## 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 selfadministered 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 microbicidal products are currently commercially available. The first generation of surfactant and polyanionic-based microbicide candidates, including SAVVY, cellulose sulfate, Carraguard, 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

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