TORONTO **STAFF REPORT**

September 10, 2002

To: Board of Health

From: Dr. Sheela V. Basrur, Medical Officer of Health

Subject: Female Condom Pilot Project

Purpose:

To report back to the Board of Health on the findings of the Toronto Public Health Female Condom Pilot Project and to make recommendations regarding the provision of female condoms to sexual health clinics, community health centres, and community and social service agencies.

Financial Implications and Impact Statement:

Resources for distribution of female condoms in 2002/2003 will come from within the Council approved 2002 male condom distribution program budget to a maximum of 5% ($19,000) of the budget. Resource implications for 2004 and beyond will be considered through the 2004 budget process.

Recommendation:

It is recommended that the Board of Health receive this report for information.

Background:

In February 2000, the Women's Outreach Network, a network of social service and clinical agencies serving women in Toronto, asked the Board of Health to provide female condoms through the existing Condom Distribution Program. This would enable low income women at high risk of sexually transmitted diseases to have access to a barrier method that they can control. The Condom Distribution Program currently provides a variety of male condoms and water-based lubricant to over 250 social service agencies in the City of Toronto including AIDS Service Organizations, sexual health clinics and community health centres.

In response to this request, the Board of Health directed staff to conduct a pilot study of female condom promotion accompanied by a social marketing campaign, service provider training, and

educational resources. The purpose of the pilot study was to document education and instruction efforts and to provide feedback on client acceptance and factors associated with initial and continued female condom use. Upon completion of the study, staff were to report back to the Board of Health on the findings.

This report documents Toronto Public Health's (TPH) activities related to these recommendations, and proposes strategies for further action. Given current budget constraints, strategies proposed for 2003 are within the current condom distribution budget.

Comments:

Need for Female Condom Availability:

Unintended pregnancy and exposure to sexually transmitted diseases including HIV, challenge women's reproductive rights and sexual health. Among women aged 15 to 44 in Toronto, rates of sexually transmitted diseases, including HIV, have increased steadily in recent years (Toronto Public Health, 2002). HIV-positive women in Ontario most often report that their exposure to the virus was as a result of being from an HIV-endemic country and/or having sex with HIV-positive men (Remis, 2000: 9). See Appendix A for incidence of sexually transmitted diseases and HIV.

Since women with an existing sexually transmitted disease are at an increased risk of contracting and transmitting HIV, prevention of all sexually transmitted diseases is necessary to prevent HIV transmission (WHO, 2000; Hitchcock, 1996). TPH analysis indicates that people living within census tracts with low income also tend to have a higher incidence of sexually transmitted diseases while high-income areas tend to have the lowest rates (Toronto Public Health, 2001; Hardwick and Patychuk, 1999).

The number of unintended pregnancies in Canada is substantial. The 1998 Canadian Contraception Study found 28% of respondents reported having had an unplanned pregnancy (Fisher, et. al. 1999: 172).

While there are a number of birth control choices available to women, the only effective method of preventing chlamydia, gonorrhoea or HIV has been the male latex condom. However, male condom use has been inconsistent, and is difficult for women to control. There is some empirical evidence to show that women, because they are the receptive partner, are at higher risk than heterosexual men of sexually transmitted diseases including HIV (WHO, 2000). In order for women to better protect themselves from unwanted pregnancy and sexually transmitted disease, they need access to methods they can control. These must include methods that do not require prescription by a physician, that are immediately reversible, produce no side effects, are non-systemic, affordable and, most importantly, prevent both pregnancy and sexually transmitted diseases, including HIV. The female condom addresses this need.

Until recently, there was little known about the use of the female condom in sexually active North American women. Among the cited barriers to their use are concerns about aesthetics, the high cost, the lack of promotion of this device as a barrier method and negative attitudes by health care providers (Artz, et al, 2000; Latka, et al, 2000).

Since 1994, when female condoms first became available in Canada, community agencies have identified a need to make female condoms available as well as male condoms. However, there was a concern that purchasing female condoms without evidence of client usage combined with a corresponding reduction in the number of male condoms distributed could lead to a potential increase in the rate of HIV infection and other STD's in Toronto.

Purpose of the Female Condom Pilot Project:

The Female Condom Pilot Project (hereafter referred to as the Pilot Project) was established to determine TPH's future involvement in the provision of female condoms while ensuring increased access to barrier options for women at high risk for sexually transmitted diseases including HIV, and unplanned pregnancy. To achieve this, TPH staff worked in consultation with community partner agencies to address the three components of the Pilot Project: Research, Social Marketing, Education and Counselling. For a list of community partners, see Appendix B. During the development of this project, faith, language, culture, racial identity, ethnicity, citizenship, socio-economic status, class, ability, sexuality and sexual orientation were factored into the project design. While women from diverse cultures were included, the project could only target English–speaking women as translated research protocols, educational materials, qualitative analysis and a separate social marketing campaign would have required a substantial budget increase.

The technical reports for all three components of the Pilot Project are on file with the Board of Health Administrator.

Research and Evaluation:

The main purpose of the research and evaluation component was to conduct a study evaluating the client education and counselling strategy.

The study took place at seven community sites in all four regions of the city which reflected the cultural diversity of the City of Toronto. One hundred and seventy-five women received the education and counselling, and 117 of them completed the study. Participants were sexually active, English speaking, low-income women from diverse ethno-cultural backgrounds at risk for sexually transmitted diseases and unplanned pregnancy. The findings of the study cannot be generalized to women whose command of English did not allow them to participate. More detailed information about the study methodology, profile of the participants and research findings are available in the technical reports which are on file with the City Clerk.

The main finding of the study was that education and counselling, accompanied by the provision of free male and female condoms increased the use of both male and female condoms. The proportion of sexual intercourse that was protected using either a male or a female condom increased by at least 20% over a two-month period. The female condom was an acceptable option for a majority of the participants, and it was a preferred method of protection against sexually transmitted diseases and unplanned pregnancy for over one third of them.

Factors that contributed to initial use of the female condom included being at high risk for sexually transmitted diseases, dissatisfaction with their current methods of birth control and sexually transmitted disease prevention, receiving appropriate education and counselling, and promotion of the female condom. Participants that liked the female condom and were comfortable inserting it were more likely to choose the female condom over the male condom. These factors, and being aged 25 and older, were associated with continued use. Practice inserting the female condom before using it for birth control and STD prevention was found to be an essential factor for continued use.

Cost is the most common barrier to use. Over half of the women in the study (the majority of whom had a low income) indicated a willingness to pay a nominal amount to acquire female condoms. This is one indicator that the female condom is an acceptable and important option. However, some women pointed out that male condoms are an expense that their male partners incur, so using the female condom might become their financial responsibility. This shift of financial responsibility would be a definite deterrent to continued use. There is evidence in the literature that price increases have the greatest impact on those with very low incomes, and cost-recovery programs exclude them entirely (Price, 2001). Furthermore, a nominal charge would entail additional administrative costs and would not result in cost recovery.

Social Marketing Campaign:

As directed by the Board of Health, the social marketing campaign targeted men and women, health care providers, educators and pharmacies. In consultation with community agency partners, the campaign was designed to appeal to both men and women. However, women (especially high-risk women) were the primary targets of this health promotion campaign.

The social marketing campaign had two purposes: to increase awareness of the female condom as a barrier option and to recruit women to participate in the pilot study. Toronto Public Health developed and focus tested a poster and pamphlet. These were distributed with female condoms and information about the campaign to community agencies, sexual health clinics, and to TPH programs that provide sexual health services to women. More specific information on the social marketing campaign is available in the summary report on file with the City Clerk.

The poster, pamphlet and recruitment information for the pilot study were placed on the City of Toronto Website. The Female Condom pages on the Website were viewed 1385 times from July to December 2001. Toronto Public Health also distributed the poster to bars, nightclubs, pharmacies, and post secondary learning centres located in the areas of the City of Toronto with high rates of sexually transmitted diseases and poverty. Print advertising was placed in local community papers for the pilot study recruitment. Pharmacies in the areas of the city with a high incidence of sexually transmitted disease were approached and 34 agreed to display the poster.

Press releases resulted in numerous electronic and print media interviews of Toronto Public Health staff. Subsequently, health promotion information requests were received from various public health departments and AIDS prevention programs throughout Canada and the United States.

Education and Counselling:

Educational resources, training manuals and promotional materials were developed and evaluated for both service providers and participants in the study. Education strategies included safer-sex negotiation and communication, skill building and insertion techniques to assure proper usage for both client and service providers.

Evaluation of the service provider training showed that service providers reported an increase in knowledge, a more positive attitude and enhanced skill in counselling clients on the use of the female condom. In addition, there was a high level of client satisfaction with the education and counselling strategy, with 97% of participants agreeing that the service provider had answered all her questions. Details about the education and counselling strategy are in the technical report on file with the City Clerk.

Implications of the Pilot Project:

The findings of the study have significant implications for TPH. Providing both female and male condoms along with education and counselling, increased the proportion of protected vaginal intercourse activity within the study group. However, cost was identified as a major barrier to use. Given that poverty is associated with higher rates of chlamydia, gonorrhoea and unplanned pregnancy, female condoms should be provided free of charge to women at high risk. Considering the increase in sexually transmitted diseases including HIV, and perinatal transmission of HIV, providing a supply of both male and female condoms, free of charge through the present Condom Distribution Program is an important prevention strategy for Toronto Public Health.

The condom distribution program was initiated in 1983 in the former City of Toronto to promote Birth Control week and was expanded in 1990 by the provincial Ministry of Health as a component of the HIV/AIDS prevention program. Prior to amalgamation, the former City of Toronto had a condom distribution budget of $370,000. There was also one time provincial funding in other former municipalities which did not continue post amalgamation. The current $370,000 budget has not been increased since amalgamation yet must be used to provide condoms to agencies throughout the larger municipality.

In the last two years, community agencies' requests for male condoms have exceeded Toronto Public Health's condom budget, and criteria for distributing fewer quantities have had to be established. These criteria will be further applied in order to adjust the distribution of male condoms to permit an initial distribution of female condoms. Programs that distribute free male condoms have been found to increase condom use, and also to be a cost-effective method for reducing HIV in communities with a high incidence rate (Creese, et al, 2002; Bedimo, et al, 2002).

Providing female condoms would place some additional pressure on the condom budget as the direct cost to TPH is approximately twelve cents for a male condom and one dollar and 60 cents for a female condom. Despite this disparity in price, it is important that both female condoms and male condoms be made available to selected agencies to enable low income women to better

protect themselves from unwanted pregnancies and sexually transmitted diseases. With the assistance of community partners, TPH will continue to identify the appropriate agencies to distribute the female condom to the intended population. However, since this is within the condom distribution envelope, some agencies will receive a reduced supply of male condoms in 2003 to accommodate initial distribution of female condoms.

It is also important to ensure that effective teaching resources be made available to community groups and health care providers distributing the female condom. The health care provider's ability to provide education and counselling will be a criterion for distribution. TPH will offer training to those agencies that can best distribute the female condom to the intended population.

In 2002 community agencies requested approximately $65,000 worth of female condoms. Fulfilling these requests would drastically reduce the availability of male condoms. TPH therefore, proposes providing up to $19,000 (5% of the budget) worth of female condoms through the Condom Distribution Program in order to develop an effective implementation strategy. To accomplish this, TPH will work in partnership with community agencies to identify distribution criteria to ensure women have access to the female condom.

Conclusions:

Toronto Public Health designed and implemented a female condom pilot project which included a social marketing campaign, educational resources and health promotion materials, and a pilot study with the intended population. The study showed that education and counselling, accompanied by the provision of free male and female condoms increased the use of both male and female condoms. Evidence shows reducing financial barriers promotes condom use and therefore, reduces STD's and unwanted pregnancies. In addition, the provision of free or at-cost contraceptives, including condoms, is a provincial requirement for all Boards of Health under the Sexual Health Program standard.

Given the findings of the study, the increase in sexually transmitted diseases, and the association of poverty with higher rates of chlamydia, gonorrhoea and unplanned pregnancy, Toronto Public Health needs to strengthen its prevention efforts by increasing the number of protection choices available to women. Providing female condoms to women at high risk for STD/HIV and unplanned pregnancy is a key step to reducing sexually transmitted diseases and unplanned pregnancy.

Resources for distribution of female condoms will come from within the 2002 condom distribution program budget to a maximum of 5% of the budget ($19,000). Continuation of female condom distribution will be determined based on an assessment of the project in 2003, and any resource implications will be identified for 2004 and beyond.

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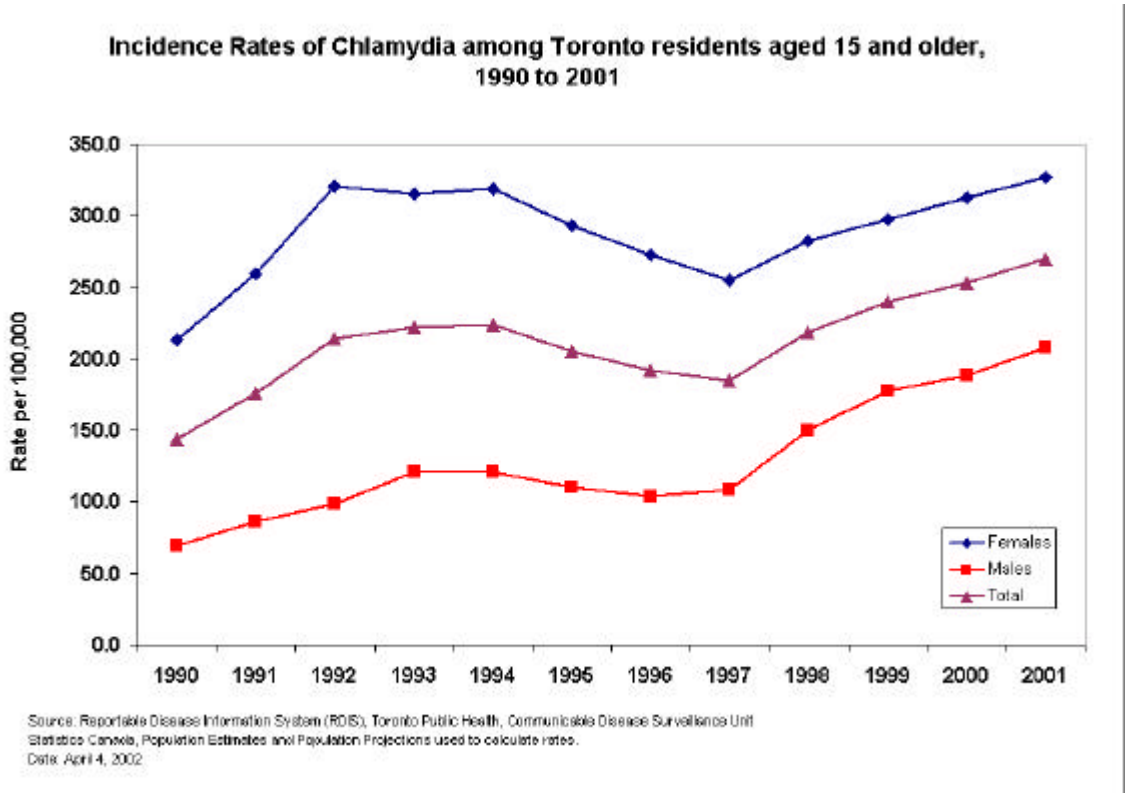
List of Attachments:

Appendix A: Incidence Sexually Transmitted Diseases and HIV in Toronto
Appendix B: List of Community Agency Partners
Appendix C: References

Appendix A – Incidence of Sexually Transmitted Diseases and HIV in Toronto

Incidence of Chlamydia Among Toronto Residents Aged 15 and Older, 1990 to 2001						
Episode Year	Females 15+		Males 15+		Total 15+	
	No. of Cases	Rate per 100,000	No. of Cases	Rate Per 100,000	No. of Cases	Rate per 100,000
1990	2200	213.5	669	69.7	2869	144.2
1991	2640	259.5	815	85.8	3455	175.7
1992	3260	320.7	934	98.8	4196	213.9
1993	3212	315.5	1137	120.5	4349	221.7
1994	3281	318.5	1156	121.2	4438	223.7
1995	3064	293.3	1064	110.2	4128	205.4
1996	2878	272.4	1007	103.6	3886	191.5
1997	2721	255.3	1070	108.8	3791	185.0
1998	3025	282.2	1488	150.1	4514	218.8
1999	3211	297.6	1771	177.3	4984	239.8
2000	3404	312.9	1893	188.4	5297	253.1
2001	3588	327.3	2105	208.2	5697	270.3

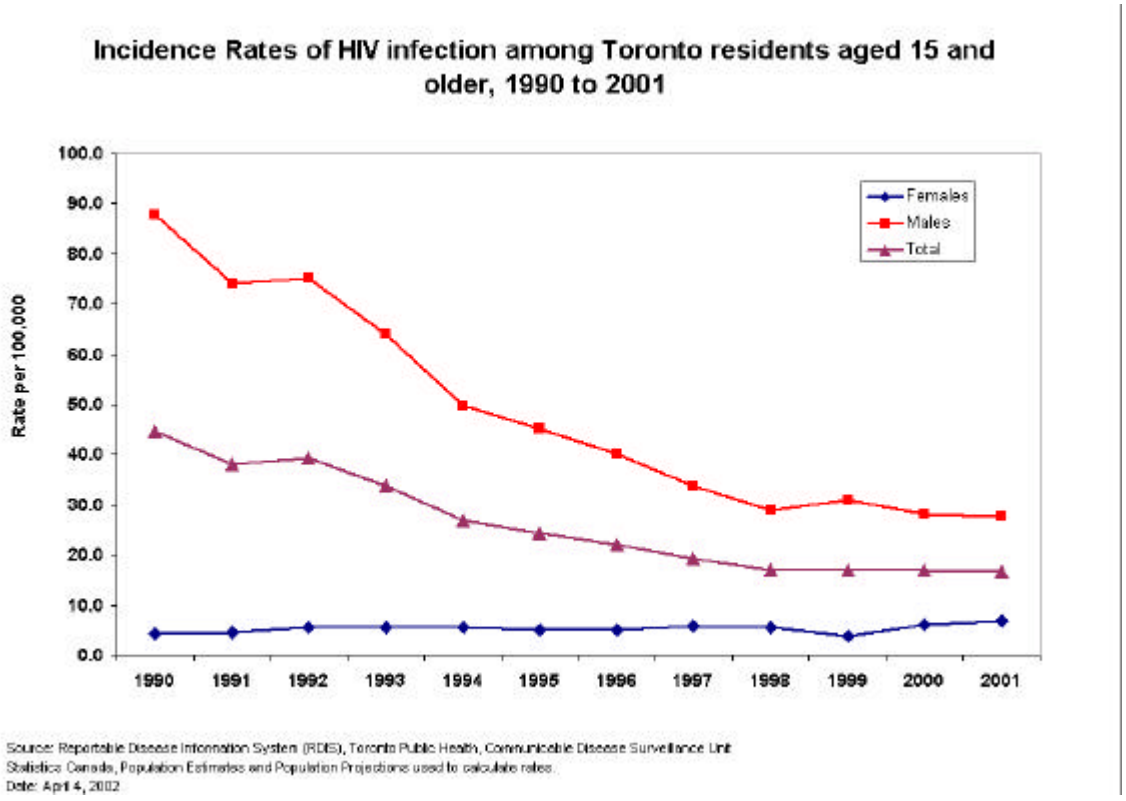
Source: Reportable Disease Information System (RDIS), Toronto Public Health, Communicable Disease Surveillance Unit
Statistics Canada, Population Estimates and Population Projections used to calculate rates
Date: April 4, 2002



Incidence of HIV Infection Among Toronto Residents Aged 15 and Older, 1990 to 2001

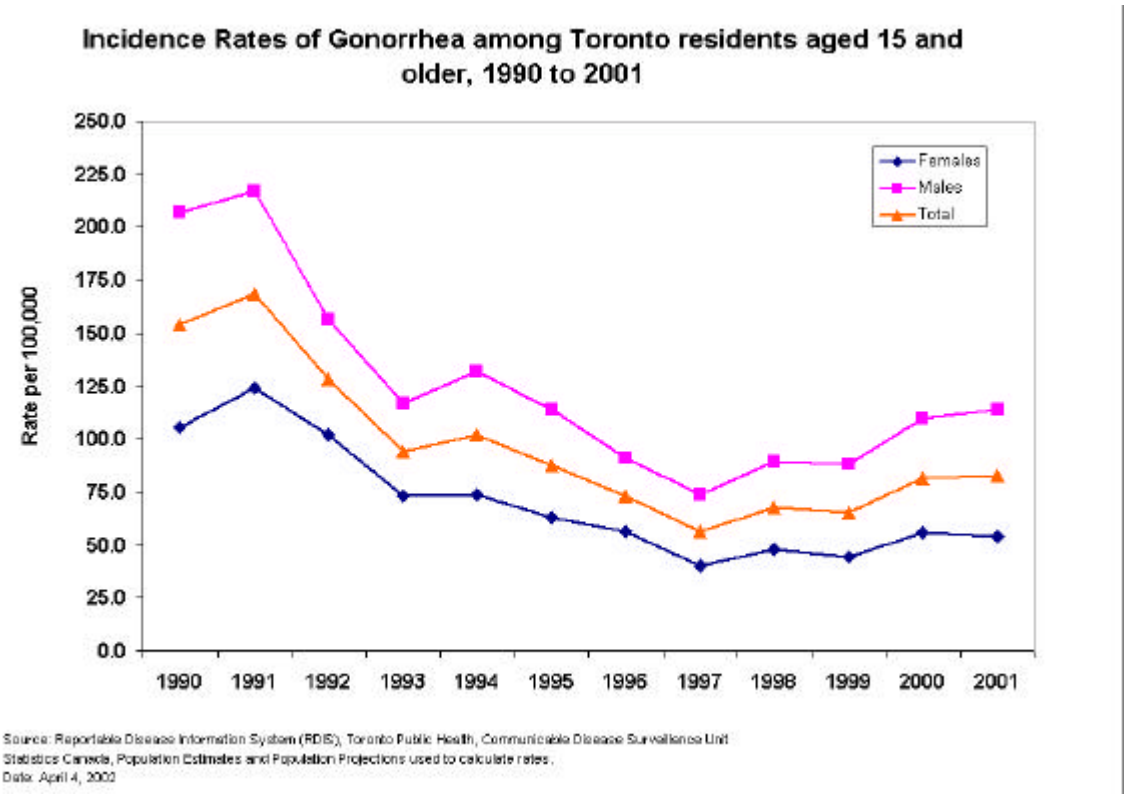
	Females 15+		Males 15+		Total 15+	
Episode Year	No. of infections	Rate per 100,000	No. of infections	Rate Per 100,000	No. of infections	Rate per 100,000
1990	45	4.4	842	87.7	888	44.6
1991	46	4.5	704	74.1	751	38.2
1992	58	5.7	710	75.1	771	39.3
1993	57	5.6	604	64.0	662	33.7
1994	57	5.5	475	49.8	532	26.8
1995	53	5.1	435	45.1	488	24.3
1996	54	5.1	391	40.2	446	22.0
1997	62	5.8	331	33.7	393	19.2
1998	60	5.6	286	28.8	349	16.9
1999	41	3.8	309	30.9	353	17.0
2000	67	6.2	284	28.3	357	17.1
2001	74	6.7	279	27.6	354	16.8

Source: Reportable Disease Information System (RDIS), Toronto Public Health, Communicable Disease Surveillance Unit
Statistics Canada, Population Estimates and Population Projections used to calculate rates
Date: April 4, 2002



Incidence of Gonorrhea Among Toronto Residents Aged 15 and Older, 1990 to 2001						
Episode Year	Females 15+		Males 15+		Total 15+	
	No. of Cases	Rate per 100,000	No. of Cases	Rate Per 100,000	No. of Cases	Rate per 100,000
1990	1089	105.7	1983	206.6	3072	154.4
1991	1260	123.9	2059	216.8	3319	168.7
1992	1038	102.1	1480	156.6	2518	128.4
1993	747	73.4	1101	116.7	1849	94.3
1994	759	73.7	1257	131.8	2016	101.6
1995	655	62.7	1102	114.2	1757	87.4
1996	594	56.2	884	90.9	1478	72.9
1997	428	40.2	724	73.6	1153	56.3
1998	517	48.2	884	89.2	1401	67.9
1999	477	44.2	878	87.9	1355	65.2
2000	609	56.0	1103	109.8	1712	81.8
2001	594	54.2	1149	113.6	1743	82.7

Source: Reportable Disease Information System (RDIS), Toronto Public Health, Communicable Disease Surveillance Unit
Statistics Canada, Population Estimates and Population Projections used to calculate rates
Date: April 4, 2002



Appendix B – List of Community Agency Partners

Community Agency Partners:

AIDS Committee of Toronto
Black Coalition for AIDS Prevention
Immigrant Women's Health Centre
Maggie's: Toronto Prostitutes' Community Service Project
Two-Spirited People of the First Nations
Voices of Positive Women
Women's Health in Women's Hands
Youth Link Inner City

Research Sites:

Crossways Sexual Health Clinic
Lawrence Heights Community Health Centre
LAMP: Lakeshore Area Multiservice Projects
Maggie's: Toronto Prostitutes' Community Service Project
Scarborough Sexual Health Clinic
South Asian Women's Centre
Warden Woods Community Centre

Appendix C - References

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Female Condom Pilot Project

Evaluation of the Education and Counselling Intervention

Technical Report of the Quantitative Research

Deborah Hardwick

Toronto Public Health

September 2002

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Table of Contents

Executive Summary

Introduction

In February 2000, the Women's Outreach Network – a network of agencies serving women in Toronto – asked the Toronto Board of Health (BOH) to provide female condoms as part of the existing Toronto Public Health (TPH) Condom Distribution Program. The BOH asked Toronto Public Health to design and implement a social marketing campaign, and conduct a pilot study with selected sexual health clinics and/or agencies in order to document education and instruction efforts, obtain feedback from clients on acceptability, and factors associated with initial and continued condom use. The goals of the Female Condom Project were:

- *Adult women and their male partners who are at high risk for sexually transmitted diseases, including HIV (STDs/HIV) and unplanned pregnancy will have access to a broader range of barrier options, and*

- *Toronto Public Health will determine their involvement in the provision of the female condoms and the nature of such an involvement based on Toronto research and evaluation.*

Toronto Public Health in partnership with several community agency partners piloted an education and counselling intervention during a five-month period beginning September 2001. The objectives of this study were:

- *To evaluate the effectiveness of the intervention in increasing the acceptability and use of the female condom and other barrier methods, among a sample of sexually active women in Toronto who are at risk of unplanned pregnancy and STDs/HIV, and who participated in the pilot project, and*

- *To identify factors associated with initial and continued female condom use among the pilot project participants.*

The intervention introduced the female condom to 175 women aged 18 to 45 in Toronto who were at high risk for sexually transmitted diseases, including HIV (STDs/HIV), and unplanned pregnancy. The intervention was designed to offer the female condom as an alternative method to the male condom to women at increased risk for STDs/HIV and unplanned pregnancy due to socio-economic and sexual risk behavioural factors. This is one of two reports that document the evaluation of the education and counselling intervention. This report focuses on the quantitative data. See Gillis (2002) for the technical report of the qualitative data.

Methods

Design

This was a prospective, cohort study without a control group. The scope of the project and ethical considerations reduced the feasibility of a randomized-control group study. It is important to note that the study took place over a short period of time (five months), which reduced the chance of history and cohort effects influencing the results. The scope of the project also made it infeasible to collect data in languages other than English.

Data Collection

Data were collected using self-administered questionnaires at three points in time: pre-intervention and about one month and two months post intervention (post 1 and post 2). The intervention was provided in two modes: individual education and counselling and peer group support sessions. In addition to the questionnaire, focus group discussions were conducted with the participants in the peer group support sessions. A sub sample of participants in the individual mode was further interviewed. The results of the focus group discussions and individual interviews are found in a separate technical report (Gillis, 2002).

Intervention

Four sites provided the individual intervention. Two of the sites were Toronto Public Health sexual health clinics and two were community partner clinics. Three sites facilitated group interventions – one was comprised of women from a specific ethno-cultural background, one of sex workers and one comprised of women from a low-income neighbourhood. Women aged 18-45, who reported having sex with a male partner at least three times in each of the previous two months were recruited to receive the intervention.

At each of the individual intervention sites, each participant met with a service provider (sexual health educator, nurse, nurse practitioner or physician). Service providers counselled the participants on anatomy, their sexual health risks, methods of STD/HIV prevention and contraception. Safer-sex negotiation with male partners and the demonstration and practice of insertion techniques using a plastic pelvic model were also provided. Each participant was offered the opportunity to insert a female condom herself and have it checked by a nurse clinician or physician.

The same topics were covered in the group intervention. However, those participants were not offered the opportunity of an insertion check at the time of the intervention because the sessions were conducted in non-clinical locations and lacked privacy. Service providers at the group interventions provided participants with the locations of sexual health clinics where an insertion check could be performed if desired. Participants in both types of interventions received as many female or male condoms and as much lube they thought they would need for each month.

Analysis

Data were analyzed using SAS, Version 8. The full sample (n=175) was included in the initial analysis. However, due to significant differences between those that dropped out of the study and those that completed the study on a number of key independent variables, final analysis was conducted on only those that completed all three questionnaires (n=117).

Results

The characteristics of the sample indicate that we were successful in recruiting participants from our intended population. The sample was comprised primarily of women with low socio-economic status as measured by their education and income. These women are least able to afford to purchase the female condom and, indeed, other methods of birth control and STD/HIV prevention. The participants came from a wide range of ethnocultural backgrounds, however most reported their first language to be English. Forty-one percent of the participants who completed the study reported previously having an STD and 70% of participants who had ever been pregnant reported at least one unplanned pregnancy. These percentages are much higher than we expect to find in the general population.

Despite methodological limitations, the results of this study are consistent with previous studies conducted in the U.S. Providing education and counselling sessions, along with unlimited quantities of male condoms, female condoms, and water-based personal lubricant, significantly increased the consistency of sexual intercourse acts that participants reported were protected by either the male or female condom over a two-month period. When comparing the mean of the difference in consistency of condom use from pre to post 1 and post 2, the percentage of sexual acts that were protected with either a male or female condom increased by 22% from pre-intervention to post 1. The increase from pre-intervention to post 2 was 20%. Almost one-quarter of participants (23%) used the female condom for 70% of sexual intercourse events at post 2. Most participants used both male and female condoms.

The intervention was effective for women as young as 18, although women between 18 and 24 may require more education and counselling sessions than those over 24. The 36 participants under age 25 were no less comfortable inserting the female condom than were participants age 25 and older. However, women under 25 were less likely to have used the female condom at least 70% of the time than were women in the older age group, at post 1. Two months after the intervention, the difference in consistency of use between the age groups disappeared. Future studies should look more carefully at the differing needs of various age groups.

Knowledge about the female condom increased post intervention, however, we were not able to find an association between knowledge and male or female condom use. Nor was there an association between attitudes toward the female

condom, previous unplanned pregnancies, or previous STDs and consistency of male or female condom use.

Consistent use of the female condom was found to be associated with liking the female condom, feeling comfortable using it, and preferring it over the male condom, both types of condoms, or neither, if the condoms were readily available free of charge. Over one-third (36%) of all participants at post 2 preferred the female condom. However 54% of those who used the female condom consistently preferred the female condom.

By the end of the study, 29% of the participants said they would pay more for the female condom than the current retail price of a male condom. At the time of the study the retail price for a female condom was about $4.00 and male condoms could easily be purchased for less than $1.00. The majority (71%) of participants would pay $1.00 or less for a female condom, including 16% that would use it only if it was free.

Conclusions

The intervention was successful in introducing the female condom to English-speaking women at risk for STDs and unplanned pregnancy in Toronto and increasing the proportion of sexual intercourse events that were protected with either a male or a female condom.

Liking the female condom, feeling comfortable using it and preferring the female condom over the male condom are associated with consistent female condom use. However, it is not known whether the consistency of use influenced participant's liking the female condom, feeling comfortable using it and preferring it, or whether these factors influenced consistent female condom use. Nevertheless, access to the female condom appears to be a major factor for continued use.

The cost of the female condom appears to be a major barrier to its use in Toronto. Since having access to a female condom increases the consistency of either male or female condom use, the cost of the female condom is also a barrier to consistent use of the male condom. Cost-effectiveness studies should be conducted to determine if the costs of free female and male condom distribution programs by governments and non-government agencies offset the costs, long and short-term, societal and individual, of STD/HIV and unplanned pregnancy.

The implications of these results, and of previous studies, for public health planners, sexual health promoters, health care providers and advocates are multiple. Female condoms are acceptable to low-income, English speaking women in Toronto who are at high risk for STDs/HIV and unplanned pregnancy. Sexual health promoters and health care providers should consider including the female condom as one method, among others, in their education and counselling

with women who participate in high risk behaviours. Public health planners and advocates should consider ensuring female condoms are freely available to women at risk, since cost is a significant barrier and poverty is associated with poor sexual health outcomes.

1. Introduction

In February 2000, the Women's Outreach Network – a network of agencies serving women in Toronto – asked the Toronto Board of Health (BOH) to provide female condoms as part of the existing Toronto Public Health (TPH) Condom Distribution Program. The BOH asked Toronto Public Health to design and implement a social marketing campaign, and conduct a pilot study with selected sexual health clinics and/or agencies in order to document education and instruction efforts, obtain feedback from clients on acceptability, and factors associated with initial and continued condom use. The goals of the Female Condom Project were:

- *Adult women and their male partners who are at high risk for sexually transmitted diseases, including HIV (STDs/HIV) and unplanned pregnancy will have access to a broader range of barrier options, and*

- *Toronto Public Health will determine their involvement in the provision of the female condoms and the nature of such an involvement based on Toronto research and evaluation.*

Toronto Public Health in partnership with eight community agency partners (listed in Appendix A) piloted an education and counselling intervention during a five-month period beginning September 2001. The objectives of this study were:

- *To evaluate the effectiveness of the interventions in increasing the acceptability and use of the female condom and other barrier methods, among a sample of sexually active women in Toronto who are at risk of unplanned pregnancy and STDs/HIV, and who participated in the pilot project, and*

- *To identify factors associated with initial and continued female condom use among the pilot project participants.*

The intervention introduced the female condom to 175 women aged 18 to 45 in Toronto who were at high risk for sexually transmitted diseases, including HIV (STDs/HIV), and unplanned pregnancy. The intervention was designed to offer the female condom as an alternative method to the male condom to women at increased risk for STDs/HIV and unplanned pregnancy due to socio-economic and sexual risk behavioural factors. This is one of two reports that document the evaluation of the education and counselling intervention. This report focuses on the quantitative data. See Gillis (2002) for the technical report of the qualitative data.

2. Background

A review of the determinants of risk for STDs/HIV, current condom practice in the population and previous studies on the introduction of the female condom highlights the need for this study. Poverty is a risk factor for many health issues, including sexual health. High rates of STDs/HIV among women and unplanned pregnancy are not only risk factors for future STDs/HIV and unplanned pregnancy, but also indicate that current condom practice is less than efficient. Other interventions among women at high risk for STDs/HIV have been found to be effective in increasing the number of sexual acts that were protected. This section of the report examines the sexual health risks for women in Toronto, current condom practice and the introduction of the female condom in North America.

Risk factors for sexually transmitted disease, including HIV, and unplanned pregnancy in Toronto

In Canada, the risk of STDs/HIV and unplanned pregnancy is increased for people with lower social economic status, including those with low income, women, and ethnocultural minorities (Health Canada, 1999). Previous occurrence of sexually transmitted disease, multiple sex partners, and trading sex for drugs or money are known risk factors for sexually transmitted disease.

In Toronto, an association between poverty and sexual health has been found. Census tracts with high levels of poverty tend to have high rates of chlamydia and gonorrhoea among both men and women, and to have high rates of births among women aged 15 - 19 (Toronto Public Health, 2001; Hardwick and Patychuk, 1999).

The City of Toronto has seen increased rates of chlamydia, gonorrhoea and HIV among women aged 15 to 44 in recent years (Toronto Public Health, 2002). Rates of chlamydia infection have increased by 53%, from 213.5 per 100,000 in 1990 to 327.3 per 100,000 in 2001 (Fig. 1). The rate of gonorrhoea decreased from 1990 to 1997 but has since increased by 35% from 40.2 per 100,000 to 54.2 in 2001 (Fig. 2). During the same periods, chlamydia and gonorrhoea rates also increased for males in the same age group by 69% and 54% respectively (Fig. 1 and Fig. 2).

Although the number of women who have HIV is low compared to men, the rate has increased 52% from 4.4 per 100,000 in 1990 to 6.7 in 2001 (Fig. 3). The HIV rate for males aged 15 – 44 has seen a 69% decrease from 87.7 per 100,000 in 1990 to 27.6 per 100,000 in 2001 (Toronto Public Health, 2002). Remis, et al (2001) report an increase in perinatal transmission of HIV and that about half of the perinatal HIV positive cases diagnosed in 2000 were among residents of Toronto. Almost two-thirds of all HIV infected infants were born to mothers from HIV-endemic countries and more than a quarter (27.3%) to mothers not from

endemic countries but also infected by heterosexual transmission.

The number of unintended pregnancies in Toronto is difficult to estimate but appears to be substantial. The 1998 Canadian Contraception Study found 28% of respondents reported ever having had an unplanned pregnancy (Fisher, et. al. 1999: 172). This is consistent with the 1995 National Survey of Family Growth in the U.S. which found that at least 30% of all pregnancies in the preceding five years had been either mistimed (i.e. earlier than planned) or unwanted (Abma, et. al, 1997).

Fig. 1

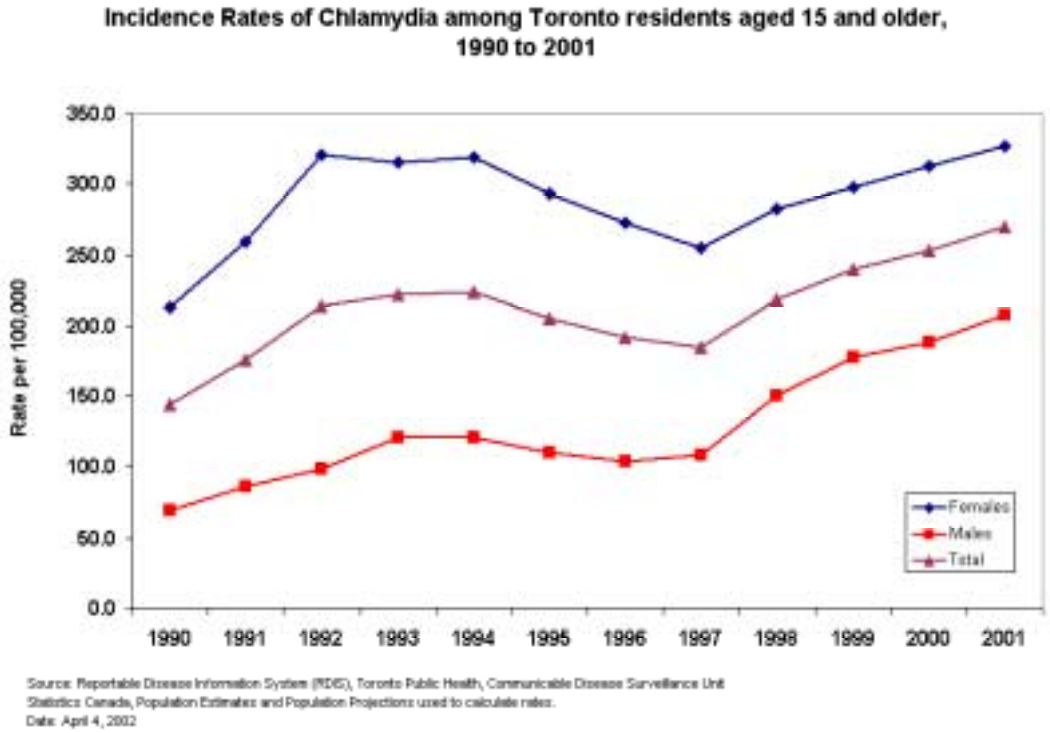
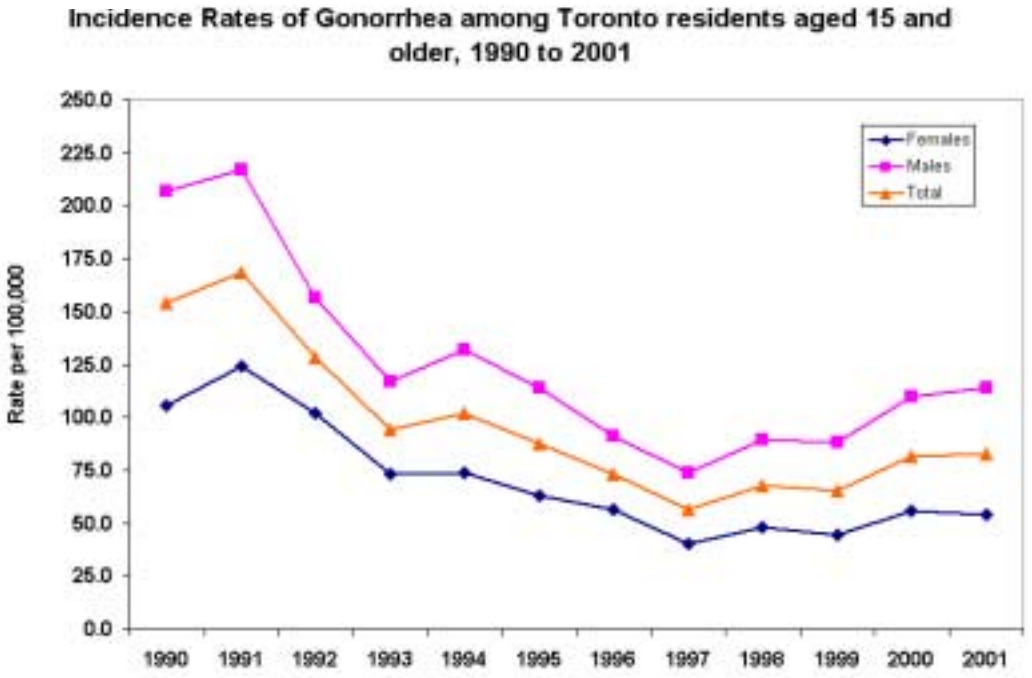
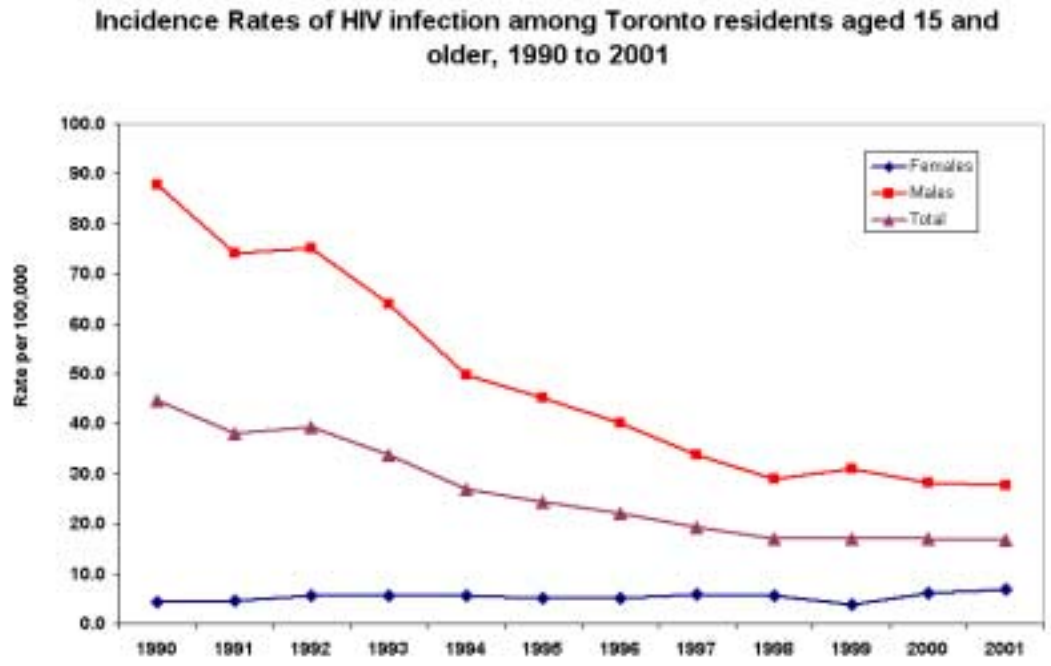


Fig. 2



Source: Reportable Disease Information System (RDIS), Toronto Public Health, Communicable Disease Surveillance Unit
Statistics Canada, Population Estimates and Population Projections used to calculate rates.
Date: April 4, 2002

Fig. 3



Source: Reportable Disease Information System (RDIS), Toronto Public Health, Communicable Disease Surveillance Unit
Statistics Canada, Population Estimates and Population Projections used to calculate rates.
Date: April 4, 2002

Current condom practice

While there are a number of birth control choices available to women, the only effective method of preventing chlamydia, gonorrhoea or HIV has been the male condom – that is, until the female condom became available. The advantage of these barrier methods is that they are effective in preventing both conception and disease transmission.

Consistent male condom use is difficult for women to control since it is their male partners that "wear" it. A Health Canada report (1999) found that 16% of Canadians aged 15-59 in a relationship of less than 1 year in duration did not use a condom the last time they had sex. Furthermore, 8% had never used a condom. The 1995 National Survey of Family Growth in the U.S. found that 82% of women aged 15 – 44 had ever used a male condom, but only 1% had ever used a female condom (Abma, et al, 1997). Only 13% of women in the U.S. were currently using a condom for contraception, and this rate was almost the same for those never married and those currently married.

Women are often at risk for STDs/HIV because of their male partners' sexual behaviour. Among married women sampled in the National Survey of Family Growth, 1.6% reported having a partner in the past twelve months who had had sex with other men since 1980. The survey also showed that 1.2% of married women had partners that injected drugs without a prescription in the previous twelve months and 4.2% reported partners having had sex with women other than their wives around the same time as having sex with the respondent, in the previous twelve months (Abma, et al, 1997). Unmarried women are at even greater risk. Over 2% reported their partners during the previous twelve months had had sex with other men since 1980. The survey also found that 4.3% of unmarried women had a sexual partner that had injected drugs without a prescription in the previous twelve months. Over a quarter (28.4%) of the unmarried women had a sexual partner in the previous year who had sex with other women around the same time as having sex with the respondent. Among unmarried women who had had sexual intercourse in the previous year, 33% had not used a condom at all and 14% had used a condom less than half the time (Abma, et al, 1997). Despite the known efficacy of male condoms in preventing conception and STDs/HIV transmission, they are not being consistently used to protect the sexual and reproductive health of women.

Despite inconsistent use of male condoms generally, programs that distribute free male condoms have been found to increase condom use, and also to be a cost effective method for reducing HIV in communities with a high incidence rate (Creese et al, 2002: Bedimo et al, 2002). While this evidence existed for male condoms, little North American evidence existed with respect to the female condom. Would the distribution of female condoms without evidence of potential client usage result in a reduction in the number of male condoms distributed, with a potential increase in the rates of STDs/HIV in Toronto?

Introducing the female condom

The female condom is a transparent polyurethane sheath that loosely lines the vagina. It is inserted into the vagina prior to sexual intercourse, to prevent STDs/HIV, and unintended pregnancy. The United States Food and Drug Administration (FDA) first licensed it for sale in 1993. The female condom has been available in Canada since 1994 and it has been available in 29 countries around the world since 1998 (Gilbert, 1999). It has been demonstrated to be an effective contraceptive method (Farr, et al, 1994; Trussell, et al, 1994) and, in laboratory tests, an effective barrier to STD transmission (Drew et al, 1990; Soper et al, 1993). Trussell et al (1994) calculated that perfect use of the female condom could reduce the annual risk of HIV infection among women having intercourse twice weekly with an HIV infected male by more than 90%. The 12-month probability of contraceptive failure during perfect use of the female condom was found to be 5.2%, a figure similar to failure rates of the diaphragm, cervical cap (Trussell et al, 1994) and the male condom (Society of Obstetricians and Gynaecologists of Canada, 2002). It is the only available woman-controlled contraceptive device effective in significantly reducing the risk of HIV/STD infections (Surratt, et al, 1998).

Few rigorous research studies on the use and acceptability of the female condom have been conducted in North America or Europe, while none have been done in Canada. U.S. studies have demonstrated that public health interventions focusing on the female condom are effective in increasing the proportion of vaginal intercourse acts that were protected by either male or female condoms (Artz, et al, 2000; Latka, et al., 2000; Witte, et al, 2000; Sly, et al, 1997). Previous studies also indicate interventions are most successful when targeted to adult women at high risk for STDs/HIV and unplanned pregnancy (Artz, et al, 2000; Latka, et al, 2000; Macaluso, et al, 2000; Witte, et al, 2000) and their male partners (El-Bassell, et al, 1998). Effective interventions include safer sex negotiation, communication skill-building and insertion techniques in education and counselling sessions and opportunities to practice inserting the female condom are provided (Artz, et al, 2000; Latka, et al, 2000; Witte, et al, 2000; Sly et al, 1997).

Studies conducted internationally have also examined the role of peer support in encouraging and sustaining female condom use. Group interventions assisted participants in talking to their partners about sex – something that is otherwise rare in the populations studied (Gollub et al, 1998; Ankrah and Attika, 1997; Mwakisha, 1996).

High cost is identified as a major barrier to the use of female condoms internationally and in Canada (Barnett, 2001; Marsden and Newman, 2001; Ankrah and Attika, 1997). Ankrah and Attika (1997) found that a majority of men who attended focus group discussions in Kenya and Brazil were willing to pay as

much for a female condom as for a male condom. In a small pilot project Marsden and Newman (2001) asked 16 Aboriginal women on Canada's West Coast how much they would be willing to pay for the female condom. Only one participant was willing to pay more than $2.00 if she had to pay for the female condom. The current (2002) retail price for a female condom in Toronto is about $4.00. Male condoms can easily be purchased for less than $1.00 each. The UNAIDS-WHO guide for planning and programming the female condom suggests that it is cost-effective in reproductive health programs targeting people at high risk (UNAIDS & WHO, 2000).

3. Methods

3.1 Design

This is a prospective, cohort study without a control group. This means that we cannot be certain the results are due to the intervention alone and are not the product of other factors. The scope of the project and ethical considerations reduced the feasibility of a randomized-control group study. It is important to note that the study took place over a short period of time (five months), which reduced the chance of history and cohort effects influencing the results.

Data were collected using self-administered questionnaires at three points in time: pre-intervention and about one month and two months post intervention (post 1 and post 2). The intervention was provided in two modes: individual education and counselling and peer group support sessions. In addition to the questionnaire, focus group discussions were conducted with the participants in the peer group support sessions. A sub sample of participants in the individual mode was further interviewed. The results of the focus group discussions and individual interviews are found in a separate technical report (Gillis, 2002).

The research design underwent a scientific and ethical review at Toronto Public Health. Prior to participating in the individual intervention, potential participants met with a data collector who asked screening questions to ensure they were within the target age group and had been sexually active within the past three months. The facilitator from each agency invited participants to the group that met these same criteria. A data collector explained the project and obtained written informed consent prior to beginning the project, in both individual and group interventions. Confidentiality was assured and participants were provided with information about the known efficacy of the female condom relative to other methods of STD/HIV prevention and contraception.

3.2 Intervention

Community-based health and social service agencies serving women at risk for STDs/HIV and unplanned pregnancy were invited to participate as research sites

for either the individual or group intervention. Four sites provided the individual intervention. Two of the sites were Toronto Public Health sexual health clinics and two were community partner clinics. Three sites facilitated group interventions – one was comprised of women from a specific ethnocultural background, one of sex workers and one comprised of women from a low-income neighbourhood. Women aged 18-45, who reported having sex with a male partner at least three times in each of the previous two months were recruited to receive the intervention.

Mandatory service provider training was provided to all community-based agency and Toronto Public Health staff who would deliver the education and counselling intervention, recruit participants or collect data. These training sessions were evaluated and found to increase participating service providers' knowledge about, and improve their attitude toward, the female condom. Participants also reported female condom counselling skill improvement. (See the Education and Counselling report for more details).

At the individual intervention sites, each participant met with a service provider (sexual health educator, nurse, nurse practitioner or physician). Service providers counselled the participants on anatomy, their sexual health risks, methods of STD/HIV prevention and contraception. Safer-sex negotiation, including discussion about ways to introduce the female condom to male partners, was provided as well as the demonstration and practice of insertion techniques using a plastic pelvic model. Each participant was offered the opportunity to insert a female condom herself and have it checked by a nurse clinician or physician.

The same topics were covered in the group intervention. However, those participants were not offered the opportunity of an insertion check at the time of the intervention because the sessions were conducted in non-clinical locations and lacked privacy. Service providers at the group interventions provided participants with the locations of sexual health clinics where an insertion check could be performed if desired. Participants in both types of interventions received as many female or male condoms and as much lube they thought they would need for each month.

3.3 Participants

All study participants were women at risk of STDs/HIV and unplanned pregnancy. Those participating in the individual intervention were recruited through a variety of methods including:

- Information posters requesting volunteers at the participating agencies,
- Referral by health care providers at participating agencies and clinics,
- Toronto Public Health news release and resulting mass media

articles (radio, newspaper),
- Newspaper advertisements.

Facilitators at each of the group intervention sites recruited participants by word of mouth and by information posters targeting their existing client base. Membership of the three groups differed in terms of the risk factors of the women. Each of these groups reflected the client base of the agency within which the intervention was provided.

A total of 175 women received the intervention and completed the pre-intervention questionnaire, 151 individually and 24 in one of the three groups. After the intervention, participants were asked to return in three to five weeks (post 1), and again three to five weeks after the second visit (post 2). At the second and third visits, additional education and counselling interventions were provided on an as-needed basis, oriented toward problem solving. Focus groups were conducted in conjunction with the intervention at group sites, and a sub-sample of 16 participants who received the individual intervention were asked to participate in an additional individual interview, after the third visit. Participants for the additional individual interview were selected based on their experiencing either success or challenges when using the female condom.

Participants in the individual intervention were telephoned to remind them of their second and third appointments and group site facilitators were encouraged to remind group intervention participants of their second and third meetings. The completion rate was 67% with 117 participants completing all three questionnaires. Other studies have had as many as 20% drop-out after one month, and 55% at six months (Artz, et al, 2000). There was no difference in the completion rate by intervention in this study.

For both individual and group interventions, all participants completed the pre-intervention questionnaire during their first visit, and post 1 and post 2 questionnaires at subsequent visits. Each participant was offered $25 and two public transit tokens for each questionnaire returned to a maximum of $75 and six tokens if all three questionnaires were returned. The 16 women who participated in the additional individual interview received another $25 and public transit tokens.

3.4 Data Collection

Questionnaires (see Appendix B) were self-administered at three points in time over approximately two months: immediately prior to receiving the education and counselling intervention (pre), approximately one month later (post 1) and one month after that (post 2). The pre-intervention questionnaire was pilot-tested. However, the number of respondents to the pilot was too small to calculate reliability of the items. Toronto Public Health and community-based agency staff providing sexual health services to participants reviewed data collection

instruments extensively. As a result we are confident in the content and face validity of the questionnaires.

Pre-intervention:

Demographic and history of risk behaviour data were collected in the pre-intervention questionnaire. Wherever possible, questions were derived from larger surveys or census questionnaires (e.g. age, income, ethno-cultural background, language first learned, history of unplanned pregnancy and STD). Knowledge, attitudes, behaviours and intentions were self-reported at pre-intervention and again at post 1 and post 2.

For the individual intervention, service providers recorded whether participants opted for an insertion check on their first intervention visit. This involved participants inserting the female condom themselves and having nurse clinicians or physicians check to ensure if it was properly placed in the vagina. Participants were asked if they returned to the clinic for an insertion check between visits in the post intervention questionnaires.

Knowledge about the female condom was measured by a five-item true / false scale. Post-hoc reliability analysis revealed this scale had low reliability (Cronbach's Coefficient Alpha < .50). As a result, knowledge was analyzed for each item separately.

The attitude score was composed of four statements rated on a scale of 1 (agree strongly) to 4 (disagree strongly). Post-hoc analysis revealed one of the items was not strongly correlated with the others and as a result it was removed from the scale. The remaining three items had high internal consistency at all three data collection points (Cronbach's Coefficient Alpha => .80). They measured how much the participant agreed that the female condom would provide another option for birth control, another option for protection against STD and more control over her sexual health than male condoms. The removed item measured the participant's attitude toward inserting the condom into her vagina.

Post-intervention:

In addition to the same knowledge and attitude questions asked in the pre-intervention questionnaire, participants were asked to rate five statements about the advantages of the female condom on a scale of 0 (strongly disagree) to 10 (strongly agree) in post-intervention questionnaires. They were also given a list of 13 problems women previously reported when using the female condom (Lynn Artz, personal communication) and were asked to rate those they experienced on a scale of 0 (not bothered at all) to 10 (extremely bothered). Despite the fact that participants in a previous study had identified these as problems, when they were presented in the format of a scale in this study, results show that the reliability and validity of the scale was questionable.

We asked participants how much they liked using the male condom (pre-intervention and post-intervention) and the female condom (post-intervention only). We also asked how comfortable they felt about inserting the female condom and how much they would be willing to pay for the male condom and for the female condom. We asked if both the male condom and female condom were easily available and fee of charge, which one they would use.

Behaviour and intentions:

Behaviour was measured at pre-intervention by asking participants how many times they had sex (defined as vaginal intercourse) during the past month with a main male partner, or with a man other than their main partner, and how many times they used a male condom. For the post-intervention questionnaires, participants were asked the same questions, but were also asked how many times they used a female condom. To help them recall their sexual behaviour, we provided participants with a diary to document their sexual activity. These diaries were intended only to serve as a memory aid and were not reviewed or analyzed by service providers or data collectors.

Intentions were measured by asking participants how likely they were to try the female condom and how likely they thought their male partner(s) would be to agree to try the female condom.

3.5 Analysis

Data were analysed using SAS, Version 8. The full sample (n=175) was included in the initial analysis. However, due to significant differences between those that dropped out of the study (dropouts) and those that completed the study (completers) on a number of key independent variables, final analysis was conducted on only those that completed all three questionnaires (n=117).

Comparisons between dropouts and completers can be found in Appendix C, Table 1. The hypothesis that there is a difference between the dropouts and completers was accepted if the 'p' value for the statistical test used (i.e. Chi square or Wilcoxon signed rank) was less than 0.05. Completers were more likely than dropouts to have a first language other than English. Dropouts were less likely to have one main sex partner in the past month, and to correctly answer all of the knowledge questions. Dropouts were more likely to have had previous experience with the male condom, to have heard of the female condom, to have had sex with a man other than their main partner in the past month, and to have traded sex for drugs or money than were completers. Dropouts also had sexual intercourse with a man other than their main partner more frequently in the previous month than did completers.

Because participants were not randomly selected to receive individual or group

intervention, comparisons of the two types of intervention were performed for descriptive purposes only. Appendix C, Table 2 compares participants by intervention mode - group or individual. Only six variables were significantly different between the two intervention modes. The hypothesis that there was a difference between the two types was accepted if the 'p' value for the statistical test used (i.e. Chi square or Wilcoxon signed rank) was less than 0.05.

A greater proportion of participants in the group intervention had a first language other than English than in the individual intervention. This difference was expected given that two of the groups consisted primarily of immigrant women. Participants in the group intervention were found to be less likely to have previously used a method of birth control or STD protection, to have ever used a male condom, and to feel comfortable inserting a female condom than were women in the individual intervention. They thought their main partners were less likely to agree to use the female condom and they scored lower on two of the knowledge questions than did those in the individual intervention. Participants in the group intervention were more likely to have traded sex for drugs or money than were participants in the individual intervention, likely due to the fact that one of the groups was comprised of sex workers.

Univariate analysis was conducted on demographic, risk factor and behaviour variables in order to describe the sample. Bivariate analyses were conducted to test the following hypotheses:

- Participants over age 24 are more comfortable with using the female condom than those 24 and younger.
- More participants state they would be more comfortable inserting a female condom following the intervention.
- More participants state that they intend to use a female condom following the intervention.
- The more women like using the female condom, the more they are willing to pay for it.
- The more consistently women use the female condom, the more they prefer it to the male condom.

Contingency tables were constructed for the above bivariate analyses and chi square statistics were calculated. For tables with two dichotomous variables, Fischer's exact test was used. The hypotheses were accepted if χ^2 $p < 0$ .05.

Age was asked as an open-end question and then dichotomised to <25 (18 – 24) and 25+ (25 – 45).

The values of the variables "like the female condom" and "willing to pay for the female condom" were regrouped to like / dislike for the former, and If free, 50 cents or less, $1.00 and more than $1.00. This was done to ensure that

expected frequencies for most cells would be greater than 5, allowing the chi square to be used.

Preference was measured by asking participants if they would prefer the female condom, the male condom, both, or neither, if the female and male condoms were both readily available and free of charge. The variable was then grouped into "female condom only" and "other".

Consistency of female condom use was also dichotomized to "more" if the participant used the female condom during 70% or more sexual acts in the previous month and "less" for less than 70%. (See more details below regarding the calculation of consistency of use).

Differences of means and medians were calculated for the following hypotheses, using the Wilcoxon signed rank test of significance for variables with non-parametric distribution in related samples. The hypotheses were accepted if the signed rank test $p < 0.05$.

- Participants over age 24 use the female condom more consistently than those 24 and younger, at both post 1 and post 2.
- Participants demonstrate an increased knowledge about the female condom following the intervention.
- For participants in the individual intervention only: Participants who received an insertion check by a nurse at the time of the intervention or between first and second visits, report fewer problems with using the female condom than women who did not have the insertion checked.
- Participants report less consistent male condom use at the post 1 than pre-intervention.
- Participants report more consistent female condom use at post 2 than post 1.
- Participants report more consistent condom use (either male or female) at post 1 and post 2 than pre-intervention.
- Participants report more consistent condom use (either male or female) at post 2 than post 1.

The main dependent variable is consistency of condom use. Consistency of condom use was measured by calculating the proportion of sexual acts that participants reported using either a male or a female condom. This calculation was performed for male condoms, female condoms and total condom use (male or female condom). Cases were excluded if the consistency of condom use was greater than 100%. Outliers in the numerator (# times had sex with main partner) were also excluded from consistency of condom use analysis. This included one case who reported having sex more than 60 times with her main partner in the past month.

To calculate the difference in consistency of condom use from pre-intervention to

post 1 and post 2, the consistency of condom use of interest (i.e. male, female or total) was used. Three sets of differences were calculated: Post 2 – Pre, Post 1 – Pre, and Post 2 – Post 1.

Pearson correlation coefficients (r) were calculated to test the following hypotheses. A strong correlation is identified as having an 'r' of 0.6 to 1 or –0.6 to –1. A moderate relationship is identified as an 'r' between 0.31 and 0.59 or –0.31 and –0.59. A weak correlation is identified as 0.2 to 0.3 or –0.2 to –0.3 and there is no relationship if 'r' is between 0 and 0.2 or –0.2. The hypothesis was accepted if the probability for the correlation coefficient was < 0.05.

- Among participants who tried the female condom, those who rated the female condom more highly used the female condom more consistently than those who rated it more poorly, at both follow-ups.

- Participants who have a more positive attitude toward the female condom are more likely to try the female condom at least once, compared to those with a less positive attitude.

Since only four respondents had not tried using the female condom by the end of the study, this last hypothesis was replaced with:

- Participants who have a more positive attitude toward the female condom are more likely to use the female condom consistently compared to those with a less positive attitude.

Attitude score was calculated by summing the scores of three likert-type items.

4. Results

4.1 Description of the Sample

The 175 participants in the original sample consisted of women between the ages of 18 and 45, with a mean age of 30 (Std Dev = 8.0). English was the first language of a majority of the participants (77.5%) and a sizeable minority (46.2%) came from white/European ethno-cultural background. The other ethno-cultural groups reflected some of the diversity of the Toronto population including Black-Caribbean (15.6%), South Asian (6.4%), Latin American (5.2%), and Mixed Ancestry (4.6%). Fewer participants came from Arab/ West Asian, East Asian, Black-African, Black-Other, First Nations/Aboriginal and Other ethno-cultural groups. The questionnaire was only available in English and only five (3.0%) of the participants needed help translating the questionnaire.

Almost 40% of the sample had a high school education or less, half were not

currently employed (50.6%) and over half (56.3%) had personal incomes lower than $25,000 per year. Eight (4.8%) reported no income at all and 21.6% had a personal income that was under $10,000 per year.

One-quarter of participants (25.6%) had never been pregnant. Of those who had been, 70% reported having had at least one unplanned pregnancy. About 60% of all reported pregnancies were unplanned. Most participants had used a method of birth control or STD/HIV protection in the past (92.5%). Of those who had used any method in the past, the most popular was the male condom (93.2%), followed by the birth control pill (80%), withdrawal (40%), spermicidal film/foam/suppository (25.5%) and 22.3% had used the emergency contraceptive pill (also known as ECP or the morning after pill). Other methods used included: female condoms (3.7%), diaphragm (5.0%), cervical cap (1.2%), sponge (11.8%), Norplant (1.2%), Depo-Provera (8.7%), intra-uterine device (14.9%), rhythm/calendar (18.0%), and lube (13.0%). Over one-fifth (21.1%) of those who had previously used a method of birth control or STD/HIV prevention also reported having had an abortion.

Most participants (93.0%) had one main or regular sex partner in the past month. The length of these relationships reflected some stability, with three-quarters having been in the relationship with their main partner for over a year. Participants had sex with their main partner an average of 13 times in the past month (median = 10), and used a male condom about half the time (mean = 6, median = 4).

About one-quarter of participants (26.3%) had sexual intercourse with a man other than their main partner in the past month. The number of other partners ranged from 1 to 40, with a mean of 5 and a median of 2. On average, participants had sexual intercourse with a man other than their main partner 7 times in the past month (median = 3). They used a male condom most of the time with these partners (mean = 6, median = 2).

Multiple sex partners is a risk factor for STDs/HIV, as is trading sex for money or drugs and having previously had an STD. Among participants attending the first intervention, 10.3% had ever traded sex for money or drugs and 55.4% reported they had **never** had an STD. We can therefore assume that 44.6% have had an STD. The types of STDs they reported included syphilis (1.7%), gonorrhea (6.9%), chlamydia (15.4%), pelvic inflammatory disease (1.7%), genital warts (4.0%), herpes (6.3%), trichomonas (2.3%), and muco-purulent cervicitus (0.6%).

Most participants (75.3%) reported they had received an HIV test in the past. Four (2.9%) participants reported they had tested positive for HIV.

4.2 Hypothesis Testing

Age and female condom use
There were twice as many participants aged 25 and older than there were under 25. Contrary to our hypothesis, the 36 participants under age 25 were no less comfortable inserting the female condom at either post 1 or post 2 than were participants age 25 and older (Fig. 4). At post 1, 36.1% of the younger group and 35.9% of the older age group felt very comfortable inserting the female condom. At post 2, 55.6% of the younger group and 31.7% of the older group felt very comfortable. The chi square at post 2 was approaching statistical significance (p = 0.0654), however, the relationship was in the opposite direction to which we had hypothesised. That is, the younger participants were more comfortable than those aged 25 and older.

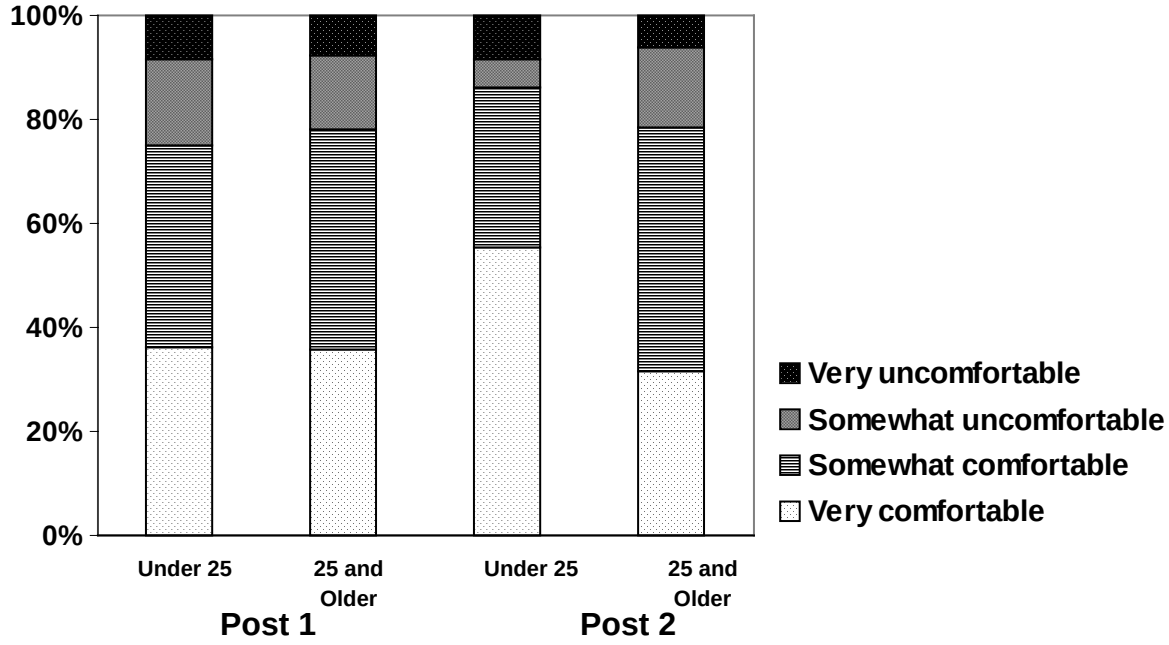


Fig. 4: Comfort inserting female condom by age group at post 1 and post 2
Source: Appendix C, 3a and 3b

At post 1, 21% of participants reported using the female condom during at least 70% of sexual intercourse acts (Appendix C, Table 4a). This increased to 24% at post 2 (Appendix C, Table 4b). At post 1, women under 25 were less likely to have used the female condom at least 70% of the time than were women in the

older age group (Fig. 5), but this association between age and consistency of female condom use disappeared at post 2. At post 1, only 5.6% of the younger women used a female condom at least 70% of the time during the past month, compared to 27.9% of women aged 25 and older. At post 2, the frequency of consistent female condom use increased for the younger group to 19.4% and decreased in the older group to 24.1% but this association was not statistically significant.

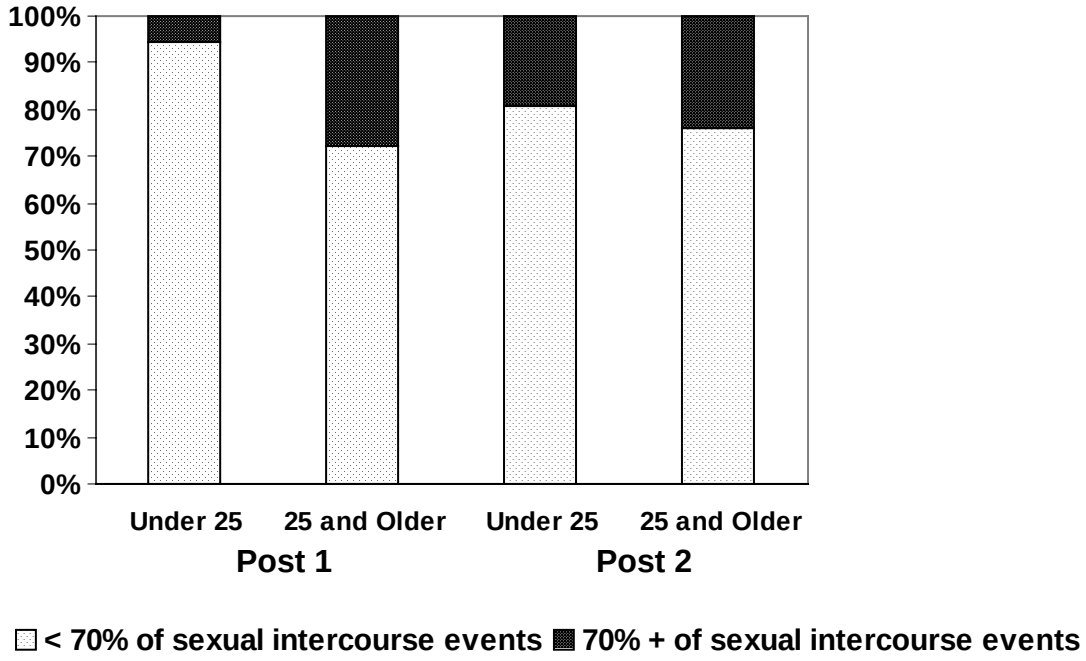


Fig. 5: Consistency of female condom use by age group at post 1 and post 2
Source: Appendix C, Tables 4a and 4b

Knowledge about the female condom
Participants correctly answered the questions measuring knowledge of the female condom more frequently at post 1 and post 2 than at pre-intervention (Fig. 6). The knowledge questions did not have a high enough internal consistency (Cronbach's coefficient alpha) to use as a scale, partly because there was a small number of items and each item was scored as either 0 if incorrect and 1 if correct. Item-by-item analysis shows there was a consistent increase in the participants' knowledge about the female condom over the course of the study. While no more than half of the participants correctly answered any of the items at pre-intervention, at least 65% and 70% correctly answered the questions at post 1 and post 2 respectively.

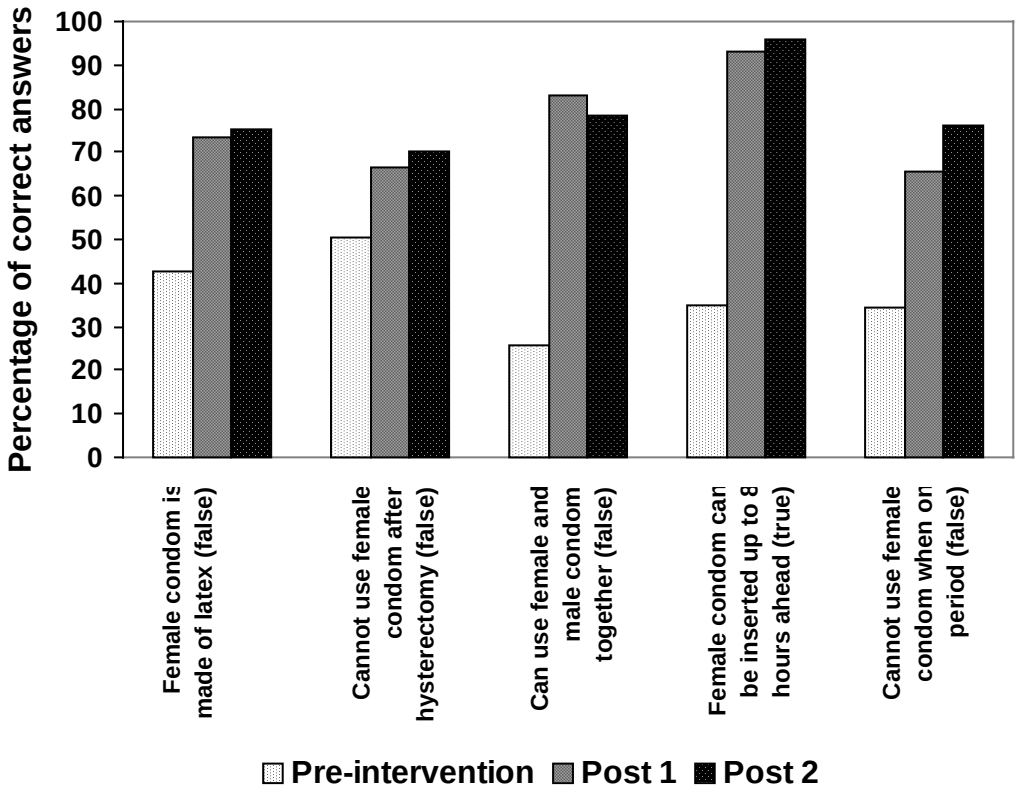


Fig. 6: Percentage of correctly answered knowledge questions at pre-intervention, post 1 and post 2

Source: Appendix C, Table 5

Effect of insertion check on problems using the female condom

Only 20 participants who completed the study opted to have an insertion check at their first visit, and only 6 (30%) of these women reported experiencing at least one of 13 possible problems using the female condom at post 1 and only 4 (20%) at post 2. Of the 97 participants that did not have an insertion check, 31% reported problems at both post 1 and post 2. The low number of participants who had an insertion check, does not allow us to draw conclusions about the impact of the insertion check component of the intervention on ease of use of the female condom.

Intentions to use the female condom

Exposure to the female condom seems to have had a negative impact on participants' intentions to use it (Appendix C, Tables 6a, 6b). However, the majority of participants said they would likely use the female condom. At pre-

intervention, over 80% said they were very likely or somewhat likely to use it, compared to 78% at post 1 and 70% at post 2.

Male or female condom use

Only about half of sexual intercourse in the previous month had been protected with a condom at pre-intervention (Fig. 7). This increased significantly at post 1 and post 2. Only male condom use was measured at pre-intervention and, as expected with the introduction of the female condom, the use of the male condom decreased dramatically at post 1 from a median of 50% to 13.3%, but increased to 15.5% at post 2. The void was filled by the use of the female condom with median usage of 40% at post 1 and 37.5% at post 2. The percentage of sexual intercourse using eithet barrier method (either the male or female condom) increased from a median of 50% at pre-intervention to 80% at both post 1 and post 2. In other words, half of the participants used condoms during at least 50% of sexual intercourse events at pre-intervention and at post-intervention half of them used condoms at least 80% of the time.

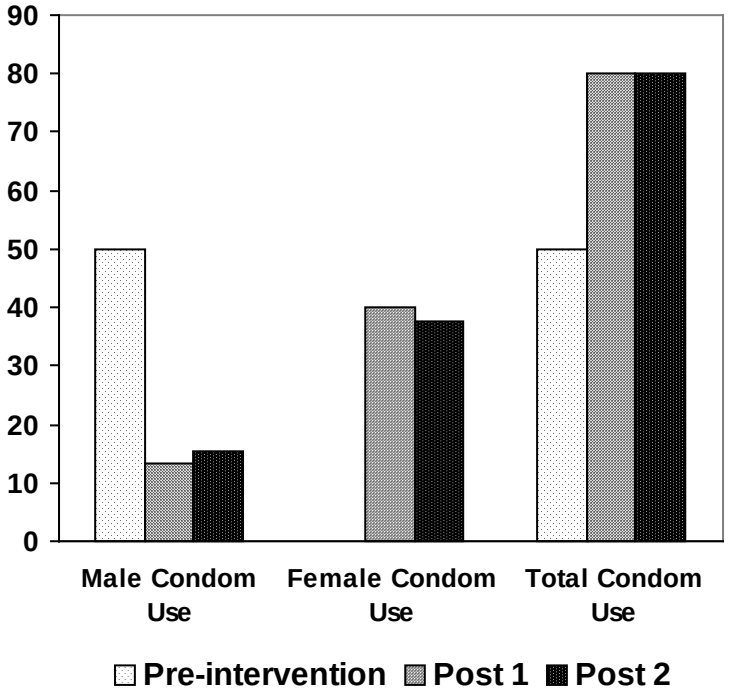


Fig. 7: Median of percentage of sexual intercourse events protected by condom use at pre-intervention, post 1 and post 2
Source: Appendix C, Table 7

When comparing the mean of the difference in consistency of condom use from

pre to post 1 and post 2, the percentage of sexual acts that were protected with either a male or female condom increased by 22% from pre-intervention to post 1. The increase from pre-intervention to post 2 was 20%. There was no significant difference between post 1 and post 2 (Appendix C, Table 8).

Variables associated with consistent condom use

One hundred of the participants who completed the study had ever been pregnant and 70% of them reported having had at least one unplanned pregnancy. However, they were no more likely to increase the proportion of protected sexual acts than the participants who had never had an unplanned pregnancy. Also, while 59% of the participants who completed the study reported previously having had an STD, they were no more likely to increase their consistency of condom use than those who had never had an STD.

The more participants disliked using the female condom, the less likely they were to use it consistently (Appendix C, Table 9). The relationship between liking the female condom and female condom consistency of use at post 1 was moderate, but statistically significant ($r = -0.41$, $p < 0.0001$) and at post 2 was weak, but statistically significant ($r = -0.28$, $p = 0.0039$).

Similarly, the less comfortable participants were with inserting the female condom, the less likely they were to use it consistently (Appendix C, Table 10). The relationship between comfort inserting the female condom and female condom consistency of use at post 1 was moderate, but statistically significant ($r = -0.36$, $p = 0.0001$) and at post 2 was weak, but statistically significant ($r = -0.23$, $p = 0.0154$).

Attitude toward the female condom at pre-intervention had no influence on how consistently participants used it at post 1 or post 2 (Appendix C, Table 11). At post 1 and post 2, the Pearson Correlation Coefficients (r) were too small to be substantively significant and were not statistically significant.

If both the male and the female condom were provided for free, 36% of participants at post 2 would choose the female condom over the male condom, both or neither (Appendix C, Table 12). Those who used the female condom consistently at post 1 and post 2 (i.e. 70% of sexual intercourse events or more) were more likely to choose the female condom, rather than the male condom or both, if both female and male condoms were available at no cost (Fig. 8). Over half (54.2%) of participants who used the female condom consistently at post 1 chose the female condom rather than the male condom or both at post 1, compared to 26.9% of those that used the female condom less often. Both consistent users and those using the female condom less consistently increased their preference for the female condom only, at post 2. The difference between them was still significant, with 59.3% of the consistent users and 29.2% of the others choosing the female condom only.

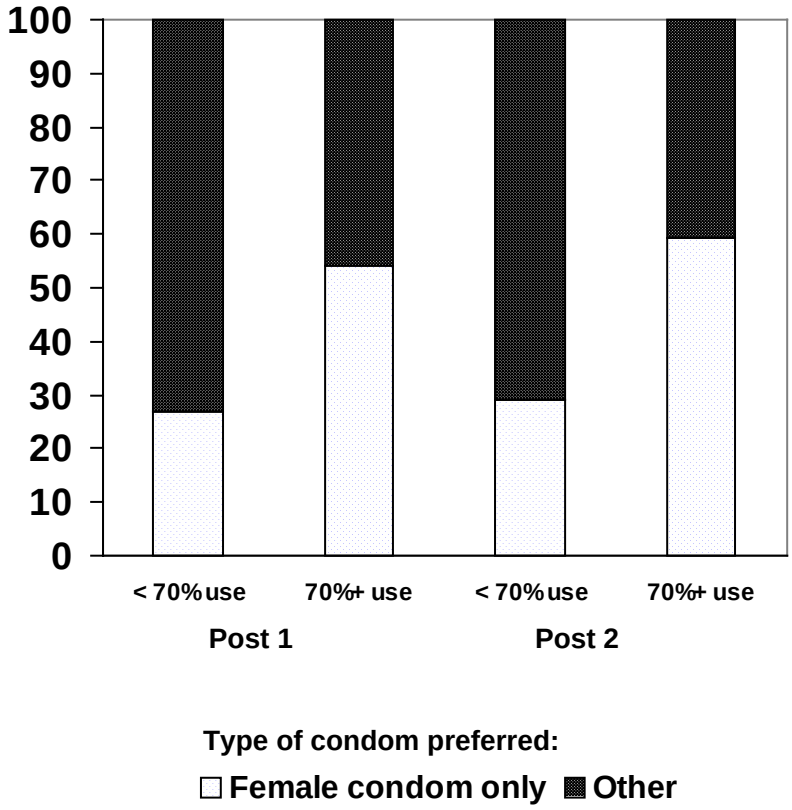


Fig. 5: Type of condom preferred by consistency of female condom use, post 1 and post 2
Source: Appendix C, Tables 13a and 13b

Cost of the female condom
Only 24% of participants at post 1 and 29.0% at post 2 were willing to pay more than $1.00 for each female condom (Appendix C, Table 14). A substantial percentage (29% at post 1 and 16% at post 2) would only use the female condom if it were free. While greater percentages of participants who liked the female condom were willing to pay more than $1.00, the association was not statistically significant.

5. Discussion

The characteristics of the sample reflect that we were successful in recruiting participants from our intended population, i.e. women at increased risk for STDs/HIV and unplanned pregnancy due to socio-economic and sexual risk

behavioural factors. The sample was comprised primarily of women with low socio-economic status as measured by their education and income. These women are least able to afford to purchase the female condom and, indeed, other methods of birth control and STD/HIV prevention.

All studies have limitations and the major ones for this study were the small sample size and the short time frame for the study. Due to time and budget constraints, and because this was a pilot project, we were only able to offer the intervention to a limited number of participants. The size of the intended population is unknown, ill-defined, and difficult to access without extensive screening which would greatly increase the cost and decrease the feasibility of the project. Agencies providing sexual health services to women at risk for STDs/HIV and unplanned pregnancy were the setting for the intervention. Since 59% of participants that completed the study previously had an STD, and 70% of participants who had ever been pregnant reported at least one unplanned pregnancy, it appears we did have a sample of women who are at risk for STDs/HIV and unplanned pregnancy. However, the lack of a control group, and self-selection into the pilot study, limits the generalizability of the results.

Our tight timelines also restricted the number of participants we were able to recruit to pilot-test the questionnaires. As a result, reliability of most of the questionnaire items was not known.

Participants appear to have increased knowledge on an item-by-item analysis but, because the scale was unreliable, we were unable to examine the relationship between change in knowledge score and consistency of condom use.

Time and budget constraints did not allow us to follow-up with participants who did not complete the study to determine why they withdrew. We do not know if they dropped out because they disliked the intervention, because they did not use the female condom, or if it was due to other factors. Comparisons at pre-intervention revealed that participants who did not complete the study had some characteristics that placed them at higher risk for STDs/HIV and unplanned pregnancy than those who completed. The final analysis could only be performed on the completers and results cannot be applied to those who dropped out.

Language was another limitation in recruiting a representative sample. Questionnaires were self-administered requiring an ability to read English. Data collectors were available to assist participants with completion of the questionnaire but only five had help with translation. However, no written translations of the questionnaires were available due to the limited scope (time and budget) of this project. Since about 77% of participants reported English as their first language, the results are not generalizable to women whose command of English did not allow them to participate.

We studied only the female participants and not their partners. As Sly, et al. (1997) and O'Leary (2000) suggest, using the female condom requires co-operation from the male partner. The participants' decreased likelihood to use the female condom is as liable to be the result of their male partner(s) refusal to use it as their own personal preferences. On the other hand, offering a choice in method to their partners (i.e. male or female condom) may have resulted in the male condom being used rather than no condom at all.

Despite the foregoing limitations, the results of this study are consistent with other previous studies. Providing education and counselling sessions by trained service providers, along with unlimited quantities of male condoms, female condoms, and water-based personal lubricant, significantly increased the total number of sexual intercourse acts that participants reported were protected by either the male or female condom. The use of male condoms initially declined when female condoms were first introduced but increased slightly the following month, with a concomitant slight decrease in female condom use. This is consistent with previous studies conducted over longer periods of time. Both Artz, et al (2000) and Latka, et al (2000) found the initial increase in female condom use declined, as did overall condom use (either male or female) slightly over time, but was still higher after six months than at pre-intervention. In this study, male condom use declined initially as participants tried out the female condom, but as time went on actually increased slightly over pre-intervention use. Having a choice between using a male or a female condom may be an important motivating factor in increasing the consistency of protected sexual intercourse activity for women who have received female condom education and counselling interventions.

The results of this study suggest that the more women use the female condom, the more they like it, feel comfortable using it and prefer it over the male condom. However, we did not test whether these factors resulted in higher consistency of use or if consistency of use resulted in women liking it more, being more comfortable inserting it and choosing the female condom over the male condom. Only 23% used the female condom at least 70% of the time and 36% preferred the female condom over the male condom and 29% would pay more for the female condom than the current retail price of the male condom. The female condom alone is the method of choice for a minority of women who use it consistently. Access to female condoms appears to be a major factor in their continued use.

Women under age 25 were less likely to use the female condom consistently at post 1 than were older women, but not necessarily so at post 2. Younger women were more comfortable inserting the female condom at post 2 than they had been at post 1. This suggests that there is an interaction between the age of women, their comfort using the female condom and their consistency of use. Younger women may need more time, and possibly more education and

counselling, to feel comfortable using the female condom. Previous studies of female condom use among young women have shown inconsistent results (Haignere, et al, 2000; McCabe, et al, 1997).

Negative attitudes toward female condoms did not appear to be a barrier to their use, contrary to previous studies (Van Devanter et al, 2002; Cabral et al, 2000). No relationship was found between attitude score at pre-intervention and later consistency of female condom use. This may be due to the fact that participants had fairly positive attitudes towards the female condom at pre-intervention. Most felt comfortable about inserting the female condom and thought they would likely use the female condom, even at pre-intervention. After using the female condom, fewer women continued to think they were very likely to use it. This suggests the female condom is not the right choice for all women.

The focus groups and individual interviews results reported elsewhere provide some insight into this finding (Gillis, 2002). Many women stated that they had participated in the study because they wanted to ensure that the female condom would be made available to other women who needed it, even though they may not chose the female condom as their first option in the future. This study attracted women who were favourably predisposed to the female condom, possibly limiting the generalization of these results to women who have less positive attitudes and less motivation to use barrier methods of protection against STD/HIV and unplanned pregnancy.

The main consistent and reliable barrier to female condom use, other than personal or couple preference, appears to be cost. Most participants were unwilling to pay more than $1.00 for the female condom. At the time of the pilot-project, the retail price for female condoms in Toronto pharmacies was about $12.00 to $15.00 for a box of three, or $4.00 to $5.00 each. The retail prices for male condoms are more variable, but a person could easily find a male condom priced less than $12.00 for twelve, or $1.00 each, in a pharmacy. If a woman has only $1.00 to spend on a barrier method, she is restricted to using the male condom. Only 28% of participants would pay more for a female condom than the current retail price of a male condom. In their interviews, some women pointed out that buying a male condom is the male partner's responsibility and if they wanted to use the female condom, the responsibility of paying for the condoms would then come out of their own very low incomes (Gillis, 2002).

6. Conclusion

This study demonstrates that an educational and counselling intervention by trained service providers, either in individual or group formats, is effective in introducing the female condom to women who are at high risk for STDs/HIV and unplanned pregnancy. Furthermore, the recipients of the intervention increased use of either the male or female condom for at least two months after the

intervention. Even though this study had some methodological limitations, these findings are consistent with previous studies conducted in the U.S. Therefore, we can assume that the results of the previous studies conducted over longer periods of time would be applicable to women in Toronto.

The intervention was effective for women as young as 18, although women between 18 and 24 may require more education and counselling sessions than those over 24. Future studies should look more carefully at the differing needs of various age groups.

Women who used the female condom more consistently liked it more, were more comfortable inserting the female condom, and would also choose it over the male condom. Future studies should clarify these associations. Does increased use of the condom increase participants' liking it, feeling comfortable with it and preferring it over the male condom or vice versa?

The cost of the female condom appears to be a major barrier to its use in Toronto. Since having access to a female condom increases the consistency of either male or female condom use, the cost of the female condom is also a barrier to consistent use of the male condom. Cost-effectiveness studies should be conducted to determine if the cost of free female and male condom distribution programs by governments and non-government agencies offset the costs, long and short-term, societal and individual, of STD/HIV and unplanned pregnancy.

The implications of these results, and of previous studies, for public health planners, sexual health promoters, health care providers and advocates are multiple. Female condoms are acceptable to low-income, English speaking women in Toronto who are at high risk for STDs/HIV and unplanned pregnancy. Sexual health promoters and health care providers should consider including the female condom as one method, among others, in their education and counselling with women who participate in high risk behaviours. Public health planners and advocates should consider ensuring female condoms are freely available to women at risk, since cost is a significant barrier and poverty is associated with poor sexual health outcomes.

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Appendix A – Community agency partners involved in the design and implementation of the Female Condom Pilot Project

AIDS Committee of Toronto (ACT)
Black Coalition for AIDS Prevention (Black CAP)
Immigrant Women's Health Centre
Maggie's: Toronto Prostitutes' Community Service Project
2-Spirited People of the First Nations
Voices of Positive Women
Women's Health in Women's Hands
Youth Link – Inner City

Appendix B – Questionnaires

FEMALE CONDOM PILOT PROJECT

Pre-intervention Questionnaire

Participant ID# ___ ___ ___ Site ___ ___ ___

Date ___ ___ ___
(Month) (Day) (Year)

PART I: Demographic Data

The questions in the following section provide us with information about you. Please remember that you do not have to answer any questions that you don't want to.

1. How old were you on your last birthday?

   ___ ___ years

2. What is the language you **first** learned in childhood and still understand?

   _____

3. Please check which ethno-cultural background that you most identify with? (PLEASE CHECK ONLY ONE)

   □ 1. Arab/West Asian (e.g., Armenian, Egyptian, Iranian, Lebanese, Moroccan)
   □ 2. East Asian (e.g. Chinese, Japanese, Korean)
   □ 3. Black – African
   □ 4. Black – Caribbean
   □ 5. Black - Other
   □ 6. Filipino
   □ 7. First Nations/Aboriginal
   □ 8. Latin American
   □ 9. South Asian (e.g. Indian, Pakistani, Sri Lankan)
   □10. South East Asian (e.g., Cambodian, Indonesian, Laotian, Vietnamese)
   □11. White/European
   □12. Mixed Ancestry
   □13. Other: (specify) _____

4. Are you currently employed?

   □1. No
   □2. Yes

5. What is the **highest** level of education that you have **completed**? (PLEASE CHECK ONLY ONE)

   □1. Some secondary (high) school or less
   □2. Completed secondary (high) school
   □3. Trades certificate or diploma
   □4. Some community college/technical college/CEGEP
   □5. Completed community college/technical college/CEGEP
   □6. Some university
   □7. Graduated university (Bachelor's degree)
   □8. Some post-graduate university or more
   □9. Other: (specify)_____

6. Into which of the following groups does your personal income fall, before taxes?

   □1. None
   □2. Under $10,000
   □3. $10,000 - $14,999
   □4. $15,000 - $19,999
   □5. $20,000 - $24,999
   □6. $25,000 - $29,999
   □7. $30,000 - $34,999
   □8. $35,000 - $39,999
   □9. $40,000 or over
   □10. Refuse to answer or don't know

PART II: Sexual History

The questions in this section tell us about your sexual history and use of birth control and STD prevention methods. Some of the questions are sensitive. Please remember that you do not have to answer any questions that you do not want to.

7. How many times have you been pregnant? (PLEASE ENTER 00 IF YOU HAVE NEVER BEEN PREGNANT)

   ____ ____ times

8. How many of these were planned?

   ____ ____ times

9. In the past, have you ever used any form of birth control or method for sexually transmitted disease prevention?

   □1. No
   □2. Yes
   □3. Not sure

10. IF YES: Check any methods of birth control or sexually transmitted disease prevention you've ever used. (YOU CAN CHECK MORE THAN ONE, IF IT APPLIES.)

    □1. Male condoms
    □2. Female condoms
    □3. Diaphragm
    □4. Cervical cap
    □5. Spermicidal Film/Foam/Suppository
    □6. Sponge
    □7. Birth Control Pills
    □8. Emergency Contraceptive Pill (Morning After Pill)
    □9. Norplant
    □10. Depo-Provera
    □11. Intra-Uterine Device (IUD)
    □12. Withdrawal
    □13. Rhythm/Calendar
    □14. Lube (vaginal lubricating gel or cream)
    □15. Abortion
    □16. Other (what was it?)
    _____

11. Are you using anything to prevent yourself from getting pregnant or getting a sexually transmitted disease or HIV right now?

    □1. No
    □2. Yes
    □3. Not sure

12. IF YES: Check which of the following methods you are currently using. (YOU CAN CHECK MORE THAN ONE, IF IT APPLIES.)

    □1. Male condoms
    □2. Female condoms
    □3. Diaphragm
    □4. Cervical cap
    □5. Spermicidal Film/Foam/Suppository
    □6. Sponge
    □7. Birth Control Pills
    □8. Emergency Contraceptive Pill (Morning After Pill)
    □9. Norplant
    □10. Depo-Provera
    □11. Intra-Uterine Device (IUD)
    □12. Withdrawal
    □13. Rhythm/Calendar
    □14. Lube (vaginal lubricating gel or cream)
    □15. Other: (specify)_____

13. Before today, have you ever **heard** of the female condom?

    □1. No
    □2. Yes
    □3. Not sure

14. IF YES: Where did you **first** hear about the female condom? (PLEASE CHECK ONLY ONE)

    □1. Special sexual health clinic
    □2. My regular doctor's office
    □3. Drug store
    □4. Magazine
    □5. Television
    □6. Poster
    □7. Family or friends
    □8. Other _____

15. Have you ever **seen** the female condom?

    □1. No
    □2. Yes
    □3. Not sure

16. Have you ever **used** the female condom?

    □1. No
    □2. Yes
    □3. Not sure

17. Have you ever **been shown how to insert** a female condom?

    □1. No
    □2. Yes
    □3. Not sure

18. Do you have one male sex partner that you consider to be your **main or regular** partner?

    □1. No ⟶ PLEASE GO TO QUESTION 22
    □2. Yes

19. IF YES: How long have you been together?

    □1. Less than 1 month
    □2. One to three months
    □3. Four months to one year
    □4. One to five years
    □5. More than five years

20. How many times did you have sex (vaginal intercourse) with your **main** partner in the past month?

    ____ ____ ____ times

21. How many times in the past month did you use a male condom with your **main** partner?
    ____ ____ ____ times

22. In the past month, how many men, **other than a main partner,** have you had sex with?

____ ____ ____ men

23.In the past month, how many times did you have sex (vaginal intercourse) with a man, **other than a main partner?**

____ ____ ____ times

24.How many times in the past month did you use a male condom with a man, **other than a main partner**?

____ ____ ____ times

25.Have you ever traded sex for money or drugs?

□1. No
□2. Yes
□3. Decline to answer

26.Please check any of the following sexually transmitted diseases your doctor or nurse ever told you that you have had. (YOU CAN CHECK MORE THAN ONE, IF IT APPLIES.)

□1. None
□2. Syphilis (Clap)
□3. Gonorrhea (Drip, Dose)
□4. Chlamydia
□5. Pelvic Inflammatory Disease (PID)
□6. Genital Warts
□7. Herpes
□8. Trichomonas (Trick)
□9. Muco-purulent Cervicitus (MPC) [inflammation of cervix]
□10. Abnormal PAP smear
□ 11. Don't know
□ 12. Other: _____

You might consider the following two questions especially sensitive and this information private. Please remember that you do not have to answer any questions you don't want to.

27. Have you ever had an HIV test?

□1. No
□2. Yes
□3. Decline to answer

28. IF YES: What was the result?

- □1. Negative
- □2. Positive
- □3. Don't Know
- □4. Decline to answer

PART III – FEMALE CONDOM KNOWLEDGE, ATTITUDES AND BEHAVIOUR

The following questions measure how much you know about the female condom. Please circle the answer that you think is correct. Don't worry if you don't know the answers yet – all this information will be covered in your education and counselling session.

29.	The female condom is made of latex.	1. True	2. False	3. Don't know
30.	Women who have had a hysterectomy can't use the female condom.	1. True	2. False	3. Don't know
31.	You can use the female condom and the male condom at the same time.	1. True	2. False	3. Don't know
32.	The female condom can be inserted into the vagina for up to eight hours before sex.	1. True	2. False	3. Don't know
33.	The female condom can't be used when you're on your period.	1. True	2. False	3. Don't know

Please indicate how strongly you agree with each of the following statements by circling the number that corresponds with your opinion.

Agree Strongly	**Agree**	**Disagree**	**Disagree Strongly**
1	**2**	**3**	**4**

34.	I believe the female condom would give me another option for birth control.	1	2	3	4
35.	I believe the female condom would give me another option for protection against sexually transmitted diseases, including HIV.	1	2	3	4
36.	I believe the female condom would give me more control over my sexual health than male condoms.	1	2	3	4
37.	It bothers me that the female condom has to be inserted into	1	2	3	4

my vagina.

38. How likely are you to use the female condom?

□1. Very likely
□2. Somewhat likely
□3. Somewhat unlikely
□4. Not very likely

39. How likely do you think **your main partner** will agree to use the female condom?

□1. Very likely
□2. Somewhat likely
□3. Somewhat unlikely
□4. Not very likely
□5. I don't have a main partner

40. How much do you like using the **male** condom?

□1. Like very much
□2. Like somewhat
□3. Dislike somewhat
□4. Dislike very much
□5. Have never used the male condom

41. How comfortable do you feel about inserting the female condom?

□1. Very comfortable
□2. Somewhat comfortable
□3. Somewhat uncomfortable
□4. Very uncomfortable

42. If you had to buy the female condom, how much would you be willing to pay for each one? (PLEASE CHECK ONLY ONE)

□1. I would only use it if I could get it for free
□2. Twenty-five cents (one quarter) or less
□3. Fifty cents
□4. One dollar
□5. $1.50
□6. Two dollars
□7. $2.50
□8. $2.50 - $4.00

43. If you had to buy the **male** condom, how much would you be willing to pay for each one? (PLEASE CHECK ONLY ONE)

□1. I would only use it if I could get it for free
□2. Twenty-five cents (one quarter) or less
□3. Fifty cents
□4. One dollar
□5. $1.50
□6. Two dollars
□7. $2.50
□8. $2.50 - $4.00

44. If both the male condom and the female condom were easily available, and free of charge, which one would you choose?

    □1. Female condom
    □2. Male condom
    □3. Both
    □4. Neither

45. Did you have help from someone to translate this questionnaire into a language other than English?

    □1. No
    □2. Yes

Thank you for taking the time to complete this questionnaire. Your responses are extremely valuable to us. Please insert your completed questionnaire into the envelope provided and return it to the person who gave it to you.

If you have any questions or concerns about this questionnaire, please call Deborah Hardwick at 416-338-0908 or the Female Condom Pilot Project at 416-527-3527.

FEMALE CONDOM PILOT PROJECT

Post 1 and Post 2 Questionnaire

Participant ID# ___ ___ ___ Site ___ ___ ___

Date _____ _____ _____
(Month) (Day) (Year)

PART I – FEMALE CONDOM KNOWLEDGE AND ATTITUDES

The following questions measure how much you know about the female condom. Please circle the answer you think is correct.

1.	The female condom is made of latex.	1. True	2. False	3. Don't know
2.	Women who have had a hysterectomy can't use the female condom.	1. True	2. False	3. Don't know
3.	You can use the female condom and the male condom at the same time.	1. True	2. False	3. Don't know
4.	The female condom can be inserted into the vagina for up to eight hours before sex.	1. True	2. False	3. Don't know
5.	The female condom can't be used when you're on your period.	1. True	2. False	3. Don't know

If you are not sure of the answers, you might consider asking your service provider about it. Or, you can call the AIDS - Sexual Health InfoLine at 416-392-2437.

Please indicate how strongly you agree with each of the following statements by circling the number that corresponds with your opinion.

Agree Strongly	Agree	Disagree	Disagree Strongly
1	2	3	4

6.	I believe the female condom would give me another option for birth control.	1	2	3	4
7.	I believe the female condom would give me another option for protection against sexually transmitted diseases, including HIV.	1	2	3	4
8.	I believe the female condom would give me more control over my sexual health than male condoms.	1	2	3	4
9.	It bothers me that the female condom has to be inserted into my vagina.	1	2	3	4

10. How much do you like using the female condom?

□1. Like very much
□2. Like somewhat
□3. Dislike somewhat
□4. Dislike very much
□5. Have never used the female condom

11. How much do you like using the **male** condom?

□1. Like very much
□2. Like somewhat
□3. Dislike somewhat
□4. Dislike very much
□5. Have never used the male condom

12. How comfortable do you feel about inserting the female condom?

□1. Very comfortable
□2. Somewhat comfortable
□3. Somewhat uncomfortable
□4. Very uncomfortable

13. If you had to buy the female condom, how much would you be willing to pay for each one? (PLEASE CHECK ONLY ONE)

    □1. I would only use it if I could get it for free
    □2. Twenty-five cents (one quarter) or less
    □3. Fifty cents
    □4. One dollar
    □5. $1.50
    □6. Two dollars
    □7. $2.50
    □8. $2.50 - $4.00

14. If you had to buy the male condom, how much would you be willing to pay for each one? (PLEASE CHECK ONLY ONE)

    □1. I would only use it if I could get it for free
    □2. Twenty-five cents (one quarter) or less
    □3. Fifty cents
    □4. One dollar
    □5. $1.50
    □6. Two dollars
    □7. $2.50
    □8. $2.50 - $4.00

15. If both the male condom and the female condom were easily available and free of charge, which one would you choose?

    □1. Female condom
    □2. Male condom
    □3. Both
    □4. Neither

Please continue to next page……

PART II – CONDOM USE

16. Have you returned to this clinic to have the insertion of the female condom checked by a service provider in the past month?

    □1. No
    □2. Yes
    □3. Not sure

17. Do you have one male sex partner that you consider to be your **main or regular** partner?

    □1. No ⟶ PLEASE GO TO QUESTION 22
    □2. Yes

18. IF YES: How long have you been together?

    □1. Less than 1 month
    □2. One to three months
    □3. Four months to one year
    □4. One to five years
    □5. More than five years

19. How many times did you have sex with your **main** partner in the past month?

    ____ ____ ____ times

20. How many times in the past month did you use a **female condom** with your **main** partner?

    ____ ____ ____ times

21. How many times in the past month did you use a **male condom** with your **main** partner?

    ____ ____ ____ times

22. In the past month, how many men, **other than a main partner**, have you had sex with?

    ____ ____ ____ men

23. In the past month, how many times did you have sex (vaginal intercourse) with a man, **other than a main partner?**

    ____ ____ ____ times

24. How many times in the past month did you use a **female condom** with a man, **other than a main partner**?

    ____ ____ ____ times

25. How many times in the past month did you use a **male condom** with a man, **other than a main partner**?

____ ____ ____ times

26. How likely are you to use the female condom, or continue to use the female condom?

□1. Very likely
□2. Somewhat likely
□3. Somewhat unlikely
□4. Not very likely

27. How likely do you think **your main partner will agree** to use the female condom, or continue to use the female condom?

□1. Very likely
□2. Somewhat likely
□3. Somewhat unlikely
□4. Not very likely
□5. I don't have a main partner

PLEASE ANSWER THE REMAINING QUESTIONS ONLY IF YOU HAVE USED THE FEMALE CONDOM IN THE PAST MONTH

PART III – SATISFACTION WITH FEMALE CONDOM USE

28. Some women have reported the following problems when using the female condom. Please indicate if you have experienced the problem. If yes, please rate how much each problem bothered you or your partner, by circling the number from 0 to 10, based on your experience in the past month.

	No	**Yes →**	**0= Not bothered at all**										**10=Extremely Bothered**
Penis entered to the side of the condom	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Outer ring pushed inside	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Condom twisted in the middle	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Felt condom moving up and down	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Felt discomfort from inner ring	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Felt discomfort from outer ring	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Felt burning, itching, or irritation	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Partner felt condom clinging to penis	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Condom made noise during sex	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Condom came out of vagina during sex	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Condom broke or tore	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Semen spilled when penis withdrawn	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10
Semen spilled when condom removed	1.No	2.Yes→	0	1	2	3	4	5	6	7	8	9	10

Some women have reported they liked some aspects of the female condom. Please rate each of the following items, based on your experience in the past month, on a scale of 0 – 10.

		0=Strongly disagree										10 = Strongly agree
29.	The female condom can be put in up to 8 hours before sex.	0	1	2	3	4	5	6	7	8	9	10
30.	The female condom allows me greater control.	0	1	2	3	4	5	6	7	8	9	10
31.	The female condom increased my sexual pleasure.	0	1	2	3	4	5	6	7	8	9	10
32.	The female condom increased my partner's sexual pleasure.	0	1	2	3	4	5	6	7	8	9	10
33.	The female condom is stronger than the male condom.	0	1	2	3	4	5	6	7	8	9	10

Thank you for taking the time to complete this questionnaire. Your responses are extremely valuable to us. Please insert your completed questionnaire into the envelope provided and return it to the person who gave it to you.

If you have any questions or concerns about this questionnaire, please call Deborah Hardwick at 416-338-0908 or the Female Condom Pilot Project at 416-527-3527.

Appendix C – Tables

Table 1: Comparison of participants who dropped out and those that completed all three questionnaires
(N=175 unless stated otherwise)

	Drop-Out N (%)	Complete N (%)	Total N (%)
Aged 25 and older (N=172)	43 (75.4)	79 (68.7)	122 (70.9)
First language other than English**	12 (20.7)	29 (24.8)	41 (23.4)
Currently employed (N=172)	37 (66.1)	48 (41.4)	84 (49.4)
High school education or less	22 (37.9)	47 (40.2)	69 (39.4)
Personal income $25,000 per year or more (N=167)	20 (35.1)	32 (29.1)	52 (31.1)
Have previously used a method of birth control or STD protection (N=173)	54 (96.4)	107 (91.5)	161 (93.1)
Have ever used a male condom*	54 (93.1)	96 (82.1)	150 (85.7)
Are currently using a method of birth control or STD protection (N=174)	47 (81.0)	89 (76.7)	136 (78.2)
Currently using a male condom	40 (69.0)	74 (63.3)	114 (65.1)
Have ever heard of the female condom (N=171)**	54 (94.7)	88 (77.2)	142 (83.0)
Have ever seen a female condom (N=172)*	38 (66.7)	53 (46.1)	91 (52.9)
Have ever used a female condom (N=174)	3 (5.3)	8 (6.9)	11 (6.3)
Have been shown how to insert a female condom (N=171)	9 (16.1)	20 (17.4)	29 (17.0)
Have one main sex partner in the past month (N=171)**	58 (85.7)	111 (96.5)	159 (93.0)
Have had sex with other than main partner in the past month (N=175)**	23 (39.7)	22 (18.8)	45 (25.7)
Have traded sex for drugs or money (n=170)*	10 (17.9)	8 (7.0)	18 (10.6)
Did not report ever having an STD	30 (51.7)	48 (41.0	78 (44.6)
Have had an HIV test (N=171)	44 (78.6)	87 (75.6)	131 (76.6)
Female condom knowledge:			
Female condom is made of latex (false)	30 (51.7)	50 (42.7)	80 (45.7)
Cannot use female condom after hysterectomy (false)	27 (46.6)	59 (50.4)	86 (49.1)
Can use female and male condom together (false)	13 (22.4)	30 (25.6)	43 (24.6)
Female condom can be inserted up to 8 hours in ahead (true)	15 (25.9)	41 (35.0)	56 (32.0)
Cannot use female condom when on period (false)*	17 (29.3)	40 (34.2)	56 (32.6)

Table 1: Comparison of participants who dropped out and those that completed all three questionnaires
(N=175 unless stated otherwise)

	Drop-Out N (%)	Complete N (%)	Total N (%)
Likely to use the female condom (N=174):			
Very likely	29 (50.0)	57 (49.1)	86 (49.4)
Somewhat likely	24 (41.4)	52 (44.8)	76 (43.7)
Somewhat unlikely	4 (6.9)	3 (2.6)	7 (4.0)
Not very likely	1 (1.7)	4 (3.5)	5 (2.9)
Main partner likely to use female condom (N=173):			
Very likely	32 (55.2)	58 (50.4)	90 (52.0)
Somewhat likely	14 (24.1)	43 (37.4)	57 (33.0)
Somewhat unlikely	8 (13.8)	8 (7.0)	16 (9.3)
Not very likely	4 (6.9)	6 (5.2)	10 (5.8)
Like using the male condom (n=172):			
Like very much	5 (8.6)	18 (15.8)	23 (13.4)
Like somewhat	27 (46.5)	42 (36.8)	69 (40.1)
Dislike somewhat	15 (25.9)	34 (29.8)	49 (28.5)
Dislike very much	11 (19.0)	20 (17.5)	31 (18.0)
Comfortable inserting female condom* (N=164):			
Very comfortable	20 (37.0)	35 (31.8)	55 (33.5)
Somewhat comfortable	23 (42.6)	52 (47.3)	75 (45.7)
Somewhat uncomfortable	7 (13.0)	20 (18.2)	27 (16.5)
Very uncomfortable	4 (7.4)	3 (2.7)	7 (4.3)
Type of condom preferred, if cost was free (n=168):			
Female condom	20 (34.5)	39 (35.5)	59 (35.1
Male condom	13 (22.4)	17 (15.5)	30 (17.9)
Both	25 (43.1)	54 (49.1)	79 (47.0)
	Mean (Standard deviation)	**Mean (Standard deviation)**	**Wilcoxon t-approximation probability (Two sided)**
Attitude score (N=169)	4.9 (1.6)	4.9 (1.9)	0.6780
# of times pregnant (N=172)	1.8 (1.8)	2.0 (1.8)	0.3757
Percent planned pregnancies (N=125) (excludes those never pregnant)	40.9 (41.0)	31.4 (36.3)	0.2688
# times had sex with main partner	10.1 (10.7)	12.0 (12.3)	0.1789
# times had sex with other than main partner**	3.0 (8.9)	0.7 (2.0)	0.0054
Percentage of sexual intercourse protected by male condom (N=163)	58.2 (44.8)	50.1 (43.4)	0.3601

* χ^2 $p<0.05$
** χ^2 $p<0.01$

Table 2: Comparison of individual and group interventions
(N=175 unless stated otherwise)

	Individual N (%)	Group N (%)	Total N (%)
Aged 25 and older (N=172)	103 (69.1)	19 (82.6)	122 (70.9)
First language other than English**	29 (19.2)	12 (50.0)	41 (23.4)
Currently employed (N=172)	74 (50.0)	11 (45.8)	85 (49.4)
High school education or less.	63 (41.7)	6 (25.0)	69 (39.4)
Personal income $25,000 per year or more (N=167)	43 (29.9)	9 (39.1)	52 (31.1)
Have previously used a method of birth control or STD protection* (N=173)	141 (94.6)	20 (83.3)	161 (93.1)
Have ever used a male condom**	137 (90.7)	13 (54.2)	150 (85.7)
Are currently using a method of birth control or STD protection (N=174)	119 (78.8)	17 (73.9)	136 (78.2)
Currently using a male condom	102 (67.6)	12 (50.0)	114 (65.1)
Have ever heard of the female condom (N=171)	124 (84.4)	18 (75.0)	142 (83.0)
Have ever seen a female condom (N=172)	79 (53.4)	12 (50.0)	91 (52.9)
Have ever used a female condom (N=174)	11 (7.3)	0	11 (6.3)
Have been shown how to insert a female condom (N=171)	24 (16.3)	5 (20.8)	29 (17.0)
Have one main sex partner in the past month (N=171)	139 (93.9)	20 (86.9)	159 (93.0)
Have had sex with other than main partner in the past month (N=175)	39 (25.8)	6 (25.0)	45 (25.7)
Have traded sex for drugs or money (n=170)**	11 (7.5)	7 (29.2)	18 (10.6)
Did not report ever having an STD	69 (45.6)	9 (37.5)	78 (44.6)
Have had an HIV test (N=171)	110 (74.8)	21 (87.5)	131 (76.6)
Female condom knowledge:			
Female condom is made of latex (false)	69 (45.7)	11 (45.8)	80 (45.7)
Cannot use female condom after hysterectomy (false)	80 (53.0)	6 (25.0)	86 (49.1)
Can use female and male condom together (false)	35 (23.2)	8 (33.3)	43 (24.6)
Female condom can be inserted up to 8 hours in ahead (true)**	55 (36.4)	1 (4.2)	56 (32.0)
Cannot use female condom when on period (false)*	54 (35.8)	3 (12.5)	57 (32.6)

Table 2: Comparison of individual and group interventions
(N=175 unless stated otherwise)

	Individual N (%)	**Group N (%)**	**Total N (%)**
Likely to use the female condom (N=174):			
Very likely	76 (50.3)	10 (43.5)	86(49.4)
Somewhat likely	67 (44.3)	9 (39.1)	76 (43.7)
Somewhat unlikely	5 (3.3)	2 (8.7)	7 (4.0)
Not very likely	3 (2.0)	2 (8.7)	5 (2.9)
Main partner likely to use female condom* (N=173):			
Very likely	81 (54.0)	9 (39.1)	90 (52.0)
Somewhat likely	51 (34.0)	6 (26.1)	57 (32.9)
Somewhat unlikely	12 (8.0)	4 (17.4)	16 (9.3)
Not very likely	6 (4.0)	4 (17.4)	10 (5.8)
Like using the male condom (n=172):			
Like very much	20 (13.3)	3 (13.6)	23 (13.4)
Like somewhat	61 (40.7)	8 (36.7)	69 (40.1)
Dislike somewhat	43 (28.7)	6 (27.3)	49 (28.5)
Dislike very much	26 (17.3)	5 (22.7)	31 (18.0)
Comfortable inserting female condom* (N=164)			
Very comfortable	52 (36.6)	3 (13.6)	55 (33.5)
Somewhat comfortable	66 (46.5)	9 (40.9)	75 (45.7)
Somewhat uncomfortable	20 (14.1)	7 (31.8)	27 (16.5)
Very uncomfortable	4 (2.8)	3 (13.6)	7 (4.3)
Type of condom preferred, if cost was free (n=168):			
Female condom	52 (35.4)	7 (33.3)	69 (35.1)
Male condom	24 (48.3)	6 (28.6)	30 (17.9)
Both	71 (48.3)	8 (38.1)	79 (47.0)
	Mean (Standard deviation)	**Mean (Standard deviation)**	**Wilcoxon t-approximation probability (Two sided)**
Attitude score (N=169)	Mean 4.9 (SD 1.9)	Mean 5.3 (SD 2.0)	0.2794
# of times pregnant (N=172)	Mean 1.9 (SD 1.8)	Mean 2.4 (SD 1.6)	0.0952
Percent planned pregnancies (N=125) (excludes those never pregnant)	Mean 32.3 (SD 37.9)	Mean 49.4 (SD 36.3)	0.0580
# times had sex with main partner	Mean 11.7 (SD 11.5)	Mean 10.3 (SD 14.1)	0.0975
# times had sex with other than main partner	Mean 1.0 (SD 2.5)	Mean 4.6 (SD 13.2)	0.7640
Percentage of sexual intercourse protected by male condom (N=163)	Mean 54.6 (SD 43.6)	Mean 42.9 (SD 46.2)	0.2367

* χ^2 $p<0.05$
** χ^2 $p<0.01$

Table 3a: Comfort inserting female condom at post 1 by age group

	Under 25 N (%)	25 and Older N (%)	Total N (%)
Very comfortable	13 (36.1)	28 (35.9)	41 (36.0)
Somewhat comfortable	14 (38.9)	33 (42.3)	47 (41.2)
Somewhat uncomfortable	6 (16.7)	11 (14.1)	17 (14.9)
Very uncomfortable	3 (8.3)	6 (7.7)	9 (7.9)
Total	36	78	114

$\chi^2 = 0.1916$, $p = 0.9789$

Table 3b: Comfort inserting female condom at post 2 by age group

	Under 25 N (%)	25 and Older N (%)	Total N (%)
Very comfortable	20 (55.6)	25 (31.7)	45 (39.1)
Somewhat comfortable	11 (30.6)	37 (46.8)	48 (41.7)
Somewhat uncomfortable	2 (5.6)	12 (15.2)	14 (12.2)
Very uncomfortable	3 (8.3)	5 (6.3)	8 (7.0)
Total	36	79	115

$\chi^2 = 7.2118$, $p = 0.0654$

Table 4a: Female condom use at post 1 by age group

	Under 25 N (%)	25 and Older N (%)	Total N (%)
Less than 70% of sexual intercourse events	34 (94.4)	57 (72.2)	91 (79.1)
70% or more of sexual intercourse events	2 (5.6)	22 (27.9)	24 (20.9)
Total	36	79	115

$\chi^2 = 7.4421$, $p = 0.0064$

Table 4b: Female condom use at post 2 by age group

	Under 25 N (%)	25 and Older N (%)	Total N (%)
Less than 70% of sexual intercourse events	29 (80.6)	60 (76.0)	89 (77.4)
70% or more of sexual intercourse events	7 (19.4)	19 (24.1)	26 (22.6)
Total	36	79	115

$\chi^2 = 0.2999$, $p = 0.5840$

Table 5: Comparison of correctly answered knowledge questions pre and post intervention

	Number and percentage of participants who answered correctly				
	Pre-intervention N (%)	**Post 1 N (%)**	**Difference at post 1 N (%)**	**Post 2 N (%)**	**Difference at post 2 N (%)**
Female condom is made of latex (false)	50 (42.7)	86 (73.5)	36 (30.8) *	88 (75.2)	38 (32.5)*
Cannot use female condom after hysterectomy	59 (50.4)	78 (66.7)	19 (50.4)**	82 (70.1)	23 (19.7)*
Can use female and male condom together	30 (25.6)	96 (82.9)	66 (25.6)*	92 (78.6)	62 (53.0)*
Female condom can be inserted up to 8 hours ahead	41 (35.0)	109 (93.2)	68 (58.1)*	111 (95.9)	70 (59.8)*
Cannot use female condom when on period	40 (34.2)	77 (65.8)	37 (31.6)*	89 (76.1)	49 (41.9)*

* Signed Rank (S) $p < .0001$
** Signed Rank (S) $p < .001$

Table 6a: Likeliness of using female condom at post 1 by likeliness of using female condom at pre-intervention

	Likeliness of using the female condom at pre-intervention				
Likeliness at Post 1	**Very likely N (Column %)**	**Somewhat likely N (Column %)**	**Somewhat unlikely N (Column %)**	**Very unlikely N (Column %)**	**Total at Post1 N (Column %)**
Very likely	23 (40.4)	11 (21.2)	0	0	35 (29.3)
Somewhat likely	23 (40.4)	27 (51.9)	3 (100.0)	3 (75.0)	56 (48.3)
Somewhat unlikely	4 (7.0)	7 (13.5)	0	1 (25.0)	12 (10.3)
Very unlikely	7 (12.3)	7 (13.5)	0	0	14 (12.1)
Total at pre-intervention (Row %)	57 (49.1)	52 (44.9)	3 (2.6)	4 (3.5)	116 (100.00)

Table 6b: Likeliness of using female condom at Post 2 by likeliness of using female condom at pre-intervention

	Likeliness of using the female condom at Pre-intervention				
Likeliness at Post 2	**Very likely N (Column %)**	**Somewhat likely N (Column %)**	**Somewhat unlikely N (Column %)**	**Very unlikely N (Column %)**	**Total at Post2 N (Column %)**
Very likely	26 (45.6)	13 (26.0)	0	0	39 (34.5)
Somewhat likely	19 (33.3)	18 (36.0)	1 (50.0)	3 (75.0)	41 (36.3)
Somewhat unlikely	6 (10.5)	11 (22.0)	1 (50.0)	0	18 (15.9)
Very unlikely	6 (10.5)	8 (16.0)	0	1 (25.0)	15 (13.3)
Total at pre-intervention (Row %)	56 (50.4)	50 (44.3)	2 (1.77)	4 (3.5)	113 (100.0)

Table 7: Consistency of condom use[1]

	Pre		**Post 1**		**Post 2**	
	Mean (Std Dev)	**Median**	**Mean (Std Dev)**	**Median**	**Mean (Std Dev)**	**Median**
Male condom use[2]	50.1 (43.2)	50.0	27.9 (32.3)	13.3	29.8 (34.5)	15.5
Female condom use[3]	--	--	45.4 (30.1)	40.0	43.2 (32.6)	37.5
Total condom use[4]	50.1 (43.2)	50.0	69.3 (34.5)	80.0	67.9 (35.5)	80.0

[1] Percent of sexual intercourse events using condom
[2] Number of times using male condom with main partner and with other than main partner / # of times had sex with main partner in past month and with other than main partner in the past month x 100
[3] Number of times using female condom with main partner and with other than main partner / # of times had sex with main partner in past month and with other than main partner in the past month x 100
[4] Number of times using male condom + number of times using female condom with main partner and with other than main partner / # of times had sex with main partner in past month and with other than main partner in the past month x 100

Table 8: Difference in participants' consistency of condom use[1]

	N	Mean (Std Dev)	Median	Wilcoxon Signed Rank
Difference from pre to post 2[2]	102	20.3 (38.9)	12.5	840, p < .0001
Difference from pre to post 1[3]	103	22.3 (40.8)	13.3	906, p < .0001
Difference from post1 to post 2[4]	103	2.2 (37.0)	0	4, p = 0.9807

[1] Consistency of condom use = Number of times using male condom + number of times using female condom with main partner and with other than main partner / # of times had sex with main partner in past month and with other than main partner in the past month x 100
[2] Difference = consistency of condom use at Post 2 minus consistency of condom use at Pre
[3] Difference = consistency of condom use at Post 1 minus consistency of condom use at Pre
[4] Difference = consistency of condom use at Post 2 minus consistency of condom use at Post 1

Table 9: Correlation between like using the female condom and female condom consistency of use

	N	Mean	Standard deviation
Post 1:			
Like using the female condom [1]	109	2.4	0.9
Consistency of female condom use at Post 1[2]	104	46.1	28.8
Pearson Correlation Coefficient (r): -0.41221, p< .0001			
Post 2:			
Like using the female condom[1]	113	2.2	0.9
Consistency of female condom use at Post 2[2]	106	46.4	29.1
Pearson Correlation Coefficient (r): -0.27780, p= 0.0039			

[1] Answer on a scale of 1 – 4, 1= Like very much, 4= Dislike very much
[2] Percent of sexual intercourse events using female condom (Number of times using female condom with main partner and with other than main partner / # of times had sex with main partner in past month and with other than main partner in the past month x 100)

Table 10: Correlation between comfort inserting the female condom and female condom consistency of use

	N	Mean	Standard deviation
Post 1:			
Comfort inserting female condom [1]	116	2.0	0.9
Consistency of female condom use at Post 1[2]	110	44.7	29.9
Pearson Correlation Coefficient (r): -0.35668, p< .0001			
Post 2:			
Like using the female condom[1]	117	1.93	0.9
Consistency of female condom use at Post 2[2]	110	44.7	29.9
Pearson Correlation Coefficient (r): -0.23048, p= 0.0154			

[1] Answer on a scale of 1 – 4, 1= Very comfortable, 4= Very uncomfortable

[2] Percent of sexual intercourse events using female condom (Number of times using female condom with main partner and with other than main partner / # of times had sex with main partner in past month and with other than main partner in the past month x 100)

Table 11: Correlation between attitude toward the female condom and female condom consistency of use

	N	Mean	Standard deviation
Post 1:			
Attitude score [1]	114	5.0	2.0
Consistency of female condom use at Post 1[2]	110	44.7	29.9
Pearson Correlation Coefficient (r): -0.17741, p= 0.0662			
Post 2:			
Attitude score[1]	114	5.0	2.0
Consistency of female condom use at Post 2[2]	117	43.5	32.5
Pearson Correlation Coefficient (r): -0.04362, p= 0.6586			

[1] Measured at pre-intervention. Three item 4-point scale, 1= Strongly agree, 4 = Strongly disagree; lower score reflects a positive attitude toward female condoms, maximum score = 15.

[2] Percent of sexual intercourse events using female condom (Number of times using female condom with main partner and with other than main partner / # of times had sex with main partner in past month and with other than main partner in the past month x 100)

Table 12: Participants' condom preference

	Pre N (%)	Post 1 N (%)	Post 2 N (%)
Type of condom you would choose, if cost was free	(n=171)	(n=144)	(n=116)
Female condom	59 (35)	42 (30)	42 (36)
Male condom	30 (18)	48 (34)	34 (29)
Both	79 (46)	50 (35)	38 (33)
Neither	3 (2)	2 (1)	2 (2)

Table 13a: Type of condom preferred by consistency of female condom[2] use at Post 1

Type of condom preferred[1] at Post 1	Use female condoms less than 70% of the time N (%)	Use female condoms 70% of the time or more N (%)	Total N (%)
Female condom only	25 (26.9)	13 (54.2)	38 (32.5)
Other	68 (73.1)	11 (45.8)	79 (67.5)
Total	93	24	117

χ^2 =6.4761, p = 0.0109

[1] Other = male condom only, both male and female condom, neither

[2] Number of times using female condom with main partner and with other than main partner / # of times had sex with main partner in past month and with other than main partner in the past month x 100, at Post 1; dichotomized at +/- 70%.

Table 13b: Type of condom preferred by consistency of female condom[2] use at Post 2

Type of condom preferred[1] at Post 2	Use female condoms less than 70% of the time N (%)	Use female condoms 70% of the time or more N (%)	Total N (%)
Female condom only	26 (29.2)	16 (59.3)	42 (36.2)
Other	63 (70.8)	11 (40.7)	74 (63.8)
Total			

χ^2 =8.0965, p = 0.0044

[1] Other = male condom only, both male and female condom, or neither

[2] Number of times using female condom with main partner and with other than main partner / # of times had sex with main partner in past month and with other than main partner in the past month x 100, at Post 2; dichotomized at +/- 70%.

Table 14: Amount participants are willing to pay for the female condom, post 1 and post 2

Amount willing to pay for the female condom	Post 1 N (%)	Post 2 N (%)
If free	33 (28.7)	19 (16.4)
50 cents or less	33 (28.7)	40 (34.5)
$1.00	21 (18.3)	32 (19.8)
More than $1.00	28 (24.4)	34 (29.3)
Total	115	116

Female Condom Pilot Project

Education and Counselling Technical Report

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Table of Contents

Introduction

In February 2000, the Women's Outreach Network – a network of agencies serving women in Toronto - asked the Toronto Board of Health (BOH) to provide female condoms as a part of the existing Toronto Public Health (TPH) Condom Distribution Program. Funded by the City of Toronto, The Condom Distribution Program supplies approximately 250 social services agencies, clinics and community health centres with a variety of male condoms and lubricant. This program is designed to reduce the rates of unplanned pregnancy and to prevent transmission of sexually transmitted diseases including HIV.

The BOH requested Toronto Public Health to design and implement a social marketing campaign to increase awareness of the female condom as a barrier method.

The BOH also asked Toronto Public Health to ensure

1. That health care providers have access to educational resources and promotional materials, and

2. To conduct a pilot study with selected sexual health clinics and/or agencies in order to document education and instruction efforts, and to obtain feedback from clients on acceptability and factors associated with initial and continued condom use.

Subsequently, Toronto Public Health, in partnership with several community agencies, developed a pilot intervention to introduce the female condom to women between the ages of 18 and 45 in Toronto who are at risk for sexually transmitted diseases, including HIV (STDs/HIV), and unplanned pregnancy. This report documents the development and evaluation of education and counselling sessions, training and materials for service providers and for clients. Detailed descriptions and findings of the pilot intervention are found in separate technical reports available from Toronto Public Health (Gillis, 2002; Hardwick, 2002).

Background

The Sex Information and Education Council of Canada (SIECCAN) conducted a literature review for the Female Condom Pilot Project (Bissell and McKay, 2000). No rigorous Canadian acceptability and use studies had been published and many of the U.S. studies were just being published at the time that we initiated our investigations. However, the Female Condom Pilot Project set out to develop a pilot study based on the information available.

Unlike developing countries where the female condom has been widely distributed and evaluated, little was known about the use of the female condom

among sexually active North American women until recently. The female condom has been available in the U.S. since 1993 and Canada since 1994. However, the sole manufacturer and distributor of the female condom in the U.S. (The Female Health Company) and its Canadian distributor (Pharmascience) confirm that relatively few North American women use the female condom. With increasing STD and HIV rates among women, the female condom could be an important innovation in women's reproductive health. Aesthetics, lack of knowledge about the female condom, and high retail cost were believed to be barriers to using the female condom in North America. Health care provider attitudes were found to be barriers in the uptake of previous novel methods of birth control (Frank et al, 1994) and feminine hygiene (Latka, 2001). This suggests that these attitudes may also present a barrier to women trying the female condom (Latka, 2001; Van Devanter et al, 2002). However, previous studies in the U.S. have shown that interventions focussing on reducing these and other barriers have been successful in documenting the acceptability of the female condom and increasing consistency of male or female condom use (Artz, et al, 2000; Latka, et al, 2000; Sly, et al, 1997; Golub, et al, 1995; Witte, et al, 1999).

Previous studies also indicate interventions are most successful when targeted to adult women at high risk for STDs/HIV and unplanned pregnancy (Artz, et al, 2000; Latka, et al, 2000; Macaluso, et al, 2000; Witte, et al, 2000) and their male partners (El-Bassell, et al, 1998). Effective interventions include safer sex negotiation, communication skill-building and insertion techniques in education and counselling sessions, and opportunities to practice inserting the female condom (Artz, et al, 2000; Latka, et al, 2000; Witte, et al, 2000; Sly et al, 1997). The Female Condom Pilot Project designed interventions based on the content and techniques used in these previous studies, while taking into consideration the needs and diversity of women in the City of Toronto.

The Role of the Education and Counselling Subcommittee

The Education and Counselling Subcommittee was formed in July 2000 to develop education and counselling procedures and resources and to deliver service provider training prior to the education and counselling intervention. This Subcommittee included representatives from TPH as well as community stakeholders that provide services to women at high risk for STD/HIV and unplanned pregnancy. The community partner agencies that participated in the Subcommittee are listed in Appendix A.

The role of the Education and Counselling Subcommittee was twofold:

1. Firstly, we had to determine the most effective way of providing information about the female condom to women who would be participating in the intervention and then develop an education and counselling intervention with relevant tools and resources.

2. Secondly, we needed to determine the best way to increase female condom knowledge and comfort level necessary for service providers who would ultimately be offering the education and counselling interventions. We then had to train the service providers accordingly.

Education and Counselling Resource Development

Female Condom Teaching Guide

In order to develop the education and counselling intervention, the Education and Counselling Subcommittee created a Female Condom Teaching Guide to be given to service providers who would be offering the education intervention to clients. Sections of this teaching guide were adapted with permission from the teaching guide created by Female Health Company (FHC). The Education and Counselling Subcommittee created other sections specific to the needs of our diverse community. Throughout the development of the teaching guide, drafts were reviewed by a number of community partners and TPH staff for feedback.

A Basic 1:1 Counselling Checklist was created for service providers to follow when offering the intervention and was included in the teaching guide. As part of the intervention, most participants were given the opportunity to practice inserting the female condom on site and having a nurse check for proper insertion. To facilitate this process, a Female Condom Insertion Checklist was also created and included in the teaching guide. The FHC's short video "Reality Female Condom" was copied with permission and included in the teaching guide. A total of 30 teaching guides were printed.

Pamphlet

A pamphlet about the female condom was created by the Education and Counselling Subcommittee and focus tested in collaboration with the Social Marketing Subcommittee. Grey Worldwide Advertising created the graphics and design of the pamphlet, based on the social marketing campaign poster artwork. The Education and Counselling Subcommittee created the content and layout of the pamphlet.

In addition to providing general information about the female condom, the pamphlet gave step-by-step instructions on how to insert the condom. The

instructions were provided in both text and diagrams. A pamphlet was given to each intervention participant. The pamphlets were also distributed more widely as part of the social marketing campaign. For more details about the social marketing campaign, please refer to the Summary Report of the Social Marketing Campaign (Macpherson and Methven, 2002).

Other resources created

To facilitate use of the female condom and data collection for the evaluation of the intervention, the Education and Counselling Subcommittee created the following resources to be given to women participating in the intervention:

- **Record of Intercourse Booklet (diary)** for women to record how many times they had intercourse, if they used either a male condom or a female condom, and any additional comments. This booklet was optional for women to use and was created as a tool should women want to remind themselves of any experiences they had with the condom. Women were not asked to show this book to any service provider or data collector. The dates of follow-up appointments and the cell phone number were also included in the booklet. A total of 600 booklets were printed.

- **Carrying Pouch** for women to discreetly carry female condoms with them. A total of 200 pouches were ordered - one for each project participant.

- **Small Flip Mirror** with the slogan "Now You Have a Choice…Ask About the Female Condom", TPH logo and the AIDS - Sexual Health InfoLine number. Mirrors were given to participants to check female condom insertion.

Service Provider Training Workshop

Rationale for service provider training

Based on previous studies, service provider training to increase knowledge about the female condom and service providers' comfort with counselling about the female condom supports effective interventions. The training, and associated resource materials and procedures, increases the consistency with which the intervention is delivered, thus providing a higher degree of validity to the findings of the study.

Objectives of the Female Condom Service Provider Training Workshop

- To make service providers cognizant of the history and issues leading to the promotion of the female condom,
- To increase the knowledge of use, benefits and insertion of the female condom (efficacy, rate of failure),
- To increase skills in demonstrating the insertion of the female condom,
- To increase confidence in providing information about the female condom,
- To explore attitudes toward the female condom as a barrier to promotion, and
- Review the educational and counselling guidelines as per the teaching guide.

Workshop description

Community-based health and social service agencies serving women at risk for STDs/HIV and unplanned pregnancy were invited to participate as research sites for either an individual or group intervention. The sites chosen provide services to women at risk for STDs/HIV and unplanned pregnancy due to socio-economic and sexual risk behavioural factors. Four sites from across the city provided the individual intervention. Two of the sites were Toronto Public Health sexual health clinics and two were community partner clinics. Three sites facilitated group interventions. All staff that were to provide the education and counselling intervention were required to attend the service provider training workshop.

Forty-four (44) service providers attended the workshops. Training workshops were provided at four different locations, using a lesson plan presented with Microsoft PowerPoint and following the teaching guide. Each workshop varied in length depending on the number of participants and was tailored to meet the specific needs of the intervention sites. Participants viewed the PowerPoint presentation and had the opportunity to view the Female Health Company video, talk about possible situations that may arise with their clients, and ask questions. Clear pelvic models and anatomy flipcharts were purchased for these training workshops and for intervention sites. Education and Counselling Subcommittee TPH representatives facilitated the training.

Service providers were given copies of the Female Condom Teaching Guide, which included a Basic 1:1 Counselling Checklist, a Female Condom Insertion Checklist and the Female Health Company's video.

Workshop evaluation

To evaluate the process and effectiveness of the Service Provider Training Workshop, we asked workshop participants to complete a self-administered questionnaire prior to the workshop and again one month later. The evaluation aimed to measure the influence of the workshop on service provider knowledge, attitudes towards the female condom, counselling skills and practice. It was expected that after the workshop, service providers would report:

- An increase in knowledge about the female condom;
- A more positive attitude toward the female condom;
- Improved skills in providing information and demonstrating insertion of the female condom; and
- Increased inclusion of female condoms in their counselling.

Of the 44 workshop participants, 26 completed both the pre-test and post-test questionnaires. The evaluation found that workshop participants increased their knowledge and self-reported counselling skills. They also reported a more positive attitude toward the female condom a month after attending the service provider training workshop. One month after the workshop, service providers had not significantly changed their counselling practice with respect to the female condom. Perhaps the service providers had not had enough time to change their practice in the time frame of the evaluation. A detailed description of the methodology and results is found in Appendix B.

Education and Counselling Interventions

Description of the interventions

The project was designed in such a way that participating women attended a total of three intervention sessions, either individually or in peer support groups. The three sessions were each one month apart. In the first session women received the education intervention (created by the Education and Counselling Subcommittee). The second and third sessions were be more informal, and participants had an opportunity to share their experiences with the female condom, ask questions and receive more condoms.

In the education intervention received by participants, women were given the information covered in the teaching guide, offered a viewing of the video, and offered all of the male condoms and female condoms they thought they would need for the month. In addition, women receiving the individual intervention were offered an insertion check. If participants ran out of condoms, needed to change appointments, or had any questions or concerns, they were encouraged to call a phone number dedicated to this project.

Client satisfaction with the interventions

We evaluated the implementation of the education and counselling interventions by asking participants to complete a client satisfaction questionnaire at their third session. Of the 115 respondents to the client satisfaction questionnaire, 19 had received the group interventions and 94 had received individual interventions. Overall, the respondents were satisfied with the education and counselling sessions they attended. They mostly agreed that the service providers delivered the education and counselling sessions as they were intended to be delivered.

However some deviation from the suggested procedures was noted. For example, providing education and counselling prior to distributing female condoms, and having follow-up sessions with the same counsellor appears to be beneficial. However, there were situations in which this was not possible.

Half of the respondents said that the counselling session was good and did not require any improvements. Other respondents recommended that more written information and more opportunities for practice be provided. Many respondents suggested more use of videos and other visuals, counselling on relationships and negotiating female condom use with partner, client feedback, and including common problems with female condoms, and some solutions, in future counselling sessions. Two respondents suggested including sexual partners in the session and four respondents suggested group sessions, especially as follow-up to the first individual counselling session. Detailed findings of this survey are found in Appendix C.

Intervention effectiveness

The ultimate evaluation of the effect of service provider training on the education and counselling intervention, and of the interventions themselves, is whether or not women try the female condom and continue to use it. The full description of the results of the education and counselling interventions are reported in separate technical reports (Gillis, 2002; Hardwick, 2002). The findings show that an education and counselling intervention by trained service providers, either in individual or group formats, is effective in introducing the female condom to women who are at high risk for STDs/HIV and unplanned pregnancy. Furthermore, the recipients of the intervention increased use of either the male or female condom for at least two months after the intervention (Hardwick, 2002). However, many women experienced some difficulty using the female condom initially. According to participants, practice was a key to reducing the problems. Additional and ongoing counselling about problems and problem solving may encourage more women to continue to use the female condom (Gillis, 2002).

Conclusions

The Education and Counselling Subcommittee of the Female Condom Pilot Project created education and counselling procedures and relevant tools and resources for the pilot study requested by the Toronto Board of Health in 2000. Also, as requested, the Subcommittee developed and delivered a training workshop to service providers.

The resources developed included:

- Female Condom Teaching Guide to assist service providers to deliver the intervention,

- Pamphlets to promote female condom knowledge and insertion instructions, and
- Other resources to encourage female condom use and to assist with the data collection for the pilot study.

Forty-four (44) service providers attended the Service Provider Training Workshop at four different sites. The workshop was evaluated and found to be successful in improving workshop participants' knowledge about and attitude toward the female condom. However, the evaluation timeframe was not long enough for service providers to have had an opportunity to significantly change their counselling practices relevant to the female condom.

After training, service providers delivered individual or group interventions at seven sites across the city of Toronto, following the procedures outlined in the teaching guide and tools and resources developed by the Subcommittee. A client satisfaction survey indicated that women who participated in the intervention were generally satisfied with the education, counselling, and supplies that they received. Analysis of the participants' comments suggest that the intervention was mostly delivered as planned. Participants offered a variety of suggestions for improving the intervention, some of which were already included in the teaching guide.

Future education and counselling interventions, and related service provider training, should consider a mix of individual and group counselling where appropriate and use a variety of resources (videos and other visuals, fact sheets or other written material). Service providers should be knowledgeable about the range of insertion and use problems, and include problem solving in their counselling.

The evaluations of the process of implementing the education and counselling intervention, and of the effectiveness of the Service Provider Training Workshop, cannot be fully understood in isolation from other parts of the Female Condom Pilot Project. As the quantitative report on the effectiveness of the intervention indicates, an education and counselling intervention by trained service providers, either in individual or group formats, is effective in introducing the female condom to women who are at high risk for STDs/HIV and unplanned pregnancy, and increasing their consistent use of either male or female condoms (Hardwick, 2000). In her focus groups and interviews with intervention participants, Gillis (2002) found that practice inserting the female condom, identifying problems and problem solving were key factors in women's female condom use.

All of these results, taken together, indicate that the education and counselling intervention, service provider training, tools and resources were appropriate for the pilot project. From the results of the pilot study, we are confident that some women in Toronto who are at risk for STDs/HIV and unplanned pregnancy find the female condom acceptable and would like to use it. Correct and consistent

use of the female condom may, therefore, be an important reproductive health option for women. But, interested women need information, counselling and support.

Health care providers in Toronto now have access to educational resources and promotional materials to help them to promote the female condom and counsel their clients. However, that is not enough. Health care practitioners providing sexual health services should receive training to increase their knowledge about the female condom, problems women encounter inserting it, improve their skills for counselling problem solving and negotiation, and increase their comfort with the female condom. The Service Provider Training Workshop in this pilot project could be expanded and offered to all agencies receiving female condoms through the Toronto Public Health Condom Distribution Program.

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Appendix A – Community Partner Agencies

Black Coaltion for AIDS Prevention (Black CAP)
Maggie's Prostitutes Information Centre
Women's Health in Women's Hands
Youthlink Inner City

Appendix B – Service Provider Training Workshop Evaluation

The Female Condom Pilot Project

Evaluation of the Service Provider Training Workshop

Stephanie Lappan-Gracon and Deborah Hardwick

Toronto Public Health

June 2002

Introduction

The female condom is the only female controlled barrier method that provides protection against unplanned pregnancy and sexually transmitted diseases (STD) including human immunodeficiency virus (HIV). With increasing STD and HIV rates among women, the female condom is an important innovation in women's reproductive health. Studies have demonstrated the acceptability of the female condom among women (Gollub, et al, 1995; Witte, et al, 1999). Studies have also focused on client's knowledge and attitudes toward the female condom as factors in predicting female condom use (Haignere, et al, 2000; Seal & Ehrhardt, 1999; Sly, et al, 1997). Little is known however, about health care providers' knowledge and attitudes toward the female condom.

Several studies in the female condom literature suggest that health care provider attitudes may be a factor in women's decisions to use the product (Van Devanter et al, 2002). Strong attitudes can interfere with the acquisition of knowledge and inadequate knowledge is a barrier to the acquisition of new skills. Indeed a study by authors Frank, Bateman & Poindexter (1994) on the contraceptive Norplant, found that the opinions about Norplant held by personnel at family planning clinics influence the method selection of their patients. Their study also concluded that participation in an in-service training was associated with greater method use by patients. It seems reasonable to suggest that similar to Norplant, the female condom is a new innovation that requires the dissemination of current knowledge and technology of contraceptive methods to health care providers. Rogers (1995) Theory of Diffusion and Innovation emphasizes the importance of diffusion in which an innovation, such as the female condom, is communicated by way of certain channels, over time, to members of a social system prior to adoption of an innovation. Thus the dissemination of knowledge of the female condom within an educational workshop may influence service provider knowledge and alter attitudes.

This study aimed to measure the influence of an educational workshop on service provider knowledge, attitudes towards the female condom, counselling skills and practice. Several research hypotheses were generated for this study. It was expected that after the training, service providers would report:

- an increase in knowledge about the female condom;.
- a more positive attitude toward the female condom;
- improved skills in providing information and demonstrating insertion of the female condom; and
- increased inclusion of female condoms in their counselling.

Methods

Study Respondents

The population sampled included a mix of nurse practitioners, public health nurses and physicians working in Toronto Public Health sexual health clinics and

partnering community health centres. A self-administered questionnaire was distributed to all 44 health care providers attending an educational workshop on the female condom. A trained data collector distributed the questionnaires just prior to the workshop. A total of four workshops were held. Two of the workshops were held at two public health clinic sites, and the other two workshops were held at community health centres.

One month after the workshop, a questionnaire was distributed to participants. Study participants were asked to return by mail, their completed questionnaire to the principal investigator. Participation was voluntary and anonymity assured.

Intervention

Participants attended an educational workshop on the female condom with an experienced STD/HIV educator. The educator briefly reviewed women's birth control practices over the last thirty years and corresponding efficacy rates. The educator also presented a brief overview of STD and HIV rates among women. The workshop then focused on introduction of the female condom in terms of its appearance, comparison to the male condom and how to insert the female condom. A transparent anatomic model was used to demonstrate insertion and female anatomy was also briefly reviewed. Positive features of the female condom for clients were emphasized.

A discussion on solving common problems with the female condom was promoted among participants. Discussions on troubleshooting ideas as well as tips for introducing the female condom to clients were discussed. Various resources in the form of presentation slides, female condom pamphlet and video from the Female Health Company were utilized to provide information and promote discussion on the female condom. Participant discussion was encouraged throughout most of the session through the interactive style of the education facilitator.

The educational workshop lasted approximately two hours in length at the public health clinic sites and about three hours in length at the community health center sites.

Instrument

The self-report questionnaire (Appendix B1) was composed of 21 questions to measure female condom knowledge, attitudes toward the female condom, counselling skills and practice. An 8-item knowledge scale measured service providers' knowledge of the female condom (questions 10 to 17 on the questionnaire). The knowledge scale was a set of statements to which respondents were to circle true / false / I don't know. The Cronbach Coefficient Alpha of the knowledge scale was .61, indicating that the scale had moderate reliability.

Participants' attitude toward the female condom was measured using a 6-item likert scale (questions 3 through 8 on the questionnaire. The attitude scale items ranged from 1 (strongly disagree) to 5 (strongly agree) for each item. Three of the six items were phrased negatively and reverse coded prior to analysis. Cronbach Coefficient Alpha of the attitude scale was .81, indicating a high degree of reliability. Two additional items measured service providers' opinions about whether the likelihood their clients would try the female condom and that they would like the female condom, using scores from 1 (strongly disagree) to 5 (strongly agree).

A two-item scale measured self-perception of skill (questions 1 and 2). The skill scale responses ranged from 1 (very low) to 5 (very high) for each of the items. Cronbach Coefficient Alpha for this scale was .77.

Participants were also asked how often during the past year that they included the female condom when counselling their clients. The options were never, occasionally, often and every time.

Data Analysis

Knowledge scores were coded 1 for correct answers and 0 for incorrect answers. Attitude items that were negative statements were reverse coded. Means and SD (standard deviation) were calculated for each scale and the differences of the means between pre and post-test were analyzed, using matched pair t-tests.

Only data on the 26 participants who completed both the pre and post-test questionnaire were included for analysis.

Results

Of the 44 participants who attended the workshop, 26 completed both the pre-test and post-test questionnaires. The pre, post and difference from pre to post test mean scores and the standard deviation for the knowledge, attitudes and skill measures are provided in Table 1.

The mean knowledge score increased by 2.0 from pre-test to post-test. ($p<.0001$), from 5 out of a maximum to 10 at pre-test to 7 at post-test.

Service providers also had a more positive attitude toward the female condom after the workshop. The mean difference on the attitude scale was 2.3 ($p < .0001$), from 15.6 out of a maximum of 30 at pre-test to 17.9 at post-test. After the workshop, they were in greater disagreement with the statement that their clients would not like the female condom, with a decrease in the mean score of 0.38 ($p = 0.0050$), from 4.0 out a maximum of 5 at the pre-test to 3.62 at post-test. However, they did not agree more strongly that their clients were likely to try the female condom with samples.

The workshop had a slight impact related to skill in demonstrating insertion and providing information to women on the female condom. Participants reported an increase in their skills in demonstrating insertion of the female condom. Their mean score increased from 3 to 4 ($p<0.0001$), out of a maximum of 5. They rated their skills in providing information about the female condom the same. With a mean of 3 at the pre and 4 at the post-test, the difference of 1 was statistically significant ($p=0.0005$).

Table 1: Change in participants' knowledge, attitude, self-perceived skills, and practice

		Pre-test	Post-test	Difference (Post-Pre)
Knowledge score	Mean	5.08	7.15	2.0†
	SD	1.65	1.07	1.5
Attitude score	Mean	15.5	17.8	2.3†
	SD	3.0	3.2	2.5
Clients will not like the FC	Mean	4.0	3.62	-0.38*
	SD	0.63	0.80	-0.63
Clients will likely try the FC	Mean	2.62	2.85	0.23
	SD	0.94	0.78	0.76
Self-perceived skill in demonstrating insertion of the FC	Mean	2.81	3.85	1.0†
	SD	0.94	1.01	0.87
Self-perceived skill in providing information about the FC	Mean	3.11	4.06	0.96**
	SD	0.99	0.84	1.26
Include FC in counselling	Mean	2.16	2.19	0.04
	SD	0.69	0.63	0.53

† $p < 0.0001$
* $p = 0.005$
**$p = 0.0005$
SD – Standard deviation
FC – Female condom

Table 2 shows that the percentage of participants that never included female condoms in their counselling over the past year decreased from 15% at pre-test to 8% at post test. Those that occasionally included female condoms in their counselling increased from 50% at pre-test to 69% post-test, and those that often did decreased from 31% to 19%. The difference of the means of 0.04 for this question was not statistically significant.

Table 2: Frequency with which participants included the female condom when counselling clients over the past year

	Pre-test	Post-test	Difference (Post – Pre)
Never	15%	8%	- 7%
Occasionally	50%	69%	19%
Often	31%	19%	-11%
Everytime	0	4%	4%
No answer	4%	0	-4%
Total	100%	100%	

Discussion

This study aimed to establish whether an educational workshop on the female condom would have an influence on service provider knowledge, attitude towards the female condom, counselling skills and practice. The results suggest that the workshop did increase participant's knowledge, improve attitudes, and increase self-perception of skills in counselling women on the female condom one month after attending the workshop. However, the workshop did not influence the inclusion of the female condom in service providers' counselling practice. This result is attributable to the one-month time period between pre-test and post-test, and that the question asked about their counselling practice over the past year. The period of one month was not sufficient for service providers to have had an opportunity to significantly change their counselling practices relevant to the female condom.

Even though service providers' knowledge and attitude did increase following the educational workshop, it may be that the workshop in itself is not enough to influence service providers to include the female condom into their counselling practice. This finding suggests that other factors may be influencing the adoption of the female condom into counselling practice. Current theories about diffusion of knowledge and innovation into practice support this idea. Rogers (1995) Theory of Diffusion and Innovation, propose that innovations such as the female

condom take time, require social systems and the influence of early majority/opinion leaders to adopt innovation into practice.

Limitations

As this study was limited to the city of Toronto and the sample size of this population was small, generalization of results to other populations is invalid. Although all 44 participants were provided with questionnaires, only 26 completed the pre test and post-test questionnaire. Thus non-respondents may introduce a bias if, in fact, they are clearly different from the sampled population. Since no demographic information was collected on the sample population, it is not possible to ascertain if there was a difference in scores among public health nurses, physicians and nurse practitioners.

Conclusion

The results of this study have several implications related to service provider counselling and the female condom. First it appears that an educational workshop on the female condom addressing such issues as knowledge deficit and counselling skill and provider attitudes is beneficial. However, an increased knowledge and a more positive attitude on behalf of the service provider may not necessarily be enough to influence the adoption of the female condom into counselling practice. The presence of other factors that prevent or encourage service providers to include the female condom when counselling their clients should be further explored. Studies that address the barriers and incentives from a service provider perspective would be useful to examine. Future educational workshops on the female condom may wish to include a discussion on the health care provider barriers or other factors that dissuade or promote the female condom in a counselling session. Future studies may also wish to compare public health nurses and community providers to determine if there are differences between these groups. Finally, the sample size of the population should be increased to validate results.

The female condom remains an important innovation in women's reproductive health. An understanding of the factors that encourage health care provider adoption of the female condom into practice remain important to examine in order to prevent increasing STD and HIV rates among women and promote quality health outcomes.

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Appendix B1 – Questionnaire

FEMALE CONDOM PILOT PROJECT

SERVICE PROVIDER PRE-TRAINING QUESTIONNAIRE

In order for the evaluators to compare your responses to this and future questionnaires, while maintaining confidentiality and anonymity, we ask you to provide an identification code known only to you. You do not need to remember this code, as we will prompt you on future questionnaires to provide the following information, which constitutes your own personal and confidential identification code.

First letter of your mother's first name	Last letter of your Mother's first name	Last letter of the town/city in which you were born	Month in which you were born (January = 01)	Day in which you were born (01,02,03, etc)	Last letter of your first name
_____	_____	_____	____ ____	____ ____	_____

For statements 1 to 2 below, please rate your skill (on a scale of 1 – 5: 1= very low and 5= very high*). Please circle your response*.

1. On a scale of 1 – 5, I would rate my skills in providing information about the female condom as

1	2	3	4	5
Very low				Very High

2. On a scale of 1 – 5, I would rate my skills in demonstrating insertion of the female condom as

1	2	3	4	5
Very low				Very High

Please continue to the next page . . .

For statements 3 to 8 below, please circle the number that best reflects how you feel (on a scale of 1 – 5)

3. Most of my clients will not like the female condom.

1	2	3	4	5
Strongly disagree	Disagree	Unsure	Agree	Strongly agree

4. Most of my clients will likely try the female condom, if we give them samples.

1	2	3	4	5
Strongly disagree	Disagree	Unsure	Agree	Strongly agree

5. I feel confident promoting the female condom

1	2	3	4	5
Strongly disagree	Disagree	Unsure	Agree	Strongly agree

6. The female condom is too difficult for most women to use.

1	2	3	4	5
Strongly disagree	Disagree	Unsure	Agree	Strongly agree

7. Most of my clients will think the female condom is unattractive

1	2	3	4	5
Strongly disagree	Disagree	Unsure	Agree	Strongly agree

8. Most of my clients will be excited about having a female-oriented method of sexually transmitted disease protection.

1	2	3	4	5
Strongly disagree	Disagree	Unsure	Agree	Strongly agree

9. In the past year, how often would you say you included the female condom when counselling a client for birth control or STD prevention?

1. Never
2. Occasionally
3. Often
4. Every time I counsel a client about birth control or STD prevention

Please answer the following true or false questions

	Please circle your response		
10. If a woman has had Female circumcision / Infibulation / FGM and can have sex and can also insert 2 fingers inside the vagina, she can use the female condom.	1. True	2. False	3. Don't know
11. While wearing the female condom, a woman cannot urinate.	1. True	2. False	3. Don't know
12. The inner ring needs to fit snugly around the cervix.	1. True	2. False	3. Don't know
13. The female condom and the male condom can be used together.	1. True	2. False	3. Don't know
14. As long as the female condom is inserted properly, any position for sexual intercourse can be used.	1. True	2. False	3. Don't know
15. Water-based lubricant is recommended for use with the female condom even though oil based lubricants will not damage the female condom.	1. True	2. False	3. Don't know
16. If inserted properly, the inner ring should be felt in the vagina.	1. True	2. False	3. Don't know
17. Lubricant is the 'problem solver' for the female condom.	1. True	2. False	3. Don't Know

18. In my opinion, the three **greatest advantages** to using a female condom are:

    1. _____
    2. _____
    3. _____

19. In my opinion, the three **greatest barriers** to using a female condom are:

    1. _____
    2. _____
    3. _____

20. Have you ever personally used the female condom?

1. Yes
2. No
3. Refuse to answer

21. Would you be willing to use the female condom in the future?

1. Yes
2. No
3. Refuse to answer

Thank you for completing this questionnaire. Your responses are valuable to us.

Please insert the completed questionnaire in the envelope provided, seal it, and return it to the address on the envelope.

Appendix C - Client Satisfaction Results

Female Condom Pilot Project

Client Satisfaction with the Education and Counselling Intervention

Deborah Hardwick

Toronto Public Health

May 2002

1. Introduction

The objective of the client satisfaction questionnaire is to evaluate the process of implementing the education and counselling intervention.

2. Methods

Participants in the intervention component of the Female Condom Pilot Project were asked to complete a short self-administered client satisfaction questionnaire at the end of the study. All but two participants who completed the study also completed a client satisfaction questionnaire. Of the 115 respondents to the questionnaire, 19 had received group intervention and 94 had received individual intervention.

The data from the questionnaires were analyzed using descriptive statistics produced with SAS, Version 8.

The questionnaire contained seven Likert-scale type questions to which respondents were asked to rate their level of agreement on a five-point scale from 1. Strongly disagree to 5. Strongly agree. Two of the questions were negatively stated, and reverse-coded. These two questions were also asked using a positively worded statement. A post-hoc analysis of the internal consistency of these questions was only moderate when all seven questions were included (Cronbach's Coeffeicient Alpha = .73). When we excluded the two negatively stated questions, the Cronbach's Coefficient Alpha was strong (.81). Each question was individually analyzed and the five positively stated items were analyzed as a single scale.

One question was an open-ended item asking what improvements could be made. The 80 responses were entered verbatim into a Word document, reviewed for commonalties and grouped accordingly.

3. Results

Almost all respondents (97%) agreed that the service provider had answered all her questions.

Individual item analysis reveals that respondents were largely satisfied with the intervention. Table 1 shows that only the negatively stated items did not have a large majority of the respondents agreeing or strongly agreeing with the statement, but most respondents disagreed or strongly disagreed with them, indicating overall satisfaction with the intervention. As shown in Table 1, respondents were least satisfied with the amount of written information (only 31%

strongly agreed there was enough) and the amount of lube they received (only 52% strongly agreed they were given enough).

As a further indication of overall satisfaction with the intervention, the scores from the five positively worded items were summed. The range of scores was from 5 (respondent strongly disagreed with each item) to 25 (respondent strongly agreed with each item). The average score was 22, again indicating high level of agreement that the intervention was satisfactory.

When asked how they would change possible future counselling sessions, half of those who answered said that the counselling session was good and did not require any changes, or that they could not suggest any changes. (See Appendix C1 for verbatim comments). Four respondents suggested more written information be provided, four suggested providing more or different opportunities to practice inserting the female condom. With respect to the type of education and counselling sessions, four respondents suggested group sessions, especially as follow-up to the first individual counselling session. Many respondents made recommendations regarding the education and counselling method and content, including: more use of videos and other visuals, counselling on relationships and negotiating female condom use with partner, client feedback, and including common problems with female condoms and some solutions. Two respondents suggested including their partners in the session.

A few suggestions referred to the scheduling of the sessions and from whom they would like to receiving the education and counselling. Suggestions included: meeting the same counsellor each session, meeting with a nurse twice, making sure to meet with a doctor before being given the female condom, and having women discuss their own experiences.

Five respondents wanted better locations and timing of the sessions. One person suggested more lube and another suggested putting the supply of condoms into a brown paper bag.

The rest of the recommendations were relevant to the pilot study only and would not apply in ongoing education and counselling sessions. This includes comments about the questionnaires, time available to complete the questionnaire, a call centre for making appointments, changing clinic locations and honorarium.

4. Discussion and Conclusion

Overall, the respondents to the client satisfaction questionnaire were satisfied with the education and counselling sessions they attended. They mostly agreed that the service providers delivered the education and counselling session as it was intended to be delivered.

Respondents provided some thoughtful suggestions for improvements in future sessions that were in keeping with their responses to the other questions, and indicated that, on a few occasions, the recommended education and counselling process was not followed precisely. Providing education and counselling prior to distributing female condoms, and having follow-up sessions with the same counsellor appears to be beneficial. The intervention was designed to deliver education and counselling first, but there may have been circumstances when this was not possible.

Future female condom education and counselling programs should consider providing more written information for respondents to take home, although no one complained about the quality of what they were given. Videotapes and other visuals should be used to augment service provider counselling. Future programs should also consider offering a combination of individual and group sessions and sessions with partners. Lastly, the respondents recognized the importance of having opportunities to practice inserting the female condom and service providers should enhance those opportunities whenever possible.

Appendix C1 - Data

Table 1: Description of agreement with statements about the education and counselling session

	Stongly disagree N (%)	Disagree N (%)	Unsure N (%)	Agree N (%)	Stongly Agree N (%)	Total N
The person or persons who provided the education and counselling was at ease talking about the female condom and answering my questions.	7 (7)	1 (1)	1 (1)	16 (15)	82 (77)	107
There was enough time during the sessions to get all the information I needed.	3 (3)	1 (1)	1 (1)	39 (34)	70 (61)	114
The sessions were too long.*	33 (29)	65 (57)	5 (4)	7 (6)	4 (4)	114
There was enough written information.	7 (6)	5 (4)	5 (4)	62 (54)	36 (31)	115
There was too much written information.*	34 (30)	73 (64)	6 (4)	1 (1)	1 (1)	115
I was given enough female condoms.	2 (2)	0	1 (1)	36 (31)	76 (66)	115
I was given enough lube.	2 (2)	5 (4)	3 (30	45 (39)	60 (52)	115

* Negatively worded statements.

Comments re: How counselling sessions could be improved
May 2002

A. Satisfied as is / Recommended no changes:

ID#	Verbatim Comment
002	I think they were excellent and I hope they continue like this. Congratulation all.
007	I was very satisfied with correspondence.
009	I think the session was well presented.
012	Nothing at all.
022	I think they were fine.
025	I was extremely impressed the ladies were wonderful.
032	No need for improvement.
035	None needed.
036	I think the session where appropriate and provided me with some support. I don't think there is much room for improvement.
037	Nothing, they did a good job (personal experience).
038	No need.
040	The sessions are perfectly.
043	The counsellor's just have to keep doing what they already did.
045	I will be very impressed.
046	Excellent overall – perhaps more literature.
049	They were very informative so quite satisfied.
054	No suggestions.
055	No problem that I can think of this.
063	Everything was great!
064	They are fine.
069	Nothing that I could think of. Everything was very discreet & professional.
072	I think they are fine, very informative.
073	The counsellors session were just fine. I had enough information.
074	Enjoyed learning about female condom project.
075	They were great.
076	They were fine.
080	Everyone, everything was great!
081	The counselling sessions were informative and great!! However, for the 2nd sessions which held; they did not have to be held in individual sessions-(Perhaps group sessions could have been held; to be interactive with other woman). To hear their views. In the individual sessions; I was only able to hear myself.
084	Go right ahead.
087	It was pretty well put together.
090	I really enjoyed my sessions. I got there is no need for improvement. My counsellor was great.
100	I think everything was perfect staff were great too. Thanks so much for all the effort.
101	They were ok for me. I don't think that they need to improve.
103	No advice.

104 I don't think they should improve.
105 They were great-helped me trouble shoot & answered all questions put forward. If they weren't so far away – I had a 1 hr. commute. – having the same counsellor follow through all three sessions.
109 No need for improvement. Possibly the questionnaires could been better worded.
112 "When everything is going fine, I am happy with this information".
115 Nothing at all.
117 ? seemed very fine to me. Thanks.

B. More written information:

ID#	Verbatim Comment
004	More information to take home on use etc for new users make sure women know how to insert what's proper.
017	More info to public e.g. women.
046	Excellent overall – perhaps more literature.
085	More written information.

C. More opportunities to practice inserting FC / follow-up re: insertion

ID#	Verbatim Comment
010	More practice to see if they are put inside properly, more condoms with a higher incentive more than 75.00 for 3 visits.
024	A female dummy to demonstrate insertion.
044	Have a different size vagina model to practice in section. That is way you could see what you are doing.
088	Allow the woman more time to learn how to insert the female condom.
120	One might want to check if people still understand how to use the female condom.

D. Who should provide education and counselling:

ID#	Verbatim Comment
014	It should be imperative that the session with the doctor is scheduled prior to receiving the female condoms. The benefits of the female condom should be reiterated prior to completing the questionnaire.
111	Being able to talk to same counsellor each session.
026	Have a couple of women who are not shy discuss there experiences.
096	I think there should be 2 meeting with nurse before to explain and after to take over.

E. Type of education and counselling sessions:

ID#	Verbatim Comment
015	Group sessions.
020	A follow up.
061	Maybe do a group session after the first interview. So people can share experiences and difficulties.
081	The counselling sessions were informative and great!! However, for the 2nd sessions which held; they did not have to be held in individual sessions-(Perhaps group sessions could have been held; to be interactive with other woman). To hear their views. In the individual sessions; I was only able to hear myself.
106	Group sessions.

F. Education and counselling sessions method and content:

ID#	Verbatim Comment
028	More videos on inserting female condom, maybe group sessions to share ideas and thoughts.
029	By sharing more visuals about the usage of the F.C.
056	More counselling on how to approach your partner with this female condom to use it.
058	Video ? Q + A period after viewing
062	More client feedback from counsellors
066	Maybe use a videotape (for use of FC)
102	Could mention common problems with female condoms and some solutions, in the first session.
118	By talking about relationships.

G. Include partner:

ID#	Verbatim Comment
113	Maybe have partner attend as well.
078	Maybe get Input from spouse as well at the session.

H. Relevant to the pilot study only:

ID#	Verbatim Comment
018	More money for my time and coloured condom.
019	Helping me to give you more info by giving me some questions to answer while researching at home.
059	Clinic location kept changing. Call messaging centre seemed shaky at first (have it arrange ahead of time). Arlene was good. Also : Wording of questionnaires is lacking one places – need a good copy edit.
070	More information tailored to prostitutes since this was our group. i.e. questionnaires specific to sex workers.
105	They were great-helped me trouble shoot & answered all questions put forward. If they weren't so far away – I had a 1 hr. commute. – having the same counsellor

follow through all three sessions.
107 By giving more days for the survey.
108 More flexibility in dates available for sessions.
109 No need for improvement. Possibly the questionnaires could been better worded.

I. Location and timing of education and counselling sessions:

ID#	Verbatim Comment
041	I am waiting for ½ hour to get in (throws off my schedule) time frame = ½ hour late for all of my sessions.
051	Better location in terms of privacy.
059	Clinic location kept changing. Call messaging centre seemed shaky at first (have it arrange ahead of time). Arlene was good. Also : Wording of questionnaires is lacking one places – need a good copy edit.
105	They were great-helped me trouble shoot & answered all questions put forward. If they weren't so far away – I had a 1 hr. commute. – having the same counsellor follow through all three sessions.
108	More flexibility in dates available for sessions

J. Supplies:

ID#	Verbatim Comment
094	More lube!
030	Brown paper bags to put condoms in.

Female Condom Pilot Project

Technical Report of the Qualitative Research

September 2002

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Table of Contents

Executive Summary

Women's options for birth control and protection against HIV and STDs are limited and every option has significant disadvantages or side effects. Many women are keen to find new methods to protect themselves and maintain their sexual health. Yet, few women in Canada are using the female condom.

The purpose of the qualitative component of the female condom study was to both elucidate information gathered through quantitative methods, and also to provide information that would be valuable to health promoters and sexual health educators who are planning and designing sexual health interventions that include the female condom. This report summarized the information collected in 16 interviews and 3 focus groups that were conducted with participants in the study.

Although some women experienced initial negative reactions to the female condom, most were willing to learn about the female condom and try to introduce it as an additional option in a hierarchy of birth control and STD prevention strategies.

A key ingredient in a recipe for successful use of the female condom is practice – both privately and with partners. Successful usage of the female condom requires a level of commitment on the part of both partners to identify and address problems or barriers to usage. However, practice in no way guaranties success. Some couples that were committed to practicing and addressing barriers and problems, eventually decided not to use the female condom.

The women in our study encountered a variety of 'technical' problems when using the female condom, including slippage, breakage, noise, discomfort and spillage. For most women in the study, these difficulties were relatively minor inconveniences that could be addressed by adjusting how they used the female condom. However, for a small minority of women these difficulties became a barrier that prevented them from using the female condom. Educators need to be familiar with the broad range of problems that women experience when learning to use the female condom, and be prepared to offer suggestions and problem solve with women.

Women and sexual health educators had high hopes that the female condom would provide the first form of woman-controlled barrier protection against pregnancy and STDs. Since its debut on the American market in 1993 and the Canadian market in 1994, it has become clear that the female condom is not 'woman-controlled,' but perhaps at best a 'women-initiated' form of protection. While a method that can be initiated by women does offer some advantages, it does not address the most universal and daunting barrier to women gaining control over their sexual health: male compliance. Female condoms require male cooperation.

Male opinions about and reactions to the female condom are a very important factor in determining women's levels of usage and acceptability of the female condom. Although

we did not speak directly to the male partners of women in this study, we asked all participants how their partners responded to the introduction of the female condom. Many women had no difficulty in getting their partners to try out the female condom. However, not all women received an enthusiastic response from their partners. Some men simply refused to try the female condom at all, while others had a litany of complaints. A few men found the female condom aesthetically repellent. Comparisons between the male and female condom were mixed. For some couples it was an easy choice, but for the majority of participants there were advantages and disadvantages to each method.

Offering the female condom as an additional risk reduction strategy within a hierarchy of options is supported by participant's continued usage and acceptability of the male condom throughout the study.

Although the female condom is not woman-controlled, the question remains, does it offer women more power or control over their sexual health generally? All women in the focus groups and interviews were asked if the female condom gave them greater control over their sexual health. No one answered with an unequivocal yes. However, in our survey, 78% of women agreed or strongly agreed by the end of the study that the female condom gave them more control over their sexual health. It seems that women interpreted this question much more broadly than we had anticipated – although the female condom did not necessarily offer them control over their sexual health, it did encourage increased feelings of power and/or control in other ways.

Several women identified that the female condom gave them a sense of control over their sexual health because they had more confidence that it would not break, whereas they were often nervous or unsure using male condoms because of the high risk of them breaking. Many women in this study really wanted to like the female condom, not because personally they were looking for another form of birth control, but because they want women who are marginalized and powerless to have alternatives. Women in the study expressed strong feelings of collective social responsibility for women who are unable to have control over their own sexual health.

Discussions of sexual pleasure offer some insight into women's understanding and interpretation of the idea of 'control.' Having risk reduction methods that do not interfere with their own sexual pleasure is a high priority for women. Women's sense of entitlement to sexual pleasure speaks to their sense of empowerment and control over their own bodies, which is a fundamental ingredient for good sexual health. Knowing how the female condom either increases or diminishes sexual pleasure is important for sexual health educators. If the female condom decreases women's pleasure they will be unlikely to continue using it.

For many women in the study the female condom neither heightened nor decreased sexual pleasure. However, for a few women the female condom caused a significant change. Some women identified that initially the female condom interfered with their sexual pleasure because they could not relax while they were using it because they did

not trust its effectiveness as a method of barrier protection. For others, the female condom was an unpleasant experience sexually because of problems with slippage, or because the rings (both inner and outer) were irritating or unpleasant. Some women found sex with the female condom more pleasurable than with male condom. While the female condom impeded women's sexual confidence in some situations, for other women, the female condom was a catalyst for increased sexual confidence.

While no woman in either the focus groups or the interviews identified that she did not have the power to negotiate safer sex, two women in the study identified significant barriers to getting their partners to practice risk reduction strategies

In the first instance, one participant in a focus group radically changed her approach to negotiating safer sex with her partner during the course of the study. Another woman in the same focus group suggested that although the female condom did not give her more power to negotiate safer sex, it gave her "leverage" in the ongoing power struggle around practicing safer sex. The second woman in our study, who experienced great difficulty in negotiating safer sex, did not find any advantage in terms of using the female condom as a tool for negotiating safer sex.

In peer support groups women can offer each other emotional support, explanations of male behaviour and examples of success stories in negotiating safer sex. Women can learn about tools, strategies for negotiation and the language and spirit of female sexual empowerment from each other. Educators cannot provide the same kind of advice, support and critique as peers. Research has identified peer support as a key ingredient in supporting women's efforts to implement risk reduction strategies (Mwakisha 1996, Gollub 1998).

The most consistent response to any question in the study was whether women had spoken to their friends about the female condom. Everyone we interviewed, and most women in the focus groups had spoken with friends or family. Many women were referred to the study by their friends. Some women actually took the initiative to distribute their supply of female condoms among their friends.

According to our survey data, at the end of our study 70% of participants were either very likely or somewhat likely to continue to use the female condom (see Table 3). Responses in the interviews and focus groups about intentions to continue using the female condom were decidedly mixed. The majority of women were somewhat interested in continuing to use the female condom – but generally non-committal.

For women who did like using the female condom, by far the most common barrier to continuing to use it was cost. Several women said that although they liked the female condom it was too expensive to keep using it if they had to buy it themselves. One woman said she would continue to use them if they were the same price as male condoms, or if they were free, but not at the price they are available for currently.

The female condom is an important addition to women's repertoire of contraceptive and HIV prevention tools. Educators and policy makers in the city of Toronto need to

carefully consider what women in this city are telling us about the female condom and respond with the support and resources that women need to integrate the female condom into their efforts to stay healthy.

1. Objectives of Qualitative Study

The purpose of the qualitative component of the female condom study was to both elucidate information gathered through quantitative methods, and also to provide information that would be valuable to health promoters and sexual health educators who are designing educational interventions that include the female condom.

An informal needs-assessment was conducted with community partners prior to the development of the research objectives. Educators clearly identified the need to hear women's stories about using the female condom, particularly in relation to the process of negotiating safer sex.

Thus, the purpose of this report is to support the objectives of the quantitative study:

1. *To evaluate the effectiveness of the interventions in increasing the acceptability and use of the female condom and other barrier methods, among a sample of sexually active women in Toronto who are at risk of unplanned pregnancy and STD/HIV, and who participate in the pilot project.*
2. *To identify factors associated with initial and continued female condom use among the pilot project participants.*

As well as,

3. *To identify and describe the techniques, tools, strategies and methods women employ to initiate and continue using the female condom.*

And finally:

4. *To identify barriers to usage of the female condom, faced by women at high risk for unplanned pregnancy and sexually transmitted diseases, including HIV.*

2. Methods

Two strategies were used to collect qualitative data for this study: focus groups and individual interviews.

Focus groups

Focus groups were conducted as part of the group interventions. The qualitative researcher attended each session with the sexual health educators. Questions were posed to the group at each session. Focus groups guides are included in Appendix A. All sessions were recorded on an audio tape recorder. Tapes were transcribed and analysed manually through a thematic analysis by the qualitative researcher. Codes and coding procedures for analysing the focus group data are included in Appendix B.

Three focus groups were conducted with groups of women who were at higher risk for experiencing unplanned pregnancy, and contracting sexually transmitted disease, including HIV. One group was comprised of sex workers, another was women who had recently immigrated to Canada, and the third group were low-income women living in a suburban geared-to-income housing development.

Every group of women received the same information from the health educators. One of the goals of the group interventions was to begin to identify how our education and counselling interventions could be adapted to meet the needs of particular communities of women. We have added this information throughout the report. While the focus groups provided us with much valuable information, the generalizability of the findings from these groups is limited. The groups were selected on the basis of a shared vulnerability to sexual health risks, but also on the basis of availability and logistical fit. There was no attempt to randomise the sample or to make it representative of the larger populations of sex workers, immigrant women, or low-income women respectively. One of the groups was a pre-existing group of women, and the other two groups contained women who were familiar with each other. While this set up is not ideal for research purposes, it does replicate the way that groups are usually formed when sexual health educators work with communities of women.

In the sex workers group the drop out rate was high. Six women came to the first session, but only 3 women came to either of the following session. Attendance in the other focus groups was nearly perfect. Since most of the women in the immigrant women's group were new to Canada, there were mixed levels of fluency in English. Also, many women in this group were actively trying to get pregnant, so they were not highly motivated to use the female condom.

Individual interviews

Interviews were conducted with 16 participants after they had completed the individual education and counselling intervention. Service providers who conducted the individual interventions referred participants for the individual interviews. Participants who had either significant success with using the female condom, or who faced significant barriers in using the female condom were invited to participate in an interview. Every service provider received information regarding selection criteria (See Appendix D), and was encouraged to refer participants. Each interview participant received $ 25 and 2 transit tokens as a honourarium for participating.

The qualitative researcher conducted all interviews. Interview questions are included in Appendix C. Interview questions were adjusted according to whether the participant had a predominantly negative or positive experience with the female condom.

All interviews were recorded on an audio tape recorder. Tapes were transcribed and analysed manually through a thematic analysis by the qualitative researcher. Codes and coding procedures for analysing the interview data are included in Appendix B.

3. Initial Interest or Attraction

Developing a thorough understanding of women's interest in and attraction to the female condom provides the basis for the development of social marketing strategies and educational initiatives that are appealing and useful for women. Most women participated in our study because they wanted more detailed information about the female condom – particularly practical information about how to use it.

A few women remember seeing information about the female condom years ago when it first came on the market. However no women reported actually using the female condom. Some women identified misconceptions about the female condom that were clarified by our educational sessions. For instance, one woman thought the female condom was used exclusively for oral sex. Others were hesitant to use the female condom because it had to be inserted inside their bodies. The size and shape of the female condom did not recommend it as something to be inserted into their vaginas. One woman commented: "The first time I used it, I thought this was going to be really weird because how am I going to get that, up that little tiny hole?"

Women were quite prolific in the adjectives and metaphors they used to describe the female condom. These ranged from a baby bottle liner, a fish out of water, and most commonly a baggie (i.e. a sandwich bag). Many women and their partners reported initial reactions of negativity or even disgust when they first saw the female condom. However, women did not let their initial doubts and reactions impede their experimentation with the female condom. Most were willing to give the female condom a try and several reported overcoming initial negative reactions and actually growing to really like the female condom. For instance, one woman reported:

> Because you know, like when you see something for the first time, like it seems like God, this thing's so gross, I don't think I can use this or whatever. But I says, you know, I said to myself let me try it, insert it for myself and try it and I tell myself it was going to be uncomfortable when I push it in you know, especially like your ring, would it make me feel uncomfortable inside. But it was normal. I walk around in it, with it…. But it was okay. Yeah, it was pretty okay.

Many women reported problems with other forms of birth control as a major motivator for their interest in the female condom and their interest in the study. Several women were unable to use male condoms due to latex allergies, persistent yeast infections, and many reported a lack of confidence in male condoms due to breakage. Women identified that they were unable to use the pill due to a variety of symptoms including depression, yeast infections, weight gain, chest pains, bloating, nausea, blood clots, and not least of all, getting pregnant.

Women using IUDs experienced bladder infections, pain, increased incidence of fibroids, and most commonly very heavy bleeding and extended menstrual cycles. A couple of women, who were using spermicidal sponges reported experiencing urinary

tract infections, and discomfort during intercourse. Two women who were using spermicidal foam did not like the 'mess' caused by the foam. One woman wanted to find a method of birth control that did not involve any kind of chemicals.

Surprisingly, many women were using the withdrawal and or the rhythm method in combination with secondary 'backup' forms of birth control in the high-risk periods of their menstrual cycle. Many of these women were quite satisfied using withdrawal and/or rhythm.

Many women who participated in the interviews and focus groups expressed high level of dissatisfaction with forms of birth control and STD prevention that they were using before the study. Many women displayed a keen interest in learning about the female condom and a willingness to address and overcome initial negative reactions.

Practice

The single most important factor for increasing women's acceptability of the female condom was practice over time. Women divided 'practice' into two stages – first practicing without a partner, and then introducing the female condom to partners and practicing with them.

Insertion

Inserting the female condom requires some skill that most women can develop through repeated practice. Participants in the individual intervention were offered the opportunity to practice inserting the female condom while they were at the clinic, and then have the insertion checked by a nurse or doctor. In both individual and group interventions women were encouraged to practice inserting the female condom and wearing it before trying to have sex with the female condom. Many women reported this strategy as a very important step in becoming comfortable and familiar with the female condom. A couple women reported a marked decrease in the time it took them to insert the female condom over several practice sessions – insertion times decreased from 10-15 minutes to under a minute. For most women there is a learning curve around inserting the female condom, however a few women were able to insert the female condom easily almost immediately.

Practicing privately before introducing the female condom into an intimate situation seems to be a key ingredient in the successful usage of the female condom. One woman who did not practice on her own before starting to have sex, sent her partner out of the room so that she could insert the female condom by herself. Some women who 'skipped' the private practice session identified in retrospect that it was a crucial step. Some women who were very comfortable with their partners, and/or who felt adept at inserting tampons, diaphragms, cervical caps or sponges did not feel they needed to practice. Some of these women discovered that their previous experience was not a predictor of success at inserting the female condom. For instance, one woman

commented: “It was just too slippery. Like I mean I’m used to using diaphragm. So I don’t have any problems with diaphragm and this was just like black magic to me.” Service providers should strongly encourage all women, even those who feel confident, to practice on their own before introducing the female condom into an intimate sexual encounter.

In interviews and focus groups women were eager to share the insertion techniques that they had developed in great detail. Several women identified that the slipperiness of the condom made it difficult to insert. One woman said that inserting the female condom was like inserting a slippery rubber band. One woman wiped the female condom before inserting it so she could get a better grip. However, one woman found that adding lube helped her to insert the female condom.

Women often experimented with different positions to facilitate insertion, such as lying down, squatting over the toilet, or standing with one leg on the bed or the toilet. Two women found they had to be very careful not to twist the female condom when they were inserting it.

Few women were interested in inserting the female condom long before having intercourse. A few women did experiment and wore the condom for 2-4 hours. Two of these women did not like getting lube from the female condom on their underwear. One woman reported that urinating with the female condom inserted created a real mess. She would not want to repeat the incident – particularly if she was on a ‘hot date.’ She worried that the urine smell would be noticeable. One woman found that the condom would not stay inside of her unless she was lying down. She tried to walk around with the condom inserted, but it just kept falling out. Although early insertion of the female condom may allow women greater control over negotiating sexual risk reduction, educators also need to be aware of the disadvantages of early insertion that may dissuade women from employing this strategy.

Women’s knowledge about their internal anatomy and comfort with their own bodies was also a barrier to successful insertion. Two women indicated that they were afraid that the inner ring might hurt them. One woman was scared that the ring would do damage inside of her:

> Participant: Yeah, because I felt when I was trying to push the ring up, I said oh my God, I wonder if it’s going to damage inside of me going up, you know, this little thing. I was so scared.
> Interviewer: Really?
> Participant: Yeah, I was scared.

A couple of women said that they never put their fingers in their vaginas. One of these women was unsure about her own internal structure. The only way she could get the female condom inserted was by having her partner push it in with his penis. A few women used this method to insert the female condom and found it quite enjoyable. One woman said that inserting this way became a form of foreplay for her and her partner.

One woman used a sex toy (shaped like a penis) to insert the female condom on her own.
Providing broad-based general information about women's sexual reproductive anatomy is important for supporting women's successful use of the female condom, as well as more generally supporting women's effort to have control over their own sexual health.

Insertion checks

Women who participated in the group sessions generally did not receive insertion checks, although we told them that they were welcome to go to a clinic to get an insertion check done. In the immigrant women's group, the participants told us that generally women in their community are more likely to trust the advice of doctors or medical professionals when it comes to discussing birth control:

> Back home, it's not good to talk about birth control or other things like that. So still in the back of our minds we have that feeling. But we can only talk with the doctor about it, no one else.

The influence of this preference manifested in the group. One of the participants only tried using the female condom twice during the first month of the study because she was afraid of using them. At the beginning of the second month she inserted the female condom at home and then went to her doctor to have an insertion check. The doctor said that it was fine. The next month she used the female condom 18 times.

Timing and applicators

For some women the time it took to insert the female condom was a significant barrier to usage. One woman said that she found it time consuming and annoying to get in. A few women suggested that they would be more interested in using the female condom if it came with an applicator. One woman suggested an applicator akin to those used for tampons would be helpful:

> I notice the same thing with tampons -- the OB ones. The ones with the applicator, I can put in, in one shot. The ones, [where I have to insert them] with the finger, it takes me a while to put it in.

Another participant suggested that the female condom would be easier to insert if it came rolled up like the male condom and the end was cone shaped, or more like a tampon.

Some women never became comfortable inserting the female condom themselves. One woman said: "It's just the insertion part is like a drag for me. I wasn't feeling too empowered." Although not every woman will become comfortable inserting the female condom, providing information, support and encouragement to practice enabled most women in the study to develop the skills needed to master insertion.

Practice with a partner

Many women reported that their initial use of the female condom was awkward or distracting. For some women 'practising' with a partner and engaging in an active process of problem solving helped to alleviate initial discomfort, and in some cases to resolve initial problems or barriers.

Two women reported that initially they found intercourse with the female condom very uncomfortable, but with practice the discomfort decreased or disappeared. One woman reported that with ongoing use she forgot the female condom was there "It become more like a part of it [sex] ." Another woman likened this process to getting used to wearing tampons:

> You get used to the feeling. It's like wearing a tampon I guess. The first time I put the tampon in it was really uncomfortable, even walking around. It's like I can remember when I was a teenager wearing it, it's like "does everybody know, like am I walking funny" you know. But now I can put them in no problem and I don't even know it's there. It's like "Oh yeah, I've got to change that right?" So it's pretty comfortable now, but I remember the first time we were a little bit iffy about it because you do feel it. I mean there's something there, until you get used to it you know.

Another woman explained that her husband also went through a learning curve in regard to being careful when he's inserting his penis. After practicing a few times he became accustomed to it and it's no longer a problem.

Two women reported that using the female condom repeatedly helped to build their confidence and comfort with the female condom and relieve a sense of worry that initially inhibited them. One couple identified that although the using the female condom did get easier over time, it never became as easy or automatic as using the male condom: it still required "more concentration" and more time to insert than would be required in using the male condom.

However, for other couples repeated practice did not help to address barriers to usage. Some couples were very committed to trying to make the female condom work for them. One couple tried five to six times before they gave up. Another couple had sex with the female condom ten to fifteen times before they finally gave up and decided the female condom was not for them.

Practice, both independently and with partners is a key ingredient for successful use of the female condom. However, practice in no way guaranties success. Although some couples were committed to practicing and addressing barriers and problems, they eventually decided not to use the female condom. They next section of the report describes in detail the specific barriers that women faced in using the female condom and strategies they used to overcome them.

4. Mechanical and Technical Difficulties

Studies on the acceptability of the female condom have identified 'mechanical' or 'technical' difficulties as barriers to usage (for instance Choi 1999). Our findings were consistent with this literature. In our survey more women reported problems with using the female condom than in similar studies, although most reported that the problems were not very bothersome (see Artz et al 2000). The interviews and focus groups reflected a similar pattern. Although a small number of women reported experiencing a wide range of problems, most also said that these problems were relatively minor. Most of the women who encountered these problems were able to resolve them with practice, by developing innovative techniques, and/or by strategizing with peers and educators.

All participants were encouraged to use the lubricant provided in the interventions as an all-purpose problem solver. Some women found that they did not experience problems even though they didn't add additional lubrication. Many women in the study were happy to use the lubricant and found it facilitated usage of the condom. Women identified that adding lube helped with noise, movement of condom, sticking to penis, and dryness. No women identified using oil-based lube as a particular advantage of the female condom. However, adding lube was not a cure-all.

Noise

Noise was not a major barrier to usage or acceptability for most women in the focus groups and interviews. Many women reported that noise was not a problem. Women did identify that there was a characteristic sound when using the female condom, but for most women this was not a concern or a problem. One woman stated that she either added lube or "turned up the music" – either way the noise didn't really matter. Some women also found that once the female condom has heated up to body temperature, the characteristic noise disappears.

Others found the noise more distracting. One woman only found the noise distracting when she was wearing the female condom in public, but not when she was having sex. A couple of women reported that the condom sounded like a sandwich bag, or that it "rattled and rustled." One woman was unable to address persistent "squeaking" of the female condom. Although she added lubricant, the squeaking never went away. For these participants the noise was a distraction or a minor inconvenience. It was a relatively minor barrier to usage.

However, the group of immigrant women who participated in the study identified the characteristic noise of the female condom as a potentially significant barrier to usage. A few women in the group identified that the condom was noisy and one individual woman in the group identified that the noise bothered her "a lot." These comments sparked a general discussion in the group about the lack of privacy for sex or intimacy that many immigrants must endure when they have recently arrived in a new country. Two or more immigrant families will often share a one-bedroom apartment when they first

arrive. This is often all the accommodation they can afford. The families will usually include children and parents or "seniors." Trying to have sex under these conditions is already difficult. The added noise of the female condom is "embarrassing."

The participants in this group also felt that the packaging of the female condom was less discrete than that of the male condom and thus more apt to cause embarrassment. Unlike male condoms, it is difficult to hold a female condom in the palm of one hand. Leaving a used female condom in the garbage could be embarrassing if a woman was living with small children and/or extended family from whom they want to keep these matters secret. The women said that it would be great if the female condom came in re-sealable pouches – like those used for sanitary napkins – that could be used to put the female condom in and dispose of it after it has been used.

Breakage

Only one participant reported that the female condom broke or tore. The participant had very long, artificial nails at the time of the study. She was only able to insert the female condom once without having it tear. She did so by having her partner insert the condom with his penis. She did not experience similar difficulties with male condoms tearing.

Slippage

Few women reported persistent problems with slippage. One woman identified that her partner's penis slipped in between the condom and the wall of her vagina the first time they used the condom, however they were able to correct this with practice. The same couple added lube because the man felt that the condom was pulling back and forth and sticking to his penis. When he pulled out the condom came with him. However, when they added more lube he felt like he was lost.

During the first month of experimentation with the female condom one couple found that the female condom kept coming out of the woman's vagina. The educator suggested adding more lube, and in the second month of the intervention they no longer experienced this problem.

One woman identified that the female condom was uncomfortable and that it pushed inside her when she was having intercourse. She added extra lube but that didn't help. She did offer that she felt her vagina was very 'tight' because she had delivered both of her children through caesarean sections.

Another woman said that she felt the female condom did not cling or adhere to the sides of her vagina; rather it felt like it was rustling around insider her:

> Participant: I felt like I sort of had a plastic bag inside me and I guess because the male condom fits tightly around the male penis and the female condom, because it's the hollow space sort of, you know, maybe it can adhere to the walls. But it didn't seem to be sort of adhering to

my [vagina] . I don't know. It felt like there was space, like a big plastic bag.

Interviewer: Space between the female condom and your vagina or space between his penis and the female condom?

Participant: definitely space between… my vagina and the condom.

Interviewer: Right. So it didn't feel like it clung to the sides.

Participant: It didn't feel like it was or it was a bit, but it would kind of move a little, like a plastic bag, how a plastic bag would be in a space… that kind of movement a bit.

Some couples found that the condom became twisted during sex and needed to be adjusted. Several women mentioned that they felt they needed to be more active in guiding the penis where it is supposed to go with the female condom. One woman said she felt like "an air traffic controller." Another woman said she really needed to show her partner where to aim his penis:

> I sort of felt like in order to landmark correctly, you almost had to hold both sides, say here honey, and aim for a bull's eye because when that wasn't done, he missed which was a bit awkward.

One woman in the sex workers group said that for this reason she would be uneasy using the female condom with clients:

> I would have an issue with the fact that I can't really see what I'm doing. I'd have to go by feel and actually letting a client insert into me and I really can't see what I'm doing. I can only feel and I don't know if you could tell. Like if you could feel that it wasn't actually inside the condom or not.

The women in this group felt that it would be a risk that clients could slip their penises between the condom and the wall of their vaginas without their knowledge.

Spillage

One woman identified that her partner did not like the fact that sperm leaked out and got all over the sheets, and that he had to twist the condom before hetook it out or more semen would spill out.

The women in the sex workers group were very concerned about semen spilling out of the condom when the penis was withdrawn and when the condom was removed from the vagina. For them it is very important that they do not make contact with client's semen:

> The biggest… safety issue with sex workers is leakage. When males withdraw from it, they've just ejaculated and depending the volume, it gets all over you. It just drops on your genitals and I mean for me that's a huge safety factor… You know, you want to always have a tissue ready.... But then when you're dealing with sex workers, you're already dealing with a very unstable clientele. Even what I would call

> regular clients who are reliable still don't have your personal safety at heart… And so in the use of something like a female condom, especially as an HIV and AIDS barrier, it's more risky I think because you're dealing with open contact… I don't even allow them to have contact with the condom. They don't put it on and they don't take it off … So with the female condom… there's a slight risk of leakage [even] when you twist and you're careful about taking it out, [there is] still a possibility because you don't know if there's any that's gone past the twist point… So the risk of dripping is how that person is dealing with it, not you, because there's not really any position you can get yourself into to ensure that it doesn't get on you at all, short of handing them tissues which become another encumbrance and saying 'before you come out, make sure you hold tissue around yourself and slide out carefully.' Then it becomes an ordeal.

Discomfort

A few women in our study reported experiencing some physical discomfort when using the female condom. A couple of participants found the inner ring of the female condom annoying, particularly when it touched their cervixes. One woman inserted the female condom improperly once, and while she was having intercourse it hit her cervix, which hurt and she bled. Normally however, the inner rings just provided a little sensation. Another woman found the outside ring consistently uncomfortable – she found she could never relax with the female condom, whereas she feels quite relaxed with the male condom. She tried to use lube to address the discomfort she was experiencing, but it did not help.

Another woman reported that the female condom hurt her partner:

Participant:	…the fact that it was also hurting him made it less. I guess it just gives less men incentive.
Interviewer:	So it was actually hurting him.
Participant:	Yeah, just the continuous friction [over] time was hurting.
Interviewer:	Even with lube?
Participant:	Yeah… it was just still painful.
Interviewer:	Right. Yeah, I haven't heard of it being actually painful for guys before. That's interesting.
Participant:	I guess it depends how quickly they ejaculate. Also because he lasts a pretty long time and I suppose the longer you last, the longer it rubs. There you go.

Although the women in our study experienced a variety of 'technical' problems when using the female condom, these problems were not insurmountable. For most women in the study, these difficulties were relatively minor inconveniences that could be addressed by changing their techniques. However, for a small minority of women these difficulties became a barrier that prevented them from using the female condom. Educators need to be familiar with the broad range of problems that women experience when learning to use the female condom, and be prepared to offer suggestions and

problem solve these issues with women. Problems with insertion underline the necessity of supportive skill-based approaches to education about the female condom.

5. Partners

Women and sexual health educators had high hopes that the female condom would provide the first form of woman-controlled barrier protection against pregnancy and STDs. Since its debut on the American market in 1993 and the Canadian market in 1994, it has become clear that the female condom is not 'woman-controlled,' but perhaps at best a 'women-initiated' form of protection. While a method that can be initiated by women does offer some advantages, it does not address the most universal and daunting barrier to women gaining control over their sexual health: male compliance. Female condoms require male cooperation.

Male opinions about and reactions to the female condom are a very important factor in determining women's levels of usage and acceptability of the female condom. Although we did not speak directly to the male partners of women in this study, we asked all participants how their partners responded to the introduction of the female condom.

Many women had no difficulty in getting their partners to try out the female condom. In our survey, 67% of women's primary partners were likely or somewhat likely to use the female condom by the end of the study. As one woman explained, "Yeah, he liked it. He doesn't mind. Anything with sex, he'll go for it. No problem. Anything at all. It didn't bother him at all." Some men liked the sensation of the female condom, and the fact that they didn't need to wear a male condom. Some couples saw the female condom as preferable to all other forms of birth control and STD protection by the end of the study, while others grew to like the female condom equally to the male condom.

The women in the immigrant women's group agreed that it was generally quite easy to talk to their husbands about the female condom. Most of their husbands took the initiative toread the literature that was distributed at the educational session. Several husbands were quite enthusiastic about using the female condom. However, one husband did not like it and removed it.

Not all women received an enthusiastic response from their partners. Some men simply refused to try the female condom at all, while others had a litany of complaints. One woman identified that her partner just didn't like his routine being tampered with. Several women were greeted with comments to the effect of "That's gross" when they tried to introduce the female condom. One man said he did not want to put his penis into something that resembled a baggy:

> So he tried it one night and he said, "What is this." I said, "This is the female condom." He said, "Oh my God, this thing is so gross you know because I had to push my thing in this long thing here… Yeah…like a bag you know… into a bag." So he wasn't comfortable with it.

Some men complained that aesthetically, they did not like to see something hanging from their partner's vagina. Two couples identified that seeing the condom hanging

down was a turn-off because it was so obvious that they were using birth control. One of these women and her partner were in fact quite committed to trying to make the female condom work for them. They 'practiced' 10-15 times, but neither of them was ever able to come to orgasm. Her partner lost his erection with the female condom – which never happens when they are using the male condom.

One woman reflected on the reasons for her partner's distaste for the female condom:

Participant: It takes away… the sex appeal. I'm not sure. [He] just said it doesn't look as nice. I mean like I don't really think that [my vulva] looks nice, but to them it looks nice without it… It was sort of like he was telling me it was gross... [laughter]
Interviewer: That's gross because it was hanging out?
Participant: The look. Yeah. The way it looks when it's hanging out of you. And then it sort of interfered with the oral pleasure, which was true.
Interviewer: And did that interfere for you or for him?
Participant: For him. He just couldn't force himself to go down there with that sticking out of me. It sort of, it turned him off.

Feeling sexually appealing is important to women. The female condom is a relatively new product on the market that does not carry an erotic charge. Two decades ago educators were struggling with how to eroticize the male condom, in the face of the emergent AIDS epidemic. By some measures those efforts were at least moderately successful. Educators need to reconsider the strategies used for eroticizing male condom use and develop appropriate strategies for doing similar work with the female condom.

Two women identified that their partners completely refused to try the female condom at all. One woman was a participant in a focus group. She and her partner were quite young. He took one look at the female condom, said it looked like a sandwich bag and refused to use it. He was however happy to consistently use male condoms. The second woman was older and married to her partner for many years. They had a young child. Despite her persistence over 2 months, he steadfastly refused to try the female condom even once:

> He was turned off by it. And he was worried about too. He thought it might push inside me, or something like that and he didn't think it looked good. So it didn't turn him on and he didn't like it. He would just want to talk about it a little and then almost like you know, shut up about that and why are you doing it anyhow and I'm not interested and you tell them that I don't like it.... Like even today, he goes "isn't that thing [the study] done yet?" Because I brought it up the other day and I go, "They're going to ask me why you didn't like it." He goes, "well it's like almost scary that it's going to get stuck inside you and you know." And I said, "Well you didn't try it, you don't know…" He doesn't understand the female anatomy maybe that there's no way to go.

One woman did not tell her partner that she was using the female condom:

> Participant: So I had thought just to see if I could, this was the kind of thing that you could use without alerting your partner. So when he looked down, it was a little disturbing I think for him… when he pulled out, it came with him which not only was a little disturbing I think for him, because I hadn't told him exactly.
> Interviewer: You didn't tell him?
> Participant: … I thought well, I'll see how this. You're not always going to say, "Honey, look, we're using this thing which looks like a shopping bag."

Her experience underlines the fact that the female condom is not a woman-controlled risk reduction, method, but instead a woman-initiated method. It is difficult if not impossible to use the female condom without the knowledge of a male partner.

Comparisons to male condom

Comparisons between the male and female condom were mixed. For some couples it was an easy choice, but for the majority of participants there were advantages and disadvantages to each method. This is consistent with results from our survey. The percentage of women who liked (somewhat or very much) using the female condom (65%) was almost equal to those who liked the male condom (63%). And, when women were asked at the end of the study if they would choose the female condom, male condom, or both methods if all were freely available, women's preferences were fairly evenly divided (36%, 29% and 33% respectively). Many people identified different situations in which they would use either the male or female condom. Opinions about the male and female condom were not easily divided along gender lines, some women as well as men preferred male condoms to female ones. The same was true for female condoms.

Several women reported that their partners preferred using the female condom to male condoms, and some couples switched to using the female condom exclusively during the course of the study. One participant said that her husband preferred the female condom because he feels suffocated by male condoms. However, she still likes to use male condoms occasionally because she doesn't have to insert them.

Several participants identified that they preferred the male condom because it was easier and quicker to use. In the words of one participant "the male condom ranks superior in terms of ease and pleasure." This participant said she would only use the female condom as a last resort. One participant identified that she was looking for a method that was simpler than the male condom, but found that the female condom was much more complicated. She found the female condom "time consuming and irritating." Both her male partners were happier to use the male condom as long as she put it on them. One participant said that she prefers male condoms when she just wants to get sex over with, because it takes her husband less time to ejaculate with male condoms.

Offering the female condom as an additional risk reduction strategy within a hierarchy of options is supported by participant's continued usage and acceptability of the male condom during the study.

Type of relationship

Some women in the study felt that they would be more comfortable using the female condom with partners they knew well and trusted rather than in more casual sexual encounters. One woman said that she could only imagine using the female condom with someone she knew well and who loved her:

> I couldn't imagine what someone's opinion might be, you know, that didn't know me. Kind of like, what the hell is this, because it's even more important I think when you first meet someone that it is very passionate and often it's very much just on a sexual level. There's no sort of like, come on, let's go through this or come on, let's try it again, sort of thing.

Similarly, one woman in the sex worker group felt she would be more likely to use the female condom in the context of a relationship than with a client. She had difficulty inserting the female condom and felt that she would need to feel more confident using it before she would use it with a client.

Another factor tied to the type of partner some women would use the female condom with was whether or not they felt at risk for STD from their partners. A few women said that they felt the increased amount of protection for genital contact was a real advantage of the female condom. One woman said that she would use the female condom when she was concerned about preventing STDs, but not in situations where she only wanted to prevent pregnancy:

> Okay, if I was having sex with a partner who had had Herpes or some sort of STD, then yes I would consider it because just due to the greater coverage it gives. Given that my current partner was a virgin before, no I don't have the incentive right now because I mean I really don't see that as a particularly advantageous birth control method. I see it more as an STD method then anything. So without enough incentive to protect from STD's, then no, I wouldn't use it.

One participant in the sex workers group agreed with this assessment:

> I don't have any confidence in condoms period as a method of birth control. They're a great barrier for HIV and STDs but even then there's a risk factor. But birth control, never.

This may explain the slightly higher percentage of women who reported that the female condom was another option for STD prevention at post 1 and post 2 (68% and 64% respectively) than those who saw it as an option for birth control (52% and 56%

respectively). Curiously, the ways that the type of relationship influences female condom usage may, in practice, contradict each other. Women most often feel at risk for HIV and STDs from partners who are not well known to them. Although sexual health educators want to encourage women to use barrier protection with long-term partners, rates of barrier protection consistently decrease with length of relationship. If women view the female condom as a method of STD prevention more than a birth control method, and if they are less likely to use the female condom in more casual sexual encounters, this may pose a significant barrier to consistent use. It would be fruitful to explore the breadth and depth of these tendencies in future research.

Multiple partners

According to the survey 25% of participants had sex with people other than their main partner over the course of the study. However, only three women discussed having sex with multiple partners during the interviews or focus groups.

One of these women said that the female condom was a turn-off for both of her partners. The second woman who had three partners during the study found that her two male partners preferred the female condom. Both male partners liked the fact that the condom heated up, and her older partner liked the fact that he didn't need to be erect to use the female condom. The same participant found that both her male partners, and her single female partner preferred the female condom to male condoms, dental dams or saran wrap for protection during oral sex. This participant also saw the female condom as a great advantage in attracting sexual partners:

> I felt like in a way, you kind of had something over other women because if they sleep with other women, obviously they have to wear protection and so I like that…. I feel I'm offering that advantage that you know, a guy doesn't have to wear a condom too, then you know that's also a bonus… You know, you always run off for something new and exciting and different. It's like an amusement park you know. You come to Wonderland we have a new ride… Maybe it's my own insecure way of thinking about things, but you know. It really is work. You've got to keep them coming back.

One of the women in the sex worker group tried using the female condom with three of her clients. Two of them were quite enthusiastic, while the third was not. One client was so enthusiastic that he requested some sample female condoms to take home and introduce to his wife.

Probing more deeply into women's experiences with using the female condom with multiple partners would be a useful avenue for future study. Some of the women who compared using the female condom with different partners, made it clear that the female condom worked better with some men than others. Women, who were unsuccessful in using the female condom with their current partners, often said that the female condom was not for them. In some cases it may have been simply that the female condom was not the best method with that particular partner. Sexual educators need to encourage

women to consider how their partners contribute to the success of using the female condom.

6. Power and Control

Although the female condom is not woman-controlled, the question remains, does it offer women more power or control over their sexual health generally? All women in the focus groups and interviews were asked if the female condom gave them greater control over their sexual health. No one answered with an unequivocal yes. However, in our survey, 78% of women agreed or strongly agreed by the end of the study that the female condom gave them more control over their sexual health. It seems that women interpreted this question much more broadly than we had anticipated – although the female condom did not necessarily offer them increased ability to enforce condom use, it did encourage increased feelings of power and/or control in other ways.

Alternate interpretation of power and control

Many women responded that issues of control were not an issue in their relationships. Furthermore, many women in the study were very self-assured and felt no inhibition to tell their partners to effectively 'Take it or leave it" (i.e. if they want to have sex, it needs to be sex with a condom).

Interestingly, many women who did feel self-assured and able to insist on safer-sex with their partners, thought that the female condom would be great for 'other' women who were less able to negotiate safer sex. In fact one women said that she 'loved' the female condom for other women, but it just wasn't for her: "I love the idea the woman can take control in the situation. On the other hand, it wasn't something that I would use… even if it was handed out free… I would not consider using the female condom." This idea that the female condom would be great for 'other' women with less power to negotiate safer sex was a theme in several interviews. Another woman commented:

> I think that it's there for you know people in Africa I think or third world countries or different countries that you know the women are suppressed a little bit and sexually they don't have any control over themselves. And I thought well that's a good idea, a very good idea and Aboriginal people as well. So I kind of thought well that's great. And so I think in some ways this has kind of skewed my positive response to it.

Many women in this study really wanted to like the female condom, not because personally they were looking for another form of birth control, but because they want women who are marginalized and powerless to have alternatives. Women in the study expressed strong feelings of collective social responsibility for women who are unable to have control over their own sexual health.

One participant commented that she participated in the study as "a public service." This attitude may explain why exposure to the female condom had a negative impact on some women's intentions to use the female condom. Women, who initially supported the female condom because of their social and/or political convictions, may have

discovered through the study that in spite of their political support of the female condom, it was not a product that they would use in their personal lives.

Several women did identify that the female condom gave them a sense of control over their sexual health because they had more confidence that it would not break, whereas they were often nervous or unsure using male condoms because of the high risk of them breaking.

Sexual pleasure

Discussions of sexual pleasure offer some insight into women's understanding and interpretation of the idea of 'control.' Having risk reduction methods that do not interfere with their own sexual pleasure is a high priority for women. Women's sense of entitlement to sexual pleasure speaks to their sense of empowerment and control over their own bodies, which is a fundamental ingredient for good sexual health. Knowing how the female condom either increases or diminishes sexual pleasure is important for sexual health educators. If the female condom decreases women's pleasure they will be unlikely to continue using it.

For many women in the study the female condom neither heightened nor decreased sexual pleasure. However, for a few women the female condom caused a significant change. Some women identified that initially the female condom interfered with their sexual pleasure because they could not relax while they were using it because they did not trust its effectiveness as a method of barrier protection. Women in the immigrant women's group highlighted this difference amongst themselves. The participants in the group, who were trying to get pregnant, found using the female condom quite pleasurable. Whereas the women in the same group who really didn't want to get pregnant found it less pleasurable because they did not have confidence in the product. For most women sexual pleasure returned to normal levels as they became accustomed to using the female condom. One woman, who reported initial unease, reported that as she became accustomed to the female condom, it became more pleasurable because she had confidence that it wouldn't break, so she could relax more and enjoy sex. Some women also reported liking the fact that the polyurethane heated to body temperature.

One participant felt that the outer ring prevented her husband from going as deep, which interfered with her sexual pleasure:

> Well the difference a little bit is the ring, the ring on the outside. Sometimes with the ring being there, it stops him from actually going inside all the way... It does take up a little bit of room. I'm not going to say he hasn't got a jumbo giant thing right… Sometimes, you know, he just wanted to put it in all the way and so I can actually feel something right. So the ring does take a little bit of room…. I mean it doesn't take that much room, just that little extra little bit. And with him, I need it.

For others, the female condom was an unpleasant experience sexually because of problems with slippage, or because the rings (both inner and outer) were irritating or

unpleasant. One couple found that the female condom was so much 'work' that it really killed any feelings of excitement. They were committed to experimenting with the female condom, but working through the difficulties inherent in the method really was a drain on their sexual energy.

Similarly, another woman said that she found the female condom so time consuming and complicated that she and her partner lost interest. . The moment was lost because of the time lag – it always took five to ten minutes to put it in. They were never able to have 'proper' intercourse – it was always 'sloppy' because her partner could not sustain his erection. A woman with an 18-month-old baby said that when her baby falls asleep 'it's like boom –let's go and have sex -- there is no time to waste.' The time needed to insert the female condom discouraged them from using it.

Some women found sex with the female condom more pleasurable than with a male condom. For instance:

> I guess it depends too on you know how you like it. I mean for me, it's like you know hard, fast things. So, sure it heats up, but you're still having like that force, that friction. You still have that, but also it's wet. So like it's comfortable. Sometimes too when you're going with a lot of friction, you can get dried out. With male condoms, it can really dry you out. So you didn't have that problem. It was easier to go longer for me just because you didn't have that friction, that drying out thing. But you still have like the banging and also you have the clitoral, the ring against the clitoris. So no for me, it was much better.

One woman identified that the movement of the female condom inside her took getting used to:

> Participant: Well the one pleasure about the male condom is that you don't feel it as much moving inside you… So with the female condom, you could feel it move and you know, I sometimes felt the inner ring.... So the displeasure was that I did feel it move inside of me, which sometimes did cause a problem. But again, I could get used to it. …it didn't hurt. It was just a different feeling and so it was like okay, is this feeling going to be a good one or is it going to be a bad one. You don't know.
>
> Interviewer: Is the jury in or [do] you… know if it was good or bad?
>
> Participant: You know what it was: it just felt... It's so peculiar to feel like a movement on the inside of the uterus because nothing in there moves or inside the cervix I guess because nothing moves… But once you know the penis is in the vagina and it's all lubricated, you don't feel, you don't care. But when you feel this sensation, I guess that's the best way I can put it, is a sensation on the inside of the cervix and the place where nothing really moves or scrapes, you know, it's a weird sensation. So you just kind of had to get used to that. It wasn't terrible. It was not terrible because you can always

> move; you know, move your pelvis somewhere… But it was not displeasure. I could work with it and I found for me to reach orgasm with that was a little bit longer then what it would be without. But again, I think that's part of the learning curve.

This participant's comments are interesting; they suggest that intercourse with the female condom is perhaps not, un-pleasurable but instead differently pleasurable. The sensations experienced during intercourse with the female condom are unfamiliar. It is the unfamiliarity, as much or more than any physical displeasure, that makes the experience of intercourse unusual or disconcerting. Part of the role of sexual health educators may be to talk about the 'different' pleasures of the female condom.

Sexual aesthetics and women's sexual confidence

Some women identified that they and/or their partners did not like the look of the ring hanging out from the woman's vagina. One woman, a former sex worker, did not find sex with the female condom pleasurable because she did not feel sexy or attractive with it in:

> It was less pleasurable because of the hanging thing happening and a little bit of noise. I didn't feel like sexy enough… Yeah, like… go down there you know and there's like this plastic, like you know, I forgot to pull it out or something…. No, no, seriously like you know, I had it in my mind. How can I look sexy with this thing hanging out of there you know…? If people are visual, they want to see what's happening you know… At least with the male condom, you can see the shape and you know like everything is there. It's just like a little rubber. This is like a whole production happening there. It's too much I find.

This participant suggested that the condom should be made in different sizes – for instance small, medium, large -- so that it wouldn't hang down so much.

One of the women in the sex workers group, suggested that because the female condom is not aesthetically pleasing women need to be more comfortable with themselves and their partners to use the female condom, as compared to the male condom:

> It's again not particularly, what's the word I'm looking for, what's the right word, aesthetically pleasing. I mean it's sort of reminiscent of any type of women's things. You know, you've got this thing that's sort of sitting outside of you. So you know, you have to be very comfortable with yourself… [T] his one person said, "this doesn't really look that great." I said, well I don't think it was really designed for aesthetics… I've only asked people I feel very comfortable with as well.

Similarly, one woman who had two partners said that she was more comfortable inserting with her older, somewhat less attractive partner, than her younger boyfriend:

Participant: I have one partner who's young and he's like a cop and he's like the most buff guy ever. And then the other guy is like 45 and he's like an older guy… But I found that I was more comfortable with the older partner in putting in front of him. With the young guy, the lights have to be off. I don't want him seeing me put it in.
Interviewer: How come?
Participant: Because okay, when you're on your back or whatever and you're putting it in right, you're reaching forward, it's bad ugly. The stomach goes with the rolls and you're like. You know… It's like that and because I guess also he's like so buff. It's a little intimidating.
Interviewer: Right. So you just turn the lights out.
Participant: Yeah, either way, as long as he does not see me put it in.
Interviewer: Right.
Participant: The other guy, I don't care. He's fine with it. He likes it.
Interviewer: That's so interesting.
Participant: Yeah. I think it's just because I'm more comfortable with him because he's not like, you know. The other guy… makes like every guy in the Calvin Klein add look bad. He makes Brad Pitt look bad.

While the female condom may impede women's sexual confidence in some situations, for other women, the female condom was a catalyst for increased sexual confidence.

Several women identified that they tend to initiate sex more since they have introduced the female condom. They used the female condom as a tool to indicate sexual interest to their partners. In one focus group a participant stated:

> So it was just a matter of when you do use it, you're in control. It's kind of like you decide if you want to have sex or not. Most of the time it's them who decide you know. They come and fish around. But you know, usually when you put it in, the intention is already there to have sex you know. So yeah, I like using the female condom…

Another woman found that inserting the female condom was a way of taking her husband on a little adventure:

> I think there's going to be a combination of both because there are times when like he initiates or if I initiate. If he initiates, he'll just take the [male] condom and that's fine. But if I initiate, then I'll be like more excited to use the female condom … Just because [it's] like I'm sort of taking him for a ride in a sense. Like he'll take me for a ride. I'll take you for a ride this time. You know what I mean? Like it's not like you take me, you initiate, we do this and then somehow I'll pay you back and I'll initiate and I'll take you for my little adventure.

Different positions

During the focus groups and interviews we asked women if they were able to use the female condom in different positions. Not all women tried using the female condom in different positions. For those that did, most agreed that it was easiest to use the female condom in Missionary position[1]. A few people found that they could use the female condom in other positions but the needed to 'be more careful.' The variety of positions that people found they could use the female condom in included Reverse Missionary[2], Doggy Style[3], Wheel Barrow[4], and Spooning[5]. A couple of women in fact preferred using the female condom in positions other than the Missionary Position.

However, there were a few exceptions. One woman, who had chronic problems with the condom falling out of her vagina, could only use the female condom in Missionary position. She said the whole time she was having sex she was completely preoccupied with it coming out. The group of sex workers that we spoke to cautioned that using the female condom in positions other then Missionary style could be more risky for women who are working in the sex trade. They felt that men would be able to slip between the condom and the vaginal wall, without a woman's knowledge, more easily in positions other than Missionary.

Lack of power and control

While no woman in either the focus groups or the interviews explicitly identified that she did not have the power to negotiate safer sex, two women in the study identified significant barriers to getting their partners to practice risk reduction strategies

In the first instance, one participant in a focus group radically changed her approach to negotiating safer sex with her partner. During the study she removed her IUD, which was causing health problems, and began to insist that her partner use the female condom. She was also allergic to latex condoms, so they weren't an option. It was remarkable to see the change in this woman's ability to make changes in her life over the course of the 2 months of the study. Woven through her comments, women in the group shout out words of encouragement and sometimes critique. It is this very potential for change that provides hope that the female condom will increase some women's control over their sexual health. We have quoted this excerpt at length:

> Participant # 1: So I said to the doctor last week and she goes "do you want me to keep it [her IUD] in for another month." I said no, I don't want to keep it in because it make me, my stomach tender and everything and my back hurts like hell too. So I said, "no, just take it out" … Well he didn't know that I took it

[1] i.e. face to face lying down with the man on top
[2] i.e. having the woman on top
[3] i.e. with a woman on her hand and knees and the man behind her
[4] i.e. woman lying on the edge of the bed with her legs in the air and the man standing on the floor
[5] i.e. lying in bed side to side with the woman in front of the man

out… I said "it's my health, so I'm going to take it out."… I'm not lying to you but there comes a time when I have to do what I have to do. That's right

Participant # 1: Christmas day he wanted it and I said, "Either you use this or nothing. I'm serious." We…women. we suffer. We suffer. Pregnancy for me, it's awful. I'm too old now to have another child.... I want to go back to work and not have another baby… He was saying it's a garbage bag; it's whatever he calls it. He calls it names. [I said] "If you don't want me to zip it out, too bad for you."

Participant # 2: You go girl.

Other Participants: [laughter]

Interviewer: And what did he say?

Participant # 1: He said, you know, does he have a choice. I said, "Yes, you have a choice" because [our youngest daughter] is only 17 months and we don't want to happen what happened before… And I said to him "I can't afford another child." But he's giving me a hard time.

Participant # 3: Oh yeah. They love to give you a hard time.

Health Educator: So is there something else that he would rather?

Participant # 1: Nothing.

Health Educator: And the male condom, he doesn't mind wearing…?

Participant # 1: He doesn't want to wear it.

Participant # 4: Not a very nice guy.

Participant # 5: No, it's just that I understand where she's coming from. Black men don't really like to wear condoms and they don't like to worry about pregnancy. It's not their thing.

Participant # 1: I said well, it's a simple thing… You're going to get used to it.

Participant # 6: Yeah. I think what you were trying to say was that some of them think that when you come up with a condom, you're telling them that they're having sex with somebody else and that they're going to bring you an STD because they don't really get concerned about pregnancy.

Participant # 1: That's what he's saying to me, yes. He said to me that if I don't trust him and he's not doing anything. "You know that I'm a man who doesn't go around and fool around." What he's trying to tell me is what she said there, that the reason why I put it onto him is because I don't trust him. I said, "No, it's not accusing. I can't take all these things. I can't take pills, nothing at all." … He knows I'm serious. He knows. So he goes "Okay whatever... Whatever you want to do is up to you."

Participant # 7: So ask him point blank, does he want to have a child?

Participant # 1: Of course he will say yes.

Participant # 7: If he wants another child, then maybe he needs to go elsewhere you know.

Participant # 5: It's hard to get domineering men to back down when it comes to sex.

Women in the group were very encouraging of the changes participant # 1 had decided to make. They supported the changes she was trying to make and commiserated with the difficulty of trying to get her partner to comply. The group's comments are consistent with studies that identify the fear of jeopardizingtrust and intimacy with partners, as a major barrier to condom use among women (Sobo 1995).

One woman in the same focus group suggested that although the female condom did not give her more power to negotiate safer sex, it gave her "leverage" in the ongoing power struggle around practicing safer sex:

> I used to have that same trouble with my husband over a period of time where you know he would always try the mind games when you say you don't want to have sex if you're not protected. You know those mind games of you know whether you love them or whether you trust them or you know. I don't know if it's a cultural thing…
>
> … You've got [to have] something to fight everything they're saying because they're always going to come back with something and it's going to be emotional. So be prepared. They fight dirty. They fight emotionally. We might fight logically but men do fight emotionally.
>
> When his libido is up, the brain goes out the window. It does, it really does because they don't think about it, you know, the pregnancy or STD or anything like that. They don't think about that stuff until they've ejaculated and all of a sudden, it hits them. [laughter]
> And you're like buddy, it's too late, you know. I've been thinking about this the whole time you know… when it comes to making that decision about whether or not we're going to use a condom or not, it really just gets down to it, let's just get busy and you know, later you worry about what's happening next.
>
> …after have three children and realizing that you know, no matter how you say you don't want to have sex, it just doesn't work, because you're thinking you know I don't want to have sex because I don't want to get pregnant… But you know, it's like so now you have the female condom in your life, okay. Well since you're insisting on giving into your urges, okay fine, I'll just put the condom in and we'll have sex because it's fine. Now I can like go. I don't have to be concerned anymore and worry about nine months later and having to push at least you still have the chance of saying you know, if I don't have the condom in, it means I'm not really interested in having sex you know and we're not going to have sex

The second woman in our study, who experienced great difficulty in negotiating safer sex, participated in an interview, and therefore did not have the benefit of a network of support. In this case the female condom did not provide any advantage in terms of negotiating safer sex:

Participant: …he complains he doesn't want to use the male condom… I said, we've got to use, you know, some kind of protection, you know…. Sometimes he wants to use it and then he doesn't want to use it you know.
Interviewer Right. So it's hard to get him to use it?
Participant: Yes, sometimes…. I said, "come on, be real," you know…what are some of these mens like. You're trying to protect yourself and they're…

Interviewer Okay. Now in terms of you feeling in control of being able to you know protect yourself sexually, did you feel the female condom gave you more control or less control then the male condom or was there a difference?
Participant: No. I think it gives. I don't know how to put it. It don't give me no more control you know. No.
Interviewer Same thing.
Participant: Yeah, it's the same thing you know.
Interviewer Do you think you'll use it again?
Participant: Sure I will use it again. I have more at home.
Interviewer Yeah?
Participant: Yeah. I'll use it with him again… He's going to get mad.
Interviewer He'll get mad, do you think?
Participant: Yeah.
Interviewer Because he doesn't want to use it.

Unlike the previous example, this woman had no apparent plan or strategy for trying to negotiate safer sex with her partner. She clearly articulates her desire to use 'protection' but she does not articulate the process she will undertake to achieve her desired goal.

Women can offer each other emotional support, explanations of male behaviour and examples of success stories in negotiating safer sex. Women can learn about tools, strategies for negotiation and the language and spirit of female sexual empowerment from each other. Educators can never provide the same kind of advice, support and critique as peers. Peer support has been identified as a key ingredient in behaviour change (Mwakisha 1996, Gollub 1998).

Friendship networks and social support

The most consistent response to any question in the study was whether women had spoken to their friends about the female condom. Everyone we interviewed, and most women in the focus groups had spoken with friends or family. Many women were

referred to the study by their friends. Some women actually took the initiative to distribute their supply of female condoms among their friends.

Some women who participated in the group sessions identified that they found attending the group beneficial. One participant stated, “I’m a lonely housewife – I like groups. As the previous section demonstrates, group interactions can be very beneficial for women. In our intervention participant satisfaction questionnaire, several women suggested that in the future we should have follow up sessions in group settings. Facilitating opportunities for peer support is a fundamental element in supporting women to use the female condom and also enabling them to develop and implement sexual risk reduction strategies in their lives.

7. Intentions to Continue Use

According to our survey data, at the end of our study 70% of participants were either very likely or somewhat likely to continue to use the female condom. Responses in the interviews and focus groups about intentions to continue using the female condom were decidedly mixed. The majority of women were somewhat interested in continuing to use the female condom – but generally non-committal.

A few women were very enthusiastic about adding the female condom to their 'toolbox' of risk reduction tools. One woman proclaimed: "…right on for that female condom. I love it! That's a keeper for me." Another woman said that 'she played on the other team now.' One woman decided to go off the pill and start using the female condom in combination with the rhythm method, two women decided to remove their IUDs and use the female condom instead.

A little less than half the women we interviewed were emphatically not interested in using the female condom. One woman told us that she really wanted another birth control option and she was hoping it would be the female condom, but through her participation in the study she has decided that she won't use the female condom.

> I really wanted to like it. I wanted to be positive about it. But is just wasn't for me… I wanted to keep trying because I thought, you know, everyone has a harder time of things when you're encountering something new. [I] t got easier, but it didn't get… more pleasurable.

She said that the only way she might consider it again is if she develops a latex allergy. Some women who did not want to continue using the female condom suggested conditions under which they might be enticed to trying the female condom again. One woman said that would consider using the female condom if it was redesigned to fit her better:

> Like unless you know it was redesigned so it fit me better... But I don't know if you can make that ring smaller without it actually falling out, you know, with the penis actually fitting through… Or just even instead of rings, if there's like something… like adhesive or something that sort of gels it to the vaginal walls or I don't know.

Another woman said she would only use the female condom again if it came with an applicator so that she could insert it faster. One woman said that in the future she would use the female condom when she was concerned about preventing STDs, but not in situations where she only wanted to prevent pregnancy.

Cost

For women who did like using the female condom, by far the most common barrier to continuing to use it was cost. Several women said that although they liked the female condom it was too expensive to keep using it if they had to buy it themselves. One woman said she would continue to use them if they were the same price as male condoms, or if they were free, but not at the price they are available for currently. Women from the sex workers group said that they use many condoms on a daily basis, so paying full price for the female condom would be prohibitive.

A few women said that buying male condoms is the man's responsibility and consequently men shoulder the cost. So, the women worried that if they switched to using the female condom the financial burden would fall on them. One woman said that if both male and female condoms were free she would prefer female condoms. However at current market prices she would only be willing to keep using them if her husband were willing to buy them.

Another woman was unsure whether her husband would be willing to pay for the condoms and unsure if he would be willing to actually going into a store and make the purchase:

Participant: I don't have enough money to buy them, because he buys the condoms. Well you know, you buy them, they're for you right? So if I have to end up buying the female condoms… I'm not going to be able to afford it. I've got two kids. You know, right now I'm laid off. So there's not much money coming in at all.

Interviewer: So do you think that if you were using female condoms it would be kind of your responsibility to buy them? Is that what you were saying?

Participant: Yeah, I guess it would be… I can't see him going into a store buying a box of female condoms. But that's just the way he is. I can see him throwing the [male] condoms on the counter no problem. I can see him doing that, but I can't see him buying the female condoms… Yeah. I'd probably be the one going to buy them… I don't know. Well [my husband] actually, he's gone in and he's bought me pads, not willingly, believe me, but when he had to, he had to right? But I think, I just don't think he would want the extra expense to go in and buy two different brands, you know, to look for the others. He knows exactly where to go. He knows exactly where they are. He's not a shopper. He knows where to get them and you know. So I'm probably going to be the one buying them for myself.

One woman in the study said that she keeps using the female condom exclusively because she doesn't want to get out of practice. Although sexual health educators have encouraged women to use the female condom as an alternative method of barrier protection, not a method to replace the male condom, it is worthwhile to consider how

important it is for women to ‘stay in practice’ and how the cost of the female condom may prohibit regular usage. Our study confirms the evidence that women need to practice repeatedly to become accustomed to using the female condom. This idea of staying in practice poses an interesting question: Does the very fact that women don’t use the female condom all the time, discourage them from using it at all? And, if this is the case what are the barriers to women using the female condom as their only method of barrier protection. If there are extended periods of time when women cannot afford to use the female condom, is it likely that they will stop using it permanently?

8. Conclusion

The female condom is an exciting new option for women who have limited options for protecting their sexual health. This study contributes to the small and growing literature of qualitative research on the usage and acceptability of the female condom.

The Toronto Public Health Female Condom Pilot Project was in part, a response to the needs of sexual health educators in the city of Toronto who needed more information about how to encourage and support women who are interested in using the female condom. It was also a response to policy makers' need for more in depth information about the female condom in order to develop policy and programmatic responses to this new option in the field of sexual health. This report responds to both these information needs.

The qualitative component of this study highlights detailed information about women's experiences using the female condom – both their successes and their struggles. This report summarizes the stories, suggestions and reflections of over forty women. It provides insights into why women might want to use the female condom and the barriers that discourage them from using it.

Both our qualitative and quantitative data demonstrate that women will use the female condom as an additional form of barrier protection, and that this option compliments or augments existing risk reduction strategies. Mechanical or technical problems, sexual aesthetics and partner responses to the female condom were relatively minor barriers to usage for the majority of women. Most women were able to address barriers to usage through continued practice, information sharing and problem solving with service providers and peers.

Our study suggests that the female condom can be used as a tool to negotiate risk reduction strategies with partners whom are resistant to practicing safer sex. The focus groups we conducted illustrated the function of peer support in supporting women's efforts to implement risk reduction strategies in their lives.

The major barrier to continued use of the female condom was cost. Even for the women who were very enthusiastic about using the female condom, the high cost of the female condom was identified as prohibitive.

The female condom is an important addition to women's repertoire of contraceptive and HIV prevention tools. Educators and policy makers need to carefully consider the experiences and insights shared by the participants in this study and respond with the support and resources that women need to integrate the female condom into their efforts to maintain good sexual health.

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Appendix A: Focus Group Guides

Focus Group #1 Guide

Primary Objective: To identify women's' knowledge and attitudes about the female condom prior to receiving the educational intervention.

1. Who has heard about the FC?
   What have you heard? [Probe individuals who have heard about FC]
2. Did anyone see the TPH posters about the FC?
   What did you think about them? Did they make you want to get more information about the FC? [Probe individuals who have seen posters]
3. Has anyone used the FC?
   Why did you decide to participate in this intervention? [Probe individuals who have used the FC]
4. Why do you (women in the group) want to try the FC?
5. What do people hope to learn in this session?

Focus Group #2 Guide

Primary Objective: To gather information about the barriers and successes women encountered during initial use of the female condom.

1. Who tried using the female condom?

For women who tried using it --

- **a)** Did you like it? Why or why not? What did you like about it?
  [Probing suggestions -- non-latex, oil-based lube, women-initiated, helped in negotiating safer sex, etc.]
- **b)** Did you have problems or difficulties using it? What were the problems? What did you dislike?
  [Probing suggestions -- noise, decreased sexual satisfaction, partner reactions, partner sexual satisfaction, etc.]
- **c)** And, how did you address these difficulties?
  [Probing suggestions -- use more lube, changing sexual positions, practised many times, talked to friends, called counsellor, etc.] .

For women who didn't use it --

- **a)** Why didn' t you try it?

[Probing suggestions -- didn' t like the look of it, partner wouldn' t use it, didn' t have sex, wanted to get pregnant, etc.]

b) Did anyone else experience these difficulties?

i. If someone has, ask individual: " What did you do to address that difficulty?"

ii. If no one has, ask group: " Does anyone have any suggestions about how to address these difficulties?"

---

2. How did you introduce the female condom to you partners?

a) What did they say?

b) Did they want to use it? Why, or why not?

c) Is it easier to get your partners to use the female condom, than male condoms? Why?

Focus Group #3 Guide

Primary Objective: To gather information about the barriers and successes with continued use of the FC, and women's intentions to continue to use the FC.

---

1. Who tried using the female condom in the last month?

For women who tried using it and had not tried it in the first month --

a) What made you decide to try it this time?

b) Did you like it? Why or why not? What did you like about it?
[Probing suggestions -- non-latex, oil-based lube, women-initiated, helped in negotiating safer sex, etc.]

c) Did you have problems or difficulties using it? What were the problems? What did you dislike?
[Probing suggestions -- noise, decreased sexual satisfaction, partner reactions, partner sexual satisfaction, etc.]

d) And, how did you address these difficulties?
[Probing suggestions -- use more lube, changing sexual positions, practised many times, talked to friends, called counsellor, etc.] .

For women who tried it in time #1 and time #2 –

a) Did you use the FC more or less than last time? Did anything change about the way you are using it?

b) Did you experience any new problems? Did any of the problems/barriers you experienced initially persist? How did you address them?

---

c) Was your partner willing to continue using it? Why or why not?

For women who didn't use it --

a) Why didn' t you try it?
[Probing suggestions -- didn' t like the look of it, partner wouldn' t use it, didn' t have sex, wanted to get pregnant, etc.]

b) Did anyone else experience these difficulties?

iii. If someone has, ask individual: " What did you do to address that difficulty?"

iv. If no one has, ask group: " Does anyone have any suggestions about how to address these difficulties?"

2. Did using the FC give you more control or a feeling of having more control over your sexual health? What about the FC gives you a greater sense of control?

3. Will you continue to use the FC? Why or why not?

4. Will you recommend the FC to your friends? Why or why not? What will you tell them about it?

5. Do you think it was useful to meet in a group to discuss the FC or would you prefer to get this information individually from a counselor? Why? What was useful about meeting with the group?

Appendix B: Codes and Coding Procedures for Qualitative Data

The codes and coding procedures for focus groups and interviews were identical, unless otherwise noted.

Since qualitative software was unavailable to use in coding data, the coding procedures were streamlined. The coding was based on 13 original codes and 9 emergent codes that we added during the coding process. The codes are as follows:

1. Initial Attraction and Reaction to female condom
2. Factors that affect usage and acceptability of female condom
3. Sexual Pleasure
4. Lubrication
5. Practicing Multiple times
6. Change over time
7. Strategies that affect usage and acceptability
8. Partners and their reactions
9. Empowerment and Control
10. Comparisons to male condoms
11. Intentions to continue use
12. Comments on Individual Intervention [only used with individual interviews]
13. Comments on Group Intervention [only used with focus group data]

Eight other themes emerged during the analysis:

14. Breakage
15. Practicing insertion privately
16. Cost
17. Slippage
18. Noise
19. Friends
20. Problems with other forms of birth control/STD prevention
21. Different Positions
22. Multiple partners

All transcripts were read and manually coded. Relevant excerpts were recorded in a logbook divided by code.

After the initial coding was done, the logbook was read over and the internal consistency of the content of each theme was verified. Where excerpts were not consistent with the code summary they were moved to other themes or eliminated from the theme logbook.

All code summaries were then reorganized into 5 overarching themes. They were as follows –

A. Reasons for interest in female condom
Initial Attraction and Reaction to female condom
Problems with other forms of birth control/STD prevention

B. Time and Practice
Practicing Multiple times
Change over time
Practicing insertion privately

C. Mechanical/Technical Difficulties
Lubrication
Slippage
Noise
Breakage

D. Partner Reactions
Partners and their reactions
Comparisons to male condoms

E. Power
Sexual Pleasure
Empowerment and Control
Different Positions
Multiple partners
Friends

F. Intentions to continue use
Intentions to continue use
Cost

G. Evaluation of Intervention
Comments on Individual Intervention
Comments on Group Intervention

The coded summaries of:

- Factors that affect usage and acceptability of female condom and
- Strategies that affect usage and acceptability

included excerpts from the range of themes – each of these sections was re-coded and integrated into the 7 over-arching themes. (A-G).

Theme G "Evaluation of Interventions" did not have sufficient data to merit inclusion in the final report. It was eliminated.
Themes A-F became chapters 1-6 in the final report.

Appendix C: Selection for Individual Interviews

A subset of twenty women will be selected from the 170 women who receive individual interventions to participate in an extended long interview that will be tape-recorded and transcribed. We will select 10 women have had particularly good experiences with the FC and 10 women who have had particularly bad experiences. We want to record the details of some women's stories. These stories will help us to identify the strategies and tools women use when trying to use the female condom. We are asking service providers who are doing individual interventions with women to select and refer women who might be suitable candidates for long interviews. If you feel that a woman would be a good candidate for a long interview at the conclusion of your final session with her ask if she would be interested and willing to have her name forwarded. If she is interested please fill out the other side of this document and give this information to the data collector at your site. Data collectors will forward these names to the Deborah Hardwick on a regular basis.

All women who participate in the long interviews will receive a $ 25.00 honourarium and TTC tokens. The interviews will take between 45 and 60 minutes and the will occur at a location which is convenient for the participant. All women who are referred might not be selected for an interview. Women may also choose not to participate after they have been contacted.

Criteria for Referral to Long Interviews

Primary Criteria –

1a) Participant has great success using the female condom – i.e. the woman has used the FC and talks about how much she likes it, or how much her partner(s) like it, or generally is really enthusiastic about the FC. This also includes women who have employed unique or innovative strategies in using the FC.

OR

1b) Participant has limited success using the female condom – i.e. the woman hates the FC, her partner hates it, or refuses to use it despite her best efforts. This also includes women who employed many strategies for trying to use the FC, none of which worked. We'd like to find out in detail why particular strategies don't work for women.

Secondary Criteria for Selection --

2a) Women who are comfortable talking about their experiences using the female condom. Women who are particularly nervous or shy to speak are not good candidates for the long interviews.

2b) Women who are articulate when they describe their use of the female condom i.e. they are very descriptive and give lots of details about how they did things. Women who reply to questions with one-word answers are not good candidates for long interviews.

Referral for Long Interviews

Please give this form to the data collector at the conclusion of your 3rd session with the participant.

- ❑ Participant has agreed that she would like to participate in a long interview.

Name of Participant _____

Phone Number _____

1. Can we leave a message here for here?
   - ❑ Yes
   - ❑ No
2. Can we mention the female condom when we leave a message?
   - ❑ Yes
   - ❑ No
3. Best time to call –
   - ❑ Daytime
   - ❑ Evening
   - ❑ Either
4. Best time for an interview?
   - ❑ Daytime
   - ❑ Evening
   - ❑ Either
5. Best day for an interview?
   - ❑ Monday
   - ❑ Tuesday
   - ❑ Wednesday
   - ❑ Thursday
   - ❑ Friday

Please take a moment to tell us a little bit about the woman you are referring –

- ❑ Participant had success using the FC
- ❑ Participant did not have success using the FC
- ❑ Other (Please describe)

Please describe briefly why this woman would be a good candidate for an extended interview –

In case we have any questions about this referral, we would appreciate having your contact information --

Name of Educator/Service Provider _____

Data Collectors –
Please collect these forms, store them in a locked file and forward them to Deborah Hardwick at TPH on a weekly basis.

Appendix D: Interview Guide

Interview Guide – Positive Experiences

a) Introduction and Initial Usage

1. Why did you decide to participate in this study?
2. How often did you use the female condom during the study?
3. What did you like about the female condom initially?

b) Problem Solving

4. Can you tell me about the first time that you used the female condom? Did you experience any problems the first time? How did you address/deal with the problems?
5. Did you do anything that made using the female condom easier, more enjoyable, pleasurable? Please elaborate.
6. Did it get easier to use the female condom the more times you tried the female condom? How did it get easier? What made it easier?
7. Did you use lube? Did using more lube make it easier or more enjoyable to use? How did it make it easier to use?
8. Did the female condom increase or decrease your sexual pleasure? How did it increase your sexual pleasure? If it had a negative effect, what did you do about it?

c) Ongoing usage and acceptability

9. Why did you keep using the female condom?
10. Are there things you like about the female condom now, that you didn' t like initially? Please elaborate.
11. Are there things you still don' t like about the female condom? What don' t you like?
12. Did anything else influence how much you used the female condom? What? How did it influence your usage?

d) Comparisons

13. Did you like the female condom more or less than male condoms? Why? Please elaborate.
14. Does the female condom give you a sense of control (over your sexual health)? Why or why not? More than the male condom? More than other forms of barrier protection?

e) Partners

15. What did your partner(s) think about the female condom? How did he react to it?
16. How did you get your partner to use the female condom? Was it easier to get your partner to use the female condom than the male condom?
17. Did your partner(s) like using the female condom more or less than male condoms? Did he say why, or what he liked/disliked?

f) Future Intentions

18. What would you tell other women who were interested in trying the female condom?
19. Will you continue to use the female condom? Why, or why not?

Interview Guide – Negative Experiences

a) Introduction and Initial Usage

1. Why did you decide to participate in this study?
2. How often did you use the female condom during the study?
3. Can you tell me about the first time that you used the female condom?
4. Did you like anything about the female condom initially? What did you like?

b) Stopping Use of female condom

5. What didn' t you like about the female condom?
6. Why did you stop using (or not use at all) the female condom?

c) Problem Solving

7. Did you try using the female condom for sexual intercourse? Did you experience any problems the first time you tried the female condom? How did you try to address/deal with the problems?
8. Did anything you did make using the female condom easier, more enjoyable, or pleasurable? What did you do?
9. Did it get easier or more difficult to use the female condom the more times you tried it? How did it get easier or more difficult?
10. Did you use lube? Did you try using more lube with the female condom? What effect did using lube have?
11. Did the female condom increase, decrease, or affect your sexual pleasure? If it decreased your sexual pleasure, did you try to do anything about it?

d) Comparisons

12. Did you like the female condom more or less than male condoms? Why?
13. Does the female condom give you a sense of control (over your sexual health)? Why or why not? More than the male condom? More than other forms of barrier protection?

e) Partners

14. What did your partner(s) think about the female condom? How did he react to it? Did he/they agree to use it?
15. Was it more difficult to get your partner(s) to use the female condom than the male condom? Why?
16. Did your partner(s) like it more or less than male condoms? Did he/they say why?

f) Future intentions

17. What would you tell other women who were interested in trying the female condom?
18. Will you ever try using the female condom again? Why, or why not? Under what conditions would you use it again?

Female Condom Pilot Project

Summary Report of the Social Marketing Campaign

Barbara Macpherson and Tracey Methven

Toronto Public Health

September 2002

Table of Contents

Introduction

In February 2000, the Women's Outreach Network – a network of agencies serving women in Toronto - asked the Toronto Board of Health (BOH) to provide female condoms as a part of the existing Toronto Public Health (TPH) Condom Distribution Program. Funded by the City of Toronto, The Condom Distribution Program supplies approximately 250 social services agencies, clinics and community health centres with a variety of male condoms and lubricant. This program is designed to reduce the rates of unplanned pregnancy and to prevent transmission of sexually transmitted diseases including HIV.

The BOH asked Toronto Public Health (TPH) to conduct a pilot study with selected sexual health clinics and/or agencies in order to document education and instruction efforts, and to obtain feedback from clients on acceptability, and factors associated with initial and continued condom use. Accordingly, a pilot intervention was developed and delivered to women aged 18 to 45 at risk for sexually transmitted diseases, including HIV (STDs/HIV) and unplanned pregnancy.

The BOH also requested TPH to design and implement a social marketing campaign to increase awareness of the female condom as a barrier method. In order to carry out the recommendations of the BOH, a Steering Committee was formed in June of 2000. The Steering Committee was comprised of members of the various sexual health programs at TPH. The project consisted of three components: the Social Marketing Subcommittee, the Education and Counselling Subcommittee and the Research Subcommittee. All Subcommittees were formed with both TPH staff and community agency staff. All Subcommittees reported to the Steering Committee through their chairs.

This report summarizes the activities and outcomes of the Social Marketing Campaign. Methodologies and results of the education and counselling intervention are found in separate reports available from Toronto Public Health (Gillis, 2000; Hardwick, 2000; Macpherson, et al, 2000).

Rationale for a Social Marketing Campaign

A scan of the literature found that men and women lacked knowledge and product familiarity about the female condom (McGill, et al, 1998; Seal & Ehrhardt, 1999). An informal survey, conducted by TPH in March 2000 with 16 pharmacies and 13 community agencies, supported these findings from previous studies (McGill et al., 1998; Seal & Ehrhardt, 1999).

The Female Health Company, the sole manufacturer and distributor, conducted an extensive consumer advertising campaign involving print media and television and radio advertisements when the female condom was initially licensed. With

neither social nor market research to guide them, the advertising was targeted to women and their male partners of middle to high social and economic status with ads appearing in magazines such as Playboy and Cosmopolitan. Education of health care providers was limited to physicians, primarily Obstetricians and Gynaecologists, and was conducted by sales promoters visiting doctors' offices. This promotional campaign did not result in expected sales and the distribution rights were given to Pharmascience in Canada in 1997 (Wiseman, J. personal contact. 2002) . Pharmascience issued a press release to relaunch the product in 1998 with some newspaper advertisements. Presently, Pharmascience advertises via direct mailing to physicians and provides brochures upon request (Wong, personal contact, 2002). It appears that commercial product marketing has not been designed to reach the end user.

Unlike in developing countries where the female condom has been widely distributed and evaluated, health care providers, pharmacists and educators in Canada have not promoted the female condom with their clients. Few pharmacies in Toronto stock them, as consumer demand is low (Slodan, 2000). It is not surprising then that women and their male partners have limited knowledge of this method, especially with a lack of social marketing to the intended population.

The Role of the Social Marketing Subcommittee

The Social Marketing Subcommittee was formed in July of 2000 to

"design and implement a social marketing campaign about the use and benefits of the female condom targeting both men and women, health care providers, educators and pharmacies etc." (BOH report March 16th, 2000).

The objectives of the social marketing campaign were to:

- increase the general awareness of the female condom as an effective barrier method for reducing sexually transmitted infections (including HIV) and unplanned pregnancies; and

- assist in recruiting participants for the research component of the project.

There were several components to the social marketing campaign, including:

- Poster and pamphlet design and distribution,
- Pharmacy outreach,
- Media launch of the social marketing campaign, and
- Design and distribution of a poster to recruit participants to the pilot study.

The Poster and Pamphlet

Content, design and production

The Sex Information and Education Council of Canada (SIECCAN) conducted a literature review on the female condom in North America to guide the project (Bissell and McKay, 2000). Information provided by the literature review, budget limitations and consultation from front line sexual health educators within TPH and from our community partners helped to inform the design, content and scope of this project. With this information it was decided that the campaign would target adult women between the ages of 24 and 44 who were sexually active with men. It was also decided that the campaign would present a sex positive, empowering image of female sexuality that would primarily appeal to women but would not alienate men.

Although it is not usual practice for TPH to promote a specific commercial product, it was important to increase familiarity of the female condom. The members of the Social Marketing Subcommittee agreed that in order for women to access the female condom, they needed to be able to recognize the product. There is also only one manufacturer of female condoms, the Female Health Company, and they hold all patents and trademarks. Further consultation between the management of the Female Health Company and TPH allowed for the product image to be printed on the poster and pamphlet.

Although there are comments in the literature that men who have sex with men (MSM) may benefit from the female condom as a barrier method during anal intercourse, MSM were excluded as a separate social marketing campaign would have been required.

The intended population for the social marketing campaign included the general public, and especially women at risk for STD/HIV and unplanned pregnancy. This includes women at risk due to both the basic determinants of health and high-risk behaviours. Many women who may be at risk for STD/HIV and unplanned pregnancy are marginalized due to language. However, production of a social marketing campaign in other languages besides English was not feasible due to financial constraints.

Given the financial limitations of the project, TPH decided that a poster and pamphlet would be the most cost-effective way of promoting the female condom. In November 2000, TPH contracted Grey Worldwide, who, in collaboration with TPH and our community partners, developed the creative concept (art work) for the campaign.

In December 2000, Grey Worldwide presented their initial creative concept, including image and text, to the Social Marketing Subcommittee.

Focus testing

The image, text and pamphlet were focus tested in mid-January 2001. Six focus groups were facilitated and were comprised of eight women each. The women were recruited through agencies working with the intended population and were conducted in convenient locations throughout the City of Toronto. Each group ran for a two-hour period at community agencies with one facilitator and one recorder. Each participant was asked to sign a letter of consent, was informed of their confidentiality and was compensated with an honorarium of fifty dollars and two transit tokens. In total, 49 women between the ages of 24 to 44 were asked a variety of questions about the creative image, poster text and the pamphlet design and text. This feedback from the focus groups was provided to Grey Worldwide to inform their revisions to the poster and pamphlet before going to print.

Distribution of Poster and Pamphlet

Community agencies and partners

The social marketing campaign was launched on June 28, 2001. TPH distributed posters, pamphlets and female condoms to its own offices as well as to the 250 community agencies, sexual health clinics, community health centres and physician offices that receive safer-sex supplies through the Toronto Public Health Condom Distribution Program.

General public distribution

In order to reach the intended population, the Social Marketing Subcommittee used a variety of methods for the dissemination of the poster beyond the 250 agencies that Toronto Public Health includes in their Condom Distribution Program.

Since the intended population of this campaign was adult women, the poster was not disseminated to youth-serving agencies or secondary schools but it was distributed to post secondary schools and Adult Learning Centres. Although the goal of the social marketing campaign was to increase general awareness of the female condom as a barrier method, it was important to primarily target adult women at high risk for STDs/HIV and unplanned pregnancy. Therefore, we contracted a street postering company to distribute 2000 posters to bars, nightclubs, restaurants and cafes in neighbourhoods of Toronto identified through geo-mapping to have high rates of STDs and high numbers of families living in poverty.

Website

The Female Condom poster was posted on the City of Toronto Website June 28, 2002 (www.city.toronto.on.ca).

Pharmacy Outreach

Pharmacies were identified as important partners in increasing awareness of the female condom and as targets of the campaign as stated in the March 2000 BOH report. Consumers purchase contraceptives, safer sex supplies and STD/HIV medication from pharmacies. They may also receive health information and counselling from pharmacists. Pharmacy outreach was therefore seen as an important strategy in reaching the intended population.

Members of the Social Marketing Subcommittee distributed pamphlets, posters and demonstration condoms to pharmacies located in neighbourhoods identified through geo-mapping to have high rates of STDs. Only privately owned pharmacies and pharmacies situated in hospitals and clinics were approached. Franchised pharmacies must receive permission from the head office of the franchise before any materials or advertising is posted. Our outreach deadlines were not sufficient for this process to occur.

Pharmacy journals were contacted but we were unsuccessful in having any articles or information about our campaign published in professional journals. Such journals requested paid advertising or did not return phone calls.

Other Social Marketing Activities

Media

A press release announcing the social marketing campaign was issued on June 28, 2001. TPH received requests for two print interviews and several information requests from other health professionals.

There was a re-release in October announcing the research study and the recruitment of volunteers. Print advertising was also placed in TO Street News, SHARE, the Etobicoke Guardian, and the York Guardian in order to recruit participants for the pilot study.

Recruitment of participants for the pilot study

The poster image was used to develop a poster and a flyer with recruitment information regarding the pilot study. The poster and flyer were developed at TPH and were distributed to community agencies and sexual health clinics identified by both TPH sexual health staff and our community partners. These

agencies were most likely to provide services to women at high risk for STDs/HIV and unplanned pregnancy.

The AIDS-Sexual Health InfoLine

The AIDS - Sexual Health InfoLine is advertised on both the Female Condom poster and pamphlet. TPH counsellors who staff the InfoLine provide telephone counselling and information on all sexual health issues, including the female condom. It is TPH practice to include the InfoLine number on all sexual health posters and pamphlets.

Special events

In October 2001, TPH was invited to participate in a Trade Show titled "Everything You Ever Wanted To Know about Sex Show". The Female Condom Project was one of the featured programs.

In November 2001, the organisers of a one-day retreat for pregnant and new mothers asked TPH to provide information about the female condom. This retreat, called "Babies and Beyond" was held at a downtown hotel and targeted middle to high income women. The retreat included a mix of social and health events.

Evaluation of the Social Marketing Campaign

Evaluation of the social marketing campaign was conducted through:

- initial focus testing of the pamphlet and poster,
- number of requests for information and posters etc.,
- number of website visits,
- response to pharmacy outreach,
- response to media release,
- response to the recruitment flyer,
- number of calls to AIDS -Sexual Health InfoLine, and
- response to special events.

Focus test results

The total number of participants in the focus testing was 49 and all were women between the ages of 24 to 44. Overall, the participants stated that the poster was effective in catching their eye and drawing them in. The participants made positive comments about the image, wording and language. Typical comments were "eye grabbing", "sexy", "self-confident", "empowering", "clear", and "to the point". Many of the women thought the use of a female naked body was appropriate although two women found the image offensive.

As for the text on the poster, most of the participants thought the wording was appropriate but did not like the original catch phrase “give your vagina a voice” and suggested this be changed to “give your vagina a choice”. The women did find the wording difficult to read due to the size and font of the lettering. Font and size of the lettering was revised. The women felt that the use of statistics was powerful and would be thought provoking for the intended audience.

The pamphlet, which was designed by the Education and Counselling Subcommittee, was focus tested at the same time. The participants were highly satisfied with the pamphlet and only a few changes to the general layout were required.

Requests for poster and pamphlets and information about the project

In addition to the 5,000 posters and pamphlets distributed in Toronto, requests regarding our campaign came from:

- Winnipeg Public Health:
- The Nation’s Health- official newspaper of the American Public Health Association;
- McMaster University Health Centre;
- City of Ottawa, Public Health Branch/ Sexual Health Centre;
- Florida Department of Health,
- Bureau of HIV/ AIDS, Brooklyn College AIDS Prevention Program,
- University of Regina;
- BC Aboriginal AIDS Awareness Program.
- Harpers Magazine, New York

Response to the Website

The Female Condom Website was the most frequently accessed City of Toronto Website during 2001**.**

The numbers of visits received are as follows:

Month:	July	August	September	October*	November*	December
# of visits	237	153	115	330	363	187

*Months with heavy recruitment of study participants through the mass media.

Given the popularity of the website, it appears that websites may be important tools in the distribution of health information.

Response to the pharmacy outreach

During a three-week period in September 2001, members of the Social Marketing Subcommittee personally contacted 149 pharmacies. Of the 149 pharmacies contacted, 34 were willing to display the poster.

It appears that the pharmacies that were contacted were not receptive to this social marketing campaign. Anecdotal information from the outreach staff suggests that some pharmacists might have been uncomfortable with the image and wording of the poster.

Alternative strategies should be used for future campaigns to be more effective in reaching pharmacists. For example, it may be helpful for outreach staff to have letters from the Medical Officer of Health announcing the campaign. Alternate venues and methods of involving pharmacists also need to be explored. Now that the results from our pilot study are available, we can approach pharmacy journals to publish the results. However, given that very few women in our study could pay the pharmacy price for the female condom, interest in stocking the female condom may remain limited.

Response to the media release

The two press releases resulted in a number of media requests including eight print media interviews and articles, nine radio interviews and one TV interview, most of them following the re-release in October. Requests were received from both local news stations as well as from the U.S. and other areas of Canada. Media can be difficult to predict and control. However, it can be very helpful in creating interest and attention to a health issue.

Immediately following the media release in October, TPH received over 100 phone calls a day for approximately ten days from women requesting information about the study. One-quarter of the participants in the individual intervention component of the pilot study said they heard about the project through the newspaper, radio and/or television.

At the end of October, the Senior Product Manager at Pharmascience advised us that as a result of the media, his staff had been ”bombarded with calls and questions in regards to Toronto Public Health’s campaign with the female condom.” (Grignon, P. personal contact, 2001).

Response to the recruitment flyer

When individuals contacted the recruitment line to enrol in the pilot study, they were asked how they found out about the project. Of those asked, only three stated that they had seen the recruitment poster. However, all recruitment posters were produced with tear-off phone number tabs. The recruitment posters which were hung in clinics, drop-in centres and shelters required frequent

replacement during the data collection phase of the study because all the tear-off phone number tabs had been used. Furthermore, 17% of the participants in the individual intervention heard about the project at agencies where the recruitment poster was posted. It is clear that many more people saw the recruitment poster than reported that they had. What is not known is how many people who took the phone number actually called the recruitment line and participated in the study.

AIDS - Sexual Health InfoLine

The InfoLine routinely collects data on the calls they receive. They kept records of the number of calls regarding information about the female condom for six months following the launch of the social marketing campaign. The InfoLine advised us they did not receive an appreciable increase in calls to the InfoLine for information about the female condom following the distribution of the poster and pamphlet.

Special Events

There was an overwhelming response to the poster and the female condom at the ”Everything You Ever Wanted to Know About Sex Show”. Staff distributed approximately 300 posters, 500 pamphlets and 250 female condoms during four days of the show. A number of people requested the study telephone number. Demand for the promotional items exceeded the supply and far more female condoms could have been distributed. It is estimated that 1400 people visited the booth. It is unknown whether the visitors to the display booth used the female condom but the event was successful in increasing awareness of the female condom as a barrier method.

It is not known if attendance at all health fairs or community events would result in the same level of interest or opportunities for health teaching. For example, at the Babies and Beyond Retreat, of the 150 women who attended, only 10 expressed interest in information on the female condom. Health care providers, who also attended the event, expressed more interest in learning about the female condom than the other attendees.

Language barrier

Language was a barrier to all aspects of the Female Condom Pilot Project. Although there were a few media interviews in some language specific newspapers and radio programs, the poster, pamphlet and educational resources were developed in English only. Since the completion of the pilot study, the poster has been translated into French for an advertising spot in Taloua—a magazine for francophone young women. Given the ethnocultural diversity of the City of Toronto and the many languages spoken here, more

ethnospecific campaigns are needed to address some of the health inequities for women who are unable to access information in English.

Conclusion

The Female Condom Pilot Project designed and implemented a social marketing campaign about the use and benefits of the female condom to increase general awareness of the female condom and to assist in recruiting participants to the pilot study. The social marketing campaign was designed according to the following principles:

- based upon the literature,
- targeted to a specific population, and
- focus tested with the intended population.

The design and distribution of a poster and pamphlet was the backbone of the campaign, under the direction of the Social Marketing Subcommittee.

After the poster and pamphlet were printed, Subcommittee members conducted a pharmacy outreach and distributed the poster to targeted community agencies and more broadly to general public venues, organized a media launch in June 2000, and posted the resources on the City of Toronto website. To assist with recruiting participants to the pilot study, a recruitment poster was designed and distributed to agencies serving adult women at risk of STDs/HIV and unplanned pregnancy due to socio-economic and sexual behavioural risk factors. The media release was reissued in October to further assist with recruiting participants to the pilot study. TPH used the posters and pamphlets to promote the use and benefits of the female condom at " the Everything You Ever Wanted to Know About Sex Show".

Despite the wide range of social marketing activities, little concrete evidence exists for the effectiveness of the campaign due to the difficulties in collecting data. Anecdotally, it appears that individual pharmacies are not receptive to health promotion by this social marketing campaign. Although pharmacies may benefit from sales of the female condom from this project, information regarding the number of sales is difficult to obtain. According to a representative at Pharmascience, market information regarding the female condom is not collected, as the category is too small to be captured for Nielson ratings. However, according to Grignon," your campaign is creating awareness our product did not have as well as a new demand for the product. Pharmascience must assure that all pharmacies in areas concerned have the Reality female condom on hand for their customers" (Grignon, P.personal contact.2001). But even if sales had increased, it would be difficult to attribute the increase to our campaign without specific market research.

The difference in response to the media releases in June and in October demonstrates the difficulty of ensuring that a health promotion campaign receives media attention. It is an unreliable strategy, but appears to have been a factor in raising the awareness of our pilot study. However, we do not know why the media took an interest in the campaign in October but not in June. Perhaps the addition of the recruitment details to the October release attracted more attention, since it was interpreted that we were asking for volunteers to have sex, and we were going to pay them to do so.

Public health attendance at special public events, such as the "Everything You Ever Wanted to Know About Sex Show", where the topic was well advertised, is an effective strategy for increasing general awareness. Placing information on the website is also a strategy that should be used more extensively in the future. Not only can people who may be interested in trying the female condom access information about it on the website, but it is also available to other agencies and organizations worldwide that may want to promote the female condom in their jurisdictions.

The poster and pamphlet were integral to all components of the social marketing campaign. In a campaign such as this, where a single image is repeatedly used in various venues and media, it is important that the image and text be properly focus-tested. Suggestions from the focus testing were incorporated into the final product, which appears to have caught the attention of large numbers of people in Toronto and across North America.

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Appendix A – Acknowledgements

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- Tracey Methven, Chair