Short report

Baseline STD prevalence in a community intervention trial of the female condom in Kenya

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Objective: We present baseline sexually transmitted disease (STD) prevalence rates from an ongoing intervention trial at Kenyan agricultural sites.
Methods: After gaining the cooperation of management, we identified six matched pairs of tea, coffee, and flower plantations and enrolled approximately 160 women at each site. Six intervention sites received an information programme and distributed female and male condoms, while six control sites received male condoms only and similar information about them. At clinic visits, we tested participants for cervical gonorrhoea (GC) and *Chlamydia trachomatis* (CT) by ligase chain reaction on urine specimens, and *Trichomonas vaginalis* (TV) by culture. The study has 80% power to detect a 10% prevalence difference during follow up, assuming a combined STD prevalence of 20%, 25% loss to follow up and intracluster correlation coefficient (ICC) of 0.03.
Results: Participants at intervention and control sites (total 1929) were similar at baseline. Mean age was 33 years, the majority were married, more than half currently used family planning, 78% had never used male condoms, and 9% reported more than one sexual partner in the 3 months before the study. Prevalences of GC, CT, and TV were 2.6%, 3.2%, and 20.4% respectively (23.9% overall), and were similar at intervention and control sites. The ICC for STD prevalence was 0.0011. Baseline STD was associated with unmarried status, non-use of family planning, alcohol use, and more than one recent sexual partner, but the highest odds ratio was 1.5.
Conclusions: Baseline results confirm a high prevalence of trichomoniasis and bacterial STD at these Kenyan rural sites. Improved STD management is urgently needed there. Our ongoing female condom intervention trial is feasible as designed.
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Keywords: gonorrhoea; *Trichomonas vaginalis*; chlamydia; condoms; cluster randomisation

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Introduction

The polyurethane female condom is approximately as effective as other barrier contraceptives.[1] It is worn in the vagina, allowing the penis to move freely inside it, is compatible with oil or water based lubricants, but is more expensive than male latex condoms.

Epidemiological studies have reported lower sexually transmitted disease (STD) incidence in female condom users.[2 3] Acceptability studies have had encouraging results,[4] raising hopes that female condom availability may result in less unprotected intercourse. To date, however, studies have generally been small and short term.

We designed a large scale trial, employing a replicable intervention programme, to test the impact of female condom introduction on STD rates at agricultural units in Kenya. Here we report features of the cohort and baseline STD prevalence.

Methods

Full trial details appear elsewhere.[5] We identified six matched pairs of tea, coffee, and flower plantations with primary healthcare clinics. One plantation within each pair (intervention site) received the female condom intervention programme relying on group meetings, puppetry and other folk media, lectures, printed materials, individual counselling, and female and male condoms. Control sites received a similar prevention programme, excluding female condoms.

SITES

The plantations are located in western Kenya near Kericho, in the Nandi Hills, and near Naivasha; and in central Kenya near Thika. They were matched for three criteria—same commodity; same area; similar size. One site per pair was randomly assigned to the intervention condition.

PARTICIPANTS

We recruited permanent female employees aged 18–50 who are sexually active, not pregnant, and do not desire pregnancy in the coming year. We screened each woman, administered informed consent, received written agreement for participation, and tested each woman for gonorrhoea, chlamydia, and trichomoniasis. Infected women were treated and retained in the study. Participants were scheduled to make study visits at baseline, 6 months, and 12 months.

SIZE

Cohorts of approximately 160 women per site were drawn from randomly sorted employee rosters. The study has 80% power to detect a prevalence difference of 10% between intervention and control sites during follow up, with baseline STD prevalence of 20%, one sided α =0.05, 25% loss to follow up, and an intracluster correlation coefficient of 0.03 (a measure of variability within clusters compared with total variability, which can reduce study power).[6]

Table 1 Features of study participants at intervention and control sites (%)

Feature	Intervention sites (n=969)	Control sites (n=960)
Age:		
18–24	11.0	9.5
25–29	22.9	25.5
30–34	21.3	22.8
35+	44.8	42.2
Highest educational attainment:		
None	27.3	26.1
Primary	63.0	60.1
Secondary	9.7	13.9
Marital status:		
Married, living with spouse	44.1	34.2
Married, not living with spouse	7.9	12.1
Married, polygamous	12.7	9.1
Unmarried, regular partner	28.0	37.3
Unmarried, no regular partner	7.3	7.4
Number of living children:		
None	4.7	5.5
1–3	47.3	45.8
4+	48.0	48.6
Current contraceptive method:		
None	42.0	40.9
Oral contraceptive	10.1	7.8
Injectable	36.3	40.2
Other	11.6	11.1
Ever use male condom	23.9	20.7
Currently use vaginal douche	23.6	21.1
Currently take alcoholic beverages	12.7	15.9
>1 sex partner in past 3 months	8.6	8.8
No precautions to avoid STD	64.3	61.4

OUTCOMES

We diagnosed chlamydial and gonococcal infections by ligase chain reaction (LCx; Abbott Laboratories, Abbott Park, IL, USA) using urine specimens. We diagnosed vaginal trichomoniasis with the InPouch TV test system (Biomed Diagnostics, San Jose, CA, USA) using self swabs. Specimens were shipped to the University of Nairobi department of medical microbiology within 24 hours, with urine specimens in cool boxes and InPouch cultures at ambient temperature. We used the odds ratio (OR) to calculate the association of baseline factors with prevalent STD.

Results

We screened 3031 women and enrolled 1929 (64%). About 17% of women approached had not been sexually active in the preceding 3 months, 16% were unwilling to participate, 11% were pregnant or desired pregnancy, and 3% were unwilling to answer questions about sex.

Women at intervention and control sites were similar (table 1): mean age 33.1 years, mostly married, with mean 3.6 living children. Women at intervention sites were more likely to be married and living with spouses. More than half the women used family planning, the most popular being the injectable hormone depot medroxyprogesterone acetate.

We queried participants about behaviours that may be associated with STD (table 1). Less than a quarter of the women reported ever using a male condom. Less than one in 10 women reported more than one sexual partner in the preceding 3 months. Most reported no special precautions taken to prevent STD, generally claiming mutual monogamy and no need for preventive measures.

Table 2 Baseline sexually transmitted disease prevalences (%) by site

Matched pair No	Study arm (n at site)	GC	CT	TV	Combined
1 (Thika)	I (157)	1.9	3.8	19.8	24.2
	C (139)	5.8	5.0	21.6	27.3
2 (Kericho)	I (198)	1.5	1.5	21.6	23.6
	C (181)	6.1	3.9	23.8	29.8
3 (Naivasha)	I (142)	1.4	2.8	10.6	13.4
	C (163)	1.8	3.1	15.2	19.6
4 (Kericho)	I (128)	3.9	4.7	22.7	26.6
	C (152)	1.3	3.9	29.9	31.2
5 (Nandi)	I (184)	1.6	4.4	24.5	27.7
	C (162)	1.9	1.2	22.8	24.1
6 (Nandi)	I (158)	1.9	1.9	13.8	15.7
	C (158)	3.1	2.5	17.5	21.3

I = intervention (female condom plus male condom), C = control (male condom only); GC = cervical gonorrhoea; CT = cervical chlamydia; TV = vaginal trichomoniasis.

Among 1922 women with STD data, the prevalences of gonorrhoea, chlamydia, and trichomoniasis were 2.6%, 3.2%, and 20.4% respectively. Gonorrhoea prevalence was 2.0% at intervention and 3.3% at control sites; chlamydia prevalence was 3.1% and 3.2%; trichomoniasis prevalence was 19.1% and 21.8% respectively. The combined STD prevalence, accounting for concurrent infections, was 23.9% overall, comprising 22.1% at intervention and 25.7% at control sites.

Site specific prevalences of gonorrhoea ranged from 1.3–6.1%; chlamydia ranged from 1.2–5.0%; and trichomoniasis ranged from 10.6–29.9% (table 2). The lowest site specific STD prevalence was 13.4%, and the highest was 31.2%. The prevalence was higher at control sites in five of the six matched pairs, but the baseline intracluster correlation coefficient was 0.0011,[7] indicating a minimal clustering effect.[6]

In stratified analysis, unmarried women, non-users of family planning, women with more than one recent sexual partner, women with the least education, and current alcohol users all had elevated STD prevalence. None of these associations was strong, however (ORs from 1.2 to 1.5). STD prevalence was not associated with age, ever use of a male condom, or use in the past 3 months. Women who currently douched had a lower prevalence (OR=0.7). When we included the above factors in a multiple logistic regression model, the ORs changed trivially.

Discussion

Urban cohorts in Kenya have higher rates of cervical infection than in this study. STD data from rural Kenya are scant. In one primary healthcare centre, the prevalences of gonorrhoea, chlamydia, and trichomoniasis were 3.8%, 6.3%, and 10.9% respectively.[8] Our study documents high STD prevalence in a large rural cohort, although plantations are not representative of rural areas generally.

Less than one quarter of study participants had ever used a male condom. Male condoms have been freely available for years at the plantation clinics, through outreach, and in dispensers at common areas. But the outreach workers did not receive regular training or time off for motivation activities; some of the

condom dispensers were found to be empty at study initiation visits; and STD prevention was not a clear management priority and had withered. Effective means of reaching men and inducing more consistent condom use is an urgent need, as is sharper motivation of managers, and better STD management by service providers.

These baseline data confirm the feasibility of our community intervention trial. Power to detect a difference in STD prevalence during follow up should be ample, since male condom use is inconsistent, the intracluster correlation is small, and baseline STD prevalence is higher than assumed in study size calculations. Cluster randomisation has equalised known risk factors, and pair matching minimises imbalances in the relatively small number of randomisation units. The internal validity of these data appears sound: baseline STD was associated with unmarried status, having more than one recent sexual partner, and alcohol use. Misclassification of the STD outcomes is unlikely, given the high sensitivity and specificity of our tests.[9 10] Misclassification of sexual behaviour variables is probable, but should not differ between the two groups. Selection bias due to selective loss to follow up will be assessed.

Two community intervention trials for HIV prevention have recently been conducted in Tanzania and Uganda, with superficially conflicting results.[11 12] The magnitude of the STD epidemics in this region demands large scale intervention, while its relative poverty requires those efforts to be cost effective and replicable. Follow up results of our study will be known later in 2000. If female condom introduction leads to substantially reduced STD transmission, the Ministry of Health and international donor agencies will need to consider widening the availability and guaranteeing the affordability of the devices in this region with high STD prevalence among women.

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Before the fieldwork, the study was reviewed and approved by the Protection of Human Subjects Committee of Family Health International (FHI), and the ethics review committee of the Kenyatta National Hospital in Nairobi.

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Contributors: PJF, MK, and MW were centrally involved in all aspects of study design, implementation, and monitoring. JJB devised the specimen handling procedures, and hired and supervised the field team. MO trained the field staff, supervised the laboratory work and monitored the fieldwork. KAR monitored the informed consent procedures and conducted the data analysis. All authors participated in writing, editing, reviewing and approving the manuscript.

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