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ORIGINAL ARTICLE

## Condom use during a community intervention trial in Kenya

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**Summary:** We conducted a cluster-randomized community intervention trial at Kenyan agricultural sites to measure the impact of female condom introduction on sexually transmitted infection (STI) prevalence. We present male and female condom use data here. Six Intervention sites received a community risk-reduction campaign and distribution of female condoms and male condoms, while 6 Control sites received the same campaign with male condoms only. Male and female condom distribution increased throughout follow-up. Self-reported male condom use increased substantially during follow-up to over 60% of the participants. The proportion of consistent male condom users at Control sites was higher than at Intervention sites, 23% vs 14% at 6 months and 24% vs 22% at 12 months. At Intervention sites, 11% and 7% of women used the female condoms all the time at 6 and 12 months, respectively, while the percentage of female condom non-users grew. Male and female condom use was hindered by male partner objections; suspicion of the study and the devices among residents; and bias against condoms by clinic service providers. A large proportion of coital acts remained unprotected during the trial. Our female condom intervention did not reduce STI prevalence, compared with male condom promotion only.

**Keywords:** Female condoms, male condoms, cluster-randomized trial, intervention trial, Kenya

### INTRODUCTION

HIV/AIDS poses an unprecedented challenge to the health and development of countries throughout sub-Saharan Africa. Adult HIV prevalences of 10% or higher have been reported in 12 countries in the region, with Botswana, Zimbabwe and Namibia reporting that 20% or higher of their adult populations are infected with the virus that causes AIDS<sup>1</sup>. Primary prevention of new infections must remain a central focus of public health strategies<sup>2</sup>.

Male latex condoms are a centre-piece of any HIV prevention package, since they are effective, widely available outside clinical settings, relatively inexpensive, generally free of side effects, and relatively easy to use. Used consistently and correctly, male condoms are highly effective in reducing the risk of HIV and other STIs during sexual intercourse<sup>3,4</sup>, cutting the risk of transmission by as much as 96% according to a recent review article<sup>5</sup>.

Important progress has been made in making condoms available to targeted groups and the

general population via social marketing and other mass distribution strategies throughout the region. Results from population-based surveys over the past decade show that steadily more condoms are being used. Between 7% and 50% of unmarried men reported current use in Mozambique and Zimbabwe, respectively, with estimates for Eritrea (47%), Malawi (19%), Tanzania (22%), Uganda (32%) and Zambia (36%) falling within this range<sup>6</sup>.

Still, these increases in distribution and sales have been inadequate to stop the spread of HIV in the region<sup>7</sup>. Condoms are underutilized, and their consistent and correct use remains an elusive goal in many communities. We set out to increase male and female condom use and reduce STI prevalence in a randomized community intervention trial<sup>8</sup>. The STI prevalence results are reported elsewhere<sup>9</sup>; here we describe the consistency of male and female condom use by study participants during the trial, correlates of condom use, and forces that limited use.

### METHODS

Details of intervention trial design appear elsewhere<sup>10</sup>. Briefly, the study measured and compared

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STI prevalence in women with and without access to female condoms. We identified 6 pairs of communities (matched on agricultural product, geographical area, and size) from tea, coffee and flower plantations in western and central Kenya. One site per pair was randomly assigned to the Intervention arm (female condom plus male condom). The female condom intervention programme involved large and small group meetings, video presentations, puppetry and other folk media, printed materials, individual counselling, and female and male condom availability. Control arm communities received male condoms only, and a similar prevention programme excluding information on female condoms. The programme operated through clinic service providers, outreach workers, community leaders and plantation management, all of whom underwent varying degrees of pre-study training.

We recruited permanent female employees, 18–50 years old, who were sexually active, not pregnant and did not desire pregnancy in the coming year. Cohorts of approximately 160 women at each site were drawn from randomly ordered employee rosters. Women made study visits at baseline, 6 months and 12 months, at which time we conducted interviews and collected STI specimens. Each interview included a short set of questions about whether condoms were used in the 3 months before the visit; if so, how consistently; if not, the main reason why not; and whether a condom was used at the last intercourse. Throughout the study, the numbers of male and female condoms distributed monthly by outreach workers and at the clinics were compiled at each site.

We calculated and compared distributions of various features of women in the Intervention and Control arms at baseline and during follow-up. We used the odds ratio (OR) to calculate the strength of association of various factors with condom consistency. Adjusted Cochran–Mantel–Haenszel (CMH) test statistics were calculated for the association of covariates like marital status with condom use, controlling for study arm and study visit. To estimate the association of categorical variables like frequency of male condom or female condom use with study arm, study visit, and covariates like marital status or age groups, we used the Grizzle–Stamer–Koch (GSK) procedure in SUDAAN<sup>11</sup>. We calculated adjusted Wald-F statistics to test for the significance of the association of each factor with condom use.

At the baseline visit, we verbally presented the detailed study fact sheet to each volunteer individually, and received from each woman written agreement to participate. Study procedures were reviewed and approved by the Kenyatta National Hospital (Nairobi) Ethical Review Committee, and the Family Health International (FHI) Protection of Human Subjects Committee.

## RESULTS

### Characteristics of study participants

We screened 3031 women and enrolled 1929 eligible volunteers. Complete follow-up data were available for 1617 women (84%)<sup>8,9</sup>. Women at Intervention and Control sites were similar, with mean age of 33.1 years and a mean of 3.6 living children. The majority were married (65% at Intervention sites and 55% at Control sites), although not all lived with their spouses (8% did not live with their spouse at the Intervention sites, 13% did not live with their spouse at the Control sites). About 90% had completed primary school or less. More than half of the women (58%) used family planning, with injectable hormone depot-medroxyprogesterone acetate, the most popular method. Condom use was rare at baseline, with nearly 80% of the women reporting that they had *never* used a male condom. Less than 10% reported more than one sex partner in the past 3 months.

### STI prevalence results

Crude STI prevalence did not vary meaningfully by study arm, either at 6 months or 12 months, for any of the specific infections or for the aggregated STI outcome. Aggregate STI prevalence fell between baseline and the 6-month follow-up visit in both the Intervention and Control arms, and then stabilized between the 6-month and 12-month follow-up (Intervention prevalence 17.1% and 18.2%, Control prevalence 17.6% and 18.4% at 6 and 12 months, respectively)<sup>9</sup>. The lack of an intervention effect, and the substantial effect of study visit, were confirmed in logistic models for each STI outcome. Prevalence was similar according to marital status, but women who did not reside with a spouse (single or reside separately) had a higher aggregate prevalence of infection.

### Self-reported consistency of male condom use

The baseline prevalence of recent male condom use was about 10% among study participants in the Control arm and over 13% among those in the Intervention arm (Table 1). Only about 2% of women reported consistent male condom use at baseline.

Use of male condoms was reported by over 60% of the participants in both study arms at 6 months, and consistent use was around 20% (Table 1). A greater proportion of women at the Intervention sites reported *any* use of male condoms, and the proportion using male condoms half of the time or more than half of the time was higher in the Intervention arm at 6- and 12-month follow-up. But the proportion of *consistent* male condom users in the Control arm was higher than in the Intervention arm at both visits, 23% vs 14% at 6 months and 24% vs 22% at 12 months. At the same time, women at Control sites were also more likely to report

Table 1. Levels of male condom use (%) in the last 3 months by study arm and study visit

Level of male condom use	Baseline		6 month visit		12 month visit	
	Control (n=960)	Intervention (n=969)	Control (n=856)	Intervention (n=881)	Control (n=798)	Intervention (n=797)
Not used*	90.0	86.6	39.8	31.9	42.7	28.9
< Half the time	4.1	6.9	23.1	27.8	20.8	25.7
About half the time	2.5	2.7	7.6	14.2	6.4	11.9
> Half the time	1.6	1.4	6.9	11.8	5.8	11.8
All the time	1.9	2.4	22.6	14.3	24.3	21.7

\*At baseline, includes women who reported never having used a male condom and women who did not use condoms in the last 3 months; during follow-up includes women who did not use male condoms since the last visit

never using male condoms in the preceding months at both visits (43% vs 29% at 12 months at Intervention sites).

Consistent male condom use was somewhat more prevalent in single women than married women ( $P=0.26$ , CMH statistics stratified by study arm and study visit), and more prevalent in women  $\leq 30$  years of age than older women ( $P=0.06$ ). In multivariate models of the consistency of male condom use during the 3 months before follow-up interview, the effects of study arm ( $P=0.02$ ) and study follow-up visit ( $P=0.04$ ) were statistically significant, while those of age group ( $P=0.37$ ) and marital status ( $P=0.85$ ) were not.

Use of a male condom during the last coital act prior to interview increased from about 5% at baseline to 30% at 6 months and 34% at 12 months among participants in the Control arm. In the Intervention arm, 6% reported using a male condom in the last coital act prior to baseline interview, rising to 34% and 42% at 6- and 12-month visits, respectively. Male condom use at last coitus was 2-4% higher among unmarried than married women. In a multivariate model of male condom use at last coitus, the effect of study visit was important ( $P=0.00$ ) as was marital status ( $P=0.03$ ), but study arm was less strongly associated ( $P=0.33$ ).

#### Female condom use in the Intervention arm

At 6 months, 39% of women at Intervention sites reported never using the female condom, and 11% reported consistent use (Table 2). At 12 months, the corresponding percentages were 58% and 7%. The main reason given by women for not using female condoms consistently was partner objection (29% at 6 months and 30% at 12 months). The second most common reason was 'didn't need protection/mutually faithful with partner' (8% and 9%, respectively).

At each visit, the unmarried study participants were approximately as likely as the married ones to report using female condoms; use differed little according to whether the woman lived with a spouse or not. Younger study participants were

more likely to report any use of female condoms than older ones, but the difference was not statistically significant. By contrast, consistent users of the female condom tended to be older than inconsistent users. In models of the frequency of female condom use, the effects of follow-up visit ( $P=0.15$ ), age group ( $P=0.24$ ) and marital status ( $P=0.34$ ) were not statistically significant.

Over 80% of female condom users liked the devices very much or fairly well at both 6- and 12-month interviews. Among women who had used both products, about 3 times as many preferred the female condom to the male condom than preferred the male device. The proportions of women who reported problems using female condoms diminished from the 6- to the 12-month visits. Almost 80% of female condom users would recommend them to friends and over 86% would pay for female condoms in the future.

#### Substitution of female condom for male condom use

We found no clear evidence of substitution of female condoms for male condom use. Cross-classifying the consistency of male condom use by female condom use showed a strong negative correlation, since the 2 methods cannot be used simultaneously. Ten per cent of women at Intervention sites reported not using any male or female condoms at 6 months; 15% reported not using either condom at 12 months. But female condom

Table 2. Level of female condom use (%) in the last 3 months among women at the Intervention sites by study visit

Level of female condom use	6 month visit (n=881)	12 month visit (n=797)
Not used*	38.6	57.8
< Half the time	29.6	20.8
About half the time	11.1	7.9
> Half the time	9.2	6.2
All the time	11.5	7.3

\*Includes women who did not use female condoms since the last visit

introduction had no apparent deleterious effect on male condom use, as the latter increased substantially at Intervention sites even with the availability of female devices. Tracking total (male and female) condom distribution by site (Figure 1) shows that in 3 matched pairs, monthly total condom distribution was higher at the Intervention site, while in the other 3 matched pairs condom distribution was higher at the Control site.

### Validity of condom self-reports

We addressed the accuracy of participants' self-reports in 2 ways. First, we compared interview data on coital frequency with total condom distribution figures. Participating women reported a mean of just over 2 coital acts per week during follow-up, or 8–9 per month, or 800–900 per 100 persons per month. The average number of male condoms distributed in the Control sites increased from about 300 to over 500 per 100 adults per month by study's end (i.e. 5 per person per month; Figure 2). At the Intervention sites, the average number of male condoms distributed varied more but averaged about 400 devices per 100 adults (Figure 2). Female condom distribution also increased during follow-up (Figure 3), reaching slightly over 200 devices per 100 adults per month. If all plantation residents had the same pattern of coital activity as the study participants, half or more of all coital acts during the study could have been protected by condoms, supporting the interview self-reports.

Second, we examined the prevalence of STI in the subgroups of women reporting consistent male condom use *vs* inconsistent or non-use, and the same comparison in subgroups of female condom users. There were only minor differences in prevalence between consistent and inconsistent users, raising doubts about the validity of those same self-reported condom use data.

## DISCUSSION

Few trials to increase condom use have been attempted, and there is a paucity of data describing the components of an effective condom promotion campaign, the correlates of consistent use, or its STI impact. Women enrolled in our study were relatively naïve to condom use at baseline, but our efforts to promote and distribute condoms were relatively successful. During a 12-month period, reported non-use of condoms among participating women declined by nearly two-thirds in both the Intervention (60%) and Control (72%) arms. There was a nearly 10-fold increase in reports of consistent condom use in both arms; by 12 months over one-fifth of the women in both the Intervention and Control arms were reporting consistent condom use. Enrolled women underwent accurate testing and received effective treatment, and a significant investment was made to

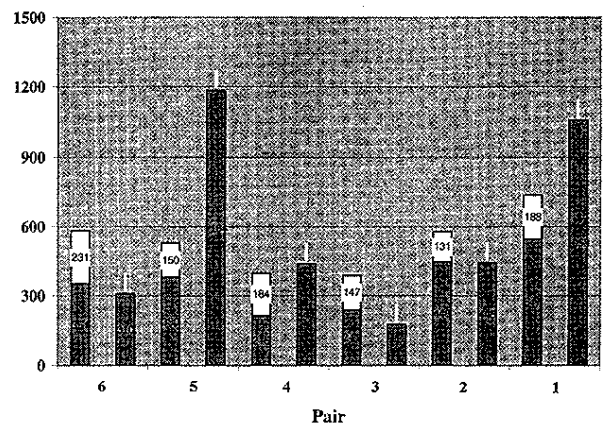


Figure 1. Mean monthly male and female condom distribution per 100 adults by matched pairs. □ female condom, ■ male condom

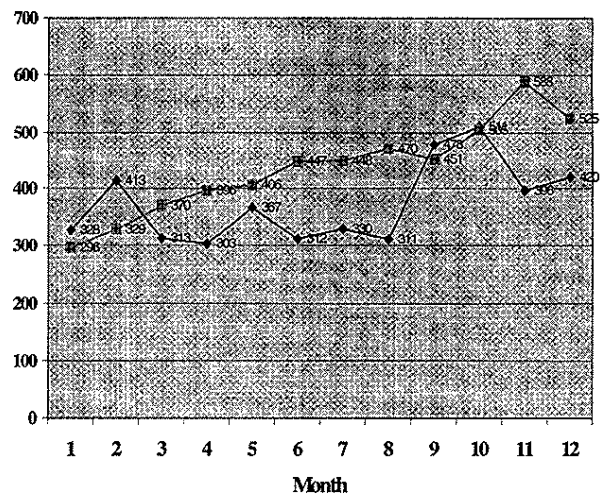


Figure 2. Mean number of male condoms distributed per 100 adults per month. ◆ Intervention, ■ Control

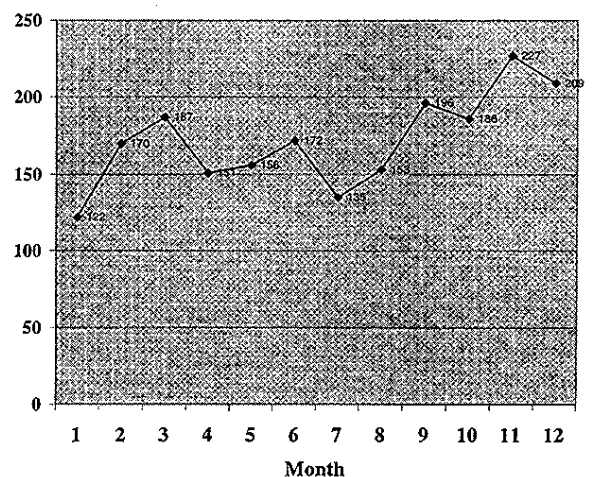


Figure 3. Mean number of female condoms distributed per 100 adults per month

train providers to diagnose and treat STIs among all clinic attenders using the national syndromic algorithms. Still, the prevalence of the measured STIs proved resistant to our programme. What went wrong?

On the STI management side, our inability to trace a substantial proportion of sexual partners of index cases guaranteed that a large reservoir of (primarily trichomonal) infection would remain in place during the observation period, generating a high incidence of infections throughout our cohort.

Turning to the prevention side, several forces operated to hinder condom use during our community trial. A large proportion of trial participants was married; the ability of married women to use condoms regularly is limited as issues of trust in a marriage decrease the ability of either partner to introduce condoms into the relationship<sup>12</sup>. Condoms remain a relatively unpopular means of fertility control for women in Kenya, particularly married women<sup>13</sup>.

At the same time, community interviews indicated that many single women engage in sexual relationships partly for financial reasons. Single women at the plantations, especially those with children, have difficulty paying for family necessities and form sexual links that yield small payments and/or foodstuffs. This dependence would serve to reduce the women's bargaining power to introduce condom use.

We expected that the female condom would become a popular alternative to male latex condoms, since the larger plastic device allows greater sensation and is preferred by a substantial proportion of new users<sup>14</sup>. We found, to our dismay, that male objection was the most commonly cited reason for non-use of the female condom. Furthermore, fewer women were able to use the female condoms as follow-up continued. Although users generally rated the device positively, the devices were being distributed to an ever shrinking pool of users.

That said, the validity of the condom use self-reports must be questioned. Retrospective questionnaire data collection tends to under-report numbers of sexual acts and condom uses, and agrees well with prospective diary data only for simple, yes/no items<sup>15</sup>. Social desirability impels respondents to over-report condom use. Our questionnaire did not inquire about numbers of condom-protected acts, but only rough proportions of condom use. Although the dichotomized use/non-use item should be accurate, it is not clear if the self-reports exaggerated the proportions of condom use. Condom distribution figures indicate that condom use increased plantation-wide throughout the study.

Yet even if we accept the broad accuracy of the condom data, there persisted a powerful force of infection at these sites. Despite the notable increases in reported condom use, approximately 80% of the women remained inconsistent users. If

the per-partnership probabilities of gonorrhoea and chlamydia acquisition are 50% and 20%, respectively<sup>16</sup>, with a similarly substantial figure for trichomoniasis, and half or more of coital acts are unprotected, STI prevalence can rebound even in a relatively short 6-month interval.

Qualitative data collection conducted in parallel with these quantitative efforts revealed widespread negative perceptions about condoms in the communities. Some community leaders, including service providers, believed that condom distribution encouraged promiscuity and that persons who have extramarital sexual contacts would be monogamous if condoms were unavailable. Other complaints about condoms included breakage rates, the 'unnaturalness' of sex with condoms, their impracticality in a setting where men decide when and how to have sex, and the vicious rumour that condoms are laced with HIV or other microbes. Service delivery assessments during the trial found that clinic-based condom promotion was infrequent. Providers who promoted condoms generally regarded the devices as disease-preventive only, and some shared the view that STI risk is a sign of immorality and culpability. The majority of providers stated that the female condom was unsuitable for most women.

Low condom use remains pervasive in the region. Nuwaha and colleagues conducted an observational study among patients receiving services for STI complaints in Uganda. Nearly 60% of the sample reported ever using a condom, while only about 15% of the sample reported using one at last act of intercourse<sup>17</sup>. Adih and Alexander found that only 25% of the respondents in a cross-sectional sample of Ghanaian adolescents age 15–24 reported using a condom at last act of intercourse<sup>18</sup>. Bakari *et al.* reported that over 80% of the Tanzanian men interviewed never used condoms despite the fact that a relatively high proportion of the respondents (37%) reported an extramarital relationship during the 3 months prior to the interview<sup>19</sup>. Low reported levels of use were found in Nairobi STI patients, where Ndinya-Achola and colleagues found only 3% condom use<sup>20</sup>.

Our study raises questions about condom promotion campaigns in the general population. The condom use increases observed were noteworthy but insufficient to bring STI prevalence below 15% in either the Intervention or Control arms. STI interventions have had disappointing results; even those rightfully regarded as successful reported fairly modest reductions in prevalence<sup>21</sup>. For some time, STI modellers have pointed to the importance of a package of interventions<sup>22</sup>, which should include condom promotion and availability, enhanced systems for STI management, and behaviour change communication. Even successful condom promotion, without accompanying behaviour change and more widespread STI diagnosis and treatment, may not be enough to bring STIs

below a critical threshold in populations similar to the high-prevalence one in which this trial was conducted.

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Welsh, Feldblum, Kuyoh and Mwarogo were centrally involved in all aspects of study design, implementation and monitoring. Kungu supervised the fieldwork and joined in informed consent and the participant interviews. All authors participated in writing, editing, reviewing and approving the manuscript.

Mr Stephen Mucike of the Family Planning Association of Kenya helped design the intervention. Ms Kelley Ryan of FHI helped design the data collection forms, monitored the informed consent process, and analysed the baseline data. We are particularly grateful for the untiring efforts of field study staff, Ephel Khasandi, Nancy Maina, Catherine Wandera, and Joel Mutai. We thank Mario Chen-Mok and Hany Zayed for statistical support.

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