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**ACCEPTABILITY OF THE FEMALE
CONDOM (FEMIDOM) WITHIN A
POPULATION OF COMMERCIAL SEX
WORKERS AND COUPLES IN SALIMA
AND NKHOTAKOTA, MALAWI**

1994

Prepared by Suzanne and James Blogg

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FOREWORD

This report contains the findings of the study carried out in late 1993. Many people have made this study possible beginning with the suggestions of Paul De Lay in 1990. By the time the study took place many of us had left Malawi for trainings or work elsewhere, but it is hoped that the importance of the female condom be realised in helping fight the spread of Human Immunodeficiency Virus (HIV). Many people have continuously supported this study as they watched Acquired Immune Deficiency Syndrome (AIDS) take its toll around them, affecting friends, family and in the workplace. It is never too late to take action and it is hoped that donor organisations will use this study as a justification for supporting programmes to implement the distribution of female condoms to those that want them.

TODAY

*A woman with a gash
so deep and wide in
her black soul
came and spilled her
self over me.*

*Asking to be held
like no-one held her*

*Asking to be fed
like no-one fed her.*

*She crawled beneath
my skirt trembling and
afraid and clasped
my lifeboat legs.*

*But I had meetings
to go to,
and a world to save.*

Gabriela Pearse 1962

SUMMARY

In this study, couples from Salima Lakeshore Agricultural Development Division (SLADD) and commercial sex workers (CSWs) in Salima and Nkhotakota, Malawi, were trained in the use of female condoms. Within the couples population 54 men and 57 women answered the questionnaires, and in the CSW group 46 answered the questionnaire. A total of 157 people participated in Phase I of the study and 153 continued in Phase II. All CSWs continued, but those that did not use a female condom in Phase I were not considered.

The age of participants ranged from below 21 (2.5%) to over 40 years (18.5%) with most women aged between 21 and 30 years (59.2%) and most men over 31 years (88%). The CSWs were predominantly aged below 31 (82.6%) whereas 52.6% of women in the couples population were over 31 years. No men were below 21 years of age.

Education of women was generally lower than that of men. The mean range of education for men was Secondary School, Form 3 to 4 (39%). Married or cohabiting women had the mean education of Standard 7 to 8 (35%) and the mean education for CSWs was no education (37%). Nearly all men were educated to at least standard 7 or 8 (94%) compared to 72% of women partners and only 17% of CSWs.

The general reaction to the female condom was positive with 103/157 (66%) of the participants liking them very much and another 49/157 (31%) liking them fairly well during Phase I. A significantly higher proportion of CSWs liked the female condom very much ($X^2 = 16.882$, $df = 2$, $p < .001$) during Phase I. Within the couples, three women somewhat disliked them and one man strongly disliked them. After Phase II of the study only two men reported not liking the female condom with all women liking them. A higher proportion of participants reported liking female condoms very much in Phase II compared to Phase I of the study: men 53.7% to 60%; women 56.1% to 67.3%; and CSWs 91.3% to 97.8%.

Most participants (82%) agreed that the female condom became easier to use with experience. One CSW commented that they didn't become easier to use as they were always easy to use.

Compared to male condoms 14/157 (8.9%) participants liked the female condom less, 19/157 (12.1%) thought they were about the same and 119/157 (76%) liked the female condom more during Phase I. More women 83/103 (80.6%) than men 36/54 (66.7%) liked the female condom more than a male condom. The results showed that there was a significant relationship between gender of the participants and their comparison of female and male condoms ($X^2 = 6.888$, $df = 2$, $p < .05$). The proportion of women who liked the female condom more than the male condom was significantly greater than the proportion of men who liked the female condom more. In Phase II of the study a higher proportion of the participants liked the female condom more than the male condom (81% compared to 76%). A higher percentage of men liked the female condom more than the male condom in Phase II (71.2%) than in Phase I (66.7%). A higher proportion of women in Phase II (86.1%) liked the female condom more than the male condom than in Phase I (80.6%).

When asked what they liked most about the female condom, the CSWs most common response (28.3%) was that it gave them personal control/power. Others liked it best for its strength (17.4%) and 'warmth' (19.6%), while others enjoyed its secretiveness - that men did not notice it (8.7%). Another response was that it felt natural or 'like skin to skin' (6.5%).

In response to the question 'what did you like least about the female condom' most CSWs answered that they found nothing to dislike (56.5%). The inner ring was the cause of most complaints (21.7%).

All groups reported some irritation or discomfort. During Phase I, 6/46 (13%) of the CSWs, 6/57 (10.5%) of the women partners and 6/54 (11.1%) of the men reported irritation/discomfort.

Of the CSWs 16/46 (34.8%) and 21/57 (36.8%) of the women partners used the female condom without the inner ring, like a male condom during Phase I. This did not change significantly during Phase II.

One CSW and 28.1% of women partners reused the female condoms during Phase I. This increased during Phase II to 2 CSWs and 56.4% of women partners. It indicates their acceptability, as women wanted to retain the female condoms they had been given.

During Phase I, 17.4% of CSWs always used a female or male condom during coitus which increased to 32.6% in Phase II. There were still many occasions when no protection was used but this did indicate an increase in acceptability in barrier methods over the study period.

When asked if they would use a female condom again in the future, 92.6% of the men, 96.5% of the women and 97.8 % of CSWs agreed they would after Phase I. The one remaining CSW said she would if improvements were made, as did one woman and three men. Only one man and one woman said they would not use them in the future. After Phase II of the study only two women partners responded that they would not use female condoms in the future and three men would only with improvements. All CSWs wanted to use them in the future.

It seems that the female condom was acceptable as both a method of contraception and STD protection to most of the participants of this study. It would be reasonable to assume that a project distributing female condoms to those that desire them would have benefits in preventing the spread of STDs and HIV, as well as avoiding unwanted pregnancies, as long as they were used consistently and correctly.

1. INTRODUCTION

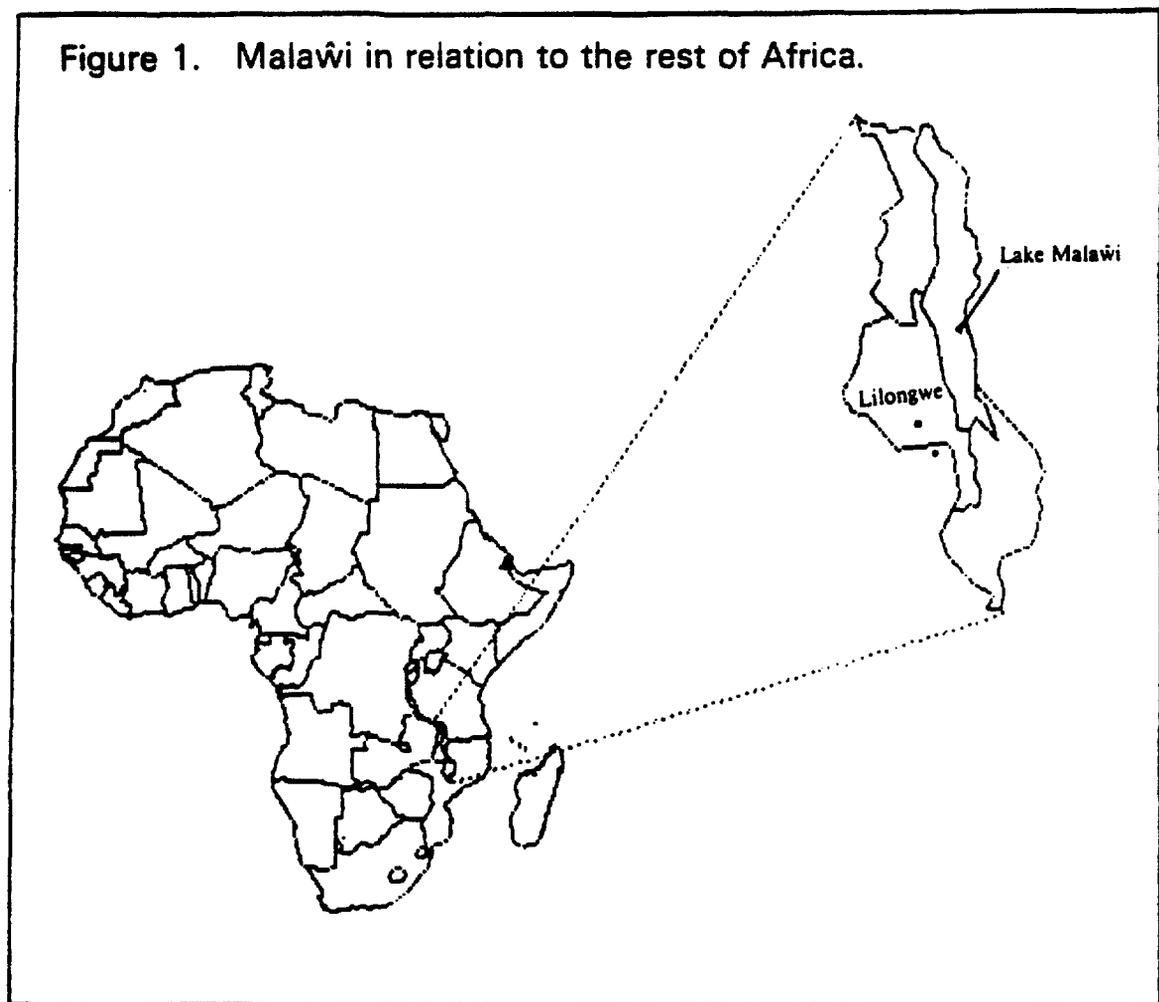
The Femidom female condom is a loose-fitting sleeve made of soft polyurethane film. A polyurethane ring is attached to the open end and remains outside of the vagina during intercourse. A firmer ring is inside the sheath to facilitate insertion into the vagina and to ensure that the female condom remains in place during intercourse. The inner ring is placed high up in the vagina behind the symphysis pubis. The device is prelubricated with silicone and additional lubricant was provided for optional use during the study.

This study examines the acceptability of the Femidom female condom among married or cohabiting couples at SLADD, as well as female commercial sex workers (CSWs) in the districts of Salima and Nkhotakota, Malawi. Acceptability issues include: general reaction of both men and women to the female condom, ease of use, perceived problems, device breakage and change in acceptability over time. Reuse of the device and use or non-use of the inner ring were also investigated.

2. BACKGROUND

2.1 MALAWI

Malawi is characterised by a high fertility rate, high infant and child mortality rates, low urbanisation, low life expectancy, high levels of malnutrition and high levels of illiteracy.¹⁸



2.1.1 Economy

Malawi, with its lack of mineral resources, high population density in relation to arable land, and land-locked status with prohibitive costs of external trade, is one of the poorest countries in Africa.¹ The main measure of their poverty is insufficient land to produce enough to feed their household, coupled with an absence of opportunities for wage income or other earnings.¹⁹

The factors contributing to the high levels of poverty in Malawi include:

- limited employment opportunities;
- low physical productivity of labour and land;
- low levels of human capital;
- limited access to land and economic rents;
- minimal income transfers; and
- rapid population growth.¹⁹

2.1.2 Population

The current population of Malawi is estimated to be about 8.7 million people, with a population density of 59 per square kilometre, making it one of the more densely populated countries in Africa. In 1992 the total fertility rate of Malawi was 7.7 and with a contraceptive prevalence rate of 7%, population doubling time has been estimated at 20 years.⁵ By the year 2000 projections suggest a population between 10.2 and 11.9 million, depending on fertility, mortality rates and the impact of AIDS.¹

2.1.3 Society

The national language of Malawi is a local dialect, Chichewa, and the official language is English. Malawi was previously known as Nyasaland and was a British colony until 1963 when self-government was granted with Dr. Hastings Kamuzu Banda as the Prime Minister, heading the Malawi Congress Party. Malawi became independent on July 6th, 1964, and a Republic on July 6th, 1966. The Malawi Congress Party Convention in 1971 bestowed the title of President for Life on Dr. Hastings Banda.²

Malawian society is complex with different tribal and linguistic groups, remote villages and growing trading centres, estates, towns and a few cities. Each of these represents a different social universe incorporating widely different cultural backgrounds and methods to meet survival needs. The majority of the population (89%) lives in rural areas where a subsistence economy dominates.¹

Pounding Song in ChiChewa

A shared husband I don't want

I want my own

Who looks on proudly as I pound,

Not somebody else's

Who when I pound

Turns his back on me!

I want a beautiful child

Who sleeps on a mattress

In a house with a wooden door! ²⁰

2.1.4 Education

Nationally, 52% of men are literate as compared to 32% of women. Malawi's formal education system has primary, secondary and tertiary levels. It is examination based with the primary system culminating in the Primary Leaving Certificate examination. This examination is taken by an estimated 25% of those who enter the first year of primary school. The examination is also used as a selection tool for the limited places in secondary school. Only about 11% of those candidates passing the examination are admitted to secondary school.¹

More girls than boys drop out of school with pregnancy and early marriage being the major reasons. This is exacerbated by the fact that, although the official school entry age is six, a considerable number of girls start school at the age of nine or older. Thus, girls will reach puberty before completing primary school. For fear of an unwanted pregnancy, some parents withdraw their daughters from school upon their reaching puberty in order to have them marry. Even when they are at school, girls may be required to help with housework and child care. This interference with school work and study time causes poor academic performance. In turn, failure leads to repeating grades, frustration and dropping out.³

It is generally agreed that four years of good quality, primary education will ensure permanent literacy. Malawi's drop-out rate is causing 71% of its children to leave the school system illiterate. Unfortunately, Malawi's primary education system suffers from both human and financial resource problems.¹

2.1.5 Health

Health practices and attitudes toward illness, childbirth, sex or nutrition forcibly illustrate the importance of belief systems. These attitudes explain why some modern health practices are rejected and why most people still consult spiritual leaders and traditional healers as well as medical personnel. The dominance of traditional medicine in many areas is due, not only to its availability, but to the fact that many people, including the well educated, believe in its efficacy.

The health status of Malawi's population is generally low, contributing to up to 33% of children in some areas dying during the first five years of life and to a low life expectancy at birth of 46 years.¹ This situation is likely to change for the worse in coming years due to the AIDS epidemic which is now estimated to affect one in five adults in urban areas and one in eight in rural areas.²¹

2.2 SALIMA LAKESHORE AGRICULTURAL DEVELOPMENT DIVISION

Salima Lakeshore Agricultural Development Division (SLADD) has its headquarters based on Lake Malawi at Senga Bay. SLADD is part of the Ministry of Agriculture and has seconded health personnel from the Ministry of Health for its public health activities. It has been supported by the European Community with the aims of increasing agricultural production, raising living standards and improving family incomes.

An evaluation in 1988 found that the social services components of the project, i.e. rural water supply, public health infrastructure, and primary health care, so far being effectively implemented, have had a positive impact on general social welfare. However, the agricultural and income objectives of the project were not achieved. Over the project period so far the agricultural production declined, the living standards deteriorated, and

the family income decreased. The report recommended extending the project by five years using residual funds of the agreement.⁴

The administrative structure of SLADD is strictly hierarchical with very formalised lines of communication and decision making. Generally both men and women are literate. Staff are employed either as casual labour or as full time public servants.

Residents often express a multiple belief system. They often believe in the dominance of spirits, especially with respect to ill health, but also accept scientific explanations. Cultural conformity, such as producing many children, is still very important but is changing with time, especially amongst the more educated.

Between 1989 and 1993, SLADD staff regularly presented late with STDs to the resident doctor.²³

2.3 COMMERCIAL SEX WORKERS AND THE BARS

2.3.1 General information

Access to those involved in commercial sex work constitutes a difficult step for AIDS preventive programs. In 1991, focus group meetings with commercial sex workers were held at STD clinics at both Salima and Nkhotakota Hospitals and in bars at Dwangwa to decide if there was any interest in the female condom. All the girls present at these meetings expressed a desire to participate in this study. A woman asked that it begin straight away, as she believed they would all be dead if they had to wait even six months for it to begin. Although most of these women knew how to use a male condom correctly and did try to insist on its use by clients, they had no way of knowing if the man was actually using one. Clients have been reported to hide behind a door and put the condom on themselves. As sex occurred in the dark, the girls often didn't even know if the client had a condom on or had used it correctly.

The female condom represents a new and potentially important addition to the existing choice of barrier method protection. There is an urgent need to give women an option which is under their control and enables them to protect themselves against STDs and AIDS.

Public health staff visited bars in the evenings before the trial period to interview potential clients and ask them if they would be interested in using the female condom. No clients were interviewed during the study period as had been initially planned. It was impractical for field staff to intercept clients after they had just visited a CSW and risk jeopardising the study.

CSWs were first administered a questionnaire on their willingness to participate, as well as other personal details to help develop a training session, at the monthly STD clinic.

The survey carried out prior to the acceptability study gave an indication of the potential client population and the commercial sex workers age, education and attitudes.

2.3.2 Population of CSWs and potential clients in survey

The CSWs came from many districts in Malawi and most had worked in other towns, trading centres and cities, implying a high degree of mobility. Only one girl had never worked anywhere else. The two most common traditional authorities recorded as places of birth were Zomba and Mangochi (each 10%) and the most common tribal languages were Chichewa (35%), Lomwe (21%) and Yao (21%).

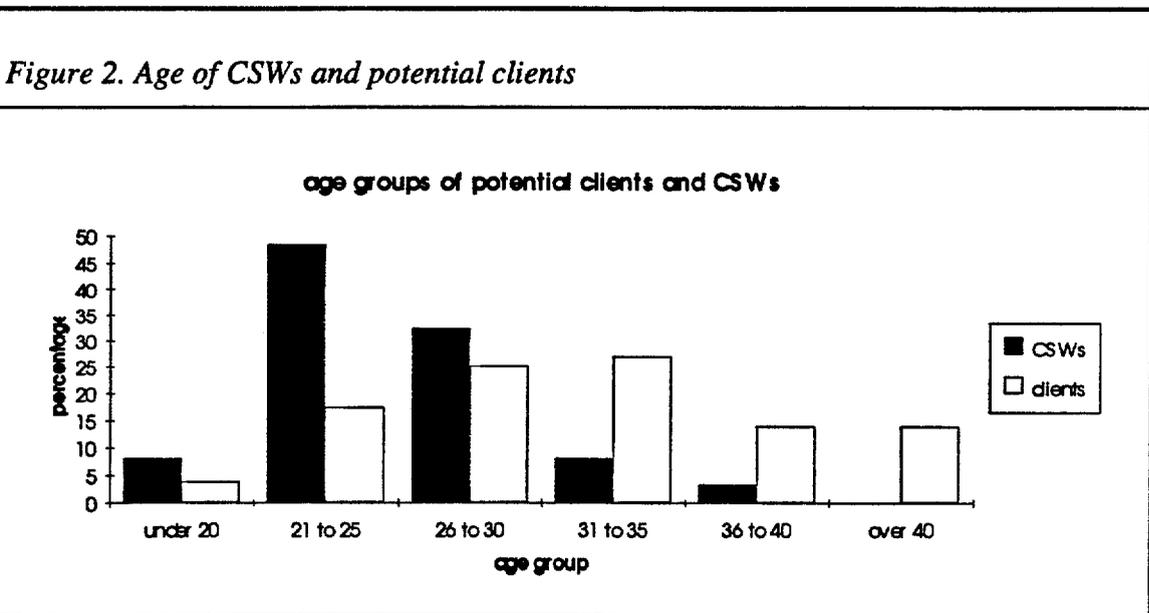
2.3.3 Age & Education of CSWs and potential clients

Generally the bar girls were younger (Figure 2) and less educated (Figure 3) than the clients.

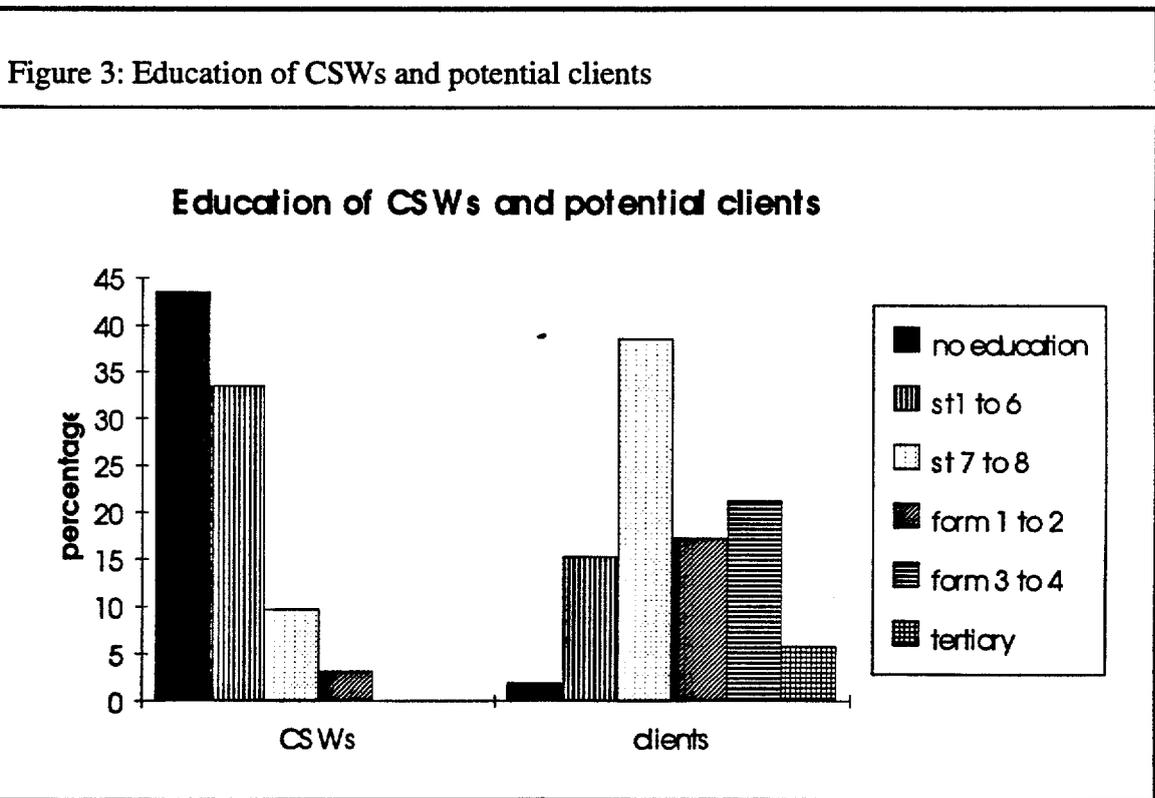
The mean age for CSWs was in the range of 21 to 25 years whereas for clients the mean age ranged between 31 and 35 years.

Most CSWs were under the age of 31 (87.3%) compared to over half the potential clients being over 31 years (53.8%). One CSW was over 40 years compared with 13.5% of potential clients.

Most of the CSWs commenced prostitution between the ages of 19 and 25 (55.6%) with 19% starting between the ages of 16 and 18 years. Two girls commenced prostitution under the age of 16. Three woman commenced prostitution over the age of 30.

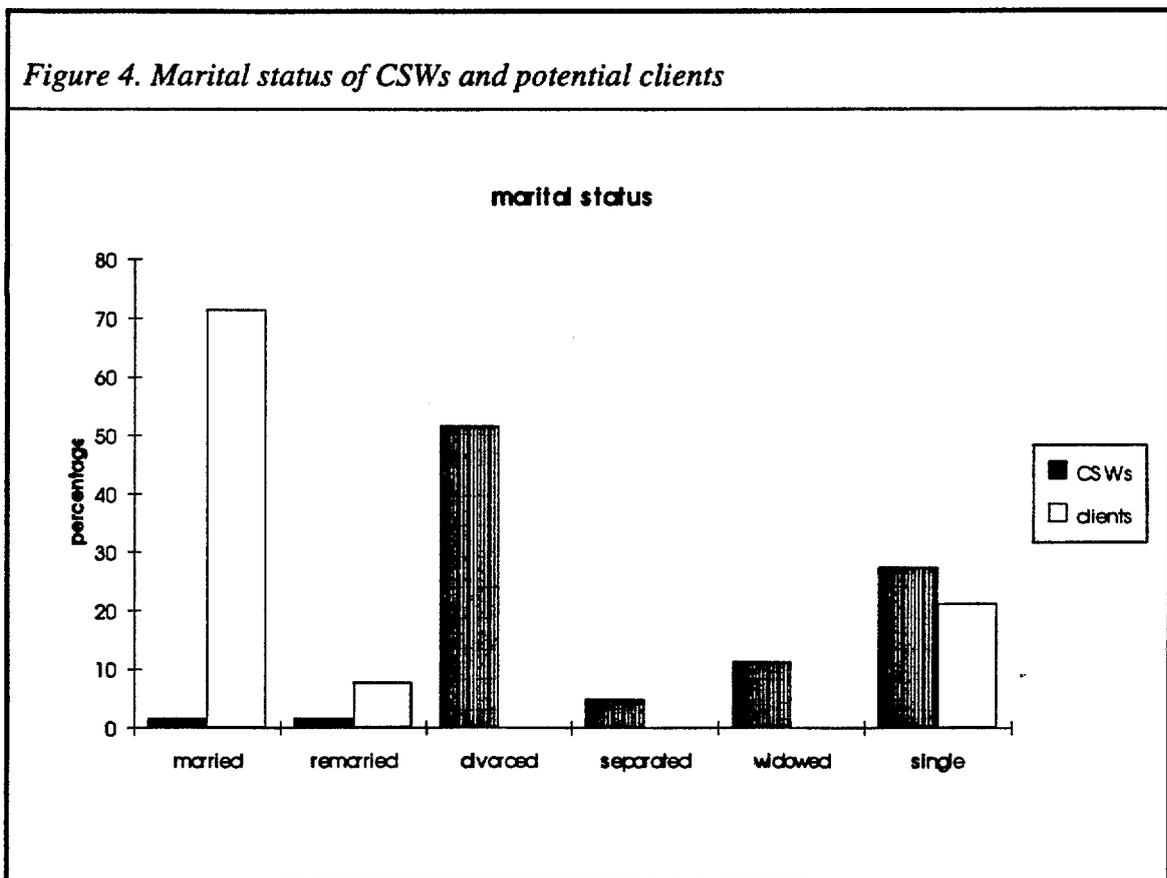


The mean education for CSWs was none and for potential clients was Standard 7 & 8. Education of CSWs ranged from no education (42.9%) to Form 1 & 2 (3.2%). Education for potential clients ranged from no education (1.9%) to tertiary level (5.8%). Only 17.3% of potential clients had an education below the level of Standard 7 compared to 87.3% of CSWs (Figure 3).



2.3.4 Marital Status of CSWs and potential clients

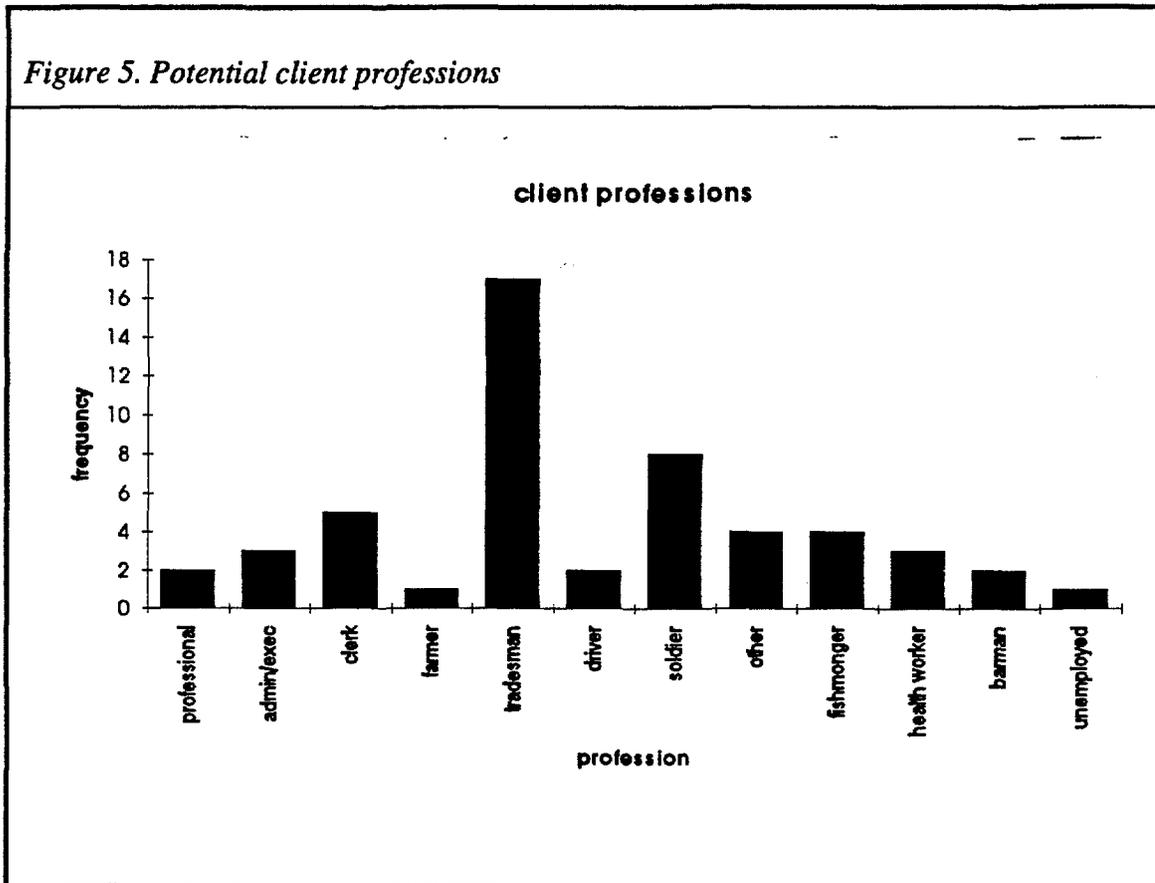
The majority of commercial sex workers were divorced (50.8%) whereas most of the potential clients were married men (79%). Only two CSWs were currently married. The other men were all single (21%) and 27% of the CSWs had never been married. The other CSWs were widowed (11%), separated or deserted (Figure 4).



The majority of the married men (73.2%) interviewed at the bars answered that they had sex with a CSW at least once a month. All the single men surveyed had sex with a CSW at least once a month.

2.3.5 Professions of potential clients

Tradesmen and soldiers made up the majority of the clientele, although a cross section of the community was represented.

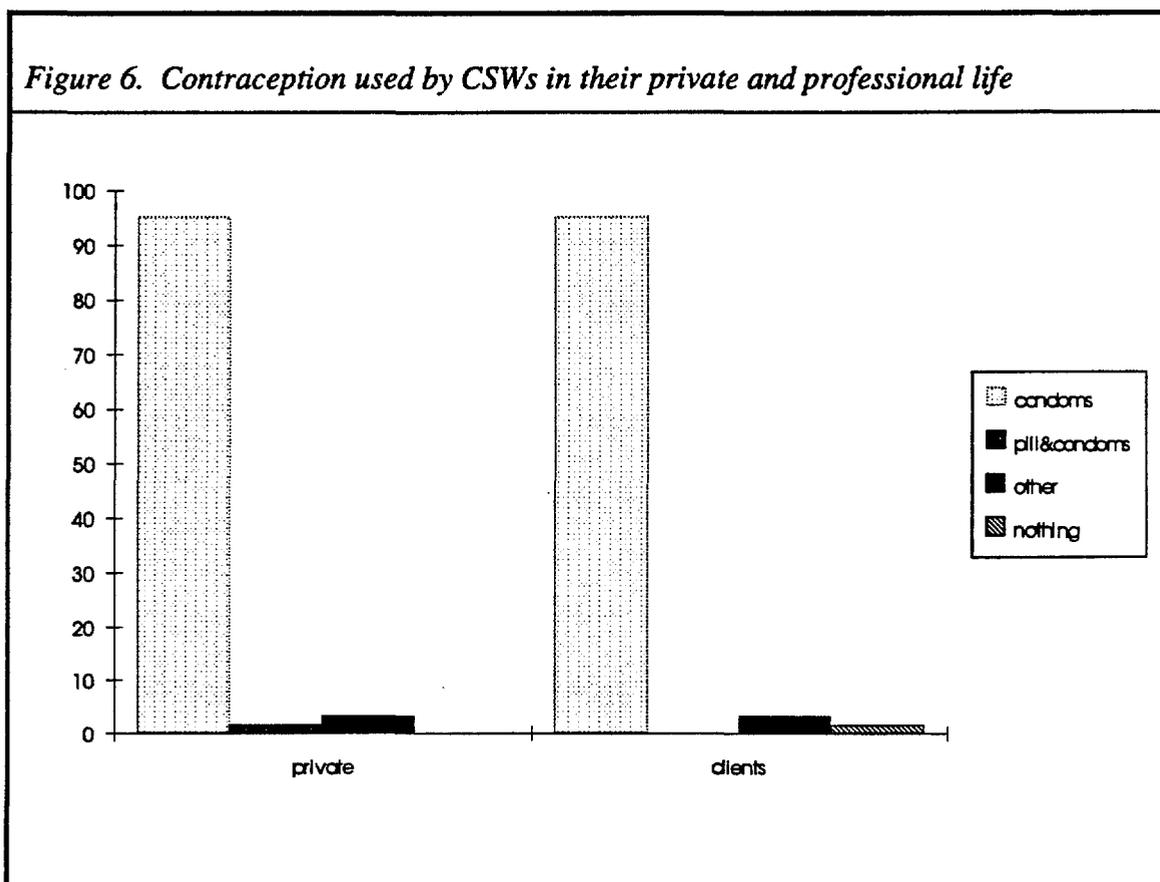


2.3.6 Use of condoms - CSWs

Most of the CSWs practised safe sex in both their private life as well as professionally (Figure 6).

Only one CSW did not use condoms with clients and one never used condoms in her private life. The most common reason for having unprotected intercourse was due to partners strongly objecting (33.9%). Another 27.4% were trying to fall pregnant.

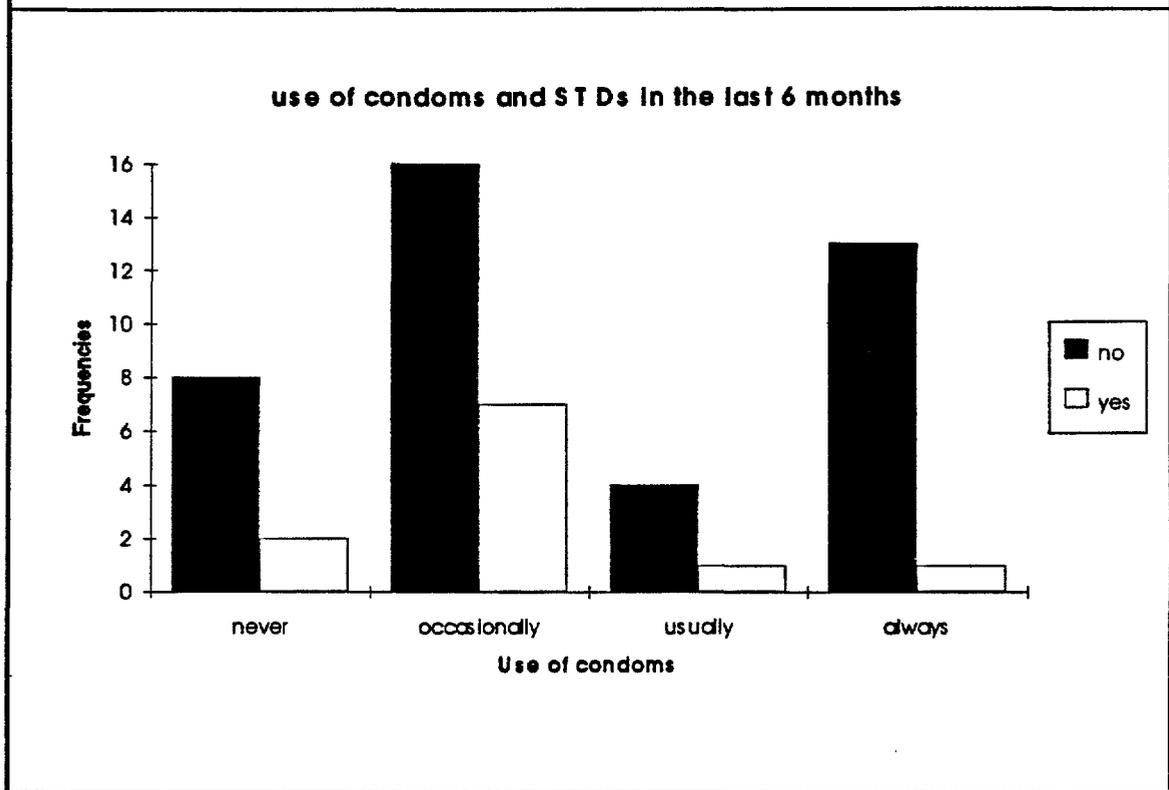
Most of the CSWs used condoms all the time with clients (47%) or most of the time (31%). Another 21% would use condoms occasionally with clients.



2.3.7 Potential Client use of condoms

Clients use of condoms varied with 31.7% always using them and 19.5% never using them. A total of 11 of the 52 men surveyed (21.2%) admitted to having an STD in the previous 6 months. Figure 7 demonstrates the use of condoms by clients and those that had or didn't have an STD in the previous 6 months.

Figure 7. The use of condoms and STDs in the last 6 months for potential clients



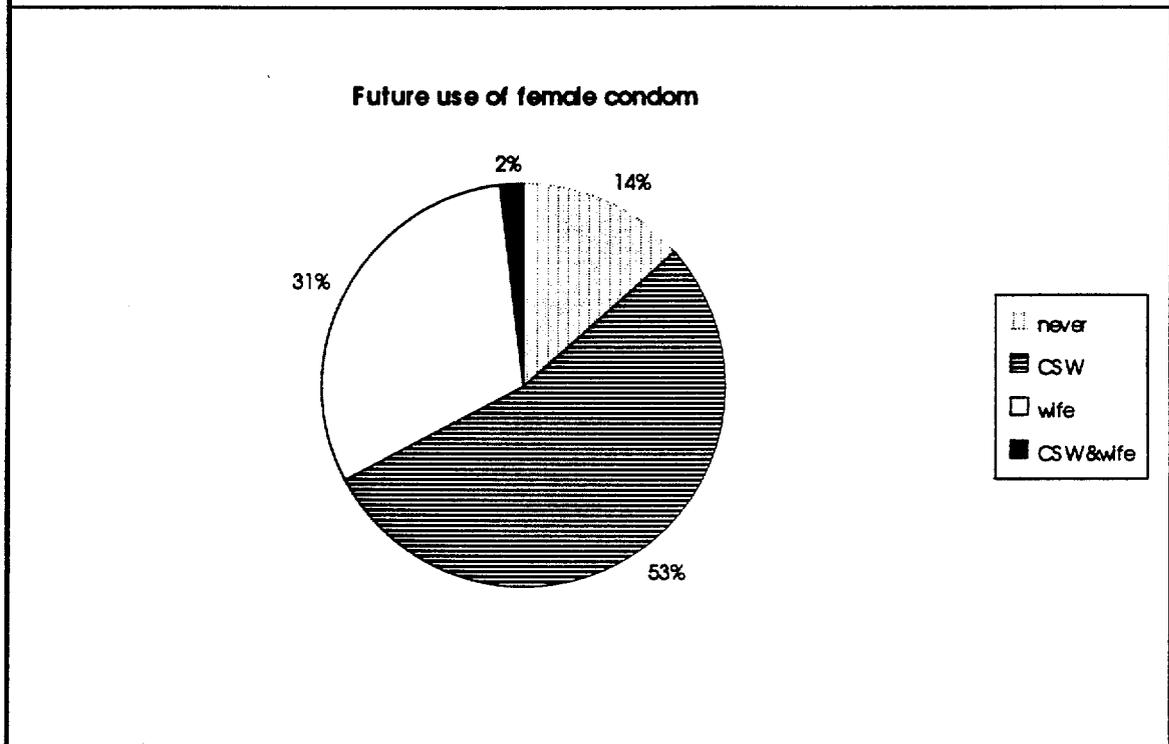
2.3.8 Willingness to use condoms

Only 13.5% of the men interviewed were not willing to try a female condom (Figure 8).

The reasons given for using male condoms were mainly for protection against STDs (69.2%) although 15.4% also used them as a contraceptive and another 15.4% never used them.

The main reason for not using condoms was due to the enjoyment of sex without them. Other reasons included having unplanned intercourse, no other partners, not worried about STDs or awkward to use.

Figure 8. Potential client consideration for using female condoms in the future.

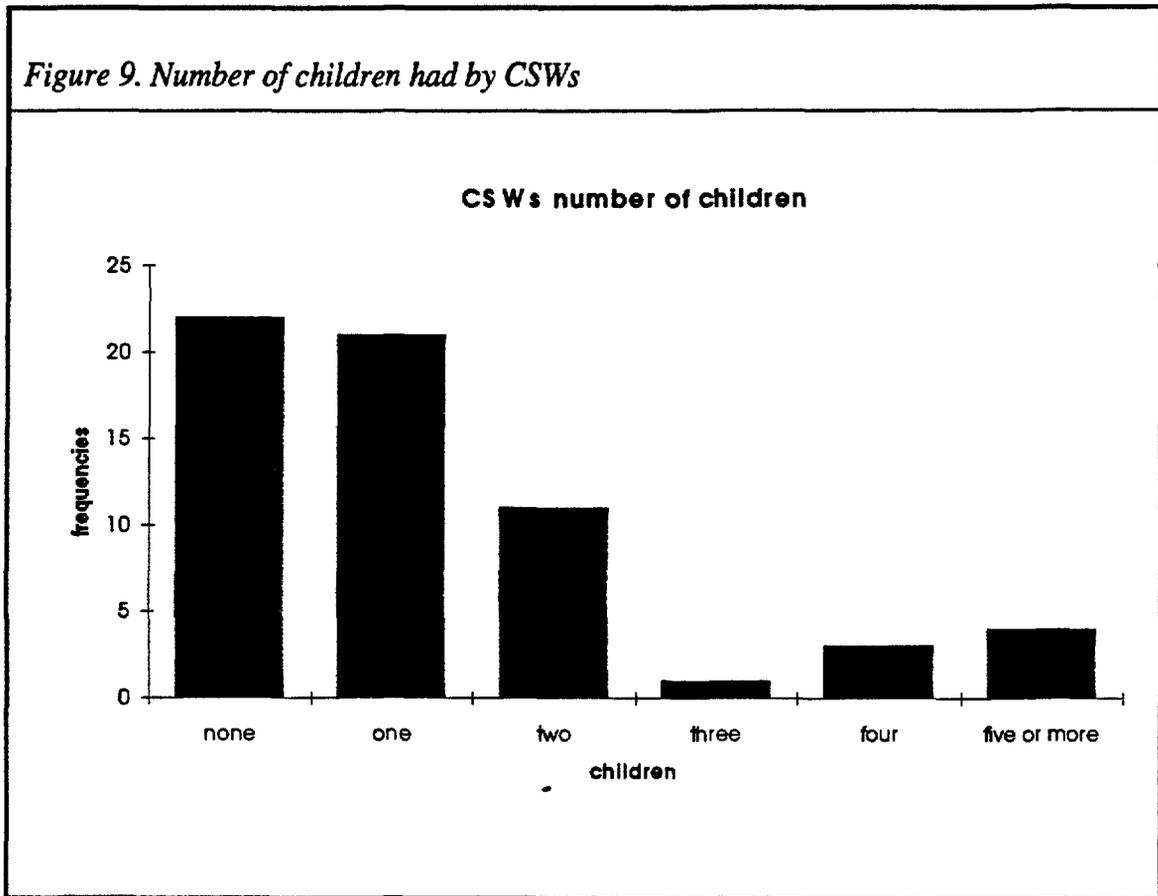


2.3.9 CSWs Dependants

Only 8 CSWs (13%) had more than two children. The most children supported by a CSW was 8 with others supporting 7, 6, 5 and 3 children. Four women each supported 4 children, 13% supported two children and 29% supported one child. Most (41.9%) did not support any children.

As well as many supporting children 58% of the CSWs supported at least one parent. Only 10% of the CSWs surveyed supported themselves alone.

Figure 9. Number of children had by CSWs



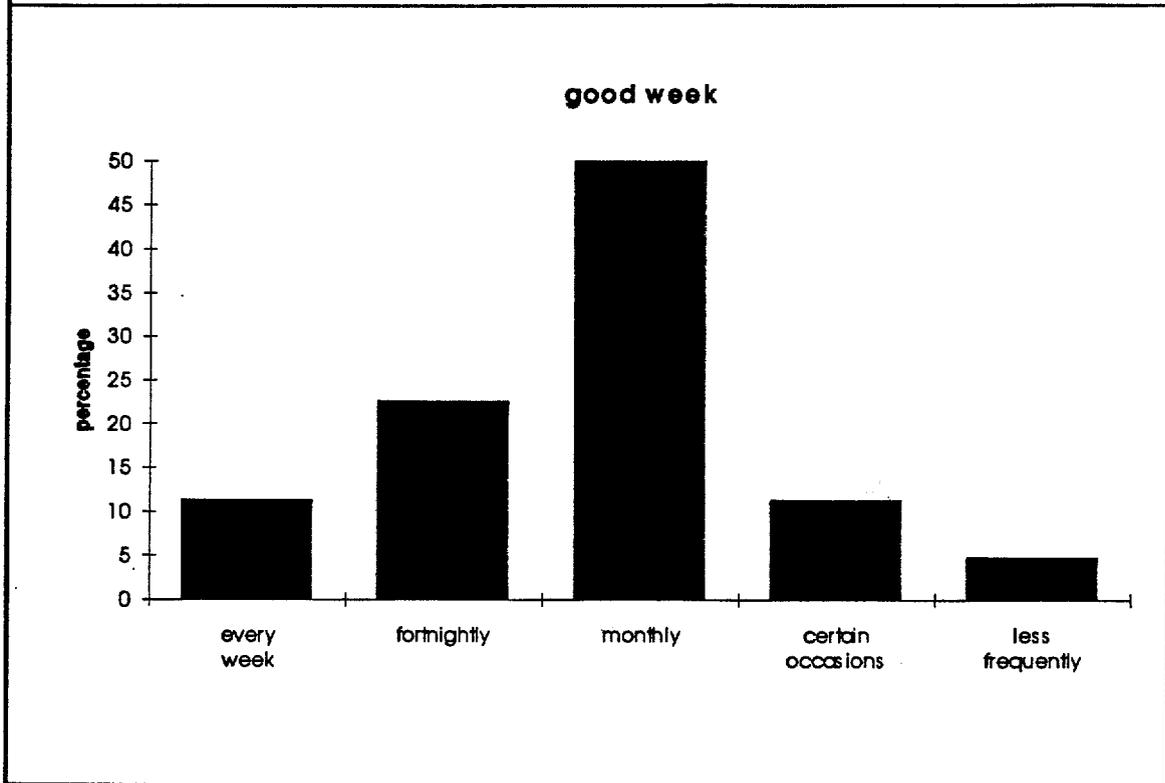
2.3.10 Relationships and clients of CSWs

Most CSWs surveyed had a current personal relationship (64.5%) and only 3 (5%) had never had a relationship. Most the girls had sex at least once a day (69.4%) and another 17 (27.4%) had sex at least once a week.

The number of clients a CSW had in a good week ranged from less than 5 (47%) to over 31(3%). In a bad week 87% had less than five clients.

A good week was most commonly once a month which corresponds to government workers receiving pay (Figure 10).

Figure 10. How often a 'Good Week' occurs for CSWs



Clients most commonly want vaginal intercourse (95%) but two CSWs had requests for hand relief and another two also did domestic work for their clients.

All CSWs interviewed wanted to participate in the acceptability study of female condoms while most considered using them with both partners and clients (53%) or with clients (42%).

2.4 Sexually Transmitted Diseases (STDs)

Epidemiological evidence shows that sexually transmitted diseases (STDs), particularly genital ulcer disease (GUD) and urethral discharge, are critical co-factors in HIV transmission, and that the transmission of STDs and HIV has common behavioural characteristics. GUD is the most common presenting STD in men in urban Malawi accounting for about 60% of men with genitourinary complaints.²⁴

Data on sexually transmitted disease in Malawi is scanty. This is, in part, due to inconsistent reporting from the districts and, in part, due to the Health Information System (HIS). The HIS does not distinguish by gender. Prior to 1990, the HIS reported all STDs collectively as 'venereal disease'. The new reporting system adopted in 1990 identifies three categories of sexually transmitted diseases: 'gonorrhoea', 'syphilis' and 'other'. In addition to the failure to report STDs, the HIS underestimates the magnitude of STDs in women reported in the outpatient departments as STDs are likely to be categorised as 'female complaints', 'skin diseases', or 'symptoms referable to the genito-urinary tract'. Moreover, syphilis serology done on antenatal clinic is reported through a laboratory reporting system and does not make it into the HIS system.²⁴

STDs are highly endemic among urban antenatal women in Malawi, with gonorrhoea, trichomoniasis, syphilis, chancroid or chlamydial infection present in 43% of the women at any one time.²⁴

Studies in bargirls in Blantyre indicated the following prevalence of STDs: gonorrhoea - 29%; trichomoniasis - 21%; positive syphilis serology - 21%; genital ulceration - 6%. This data indicated that bargirls, a core transmitter group, have a very high level of STDs.²⁴

2.4.1 STD Control

Recommendations resulting from the evaluation of the efficacy of STD antibiotics for treatment of the common syndromes of urethritis and genital ulcer disease in men in Malawi included the following.

- Interventions to address the strong correlation between urethritis and genital ulcer disease and prostitute contact should be intensified. The high prevalence of reported alcohol use suggests that this may also play a role. These interventions might include aggressive condom promotion and ensuring the availability of condoms in establishments where alcohol is consumed and accelerated, improved access to STD care for prostitutes through the bar girl clinics.
- General STD education should be started to motivate symptomatic individuals to seek effective care early as well as address the prevention efforts such as partner referral, condom use and compliance with therapy.²⁴

2.4.2 HIV Vaccines

HIV vaccines can be divided into two broad categories, those that prevent the acquisition of HIV (prophylactic vaccines) and those that delay or prevent progression of disease in those already infected (therapeutic vaccines). Although considerable progress has been made, formidable obstacles remain.²²

Obviously it would be ethically irresponsible of a researcher to obtain consent to the vaccine test from a subject without informing him, at length and with diligence, about his need to adopt a variety of precautionary measures. Each time the subject returned for following-up and testing, it would again be incumbent on the researcher to urge safe behaviour. And yet, to the degree that the researcher is an effective educator, he will reduce the value of the subject as a test case for the vaccine.²⁸

Many questions related to the conduct of HIV vaccine trials in the developing world remain unanswered.²²

2.5 FEMALE CONDOM

The female condom consists of a soft, loose-fitting polyurethane sheath with a flexible ring at each end. The outer ring covers the vulvar mucosa.

The major questions about the effectiveness of the female condom in the prevention of the transmission of HIV are: its efficacy as a physical barrier; its durability and performance during use; its acceptability; and its availability.

In vitro studies have shown that intact polyurethane condoms are an effective barrier to cytomegalovirus and human immunodeficiency virus,⁶ as well as gas and dye particles smaller than HIV, herpes virus or hepatitis B virus.²⁵

No serious side-effects or allergies to the polyurethane female condom have been reported to date.²⁶

Clinical studies suggest that the polyurethane female condom is more durable and less likely to break than the latex male condoms. In studies of the 'Reality' brand condoms sponsored by the manufacturer (Wisconsin Pharmacal Co.), only 0.6% (3/521) of female condoms leaked after being used for one act of intercourse when tested by the standard ASTM water leak test. Under the same conditions, 3.5% (18/516) of male condoms leaked ($p < 0.001$). Using questionnaires to determine the rate of vaginal exposure to semen due to either slippage or tears in 50 couples, the female condom was again superior (2.7% vs. 8.1%, $p = 0.03$). This was confirmed by vaginal swabs in 15 women (after episodes of intercourse each) in which no evidence of sperm was found (95% CI 0-4.5%).⁷ Overall, breakage rates in studies of the polyurethane female condom range from 0 to 9%, compared to 0 to 12% for the latex male condom.²⁶

Other studies^{8,16,17,27} have suggested higher rates of problems with the use of the female condom, including frequent slippage of the outer ring into the vagina, the penis entering

between the outer ring and vaginal wall (effectively missing the condom), and the condom slipping out of position.

Studies of the acceptability of the female condom to date give widely varying results depending on the country in which they are conducted, the population studied and the means of recruiting and educating study subjects. Most women who found the condom unacceptable rejected it because of physical discomfort or objections to the appearance or noise of the condom. The introduction of the female condom into sex worker populations did not necessarily empower the women to use them. Despite having the option of both the male and female condoms, CSWs in Thailand and Cameroon still reported multiple episodes of unprotected sex.^{17,27}

Female condoms can have a role in the prevention of HIV-transmission and other devastating consequences of STDs such as PID, ectopic pregnancies, infertility, urethral stricture, congenital syphilis and neonatal ophthalmia. While male condoms have, over the last several years, become increasingly important as a method to slow the transmission of sexually transmitted diseases, their acceptance is limited because of real and perceived drawbacks inherent in the method.

3. METHODOLOGY

3.1 CRITERIA

- must be at least 18 years of age
- must be protected against pregnancy by oral contraceptives, an IUD or female sterilisation; and not be pregnant or breast feeding at the time of the study;
- must be willing to give their candid opinions in a face-to-face interview about the study products;
- must be willing to sign an Informed Consent form (Appendix 3).

3.2 COMMERCIAL SEX WORKERS

Participants were recruited from the client population of the STD clinics at Salima and Nkhotakota District Hospitals. Eligible participants were active CSWs with multiple sex partners and were also using a current effective, modern method of contraception, not pregnant or breast feeding and not suffering from STDs according to clinic screening. Tests were carried out to detect syphilis (VDRL), gonorrhoea and yeast infections (gram stain) and a physical examination for herpes simplex (HSV) and chancroid. After infections resolved and were reviewed by the clinical officer, volunteers could join the study. A total of 46 CSWs participated in the study; 26 from Salima and 20 from Nkhotakota.

The CSWs were trained in the use of the female condom under the direction of the study investigators. Each CSW was given a study packet containing 20 female condoms, 20 standard male latex condoms and a coital log to record the number of encounters and the protective method(s) used.

After using the devices CSWs were interviewed by the public health inspector or clinical officer who translated and completed the questionnaire and reviewed the coital log for each woman. This was carried out within four weeks of receiving the condoms. Those who were willing to participate in the second phase of the study were given a second study packet containing 20 female and 20 male condoms and a coital log.

After using the devices in Phase II of the study, participants were again interviewed within 4 weeks of receiving the study packet by the public health inspector. Extra condoms were made available at the hospital for those that requested more during the study period.

3.3 COUPLES

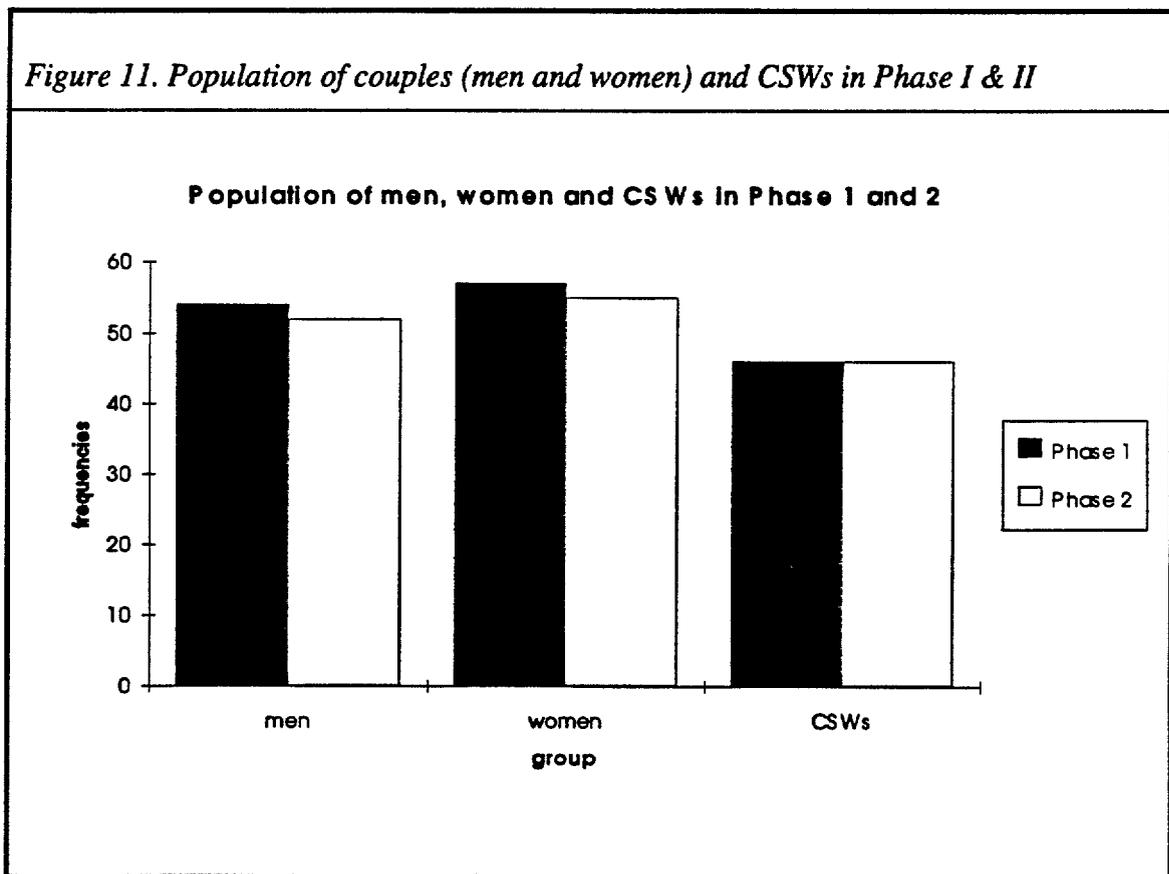
The female condom was presented to this group as an alternative method of child-spacing, not just for STD control. Many couples had expressed concern over the need for a contraceptive and some partners were concerned about the risk of AIDS from extra-marital activities.

Staff from SLADD Head Quarters, Senga Bay, took part in a training session on insertion and the use of the female condom and were instructed in other child spacing techniques. Separate trainings were held for men and women as this was deemed most appropriate by participants. Couples were then invited to participate in the female condom acceptability study. Participants were eligible if they were using an effective, modern method of contraception, not pregnant or breast feeding.

Each couple was given a supply of five female condoms and five standard male latex condoms. After four weeks investigators contacted participating couples at their homes to complete the initial questionnaires. Additional supplies of both types of condoms were distributed at this time. After another four weeks, couples were again contacted to complete the second questionnaire.

4. DATA ANALYSIS

Within the couples population 54 men and 57 women answered the questionnaires and in the commercial sex population group 46 answered the questionnaire. One CSW was not included in the study due to her repeated denial of being a bar girl and consequent inability to honestly answer the first questionnaire. A total of 157 people participated in Phase I of the study and 153 continued participating in Phase II.

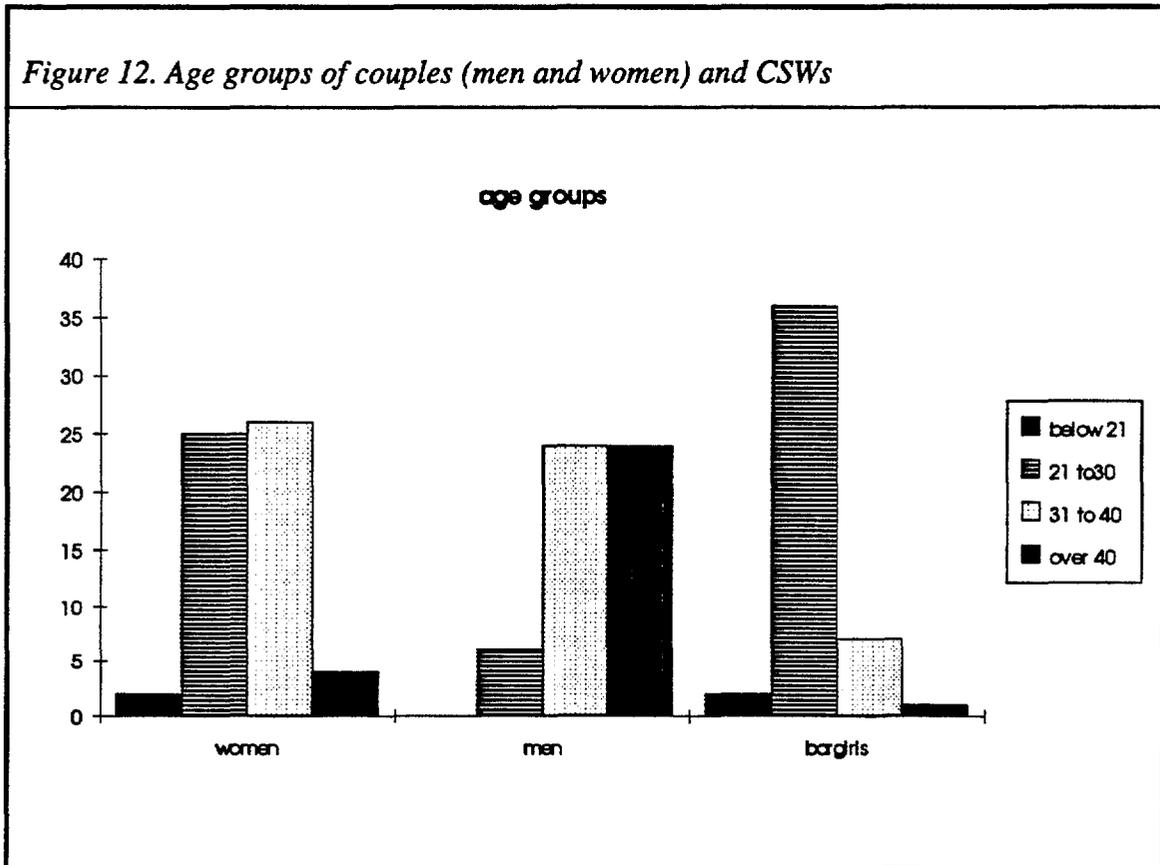


4.1 ACCEPTABILITY OF THE FEMALE CONDOM STUDY - PHASE I

4.1.1. AGE

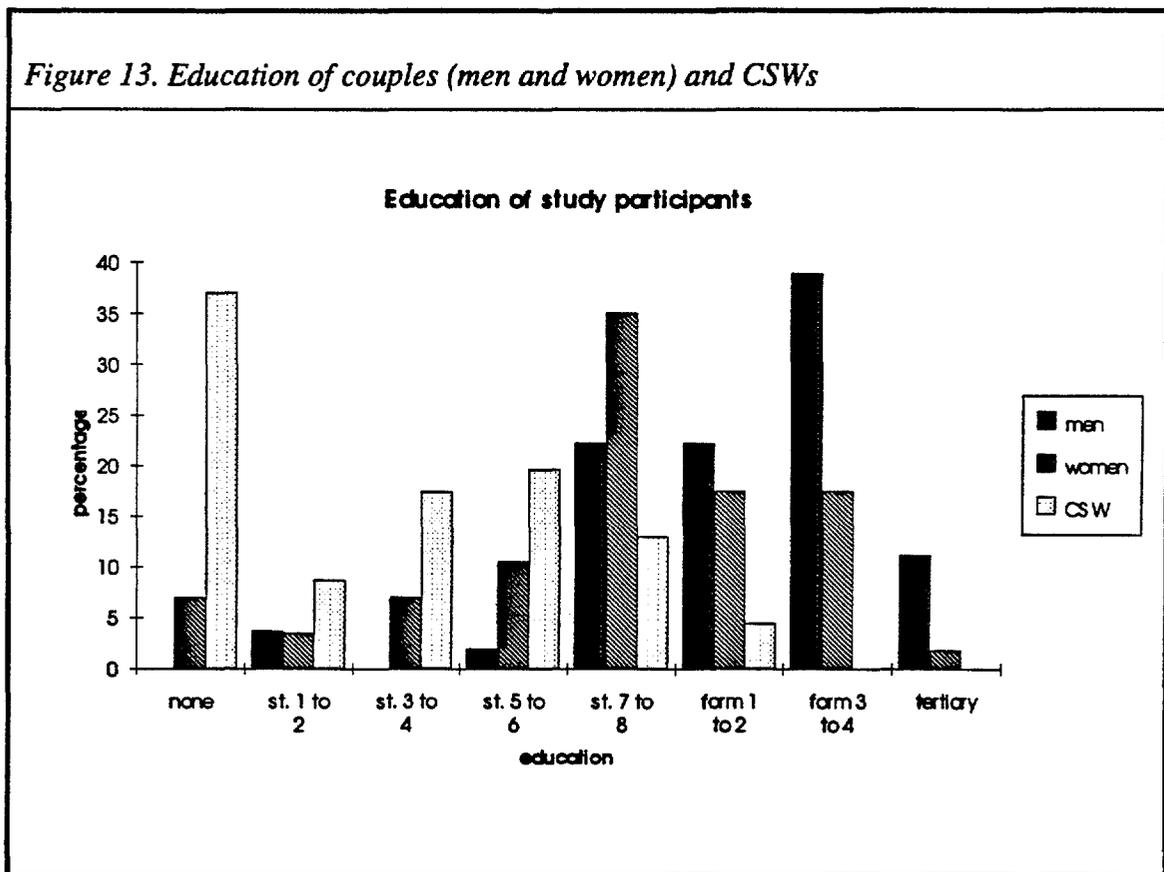
The age of participants ranged from below 21 (2.5%) to over 40 years (18.5%) with most women aged between 21 and 30 years (59.2%) and most men over 31 (88%). The CSWs were predominantly aged below 31 years (82.6%) whereas 52.6% of women in the couples population were over 31 years. No men were below 21 years of age.

Age groups differed among the groups with men generally representing an older population than the women. Only one bar girl was over 40 years.



4.1.2 EDUCATION

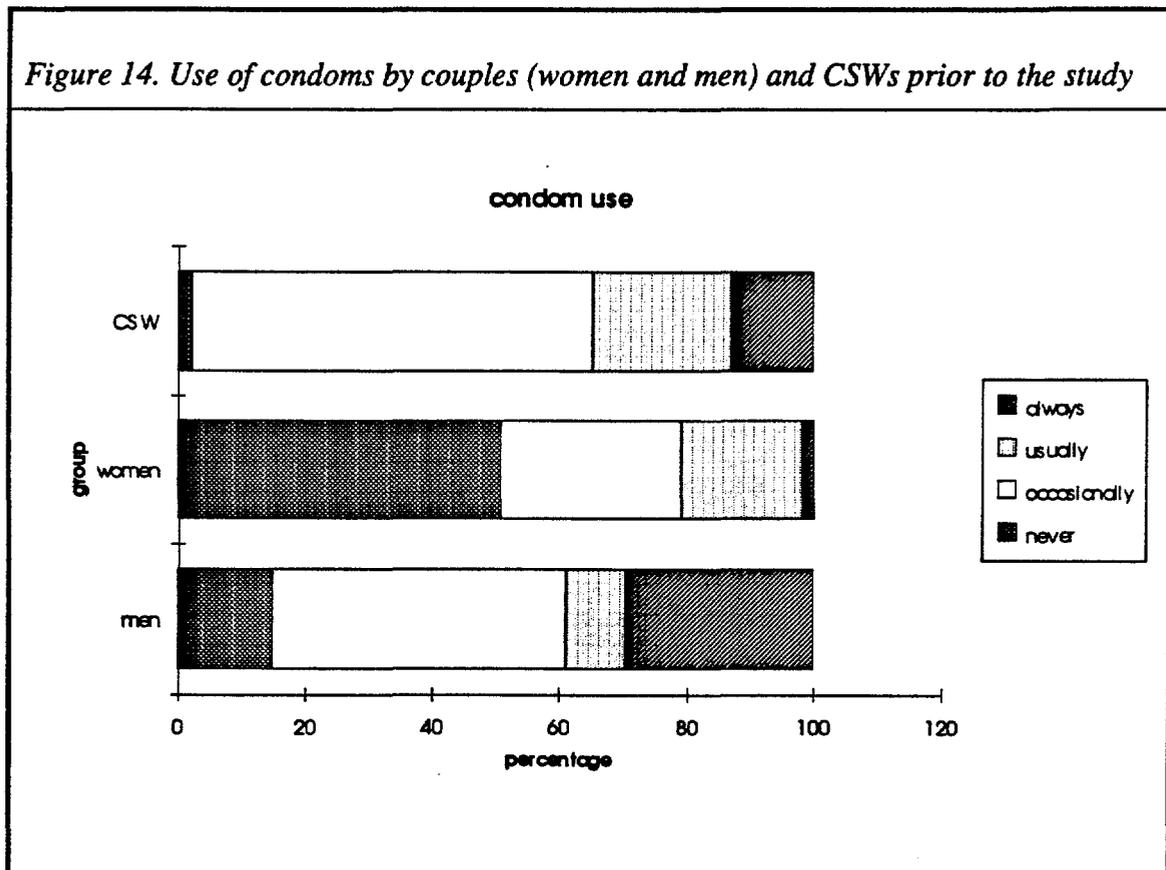
Education of women was generally lower than that of men. The mean range of education for men was secondary school, form 3 to 4 (39%). Married or cohabiting women had the mean education of standard 7 to 8 (35%) and most CSWs had no education (37%). Nearly all men were educated to at least standard 7 or 8 (94%) compared to 72% of women partners and only 17% of CSWs.



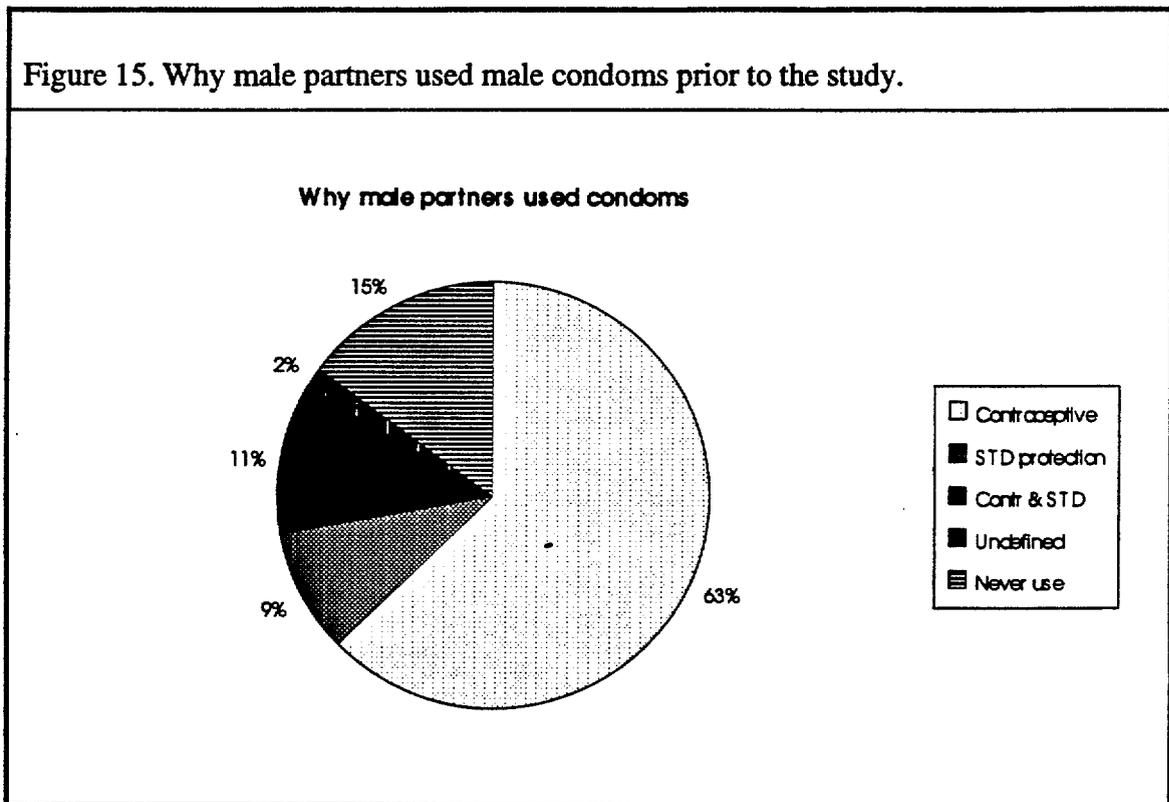
Men generally received a higher education than women and CSWs generally had a lower education than the other women.

4.1.3. Use of male condoms prior to the study

Within the couple population more women than men had never used a male condom. Only one CSW had never used a male condom whereas 29/57 (50.9%) of the women in the couple population had not used a male condom (Figure 14). Of the men 37/54 (68.5%) used condoms only with their wife.



The reasons given for using a male condom was mainly as a contraceptive only (63%) (Figure 15).



4.1.4. Use of condoms in study packet - couples Phase I

All men and women used at least one female condom, although 10.5% of women and 16.7% of men did not use a male condom (Table 1).

Table 1 : Use of male condoms by couples during phase I

male condom use	women n=57	men n=54
did not use any	6 (10.5%)	9 (16.7%)
used one	3 (5.3%)	12 (22.2%)
used more than one	39 (68.4%)	21 (38.9%)
used all (5)	9 (15.8%)	12 (22.2%)

4.1.5 General Reaction to the female condom during phase I

In Phase I the general reaction to the female condom was positive with 103/157 (66%) of the participants liking them very much and another 49/157 (31%) liking them fairly well. A significantly higher proportion of CSWs liked the female condom very much ($X^2=16.882$, $df = 2$, $p<.001$). Within the couples, three women somewhat disliked them and one man strongly disliked them.

Table 2: General reaction of couples (men & women) and CSWs to the female condom during Phase I

General Reaction	men n=54	women n=57	CSW n=46
liked it very much	29 (53.7%)	32 (56.1%)	42 (91.3%)
liked it fairly well	23 (42.6%)	22 (38.6%)	4 (8.7%)
no opinion, neutral	1 (1.9%)	0	0
somewhat disliked	0	3 (5.3%)	0
strongly disliked	1 (1.9%)	0	0

4.1.6 Comparison of the female condom to the male condom during Phase I

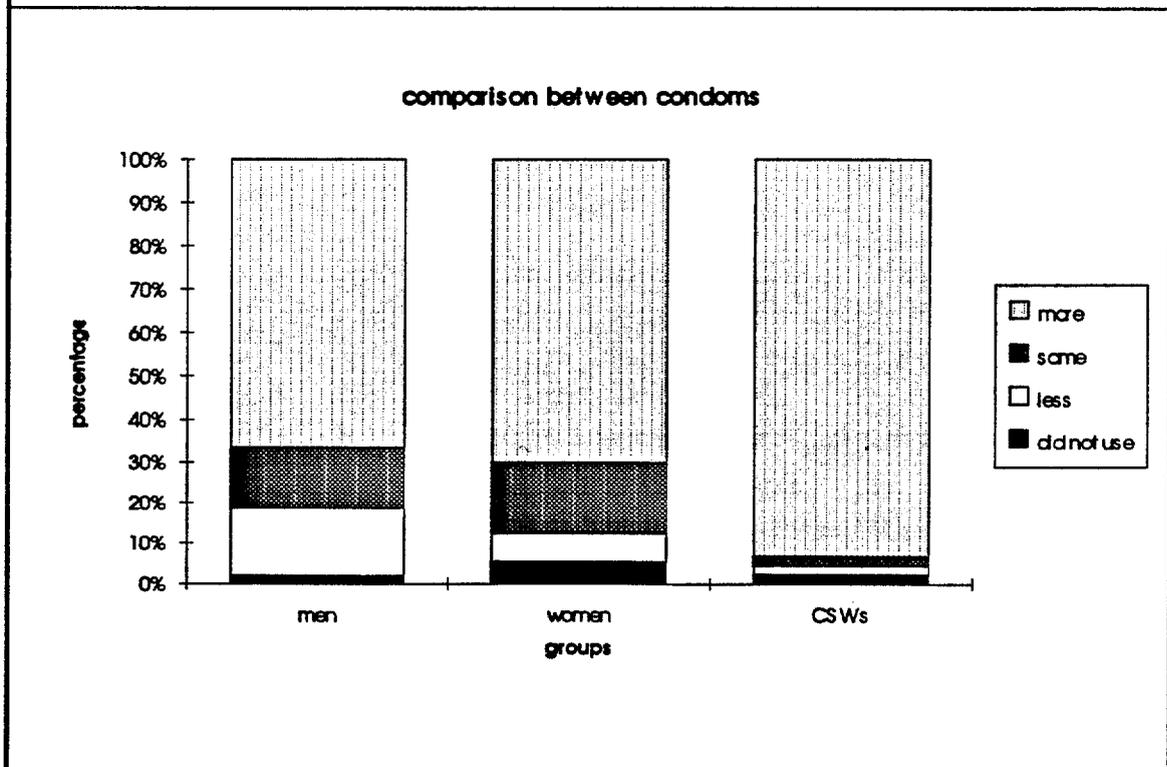
Compared to male condoms 14/157 (8.9%) participants liked the female condom less, 19/157 (12.1%) thought they were about the same and 119/157 (76%) liked the female condom more. More women 83/103 (80.6%) than men 36/54 (66.7%) liked the female condom more than a male condom. The results show that there was a significant

relationship between gender of the participants and their comparison of female and male condoms ($X^2 = 6.888$, $df = 2$, $p < .05$). The proportion of women who liked the female condom more than the male condom is significantly greater than the proportion of men who liked the female condom more.

Table 3 : Comparison of the female condom to the male condom by couples (men & women) and CSWs during Phase I

comparison	men	women	CSWs
did not use	1 (1.9%)	3 (5.3%)	2 (4.3%)
less	9 (16.7%)	4 (7%)	1 (2.2%)
same	8 (14.8%)	10 (17.5%)	1 (2.2%)
more	36 (66.7%)	40 (70.2%)	43 (93.5%)

Figure 16: Comparison of the female condom to the male condom by couples (men & women) and CSWs during Phase I



4.1.7 CSWs opinion of the female condom during Phase I

When asked 'what did you like most about the female condom' the CSWs most common response (28.3%) was that it gave them personal control/power. Others liked it best for its strength (17.4%) and warmth (19.6%) while others enjoyed its secretiveness, that men did not notice it (8.7%). Another response was that it felt natural or 'like skin to skin' (6.5%). Other comments included that it was sexually satisfying to use, sometimes reaching orgasm, no need to clean the vagina and less complaints from clients. One woman preferred a male condom due to the inner ring.

In response to the question 'what did you like least about the female condom' most answered that they found nothing to dislike (56.5%). The inner ring was the cause of most complaints (21.7%). Others did not like directing the penis, inserting it, the outer ring, that it covered the labia and another found it too oily. One found that it stopped the client from stimulating her clitoris with his hand.

4.1.8 Position of female condom during intercourse for couples and CSWs during Phase I

Table 4 : Position of female condom during intercourse for couples and CSWs during Phase I

<i>Position of female condom</i>	men n=54		women n=57		CSWs n=46	
	no	yes	no	yes	no	yes
female condom did not stay in place	47 (87%)	7(13%)	46(81%)	11(19%)	39(85%)	7(15%)
the outer ring got pushed up into the vagina	51 (94%)	3(6%)	53(93%)	4(7%)	41(89%)	3(11%)
the penis was inserted between the outer ring and the vagina	51(94%)	3(6%)	54(95%)	3(5%)	44(96%)	2(4%)

4.1.9 Irritation/discomfort from the female condom during Phase I

All groups reported some irritation. Of the CSWs 6/46 (13%) reported some irritation/discomfort. In the couples 6/57 (10.5%) women and 6/54 (11.1%) men reported irritation (Table 5).

Table 5: Irritation or discomfort from the female condom for couples and CSWs during Phase I

Irritation/discomfort from the female condom	men n=54		women n=57		CSWs n=46	
	no	yes	no	yes	no	yes
discomfort from outer ring (partner or self)	51(94%)	3(6%)	56(98%)	1(2%)	42(91%)	4(9%)
general irritation/discomfort	48(89%)	6(11%)	51(90%)	6(10%)	40(87%)	6(13%)

No one reported any breakages although one man did comment that he did not know if any broke.

4.1.10 Reuse and Use without the inner ring during Phase I

Of the CSWs 16/46 (34.8%) and 21/57 (36.8%) of the women used the female condom without the inner ring, like a male condom. This option had been mentioned in the training.

Only 3 of the women and one CSW felt that they did not have enough information/instructions to use the female condom.

One CSW and 16(28.1%) women reused the female condoms. This may be due to the women partners receiving only 5 female condoms in each study packet compared to CSWs receiving 20 although they were encouraged to ask for more if they needed them.

4.1.11 Future Use of the Female Condom

When asked if they would use a female condom again in the future 92.6% of the men, 96.5% of the women and 97.8 % of CSWs agreed they would. The one remaining CSW said she would if improvements were made as did one woman and three men. Only one man and one woman said they would not use them in the future.

4.2 ACCEPTABILITY OF THE FEMALE CONDOM - PHASE II

In Phase II of the study one couple did not continue (Study No. 3), one woman discontinued as her husband was away (Study No. 11) and one man discontinued as his wife had a month old baby and it was culturally inappropriate for them to have sexual intercourse, although he did use one in Phase I of the study (Study No. 13). All CSWs continued and any participants that did not use a female condom in Phase I were not considered.

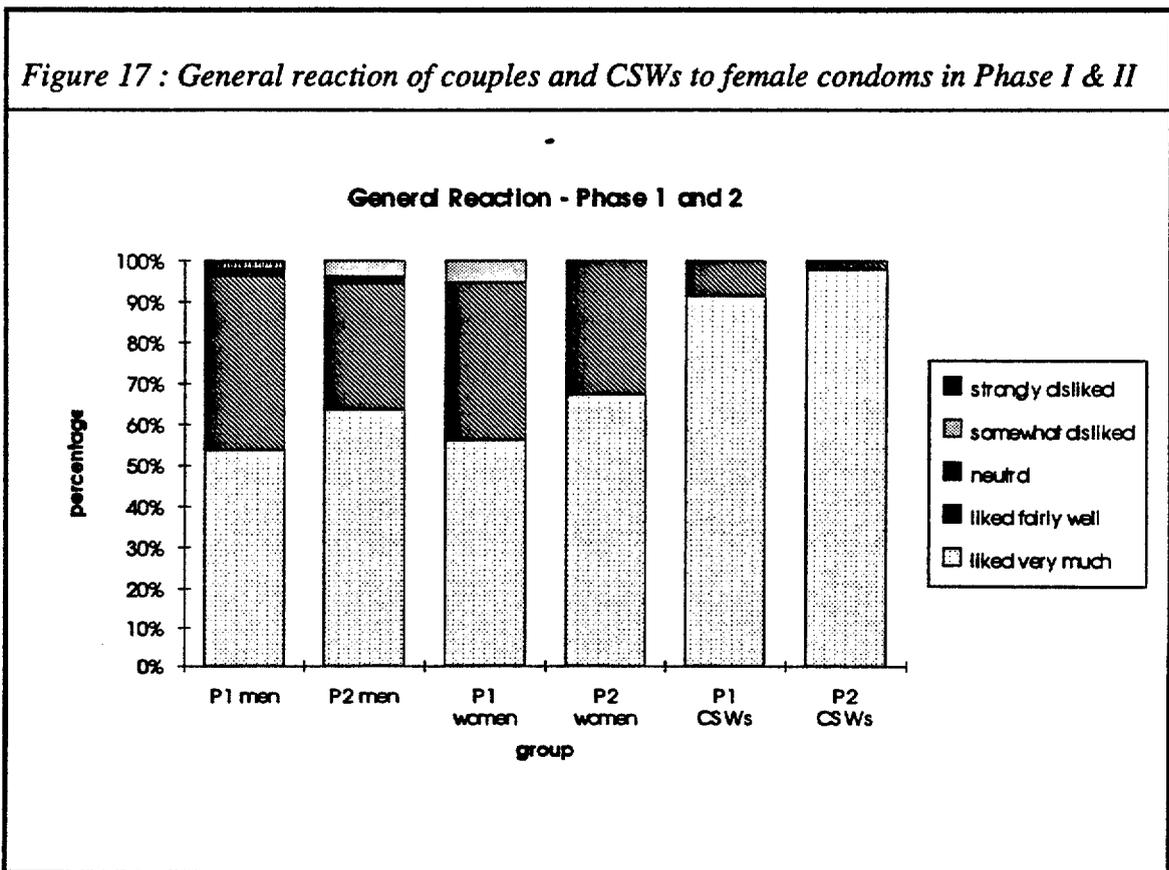
4.2.1 General Reaction to the female condom during Phase II

Only two men reported not liking the female condom in Phase II of the study with all women liking them. The man that strongly disliked the female condom in Phase I due to the inner ring hurting him (Dr Blogg commented that it seems the female condom was not pushed in far enough) participated again in Phase II, reporting that he somewhat disliked it. When asked if he would use it in the future he commented that only if improvements were made and that he was not skilled at inserting it in position. He had experience with male condoms with bar girls and only used the female condom once in Phase I. He liked the male condoms more. Another man that reported he disliked them in Phase II had liked them fairly well in Phase I. He had never used male condoms prior to the study but liked

female condoms less than the male condoms. He reported using two of each in Phase I and one of each in Phase II, due to disliking them both. It caused him no irritation.

Table 6: General reaction of couples and CSWs to the female condom during Phase II

General reaction	men n = 52	women n=55	CSW n=46
liked them very much	33 (63.5%)	37 (67.3%)	45 (97.8%)
liked them fairly well	16 (30.8%)	18 (32.7%)	1 (2.2%)
no opinion, neutral	1 (1.9%)	0	0
somewhat disliked them	2 (3.8%)	0	0



A higher proportion of participants reported liking female condoms very much in Phase II compared to Phase I of the study; men 53.7% to 60%, women 56.1% to 67.3% and CSWs 91.3% to 97.8%.

4.2.2 Ease of use of female condom with experience

Most participants (82%) agreed that the female condom became easier to use with experience (Table 7). One woman commented that they did not become easier to use as they were always easy to use.

Table 7: Female condom ease of use for couples and CSWs during Phase II

Easier to Use	Men n=52	Women n=55	CSWs n=46
No	9 (17.3%)	6 (10.9%)	11 (23.9%)
Yes	43 (82.7%)	48 (87.3%)	35 (76.1%)

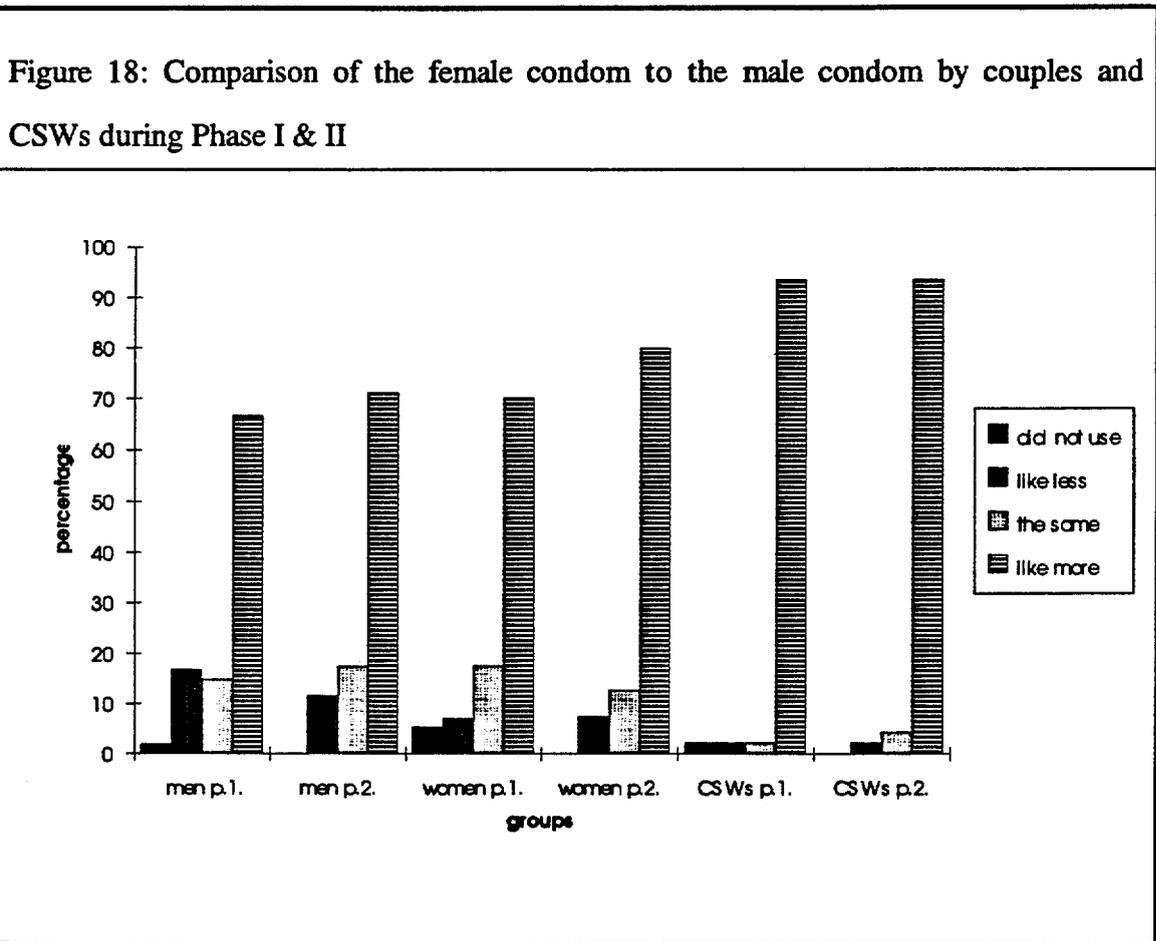
4.2.3 Comparison of the female condom to the male condom, phase II

A slightly higher percentage of men in Phase II liked the female condom more than the male condom (71.2%) than in Phase I (66.7%). A higher proportion of women liked the female condom more than the male condom (86.1% compared to 80.6% in Phase I (Figure 18).

Table 8: Comparison of the female condom to the male condom by couples and CSWs during Phase II

comparison with male condom	men n=52	women n=55	CSWs n=46
less	6(11.5%)	4 (7.3%)	1 (2.2%)
same	9 (17.3%)	7 (12.7%)	2 (4.3%)
more	37(71.2%)	44 (80%)	43 (93.5%)

More women than men like the female condom more than the male condom, although the majority of the men also liked them more.



4.2.4 Position of the female condom during intercourse

In Phase II there was a decrease in the reporting of female condoms that did not stay in place for couples, but over double the number of incidents that were reported by CSWs during Phase I (15% to 35%).

During Phase II there was less reporting of the penis being inserted between the outer ring and the vagina, with only 5 men and no women having this problem. During Phase I, 3 men and 5 women had reported this problem.

Only one woman reported the incident of the outer ring being pushed up into the vagina during Phase II compared to 7 women in Phase I. This was reported by 4 men in Phase II compared to 3 men during Phase I (Table 9).

Table 9 : Position of female condom during intercourse for couples (men and women) and CSWs during Phase II

<i>Position of female condom</i>	men n=52		women n=55		CSWs n=46	
	no	yes	no	yes	no	yes
female condom did not stay in place	46(89%)	6(11%)	51(93%)	4(7%)	34(74%)	12(35%)
the outer ring got pushed up into the vagina	48 (92%)	4(8%)	54(98%)	1(2%)	46(100%)	0
the penis was inserted between the outer ring and the vagina	47(90%)	5(10%)	55(100%)	0	46(100%)	0

4.2.5 Irritation/discomfort from the female condom during Phase II

During Phase II there was a general decrease in the reporting of irritation or discomfort by couples and CSWs. The outer ring still caused 2 men and 1 woman partner to report discomfort. Only 2 men, 6 women partners and 3 CSWs reported general irritation/discomfort during Phase II (Table 10).

Table 10: Irritation or discomfort from the female condom for couples (men & women) and CSWs during Phase II

Irritation/discomfort from the female condom	men n=52		women n=55		CSWs n=46	
	no	yes	no	yes	no	yes
discomfort from outer ring (partner or self)	50(96%)	2(4%)	54(98%)	1(2%)	46(100%)	0(0%)
general irritation/discomfort	50(96%)	2(4%)	50(91%)	6(9%)	43(94%)	3(6%)

4.2.6 Reuse of the female condom during Phase II

There was an increase of women partners who reused female condoms (28.1% Phase I to 56.4% during Phase II). Only 2 CSWs reused female condoms, with only 1 CSW reusing female condoms during Phase I (Table 11).

Table 11: Reuse of the female condom by women partners and CSWs during Phase II

	women n=55	CSWs n=46
no	24 (43.6%)	44 (95.7%)
yes	31 (56.4%)	2 (4.3%)

4.2.7 Use of female condom without the inner ring during Phase II

Using the female condom without the inner ring was almost the same in Phase I and Phase II of the study. Of the CSWs, 37% in Phase II and 34.8% in Phase I used the female condom in this way, as did 36.4% of women partners in Phase II compared to 36.8% in Phase I (Table 12).

Table 12: Use of the female condom without the inner ring by women partners and CSWs during Phase II

	women n=55	CSWs n=46
no	35 (63.6%)	29 (63%)
yes	20 (36.4%)	17 (37%)

4.2.8 Breakages

Although no one reported any breakages, there was some confusion when men tried to answer this question. One man again commented that he did not know if any had broken and another 2 reported breakages while trying to insert them, another three while using them and another one while removing it. The other 46 confirmed that there were no breakages out of the 51 who previously answered that there were no breakages. No women reported any breakages during Phase I or II.

4.2.9 Future Use of Female Condoms

Only two women responded that they would not use female condoms in the future and three men would only with improvements. All CSWs wanted to use them in the future.

4.3 COITAL LOGS OF CSWs

The coital logs were the most difficult component of the training for CSWs as many of the women were illiterate. Even though many of the CSWs did complete the coital logs correctly, others are inaccurate with 21.7% in Phase I and 17.4% in Phase II not corresponding to the number of female and male condoms reportedly used in the questionnaire. What is interesting from the reporting in the coital logs is that it shows the percentage of coital acts with no protection. With the provision of female and male condoms in unlimited supply being potentially available 17.4% of CSWs in Phase I always used a condom which increased to 32.6% in Phase II. There are still many occasions when no protection is used.

5. DISCUSSION

It seems that the female condom was acceptable as both a method of contraception and STD protection to most of the participants of this study. It was more acceptable to a high risk group, the CSWs, than to the couples. This may be due to their perception of their own risk of AIDS and also their desire to have some control in protecting themselves. The CSWs perceived themselves to be at risk of HIV and the couples were generally highly educated.

There was an increase in the number of women partners reusing female condoms during Phase II of the study, indicating their perceived need to make them last longer. This is also an indicator of acceptability.

Prior to its starting, this study had been discussed amongst the Salima and Nkhotakota population for about two years. During this time AIDS reached a higher public profile through local deaths and media coverage. This resulted in a high degree of anticipation. An extensive training took place with the participants prior to the study which may have contributed to the favourable results with regards to acceptability.

6. CONCLUSIONS

HIV/AIDS is a major women's issue in Malawi. Personal experience and strong local support prompted this study which hopefully will be followed by evaluated programs in female condom distribution. The symbolic importance of the female condom should not be understated: it is the first woman-controlled barrier method officially recognised as a means for the prevention of sexually transmitted disease. It is entirely reasonable to assume the method effectiveness of the female condom to be equivalent to that of the male condom.

A majority of both the men and women that participated in this study found the female condom to be acceptable with very few not wanting to use it in the future. Most people in Malawi are aware of the terrible tragedy that surrounds them as AIDS takes its toll. There exists a perceived need for barrier methods, not just to avoid pregnancy, but also for safe sex.

Cultural norms of female submission and passivity in sexual negotiation is a major barrier among most African women when it comes to insisting on male condom use during sexual intercourse. With the female condom the women have control over safe-sex practices without having to challenge the power of their male partners. Another advantage of the female condom is that most of the men and women liked it more than the male condom, making it another option for those that do not like male condoms.

It would be reasonable to assume that a project distributing female condoms to those that desire them would have benefits in preventing the spread of STDs and HIV as well as avoiding unwanted pregnancies as long as they were used consistently and correctly. It is time that a device that women have control over to protect themselves from STDs was made available.

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