

SEX WORK

A prospective study assessing the effects of introducing the female condom in a sex worker population in Mombasa, Kenya

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Objective: To assess the impact and costs of adding female condoms to a male condom promotion and distribution peer education programme for sex workers in Mombasa, Kenya.

Design: A 12 month, prospective study of 210 female sex workers.

Methods: We interviewed participants about their sexual behaviour every 2 months for a total of seven times and introduced female condoms after the third interview. We also collected cost data and calculated the cost and cost effectiveness of adding the female condom component to the existing programme.

Results: Introduction of the female condom in an HIV/AIDS prevention project targeting sex workers led to small, but significant, increases in consistent condom use with all sexual partners. However, there was a high degree of substitution of the female condom for male condoms. The cost per additional consistent condom user at a programme level is estimated to be \$2160 (£1169, €1711) (95% CI: 1338 to 11 179).

Conclusions: The female condom has some potential for reducing unprotected sex among sex workers. However, given its high cost, and the marginal improvements seen here, governments should limit promotion of the female condom in populations that are already successfully using the male condom. More research is needed to identify effective methods of encouraging sex workers to practise safer sex with their boyfriends.

Condom use is widely recognised as the primary mode of HIV prevention among high risk populations. However, male condoms are stigmatised in Kenya, even among men who are known to frequent sex workers.¹ Male condom use with regular clients and boyfriends of female sex workers is particularly low.^{2,3}

The female condom has been proposed as an alternative to the male condom for couples who do not wish to use the male condom. Numerous studies have indicated that sex workers find the device an acceptable, and sometimes preferable, method to the male condoms.^{4–7} Recent qualitative research in Mombasa, Kenya, revealed that sex workers were willing and able to introduce the female condom to partners with whom they do not consistently use male condoms, such as regular clients and boyfriends (Toroitich-Ruto, Brelsford, Thomsen, unpublished manuscript). However, because female condoms cost more, if they substitute for male condoms, the overall costs of a prevention programme would increase without increasing the overall proportion of protected acts and averting infections.⁸ We carried out a 12 month prospective study of the effects and costs of adding female condoms to an existing male condom promotion and distribution project for sex workers in Mombasa, Kenya.

METHODS

Design

We used a prospective design with three pretests (O₁–O₃) and four post-tests (O₄–O₇). We did not have a control group because the sex worker population in Mombasa is a relatively small, enclosed community. Therefore, there was a high risk that individuals in a control group would obtain female condoms from their colleagues.

Study site

Participants lived and/or worked in the Kisauni division of Mombasa District, a major sea port and trucking centre on

the Trans-East African highway. Kisauni, a popular tourist spot, is characterised by many bars, guesthouses, and discos. Most sex workers are street or bar based, and charge between \$5 and \$55 per client. Their regular clients (someone who they see on a regular basis and who is usually expected to pay for sex) and boyfriends (don't pay for sex) are often employed in local factories or are *matatu* (minibus) touts.⁹

Population

We recruited participants through an existing HIV prevention peer education project run by the International Centre for Reproductive Health in Mombasa. Peer educators provided a list of 329 peer sex workers (out of a potential 2382 sex workers identified by the programme in Kisauni) with whom they had regular contact. The study team then selected a random sample of 255 sex workers who were asked to come to the recruitment centre for screening. We enrolled the first 210 who were eligible according to study inclusion/exclusion criteria. Written informed consent was obtained at study entry. The ethics committees of Kenyan National Hospital and the sponsoring institution in the United States approved the study.

Procedures

Peer educators asked the selected potential participants to come to a community resource centre for sex workers in Kisauni. Women who fulfilled the inclusion criteria were interviewed on their sexual behaviours every 2 months for 1 year. At the first and last interviews, trained nurses instructed them to self swab for vaginal fluids, which we later analysed for prostate specific antigen and compared them with self report of condom use. The results of these analyses are presented elsewhere.¹⁰

Intervention

The intervention consisted of female condom education through peer education and IEC (information, education,

communication) materials, as well as the provision of female condoms. Four months after enrolment in the study, each participant received 20 female condoms per month for 8 months free of charge via her peer educator. Additional condoms were distributed by study personnel during interviews when it was discovered that the participant had run out or had not received her quota from the peer educator.

The female condom was introduced into an existing peer education programme with female sex workers, where activities included weekly group and spontaneous individual education on sexual and reproductive health topics. IEC materials were developed to highlight the role of male and female condoms in STIs, including HIV, and pregnancy prevention. In particular, sex workers were encouraged to always use a condom, even with a steady partner, and to first use a male condom, but to try a female condom if that did not work.

Study outcomes and analyses

Condom use

The primary outcome was consistent condom use (every sex act protected) with all sexual partners in the 7 days before each interview. This outcome was chosen because of the importance of 100% condom use among populations at high risk for HIV, such as sex workers. The 7 day time period was chosen because of previous work with this population, which indicated that sex workers could comfortably count clients back this far, but not farther.¹¹ Secondary outcomes of interest were the number and proportion of protected sexual acts with different partner types.

The homogeneity of the proportion of consistent condom use with all partners before the introduction of the female condom and at the end of the intervention (visits O₃ and O₇), was tested in a one sided McNemar test with 0.05 significance level. The odds of consistent condom use in the last 7 days during the post-intervention period relative to the pre-intervention visits were estimated in bivariable and multivariable logistic models for repeated measures. Covariates included age, type of sexual partners (casual, regular, or boyfriend), having ever been pregnant, use of condoms for contraceptive purposes, and numbers of partners at baseline. Odd ratios and their 95% confidence intervals were calculated.

Significance tests were two sided (unless noted otherwise) at the 0.05 level. The statistical package used was SAS, version 9.

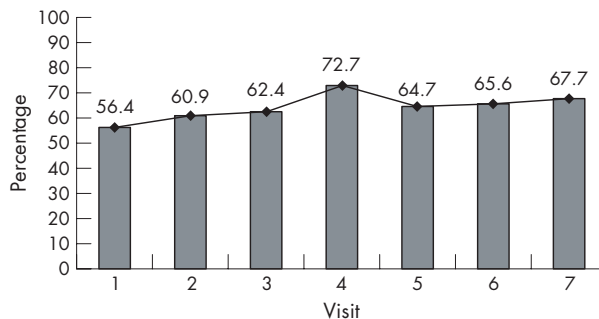


Figure 1 Percentage of participants reporting consistent condom use with all partners by study visit. The female condom was introduced immediately after visit 3. Adjusted OR for consistent condom use after female condom introduction was 1.7 (95% CI: 1.4 to 2.2) unadjusted estimate was 1.5 (95% CI: 1.2 to 1.9).

Cost data

The cost analysis was designed to determine (a) what additional resources would be required to support provision of female condoms through an existing peer promotion programme, and (b) the cost effectiveness of the intervention. In consultation with programme personnel, we identified the resources used during the intervention and assigned a cost to each resource. We used this information to first compute the cost of the study intervention serving the study participants and then estimated the annual cost of serving the 2382 sex workers identified in Kisauni. This included annualising capital expenses and scaling up the supplies to reach a larger population. This estimate was used to assess the cost effectiveness of adding female condoms at the programme level. (Equipment and training costs were annualised using expected useful life of investment (3–10 years depending upon type of equipment and 3 years for training) and a discount rate of 8.9% representing the treasury bill rate from the Central Bank of Kenya during the intervention (www.centralbank.go.ke/treasurybills/results.asp).

Data were analysed using MS-Excel spreadsheets.

RESULTS

Analysis population

A total of 210 sex workers were recruited in the study from January to February 2004. At 12 months 92% (195/210) were

Table 1 Number and percentage of study participants with consistent/inconsistent condom use in the last 7 days before and after female condom (FC) introduction by time period and type of partner including test of homogeneity over time

Type of partner	Before FC introduction (O ₃)	After FC introduction (O ₇)				Total		McNemar test statistic	p Value*
		Inconsistent (any act unprotected)		Consistent (all acts protected)					
		No	(%)	No	(%)	No	(%)		
All	Inconsistent	35	23.49	25	16.78	60	40.27	1.55	0.04
	Consistent	14	9.40	75	50.34	89	59.73		
	Total	49	32.89	100	67.11	149†	100.00		
Casual clients	Inconsistent	0	0.00	1	0.91	1	0.91	NA	NA
	Consistent	0	0.00	109	99.09	109	99.09		
	Total	0	0.00	110	100.00	110	100.00		
Regular clients	Inconsistent	0	0.00	5	6.41	5	6.41	1.33	0.05
	Consistent	1	1.28	72	92.31	73	93.59		
	Total	1	1.28	77	98.72	78	100.00		
Non-paying boyfriends	Inconsistent	34	43.04	9	11.39	43	54.43	0	0.5
	Consistent	9	11.39	27	34.18	36	45.57		
	Total	43	54.43	36	45.57	79	100.00		

*One sided p value for the extent of agreement between condom use before and after female condom introduction.

†Two participants are excluded because of unavailable consistency data with all partners at O₇.

followed up. Present at both O₃ and O₇ were 151 (71.9%) who were included in the McNemar test for primary analysis of consistent condom use. All participants who were present at O₁ and at least one other visit were included in the bivariable and logistic models for consistent condom use (n = 196; 93.3%).

Background characteristics

The average study participant was 29 years old, had been pregnant, and was using at least one method of contraception (data not shown). Of these, the majority used male condoms for contraception (76%), one third used injectables, and 23% used oral contraceptives. In the 7 days before study enrolment, study participants reported having, on average, coitus with five casual clients, two regular clients, and one boyfriend. Almost 11% reported having been physically assaulted by a sexual partner in the last 12 months. There were no differences in baseline characteristics between the included and excluded primary or secondary analysis populations with regard to age, marital status, parity, contraceptive use, or self report of STIs.

Consistent condom use

Of the 151 participants at O₃ and O₇, 149 participants had consistency condom data. In this group, the proportion of participants reporting consistent condom use with all partners increased from 59.7% (89/149) (table 1) just before female condoms were introduced, to 67.1% (100/149) at the last visit (p = 0.04). This increase was because 42% (25 of 60) of the previously inconsistent condom users became consistent users at the final visit. Of those who were previously consistent condom users, 16% (14 of 89) reported inconsistent condom use at the last visit. Within specific partner types, we only saw a change in consistent condom use with regular clients (94–99%; p = 0.05). Eight women reportedly never used condoms.

In the logistic model for consistent condom use the likelihood (odds ratio) that a participant would become a consistent condom user after the introduction of the female condom was 1.7 (95% CI: 1.4 to 2.2). Figure 1 shows the percentages used in the logistical models.

Comparing the women who reported inconsistent condom use at the end of the study (n = 50) with reported users (n = 116), we found inconsistent users to be more likely to have a boyfriend or a larger number of partners than the consistent condom users.

Number of clients

The mean number of casual clients in the 7 days before the interviews decreased steadily from 4.9 during recruitment to 2.5 a year months later (table 2). This decrease was statistically significant (p < 0.001). Similarly, the mean number of regular clients decreased from 1.9 at recruitment to 1.3 at the last visit (p < 0.001). There was a steady downward trend over the whole study for both of these decreases. The average number of sexual partners who were boyfriends remained around one during the study.

Unprotected sex acts

Study participants reported a declining mean number of unprotected coital acts with all partners over time: 1.7 before the female condom introduction to 1.4 after (p = 0.01) (table 2). Similarly, the mean number of coital acts decreased from 13.3 during the three pre-intervention observations to 10.1 during the post-intervention visits (p < 0.001). The trend over the whole study period (before and after female condom introduction) was steadily downward.

In looking at specific types of partners, the mean number of total and unprotected coital acts with casual and regular

partners, but not boyfriends, declined over time. The observed decreases all followed the same downward trend starting in the male condom phase of the study.

Male versus female condom use

The proportion of sex acts protected by male condoms decreased from 84.3% before the introduction of the female condom to 56.5% after (p < 0.001) (table 2). The declines in male condom use were offset by the increases in female condom use. However, female condom use did experience a steady downward trend after its introduction (from 34.9% to 29.4%).

Costs

The total cost of the 9 month intervention was \$54 139 (£29 453, €42 622.8) or approximately \$258 per participant (table 3). When scaled up to reach the 2382 sex workers in the Kisauni division, the annual cost for female condom promotion is estimated to be \$380 081 or about \$160 per person

Using the increase in the number of sex workers reporting consistent condom use after the introduction of the female condoms as the effectiveness measure (and adjusting the observed increase in consistent condom users from 11 to 16 to simulate no loss to follow up in a non-study population) (the 95% confidence interval for this increase is three to 25 additional consistent condom users), we calculated cost effectiveness. The first row in table 3 shows the incremental cost per additional consistent condom user, which was \$3384. When the intervention is scaled up to include the whole programme in Kisauni (row two), the estimated incremental cost per additional user is \$2160. The majority of costs for the female condom promotion programme are for the female condom commodities. Therefore, the cost of the programme is sensitive to the extent of substitution of female condoms for male condoms. The third row of this table shows a hypothetical situation whereby the number of female condoms required is reduced by 50%, owing to less substitution, reducing the estimated incremental cost per additional consistent condom user (row three) to \$1140.

DISCUSSION

Introducing the female condom into a male condom programme resulted in a small, but significant, increase in the proportion of sex workers reporting 100% condom use with all partners. This result replicates what has been found in other sex workers,^{12 13} and high risk populations^{14–16}—namely, that complementing male condom promotion programmes with the female condom increases reported condom use. However, these increases have not always been accompanied by decreases in sexually transmitted infections.^{13 16} This discrepancy usually gives rise to a discussion on the validity of self reported condom use.¹⁷ Our analyses of the prostate specific antigen (PSA) samples at baseline and the final follow up indicated that although there was under-reporting of unprotected sex, these levels remained constant during the study, implying that the changes that we witnessed in consistent condom use were real.¹⁰

While over-reporting of protected sex may not have influenced the consistent condom use outcome, it is possible that contact with the research staff could have been responsible for some of the other positive effects of the intervention that we observed. For example, the reported number of casual and regular clients decreased by 50%, and 30%, respectively, during the study, although this was not a specific objective of the intervention. Similarly, the reported total number of coital acts and the number of unprotected acts with all partners decreased over time by 25% and 20%, respectively. Discussions with the sex workers after the study

Table 2 Mean number of clients, coital acts, and unprotected coital acts (SD), by partner type and study visit, and percentage of coital acts protected by male and female condoms in the last 7 days, by study visit

Covariates	Study visit														p Value					
	O ₁		O ₂		O ₃		O ₁ -O ₃		O ₄		O ₅		O ₆			O ₇		O ₄ -O ₇		
	No		No		No		No		No		N	No		No			No		No	
Number of subjects	196		185		191		196		185		186		179		184		193			
Number of clients in last 7 days	4.9 (5.61)	4.5 (4.61)	3.3 (4.08)	-	3.5 (4.22)	2.7 (2.71)	2.4 (2.83)	2.5 (3.09)	0.0009*											
Casual	1.9 (2.34)	1.6 (1.98)	1.2 (1.2)	-	1.3 (1.31)	1.1 (1.2)	1.1 (1.18)	1.3 (1.41)	<.0001*											
Regular	0.9 (0.81)	0.8 (0.69)	0.7 (0.59)	-	0.7 (0.55)	0.7 (0.57)	0.7 (0.56)	0.7 (0.56)	0.109*											
Boyfriend	1.42 (0.93)	1.50 (1.00)	10.7 (0.66)	-	11.3 (0.6)	10.2 (0.59)	9.9 (0.56)	9.0 (0.63)	<.0001†											
Number of coital acts	8.7 (0.77)	8.2 (0.68)	6.3 (0.53)	13.3 (0.51)	6.6 (0.54)	5.5 (0.45)	5.1 (0.44)	5.0 (0.45)	<.0001†											
Casual	4.9 (0.32)	4.9 (0.40)	3.5 (0.23)	7.7 (0.39)	3.5 (0.22)	3.3 (0.22)	3.3 (0.19)	3.3 (0.25)	<.0001†											
Regular	3.7 (0.26)	4.4 (0.29)	3.8 (0.25)	4.0 (0.15)	3.4 (0.21)	3.9 (0.23)	4.1 (0.25)	3.7 (0.30)	<.0001†											
Boyfriend	1.7 (0.23)	1.7 (0.24)	1.5 (0.20)	1.7 (0.13)	1.1 (0.17)	1.4 (0.20)	1.6 (0.24)	1.3 (0.21)	0.015†											
Number of unprotected coital acts	0.4 (0.18)	0.1 (0.04)	0.0 (0.01)	0.2 (0.06)	0.0 (0.00)	0.0 (0.00)	0.0 (0.02)	0.0 (0.0)	0.0003†											
Casual	0.3 (0.08)	0.2 (0.09)	0.2 (0.08)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.02)	0.0 (0.03)	<.0001†											
Regular	1.7 (0.19)	2.1 (0.26)	2.0 (0.26)	2.0 (0.26)	1.5 (0.23)	2.0 (0.26)	2.1 (0.30)	1.9 (0.29)	0.260†											
Boyfriend	84.8	84.5	83.6	84.3	55.6	57.2	56.7	56.6	<.0001†											
% All coital acts protected by male condoms	0.6	0.8	0.0	0.5	34.9	29.1	27.4	25.7	<.0001†											
% All coital acts protected by female condoms																				

*p Value for the difference across visits.

†p Value for the difference between the average of visits O₁-O₃ and the average of visits O₄-O₇.

revealed that the participants may have been positively influenced by their numerous contacts with study personnel, both because the process of counting sex acts raised their awareness of how much (sometimes unpaid) sex they were having, and because study personnel also provided information on sexual health after the interviews were completed, according to the study protocol. This fact, combined with the fact that most of the downward trends started before the introduction of the female condom, raises questions about the degree to which the female condom was instrumental in the decline of some of these risky behaviours. However, it cannot be denied that a sharp drop in the number of unprotected coital acts, and a sharp increase in consistent condom use, was observed directly after the introduction of the female condom, indicating some effectiveness.

Other limitations to this study were the small study size and the pre-post intervention design. The small study size was a result of budgetary constraints in a study where participants come from a highly mobile population, and thus need to be followed up every 2 months in order for them not to go missing. It is because of this intensive follow up carried out by the research assistants that we were able to retain 92% of the participants over the 12 month study period.

Condom migration

In our study, about 30% of male condom use before female condom introduction was replaced by female condoms despite messages emphasising its use only when using a male condom was not possible. Such “condom migration” does not seem to lead to more sexually transmitted infections,¹⁸ but it has cost implications. The cost of the female condoms alone—\$108 per sex worker over 9 months—would represent a substantial investment by the Kenyan Ministry of Health, which spent \$70 per capita on health in 2002. Therefore, it seems unlikely that the female condom intervention could be expanded without donor assistance. In addition, because female condoms are currently much more expensive than male condoms, whenever the majority of female condoms are used as a substitute for a male condom there is limited public health impact from the intervention but there is a marked increase in cost.

The great uptake of female condoms by women who were already successfully using (mostly free) male condoms may be explained by several factors. Firstly, our monitoring reports revealed that peer educators’ distribution of male condoms dropped by about half in the last 4 months of the study, which was probably because of the arrival of the Muslim holy month of Ramadan and a shortage of Ministry of Health condoms. Thus, study participants may have been “replacing” male condoms with female condoms because they did not have enough male condoms. Secondly, there is the novelty effect. It is not uncommon for a new product to take over a portion of an existing market, to be followed by a subsequent decline after the novelty wears off (as we saw here). Finally, in our formative research phase, Mombasan sex workers told us that they could secretly use the female condom with unsuspecting clients who would pay more for (seemingly) condomless sex. Thus, the female condom may have been picked up by sex workers as much for its money making potential as for its protective effects.

Continuing “condom gap” with boyfriends

Although our formative research indicated that the female condom had a potential role in filling the “condom gap” with sex workers and their emotional partners, introducing the female condom did not result in an increase in protected sex with boyfriends. A low risk perception with regular clients and boyfriends, and thus less insistence on condom use, is not uncommon in sex worker populations.^{2 19} Further, few

Table 3 Incremental cost effectiveness analysis of female condom introduction

	Incremental cost	Increase in number of consistent condom users after female condoms introduced (95% CI)	Incremental cost per year per additional consistent condom user (95% CI)
Intervention	\$54 139	16* (3 to 25)	\$3384 (2166 to 18 046)
Scaled up programme†	\$380 081	176 (34 to 284)	\$2160 (1338 to 11 179)
Scaled up programme with 50% reduction in number of female condoms required	\$200 597	176 (34 to 284)	\$1140 (706 to 5900)

*This figure has been altered from the actual increase found in the study to indicate the number that would have become consistent condom users if there was no loss to follow up $[(0.6711 \times 210) - (0.5973 \times 210) = 16]$. Assumes those lost to follow up had same behaviours as those who stayed in study.

†Figures reflect increases from the study sample (n=210) to all sex workers in the Kisauni programme (n=2382). The cost of scaling up the intervention assumed that besides additional condoms required to serve a larger group (91% of scale up costs) that there would also be increased communication costs and office supplies proportional to the increase in persons served in order to document the increased activities. We assumed that personnel costs would not increase since programme staff are already contacting these people with the male condom promotion messages.

male condom promotion programmes have been successful in increasing these levels, indicating limitations to peer education programmes that cannot be overcome simply by introducing a new device.¹³ The fact that consistent condom users in this study were less likely to have a boyfriend supports this conclusion.

CONCLUSION

The female condom shows limited promise in increasing consistent condom use. Whether or not the increases seen here are programmatically significant is best judged by programme planners and policy makers in individual countries, depending on the public health priorities of those countries. However, one consideration that should be taken into account is the cost. Although some replacement is to be expected with a new product, the reduction of male condom use by 30% is problematic because of the high cost of the female condom. If female condom programmes are to be expanded, the messages surrounding their introduction should be fine tuned to avoid promoting this product where the male condom is already used.

In addition, alternatives for promoting safer sex with boyfriends of sex workers, including the use of male or female condoms, need to be explored. Suggestions provided by the sex workers themselves for narrowing this "condom gap" included promoting the female condom as a family planning method, empowering women financially to reduce their dependence on boyfriends, and encouraging men to go for voluntary HIV counselling and testing to help them better understand their own risk of infection.

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CONTRIBUTORS

SCT designed and oversaw the study, she also wrote the major portions of the introduction, results, and discussion; WO was the

Key messages

- The female condom shows some limited promise in increasing consistent condom use among sex workers and their partners
- Because of the relatively high cost of female condoms, and the likelihood of sex workers substituting them for male condoms, they should be promoted only where male condoms are not currently being used 100% of the time
- More strategies are needed to encourage sex workers to protect themselves when having sex with this category of partner

research coordinator and wrote a portion of the methods section; ELW directed the development and implementation of the statistical analysis plan and contributed in writing the results section; HOT implemented the statistical analysis programming; CT-R supervised the conduct of the study; RH was the study economist and conducted all economic analyses; NK supervises the sex worker peer education programme; SL was the principal investigator for the study. All authors were involved in the design of the study and the review of the manuscript.

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There are no competing interests.

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