in HIV vaccine trials²⁴—may enhance participants' comprehension of informed consent, the concepts of randomization and placebos, and the need for consistent use of both the candidate product and condoms during every act of sexual intercourse. Some researchers conducting microbicide trials have stepped up efforts to enhance the consent process, explain trial procedures, and test participants' comprehension,²⁵ especially their understanding of the candidate microbicide, using various small media tools. Such explanation and testing should take place regularly throughout a trial. Flipcharts, videos, study booklets, and recruitment scripts in local languages are now being used in South African microbicide trials.²⁶

Once a microbicidal product becomes available, future studies should explore providers' attitudes and their potential impact on the messages delivered, the degree of concordance between providers' attitudes and the educational/counseling messages they promote, and how providers influence participants' perceptions and use of microbicides. Posttrial marketing of microbicides must address users' beliefs about product efficacy to ensure they adequately comprehend its benefits and risks. Without this long-term support, women's enthusiasm for microbicides and their desperation for an alternate form of protection against HIV may reduce the population-level impact of microbicides as an effective HIV prevention intervention. ■

About the Authors

Joanne E. Mantell is with the HIV Center for Clinical and Behavioral Studies, New York State Psychiatric Institute

and Columbia University, New York, NY. Neetha S. Morar and Gita Ramjee are with the Medical Research Council, HIV Prevention Research Unit, Durban, South Africa. Landon Myer is with the Infectious Diseases Epidemiology Unit, School of Public Health and Family Medicine, University of Cape Town, Cape Town, South Africa, and the Department of Epidemiology, Mailman School of Public Health, Columbia University, New York.

Requests for reprints should be sent to Joanne E. Mantell, MS, MSPH, PhD, HIV Center for Clinical and Behavioral Studies, New York State Psychiatric Institute, Columbia University, 1051 Riverside Dr, Unit 15, New York, NY (e-mail: jem57@columbia.edu).

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Contributors

G. Ramjee and J.E. Mantell designed the study. J.E. Mantell and L. Myer analyzed the data and wrote the article. N.S. Morar and L. Myer assisted with study design. G. Ramjee and N.S. Morar contributed to the writing of the article.

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Human Participant Protection

The Research Ethics Committee of the University of Natal approved the study design, protocol, and informed consent process.

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