



# The Female Condom and STDs: Design of a Community Intervention Trial

PAUL J. FELDBLUM, PHD, JOB J. BWAYO, MD, MAUREEN KUYOH, MA,  
MICHAEL WELSH, PHD, KELLEY A. RYAN, BA, AND MARIO CHEN-MOK, PHD

**OBJECTIVES:** The main purpose of this study is to compare sexually transmitted disease (STD) prevalence in cohorts of women with and without access to female condoms.

**METHODS:** Six matched pairs of communities were identified from Kenya tea, coffee and flower plantations. One community within each pair was randomly selected to receive the female condom intervention. Approximately 160 eligible women were enrolled at each site. Female condom communities underwent an education program on use of female and male condoms and STDs, comprising group meetings, puppetry and other folk media, and training of clinic service providers and community outreach workers. Control communities received similar information on use of male condoms (freely available at all sites). At baseline, participants were tested for cervical gonorrhea and chlamydia and vaginal trichomoniasis, to be repeated at 6 and 12 months. The study has 80% power to detect a 10% prevalence difference, assuming an aggregate STD prevalence of 20% with 25% loss to follow-up and intracluster correlation of 0.03.

**RESULTS:** Among 1929 women at baseline, the mean age was 33.1 years; 78% had never used a male condom. The prevalences of gonorrhea, chlamydia and trichomoniasis were 2.6%, 3.2% and 20.4%, respectively (23.9% overall). The intracluster correlation based on these data was near zero.

**CONCLUSIONS:** Comparable pairs of study sites have been selected. STD prevalence is sufficiently high, and the variation between sites is acceptably low. The study is feasible as designed.  
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**KEY WORDS:** Condoms, female, Epidemiologic Methods, Intervention Studies, Cluster Randomization, Intracluster Correlation, *Trichomonas Vaginitis*, Gonorrhea, Chlamydia, Kenya.

## INTRODUCTION

Public health interest in barrier methods of contraception, including male and female condoms, has been invigorated because they are the only contraceptives that can reduce the risk of contracting or transmitting sexually transmitted diseases (STDs). But barrier prevalence and consistency of use, and impact, remain low in most populations, even among groups at high risk of contracting STD.

The female condom (Reality® in the U.S.) is as effective a contraceptive as other barrier products (1, 2). It is made of polyurethane, a stronger material than the latex used for male condoms. Other advantages include: its loose fit in the vagina, allowing the penis to move freely inside it; it covers the vulva during coitus; it can be used with oil-based or water-based lubricants; and it is female-inserted and so

(at least partly) female-controlled. Disadvantages include the device's relatively high price (about U.S. \$3, with a public-sector price of about U.S. \$0.60) and its unsightly extrusion from the vaginal canal. Laboratory studies have found that the female condom is impermeable to various STD organisms, including HIV (3). In one human use study, women with recurrent vaginal trichomoniasis were assigned to a group using the female condom or a control group of non-users. Following a 45-day period of their usual sexual activity, re-infection with trichomonas occurred in 14% of controls, 14.7% of non-perfect users, and in none of the 20 perfect users of the female condom (4). A second study found that a group of sex workers receiving female condoms and male condoms had a one-third lower incidence of STDs than a comparable group of women relying on male condoms alone (5).

Women's health advocates enthuse about a device that empowers women at risk of STD to protect themselves (6). Acceptability studies in the developing world have been encouraging (7), including two studies in Kenya (8, unpublished FHI report). A female prophylactic may have a greater impact on infection among women than male devices—the man's accession to his partner's female condom use may be

From the Family Health International (P.J.F., K.E.R., M.C.M.), Research Triangle Park, NC; University of Nairobi, Department of Medical Microbiology (J.J.B.), Nairobi, Kenya; and Family Health International (M.K., M.W.), Nairobi, Kenya.

Address reprint requests to: Paul Feldblum, PhD, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709.

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#### Selected Abbreviations and Acronyms

CBD	= Community-based distributor
FGD	= Focus group discussion
FHI	= Family Health International
HIV	= Human immunodeficiency virus
ID	= Identification
ICC	= Intracluster correlation
IEC	= Information, education, communication
LCR	= Ligase chain reaction
ml	= Milliliter
STD	= Sexually transmitted disease
US	= United States

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easier to achieve than his active decision to wear a male condom (6). Offering the female condom as one choice among barrier methods has resulted in less unprotected intercourse in at least three settings: a U.S. STD clinic (9); a Zambian STD clinic (10); and a cohort of Zimbabwean sex workers [unpublished report cited in (7)].

Yet to be demonstrated is whether distribution of a female barrier method can reduce STD rates on a large scale. Interventions have generally described process information and self-reported behavior change without STD data (11). Until recently, weak designs were common, leading to calls for randomized studies of HIV/STD interventions (11, 12).

We designed a randomized community intervention trial in Kenya to determine the effect of introducing female condoms in communities with a high prevalence of STDs. This article describes the design and analysis of the trial, and presents results from its baseline phase. The primary objective of the trial is to measure and compare STD prevalence in cohorts of Kenyan women with and without access to female condoms as part of a replicable intervention. Secondary objectives are to: compare the incidence of STD syndromes (vaginal discharge; genital ulcer; lower abdominal pain) in cohorts with and without female condoms; measure the impact of female condom introduction on the consistency of male condom use; collect acceptability information among female and male users of female condoms; and compile cost data on female condom provision.

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## METHODS

### Study Sites and Matching

The community is the unit of randomization. Study sites comprise agricultural plantations that offer primary health care, family planning services, and have active male condom promotion and distribution programs. The sites employ large numbers of women who reside on the plantations. We selected six matched pairs of communities in central and western Kenya from among coffee, tea and flower plantations, after securing the cooperation of management, using

three matching criteria: same agricultural product; same geographical area; no more than five-fold difference in number of permanent employees. Once identified and paired, a computerized random number algorithm was used to designate one site per pair to intervention condition. The sites were distant enough to preclude social or sexual contacts between intervention and control participants, none of whom own private vehicles.

### Informed Consent and Ethical Considerations

At baseline, eligible women were informed in small groups about study procedures, risks and benefits. Each woman then had a private interview to sign or verbally attest to the Volunteer Agreement. The documents were written at a 6th-7th grade English reading level (Fry method), translated into Kiswahili for the fieldwork, and back-translated into English to confirm accuracy. Study files and master lists with participants' contact information are kept in locked file cabinets at the clinics.

Interviewers and clinic staff were trained in the protection of study participants (voluntariness of participation, need for confidentiality, and sensitivity in interviewing). Site management was informed that they will not have access to participants' sexual or STD data.

### Study Cohorts and Eligibility

Lists of permanent female employees were furnished by management at each site, participant ID numbers were assigned to each in sequence, and the list was randomly sorted. Women were called to the site clinic for screening, informed consent and interview in manageable groups of 20 per half-day until approximately 160 women were enrolled. Women found to be infected at the baseline visit were treated and retained in the cohort.

Inclusion criteria included:

- permanent female employee 18-50 years old
- willing to sign an informed consent document
- willing to return for follow-up visits and give urine samples and vaginal specimens
- willing to answer questions about sexual activity and condom use.

Exclusion criteria included:

- pregnant, within 42 days of pregnancy or desiring pregnancy within 12 months
- using spermicidal contraceptive.

The creation of cohorts of female employees, rather than repeated cross-sectional sampling, took advantage of the stable populations of permanent employees at the sites, along with the relatively short intervention period (13). Study participants are scheduled to make visits at baseline, and at 6 months and 12 months after baseline, for the

ascertainment of prevalent STD, and the recording of background and behavioral data.

### Study Outcomes and Physical Specimens

The study STD outcomes are vaginal trichomoniasis and cervical chlamydia and gonorrhea infections. Chlamydial and gonococcal infections are diagnosed by ligase chain reaction (LCR) (Abbott Laboratories, Abbott Park, IL, USA) using urine specimens and following the manufacturer's instructions. The sensitivity and specificity of this test for chlamydia are 94% and virtually 100% respectively (14), superior to antigen tests and culture, although urine LCR does not distinguish between cervical and rarer urethral infection. LCR accuracy for gonorrhea diagnosis is estimated to be similar to that for chlamydia.

At each visit, women provide a urine specimen. The first 15–20 ml of voided urine are collected in sterile plastic urine collection cups, which are labelled and immediately placed on ice (2–8°C). Urine specimens in cool boxes arrive at the University of Nairobi Department of Medical Microbiology within 24 hours of collection: from field sites near Nairobi, specimens are transported to the laboratory on the day of collection; from more distant sites, the specimens are stored at 2–8°C and shipped by courier. The specimens are stored at –20°C or below at the laboratory, and processed within 30 days of collection.

Vaginal trichomoniasis is diagnosed by the InPouch™ TV test system (Biomed Diagnostics, San Jose, CA, USA) (15). This test has been found to be more sensitive than wet mount or traditional culture, and is technically easy and suitable for resource-poor settings (16, 17). Vaginal specimens are collected using swabs from the posterior fornix. The swab is immediately inserted into the pouch, which is maintained and transported at ambient temperature to the Nairobi laboratory. The specimen is incubated at 37°C for 18–24 hours and the pouch is examined microscopically under low power for motile trichomonads daily for up to 5 days.

The Department of Medical Microbiology promptly notifies clinic staff of positive test results. Infected women are confidentially notified by clinic workers and requested to return for treatment. The Kenyan Ministry of Health supplies the study with STD drug kits to ensure that study participants, and other plantation residents, are treated during the study period.

The 6-month and 12-month STD figures do not furnish true incidence rates: they miss asymptomatic infections that occur and resolve in the interim between lab tests; they do not account for treatment failures that allow persistent infection; and they lack precision on the timing of infection. Incidence estimates will derive from data on STD syndromes ascertained among all plantation workers.

### Study Size

Baseline STD prevalence data were not available from the study sites, so we reviewed findings from other cohorts in Kenya. The prevalences of cervical gonococcal and chlamydial infection among two series of Nairobi antenatal clinic attenders were 6.4% and 8.9% (18), and 9.6% and 7.9%, respectively (19). Among women attending family planning clinics in Nairobi, the prevalence of cervical gonorrhea was 3.2%, and 5.2% for trichomoniasis (20). In a randomized study of mass treatment of pregnant Nairobi women, 5.5% and 4.2% of control women were infected with chlamydia and gonorrhea, respectively (21). In a 1994 antenatal series in Nairobi, the prevalences of chlamydia, gonorrhea and trichomoniasis were 8.8%, 2.4% and 19.9% respectively (22). Finally, in a Nairobi family planning clinic, the prevalence of gonorrhea was 0.5% and 5.0% for chlamydia (23). All these studies used less sensitive methods for detecting the infections and probably underestimated the rates.

In study size calculations, we made the following assumptions. 1) The baseline prevalence of the three STDs will be 20% overall, comprising 5% gonococcal, 5% chlamydial and 10% trichomonal infections. 2) Because few infected male partners will come to the clinic for treatment, the incidence of infection will be sufficient to result in a similar prevalence of infection within 6 months at the control sites (3)<sup>1</sup>. The planned study size must have at least 80% power with an alpha of 0.05 (one-sided) to detect a prevalence difference of 10% between intervention and control communities at each time point, a halving of the rate. In the absence of accurate baseline data, we assumed that about a quarter of coital acts would be protected by male condoms, and that the proportion of protected acts would be doubled at the intervention sites.

In cluster randomization, the intracluster correlation (ICC) considers between-person and between-cluster variation jointly (24, 25). As it increases, the larger must be the study size to retain the same power as in a randomized trial of a like number of individuals. Along with the number of communities allocated to each condition, the ICC is the critical determinant of study size (26). Also, a longitudinal sample tends to be more powerful than repeated cross-sectional surveys (26, 27). Although intracluster correlation tends to be small, published estimates are rarely available.

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<sup>1</sup> Partner notification is done using the Ministry of Health system, with cards issued to index cases for their sexual partners. Unfortunately, partner notification is incomplete at most sites, one probable reason being women's fear of violent retribution. We too were concerned about violence against women. There was one case of a violent reaction by a sexual partner to the study participant's STD at baseline. The man was brought to the clinic and counseled, after which he allowed the woman to continue in the study. The service providers and site managers were able to intervene in these rare instances of violence.

**TABLE 1.** Study site requirements for female condom intervention trial

Intracluster correlation	Number per site	Number of sites	Total n required	Adjusted n <sup>a</sup>
0.020	100	10	1000	1333
0.025	160	10	1600	2133
0.025	100	12	1200	1600
0.030	500	10	5000	6667
0.030	120	12	1440	1920
0.035	300	12	3600	4800
0.035	100	14	1400	1867
0.040	220	14	3080	4107

<sup>a</sup>Allows for 25% loss to follow-up.

Our study size calculations varied the ICC, the number of study sites, and the number of women in each cohort (see Table 1). The final decision on study size factored in logistical considerations. Assuming an ICC of 0.03, we identified 12 sites, with a resulting study size of 1440 participants, adjusted to 1920 (160 per site) to allow for 25% loss to follow-up. A preliminary analysis was planned to assess the adequacy of the intracluster correlation estimate and other assumptions in the study size determination (results below).

### Information, Education & Communication (IEC) Program

It is critical to instruct and motivate potential users of the novel female condom, at the same time that male condom use is encouraged and STD information is disseminated. Also, the presence and activities of the study staff must be explained to often-skeptical plantation residents. The IEC program, designed to be uncomplicated and replicable, nevertheless includes multiple sources of information. The intervention lasts 12 months at all sites, targeting all sexually active members of the community and working to change community norms. We trained and operate through clinic service providers, community leaders, plantation managers, and outreach workers. The intervention disseminates a reinforcing set of messages on prevention and management: protect yourself; AIDS is a reality; condoms protect against STDs; there are male and female condom alternatives [intervention sites]; recognize the signs and symptoms of STD; comply with STD treatment; treatment of contacts is important. Information about male condoms is disseminated at both intervention and control communities, and male condoms continue to be freely available at multiple distribution points. Thus a *de novo* male condom program is not instituted, but rather the standard approach to STD prevention prevails as a control condition.

The theoretical basis of the intervention can be traced to theories of social learning and cultural change (28-30). These models suggest that the communication of innovative

ideas through certain channels over time within a social system can lead to sustained behavior change. This approach with multiple reinforcing messages and communication channels has been shown to enhance the adoption of family planning in Kenya.

**Message Development.** Prior to the initiation of fieldwork, a workshop was held for Kenyan family planning professionals to develop IEC messages to promote use of the female condom. Draft posters and brochures were pre-tested at non-study plantations, revised, printed, and then distributed throughout the study sites.

**Training of Service Providers.** The role of the counselor in motivating correct and consistent use has been observed in numerous contraceptive studies (31). This may be an especially cogent issue for female barrier methods, where women's discouragement due to initial difficulties in insertion and removal may be overcome with supportive counseling.

Before the study began, 5-day training sessions were organized for plantation clinic staff, covering: the study protocol and questionnaires; the informed consent process; and syndromic management of STDs. Staff were taught the proper placement and use of the female condom using anatomical models, the benefits of barrier use, and ways to motivate use of the device. A comprehensive list of problems and the range of user and partner reactions were discussed, with role-playing to model client concerns.

Three-day training courses instructed outreach workers at the sites in male and female condom use and condom motivation. These were generally contraceptive community-based distributors (CBDs) already in place at the plantations, who are a credible source of supplies and information on reproductive health in their communities.

**Folk Media.** The Family Planning Association of Kenya has established puppetry troupes for carrying out health education on family planning and STD prevention. These puppetry troupes were trained to enable them to develop skits about the female condom. In addition to these traveling troupes, most of the study sites have extant folk media troupes for family planning IEC, which were also trained to include messages on the female condom (at intervention sites).

**Community Orientation and Education.** Initial orientation meetings were held to introduce and promote the use of condoms and the risks of STDs. The puppetry troupes were instrumental in bringing large crowds for these initial contacts with study staff. Women and men were encouraged to ask questions about the study, and the device. Enrollment and data collection only commenced after these orientations. Community meetings, popularly known as "barazas," continue to disseminate information on the study, condom use, and STD prevention.

We expect the service providers, each of whom is paid a stipend, to set up group meetings and give regular lectures

on STDs. We also encourage frequent folk media presentations by means of competitions and prizes for the best songs and dances. The above events are not scheduled in advance, however. The family planning puppetry troupe based in Kisumu visits each site every 3–4 months to participate in barazas.

**Participant Training.** Study participants are encouraged to return to the clinic at any time to discuss problems incurred with the early use of the female (and male) condoms. Counseling makes use of pelvic models to demonstrate use of the female condom, and penis models for male condom use. Couples who come to the clinic together are counseled jointly.

Previous research has also shown the importance of encouraging women not to abandon the female condom early in use; some users have a relatively steep learning curve (32). Often women at high STD risk have not used other female barrier methods and may feel uncomfortable and inept at placing the female condom. The “three tries” guideline is stressed, encouraging women not to abandon the device until they have made at least three attempts to use it.

**Process Evaluation.** To evaluate the consistency of IEC activities at intervention and control sites, all group IEC activities are recorded monthly. The numbers of women counseled about the female condom by the clinicians are tallied, as are the numbers of condoms distributed by CBD workers. Process evaluation will measure the intensity of the IEC activities; will compare those activities at intervention and control sites; and will determine whether the IEC program conformed to the study protocol.

### Focus Groups

To enrich the study with qualitative data, focus group discussions (FGDs) were scheduled for three intervention sites soon after inception of the study activities, and then approximately 6 months later. After introduction of the female condom at the site, two groups of 8–10 women, and two groups of 8–10 men, are identified by service providers and selected purposively based on age and sex. Focus group participants are 18–50 years of age, willing to participate (oral informed consent) and willing to discuss frankly sexual matters. All sessions are facilitated by a Kenyan female researcher with experience in qualitative methods. Their initial reactions to and attitudes toward the device are explored, including issues of control, intimacy, comfort, empowerment, health promotion, knowledge of the body, and perceptions of partners. Community views of the intervention program are drawn out. The discussions are tape recorded and transcribed to complement the information gathered by the note takers. Data will be analyzed manually, tracking key themes raised during the discussion, and results from the earliest FGDs will be used to shape the messages in the intervention.

Independent of the FGDs, in-depth interviewing of opinion leaders will be done at the same sites. Seeking the opinions of community leaders should strengthen the intervention’s links with community, a crucial element in Kenya where the influence of community leaders is pronounced. In-depth interviews will be conducted with site management, village elders, religious leaders and teachers to solicit their ideas and secure their support. These interviews will be analyzed and reported along with the focus group data.

### Data Management

Data collection forms are carried from the field to the Department of Medical Microbiology in Nairobi, where double data entry is done in Epi-Info. Data files are transmitted electronically to FHI in North Carolina, USA, where they are loaded in the BBN Clintrial system for checking and querying, and exported to SAS analysis files.

### Analysis

The primary objective is to measure and compare STD prevalence rates in cohorts of women with and without access to female condoms. We are interested in the effect of adding female condoms to available male condoms for STD prevention, regardless of whether and how often the female condoms were actually used. We will conduct an intent-to-treat analysis in which all participants with needed data will be included for the primary analysis. Other sub-populations may be used in analyses for secondary objectives.

**Cohort Study: Primary Objective.** Sociodemographic features of the intervention and control cohorts will be compared within matched pairs, and pooled proportions will be calculated (33). We will measure and compare the prevalences of cervical and vaginal infection by assigned group. The dependent variable for analysis is STD infection; any participant with one or more of gonorrhea, chlamydia and trichomoniasis will be designated STD-positive. Prevalence will be measured at baseline and each follow-up visit (6 and 12 months). The independent or exposure variable is group assignment (intervention vs. control). Prevalence ratios will be estimated for these factors, with the control group as the referent. A weighted paired *t*-test approach will be used to compare prevalence between groups at 6 months and 12 months (34). The odds ratio and the corresponding confidence interval will be obtained (35), taking into account matching and clustering.

Finally, a mixed effect model will be used to adjust for confounders of group differences at each time point as well as over time. Random effects will be included in the model to account for the multilevel structure of the data (36). A multilevel model of the data assigns repeated measures of STD status to level 1, women to level 2, and community to level 3, with units on one level recognized as being grouped, or nested, within units of the next higher level.

**Cohort Study: Secondary Objectives.** To measure the impact of female condom introduction on the incidence of STD syndromes, cases of specific STD syndromes are recorded on tally sheets already in use at the sites, and incidence rates will be calculated using estimates of the denominator populations residing at the sites.

The impact of female condom introduction on male condom use consistency will be examined by comparing the self-reported proportions of coital acts with male condom use in the intervention and control cohorts. Although female condom introduction may result in some substitution of female for male condom use, the STD outcomes are of ultimate interest irrespective of which devices were used for protection.

The acceptability of the female condom will be evaluated by interviewing women in the intervention cohort sites along standard parameters: best and worst features; preferences for female or male condoms; frequency of use; time trend of use; problems encountered during use; and male partner reactions and preferences.

The cost of the female condom intervention will be assessed by summarizing the costs of the devices, study staff, and educational materials. Approximate numbers of STDs averted in the female condom cohorts will be estimated (if that result obtains), and the cost per prevented case and its expected sequelae will be computed.

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## BASELINE RESULTS

We summarized baseline data from all 12 sites to assess the accuracy of statistical assumptions made in study size determinations, and to monitor characteristics of the participants.

About 16% of women approached were unwilling to participate, and about 17% had not been sexually active in the preceding 3 months. Two-thirds of women approached (1929 of 3031) were eligible and agreed to participate; we collected full STD test information on 1922 women. Their mean age was 33.1 years, 60% were married, and 9% reported more than one sex partner in the past 3 months. Slightly over half were currently using contraception, with the most popular method being injectables (38%). Seventy-eight percent had never used a male condom.

The prevalences of gonorrhea, chlamydia and trichomoniasis were 2.6%, 3.2% and 20.4%, respectively. Trichomoniasis prevalence ranged from 11 to 30%, but was similar within pairs. The combined STD prevalence, accounting for concurrent infections, was 23.9%. The estimate of the intracluster correlation based on these data was near zero (37), showing that the variation between communities within a pair was similar to the variation within communities (34).

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## DISCUSSION

Intervention at the community level offers the opportunity to change group norms of sexual and preventive behavior. The program can operate simultaneously on the individual, community and infrastructural levels, by making available the prophylactic devices, increasing knowledge and encouraging safer sexual norms, and broadening the services available at clinical contact points (38).

Intervention research at the group level may be cost-effective, may avoid contamination of individuals assigned to the control condition, and may enhance the generalizability of the results (39). As with individual-level assignment, group randomization serves to balance known and unknown confounders. Pair matching minimizes imbalances in the relatively small number of randomization units (25). And comparison groups that do not receive the intervention guard against the possibility that changes are due to secular trends, rather than the intervention.

Although community and work-site interventions to reduce smoking and other risk factors for cardiovascular disease have generally had disappointingly minor impacts (40, 41) infectious diseases may be more amenable to large-scale intervention, in that cases prevented rebound to the benefit of other members of the cohort. Thus prevention at the individual level translates to primary prevention at the population level (42). A recent review of HIV prevention studies among women found that the majority of African studies reported reduced levels of risk behaviors in the intervention groups, mainly increased self-reported condom use (43). A large community intervention trial has demonstrated that improved STD treatment can reduce the incidence of HIV infection (33). Another community trial in Uganda on the impact of mass treatment of STD on HIV incidence had more disappointing results (44).

Our community intervention trial in Kenya is feasible. We have succeeded in identifying comparable pairs of study sites; gaining the cooperation of plantation management; designing the intervention program and IEC materials; hiring and training study staff; training clinical staff; providing sufficient female condoms and STD diagnostic tests; enrolling adequate numbers of participants; and identifying a high prevalence of the relevant STDs. The remaining threats to the success of the study relate to bias and power.

### Bias Considerations

Misclassification of the STD outcome variables is unlikely, as the study uses extremely accurate diagnostic techniques. Although the STD syndromes are an imperfect subset of all infections, misclassification should be similar in intervention and control sites. Misclassification of behavioral variables is possible, but we do not expect it to differ between the two experimental groups. Misclassification of exposure to the female condom may occur, since small numbers of

female condoms may be used by women in the control cohorts. The analysis will ignore such contamination, or diffusion of the intervention into control cohorts (45), which would lead to a reduced estimate of effect.

Selection bias can occur if participants with certain features and propensities for STD leave the study in disproportionate numbers. Loss to follow-up should not be great, however, given the stability of permanent employees on the plantations, and the relatively short follow-up period. Selective loss will be assessed by comparing features of women followed with those lost.

Detection bias can occur if women inserting female condoms are made more aware of symptoms of STD than non-users. This might in turn drive them to seek care between the regularly scheduled visits. If this prevails, it will serve to attenuate the protective effect of the female condom. The effect of multiple interviews and STD testing may change the behavior and risk profile of participants (27), but this should be similar in intervention and control cohorts.

### Power Considerations

Study power may be compromised if a high proportion of women use male condoms consistently, making it difficult to detect a difference in STD rates due to the female condom. Our baseline analysis found male condom use to be uncommon, however. Also, power will be reduced if an appreciable proportion of symptomatic women seek treatment away from the plantation clinics because of the perceived stigma of STD. Our study orientation and IEC efforts have emphasized that STDs are best treated at the plantation clinics, and that no social or employment repercussions will accrue. Finally, if STD rates are diminishing as part of larger societal trends, it may not be possible to detect a difference between intervention and control sites (40). No current evidence exists for such trends.

The results presented above indicate that the study size determined for the study will provide sufficient power to test the hypothesis of interest. First, the intracluster correlation is smaller than assumed for study size calculations (37). But a note of caution is needed. The intracluster correlation obtained here derives from baseline data, while the figure that will play a role during the final analysis will be calculated from follow-up prevalence data (i.e., after intervention). The baseline estimate is encouraging, and suggests that clustering effects are not a problem. Second, the STD prevalence found in this analysis is higher than that assumed in the study size calculations. A higher prevalence is associated with lower variance estimates. In addition, if the effect size were to be revised based on this estimate of prevalence, it is likely that we will be interested in a larger effect size, probably a halving once again. These factors point to increased power based on the current sample size. Recruitment of additional communities does not seem necessary.

In conclusion, this study parallels recent recommendations (46): it will measure the effectiveness of the female condom rather than its efficacy; it will test a program in which female condoms are offered along with male devices at the intervention sites; and it will measure STD impact at the community level. Results should be available mid-year 2000.

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