

Microbicide Acceptability Among High-Risk Urban U.S. Women: Experiences and Perceptions of Sexually Transmitted HIV Prevention

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Objectives: The objectives of this study were to measure microbicide acceptability among high-risk women in Hartford, Connecticut, and contextual factors likely to affect acceptability and use.

Goal: The goal of this study was to assess usefulness of microbicides for HIV/sexually transmitted infection (STI) prevention for high-risk women.

Study: Ethnographic interviews (n = 75) and a survey (n = 471) explored women's perspectives on HIV/STI prevention, vaginal contraceptives similar to microbicides, and microbicide acceptability. Participants (n = 94) in a 2-week behavioral trial used an over-the-counter vaginal moisturizer to simulate microbicide use during sex with primary, casual, and/or paying partners.

Results: Findings showed limited experience with vaginal contraceptives, but high interest in microbicides as an alternative to condoms, indicated by an acceptability index score of 2.73 (standard deviation, 0.49; scale of 1–4) in the overall sample. General microbicide acceptability varied by ethnicity, prior contraceptive and violence/abuse experiences, relationship power, and other attitudinal factors. The simulation trial indicated significant willingness to use the product in various locations and with all types of partners.

Conclusions: Vaginal microbicides may improve prevention outcomes for high-risk inner-city women.

HIV AND ITS VIRTUALLY INEVITABLE consequence, AIDS, continues to spread rapidly around the globe. Increasingly, its impact on women gains significance in terms of both the number of women now being infected and the implications this has on the rapid transmission of HIV to their children and sex partners. Worldwide, an estimated 2 million women were newly infected with HIV in 2002, representing 48% of the total new infections. Most of that transmission was through heterosexual sex.^{1,2} Women now comprise 50% of the 38.6 million adults living with HIV/AIDS. Globally, most of the women at risk or infected with HIV

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are of reproductive age and may want to have children, thereby reducing their ability to take preventive measures and increasing possible vertical transmission.

The global AIDS epidemic and ongoing threat of other infectious sexually transmitted diseases has heightened the urgency of calls in recent years for products that protect against sexually transmitted infections (STIs) both in addition to and exclusive of preventing pregnancy.^{3–9} Particularly needed are women-initiated prevention methods such as topical microbicides. A microbicide is any product that can kill or prevent infection from one or more microbes that can be transmitted during sexual intercourse. Microbicides for HIV prevention have been in development for nearly 2 decades. Numerous products are being tested in clinical trials as gels, creams, foams, or suppositories that can be inserted before sex to provide a protective cover or that contain some mechanism to inactivate or block the infectious agent.^{10–16} Some of the compounds being tested are contraceptive and some are not. Some can be used without partner awareness, offering the user a concealable means of protection. A few are being tested for both vaginal and rectal use.¹⁷ Early safety trials of microbicide candidates are also testing other factors such as how well they protect from various transmissible diseases in addition to HIV, their longevity and durability (eg, how well they cover, how long before sex they can be inserted, and how long they last), preferred form (gel, foam, and so on), the most effective mechanisms for application, and their effects on sexual sensation and pleasure or discomfort during sexual activity.^{18–21}

Several studies have been conducted recently to assess women's openness to various types of microbicides, their preferences (both in the abstract in the absence of trial products and in early testing of specific products), their willingness to try new products in association with sexual activity in various circumstances, and their responses to preliminary product trials.^{3,10,22–29} These studies identified variations in preferences on the basis of age, income level, marital status, education levels, ethnic background, and current use of condoms. One U.S. study that explored these issues with women at high risk of HIV infection identified several likely cultural preferences and differences that could potentially affect use of

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microbicides. These included dislike of or disregard for touching the genitalia, preferring wet versus drier sex, and being concerned with the smell and taste of a product.²² These studies indicate the need for multiple options on the market to address the changing needs of different groups of women depending on their individual circumstances, the context of use, and personal preferences. These findings also suggest the need for further exploration of factors affecting the probable acceptability of microbicides among high-risk women. Better understanding of the specific contexts that create the need for products with particular characteristics is essential as development of microbicides proceeds.

Our own work in Hartford, Connecticut, focused on microbicide acceptability and readiness among women at high HIV risk in an urban U.S. context and the potential of microbicides to be a viable option for preventing sexually transmitted HIV and other STIs. In our study, called Project Protect, we were interested in understanding whether such products fit with the needs of these women, and the factors and conditions that influence whether and when high-risk women will use them. We explored their perspectives on HIV/STI risk and prevention, their experiences with contraceptives that are similar to many microbicides being tested, and the social contexts and relationship factors affecting their willingness and ability to use microbicides during sex with various types of partners. We report on the findings of this study.

Methods

In designing Project Protect, we sought to integrate methods successfully used in previous studies assessing women's prior contraceptive experiences and preferences for microbicide characteristics, and to expand on these with exploratory ethnographic approaches designed to assess conceptual framing of microbicides and other prevention methods.^{3,22–26} We also designed the study to explore more fully the personal and social contextual factors that affect current efforts to prevent HIV, perceived interest in and willingness to use microbicides, and sexual practices with the introduction of a vaginally inserted microbicide-like product. For these reasons, we used a combination of qualitative and quantitative methods to assess microbicide readiness and acceptability in the study population. These included ethnographic elicitation interviews, a risk and attitudinal survey, and a simulation trial of microbicides using an over-the-counter product. All research activities, including all components of the microbicide simulation trial, were reviewed and approved by an Institutional Review Board for acceptable protections of human subjects; all participants provided informed consent before engaging in any research activities.

Study Population and Recruitment

Project Protect targeted women who were active heroin or cocaine/crack users, drug injectors, sex partners of drug injectors or crack users, and women who exchanged sex for drugs or money. To reach, identify, and recruit these high-risk women for participation in this study, we used a targeted sampling strategy^{30,31} using street outreach for targeted recruitment of these hidden populations, combined with referral from other study participants, social and health service agencies that serve these women in the city, and referrals from men and women in our other ongoing HIV prevention studies with high-risk populations. Hidden populations of women at high HIV risk are more difficult to reach than high-risk men because women often are not on the streets procuring or using drugs and may have children; thus, many tend to stay in their homes or other less public places. As a result, referral from friends, partners, other peers, and service providers is necessary for locat-

ing a sufficient number of individuals who are at highest risk. Based on our prior studies documenting risk populations in the city, we expected to recruit a sample that was approximately 40% African/Caribbean American, 40% Puerto Rican/other Latino, and 20% non-Hispanic whites and other ethnic groups. Street outreach and agency referral focused on locations high-risk women were known to frequent.

Women recruited or referred into the survey and simulation trial were briefly screened to determine if they were sexually active within the prior 30 days before being given an appointment to enter the study, although this was not necessary for women who participated only in the ethnographic exploratory exercises and focus groups. Men recruited for the men's focus groups were referred from our other ongoing studies of drug users. Other eligibility criteria for all components of the study included being 18 years of age and assessed to be able to understand and provide informed consent. Women entering the simulation trial were additionally screened for a variety of physical symptoms that might indicate an active STI and for pregnancy or intention to get pregnant within the subsequent month, any of which resulted in exclusion from the trial. Anyone indicating possible infection with an STI was referred to medical services immediately after completion of the interview. Interviewers also had discretionary ability to refuse participation of anyone who appeared too drunk or high to understand the requirements and risks of the project or other aspects of informed consent.

Ethnographic Methods

We began the study with a series of ethnographic elicitation techniques with individuals and groups recruited from the target population. These exercises were designed to obtain information about knowledge and cultural framing of various options for pregnancy and HIV/STI prevention; prior use of contraceptive methods similar to microbicides currently under development; product type preferences; reactions to specific products and application mechanisms; and social, cultural, or personal conditions and factors affecting preferences and utilization with various types of sex partners in different situations.

The elicitation exercises included a free listing of pregnancy/HIV prevention options, followed by a pile-sorting exercise³² with groups of women from the target population. In the free-list exercise, we asked a small number of women ($n = 10$) to list every way they could think of or had heard of to prevent pregnancy or HIV/STI. We also asked them which of these they had ever used and their experiences with these methods. The pile-sort exercise required placing each of these free-listed methods on a numbered card. We included the name of the item in English and Spanish, and when appropriate, a picture of the item, not possible with most behavioral methods (eg, selecting clean partners). We then asked 24 women who did not participate in the free-list exercise to sort these prevention methods into piles of items they thought were related. The interviewer documented which items each person grouped together and the reasons she gave for their association. The pile-sort data were analyzed with ANTHROPAC³³ using Johnson's hierarchical clustering and nonmetric multidimensional scaling (MDS) and graphed on a 2-dimensional scale representing a "cognitive map" of prevention options. The cluster analyses and MDS are designed to assess how frequently respondents grouped specific items together. We interpreted these clusters and the cognitive map both deductively on the basis of our theoretical model and inductively using the responses women gave as their reasons for grouping items they considered related.

In addition to these elicitation exercises, we conducted 4 focus group interviews with 6 to 10 women each and 3 with 8 to 10

high-risk men each. (The men were not related to the women in the focus group samples.) After explaining microbicides and demonstrating their potential forms using contraceptives as similar models, we asked the women about their experiences with contraception and HIV/STI prevention, issues and barriers to prevention or problems they have encountered, their ideas about the potential benefits of microbicides, characteristics of the ideal microbicide, and methods they believed would successfully spread the word about microbicides when these products should become available on the market. We asked the men their reactions to the idea of microbicides after giving the same explanation and demonstration of potential microbicide forms and explored the potential benefits or problems they imagined these products might have. We asked both men and women to talk about their interest in microbicide use with different types of sex partners, including primary, casual, and paying or paid partners.

Risk and Attitudinal Survey of Microbicide Acceptability

Findings and feedback from the elicitation exercises and focus group interviews, supplemented with methods used in prior microbicide acceptability assessments,^{22–26} informed construction of a survey on microbicide readiness and acceptability. This survey assessed factors associated with contraceptive choices and experiences and responses to possible characteristics of microbicides. It measured sociodemographic characteristics, drug use and sexual practices, current HIV risks associated with drug use and sex, perceived risks, exposure to partner violence/abuse, STI and other health history, reproductive history and intentions, partner and sexual relationship factors, psychologic factors, and willingness to participate in limited trials or, if available, clinical trials of microbidental products. Microbicide acceptability was measured through an index that included 21 items on the relative acceptability of certain characteristics using a Likert scale from 1 to 4 (1 = very unacceptable; 4 = very acceptable) derived from similar surveys.^{22,26} Participants responded to questions that were neutral (“What if microbicides were a gel?”), negative (“What if a small amount leaked out after sex?”), and positive (“What if the microbicide had a pleasant taste?”). The microbicide acceptability index derived from this set of items demonstrated high internal consistency ($\alpha = 0.90$).

Microbicide Simulation Trial

After completion of the survey with the first 300 women, we began to ask all new study participants if they would be willing to participate in a “microbicide simulation” trial. In this simulation trial, they would use an over-the-counter vaginal moisturizer during regular vaginal sex for a 2-week period followed by a second 2-week trial if the first was successful (ie, they were able to use the product at least once during a regular sexual encounter). We asked them to document all their sexual activity during this period and return for a follow-up assessment after each trial period. Women who agreed to participate in the trial were asked to provide informed consent specifically for this trial and were screened for current symptoms that indicated the possibility of an active STI, possible pregnancy or interest in pregnancy, and inability or unwillingness to document their sexual activity over the trial period or return for the follow-up interview(s). Women who indicated any of these conditions or declined consent were excluded from the simulation trial and left after completing the survey. The product used in this trial was selected because it closely resembles several vaginal microbicides currently in advanced clinical trials and has been used as the placebo in some of these safety trials (A. Profy and T. Moench, personal communication, April 2001).

Participants who completed the full survey and passed the eligibility screening were shown the surrogate product, provided in single-dose, prefilled plastic applicators, opened by breaking off a small plastic tab to apply by inserting directly into the vagina. This moisturizing product is composed of glycerin and water and has no contraceptive or microbicidal attributes. Women were given oral and written directions on the proper way to apply the product for this microbicide simulation study, strongly cautioned both verbally and in the written instructions that the product does not prevent either pregnancy or HIV/STI, and asked to apply 1 dose of the product before every act of vaginal intercourse over the next 2-week period and to use a male or female condom during every sexual encounter. We also asked them to bring back the removable plastic tabs from opened product applications and to document each sexual encounter either on an encounter form or to use our anonymous and toll-free 800 telephone number to call in their responses to the same set of questions.

Encounter forms documented the time and place of the sexual encounter; the type of sex partner (primary, casual, paying); whether male or female condoms were used; whether the product was used; and any problems, complications, interruptions, or partner responses to the use of the product during that sexual encounter. Women were provided sufficient doses of the product and more-than-sufficient condoms for the 2-week period, given a booklet of encounter forms, and scheduled for a return appointment 2 weeks later. The follow-up surveys assessed their sexual activity during that period with all types of partners, their use of the product and condoms, their attitudes and partners' attitudes toward the product and microbicides in general as a result of the trial and for those in the first trial, whether they were interested in participating again in a second trial for which they received a second screening for continued eligibility.

Statistical Analyses of Survey and Posttrial Data

The survey and posttrial interview data were entered into SPSS 11.0. Microbicide acceptability was measured as the mean of all scores on the 21-item acceptability scale. Mean microbicide acceptability differences by demographic factors were analyzed using analyses of variance and *t* tests. To assess microbicide acceptability within the sample, we used hierarchical regression analyses to determine the extent to which HIV risk and psychologic variables explained a significant portion of the variance after controlling for the main effects of age, ethnicity, marital/partner status, and education. Selection of variables for the hierarchical regression model was based on theoretical considerations, regardless of the degree of association at the bivariate level. The regression model consisted of 3 blocks. The first block contained those variables for which we wanted to control. The second block contained personal and relational characteristics of the participants. The final block contained attitudinal variables and was used to assess whether attitudes about personal risk and relationship power would account for a significant amount of variance above and beyond what was accounted for by the other variables in the model. Analyses of the simulation trial data reported here include rates of product and condom use indicated both in posttrial surveys and on sexual encounter forms, participants' and their partners' responses to the product, and associations of use during sex with various types of partners (primary, casual, paying).

Results

Ethnographic Elicitation Exercises and Focus Group Interviews

The exploratory ethnographic component of the study revealed the perceived and real limits of available HIV/STI prevention

approaches for these women, as well as their generally limited experience with vaginal products for contraceptive or other uses. Ten women (4 black, 4 Puerto Rican, and 2 non-Hispanic whites) participated in the initial free-listing exercise to generate an inventory of known pregnancy and HIV prevention options. The list from the 10 women comprised 23 items, including the following (number of women who mentioned each item, indicated in parentheses): condoms (10); avoiding sex (10); birth control pills (10), Depo-Provera shot (Pfizer, New London, CT) (7); IUD (4); diaphragm (4); operation (hysterectomy; tubal ligation) (2); Norplant (Population Council, Washington, DC) (2); contraceptive gel (2); contraceptive foam (2); and 1 mention each of: female condom, sex without intercourse, withdrawal, select clean partners, keep body clean, stop and think before you act, get regular checkups, trust your partner, refuse sex with someone because of a bad feeling about him, have a long-term partner, take a chance, douche, and Norforms (feminine deodorant suppositories, C. B. Fleet, Lynchburg, VA). To this participant-generated list we added 10 items for the subsequent pile-sort exercise, including contraceptive sponge, film, and cream (to cover the range of vaginal contraceptive products), as well as contraceptive patch, morning-after pill, rhythm method, washing before and after sex, urinating immediately after sex, and male condoms with spermicide.

The 24 women who participated in the pile-sort exercise included 14 blacks, 8 Puerto Ricans, and 2 non-Hispanic whites. Statistical analysis of their card sorts revealed 2 large groupings and, within them, a number of smaller subgroupings. We identified the 2 large clusters of related items as: 1) medical or mechanical prevention options and 2) behavioral prevention options. Under the domain of medical/mechanical were clustered condoms, pills, other hormonal contraceptives, sterilization operations, and all

vaginal products. Within this broad category, long-acting contraceptives (Depo-Provera, Norplant, IUD, patch) and the diaphragm formed a tight subgroup. In women's verbal explanations provided during the pile-sort exercise, those who grouped these items together described them as working well for contraception and methods they had used. Contraceptive gel, foam, sponge, and cream formed another tight cluster within the larger grouping; however, women often described this subgroup as methods that do not work or that they did not like or, frequently, as methods they had never heard of. Also notable was that among the mechanical methods, the female condom was least often grouped with any other prevention methods and commonly mentioned as unfamiliar. Under the behavioral domain were practices such as avoiding, refusing, or modifying sexual behavior, partner selection, and hygiene. Women's descriptions of this cluster included "not really using anything" and "still putting yourself at risk for diseases." This suggests they recognize the need to take steps beyond partner selection or trying to avoid sex or sexual intercourse to prevent pregnancy or STIs.

When the pile-sort data were analyzed using MDS and graphed 2-dimensionally, the resulting "cognitive map" illustrated additional aspects of the relationships among these prevention methods for these women (see Fig. 1). The 2 primary domains participants created in their pile sorts are evident as a continuum from the more medical/mechanical to the more behavioral along the x axis of the map. The pattern along the y axis suggests grouping that reflects a general trend regarding degree of internal locus of control, a key factor in our theoretical model hypothesized to influence women's prevention practices. The trend moves from methods requiring a greater sense of personal power to those methods more commonly used when a woman feels less empowered to take preventive

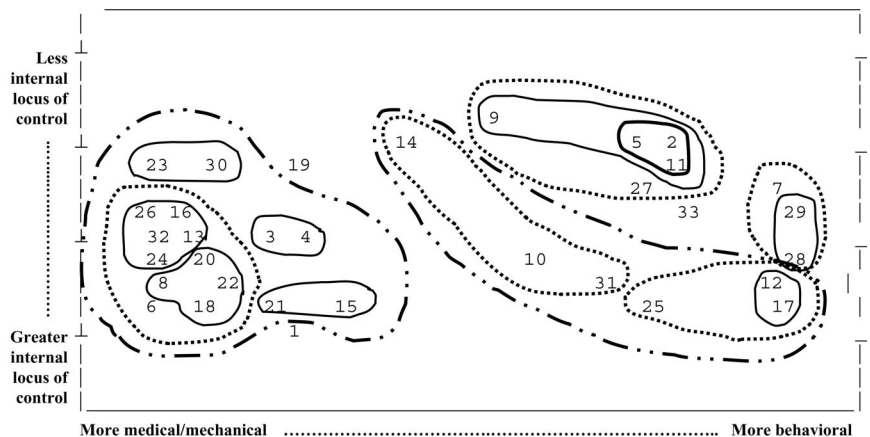


Fig. 1. Cognitive map (A) of means of pregnancy and HIV/sexually transmitted infection prevention methods for high-risk women in Project Protect

- Key**
- 1—female condom
 - 2—wash before sex
 - 3—morning after pill
 - 4—birth control pills
 - 5—wash after sex
 - 6—contraceptive film
 - 7—selecting clean partners
 - 8—contraceptive gel
 - 9—douche
 - 10—sex without intercourse
 - 11—keep body clean
 - 12—stop and think before you act
 - 13—contraceptive patch
 - 14—withdrawal
 - 15—condoms
 - 16—Depo shot
 - 17—avoid sex
 - 18—contraceptive sponge
 - 19—rhythm method
 - 20—contraceptive foam
 - 21—male condoms with spermicide
 - 22—contraceptive cream
 - 23—hysterectomy
 - 24—diaphragm
 - 25—refuse sex with someone because of a bad feeling
 - 26—Norplant
 - 27—getting regular check-ups
 - 28—trusting your partner
 - 29—have same partner for a very long time
 - 30—surgical sterilization
 - 31—take a chance
 - 32—IUD
 - 33—"pee" immediately after sex

Stress in 2 dimensions is 0.155

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action. For example, within the behavioral sector refusal of sex (25, 12, 17), which happens before risk occurs, may be feasible only for women who have more control over the sexual encounter. By contrast, douching (9) and other attempts to be clean before or after sex (5, 2, 11) are a last resort for women who are unable to avoid a risky sexual encounter.

When asked to describe their experiences using the methods of HIV/STI and pregnancy prevention available to them, the women who participated in these exploratory exercises gave a variety of responses. For contraception, they clearly preferred and most commonly used pills or long-lasting hormones (Depo-Provera, Norplant) because of their effectiveness and convenience. They recognized avoiding sex as an effective means of preventing both HIV/STI and pregnancy but considered it a less preferred method. Regarding condoms (predominantly referring to male condoms), they expressed ambivalence, with comments like: "I felt in control [when using them], safe from getting pregnant and sick, including with casual partners.. But physically, it [sex] was not the same feeling" (Puerto Rican, age 26); "I can't control use of a condom; but it's good for protection—glad to have something" (black, age 54); "I used them in the '80s, but not [now] with my partner [of 14 years], I don't like them because they break, you're always taking a risk" (Puerto Rican, age 30). However, despite this ambivalence, women indicated they believed condoms were the safest and most reliable method of STI prevention and frequently chosen for contraception as well.

By contrast, participants had very limited experiences with vaginal contraceptive products, and those who had (and some who had not) ever used them generally expressed negative reactions to them. For example, women made comments like: "I never used [contraceptive gel], had it but didn't use it, it was too messy" (black, age 46); "I used [gel] two times with my oldest son's father, I used it with condoms, it helped with lubrication, but I don't like it because it's too much chemicals" (Puerto Rican, age 30); "I used [contraceptive foam] once, didn't like how it felt, didn't like inserting it, I was embarrassed" (non-Hispanic white, age 30); but "I liked the [diaphragm with gel] because I can do it myself anywhere, at first I didn't like putting it on" (Puerto Rican, age 33). These comments illustrate the general discomfort and disinclination women felt regarding vaginal contraceptive use.

After the card-sorting exercises, we conducted focused group interviews with 28 women, including 10 blacks, 8 Puerto Ricans, 7 non-Hispanic whites, and 3 West Indians. Women in the focus groups identified several problems they encountered protecting themselves from diseases and unwanted pregnancy. These include trust issues, lack of control in relationships, overcoming shame associated with addiction or sex work, fear of harm to themselves or their children, fear of rejection, and loss of self-esteem. They pointed out that benefits of a microbicide include "put[ting] power back in the hands of women" and providing a choice of protection options in addition to condoms. These women thought the ideal microbicide would be inexpensive, simple to use, effective, discreet, comfortable, fast-acting, easily accessible, long-lasting, and affordable. In their general enthusiasm for having a prevention option like microbicides, they identified a number of venues for promoting them to women at risk, including billboards, radio and television, public announcements, bus stop posters, the needle exchange van, social service organizations, training parole/probation officers, providing free samples and educational materials in the mail and places such as college campuses, and making it part of health education in schools.

We also conducted focused group interviews with a total of 30 men, including 18 blacks, 8 Puerto Ricans, and 4 non-Hispanic whites, to assess their reactions to the concept of microbicides.

Some indicated concern about their primary partner using a microbicide because it raised issues of trust. Others expressed support for the idea to relieve some of their own burden of responsibility for disease prevention and indicated they would like having an alternative to condoms. Quite a few men, however, raised concerns about the likely efficacy of microbicides for HIV/STI or pregnancy prevention and indicated they would probably still use a condom if their partner were using a microbicide. Concern about efficacy was noticeably lacking in the focus groups with women.

In general, the exploratory ethnographic exercises and interviews we conducted in the first year of the study indicated that these high-risk women were very positive about the idea of vaginal microbicides and expressed interest in having an alternative to male condoms, especially one they could control. High-risk men also indicated support, although they had greater reservations about efficacy. However, despite general support for the idea of having a microbicide available for prevention, overall findings from our initial elicitation exercises suggested very limited preparedness within this high-risk population for use of microbicides for HIV/STI prevention based on limited parallel experience with other vaginal products.

Microbicide Acceptability Survey

A total of 475 women completed surveys; however, 4 women who identified as being lesbians and who only had sex with women in the prior 30 days were excluded from the analyses reported here because we were interested in understanding the choices for HIV/STI prevention that women involved in sex with men might make. The demographic and risk characteristics of the 471 women in this sample are reported in Table 1. Many of these women reported being active drug users or commercial sex workers, and many indicated significant risk for exposure to HIV through injection drug use or unprotected sex. History of STIs among women in this study was very high; yet, they were also inconsistent condom users, reportedly using condoms in less than half of all vaginal and anal sexual encounters in the previous 30 days. Although they acknowledged the efficacy of condoms for pregnancy and HIV/STI prevention, consistent condom use remains low, particularly with more intimate partners. This is consistent with other studies of condom use among high-risk women.^{34–37}

Like the women who participated in our exploratory ethnographic interviews, women in the survey sample had limited experience with vaginal products, especially for contraception. Reported contraceptive use in the prior 30 days included male condoms (56.5%), female condoms (9.8%), and very limited use of oral contraceptives (2.8%) and Depo-Provera (2.5%). Approximately two thirds reported familiarity with vaginal contraceptive foam, cream, and gel, but less than one fifth had ever used any of these products.

Overall responses to the microbicide acceptability items were more positive than negative, resulting in a mean score on the index of 2.73 (standard deviation [SD], .49; scale of 1–4). Microbicide acceptability varied by several factors, most notably by ethnicity ($P < 0.01$). Post-hoc analyses revealed that non-Hispanic whites had significantly higher scores (mean, 2.99; SD, .43) than Puerto Ricans/other Latinas (2.72; SD, .46), African/Caribbean Americans (mean, 2.65; SD, .52), and other/mixed ethnic groups (2.59; SD, .46). None of the other ethnic groups were significantly different from one another. Microbicide acceptability was also significantly correlated with having graduated from high school ($r = .10$, $P < 0.05$), being an injection drug user ($r = .10$, $P < 0.05$), and being HIV-negative ($r = .15$; $P < 0.01$).

We conducted hierarchical regression analyses to examine the differential percentage of variance accounted for by these groups

TABLE 1. Demographic and Risk Characteristics of Women in the Microbicides Acceptability Survey Sample (N = 471)

| | N (Range) | % (Mean) |
|---|-----------|-------------------|
| Ethnicity | | |
| African/Caribbean American | 208 | 44.2 |
| Puerto Rican/other Latina | 169 | 35.9 |
| Non-Hispanic white | 73 | 15.5 |
| Asian/Native American/mixed ethnicity | 21 | 4.5 |
| Age | (18–66) | (36.5, SD = 8.54) |
| Marital status | | |
| Single | 248 | 52.7 |
| Married | 125 | 26.5 |
| Separated/divorced/widowed | 98 | 20.8 |
| Education: high school diploma/GED obtained | 223 | 47.4 |
| Sexual partner experiences/risk | | |
| Has a primary/main partner | 371 | 78.8 |
| Knows/suspects primary partner has HIV | 23 | 4.9 |
| Has casual partner(s) | 110 | 23.6 |
| Knows/suspects casual partner has HIV | 4 | .8 |
| Has paying partner(s) (exchanged sex for money/drugs) | 111 | 24.6 |
| Knows/suspects paying partner(s) has HIV | 6 | 1.3 |
| Drug risk in prior 30 days: | | |
| Injected drugs | 107 | 22.7 |
| Smoked crack | 230 | 48.8 |
| Sniffed cocaine | 107 | 22.7 |
| Injection drug using sex partner* | 74 | 15.7 |
| History of STI/HIV (self-reported) | | |
| Ever had an STI not including HIV | 320 | 67.8 |
| No. of separate STIs | (0–8) | (1.63, SD = 1.64) |
| Had STI treated within last year | 91 | 19.3 |
| Has HIV/AIDS | 47 | 10.0 |
| Condom use in last 30 days (% of encounters) [†] | | |
| All encounters [‡] | | 46.6 |
| With primary partners | | 35.1 |
| With casual partners | | 64.8 |
| With paying partners | | 77.0 |

*Only asked about primary and casual partners.

[†]Includes vaginal and anal sex only.

[‡]In all categories, percent of condom use during vaginal and anal sex ranged from 0 to 100 percent.

of variables from the personal, relational, and attitudinal domains to predict microbicide acceptability (see Table 2). We were also interested in estimating the adjusted effect size and direction of association for each individual predictor variable. After controlling for the effects of ethnicity, age, marital status, and education level (block 1 in the regression analyses), microbicide acceptability scores were negatively related to having experienced either physical or sexual violence, but not significantly related to other HIV drug- and sex-risk conditions (block 2). Regarding attitudinal factors (block 3), acceptability was negatively related to AIDS risk perceptions and positively related to an internal locus of control for STI prevention (ie, a sense that prevention from STI infection results from one's own actions). Additionally, although only marginally significant, prior experience with vaginal contraceptive products was positively correlated with microbicide acceptability, and having power within the sexual relationship was negatively correlated with microbicide acceptability scores (ie, those women with perceived less power were more positive about microbicides). An examination of interaction effects between ethnicity and the independent variables revealed no significant interactions. The change in explained variance (R^2) between the variables controlled for in the first block and the personal variables in the second block of the regression analyses were not significant. However, the change between the personal variables (block 2) and relational and attitudinal variables (block 3) was, indicating that attitudinal variables accounted for a significant percentage of the variance above

and beyond that accounted for by personal risk characteristics. The percentage of variance accounted for by this model was 15.5%, and the overall relationship was significant ($F_{21,303} = 2.64, P < 0.01$).

These findings suggest that although this high-risk population generally considers microbicides to be an acceptable option for HIV prevention in the abstract, microbicide use might depend on women's prior experience with other vaginal products and their relative sense of power and control in relationships. Notably, women who perceived themselves to be at greater risk for HIV reported lower microbicide acceptability scores, the reasons for which are unclear from these data. More investigation is needed to understand why these women find this HIV-prevention option less attractive. However, even with these variations among women in this study, many (83.4%) indicated a strong interest in participating in clinical trials of microbicides if these should be conducted locally. Participants' interest in trying microbicides was also evident in their reports during the project's simulation trial.

Microbicide Simulation Trial

Findings from the study's microbicide simulation trial were quite surprising given the limited prior experience among study participants with vaginal products. A total of 126 women, whose demographic and risk characteristics matched those of the overall survey sample, were screened for the first 2-week trial, of whom

TABLE 2. Summary of Hierarchical Regression Analyses for Variables Predicting Microbicide Acceptability (N = 471)*

| | B [†] | SE B [‡] | P |
|--|----------------|-------------------|-------|
| Block 1 | | | |
| Ethnicity (African American, reference group): | | | |
| Puerto Rican/other Latina | .10 | .07 | .17 |
| Non-Hispanic White | .27 | .09 | .00* |
| Other/mixed ethnicity | -.11 | .14 | .43 |
| Age | .00 | .00 | .89 |
| Marital status (married/partnered, reference group): | | | |
| Single | -.02 | .07 | .71 |
| Separated/divorced/widowed | .00 | .08 | .96 |
| Education level (high school educated, reference group) | .05 | .06 | .39 |
| Block 2: [§] | | | |
| Partner types (has only a primary partner, reference group): | | | |
| Multiple partners (primary/casual only) | .09 | .07 | .22 |
| Paying partners (may also have primary/casual partners) | .04 | .07 | .57 |
| Drug use (drug-free, reference group): | | | |
| Injects drugs only | -.06 | .12 | .64 |
| Smokes crack only | -.00 | .09 | .98 |
| Injects drugs and smokes crack | .16 | .11 | .13 |
| Sniffs cocaine | .02 | .13 | .87 |
| Only uses other drugs | -.06 | .09 | .50 |
| Vaginal product experience | .04 | .02 | .07 |
| No. of STIs | .01 | .02 | .56 |
| History of physical or sexual violence | -.02 | .01 | .03** |
| Block 3: | | | |
| Relational power | -.12 | .07 | .06†† |
| STI internal locus of control | .12 | .06 | .05** |
| Sexual assertiveness | .02 | .02 | .32 |
| Perceived AIDS risk | -.16 | .06 | .01** |

*R² = .07 for Block 1; R² = .12 for Block 2; R² = .16 for Block 3.

[†]B refers to the unstandardized coefficient of the estimated regression model, that is, the effect of this variable in explaining microbicide acceptability.

[‡]SE B refers to the standard error of the estimated coefficient B.

[§]Change in R² from Block 1 to Block 2 = .05 (n.s.).

^{||}Change in R² from Block 2 to Block 3 = .04.**

††P < .01; **P < .05; †P < .10.

22 were deemed ineligible (primarily because of reported possible STI symptoms) and 10 did not return for the follow-up interview. The remaining 94 who completed trial 1 reported having used the microbicide simulation product an average of 4.87 times (SD, 3.88; range, 1–30) during the 2-week trial period. This varied by partner type as indicated in Table 3.

All the women with primary partners and all those with casual partners used the product at least once with that type of partner during the trial, whereas nearly all participants with paying partners also did so. Notably, women in the trial reported using the

product on average more frequently than they reportedly used male condoms. (Female condom use was negligible.) However, overall reported condom use during the 2 weeks of the trial was still higher on average than reported use with all partner types during the 30 days before entering the study (see Tables 1 and 3). Approximately two thirds of women with each type of partner said they liked using the product with that partner, and approximately one third thought it was too messy or drippy. Over half (53.2%) of the women with primary partners said that their partner reported liking the product, although this was true of less than one third of women

TABLE 3. Sexual Activity and Use of Product and Condoms During 2-week Microbicide Simulation Trial 1

| Practices During the 2-week Trial 1 Period | Women with Primary Partners (n = 78) | Women with Casual Partners (n = 11) | Women with Paying Partners (n = 14) |
|---|--------------------------------------|-------------------------------------|---|
| Used product at least once with that partner* | 100% | 100% | 92.9% |
| Average no. of sexual encounters | 5.33 (SD 3.06) (range 1–13) | 2.73 (SD 1.85) (range 1–7) | 10.64 (SD 11.33) (range 2–45, median 7) |
| Average times used the product | 4.05 (SD 2.02) (range 1–11) | 2.73 (SD 1.42) (range 1–5) | 8.62 (SD 7.53) (range 2–30, median 7) |
| Average times used male condoms | 3.23 (SD 2.95) (range 0–12) | 2.45 (SD 1.51) (range 1–5) | 8.36 (SD 6.39) (range 1–20, median 6) |
| Percent of times used condoms during sex | 82.1% | 92.9% | 87.7% |

*Percentage indicates the percent of women with this type of partner who reported using the microbicide simulation product with that (those) partner(s) during the trial.

commenting on casual (30%) and paying (25%) partners. Male partners also reported that it made sex better (9.1% of primary, 10% of casual, and 16.7% of paying partners), although a few also said it was too messy or drippy (16.9% of primary partners, 10% of casual partners, and 8.3% of paying partners). Thus, the overall response of women and their partners to the microbicide simulation product when used before regular vaginal intercourse was generally positive.

The issue of stealth or clandestine use of an HIV prevention method for women concerned about partner resistance is often noted as a significant advantage of microbicides. However, possibly because they were in a research project and were documenting their sexual encounters, women in the simulation trials reported that they commonly informed their partners that they were using the product. Specifically, 85.8% of primary partners knew the participant was using the product and 63.6% of women with casual partners said some or all of them knew, but 61.5% of women with paying partners did *not* tell those partners when they were using the product. Altogether, partners were aware of the participants' use of the product during 65.7% of encounters.

Sexual encounter forms women completed to document their sexual activity during the 2-week trials confirmed extensive use of the product with various types of partners and in various settings. Altogether, women who participated in the first trial completed 519 sexual encounter forms. Five forms did not contain adequate data on product use and were dropped from further analysis. The remaining 514 encounter forms indicated that the 94 women in the trial used the product 432 times, or during 84.0% of encounters, including 274 (82.5%) times with primary partners, 44 (86.3%) times with casual partners, and 110 (88.0%) times with paying partners. Four encounters with a partner whose type was unspecified involved the use of the simulation product. (Women in the trial recorded 6% more product use on encounter forms than they reported in follow-up surveys; however, the number of returned tabs from opened product applicators was within 2 percentage points higher than the number of uses recorded on encounter forms.) During the first trial, women generally used the microbicide simulation product in a home (377 encounters), but also used it in hotels or motels (55 encounters), in cars (40 encounters), and in public or other areas (38 encounters), reportedly including in the library, a garage, a rooftop, a tent, bars, and clubs.

Participants indicated that use of the simulated microbicide did not interfere with sex during 93.8% of these encounters. The most commonly reported reason for failing to use the product during sexual encounters as documented on the encounter forms was forgetting (27.5%), followed by not wanting to interrupt sex (18.5%), partner refusal (13.4%), and inconvenience or a bad location for use (10.0%). A small number (6.3%) reported being too high or drunk to apply the product before sex. These encounter forms highlight the considerable willingness and ability of this high-risk group of women to incorporate the practice of applying a vaginal microbicide during sexual activity with most any kind of partner in both ordinary and extraordinary circumstances in which they might be having sex.

Discussion

Mathematical models estimating the potential value of introducing a microbicide into populations facing high rates of new infection suggest that even a relatively ineffective microbicide could have a significant positive effect on reducing sexually transmitted HIV. One model estimated that introduction of a 40% efficacious microbicide into 73 lower-income countries could avert 2.6 million HIV infections over 3 years in men, women, and infants, even

assuming that only 20% of people likely to be reached used it in only 50% of sexual encounters in which condoms were not used.³⁸ The high and increasing rates of HIV and other sexually transmitted diseases among women is a compelling reason to support greater efforts directed toward microbicide research and development. Unfortunately, financial support for development and testing of microbicides has been extremely limited and microbicides are still considered with great skepticism, even among many in the field of HIV/AIDS prevention.^{16,19,20} Thus, although many products have been identified as potentially effective microbicides, exceedingly few have made it to the efficacy stage (phase III) of clinical trials.

Our Hartford study of microbicide acceptability and readiness among women at risk suggests that there could be a substantial benefit to making microbicides available as an additional option for high-risk women to protect themselves from HIV and other STIs. This study and others^{3,10,12,22} confirm the willingness and interest of high-risk women to use microbicides, as indicated by the high ratio of microbicide simulation product use to sexual encounters with all types of partners in the Project Protect trial period. The positive response to the simulated microbicide was surprising, given participants' prior experiences with vaginal products, although in light of their general concerns about currently available prevention options and their commonly expressed interest in using microbicides, their readiness to try the simulated product makes sense. These findings also suggest the potential acceptability, and hence value, of other woman-initiated, vaginally inserted prevention options such as the female condom. However, although the higher rate of product use over condom use during the trial may be an artifact of participating in the trial itself and not a clear preference for microbicides versus (primarily male) condoms, it suggests the need to understand better the issue of "condom migration"³⁹ with the introduction of an alternative prevention option such as microbicides.

Reported differences in microbicide acceptability with different types of sex partners and among women of different ethnic groups indicate that microbicides may not necessarily be appropriate or desirable for some women or in some contexts. Overall rates of use of the simulation product during the trial suggests feasibility for many high-risk women to incorporate the practice of using microbicides into their regular sexual activity. Much greater understanding of the social dynamics of microbicide use and negotiation, particularly for women at high risk, is needed. Also needed is a fuller exploration of the gender role, identity, and sexuality issues that intersect with personal and environmental risk factors to intervene and impede women from using microbicides or compel them to use them as an alternative to male or female condoms. The notable difference between women and men in the focus groups regarding the importance of product efficacy (with men indicating greater concern about this than women) suggests that women may be more focused on increasing their prevention options, self-reliance for prevention, and having a surreptitious option, even if it is somewhat less efficacious than the current male-initiated options. Men, by contrast, may be more comfortable with a product of known efficacy, despite its inconveniences and discomforts with which they are familiar and able to control. Greater understanding of men's and women's preferences and the dynamics of their negotiations of these around prevention are needed.

This study had several limitations. First, the sample, although guided by a targeted sampling plan,³¹ is not necessarily representative of all women at risk in Hartford because of the hidden and stigmatized nature of HIV risks and the difficulty of finding and recruiting women who are consequently at highest risk. Second, because we lacked a true microbicidal product for women to view

and try, responses to the microbicide acceptability questions were based on women's perceived preferences for hypothetical characteristics. Related to this, although women's use of the product in our simulation trial was promising, the trial itself is only able to suggest high-risk women's *likely* interest in and ability to use microbicides in their real-life contexts. Thus, to gain a more accurate understanding of women's attitudes toward microbicides and their willingness and ability to use them, acceptability studies in naturalistic contexts that accompany clinical trials remain essential.

The urgency for women locally and globally to have alternative, women-initiated HIV/STI prevention approaches provides a compelling rationale for the promotion of topical microbicides. Such urgency calls us to press for significantly greater financial and political support for rapid microbicide development (both vaginal and rectal), clinical trials, and acceptability testing. This would be enhanced through greater dissemination of information on the status of microbicide development and the potential contribution of this important prevention method for reducing the spread of HIV.

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