

Potential Impact of Vaginal Microbicides on HIV Risk Among Women With Primary Heterosexual Partners

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This article explores the potential public health consequences of anti-HIV microbicide adoption among women in high-risk communities, using data from an exploratory study to illustrate key points. A brief quantitative survey was administered to 71 drug-using women with primary heterosexual partners in New York City. Only 37% of women reported recent condom use with a primary male partner. A total of 86% expressed willingness to use a microbicide with a primary partner. Among women using condoms, 50% believed they would decrease condom use if they started using a vaginal microbicide. Although overall condom use and intended condom migration was low among women with HIV-infected partners, universal promotion of microbicides could nonetheless lead to an increase in HIV risk among specific subgroups of women, indicating the importance of promoting continued condom use. Further research is needed to inform public policy decisions before the availability of the first commercial microbicide.

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Over the past 2 decades, women have increasingly shouldered the burden of the global HIV pandemic (Joint United Nations Programme on HIV/AIDS [UNAIDS], 2004), with the majority of infected women acquiring HIV through sexual contact with a primary male partner (O'Leary, 2000). These trends are the result of multiple factors. Women may be biologically more susceptible to heterosexual transmission of HIV than men, especially through receptive anal intercourse (Boily et al., 2009; Mastro & Kitayaporn, 1998; Padian, Shiboski, & Jewell, 1991). In addition, gender-based social inequalities limit women's options with regard to protective

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sexual behavior (Higgins, Hoffman, & Dworkin, 2010; Quinn & Overbaugh, 2005; Remien, Halkitis, O'Leary, Wolitski, & Gomez, 2005). Latex condoms, currently the only effective form of barrier protection against HIV, are under the control of men, who often are unwilling to use them, especially in the context of primary relationships (Conley & Collins, 2005).

Vaginal microbicides represent a female-initiated form of barrier and/or chemical protection that can potentially empower women with a means of self-protection. Vaginal microbicides are self-administered chemical compounds, most commonly in the form of a gel, that women can apply intravaginally before sexual intercourse to prevent or reduce HIV transmission. Modeling studies indicate that even a partially effective microbicide could have a major effect on the global HIV pandemic (Watts, 2002). Despite more than 10 years of development efforts, no effective microbicide products are currently commercially available. The first generation of surfactant and polyanionic-based microbicide candidates, including SAVVY, cellulose sulfate, Caraguard, Buffergel, and PRO2000, failed to demonstrate HIV prevention efficacy in phase III trials (Morris & Lacey, 2010). However, the field remains heavily funded, active, and optimistic. Newer second-generation microbicides based on antiretroviral formulations, such as tenofovir, dapivirine, UC781, and MIV-150, have shown considerable promise. For example, tenofovir, which is set for phase IIb clinical trial evaluation in 2010, has shown significant efficacy in animal models and human explant cultures (McGowan, 2010). Altogether, 50 candidate microbicides are in the development pipeline, including 13 in clinical development (Alliance for Microbicide Development, 2009). If shown to be effective, these second-generation microbicide products could be licensed within 5–10 years (Wilson, Coplan, Wainberg, & Blower, 2008).

Although it is anticipated that the first commercially available vaginal microbicides will be less effective at preventing HIV than latex condoms, the enormous potential of this new technology lies in its enhanced acceptability and usability by women. As our experience with the female condom has demonstrated, the importance of the acceptability of any new HIV prevention technology cannot be overstated

(Kaler, 2004). It is, therefore, critically important that the public health sector in the United States prepares for the introduction of commercially available vaginal microbicides (Van de Wijgert & Coggins, 2002). Although many American women have expressed a keen interest in vaginal microbicides (Darroch & Frost, 1999), the issues surrounding their acceptability and preference in relation to condom use are complex and have not received adequate attention. One complexity involves the potential reduction of condom use that might result from the introduction and adoption of microbicides.

Because the first commercially available vaginal microbicides will most likely be less effective at preventing HIV than latex condoms, reductions in condom use concomitant with microbicide adoption—a phenomenon termed “condom migration”—could potentially lead to increases in HIV incidence (Foss, Vickerman, Heise, & Watts, 2003). The term, thus, implies that some women or couples might “migrate” away from condom use or replace condoms with the use of less effective microbicides. Thus, the effect of vaginal microbicides on the U.S. epidemic will not only depend on the efficacy of the microbicide but also on current rates of condom use in various risk groups, and on changes in condom use behavior after the adoption of microbicide products. The use and acceptability of condoms and vaginal microbicides for prevention of sexually transmitted infections (STI) is highly conditioned by relationship context. Short, Rosenthal, Auslander, and Succop (2009) found that young women in primary heterosexual relationships characterized by high relationship satisfaction were more likely to use a proxy microbicide. They concluded that future “...interventions to enhance [microbicide] uptake should consider the relationship context” (p. 313). Given the high rates of sexually transmitted HIV in African-American and Latina women, especially from primary male partners, we examined issues of microbicide acceptability and condom migration in these risk groups and relationship contexts.

The primary aim of this report is to begin a dialogue that explores epidemiological, clinical practice, and policy implications concerning future dissemination and prevention guidelines related to anti-HIV vaginal microbicides among women at risk for HIV from a primary male partner. Specifically, we explored

levels of risk and condom use among women from a high HIV-prevalent urban community, described women's willingness to use a vaginal microbicide with a primary male partner, examined whether microbicide acceptability was influenced by level of microbicide efficacy, and described how microbicide adoption might affect condom use practices and risk reallocation (i.e., potential condom migration). Findings from this exploratory study, although based on a small sample, were supported by the published data and will serve to frame the discussion and illustrate how potential changes in condom use with the adoption of microbicides might alter HIV risk profiles among women in high-risk communities.

Methods

In an exploratory study, a brief quantitative survey was administered to 71 female participants enrolled in an HIV and/or STI prevention intervention in Central and East Harlem and the South Bronx in New York City. The survey was administered using audio computer-assisted self-interview and lasted approximately 15 to 20 minutes. Women were at least 18 years of age, self-reported the use of crack/cocaine or heroin (injected or noninjected) in the prior 30 days, were uninfected with HIV or of unknown serostatus, and had a current male sex partner identified as a primary partner for at least 6 months.

The quantitative survey consisted of 29 items divided into 4 sections: demographics, substance use, sexual risk behavior and HIV status, and microbicide-related items. Questions were adopted or developed by the research team on the basis of prior experience and the published data. Only observed measures based on behavior or behavioral intentions were included in the survey; thus, the questionnaire contained no scales. Prior psychometric studies are referenced for each section. Demographics included age, race/ethnicity, education, employment status, marital status, and whether the couple was trying to conceive. Substance use items were adopted from the Risk Behavior Assessment survey (Dowling-Guyer et al., 1994) and examined previous 30-day use of injection and noninjection illicit drugs as well as syringe-sharing behavior with a primary male partner. The sexual risk behavior

section collected data on frequency of condom-protected and unprotected vaginal and anal intercourse with a primary partner in the previous 30 days (Dowling-Guyer et al., 1994). Women who used condoms were also asked whether the primary reason for condom use was for contraception or disease protection. HIV status of the female participant and her primary partner was measured on women's self-reports.

The microbicide section of the survey consisted of five separate questions. These questions elicited women's opinions on whether they would use a microbicide product with a primary male partner, how frequently they might use a microbicide product (if use was intended), and whether they thought using a microbicide might alter the use of condoms (potential condom migration). Prior research has shown that women's intentions regarding microbicide use are influenced by perceived effectiveness of the microbicide to prevent HIV (Terris-Prestholt, Kumaranayake, MacPhail, Rees, & Watts, 2007). In our study, participants were randomly assigned to receive one of two different microbicide descriptions—40% or 80% effective at preventing HIV. This permitted a test of whether variation of perceived microbicide effectiveness influenced women's responses regarding intended use.

No interventions were administered as part of the microbicide survey. However, before beginning the survey, women were asked to view one of the two randomly assigned educational videos on vaginal microbicides. Both videos included demonstration of a microbicide gel applicator using a vaginal model and a description of microbicide properties such as its timing of use and lubricating quality. Each video then described a specific hypothetical microbicide that differed with regard to efficacy—either 40% or 80% effective at preventing HIV. The five microbicide survey items were then matched to the randomly selected video for each subject. For example, women were asked: "If a vaginal microbicide was available that was (40% or 80%) effective at preventing HIV, would you begin using the microbicide gel during sex with your main partner?" With regard to condom migration, women who reported condom use and a willingness to use microbicides were asked:

How do you think using a vaginal microbicide might affect your use of condoms? (a) We would continue using condoms as before, but also use the microbicide; (b) We would use condoms less when using the microbicide; or (c) We would stop using condoms altogether and only use the microbicide.

Fisher's exact or Mantel-Haenszel tests were used to assess factors associated with microbicide acceptability and perceived condom migration. Informed consent was obtained at enrollment, and participants were paid \$15 for their participation. An institutional review board approved all study protocols.

Results

Descriptive characteristics and study results are presented in [Tables 1 and 2](#). All women were uninfected with HIV or of unknown serostatus by study design. Only 37% (26 of 71) of women reported any use of condoms with a primary partner in the previous 30 days; only 14% reported consistent condom use. Women who had unprotected sex with a primary partner reported an average of 10 unprotected vaginal sex acts in the previous 30 days. Although 70% (7 of 10) of women with an HIV-infected partner reported any condom use—compared with 31% (19 of 61) of women with uninfected partners—only 20% (2 of 10) used condoms consistently with an HIV-infected partner. Among those who reported any condom use, 77% (20 of 26) reported “protection of HIV and other sexually transmitted diseases” as the reason, whereas 39% responded that condom use was to “avoid getting pregnant.” Approximately 21% (10 of 71) of women were trying to conceive.

A total of 86% (61 of 71) of women expressed willingness to use an anti-HIV microbicide with a primary partner as compared with 100% (10 of 10) of women with an HIV-infected partner. Intended vaginal microbicide use was 90%, 81%, and 87% among consistent, intermediate, and noncondom users, respectively. Women's intention to use a microbicide with a primary partner was not associated with the level of effectiveness of the microbicide: 86% of

women in both groups (i.e., those randomly assigned to either the 40% or 80% effective microbicide) expressed a willingness to use the product.

Among women currently using condoms with a primary partner and willing to try a microbicide, 50% (10 of 20) believed they would discontinue or decrease condom use if they started using a vaginal microbicide, even if the microbicide was less effective than condoms at preventing HIV. Observed differences in intended condom migration across condom use categories did not reach statistical significance, perhaps because of the small sample size, especially the small subsample of condom users. Similarly, observed differences in perceived condom migration based on microbicide efficacy did not attain statistical significance. However, even with the small sample, a statistically significant difference was detected with regard to intended condom migration between women with an HIV-infected primary partner (14% condom migration) and those with an uninfected partner (69% condom migration).

Discussion

Our survey revealed low reported condom use and frequent unprotected sex, even among HIV-serodiscordant couples. High-risk sexual behaviors have been reported in previous studies involving mixed serostatus couples (Kalichman, Rompa, Luke, & Austin, 2002; Van der Straten, Gomez, Saul, Quan, & Padian, 2000). Thus, assuming a safe and effective product, vaginal microbicides will provide a substantial protective benefit for women who are at high risk but who do not use condoms in the context of a primary partnership. Acceptance and use of microbicides by women in these relationships will reduce the risk of HIV substantially, and the public health goal should be to maximize microbicide acceptability and use in these women (Karmon, Potts, & Getz, 2003).

Nearly 1 in 4 women in our sample reported intermittent condom use with a primary partner; 81% of these women expressed a willingness to use vaginal microbicides and, among these, more than half anticipated the occurrence of condom migration. Although these results should be viewed with

Table 1. Sample Characteristics, Drug Use, and Sexual Behavior (N = 71)

Demographics	
Age ($M = 40.7$; $SD = 6.89$; Range = 24-56) Median	42
Race/ethnicity	
Latina	56.3 (40/71)
African American	28.2 (20/71)
White/Other	15.5 (11/71)
Completed high school or equivalent	54.9 (39/71)
Employment status	
Unemployed	59.2 (42/71)
Public assistance	29.6 (21/71)
Employed	4.2 (3/71)
Other	7.0 (5/71)
Marital status	
Single (never married)	19.7 (14/71)
Legally married	32.4 (23/71)
Common law/living as married	42.3 (30/71)
Divorced or separated	4.2 (3/71)
Widowed/Other	1.4 (1/71)
Drug use	
Used injected drugs previous 30 days	28.2 (20/71)
Used injected drugs ever	57.8 (41/71)
Used non-injected drugs previous 30 days	77.5 (55/71)
Sexual risk behavior (with primary partner in previous 30 days):	
Condom use (vaginal and anal sex):	
Consistent (100% condom use)	14.1 (10/71)
Intermediate (some condom use but not consistent)	22.5 (16/71)
None (no condom use)	63.4 (45/71)
Among those who had any unprotected sex ($n = 61$), times unprotected vaginal sex (SD)	10.3 (9.2)
Among those who used condoms (intermediate or consistent; $n = 26$), times used condoms for vaginal sex (SD)	5.0 (5.8)
Percent had anal sex	22.5 (16/71)
Among those who had anal sex ($n = 16$), number of times anal sex (SD)	3.25 (2.3)
Among those who had anal sex ($n = 16$), times used condoms for anal sex (SD)	0.8 (1.5)
Percent of women trying to get pregnant	21.1 (15/71)
Percent of women reporting HIV-infected main partner	14.1 (10/71)
Any condom use in previous 30 days by male partner's HIV serostatus	
Partner infected	70.0 (7/10)
Partner uninfected	31.2 (19/61)

NOTE: Percentage given unless otherwise indicated.
 SD = Standard Deviation.

caution given our small sample, they illustrate the need to understand the factors that influence HIV risk and potential risk reallocation in this group.

Whether HIV risk will increase or decrease among intermittent condom users will depend on the balance between microbicide efficacy and the extent of condom migration in the context of premicrobicide levels of condom use (Foss et al., 2003). Primary couples who use condoms intermittently will have to be assessed on a case-by-case basis. Some condom migration may be permissible without increasing overall risk if premicrobicide condom use is on the lower end, or if microbicide efficacy is high, or if a combination of these factors leads to a reduction of overall risk. This will require close monitoring by public health providers with the objective of promoting condom use at premicrobicide levels, while endorsing microbicide use as an additional protective agent.

Sexual partnerships characterized by consistent or high rates of condom use have the greatest potential for condom migration and resulting increases in HIV transmission (Foss et al., 2003; Karmon et al., 2003; Smith, Bodine, Wilson, & Blower, 2005). A subset of women in our sample—about 14%—reported consistent condom use with a primary partner; 90% of these expressed a willingness to use a vaginal microbicide; and nearly half reported that they would discontinue or reduce condom use with the adoption of microbicides. These findings, although preliminary, are not surprising given the importance of close intimate contact in primary relationships. Under these conditions and assuming a microbicide that is less effective than condoms, HIV incidence might increase in this group of women. The public health response in such cases should be to promote sustained condom use at premicrobicide levels. Microbicide promotion may not be beneficial in this context, especially if there is a strong association between microbicide adoption and decreased condom use.

Self-reported data on condom use among high-risk heterosexual couples suggest that consistent and intermittent condom use groups may be even larger than reported here. For example, based on prior 30-day self-reported sexual behavior among HIV-serodiscordant couples in Harlem and South Bronx, New York City, 31% of couples reported using condoms consistently during vaginal intercourse, 20% reported intermittent use, and 49% reported no

Table 2. Intentions Regarding Vaginal Microbicide Use and Condom Migration (*N* = 71)

	%	<i>p</i> Value ^a
Microbicide acceptability:		
Intention to use microbicide with partner	85.9 (61/71)	
By partner HIV serostatus (based on female report)		
Partner infected	100.0 (10/10)	.34
Partner uninfected	83.6 (51/61)	
By condom use category ^b		
Consistent (100% condom use)	90.0 (9/10)	.97
Intermediate (some condom use but not consistent)	81.3 (13/16)	
None (no condom use)	86.7 (39/45)	
By efficacy of microbicide		
40% effective hypothetical microbicide	85.7 (30/35)	1.00
80% effective hypothetical microbicide	86.1 (31/36)	
Perceived condom migration:		
Intention to discontinue or decrease condom use with partner if started using microbicide (<i>n</i> = 20)	50.0 (10/20)	
By partner HIV serostatus (based on female report)		
Partner infected	14.3 (1/7)	.03
Partner uninfected	69.0 (9/13)	
By condom use category		
Consistent (100% condom users)	44.4 (4/9)	.32
Intermediate (some condom use but not consistent)	54.6 (6/11)	
None (no condom use)	NA	
By efficacy of microbicide		
40% effective hypothetical microbicide	45.5 (5/11)	1.00
80% effective hypothetical microbicide	55.6 (5/9)	

a. Fisher's exact test used to estimate *p* values unless otherwise indicated.

b. Mantel-Haenszel test.

use of condoms (McMahon, Tortu, Pouget, Hamid, & Torres, 2004). Thus, the proportion of women who use condoms with primary partners and who are susceptible to condom migration might be quite large. Moreover, this study did not include other sexual partnership types characterized by even higher rates of condom use (e.g., new, casual, and sex exchange partnerships), for which condom migration and subsequent increases in HIV risk might be substantial.

In our study, level of microbicide efficacy (40% vs. 80%) did not influence women's intentions to use a microbicide with a primary partner. In contrast, a study involving 1,017 women from Johannesburg, South Africa (Terris-Prestholt et al., 2007), found that microbicide efficacy (35% vs. 95%) was an important predictor of women's preference for microbicide use. It is not clear whether the inconsistent findings are due to differences in

the sample, partnership type, efficacy levels, or some other factors.

One encouraging finding from our study was that intended condom migration was substantially lower among women with HIV-infected primary partners as compared with those with uninfected partners (14% vs. 69%). This indicated that the women in our study who were in serodiscordant relationships understood the importance of maintaining condom use to fully protect themselves against HIV. This finding must be tempered, however, by the caveat that a substantial proportion of women are unaware of their primary partners' HIV serostatus (McMahon et al., 2004). Moreover, this finding may not generalize to other populations. In a safety and acceptability study of a candidate microbicide gel in South Africa, Ramjee et al. (2007) found that more than 60% of HIV-infected female and male participants preferred to use a microbicide alone instead of using it with a condom.

This study has several limitations, including a limited sample size and the hypothetical description of the microbicide on which women reported their perceived acceptability. Self-reports of behavioral intentions, although used extensively in the data published on health behavior, have an uncertain relation to actual behaviors and may be subject to additional bias, such as social desirability. Thus, our empirical findings should be viewed with caution. In addition, the sample was composed of drug-using women from a high-risk community and our results may not generalize to other populations in other settings. We did not examine women's attitudes toward other factors, such as the cost of microbicides and potential side-effects, which might influence not only women's willingness to use a microbicide but also intended condom migration.

Conclusions

Given that 86% of our sample expressed a willingness to use vaginal microbicides with a primary partner and 77% endorsed protection against HIV as the reason for condom use, there was clearly a perceived need for HIV protection among women with primary sexual partners. However, if the high levels of condom migration among condom users in this sample is any indication of the larger population in high-prevalent communities, then the public health sector needs to become aware, informed, and prepared to implement policy decisions before the availability of commercial microbicides to address and avert any potential adverse consequences to public health. This exploratory study suggests that microbicide adoption coupled with subsequent reductions in condom use might result in an overall increase in HIV risk within specific groups of women in high-risk populations. Although this conclusion is based on a small sample of women with primary male partners, it nonetheless underlines the need to examine these issues more carefully based on further empirical research and prepare an appropriate public health response.

Clinical Considerations

- Monogamous women who are sexually active with a primary male partner may nonetheless be at substantial risk for HIV and other STIs, especially in communities with high prevalence rates for STIs.
- Only 1 in 5 of the women in our study who had HIV-infected male partners used condoms consistently for protection. Therefore, it should not be assumed that married or monogamous women are not in need of risk reduction counseling.
- Adoption of anti-HIV vaginal microbicides by women could result in an increase of HIV risk if less effective microbicides replace more effective condom use. Nurses and other clinical care professionals will need to assess the costs and benefits of vaginal microbicide use on a case-by-case basis.

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