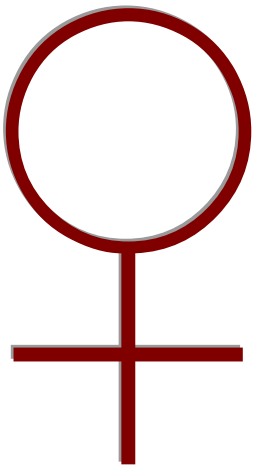
FEMALE CONDOM

Annotated Bibliography

1996-2009



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Compilation and Organization of Entries

This publication is a compilation of select journal articles and reports related to the female condom from 1996 through 2009. The bibliography was developed by conducting an extensive literature search utilizing MEDLINE (The National Library of Medicine's premier bibliographic database) and web-based resources. The entries are electronically linked to PubMed (a service of the National Library of Medicine), publisher's web sites, or actual reports available via the web.

The entries in this bibliography are grouped by major topic areas printed in large, bold-faced type under which they are arranged alphabetically by author. If an article covers more than one topic, the abstract is grouped under the principal topic and cross-referenced under the secondary topic(s). The cross-reference will give directions to see the principal topic area for the abstract.

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I. ACCEPTABILITY/FACTORS AFFECTING USE

Artz L, Demand M, Pulley LV, et al. Predictors of difficulty inserting the female condom. Contraception. 2002;65(2):151-157.

This article describes the frequency of initial difficulty inserting the female condom and identifies predictors of insertion difficulty among women at risk of sexually transmitted diseases (STDs). Female STD clinic patients (n = 1144) were taught how to insert the female condom by using an anatomic model, then given an opportunity for self-insertion practice. Correct placement of the condom was verified by a nurse clinician, and the number of attempts required for correct insertion was recorded. Sociodemographic and psychosocial predictors of refusing the insertion practice and of difficulty inserting the female condom were evaluated using logistic regression. Only 5% of study participants refused the self-insertion practice. Women who never had a Papanicolaou smear test, did not use tampons, never used an inserted method of STD prevention/birth control, and disliked the insertion features of intravaginal barrier methods were more likely to refuse the self-insertion practice. Of those who attempted self-insertion, 25% were unable to insert the female condom correctly on the first attempt. Women who never expressed their sexual likes and were indifferent to the positive features of intravaginal contraceptive methods were more likely to experience difficulty their first insertion attempt. Other variables associated with insertion difficulty included longer fingernails. Insertion refusal and difficulty affect use of the female condom for a sizable proportion of women. Women in this study who refused the self-insertion practice had greater aversion to inserting intravaginal barrier methods. Women who had initial difficulty inserting the female condom had a different profile from those who refused and can benefit from intensive skills training that includes supervised self-insertion practice.

Barbosa RM, Kalckman S, Berquo E, et al. Notes on the female condom: experiences in Brazil. International Journal of STD and AIDS. 2007;18(4):261-266.

A nationwide effort to introduce the female condom (FC) into public health services was undertaken in Brazil in 1998-99. To this end, the Ministry of health sponsored a national research group of public health professionals, aided by local field workers and supervisors to conduct a preparatory study at 20 sites in six cities. Clinic health workers were trained to conduct the study. Following an educational session, 2382 women volunteered to use the FC and to report their experiences at follow up. Among those seen at 15 days, 1782 had used the FC at least once; among those seen at the 90-day follow-up, 1453 women had used it at least once, while 1296 of them liked it and wished to continue its use. Among these 1296 women, barrier use at last intercourse (either with a male or female condom) was more than double at 90 days what it had been at baseline: 70% compared with 33%. Clinics providing active health-education activities achieved higher rates of follow-up and of FC acceptability. These findings suggest that in Brazil, the introduction of the FC at public health centres could lead to high initial adoption rates and that continued use would be effective in encouraging safer sex. The level of health education and type of clinic are likely to influence the effectiveness of a future programme.

Beksinska ME, Rees VH, McIntyre JA, et al. Acceptability of the female condom in different groups of women in South Africa – a multicentred study to inform the national female condom introductory strategy. South African Medical Journal. 2001;91(8):672-678.

To assess the acceptability of the female condom to different groups of women and their partners in South Africa. The study recruited 678 women from five centres to an acceptability trial of the female condom. Acceptability and successful use varied between the centres. Factors affecting successful use and willingness and intention to use the method again. In total, 209 women used the condom at least once. Discontinuation rates were high, with partner reluctance to try the method as the main reason given for discontinuation at all sites. Women who had previous experience with the male condom or who received a more intensive training session generally found the device easier to use. The main issues concerning women were over-lubrication (27%) and concern that the device was too large (28%). The majority of women said that they would be interested in using the method again (86%) and would recommend it to friends (95%). Overcoming partner opposition is an important issue to address when introducing the method. The study was used to address the national introductory strategy of the female condom, which began in 1998.

Bogart LM, Cecil H, Pinkerton SD. Hispanic adults' beliefs, attitudes, and intentions regarding the female condom. Journal of Behavioral Medicine. 2000; 23(2):181-206.

The present study used the theory of planned behavior (TPB) (Ajzen, 1985) augmented by AIDS knowledge to investigate factors influencing intentions of Hispanic adults to use the female condom. A total of 146 persons (75 women and 71 men; mean age 27 years) recruited from community-based organizations completed an anonymous survey regarding intentions to use the female condom and their main sex partner. The TPB model had greater predictive utility for women's, than for men's, female condom use intentions. For men, attitudes and norms did not predict female condom use intentions, but greater AIDS knowledge was related to lower intentions to use the female condom, above and beyond the TPB constructs. Perceived behavioral control, operationalized as self-efficacy, significantly increased the predictive utility of the TPB model for women's female condom use intentions but not for men's. Behavior change strategies to increase female condom use are discussed in light of these findings.

Buck J, Kang MS, van der Straten A, et al. Barrier method preferences and perceptions among Zimbabwean women and their partners. AIDS and Behavior. 2005;9(4):415-422.

In Zimbabwe, adult HIV prevalence is over 25% and acceptable prevention methods are urgently needed. Sixty-eight Zimbabwean women who had completed a barrier-methods study and 34 of their male partners participated in focus group discussions and in-depth interviews to qualitatively explore acceptability of male condoms, female condoms and

diaphragms. Most men and about half of women preferred diaphragms because they are female-controlled and do not detract from sexual pleasure or carry stigma. Unknown efficacy and reuse were concerns and some women reported feeling unclean when leaving the diaphragm in for six hours following sex. Nearly half of women and some men preferred male condoms because they are effective and limit women's exposure to semen, although they reportedly detract from sexual pleasure and carry social stigma. Female condoms were least preferred because of obviousness and partial coverage of outer-genitalia that interfered with sexual pleasure.

Bull SS, Posner SF, Ortiz C, et al. Knowledge of, attitudes toward, and stage of change for female and male condoms among Denver inner-city women. Journal of Urban Health: Bulletin of the New York Academy of Medicine. 2003;80(4):658-666.

Despite availability for a decade and documented acceptability among some groups of women for the method, female condom use is still rare. We surveyed 198 young women (15-25 years old) living in the inner city of Denver about their knowledge of, attitudes toward, and practices regarding female and male condoms. Most (75%) women had ever considered using male condoms; 32% had ever considered using female condoms; and use of either was sporadic. We examined predictors for being in either precontemplation or a later stage along the change continuum at both the bivariate and multivariate levels. Our findings suggest that African Americans and younger women are more likely to contemplate using female condoms. Both lack of knowledge and positive attitudes toward female condoms in this sample suggest that programs designed to raise awareness and knowledge of female condoms while improving their image are needed.

Cabral RJ, Posner SF, Macaluso M, et al. Do main partner conflict, power dynamics, and control over use of male condoms predict subsequent use of the female condom? Women and Health. 2003;38(1):37-52.

This study assessed hypotheses that measures of power and control over male condom (MC) use would predict use of the female condom (FC) among women with main partners from two public STD clinics (n = 616). The women (mean age 24 years, 87% African American) were enrolled in an intervention study to promote barrier contraceptive use and were interviewed at baseline and at 6 monthly follow-up visits. Seven baseline predictor variables were assessed: her having requested MC use, his having objected, her having wanted a MC used but not asking, percentage of MC use, perceived control over MC use, anticipated consequences of refusing unprotected sex, and physical violence. In the first Poisson regression analysis, none of the hypothesized predictors was significantly associated with FC use during follow up. In the second regression analysis, which assessed the influence of the hypothesized set of predictors on follow-up FC use in situations when MCs were not used, we found two effects. Either nor or inconsistent MC use before study entry was associated with less subsequent FC use; women who reported, at study entry, having more control over MC use were more likely to use FCs during follow up. We found no evidence of adoption of the FC by women in relationships marked by history of conflict over the MC, circumstances in

which alternatives are most needed. On the contrary, we found that women with a history of control and consistent use of MCs were the most likely users of FCs when MCs were not used.

Cecil H, Pinkerton SD, Bogart LM. Perceived benefits and barriers associated with the female condom among African-American adults. Journal of Health Psychology. 1999;4(2):165-175.

This study examined perceived benefits and barriers associated with intentions to use the female condom among a sample of 143 African-American adults in Milwaukee, USA. Participants completed a self-report questionnaire. Aesthetics and contraceptive efficacy predicted women's intentions to use the female condom with a main sex partner. For men, intentions to use the device with a main partner were predicted by beliefs that the female condom is affordable, would prevent STDs, that their partner would not be angry about female condom use, and knowing how to use the device. Interventions to promote this device need to be tailored differently for men and women.

Chen MP, Macaluso M, Blackwell R, et al. Self-reported mechanical problems during condom use and semen exposure. Sexually Transmitted Diseases. 2007; 34(8):557-562.

The objective of this study was to compare self-reported condom use problems and objectively determined semen exposure in 2 populations. Two randomized crossover trials in the United States and Brazil compared the failure rates of the female condom (FC) and male condom (MC). Participants used both condom types, completed condom-specific questionnaires to report problems, and collected pre-coital and post-coital samples of vaginal fluid. Prostate-specific antigen (PSA) was detected by immunoassay. Problems with condom use were reported less frequently in the Brazilian study (rate difference: FC = 24%, $P < 0.0001$, MC = 5%, $P = 0.003$). By contrast, the PSA detection rates were similar for both the FC and the MC (rate difference: FC = 2%, MC = 1%, not significant). These results suggest that the PSA detection rate was similar in the 2 study groups and that self-reported problems may be a less reliable measure of condom failure. Use of biomarkers of condom failure like PSA may help to strengthen the validity of studies promoting behavior change for the prevention of sexually transmitted diseases.

Choi KH, Gregorich SE, Anderson K, et al. Patterns and predictors of female condom use among ethnically diverse women attending family planning clinics. Sexually Transmitted Diseases. 2003;30(1):91-98.

The female condom is a viable option for women to protect themselves from HIV infection and other sexually transmitted diseases. The goal was to examine the level of female condom use and factors associated with frequency of use among US women living in San Francisco and Oakland, California. Of 238 women recruited from family planning clinics from July 1998 to April 1999, 206 were interviewed at both baseline and 3-month follow-up (a 92% retention rate). We observed a significant increase in vaginal

sexual acts protected by the female condom during the study but no reduction in male condom use. Overall, 82% of women reported using a female condom at least once, but the proportion of sexual acts protected by the female condom was only 17%. Multivariate analyses showed that female condom use was associated with suggesting female condom use to one's partner, less concern about device appearance, and a partner's positive attitude about the female condom. Our data indicate that female condom use supplements male condom use and leads to an increase in protected sex. The results also suggest that attitudinal and communication factors can increase female condom use.

Choi KH, Roberts KJ, Gomez C, et al. Facilitators and barriers to use of the female condom: Qualitative interviews with women of diverse ethnicity. Women and Health. 1999;30(1):53-70.

Women in the United States, particularly African-Americans and Hispanics, are at increased risk for HIV. The female condom now offers women a potentially important option for HIV prevention, yet few efforts have been made to increase its use. To elucidate strategies to promote the use of the female condom, we conducted in-depth interviews with 62 women recruited from the four major racial/ethnic groups of the U.S. (African-American, Asian-American, Hispanic, and white). Subject recruitment took place at a family planning clinic in San Francisco during 1996-97. We identified four major types of facilitators and barriers to use of the female condom: mechanical, psychosexual, interpersonal, and situational. Specifically, the mechanical facilitators and barriers included positive and negative aspects of the device, and difficulty with insertion. The psychosexual factors were female empowerment, more options for contraception and disease prevention, discomfort with vaginal insertion, and condom use norms. The interpersonal factors included: enhanced communication, relationship status, partner preferences, and partner objections. Finally, the situations that made women disinclined to use the device were: no access to the female condom when having sex and using other forms of contraceptives. The implications of these findings for HIV prevention and future research are discussed.

Coffey PS, Kilbourne-Brook M, Austin G, et al. Short-term acceptability of the PATH woman's condom among couples at three sites. Contraception. 2006;73 (6):588-593.

The objective of this study is to evaluate acceptability of the PATH Woman's Condom among user populations in Mexico, South Africa and Thailand. A nonrandomized, nonblinded, nonsignificant risk study was conducted among 20 couples per site. Data were collected via structured questionnaires after the first, second and third condom uses and through in-depth interviews after all condoms were used. Women from all sites reported that the PATH Woman's Condom was easy and comfortable to insert, and the pouch and ring were very stable during use. Both women and men reported that the comfort and sensation of sex while using the condom was acceptable. The PATH Woman's Condom is easy to use, stable during use, comfortable and satisfactory during

sex among users from diverse populations and cultures. The iterative user-driven product development process helped ensure that this new product addresses a wide range of user preferences.

Dowdy DW, Sweat MD, Holtgrave DR. Country-wide distribution of the nitrile female condom (FC2) in Brazil and South Africa: a cost-effectiveness analysis. AIDS. 2006;20(16):2091-2098.

The objective of this study is to evaluate the cost-effectiveness and potential impact of expanded female condom distribution. Cost-effectiveness analysis assessing HIV infections averted annually and incremental cost per HIV infection averted for country-wide distribution of the nitrile female condom (FC2) among sexually active individuals, 15-49 years, with access to publicly distributed condoms in Brazil and South Africa. In Brazil, expansion of FC2 distribution to 10% of current male condom use would avert an estimated 604 (5-95th percentiles, 412-831) HIV infections at $20,683 (5-95th percentiles, 13,497 – 29,521) per infection averted. In South Africa, 9,577 (5-95th percentiles, 6,539 – 13,270) infections could be averted, at $985 (5-95th percentiles, 633 – 1,412) per infection averted. The estimated cost of treating one HIV-infected individual is $21,970 (5-95th percentiles, 18,369 – 25,719) in Brazil and $1,503 (5-95th percentiles, 1,245 – 1,769) in South Africa, indicating potential cost savings. The incremental cost of expanded distribution would be reduced to $8,930 (5-95th percentiles, 5,864 – 13,163) per infection averted in Brazil and $374 (5-95th percentiles, 237 – 553) in South Africa by acquiring FC2s through a global purchasing mechanism and increasing distribution threefold. Sensitivity analyses show model estimates to be most sensitive to the estimated prevalence of sexually transmitted infections, total sexual activity, and fraction of FC2s properly used. Expanded distribution of FC2 in Brazil and South Africa could avert substantial numbers of HIV infections at little or no net cost to donor or government agencies. FC2 may be a useful and cost-effective supplement to the male condom for preventing HIV.

El-Bassel N, Krishnan SP, Schilling RF, et al. Acceptability of the female condom among STD clinic patients. AIDS Education and Prevention. 1998;10(5):465-480.

This study examines the acceptability of the female condom among African American and Latino patients from two inner-city sexually transmitted disease (STD) clinics through focus group discussions. Prior to the initial focus group sessions, 90% (n = 90) had heard about the female condom, 8% (n = 8) had seen it, and 2% (n = 2) had used it. Among the 41 participants (22 males and 19 females) attending a second focus group session, 85.4% (n = 35) had used the female condom at least once. Female study participants who had previous experience inserting a barrier contraceptive device, such as a diaphragm, indicated that they felt more comfortable inserting the female condom than those who had never used such a device. Male participants indicated that they were more comfortable using the female condom with their steady partners than with casual partners, whereas female participants indicated no such distinctions. These and other study findings suggest the need to promote and expand the use of the female condom as a device that protects women from STD transmissions including HIV and AIDS.

El-Bassel N, Krishnan SP, Witte S, et al. Correlates of intention to use the female condom among women taking methadone. Women's Health Issues. 1998;8(2):112-122.

The current study was designed to generate descriptive data on the correlates of intention to use the female condom. The correlates of actual use were not examined because only 6.1% (n=9) of the total sample had ever used the device. The study was modest in its focus, designed not to test hypotheses but to examine whether there were relationships between intention to use the female condom and 1) the participant's demographic background; 2) her attitudes toward the female condom; 3) her attitudes toward the male condom and its use; 4) her perception of her sexual partner's reaction to the female condom; 5) her perception of her own safer sex communication skills and ability to persuade her partner(s) to practice safer sex; and (6) social norms toward the female condom and its use.

Fernandez ML, Garrido JM, Alvarez AC. A qualitative study of the viability of usage of the female condom among university students. International Journal of Clinical and Health Psychology. 2006;6(1):189-199.

The objective of this qualitative study is to assess the viability of the use of the female condom among Spanish university students. To reach this objective, we adopted a qualitative research approach. This is the first research on the viability of female condom use using a Spanish sample with young adult participants. Four groups were formed, consisting of sixteen individuals with an age range between 18 and 24. Two of these groups were formed exclusively of women, one group solely of men and a fourth group was mixed. Discussion themes for the groups were as follows: Image of, knowledge about, access to and availability of the female condom. The results demonstrate that gender and type of couple (steady vs. casual) condition the use of the female condom. Our research also confirms that knowledge and experience gained by young people in the use of the male condom will tend to bias them unfavourably against the female condom in favour of the more familiar male one.

Fernandez ML, Garrido JM, Castro YR, et al. Assessing female condom acceptability among heterosexual Spanish couples. The European Journal of Contraception and Reproductive Health Care. 2008;13(3):255-263.

The objective of this study was to assess the acceptability of the female condom in a sample of young heterosexual Spanish couples. The sample was made up of 45 couples (90 participants) from Spain. The age range was from 19 to 42 years. The study was carried out in the three stages: pre-trial, post-trial, and follow-up (one year later). Before the intervention, 88 participants (97.8%) had heard about the female condom, although 73 participants (81.2%) claimed to know very little about the method, and barely one-third had seen one. The appraisals after the trial period reveal differing levels of satisfaction with the method, with no significant differences found by gender. Those participants who used a greater number of condoms during the trial period pointed out

more positive points about the method, but also more negative points. Of the 17 couples who continued to participate in the follow-up stage (one year after the trial stage), only one 5.9%) still used the female condom. However, 10 men (58.8%) and 8 women (47.1%) expressed a willingness to use it in the future, and 12 women (70.6%) and 11 men (64.7%) had told friends and acquaintances about it. This study reveals that although the female condom is considered to be a useful method, it is still largely unknown and require further promotion if it is to be used by young couples.

Francis-Chizaroro M, Natshalaga NR. The female condom: Acceptability and perception among rural women in Zimbabwe. African Journal of Reproductive Health. 2003;7(3):101-116.

This study was conducted to generate data for developing an action plan for accessing the female condom through primary health care centres in Zimbabwe. It used both quantitative and qualitative methods to gather information from sexually active women and men on the perception and acceptability of the female condom among users in rural areas of Zimbabwe. The findings show that very few women had used the female condom prior to the survey. Several women (93%) liked the condom especially young women aged 20-39 years (83%), compared to older women aged 40 years and above (11%). Both women and men liked the dual role of contraception and protection against STIs including HIV/AIDS played by the female condom. Most women (98%) felt that it is important for women to have their own condom. However, both men and women pointed out that it will be difficult to introduce the female condom in married situations due to the stigma associated with condoms in general. Over 80% of women said they will have to seek permission from their partners to use the female condom. Women had problems with inserting the condom and were concerned with lubrication, size and appearance, and how to dispose of used condom. Regarding cost, 77% felt that the female condom is too expensive given that the male condom can be obtained free from health centres. The cost of the female condom could hinder its continued use and would encourage women, especially commercial sex workers, to re-use it. Respondents still require more information relating to side effects (45%), effectiveness in STIs prevention including HIV/AIDS (44%), proper use (43%) and cost (32%).

Green G, Pool R, Harrison S, et al. Female control of sexuality: Illusion or reality? Use of vaginal products in south west Uganda. Social Science and Medicine. 2001;52(4):585-598.

This paper reports on a trial of vaginal products that were distributed and used by 131 women and 21 men in south west Uganda. It focuses specifically upon the issue of female control in heterosexual relationships and examines whether methods which are ostensibly under women's control, will in practice give women greater control of their sexual health. Participants were invited to select two from a range of vaginal products that included the female condom, contraceptive sponge, film, tablets, foam and gel, and use each for five weeks and their favourite product for a further three months. They were interviewed up to seven times over a five-month period. Although the women perceived that a major advantage of the products (with the exception of the female condom) was

that they could be used secretly, less than 40% were using the products without their partner's knowledge after one week and this proportion declined over time with only 22% using the products secretly after ten weeks. In the main male partners were told as women felt it their duty to inform them. In general the women were very much more positive about the products than they were about the male condom, as were the men. A contributory factor to their popularity among women was the greater control they gave them. Even though, use of these products in practice often involved negotiation with male partners, the fact that use was contingent on women's action was empowering and increased somewhat their ability to control their sexual health.

Haignere CS, Gold R, Maskovsky J, et al. High-risk adolescents and female condoms: Knowledge, attitudes, and use patterns. Journal of Adolescent Health. 2000;26(6):392-398.

To explore data on high-risk male and female adolescents' attitudes towards female condoms, compared with male condoms. Exploratory survey research was utilized with a convenience sample of 65 high-risk adolescents at an emergency homeless shelter. A peer-led intervention was conducted and pre-test and post-test interviews explored barriers to female condom use. The intervention consisted of 15- to 30-minute small group sessions, discussing female condoms' construction; purpose of the rings; efficacy preventing pregnancy and sexually transmitted infection (STIs); and how to lubricate, insert, and use. Content and Chi-square analyses were utilized. Sixty-three percent used male condoms as their primary contraceptive method; almost half (48%) said they always used male condoms, but 44% reported having sex without a male condom at least once in the 2 weeks prior to pre-test. Ninety-five percent had heard of the female condom, half 'good' and 24% 'bad' things, but only 15% had ever used one. At post-test all respondents gave reasons they might use female condoms in the future, and 77% gave reasons why they might not. Most (73%) adolescents said they would still prefer the male to the female condom. The major potential barriers to adolescents' female condom use were not having female condoms available and/or females feeling uncomfortable inserting them. Female condoms should be offered to adolescents as an *additional choice* rather than as *replacements* for male condoms. Further research is needed to assure access, availability, and comfort with female condoms and male participation in their use.

Hart GJ, Pool R, Green G, et al. Women's attitudes to condoms and female-controlled means of protection against HIV and STDs in South-Western Uganda. AIDS Care. 1999;11(6):687-698.

The consistent and correct use of the male condom makes it highly effective in both disease prevention and as a contraceptive method. However, it is also well recognized that its use is under men's control. Because of this vital limitation, there have been frequent calls for female-controlled methods of HIV prevention, particularly from women from sub-Saharan Africa. Here we report on data collected in focus-group discussions (FGDs) with women aged 17-54 in South-Western Uganda. A total of 138 women, from rural villages, urban family planning clinics and a truck-stop town, were recruited to participate in 18 FGDs on the male condom, the female condom and existing

formulations of vaginal microbicidal products. Three themes emerged: (i) problems with men's control over the male condom, (ii) the importance of control over and secrecy about protective measures and (iii) sexual pleasure associated with different methods. We found that the female condom, while being perceived as an improvement over the male condom, was recognized as having limited value because of the need to agree its use prior to sex taking place. Other products were considered to be significantly better than the female condom; the sponge, in particular, was perceived as having advantages over every other product. Women like the fact that it could be inserted some time before, and left in place some time after, sexual intercourse, that it was effective for multiple instances of intercourse, and that men would be unaware that it was being employed. Female-controlled methods to prevent sexually transmitted infections, including HIV, and to increase reproductive choice, hold the promise of ceding some control over sexual and reproductive health to women.

Hirky AE, Kirshenbaum SB, Melendez RM, et al. The female condom: Attitudes and experiences among HIV-positive heterosexual women and men. Women and Health. 2003;37(1):71-89.

The female condom is a potentially effective method for the prevention of HIV, other sexually transmitted disease, and pregnancy. This study describes attitudes toward and experiences with the female condom of 89 HIV-positive individuals (n=56 women; n = 33 men) reporting heterosexual behavior. Qualitative interviews were conducted to inform the design and implementation of a cognitive-behavioral risk-reduction and health-promotion intervention. Most respondents (n = 78) had seen or heard of the female condom. However, relatively few (n=14 women; n=5 men) had used it at least once. Reactions from both women and men across user groups, regardless of favorable or unfavorable attitude or experience with the female condom, centered around a similar set of factors: aesthetics, difficulties with the male condom, male partner reaction, beliefs about efficacy, and lack of training. These findings underscore the need for additional research and comprehensive education efforts aimed at both technical use and communication skills-building in order to realize the potential of the female condom as an alternative barrier method.

Hou L-Y, Qiu H-Y, Zhao Y-Z, et al. A crossover comparison of two types of female condom. International Journal of Gynecology and Obstetrics. 2009 November 25 [Epub ahead of print].

The objective of this study was to compare the performance and acceptability of 2 types of female condoms (FCs) among female sex workers (FSWs) in China. The present crossover survey trial was conducted in Enping City between September and December 2007. There were no significant differences between the 2 types of condoms in cumulative rates of episodes of misdirection; participants experiencing discomfort or feeling the outer or inner ring of an FC; or the clinical breakage or turning inside out of an FC. The rates of total clinical failures were similar for both FC types. Moreover, 59.5% of the survey participants reported that either type was acceptable to them. There

were no statistically significantly differences in performance between the 2 types of FCs tested, and most participants would accept using either in the future.

Jivasak-Apimas S, Saba J, Chandeying V, et al. Acceptability of the female condom among sex workers in Thailand: Results from a prospective study. Sexually Transmitted Diseases. 2001;28(11):648-654.

The female condom may provide women with the first female-controlled barrier method that is effective against sexually transmitted diseases, including HIV infection. This study evaluated the acceptability of the female condom among sex workers in Thailand. Data on use and acceptability of the female condom were collected using a structured questionnaire during an 8-week follow-up. Analyses included 148 women who were still in follow-up at week 8. Sex workers used, on average, 2.8 female condoms per week. The overall satisfaction rate with the female condom was 68%, although, among users, 31% had difficulties in device insertion, 37% had pain from the inner ring, and 22% reported itching sensations. The main reason for using the female condom in the future was its perceived safety, and the main reason for not using it would be the client's refusal. Two-thirds of the sex workers were satisfied with the female condom. Difficulties at insertion, discomfort during use, and clients' attitude were potential obstacles to the use of the female condom in the future.

Jones DL, Weiss SM, Chitalu N, et al. Acceptability and use of sexual barrier products and lubricants among HIV-seropositive Zambian men. AIDS Patient Care and STDs. 2008;22(12):1015-1020.

This study assessed the acceptability and preference for sexual barrier and lubricant products among men in Zambia following trial and long-term use. It also examined the role of men's preferences as facilitators or impediments to product use for HIV transmission reduction within the Zambian context. HIV-seropositive and –serodiscordant couples were recruited from HIV voluntary counseling and testing centers in Lusaka between 2003 and 2006; 66% of those approached agreed to participate. HIV seropositive male participants participated in a product exposure group intervention (n = 155). Participants were provided with male and female condoms and vaginal lubricants (Astroglide® [BioFilm, Inc., Vista, CA] & KY® gels [Johnson & Johnson, Langhorne, PA], Lubrin® suppositories [Kendwood Therapuetics, Fairfield, NJ]) over three sessions; assessments were conducted at baseline, monthly over 6 months and at 12 months. At baseline, the majority of men reported no previous exposure to lubricant products or female condoms and high (79%) levels of consistent male condom use in the last 7 days. Female condom use increased during the intervention, and male condom use increased at 6 months and was maintained over 12 months. The basis for decisions regarding lubricant use following product exposure was most influenced by a preference for communicating with partners; participant preference for lubricant products was distributed between all three products. Results illustrate the importance of development of a variety of products for prevention of HIV transmission and of inclusion of male partners in interventions to increase sexual barrier product use to facilitate barrier acceptability and use in Zambia.

Kalichman SC, Rompa D, Cage M. Factors associated with female condom use among HIV-seropositive women. International Journal of STD and AIDS. 2000; 11(12):798-803.

Female condoms are an effective option for preventing sexually transmitted diseases (STDs), including HIV transmission. Little is known, however, about female condom use in women living with HIV/AIDS. Ninety HIV-positive women completed measures of demographic characteristics, exposure and use of female condoms, attitudes toward female and male condoms, sexual behaviours, and substance use. Most women (77%) had been exposed to female condoms, however only 30% reported lifetime use, 16% reported recent use, and only 6% of the sample used female condoms as much or more than they used male condoms. The only factors consistently associated with female condom use were positive attitudes toward female condoms. Women who recently used female condoms were also more likely to have multiple male sex partners and reported fewer unprotected intercourse occasions. Female condoms are therefore used by a small number of HIV-infected women, particularly those with more than one male sex partner. Female condom use may be enhanced by removing barriers to their use, increasing cooperation of male partners, and enhancing proficiency of use.

Kelvin EA, Smith RA, Mantell JE, et al. Adding the female condom to the public health agenda on prevention of HIV and other sexually transmitted infections among men and women during anal intercourse. American Journal of Public Health. 2009;99(6):985-987.

Legal barriers to conducting public health research on methods of protection for anal intercourse were lifted in the United States in 2003 when the US Supreme Court invalidated all state antisodomy laws. Although research funding has been available for the development of rectal microbicides, the female condom, which has already been approved for vaginal use, has not been evaluated for anal use. Although there is no evidence that the female condom is safe for anal intercourse, it has already been taken up for off-label use by some men who have sex with men. This demonstrates the urgent need for more protection options for anal intercourse and, more immediately, the need to evaluate the safety and efficacy of the female condom for anal intercourse.

Klein H, Eber M, Crosby H, et al. The acceptability of the female condom among substance-using women in Washington, DC. Women and Health. 1999;29(3):97-114.

This research is based on structured interviews, semi-structured interviews, and informal firsthand observation of women residents of Washington, DC who used crack and/or injected drugs during the previous 30 days. The study entailed introducing these women to the female condom, exposing them to an HIV risk reduction intervention teaching them how to use it and how to negotiate its use with their sexual partner(s). Women were tested for HIV and asked to return one week later for their results. They were asked to try the female condom within that first week. Upon returning for their tests results,

ethnographers discussed with them their experiences with the female condom. They were re-interviewed for follow-up three months later to assess changes in behavior from baseline as well as their longer term experiences with and opinions of the female condom. The data presented in this paper are based on the interviews conducted one week after baseline. Of particular interest and concern to this research were: women's perceptions of the female condom prior to and subsequent to using it, women's partners' perceptions of the female condom after being introduced to it, and potential barriers to use. In all, 131 women, mostly African-American, took part in this study, which was conducted during the winter of 1997-1998.

Kulczycki A, Kim DJ, Duerr A, et al. The acceptability of the female and male condom: A randomized crossover trial. Perspectives on Sexual and Reproductive Health. 2004;36(3):114-119.

Although studies have assessed the acceptability of male and female condoms, comparative trial data are lacking. A sample of 108 women in stable relationships recruited from an urban, reproductive health clinic were randomly assigned to use 10 male or female condoms, followed by use of 10 of the other type. A nurse provided instruction in correct method use. Demographic information was collected in a baseline questionnaire; acceptability data were collected in follow-up and exit questionnaires and coital logs. Nonparametric and chi-square statistics were used to analyze measures of the methods' relative acceptability. Bowker's test of symmetry was adapted to test the null hypothesis of no difference in acceptability between condom types. Participants used 678 female and 700 male condoms. Although neither method scored high on user satisfaction measures, the 63 women completing the study protocol preferred the male condom to the female condom for ease of application or insertion, ease of removal, general fit, feel of the condom during intercourse and ease of penetration. Participants reported that their partner also favored the male condom, although women generally appeared to like this method more than their partner did. In a direct comparison between the methods at the end of the study, women generally judged male condoms superior on specified preference criteria. Across a range of criteria, the female condom was less acceptable than the male condom to most women and their partners. Although both types had low acceptability, they are needed and valid methods of pregnancy and disease prevention. That neither rated high on user satisfaction measures underscores the need for more barrier methods that women and men can use.

Latka M, Joanis C, Glover L. Acceptability of the Reality female condom and a latex prototype. Journal of Urban Health: Bulletin of the New York Academy of Medicine. 2001;78(4):614-626.

We report on the comparative acceptability of a prototype latex female condom and the polyurethane Reality® female condom. We also identified factors associated with acceptability, measured via a composite index with domains related to ease of insertion, noise, and comfort during insertion and use. There were 135 couples in this randomized crossover trial. The average age was 30 years; more than 60% had education beyond high school; 40% were married; and participants were at low risk for sexually transmitted

disease and pregnancy (due to the investigational status of the prototype). Participants were asked to use three of each of the study condoms during a 6-week period. Acceptability ratings on 12 items were summed into a composite index for each participant by condom type. The index midpoint (range) for females was 48 (12-84), and it was 32 (8-56) for males, with lower scores indicating higher acceptability (men completed only a subset of the acceptability questions). Both condoms were equally acceptable: Mean scores were 37 and 40 for the women's ranking of the prototype and Reality, respectively (P = .07) and 29 and 30 for men's rankings, respectively (P = .35). Multiple regression models to predict acceptability scores by gender were somewhat uninformative (most R^2 values were less than 0.10). Nevertheless, minority ethnicity (African American or Hispanic vs. white) was associated with higher acceptability by both genders for both condom types. Among women, for both condom types, less education (less than high school compared with high school or beyond) was associated with higher acceptability. Female condom acceptability may not be equally distributed across demographic groups, which is important for health educators to keep in mind when promoting the female condom.

Macaluso M, Demand MJ, Artz LM, et al. Partner type and condom use. AIDS. 2000;14(5):537-546.

To examine the association between type of sexual partnership and condom use consistency. A prospective follow-up study of women attending two urban clinics for sexually transmitted diseases (STD). Sexual diaries recording barrier method, partner initials and partner type for each act of intercourse were kept by 869 women. Condom use by partner type was evaluated in three ways in the entire group: among women who encountered multiple partners, during months in which women encountered multiple partners, and within sexual partnerships that changed status during the study. Consistency of condom use was higher with new and casual partners than with regular partners in the entire group and among women who encountered multiple partners. In months in which partners of different types were encountered, condom-use consistency was higher with new and casual partners than with regular partners. Consistent condom use decreased in partnerships that changed status from new to regular. The female condom was used more often with regular partners than with new or casual partners in the entire study group, among women who encountered multiple partners, and during months in which a woman achieved consistent use with her regular partner. This study provides strong evidence that condom use behavior is modified by partner type. Observations about condom use and partner type made in cross-sectional or retrospective surveys also hold in the present longitudinal analyses of individual women and of partnerships that change status. The female condom may be an important option for achieving consistent protection within stable partnerships.

Macaluso M, Wang X, Brill I, et al. Participation and retention in a study of female condom use among women at high STD risk. Annals of Epidemiology. 2005; 15(2):105-111.

Differential participation and retention can bias the findings of a follow-up study. This problem was evaluated in a study of barrier contraception among women at high STD risk. The goal of this study was to identify predictors of participation and retention and determine whether they could influence study results. Six-month follow-up study of women attending STD clinics. Determinants of participation and retention were evaluated using logistic and proportional hazards models. Agreement to participate was associated with young age, black race, low education and income, older age at first intercourse, the number of lifetime partners, and STD history. Early attrition was associated with young age, non-black race, higher income, lack of interest/commitment to using the female condom, high coital frequency, not STD history, not using a birth control method at baseline, and with inconsistent condom use, high coital frequency, and pregnancy during follow up.

Mantell JE, Hoffman S, Exner TM, et al. Family planning provider's perspectives on dual protection. Perspectives on Sexual and Reproductive Health. 2003;35 (2):71-78.

Family planning providers can play an important role in helping women to identify their risk of HIV and other sexually transmitted diseases (STDs) and to adopt preventive measures. In-depth investigation of providers' attitudes about approaches to STD risk assessment, contraceptive counseling and dual protection—concurrent protection from STDs and unintended pregnancy—has been limited. In semi-structured interviews conducted in 1998, 22 health care providers from a large New York City agency offering contraceptive and STD services described how they balanced STD and pregnancy concerns, viewed risk assessment and assessed various contraceptive methods. STD prevention was seen as an integral part of family planning counseling, and most providers believed that risk assessment should be conducted universally. Providers viewed dual protection as use of condoms along with an effective contraceptive; few advocated use of the male or female condom alone. The female condom was believed to be a disease prevention method of last resort and was considered appropriate only for specific groups of women. Although providers lacked understanding about the effectiveness of the female condom and how to counsel clients concerning its use, they expressed interest in learning more. Training is needed to reduce providers' negative perceptions of the female condom and to reinforce the importance of individualized counseling tailored to women's specific circumstances. Studies are needed on how to encourage family planning providers to promote male and female condoms as effective contraceptive methods.

Mantell JE, Hoffman S, Weiss E, et al. The acceptability of the female condom: Perspectives of family planning providers in New York City, South Africa, and Nigeria. Journal of Urban Health: Bulletin of the New York Academy of Medicine. 2001;78(4):658-668.

This article seeks to fill the gap in female condom acceptability research by examining family planning (FP) providers' attitudes and experiences regarding the female condom in three countries (South Africa, the US, and Nigeria) to highlight providers' potential integral role in the introduction of the female condom. The case studies used data drawn from three independent projects, each of which was designed to study or to change FP providers' attitudes and practices in relation to the female condom. The case study for New York City used data from semistructured interviews with providers in one FP consortium in which no special female condom training had been undertaken. The data from South Africa were drawn from transcripts and observations of a female condom training program and from interviews conducted in preparation for the training. The Nigerian study used observations of client visits before and after providers were trained concerning the female condom. In New York City, providers were skeptical about the contraceptive efficacy of the female condom, with only 8 of 22 providers (36%) reporting they would recommend it as a primary contraceptive. In South Africa, providers who had practiced insertion of the female condom as part of their training expressed concern its physical appearance and effects on sexual pleasure. However, they also saw the female condom as a tool to empower clients to increase their capacity for self-protection. Structured observations of providers' counseling interactions with clients following training indicated that Nigerian providers discussed the female condom with clients in 80% of the visits observed. Despite the lack of a uniform methodology, the three case studies illuminate various dimensions of FP providers' perceptions of the acceptability of the female condom. FP providers must be viewed as a critical factor in female condom acceptability, uptake, and continued use. Designing training programs and other interventions that address sources of provider resistance and enhance providers' skills in teaching female condom negotiation strategies may help to increase clients' use of the female condom.

Marshall S, Giblin P, Simpson P, et al. Adolescent girls' perception and experiences with the Reality female condom. Journal of Adolescent Health. 2002;31(1):5-6.

Traditionally, the latex male condom has been the only barrier method for prevention of sexually transmitted disease (STD) prevention. In 1993, the Food and Drug Administration approved the Reality Female Condom (FC). It is a disposable pre-lubricated polyurethane 7-inch vaginal pouch which lines the vagina. It has two flexible rings, the inner ring is used to insert the condom and hold it in place, the outer ring partially covers the labia [1]. Its safety, effectiveness (74% to 95% typical use and 89% to 98% perfect use), and acceptability (50% to 80%) in adult women has been reported [1, 2]. The study assesses the acceptability of the FC to adolescent girls, and examines whether experience with other vaginal products affects its use.

Meekers D, Richter K. Factors associated with use of the female condom in Zimbabwe. International Family Planning Perspectives. 2005;31(1):30-37.

Because women can initiate use of the female condom, the method is believed to make it easier for women to protect themselves against sexually transmitted infections (STIs), including HIV infection. Evidence is lacking about factors associated with trying the female condom and using it consistently. A sample of 1,740 sexually active consumers visiting retail outlets in urban Zimbabwe that sell male or female condoms were surveyed in 1998, one year after a social marketing campaign had begun. Logistic regression analyses were conducted to assess factors associated with ever-use of the female condom and consistent use (always or often) with marital and regular nonmarital partners. Perceived ease of use and affordability of the product and prior use of the male condom were associated with men's and women's ever-use. Consistent use with marital partners was negatively associated with reporting multiple partners in the past year (odds ratio, 0.3) and positively associated with using the device for pregnancy prevention (5.4) and previously using the male condom (8.0). Consistent use with regular nonmarital partners was associated with numerous variables, including perceived ease of use (1.9) and effectiveness for STI prevention (3.8), low HIV risk perception (2.4), and use for pregnancy (2.9) and STI (2.3) prevention. Perceived affordability and ease of use may encourage couples to try the female condom but may not lead to consistent use. Because the reasons for use can vary between marital and nonmarital relationships, the female condom may need to be positioned differently for different target populations.

Minnis AM, Padian NS. Choice of female-controlled barrier methods among young women and their male sexual partners. Family Planning Perspectives. 2001;33 (1):28-34.

Little is known about the factors associated with the choice of female-controlled, over-the-counter barrier contraceptive methods among women and their male sexual partners. Predictors of method choice were assessed following an educational presentation on contraceptive use and risk reduction among 510 sexually active females aged 15-30 who were recruited in the San Francisco Bay Area. In addition, the primary partners of 160 of these women participated in the survey. Twenty-two percent of women who enrolled in the study alone, 25% of those who enrolled with their main partner and 18% of these male partners chose female-controlled, over-the-counter barrier methods alone. The strongest predictor of this choice was current use of a hormonal contraceptive both for women who participated in the study on their own (odds ratio, 2.1) and for those who enrolled their partner in the study (odds ratio, 6.3). Female-controlled methods were also chosen significantly more often by teenagers than by older women; for example, among those who enrolled with a male partner, the odds ratio for selection of a female-controlled barrier method by women younger than 18 was 6.0. Among women who enrolled without a partner, those who had had multiple partners in the previous six months and those who were current users of male condoms were less likely to choose female-controlled methods (odds ratios, 0.7 and 0.5 respectively). Although the majority of participants did not choose female-controlled, over-the-counter barrier methods without also choosing male condoms, such female-controlled methods appear to offer an

acceptable alternative for prevention of sexually transmitted infections. They may be a particularly attractive option for individuals using hormonal contraceptives and for teenage women.

Minnis AM, Shiboski SC, Padian NS. Barrier contraceptive method acceptability and choice are not reliable indicators of use. Sexually Transmitted Diseases. 2003;30(7):556-561.

The need for safe and effective female-controlled methods that protect against sexually transmitted pathogens is widely recognized. Product effectiveness is inextricably bound to use, and, therefore, the needs and preferences of potential consumers must be considered. The degree to which measures of acceptability correlate with actual barrier method use remains unexamined. The goal was to evaluate associations between measures of acceptability and use of existing over-the-counter barrier methods. In the San Francisco Bay Area, 510 females aged 15 to 30 years were recruited from reproductive health clinics for this longitudinal study. Neither hypothetical acceptability nor product choice predicted use. Fewer than 50% of participants who chose a female-controlled method used it. Similarly, method satisfaction was not associated with use (14.3-51.4% of satisfied users used the method again). However, dissatisfaction was predictive of low levels of subsequent use (0-15.3% used the method again). Male condoms were used despite dissatisfaction. The lack of association among assessments of acceptability, choice, satisfaction, and use suggests a need to reframe how product acceptability is evaluated in prevention research so it is more predictive of method use.

Murphy ST, Miller LC, Moore J, et al. Preaching to the choir: Preference for female-controlled methods of HIV and sexually transmitted disease prevention. American Journal of Public Health. 2000;90(7):1135-1137.

This study assessed interest in female-controlled methods of HIV and sexually transmitted disease (STD) prevention. Surveys were conducted with 168 African American women, aged 18 to 32 years, who had had unprotected sex and at least 3 sexual partners in the last 2 years. Of 44 potential features, "female control" (where women control the method by either wearing or applying it) ranked 22nd in average importance. Women who rated female control as highly important had fewer sex partners and fewer STDs and were more likely to use existing prevention methods frequently. Female control may be of less interest to women most at risk for HIV and other STDs. This under-scores the need to take the priorities and preferences of women into consideration when developing new prevention methods.

Mutiso SM, Kinuthia J, Qureshi Z. Contraceptive use among HIV infected women attending Comprehensive Care Centre. East African Medical Journal. 2008;85 (4):171-177.

The objective of this study was to determine contraceptive use among HIV infected women attending Comprehensive Care Centre at Kenyatta National Hospital. Hospital based cross-sectional descriptive study. Comprehensive Care Centre (CCC), Kenyatta

National Hospital. The study group was non-pregnant HIV positive women on follow up at the CCC. A total of 94 HIV infected women were interviewed between may 2006 and August 2006 through a pre-tested interviewer administered questionnaire. Consecutive women willing to participate in the study were interviewed. Current contraceptive use, contraceptive methods, source of contraception, reproductive intention and unmet need of family planning. The mean age of the respondents was 34 years, 47.9% were married, all had formal education and 74.6% were employed. Eighty six percent of the respondents did not have reproduction intentions in the next two years; however, only 44.2% of the respondents were using contraception. Condoms were the most popular (81.5%) contraceptive method. Female condom was used by 10.5% of the respondents. Norplant was the only long term contraceptive method and was used by only 2.6%. Dual method of contraception was practiced by 13.5% of the respondents. Majority of the respondents obtained contraceptives from private sector (42.9%) with less than 10% getting them from CCC. The unmet need for family planning among the study group was 30%. Marital status and regular sexual partner were significantly associated with contraceptive use. Although majority of respondents did not have reproduction intentions in the next two years, use of contraception was low with only 44% being on a method. Use of long term contraceptive methods was low among respondents. Majority of the respondents obtained contraceptives away from CCC. The unmet need for family planning was high at 30%.

Napierala S, Kang MS, Chipato T, et al. Female condom uptake and acceptability in Zimbabwe. AIDS Education and Prevention. 2008;20(2):121-134.

As the first phase of a two-phase prospective cohort study to assess the acceptability of the diaphragm as a potential HIV/STI prevention method, we conducted a 2-month prospective study and examined the effect of a male and female condom intervention on female condom (FC) use among 379 sexually active women in Harare, Zimbabwe. Reported use of FC increased from 1.1% at baseline to 70.6% at 2-month follow-up. Predictors of FC uptake immediately following the intervention included interest in using FC, liking FC better than male condoms, and believing one could use them more consistently than male condoms. Women reported 28.8% of sex acts protected by FC in the 2 weeks prior to last study visit. Though FC may not be the preferred method for the majority of women, with access, proper education, and promotion they may be a valuable option for some Zimbabwean women.

Neilands TB, Choi K-H. A validation and reduced form of the Female Condom Attitudes Scale. AIDS Education and Prevention. 2002;14(2):158-171.

The Female Condom Attitudes Scale is an instrument comprising five correlated factors derived from 15 Likert-scale survey items that measure women's attitudes toward the female condom. This scale originated from the 30-item scale of Choi, Gregorich, Anderson, Grinstead, and Gomez (2001; manuscript under review). Exploratory factor analysis of this scale extracted eight correlated factors. Reliability coefficients and confirmatory factor analyses refined the instrument by reducing the number of factors to five and halving the number of items. The reduced form of the Female Condom

Attitudes Scale demonstrated both construct and convergent validity by predicting self-reported female condom use behavior. It also correlated with self-efficacy to use male condoms, sexual comfort, and attitudes toward the male condom. The five factors remaining in the final survey instrument were Sexual Pleasure Enhancement, Inconvenience, Improved Prophylaxis, Sexual Pleasure Inhibition, and Insertion Reluctance. Implications of these findings for basic and applied intervention research are discussed.

Okunlola MA, Morhason-Bello IO, Owonikoko KM, et al. Female condom awareness, use and concerns among Nigerian female undergraduates. Journal of Obstetrics and Gynaecology. 2006;26(4):353-356.

A cross-sectional study of female condom awareness, usage and concerns amoung the female undergraduates of the University of Ibadan was conducted in September 2004. The results of 850 out of the 879 female students interviewed were used for analysis (96.6%). Over 80% had knowledge of the female condom as a form of modern contraception and the majority of them learn about it through the mass media (39.9%) and health workers (34.4%). However, only 11.3% had ever used the female condom, with most (40%) using it to prevent both unwanted pregnancy and sexually transmitted infections including HIV (STI/HIV). The sexual partners' approval was appreciable, accounting for about 42.7% among those that had experience of the female condom usage. Major concerns mentioned such as difficulty of inserting it into the vagina and lack of sexual satisfaction, were not different from those in earlier studies. The result of this study looks promising judging from a high awareness level of the female condom, even though its usage is low. The female condom may be an alternative strategy to combat unsafe sexual practices and its sequelae in a country like Nigeria that is male dominated.

Pool R, Hart G, Green G, et al. Men's attitudes to condoms and female controlled means of protection against HIV and STDs in south-western Uganda. Culture, Health and Sexuality. 2000;2(2):197-211.

There is widespread demand for the development of female controlled methods of protection against sexually transmitted diseases (STDs) and HIV. The success of such methods will not only depend on their acceptability to women but also to their male partners. This paper reports on men's attitudes to female controlled methods in south west Uganda. Data was gathered in individual interviews with 50 men and 7 focus group discussions with 42 men. Male attitudes to the male condom, the female condom and female controlled methods of protection generally were characterized by ambiguity and anxiety. They liked the male condom because it protects against infection and unwanted pregnancy, but were worried by rumours that it was unreliable. The central theme in the discussions was men's anxiety about retaining control over their female partners. The men wanted women to be protected (and therefore safe as potential partners) but they also wanted to remain in control, at least to some extent, of the means of protection. Once suitable female controlled methods have been identified, it will be necessary to use

education and social marketing in such a way that men can be reassured of the positive benefits of these products to them, as well as to women.

Pool R, Whitworth JAG, Green G, et al. An acceptability study of female-controlled methods of protection against HIV and STDs in south-western Uganda. International Journal of STD and AIDS. 2000;11(3):162-167.

We aimed to assess the acceptability of a variety of formulations of female-controlled methods of protection against HIV and STDs among men and women in south-western Uganda. Pilot interviews were carried out with 50 men and 55 women and 25 focus group discussions (FGDs) were held with 138 women and 42 men. The female condom, foaming tablets, sponge, foam, gel and film were demonstrated to 146 women and 35 of their male partners, who then tried out 2 of the products. They were interviewed 7 times during the course of 5 months. At the end experiences were evaluated during a second series of FGDs. Sixty-five (45%) women completed the trial. The main reasons for non-completion were related to geographical mobility. Product preference after the initial demonstration was similar to that at the end of the trial. The most popular formulations were the sponge (25% of the women), foaming tablets (23%), and the female condom (19%). The foam was of medium popularity (16%). The gel (9%) and film (7%) were least popular. Ten per cent of the women and 14% of the men reported products interfering with sexual enjoyment; 24% of the women and 67% of the men said products increased enjoyment. 'Dry sex' is not popular in this area and increased lubrication was an important determinant of acceptability. Age, level of education and location did have some effect on preference. Although secrecy was a dominant theme in the FGDs, 87% of the women had informed their partners by the end of the trial. The products were generally well received. Female control was an important issue for both sexes. Male attitudes were ambivalent because female ownership of products increased women's control. Although they have clear preferences, women appear to accept the products generally and might use a single available product just as readily if choice was limited, as long as it conforms to general cultural preferences, such as those relating to wet/dry sex.

Posner SF, Bull SS, Ortiz C, et al. Factors associated with condom use among young Denver inner city women. Preventive Medicine. 2004;39(6):1227-1233.

Despite the availability of condoms and theoretically based interventions to promote their use, sexually active women aged 15 to 25 years continue to put themselves at risk for sexually transmitted diseases and unintended pregnancy. One hundred ninety-eight inner city women were interviewed about knowledge and attitudes about condoms. Using the Transtheoretical Model, regression techniques were used to identify factors associated with condom use at last sex and the proportion of acts protected by a condom in the last 90 days. Constructs including intention to use (OR = 1.69, CI 1.07 – 2.65) and positive outcome expectancies (OR = 1.59, CI 1.03 – 2.46) were associated with condom use at last act of sexual intercourse. Similarly, intention to use condoms (RR = 1.58, CI 1.37 – 1.82), positive outcome expectances (RR = 2.71, CI 2.41 – 2.99), perceived peer's use of condoms (RR = 2.25, CI 1.95 – 2.60), and number of places condoms were discussed (RR 1.05, CI 1.02 – 1.07) were associated with the proportion of protected acts.

Constructs specified in the Transtheoretical Model are useful in describing condom use and have implications for targeting human immunodeficiency virus (HIV)/sexually transmitted diseases (STD)/unintended pregnancy interventions.

Rasch V, Yambesi F, Kipingili R. Acceptance and use of the female condom among women with incomplete abortion in rural Tanzania. Contraception. 2007;75(1):66-70.

This study describes the outcome of a post-abortion care intervention aimed at introducing the female condom as a means of preventing women from having unwanted pregnancies and sexually transmitted infections (STIs)/HIV. Post-abortion contraceptive counseling and services were offered to 548 women admitted to the Kagera Regional Hospital for incomplete abortion. The counseling included information about STI/HIV and the use of male or female condom. In total, 521 (95%) women accepted contraception. Contraceptive use was assessed 3 months after abortion among 475 (91%) women. The female condom was accepted by 201 of 521 (39%) and was used by 158 of 521 (30%). Women who had experienced an unsafe abortion, had attended secondary school or earned an income were more likely to accept the female condom. The women were generally satisfied with the method, and the majority intended to use it again. Post-abortion care programs provide an excellent entry point for introducing the female condom as a contraceptive method for the prevention of both repeat unwanted pregnancies and STI/HIV infection.

Ray S, Maposhere C. Male and female condom use by sex workers in Zimbabwe: Acceptability and obstacles. Reproductive Health Matters. 1997;1:97-108.

Methods that are thought of as being women-controlled, such as female condoms, still need the willingness of men to be used in many situations. Women who are socio-economically disadvantaged have fewer skills and opportunities to negotiate for safer sex, to prevent sexually transmitted infections or unwanted pregnancies. This paper draws on issues arising from two studies conducted in Zimbabwe on the acceptability of female condoms to different groups of women sex workers and the responses they report from their partners, which found high levels of satisfaction with this method. However, technological solutions to the HIV epidemic should not distract from the reasons why many women cannot negotiate for protection from infection. The nature of relationships plays a crucial role in determining whether negotiation for male or female condom use is successful or not. Many of the mechanical obstacles to use of female condoms can be overcome by sympathetic and knowledgeable support from health workers. The role of women's support groups in orienting the attitudes of health workers and encouraging social approval for behavior change is also essential. Significant shifts in values and ideology are needed to support women and men in changing the power balance in their relationships if good sexual health is to be achieved.

Ray S, van de Wijgert J, Mason P, et al. Constraints faced by sex workers in use of female and male condoms for safer sex in Urban Zimbabwe. Journal of Urban Health: Bulletin of the New York Academy of Medicine. 2001;78(4):581-592.

We investigated whether female condoms are acceptable to sex workers in Harare and whether improved access to male and female condoms increases the proportion of protected sex episodes with clients and boyfriends. Sex workers were randomly placed in groups to receive either male and female condoms (group A, n = 99) or male condoms only (group B, n = 50) and were followed prospectively for about 3 months each. We found a considerable burden of human immunodeficiency virus (HIV) and sexually transmitted infections (STIs) in our cohort at enrollment (86% tested HIV positive and 34% had at least one STI). Consistent male condom use with clients increased from 0% to 52% in group A and from 0% to 82% in group B between enrollment and first follow-up 2 weeks later and remained high throughout the study. Few women in group A reported using female condoms with clients consistently (3% - 9%), and use of either condom was less common with boyfriends than with clients throughout the study (8% - 39% for different study groups, visits, and types of condom). Unprotected sex still took place, as evidenced by an STI incidence of 16 episodes per 100 woman-months of follow-up. Our questionnaire data indicated high self-reported acceptability of female condoms, but focus group discussions revealed that a main obstacle to female condom use was client distrust of unfamiliar methods. This study shows that a simple intervention of improving access to condoms can lead to more protected sex episodes between sex workers and clients. However, more work is needed to help sex workers achieve safer sex in noncommercial relationships.

Ruminjo JK, Steiner M, Joanis C, et al. Preliminary comparison of the polyurethane female condom with the latex male condom in Kenya. East African Medical Journal. 1996;73(2):101-106.

This paper summarizes acceptability data published to date on the innovative female condom, and presents an additional study comparing the acceptability of the female condom and the latex male condom in a sample of low risk women attending private obstetrician/gynaecologists' clinics in Nairobi, Kenya. Eighty-four percent of all subjects who completed interviewer-assisted questionnaires reported that they liked using the female condom, and more than two-thirds of all the women liked the female condom as much or better than the male condom. Fifty-five percent of the women would use the device in future if it were available. The least liked features were that the device was too large for easy insertion, messy to handle, and reduced sensation. Use became easier and more comfortable with experience. The most liked features were that the device made sex more enjoyable, protected against sexually transmitted diseases and pregnancy, and was under the woman's control. Male partner response was slightly less favourable, and sometimes resulted in women's noncompliance or discontinuation of use, despite the fact that such a device is supposed to empower women. This study provides preliminary data indicating that the female condom is a fairly acceptable method for some Kenyan couples, but recommends further research into safety, cost-effectiveness and hindrances to acceptability.

Salabarria-Pena Y, Lee JW, Montgomery SB, et al. Determinants of female and male condom use among immigrant women of central American descent. AIDS and Behavior. 2003;7(2):163-174.

This study was designed to determine factors that influence female and male condom use among Central American women, applying the theory of planned behavior. A cross-sectional design was employed and a sample of 175 Central American women, 18-50 years old, was recruited from a community-based clinic in Los Angeles County. Participants in this study were interviewed face-to-face. Attitude, subjective norm, and perceived behavioral control explained 41% and 45% of the variation in the intention to use male and female condoms, respectively. Respondents' friends and mothers influenced their subjective norms. Beliefs regarding sexual sensation and sexually transmitted infection/pregnancy prevention affected respondents' attitudes toward condoms. Trust issues were also a major factor affecting attitudes toward female condoms. Condom use and sex negotiation skills predicted control over condoms. Results of this study can be used to design HIV/AIDS prevention programs that help women feel control over condom use and their sexual behavior.

Saul J, Moore J, Murphy ST, et al. Relationship violence and women's reactions to male- and female-controlled HIV prevention methods. AIDS and Behavior. 2004; 8(2):207-214.

This study examined the association of relationship violence and preference for three HIV prevention methods among 104 African American and Hispanic women who were at some risk for heterosexual transmission of HIV and other sexually transmitted diseases (STDs). Women completed a brief questionnaire on sexual behaviors and history of relationship violence. All women then watched a video describing three HIV/STD prevention methods (male condoms, female condoms, and vaginal spermicide) that included a discussion of method effectiveness, how to use each method, and their benefits and limitations. Participants then completed a questionnaire assessing their reactions to each of the three HIV prevention methods discussed in the video. Women in violent relationships indicated less likelihood of using male condoms and greater likelihood of using female-controlled methods, particularly vaginal spermicide, than women in nonviolent relationships. In addition, a higher percentage of women in violent compared to nonviolent relationships expected their partners to prefer the vaginal spermicide and a lower percentage expected partners to prefer male condoms. These data suggest that the current focus on finding alternative HIV prevention methods for women in violent relationships is warranted and that a vaginal microbicidal product may be the preferred alternative for this group of women and their male partners.

Seal DW, Ehrhardt AA. Heterosexual men's attitudes toward the female condom. AIDS Education and Prevention. 1999;11(2):93-106.

This article addresses heterosexual men's familiarity with the female condom and their attitudes toward this barrier method. Qualitative interviews were conducted with 71

ethnically diverse and heterosexually active men who were recruited in sexually transmitted disease (STD) clinics or through word of mouth in communities with high HIV/STD seroprevalence in New York City during fall 1994 to fall 1995. Only one man reported previous experience with the female condom. The large majority of men had no or limited knowledge of the female condom. Men's reactions to learning about this method ranged from positive to negative, although most men reported willingness to have sex with a partner who wanted to use the female condom. Positive reactions included: endorsement of a woman-controlled condom and her right to use it, the potential for enhancing one's sexual pleasure, and an eagerness to have new sexual experience. Negative reactions centered on the "strangeness" and "bigness" of the female condom, concerns about prevention efficacy, and concerns about reductions in sexual pleasure. Our findings highlight the need for HIV prevention programs that target heterosexual men and promote the use of the female condom.

Sly DF, Quadagno D, Harrison DF, et al. Factors associated with use of the female condom. Family Planning Perspectives. 1997;29(4):181-184.

Black, Hispanic and white women recruited for an HIV prevention intervention were instructed in the use of the female condom and encouraged to try the device. Of the 231 women who completed the intervention, 29% tried the condom over the course of a month; 30% of those who tried it used it during at least half of their sexual encounters. Both ethnicity and age were associated with trying the device: Nearly 40% of black women and 30% of Hispanic women did so, compared with 18% of white women; 37% of those aged 25-34 tried the female condom, compared with 22% of women younger than 25. Trying the device was more likely among women living with a partner, those with a history of sexually transmitted disease infection, women who had had an HIV test, those who did not believe that the method afforded them a greater degree of overall control than did the male condom and those who had no prior knowledge of the device. Among women who used the device during at least half of their sexual encounters, 27% were black and 44% were Hispanic; 38% were younger than 25, and 43% were single. More regular users were about half as likely as less regular users to experience difficulty with insertion and one-eighth as likely to report the device slipping during the use; they were more likely than less regular users to report that sex was more pleasurable with the female condom than with the male condom.

Smit J, Beksinska M, Vijayakumar G, et al. Short-term acceptability of the Reality® polyurethane female condom and a synthetic latex prototype: A randomized crossover trial among South African women. Contraception. 2006; 73(4):394-398.

This multisite, randomized, crossover trial comparing the acceptability of the Reality® female condom (FC1), with a new synthetic latex prototype (FC2) of similar design and appearance to FC1, was conducted in Durban, South Africa. In total, 276 women were enrolled and 1910 FC1 condoms and 1881 FC2 condoms were used by 218 and 216 women, respectively. Overall experience of use was reported as good for over half the participants with both condom types (FC1 = 50.9%, FC2 = 55.1%). Similar acceptability

issues were reported in like proportions for FC1 and FC2, with features such as the lubricant (FC1 = 36.7%, FC2 = 37.0%) and the material (FC1 = 36.2%, FC2 = 29.2%) most commonly viewed positively for both condom types. Negative aspects commonly reported for both female condoms were the lubricant (FC1 = 30.3%, FC2 = 31.5%) and the appearance (FC1 = 29.8%, FC2 = 34.0%). Preference for FC1 was 29.5% and was slightly higher for FC2 (36.6%). Some women felt that there was no real difference between the two devices (33.8%). The acceptability of FC1 and FC2 was comparable, and women who find FC1 acceptable to use should also find FC2 acceptable.

Smita J, Neelam J, Rochelle DY, et al. Comparative acceptability study of the Reality® female condom and the version 4 of modified Reddy female condom in India. Contraception. 2005;72(5):366-371.

Affordable, acceptable and effective female controlled options are required worldwide for prevention of human immunodeficiency virus (HIV) infection and other sexually transmitted diseases. We carried out a comparative acceptability study of Reality® and Reddy (version 4) female condoms. Sixty eligible couples were enrolled and randomly assigned to use either Reality or Reddy condom first. They used three Reality condoms and three Reddy condoms each with at least one condom use per week. Reddy female condom had a significantly better acceptability than Reality condom among women who were less educated and who had not used male condom before. In spite of higher acceptability score, participants were less confident about the Reddy condom for protecting them from HIV disease or pregnancy as compared to a male condom. Female condoms are being introduced in India. This study has generated data that is suggestive of optimism for this female controlled option.

Spizzichino L, Pedone G, Gattari P, et al. The female condom: knowledge, attitude, and willingness to use. The first Italian study. Annali Dell'Istituto Superiore di Sanita. 2007;43(4):419-424.

Women account for nearly half the people living with HIV worldwide. This situation makes it necessary to improve prevention actions targeting women: the female condom is a good option. The study was conducted, the first in Italy, in a public AIDS Center on a sample of 162 participants (66.7% female, 33.3% men) who requested the HIV test. The objectives were: assess the current knowledge of the female condom; collect information on opinions, impressions and willingness to use the female condom. Participants were administered a Lickert-scale questionnaire after post-test counseling. The results are in line with international studies and show an early positive response, characterized by interest and openness to innovation, followed by resisting to use the female condom.

Surratt HL, Wechsberg WM, Cottler LB, et al. Acceptability of the female condom among women at risk for HIV infection. American Behavioral Scientist. 1998; 41(8):1157-1170.

Few HIV/AIDS educational programs have been tailored specifically for women, and most have promoted methods requiring the full participation and cooperation of male partners. This study introduced drug-involved women to the female condom – a female-controlled method of protection from HIV and other sexually transmitted diseases. The primary aim was to assess the acceptability of this new device among high-risk women in St. Louis, San Antonio, and Rio de Janeiro. All respondents participated in a female condom education program, were asked to try the condom, and to report their experiences at two points of contact. Outcome data indicated that a sizable proportion of the women followed up used the female condom during vaginal sex on one or more occasions. In addition, many women also preferred the female condom to the male condom in terms of overall satisfaction, suggesting that there is a viable role for this device in the HIV prevention field.

Telles Dias PR, Souto K, Page-Shafer K. Long-term female condom use among vulnerable populations in Brazil. AIDS and Behavior. 2006;10(Supp. 7):67-75.

We carried out an evaluative study on factors associated with long-term use of female condoms for STI/HIV prevention. A total of 255 women and 29 men who were using female condoms for at least 4 months participated in qualitative/quantitative interviews. The study was conducted in six Brazilian cities. Four primary themes were identified as influencing acceptability and adoption of the female condom: (1) personal "assistance" (counseling) during the early adoption phase; (2) safety; (3) pleasure; and (4) increased sense of power for safer sex negotiation. Alternate use of male and female condoms was the norm among participants, but for approximately one third of the sample, the female condom was the preferred option for safer sex. The study findings suggest that providing clients with explicit and sustained intervention strategies may have a decisive influence on long-term adoption of female condoms.

Torres MI, Tuthil R, Lyon-Callo S, et al. Focused female condom education and trial: Comparison of young African American and Puerto Rican women's assessments. International Quarterly of Community Health Education. 1998-1999;18(1):49-68.

This article compares the experience of young African-American and Puerto Rican women with the female condom during a thirty-day trial period by examining qualitative data from participant observations and in-depth interviews conducted at the end of the trial. Research was funded by CDC and conducted in two neighborhood health centers in the city of Springfield, Massachusetts. Salient findings identify inter-group similarities and differences in the local sociocultural community context in which African-American and Latina young women considered using the female condom as a method of protection against unplanned pregnancy and sexually transmitted infections, including HIV, adopted strategies to introduce and negotiate the device with male partners, and communicated

their experiences in post-trial interviews. Inter-group diversity is highlighted in community structures for promoting sexual health protection, and in women's patterns of communication, descriptions of their male partner's reactions to the device and trial activities and suggestions for health education focused on the female condom. Potential implications of these findings for future research and interventions in multicultural communities are also discussed.

Welbourn A. Sex, life and the female condom: Some views of HIV positive women. Reproductive Health Matters. 2006;14(28):32-40.

This article offers some insights into the experiences of HIV positive women with the female condom, drawing on my own personal experience and responses of 18 members of the International Community of Women Living with HIV/AIDS to an e-mail survey conducted in 2005. Major barriers reported to female condom use were cost and sporadic or very limited access. All respondents talked about needing to negotiate the use of female condoms with their male sex partners. Most felt more in control and more confident during sex when using the female condom than with the male condom or unprotected sex. Concerns about female condoms appear to be common, especially among women who have never used one; those who had used the female condom for long periods of time said good things about it. Women reclaiming our bodies is a central part of the joy and the challenge of promoting the female condom. For HIV positive women and girls, using a condom is more than protection against pregnancy, but a matter of life and death greater than the risks pregnancy can bring. Female condoms could make a critically important contribution to protecting HIV positive women's sexuality and continued sexual activity, as a fundamental part of our sexual and reproductive rights, if only they were more widely available and affordable.

Witte SS, El-Bassel N, Wada T, et al. Acceptability of female condom use among women exchanging street sex in New York City. International Journal of STD and AIDS. 1999;10(3):162-168.

Greater access to alternative female-initiated barrier methods, such as the female condom, is needed among women exchanging street sex. This study describes knowledge of and experience with the female condom among 101 women exchanging sex for money and drugs on the streets of New York City, and examines the acceptability of female condom use as an alternative barrier method for HIV/STD prevention among this population. Female condom use among this sample of sex workers was found to be related to having a regular sexual partner, living with someone who is a drug or alcohol abuser, not being homeless, using alcohol or intravenous heroin, having heard of the device, and having discussed the device with other women or with a regular sexual partner. Despite decreased acceptability post-use, most sex workers indicated an intention for future female condom use.

Witte SS, Wada T, El-Bassel N, et al. Predictors of female condom use among women exchanging street sex in New York City. Sexually Transmitted Diseases. 2000;27(2):93-100.

Alternative female-initiated barrier methods, such as the female condom, are needed among women exchanging street sex to enhance their ability to protect themselves from HIV and STD infection. To describe predictors of female condom use among 96 women exchanging sex for money and drugs on the streets of New York City. A total of 113 sex workers received a baseline interview, a demonstration on proper female condom use, and 10 female condoms. A total of 101 sex workers received a followed-up evaluation at 2 weeks, of which 96 were included in data analysis. Predictors of condom use were analyzed for (1) any type of use; and (2) use with commercial partners. The strongest predictors of female condom use among this sample of sex workers were (1) living with someone with a drug or alcohol problem; (2) having heard of the female condom; and (3) homelessness. Current physical or sexual abuse by a commercial partner and marriage decreased the probability of female condom use. Female condom distribution encouraged sex workers who may be most vulnerable or who reported characteristics or behaviors associated with the highest sexually transmitted disease and HIV risk to try female condoms with commercial partners. Implications for intervention development include the need to develop innovative programs provided on the street (e.g., through peers) that can access homeless, drug-using sex workers in the most at-risk environments.

Xu JX, Leeper MA, Wu Y, et al. User acceptability of a female condom (Reality) in Shanghai. Advances in Contraception. 1998;14(4):193-199.

Thirty married couples evaluated the Reality female condom on questionnaires about its acceptability for 300 acts of coitus (10 per couple). An analysis of the summary questionnaires showed: 90% of couples considered the female condom an acceptable method and 87% felt it was a good contraceptive device; the majority of couples (87%) found it easy to use; and 80% of females and 73% of males reported that, in comparison with the male condom, the effect on sexual pleasure was either improved or no different. A little more than half of the couples (55%) preferred it to male condoms. To look at the learning curve effect, an additional analysis was completed by pooling the first 5 applications of each user and comparing the results with the pooled results of the second 5 uses. All the findings suggest that a certain proportion of couples of childbearing age will choose the Reality female condom for contraception if it enters into the Chinese market. As a new contraceptive barrier device, the female condom may require a certain amount of education and awareness before it will be fully recognized as an important option to help prevent pregnancy as well as sexually transmitted infections.

Zachariah R, Harries AD, Buhendwa L, et al. Acceptability and technical problems of the female condom amongst commercial sex workers in a rural district of Malawi. Tropical Doctor. 2002;33(4):220-224.

A study was conducted among commercial sex workers (CSWs) in rural southern Malawi, in order to (a) assess the acceptability of the female condom and (b) identify

common technical problems and discomforts associated with its use. There were 88 CSWs who were entered into the study with a total of 272 female condom utilizations. Eighty-six (98%) were satisfied with the female condom, 80% preferred it to the male condom and 92% were ready to use the device routinely. Of all the utilizations, the most common technical problem was re-use of the device with consecutive clients, 6% after having washed it, and 2% without any washing or rinsing. The most common discomforts that were reported included too much lubrication (32%), device being too large (16%), and noise during sex (11%). This study would be useful in preparing the introduction of the female condom within known commercial sex establishments in Malawi.

See Also:

COMMENTARY/LITERATURE REVIEWS: Brown H. The Female Condom: Women control STI protection. Population Reference Bureau, March, 2003.

COMMENTARY/LITERATURE REVIEWS: Cecil H, Perry MJ, Seal DW, et al. The female condom: What we have learned thus far. AIDS and Behavior. 1998;2(3):241-256.

COMMENTARY/LITERATURE REVIEWS: Elias CJ, Coggins C. Female-controlled methods to prevent sexual transmission of HIV. AIDS. 1996;10(Suppl. 3):S43-S51.

COMMENTARY/LITERATURE REVIEWS: Gilbert LK. The Female Condom (FC) in the US: Lessons learned. Female Health Foundation, 1999.

COMMENTARY/LITERATURE REVIEWS: Lamptey P, Schwarzwalder A, Ankrah EM, et al. The female condom: From research to the marketplace. Arlington, Virgina: Family Health International, 1997.

COMMENTARY/LITERATURE REVIEWS: Mantell JE, Dworkin SL, Exner TM, et al. The promises and limitations of female-initiated methods of HIV/STI protection. Social Science and Medicine. 2006;63 (8):1998-2009.

EFFICACY: Trussell J. Contraceptive efficacy of the Reality® female condom. Contraception. 1998;58(3):147-148.

NEGOTIATION WITH PARTNERS: Choi KH, Wojcicki J, Valencia-Garcia D. Introducing and negotiating the use of female condoms in sexual relationships: Qualitative interviews with women attending a family planning clinic. AIDS and Behavior. 2004;8(3):251-261.

NEGOTIATION WITH PARTNERS: Penman-Aguilar A, Hall J, Artz L, et al. Presenting the female condom to men: A dyadic analysis of effect of the woman's approach. Women and Health. 2002;35(1):37-51.

NEGOTIATION WITH PARTNERS: Rivers K, Aggleton P, Elizondo J, et al. Gender relations, sexual communication and the female condom. Critical Public Health. 1998;8(4):273-290.

RE-USE: Pettifor AE, Beksinska ME, Rees HV, et al. The acceptability of reuse of the female condom among urban South African women. Journal of Urban Health: Bulletin of the New York Academy of Medicine. 2001;78(4):647-657.

USE BY MEN WHO HAVE SEX WITH MEN (MSM): Gibson S, McFarland W, Wohlfeiler D, et al. Experiences of 100 men who have sex with men using the Reality® condom for anal sex. AIDS Education and Prevention. 1999;11(1):65-71.

USE BY MEN WHO HAVE SEX WITH MEN (MSM): Gross M, Buchbinder SP, Holte S, et al. Use of Reality "Female Condoms" for anal sex by US men who have sex with men. American Journal of Public Health. 1999;89(11):1739-1741.

USE BY MEN WHO HAVE SEX WITH MEN (MSM): Renzi C, Tabet SR, Stucky JA, et al. Safety and acceptability of the Reality condom for anal sex among men who have sex with men. AIDS. 2003;17(5):727-731.

II. COMMENTARY/LITERATURE REVIEWS

Brown H. The Female Condom: Women control STI protection. Population Reference Bureau, March, 2003.

Although women make up almost half of all people infected with HIV worldwide and 58 percent in sub-Saharan Africa, they have limited options for preventing infection. Women are biologically more vulnerable to transmission from an infected partner than men are. More important, economic, social, and cultural disempowerment means that the current HIV prevention strategies of abstinence, monogamy, condom use, fewer partners, and treatment of sexually transmitted infections (STIs) are not feasible for many women, since they often lack the ability to negotiate safe sex. There is, therefore, an urgent need for HIV prevention strategies that give women greater control. The female condom is the only female-controlled safe-sex method available. While this method is effective and relatively well-accepted by women, its usefulness is limited by cost, men's negative attitudes, its contraceptive properties, and practical aspects of its use. The female condom is a lubricated polyurethane sheath with a flexible ring on each end. One ring covers the cervix like a diaphragm; the other remains outside, partly covering the labia. More than 70 countries have approved its use, including the United States in 1993, Zimbabwe in 1996, and Ghana in 2000.

Brown S, Wimberly Y. Reducing HIV/AIDS transmission among African-American females: Is the female condom a solution? Journal of the National Medical Association. 2005;97(10):1421-1423.

The fastest growing number of HIV/AIDS cases in the United States occur in minority women. The majority of women infected with HIV (approximately 69%) are African Americans. According to the Centers for Disease Control and Prevention, the most frequently reported mode of infection for women is heterosexual transmission. Studies have also shown that both male and female condoms are an effective, though not absolute, mode of prevention against the transmission of HIV/AIDS. Despite this well-known fact, female condoms are underutilized and viewed by some as an unreasonable option in the fight against HIV/AIDS.

Cecil H, Perry MJ, Seal DW, et al. The female condom: What we have learned thus far. AIDS and Behavior. 1998;2(3):241-256.

High rates of sexually transmitted diseases (STDs), including HIV, and unplanned pregnancies persist in the United States. Women are more likely than men to be infected with an STD and to bear the burdens associated with unplanned pregnancies and with STD-associated complications. Condom use is advocated for sexually active individuals. However, for some persons condom use remains infrequent and inconsistent; this is particularly true for women, who may face substantial barriers (e.g., partner aggression) to enacting consistent condom use. The female condom is the only female-controlled barrier method currently available to protect women from STDs and unplanned pregnancies. In this paper, we review and summarize the literature on the female

condom with regard to efficacy, use-effectiveness, and acceptability among potential and current users. In addition, we identify gaps in the literature and suggest paths for future research.

Elias CJ, Coggins C. Female-controlled methods to prevent sexual transmission of HIV. AIDS. 1996;10(Suppl. 3):S43-S51.

Women throughout the world face a growing risk of infection with HIV. Consistent condom use, one cornerstone of primary prevention strategy, is not always feasible for many women. Consequently, women urgently need infection prevention technology that is within their personal control. This session will review current efforts to develop and test female-controlled methods for preventing sexual transmission of HIV and other sexually transmitted pathogens. Both physical and chemical methods will be summarized, including recent findings concerning the efficacy and acceptability of the vaginal pouch (female condom), as well as an overview of research on vaginal microbicides. Data from studies of existing over-the-counter spermicides will be reviewed. The wide range of novel microbicidal products currently being evaluated in the laboratory and early clinical trials demonstrate the breadth of possibilities presented by chemical barrier methods. However, formidable challenges face public and private sector research and development efforts. This session will conclude by highlighting several issues related to the clinical evaluation and introduction of female-controlled prevention technology.

Gilbert LK. The Female Condom (FC) in the US: Lessons learned. Female Health Foundation, 1999.

The female condom (FC) has been available in the United States, the United Kingdom and certain European countries for approximately four years. Over the past two years, with the support and encouragement of the United Nations Global programme on AIDS (UNAIDS) and the World Health Organization, FC has been gradually introduced into prevention programs of various developing countries where the AIDS epidemic is rampant, including Zimbabwe, Zambia, Uganda and South Africa, among others. Much work has been done to evaluate the efficacy and acceptability of FC around the world. This monograph is a review of the literature on FC studies, particularly in the U.S., through the fall, 1998. It provides a ready reference for counselors, trainers, health care providers, educators, governments, donors and others interested in learning about the female condom as an important contribution to Global Public Health in terms of prevention of sexually transmitted infections and diseases, including HIV/AIDS, and unintended pregnancy.

Gollub EL. The female condom: Tool for women's empowerment. American Journal of Public Health. 2000;90(9):1377-1381.

International and US experience with the female condom has shown that the device empowers diverse populations of women, helping them negotiate protection with their partners, promoting healthy behaviors, and increasing self-efficacy and sexual confidence

and autonomy. This commentary reflects on some approaches that have been taken to study empowerment and makes several observations on the political and scientific initiatives needed to capitalize on this empowerment potential. Women's interest in the female condom indicates a need for more women's barrier methods to be made available. For some women, cultural proscriptions against touching the genitals may create initial hesitancy in trying these methods. But the disposition of regulatory agencies and the attitudes of health care providers has unfortunately exaggerated this reticence, thereby effectively reducing access to these methods. Also, lack of important detail in clinical studies restricts our capacity to introduce the female condom, or similar methods, under optimal conditions. Future trials should prioritize community-based designs and address a range of other critical health and social issues for women. Women's need for HIV/AIDS prevention technologies remains an urgent priority. Both political and scientific efforts are needed to realize the public health potential embodied in the female condom.

Hatzell T, Feldblum PJ, Homan RK, et al. The Female Condom: Is "Just as Good" good enough? Sexually Transmitted Diseases. 2003;30(5):440-442.

Evidence supporting the effectiveness of the female condom has accumulated steadily in the past decade. Is it finally sufficient to convince the majority of public health policy makers to invest in the method? The answer appears to be "not yet." Public sector and donor support for female condom distribution is still weak in most countries facing the full enormity of the HIV/AIDS epidemic. What will it take to convince more decision makers of the value of including the female condom among the relatively few options currently available for the primary prevention of HIV and other STIs? The results reported by French and colleagues in this issue may move reluctant decision makers in the right direction. The study edges towards a head-to-head comparison of the effectiveness of male and female condoms in preventing new infections. Study participants were randomly assigned to one of two study arms: one receiving training, support, and supplies for male condom use; the other similarly equipped for female condom use. Unavoidably, the latter group had access to male condoms outside the clinic, as they are widely available in the urban setting in which the study was conducted. As male condoms are the standard of STI prevention for sexually active persons, it is entirely appropriate that the investigators did not discourage participants in the female condom arm from using male condoms during the study. Since women in the female condom group and used male condoms to an unknown degree, the results cannot be construed as a direct comparison of the efficacy of the two devices. Rather, it is a comparison of the effectiveness of two prevention programs, one with and one without female condoms.

Hoffman S, Mantell J, Exner T, et al. The future of the female condom. Perspectives on Sexual and Reproductive Health. 2004;36(3):120-126.

More than 10 years have elapsed since the female condom became widely available, and it remains the only female-initiated means of preventing both pregnancy and sexually transmitted diseases (STDs), including HIV infection. The female condom was

developed as an alternative to the male condom, and it was hailed as a method that would enable women to have greater control over their own protection from disease. With the support of the Joint United Nations Programme on HIV/AIDS (UNAIDS), public and private funders, and the manufacturer, more than 90 developing countries have introduced the method through public distribution, social marketing campaigns or commercial outlets. In several countries that have actively promoted its use, such as South Africa, Brazil, Ghana and Zimbabwe, steadily increasing female condom sales to the government suggest that effective programs can generate demand.

Kaler A. "It's some kind of women's empowerment": the ambiguity of the female condom as a marker of female empowerment. Social Science and Medicine. 2001;52(5):783-796.

The female condom is the latest in a series of sexual and reproductive technologies to be imported into the third world, following the contraceptive pill, the Depo-Provera injection, the latex male condom, and others. It is an example of "traveling technology", which accrues different meanings and connotations in the different settings into which it is introduced in its journey through the circuits of international technological diffusion, from the headquarters of international NGOs and bilateral aid programs, through the bureaucracies of national ministries of health to the communities in urban and rural settings where the condoms are distributed. The female condom almost always carries connotations of women's empowerment, and the possibility of greater sexual autonomy for women. This association is a result of the female condom being the first new "post-Cairo" technology, the diffusion of which was spurred by the consensus reached at the 1994 International Conference on Population and Development in Cairo, at which the need to promote women's empowerment was moved to the center of international family planning and population movements. However, I demonstrate that "empowerment" is an ambiguous term, interpreted in different ways in different contexts. I illustrate this through interviews conducted in 1998 and 1999 with stakeholders in the female condom in Cape Town, Nairobi, and in rural western Kenya. These stakeholders range from directors of US-based development programs to heads of national AIDS-prevention efforts to community-based distributors and primary health care nurses at the village level. I argue that three different notions of empowerment are being articulated with respect to the female condom – two which correspond to Maxine Molyneux's typology of strategic and practical gender interests, and a third in which women's empowerment is conceived of as something which diminished the power of men. I argue further that the disjunctures between these three different notions of what "empowerment" means will pose a challenge for people at all levels which are seeking to make the female condom more widely accessible to women at risk of HIV/AIDS.

Kaler A. The future of female-controlled barrier methods for HIV prevention: Female condoms and lessons learned. Culture, Health and Sexuality. 2004;6(6): 501-516.

In the context of HIV/AIDS, there is increasing interest in female controlled barrier methods. HIV prevention suffers from a critical 'technology gap': namely, the lack of

products to enable women to reduce their own risk of sexually transmitted infection, independent of their male partners. An ideal technology should be low-cost, free of side effects, effective against both HIV and other STIs, and undetectable by male sexual partners. A first generation of barriers is already in circulation: namely, female condoms (FCs). But what can we learn from FCs that will help to increase the chance that programmes focused on other barrier methods will be successful? This paper draws on lessons from the past decade of FC programming. Interviews with 34 professional stakeholders in FC programming from the USA and South Africa highlight a number of factors that can help create public and institutional cultures, in which barrier methods can be considered feasible and can be put into use.

Lamptey P, Schwarzwalder A, Ankrah EM, et al. The female condom: From research to the marketplace. Arlington, Virgina: Family Health International, 1997.

Many women around the world have made it clear that they want the female condom. In acceptability studies and other types of introductory research, women and their partners have repeatedly said they would keep using the female condom if it were available. This overriding message emerged from the two-day working conference, "The Female Condom: From Research to the Marketplace," held May 1 and 2, 1997, in Arlington, VA. Family Health International's AIDS Control and Prevention (AIDSCAP) Project sponsored and coordinated the conference through its Women's Initiative, with funding from the U.S. Agency for International Development (USAID). The more than 130 participants from 19 countries included experts from service programs, research projects, governments, women's advocacy groups, manufacturers and product developers, marketing experts and the donor community. The conference explored unresolved issues surrounding the female condom and ways to increase its availability, especially to women in the developing world. The female condom offers women a way to protect themselves from sexually transmitted disease (STD) and unintended pregnancy. Research has shown it to be safe, effective if used consistently and correctly, in demand and acceptable to many women and men. While it is not yet generally available, affordable, promoted or marketed to full scale, it has been approved for sale in a growing number of countries at a public price. Conference participants identified cost as a major barrier to widespread availability of the female condom. To bring the device to the marketplace, it was agreed, the private sector is one important option to pursue. Another critical issue is funding from donors, who must coordinate their efforts effectively, efficiently and as expeditiously as possible where HIV/AIDS prevention is concerned. The public health community, women's organizations, the private sector and governments need to address the individual and societal factors that put women at risk of STDs. Specifically, these groups should provide women with a method over which they have some control to prevent STDs and unintended pregnancy.

Latka M. Female-initiated barrier methods for the prevention of STI/HIV: Where are we now? Where should we go? Journal of Urban Health: Bulletin of the New York Academy of Medicine. 2001;78(4):571-580.

The female condom has been on the US market for over 8 years and was hailed as a method that would allow women greater control in protecting themselves against unwanted pregnancy and sexually transmitted infections. However, since its launch, promotion of the female condom has met with challenges that vary from provider bias against the device, concerns about efficacy, and doubts about whether it will be used. While daunting, many of these challenges are not unique to the female condom. In fact, they parallel those of the tampon when it was first promoted in the US or menstrual hygiene in the early 1930s. Many providers were initially opposed to the tampon; early users found the tampon inadequate. Ten years after the introduction of the tampon and despite mass marketing, acceptability was mixed and use was modest (25% prevalence in a 26-city survey). Similar to female condom use observed in current-day prospective studies, users did not use the tampon exclusively or even predominantly. The story of the tampon demonstrates that a method does not have to be adopted by all users immediately to play an important role, and that even initially controversial methods can become widely accepted as mainstream. The early history of the tampon sheds perspective, and hope, on where we stand with the female condom. While much-needed work is under way to develop microbicides, we should take advantage of the fact that the female condom is already available and promote it to those in need now.

Mantell JE, Dworkin SL, Exner TM, et al. The promises and limitations of female-initiated methods of HIV/STI protection. Social Science and Medicine. 2006;63 (8):1998-2009.

New methods are now available, and others are being developed, that could enable women to take the initiative in preventing sexually transmitted infections. However, attempts to capitalize on "female-controlled" preventive methods thus far have met with limited success. Female-initiated methods were introduced to intervene in the state of gender relations and assist women who are disempowered vis-à-vis their male partners. Paradoxically, however, we underscore that it is the very structure of regional and local gender relations that shapes the acceptability (or lack of acceptability) of these methods. This paper specifically addresses how the structure of gender relations – for better and for worse – shapes the promises and limitations of widespread use and acceptance of female-initiated methods. We draw on examples from around the world to underscore how the regional specificities of gender (in) equality shape the acceptance, negotiation, and use of these methods. Simultaneously, we demonstrate how the introduction and sustained use of methods are shaped by gender relations and offer possibilities for reinforcing or challenging their current state. Based on our analyses, we offer key policy and programmatic recommendations to increase promotion and effective use of women-initiated HIV/STI protection methods for both women and men.

Mauck CK, Weaver MA, Schwartz JL, et al. Critical next steps for female condom research – report from a workshop. Contraception. 2009;79(5):339-344.

In addition to a standard slippage and breakage study, the United States Food and Drug Administration (USFDA) currently requires a contraceptive effectiveness trial to be carried out as part of the pathway to regulatory approval for new female condoms. In an attempt to explore acceptable alternatives to expensive and resource-consuming Phase 3 contraceptive effectiveness trials, the United States Agency for International Development (USAID) recently requested that CONRAD organize a 1-day meeting of investigators in the female condom and semen biomarker fields. The charge to the group was to devise a study design that would validate a biomarker against a biological end point, such as pregnancy or a sexually transmitted infection (STI), so that the validated marker could be used to augment a slippage and breakage study for approval of new female condoms, eliminating the need for the currently required contraceptive effectiveness trial.

Sakondhavat C. Challenges to female condom integration into condom programming. International Journal of STD and AIDS. 2002;13(7):444-448.

Condoms are a highly effective means of preventing human immunodeficiency virus (HIV) transmission and their use is increasing in many parts of the world. Currently, the only widely-available effective method to prevent the heterosexual transmission of HIV is the use of male condoms. However, even where HIV prevalence is high, as is the case in some developing countries, condom promotion projects, involving constant condom availability and regular counseling, have been unable to attain levels of use about 70% except in limited targeted populations.

See Also:

ACCEPTABILITY/FACTORS AFFECTING USE: Ruminjo JK, Steiner M, Joanis C, et al. Preliminary comparison of the polyurethane female condom with the latex male condom in Kenya. East African Medical Journal. 1996;73(2):101-106.

EFFICACY: Minnis AM, Padian NS. Effectiveness of female controlled barrier methods in preventing sexually transmitted infections and HIV: Current evidence and future research directions. Sexually Transmitted Infections. 2005;81(3):193-200.

PROMOTION: Kaler A. The female condom in North America: Selling the technology of 'empowerment'. Journal of Gender Studies. 2004;13(2):139-152.

PROMOTION: Warren M, Philpott A. Expanding safer sex options: Introducing the female condom into national programmes. Reproductive Health Matters. 2003;11(21):130-139.

III. EFFICACY

Beksinska M, Joanis C, Manning J, et al. Standardized definitions of failure modes for female condoms. Contraception. 2007;75(4):251-255.

Definitions of male condom failure modes are now well documented, and failure events are usually reported as the proportion of the total number of condoms used and the proportion of men/couples who experience an event. The lack of standardized definitions for female condom (FC) failure has led to variability in reporting and hence difficulties in making comparisons across studies. As a result, the World Health Organization convened a technical review committee meeting in January 2006 through which the members compiled and agreed to a standard list of terms and definitions for each of the failure modes. These failure modes apply to FCs currently marketed or in advanced stages of clinical testing. They were designed to assist in the review and comparative assessment of different FCs.

Beksinska M, Smit J, Mabude Z, et al. Performance of the Reality® polyurethane female condom and a synthetic latex prototype: A randomized crossover trial among South African women. Contraception. 2006;73(4):386-393.

This multisite, randomized, crossover trial comparing the performance of the Reality® female condom (FC1) with a new synthetic latex prototype (FC2) was conducted in Durban, South Africa. In total, 276 women were enrolled and 201 women completed the study. Altogether, 1910 FC1 condoms and 1881 FC2 condoms were used. Total breakage was 0.73% in FC1 and 0.85% in FC2 (95% confidence interval, -0.64 to 0.87). The number of clinical breakages (those that could result in a pregnancy or sexually transmitted infection) was similar for each condom type (FC1, n=9; FC2, n=8). Incorrect penetration (penis between condom and vaginal wall) was 1.26% and 0.64% for FC1 and FC2, respectively. Outer ring displacements (outer ring pushed into the vagina partially or fully) were comparable for both condoms (FC1, 3.14%; FC2, 2.98%). Slippage (condom came out of the vagina) was rare and reported in 0.37% or less of devices used. Total clinical failure was 5.24% in FC1 and 4.3% in FC2. The FC1 and FC2 performed comparably within this trial.

Choi KH, Hoff C, Gregorich SE, et al. The efficacy of female condom skills training in HIV risk reduction among women: A randomized controlled trial. American Journal of Public Health. 2008;98(10):1841-1848.

We evaluated the efficacy of skills training designed to increase female condom use among women. We conducted randomized controlled trial of 409 women, recruited from family planning clinics in northern California, who were randomly assigned to the experimental 4-session female condom skills training intervention or the comparison 4-session women's general health promotion intervention. Participants received condom use instructions at baseline and male and female condoms during the study. They completed audio computer-assisted self-interviews at baseline and at 3 and 6 months. At 3 and 6 months, women in the experimental group were more likely than those in the

comparison group to have used the female condom at least once in the prior 3 months. The increase in the percentage of sexual acts protected by female condoms from baseline to the 6-month follow-up was greater for the experimental group. The percentage of sexual acts during which any condom was employed was higher in the experimental group at 6 months. There were no group differences in male condom use. Outcomes suggest that skills training can increase female condom use and protected sexual acts without reducing male condom use among women.

Feldblum PJ, Bwayo JJ, Kuyoh M, et al. The female condom and STDs: Design of a community intervention trial. Annals of Epidemiology. 2000;10(6):339-346.

The main purpose of this study is to compare sexually transmitted disease (STD) prevalence in cohorts of women with and without access to female condoms. Six matched pairs of communities were identified from Kenya tea, coffee and flower plantations. One community within each pair was randomly selected to receive the female condom intervention. Approximately 160 eligible women were enrolled at each site. Female condom communities underwent an education program on use of female and male condoms and STDs, comprising group meetings, puppetry and other folk media, and training of clinic service providers and community outreach workers. Control communities received similar information on use of male condoms (freely available at all sites). At baseline, participants were tested for cervical gonorrhea and chlamydia and vaginal trichomoniasis, to be repeated at 6 and 12 months. The study has 80% power to detect a 10% prevalence difference, assuming an aggregate STD prevalence of 20% with 25% loss to follow-up and intracluster correlation of 0.03. Among 1929 women at baseline, the mean age was 33.1 years; 78% had never used a male condom. The prevalences of gonorrhea, chlamydia and trichomoniasis were 2.6%, 3.2% and 20.4%, respectively (23.9% overall). The intracluster correlation based on these data was near zero. Comparable pairs of study sites have been selected. STD prevalence is sufficiently high, and the variation between sites is acceptably low. The study is feasible as designed.

Feldblum PJ, Kuyoh MA, Bwayo JJ, et al. Female condom introduction and sexually transmitted infection prevalence: Results of a community intervention trial in Kenya. AIDS. 2001;15(8):1037-1044.

The objective of this study was to measure the impact on sexually transmitted infection (STI) prevalence of a female condom introduction and risk-reduction program at Kenyan agricultural sites. The authors conducted a cluster-randomized trial to determine whether a replicable, community-level intervention would reduce STI prevalence. Six matched pairs of tea, coffee and flower plantations were identified. The six intervention sites received an information/motivation program with free distribution of female and male condoms, and six control sites received only male condoms and related information. Participants were tested for cervical gonorrhea and chlamydia by ligase chain reaction on urine specimens, and vaginal trichomoniasis by culture, at baseline, 6 and 12 months. Participants at intervention (n=969) and control sites (n=960) were similar; baseline STI prevalence was 23.9%. Consistent male condom use was more than 20% at 12 months. Consistent female condom use was reported by 11 and 7% of intervention site women at

6 and 12 months. Unadjusted STI prevalence was 16.5 and 17.4% at 6 months, and 18.3 and 18.5% at 12 months, at the intervention and control sites, respectively. Logistic regression models confirmed the null effect of the female condom intervention. Female condom introduction did not enhance STI prevention at these sites. It is unclear which aspects of the intervention – STI education, condom promotion, case management – were associated with decreased STI prevalence from baseline to follow-up.

Feldblum PJ, Kuyoh M, Omari M, et al. Baseline STD prevalence in a community intervention trial of the female condom in Kenya. Sexually Transmitted Infections. 2000;76(6):454-456.

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

Fontanet AL, Saba J, Chandelying V, et al. Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: Results from a randomized controlled trial. AIDS. 1998;12(14):1851-1859.

The male condom is the most effective barrier method available for protection against sexually transmitted diseases (STDs), including HIV infection. There is an urgent need to develop and evaluate other prevention methods, such as the female condom. This study estimated the additional protection against STDs offered to sex workers by giving them the option of using the female condom when clients refused to use a male condom. Sex establishments in four cities in Thailand were randomized into two study groups: one in which sex workers were instructed to use male condoms consistently (male condom group); and one in which sex workers had the option of using the female condom

if clients refused or were not able to use male condoms (male/female condom group). Randomization was done by sex establishments, and not by individuals, to minimize sharing of female condoms across study groups. The proportion of unprotected sexual acts (defined as sexual acts in which condoms were not used, tore, or slipped in or out) and incidence rate of STDs (gonorrhea, chlamydial infection, trichomoniasis and genital ulcer disease) were measured over a 24-week period and compared between the two study groups. Results are available from 34 sex establishments (249 women) in the male/female condom group, and 37 sex establishments (255 women) in the male condom group. Condom use was very high in both groups (97.9 and 97.3% of all sexual acts, respectively, $P > 0.05$). Male condom use was lower in the male/female condom group when compared with the male condom group (88.2 and 97.5%, respectively, $P < 0.001$). However, this reduction in male condom use was counterbalanced by the use of female condoms in 12.0% of all sexual acts in the male/female condom group, contributing to a 17% reduction in the proportion of unprotected sexual acts in this group when compared to the male condom group (5.9 versus 7.1%, respectively, $P = 0.16$). Female condom use was sustained over the entire study period. There was also a 24% reduction in the weighted geometric mean incidence rate of STDs in the sex establishments of the male/female condom group compared to the male condom group (2.81 versus 3.69 per 100 person-weeks, $P = 0.18$).

French PP, Latka M, Gollub EL, et al. Use-effectiveness of the female versus male condom in preventing sexually transmitted disease in women. Sexually Transmitted Diseases. 2003;30(5):433-439.

Data are limited on the female condom's effectiveness against STDs. The goal was to compare STD rates between women given small-group education on, and free supplies of, either female or male condoms. Female patients at an STD clinic (n = 1442) were randomly assigned to condom type and followed via medical records for STDs (gonorrhea, chlamydia, early syphilis, or trichomoniasis). In an intention-to-treat analysis, the odds ratio for a comparison of STD occurrence between the female and male condom groups was 0.75 (95% confidence interval [CI], 0.56-1.01), and it did not change with adjustment. In a second analysis among women returning for subsequent screening, incidence rates for the first new postintervention STD per 100 woman-months of observation were 6.8 in the female condom group and 8.5 in the male condom group (rate ratio = 0.79 [CI, 0.59 – 1.06]). Compared with those provided with male condoms alone, women counseled on, and provided with, female condoms fared no worse and experienced a nonsignificant reduction in STDs.

Galvao LW, Oliveira LC, Diaz J, et al. Effectiveness of female and male condoms in preventing exposure to semen during vaginal intercourse: a randomized trial. Contraception. 2005;71(2):130-136.

Comparison of male condom (MC) vs. female condom (FC) with respect to self-reported mechanical and acceptability problems and semen exposure using prostate-specific antigen (PSA) as an objective biological marker and evaluation of the effect of an educational intervention on self-reported problems and semen exposure, by condom type.

Four hundred women attending a family planning clinic in Brazil were randomized and either received in-clinic instruction or were encouraged to read the condom package insert; all used two FCs and two MCs. We measured the rates of self-reported user problems with MC and FC use and the rates of semen exposure during use (assessed by testing vaginal fluid for PSA). The educational intervention group reported fewer problems with either condom as compared with the control group ($p = .0004$, stratified by condom type). In both groups, self-reported problems were more frequent with FC use than with MC use ($p < .0001$, stratified by intervention). The educational intervention did not significantly reduce semen exposure. Overall, semen exposure occurred more frequently with FC use (Postcoital PSA, > 1ng/mL; 22%) than with MC use (15%); the difference, however, was small and nonsignificant for high PSA levels ($\geq$ 150 ng/mL; 5.1% for FC vs. 3.6% for MC). In this study, the FC was less effective than the MC in preventing semen exposure during use and led more frequently to self-reported user problems. Both devices were highly protective against "high-level" semen exposure, as measured by postcoital PSA levels in vaginal fluid. In-clinic education may reduce user problems and increase acceptability and use of both devices.

Hoke TH, Feldblum PJ, Van Damme K, et al. Temporal trends in sexually transmitted infection prevalence and condom use following introduction of the female condom to Madagascar sex workers. International Journal of STD and AIDS. 2007;18(7):461-466.

We followed 1000 sex workers in Madagascar for 18 months to assess whether adding female condoms to male condom distribution led to increased protection levels and decreased sexually transmitted infections (STIs). For months 1-6, participants had access to male condoms only; in the final 12 months, they had access to male and female condoms. We interviewed participants about condom use every two months and tested for Chlamydia, gonorrhoea and trichomoniasis every six months. Following six months of male condom distribution, participants used protection in 78% of sex acts with clients. Following female condom introduction, protection at months 12 and 18 rose to 83% and 88%, respectively. Aggregate STI prevalence declined from 52% at baseline to 50% at month 6. With the female condom added, STI prevalence dropped to 41% and 40% at months 12 and 18, respectively. We conclude female condom introduction is associated with increased use of protection to levels that reduce STI risk.

Holmes L, Ogungbade GO, Ward DD, et al. Potential markers of female condom use among inner city African-American Women. AIDS Care. 2008;20(4):470-477.

Despite the availability of the female condoms and theoretically based interventions to promote its use, studies have indicated a low level of acceptability of their use among women in most populations. We aimed to determine female condom use prevalence and the potential markers among African-American women. In an intervention trial to test the efficacy of the Information-Motivation-Behavioral Skills model in increasing condom use, we utilized the baseline data of 280 subjects and examined the potential predictors of female condom use. Chi square statistic and unconditional logistic regression were used to test for group independence among users and non-users of the female condom and to

assess the potential markers of female condom use respectively. After adjustment for relevant covariates associated independently with female condom use, the significant potential markers for female condom use were age, multiple sexual relationships, knowledge of female condom, and educational status. Women having multiple sexual relationships compared with a monogamous relationship were five times more likely to use the female condom, while women with high school education were three times more likely to use the female condom; prevalence odds ratio, POR = 5.32, 95% CI = 1.79 – 15.83 and POR = 3.01, 95% CI = 1.01 – 8.93. Women who were not knowledgeable of the female condom, compared to those who were, were 81% less likely to use the female condom, POR = 0.19, 95% CI = 0.08 – 0.45. Among African-American women in this sample, knowledge of female condom use, age, educational status, and multiple sexual relationships were significant markers of female condom use. This study is therefore suggestive of the need to educate African-American women on female condom use, given the obstacles in male condom negotiation, especially among the socio-economically challenged.

Latka MH, Kapadia F, Fortin P. The female condom: Effectiveness and convenience, not "female control," valued by U.S. urban adolescents. AIDS Education and Prevention. 2008;20(2):160-170.

Data on adolescents' views regarding the female condom are limited. We conducted seven single-gender focus groups with 47 New York City boys and girls aged 15-20 years (72% African American, 43% ever on public assistance; 72% sexually active; 25% had either been pregnant or fathered a pregnancy). Conceptual mapping was performed by participants to reveal the characteristics of protective methods deemed important to them. During analysis we specifically evaluated how the female condom was mapped. Girls consistently organized methods by, and thus were concerned about, contraceptive effectiveness, side effects, and availability (over the counter vs. provider controlled). Participants tended to classify the female condom with the male condom rather than as "female controlled." Maps varied among boys but contraceptive effectiveness was an important theme. Boys, but not girls, consistently and variously articulated an awareness of sexual pleasure when discussing this topic. Emphasizing the female condom's contraceptive effectiveness, lack of side effects, and availability may be important when counseling adolescents.

Lawson ML, Macaluso M, Duerr A, et al. Partner characteristics, intensity of the intercourse, and semen exposure during use of the female condom. American Journal of Epidemiology. 2003;157(4):282-288.

The objective of this study was to assess how characteristics of the intercourse and the couple relate to semen exposure during use of the female condom. From 1996 to 1998, 210 women in Birmingham, Alabama, were trained to use the female condom and follow study procedures during a group session and individually practiced inserting the device. The outcome was semen exposure as defined by comparing pre- and postcoital prostate-specific antigen levels in vaginal fluid. Women who had high income levels had lower rates of semen exposure (odds ratio (OR) = 0.3, 95% confidence interval (CI): 0.2, 0.7),

while those in a relationship of less than 2 years were at greater risk (OR = 2.4, 95% CI: 1.3, 4.1). Couples with a large disparity in vaginal fundus size and penis size were at increase risk of semen exposure (OR = 2.7, 95% CI: 1.2, 6.0). Engaging in very active intercourse also increased the risk (OR = 1.7, 95% CI: 1.1, 2.6). Thus, the protective effect of the female condom appears to be a function of user- and intercourse-specific characteristics. Future studies of male condom efficacy should focus on collecting detailed data about the users and characteristics of intercourse to predict failure accurately.

London S. Method-related problems account for most failures of the female condom. International Family Planning Perspectives. 2003;29(3):147-148.

The female condom rarely breaks during use, but an efficacy study conducted in 1996-1998 indicates that slippage occurs in nearly one in 10 uses and women may be exposed to semen in up to one in five uses. Although the risk of exposure is higher among women who have mechanical problems with the condom rather than acceptability problems or no problems, about half of exposures occur during uses in which couples have no problems. A separate set of analyses using the same data set shows that women also have an increased risk of being exposed to semen while using the female condom if they are in a shorter-term relationship, if there is a large disparity between the size of their vagina and the size of their partner's penis, and if intercourse is very active.

Macaluso M, Blackwell R, Jamieson DJ, et al. Efficacy of the male latex condom and of the female polyurethane condom as barriers to semen during intercourse: A randomized clinical trial. American Journal of Epidemiology. 2007;166(1):88-96.

In this 2000-2001 study, the authors compared the effectiveness of the male latex condom and the female polyurethane condom by assessing frequency and types of mechanical failure and by evaluating semen exposure during use. Eligible women from Birmingham, Alabama, were randomly assigned to begin the study with 10 male condoms and then switch to 10 female condoms (n = 55), or vice versa (n = 53), and were trained to use both types. Data collection include questionnaires for each condom use and measurement of prostate-specific antigen in specimens of vaginal fluid taken before and after intercourse. Participants returned 700 male condoms and 678 female condoms, and they reported mechanical problems for 9% and 34%, respectively. Moderate-high postcoital prostate-specific antigen levels ($\geq$22 ng/ml) were detected in 3.5% of male condom uses and 4.5% of female condom uses (difference = 1%, 95% confidence interval: -1.6, 3.7). Moderate-high prostate-specific antigen values ($\geq$22 ng/ml) were more frequent with mechanical problems (male condom, 9.6%; female condom, 9.4%) but less frequent with other problems (3.0% and 0.9%) or correct use with no problems (2.7% and 2.5%). This study indicates that although mechanical problems are more common with the female condom than with the male condom, these devices may involve a similar risk of semen exposure. Objectively assessed semen exposure is associated with self-reported mechanical problems.

Macaluso M, Lawson ML, Hortin G, et al. Efficacy of the female condom as a barrier to semen during intercourse. American Journal of Epidemiology. 2003;157(4):289-297.

In 1996-1998, the authors measured prostate-specific antigen (PSA) in vaginal fluid to assess the frequency of female condom failure and to evaluate the association of self-reported failure with semen exposure. Women at low risk of sexually transmitted diseases (n=210) were recruited in Birmingham, Alabama. They were trained to use the female condom, sample vaginal fluid before and after condom use, and complete forms to report problems during each use. Semen exposure was assessed by comparing pre- and postcoital PSA levels in vaginal fluid. A total of 175 women used 2,232 condoms. The rate of semen exposure ranged from 7% to 21% of condom uses, depending on the exposure criterion. Exposure was more likely (21-34%) and more intense (mean postcoital PSA, 24.7 ng/ml) if participants reported a mechanical problem versus other problems or no problems (exposure rate, 5-20% in both instances; mean postcoital PSA, 9.6 and 7.8 ng/ml, respectively). In logistic regression analyses for repeated measurements, user-reported problems accounted for less than 59% of the instances of semen exposure. The female condom prevented semen exposure in 79-93% of condom uses. Exposure was associated with user-reported problems but also occurred in their absence. Reported problems and semen exposure decreased with user experience.

Marseille E, Kahn JG, Billinghurst K, et al. Cost-effectiveness of the female condom in preventing HIV and STDs in commercial sex workers in rural South Africa. Social Science and Medicine. 2001;52(1):135-148.

We assessed the cost-effectiveness of the female condom (FC) in preventing HIV infection and other STDs among commercial sex workers (CSWs) and their clients in the Mpumulanga Province of South Africa. The health and economic outcomes of current levels of male condom (MC) use in 1000 CSWs who average 25 partners per year and have an HIV prevalence of 50.3% was compared with the expected outcomes resulting from the additional provision of FCs to these CSWs. A simulation model calculated health and public sector cost outcomes assuming 5 years of HIV infectivity, 1 month of syphilis and gonorrhea infectivity, and FC use in 12% of episodes of vaginal intercourse. Delayed infections and interactions between STDs and HIV were modeled. The simulation was extended to non-CSWs with as few as one casual partner per year. We conducted multiple sensitivity analyses. The program would distribute 6000 FCs annually at a cost of $4002 and would avert 5.9 HIV, 38 syphilis, and 33 gonorrhea cases. This would save the public sector health payer $12,090 in averted HIV/AIDS treatment costs, and $1,074 in averted syphilis and gonorrhea treatment costs for a net saving of $9163. Sensitivity analyses indicate that the economic findings are robust across a wide range of values for key inputs. The program generates net savings of $5421 if HIV prevalence in CSWs is 25% rather than 50.3% and savings of $3591 if each CSW has an average of 10 clients per year rather than 25. A program focusing on non-CSWs with only one casual partner would save $199. We conclude that a well-designed FC program oriented to CSWs and other women with casual partners is likely to be highly cost-effective and can save public sector health funds in rural South Africa.

Minnis AM, Padian NS. Effectiveness of female controlled barrier methods in preventing sexually transmitted infections and HIV: Current evidence and future research directions. Sexually Transmitted Infections. 2005;81(3):193-200.

To evaluate evidence for the effectiveness of female controlled physical and chemical barrier methods in preventing STI/HIV transmission, to examine recent reviews on microbicide development, and to highlight promising research directions. To discuss challenges in conducting effectiveness research and in translating results to public health intervention. Systematic review of articles that examined the disease prevention effectiveness of at least one female controlled barrier method. Review of conference abstracts that presented clinical and preclinical microbicide data. Randomised controlled trials provide evidence that female condoms confer as much protection from STIs as male condoms. Observational studies suggest that the diaphragm protects against STI pathogens. Several microbicide effectiveness studies are under way and new directions, such as adaptation of therapeutic agents as preventive products, are being examined. Substantial attention is now given to product formulation and novel delivery strategies. Combining microbicide products with different mechanisms of action as well as combining chemical and physical barriers will be necessary to maximize prevention effectiveness. Increased investment in the development and identification of female controlled barrier methods offers promise that additional products will be available in the years ahead. Generalising trial results to a community setting, promoting products that may be less effective than male condoms, and bringing an effective product to scale introduce public health challenges that warrant attention. The need for female controlled barrier methods that provide women with the opportunity to take an active role in reducing their STI/HIV risk are urgently needed and constitute an essential tool to prevent continued spread of these infections.

Schwartz JL, Barnhart K, Creinin MD, et al. Comparative crossover study of the PATH woman's condom and the FC Female Condom®. Contraception. 2008; 78(6):465-473.

Only one female condom [FC1 Female Condom (FC1)] is currently marketed, but it is poorly utilized, perhaps due to difficulty with insertion, discomfort and suboptimal functional performance during intercourse. The Program for Appropriate Technology in Health (PATH) Woman's Condom (WC) was developed in an effort to overcome these obstacles. This was a randomized crossover study to evaluate the functional performance, safety and acceptability of the FC1 and WC. Seventy-five couples were assigned to one of two condom use sequences (WC/FC1 or FC1/WC) at three centers. Four condoms of the first type were used by couples in four acts of intercourse at home over a 2-4 week period. After a follow-up visit, these procedures were repeated with the second assigned condom type. In a sub-study of participants (n = 25), a colposcopy was performed prior and subsequent to the first condom use of each of the two condom types. Condom performance was evaluated by calculating measures of function from questionnaires completed by the couple after each condom use. Safety was evaluated by reported urogenital symptoms with a given condom during or immediately following

condom use and colposcopic signs of genital irritation in the sub-study. Acceptability of each given condom type was measured by questionnaire. Total condom failure (slippage, breakage, etc., divided by the number of female condoms opened) was 31% for the WC and 42% for the FC1. Total clinical failure (slippage, breakage, etc., divided by the number of female condoms used) was 17% for the WC and 24% for the FC1. The proportion of condom failures was 10.9 percentage points less, and the proportion of clinical failure 6.7 percentage points less, when couples used the WC compared to the FC1 (90% CI: -18.5 to -3.3 and -12.6 to -0.8, respectively). Fewer women reported symptoms of urogenital irritation when using the WC vs. the FC1 either overall or when analyzing each use of the condom [woman as unit: -20 percentage points (90% CI: -30.5 to -9.3); condom use as unit: -12.3 percentage points (90% CI: -18.0 to -6.7)]. A similar result was seen for signs of urogenital irritation [woman as unit: -20 percentage points (90% CI: -42.7 to 4.8)]. Among participants with a preference, WC was preferred over the FC1 by twice as many males and by 2.6 times as many females. While both female condoms were safe and acceptable in short-term use, the PATH Woman's Condom leads to less failure, was associated with fewer adverse events, and was more acceptable than the FC1 Female Condom.

Trussell J. Contraceptive efficacy of the Reality® female condom. Contraception. 1998;58(3):147-148.

A clinical trial was conducted in 10 centers throughout Japan to assess the contraceptive efficacy and acceptability of the Reality® female condom. All 195 subjects who were enrolled contributed data on acceptability and 190 contributed data on efficacy (five subjects, none of whom became pregnant, were excluded from the efficacy and analysis: two because of low coital frequency, one for not providing coital diaries or usage feeling questionnaires, and two for use of other methods of contraception). The 6-month life table probability of becoming pregnant was 3.2% during typical use and 0.8% during correct and consistent use of the condom.

Valappil T, Kelaghan J, Macaluso M, et al. Female condom and male condom failure among women at high risk of sexually transmitted diseases. Sexually Transmitted Diseases. 2005;32(1):35-43.

The objective of this study was to study the frequency and determinants of breakage and slippage during female and male condom use. The goal of this study was to determine condom breakage and slippage rate. The authors conducted a 6-month prospective follow-up study of women attending 2 sexually transmitted disease clinics. Breakage and slippage rates were computed. Logistic regression was used to evaluate baseline characteristics and time-dependent behaviors. A total of 869 women used condoms in 20,148 acts of intercourse. Breakage was less common for female condoms (0.1%; 95% confidence interval [CI], 0.05-0.21) than for male condoms (3.1%; 95% CI, 2.80-3.42). Slippage was more common for female condoms (5.6%; 95% CI, 5.10-6.13) than for male condoms (1.1%; 95% CI, 0.90-1.28). Rates significantly decreased with use and increased with number of previous failures. From first use to > 15 uses, combined failure rate fell from 20% to 1.2% for female condoms ($P < 0.0001$) and 9% to 2.3% for male

condoms (P < 0.01). Both condoms may provide good protection against sexually transmitted diseases. Experience determines success with either condom.

Vijayakumar G, Mabude Z, Smit J, et al. A review of female-condom effectiveness: Patterns of use and impact on protected sex acts and STI incidence. International Journal of STD and AIDS. 2006;17(10):652-659.

We conducted a systematic review of 137 articles and abstracts related to various aspects of the female condom, as well as a closer analysis of five randomized controlled trials on effectiveness. These five studies indicated strongly the benefits of female-condom use in increasing protected sex acts, and two studies found promising decreases in sexually transmitted infection (STI) incidence with the introduction of the female condom. Ten studies provided detailed information on patterns of long-term use, many suggesting that the female condom reaches women less likely to use other dual protection methods. There exists limited but convincing evidence that the female condom is effective in increasing protected sex and decreasing STI incidence among women. Future research on the female condom must move away from assessing acceptability and focus on assessing effectiveness and improving impact in diverse settings.

See Also:

COMMENTARY/LITERATURE REVIEWS: Brown S, Wimberly Y. Reducing HIV/AIDS transmission among African-American females: Is the female condom a solution? Journal of the National Medical Association. 2005;97(10):1421-1423.

COMMENTARY/LITERATURE REVIEWS: Cates W, Steiner MJ. Dual protection against unintended pregnancy and sexually transmitted infections. Sexually Transmitted Diseases. 2002;29(3):168-174.

COMMENTARY/LITERATURE REVIEWS: Cecil H, Perry MJ, Seal DW, et al. The female condom: What we have learned thus far. AIDS and Behavior. 1998;2(3):241-256.

COMMENTARY/LITERATURE REVIEWS: Elias CJ, Coggins C. Female-controlled methods to prevent sexual transmission of HIV. AIDS. 1996;10(Suppl. 3):S43-S51.

COMMENTARY/LITERATURE REVIEWS: Gilbert LK. The Female Condom (FC) in the US: Lessons learned. Female Health Foundation, 1999.

COMMENTARY/LITERATURE REVIEWS: Hatzell T, Feldblum PJ, Homan RK, et al. The Female Condom: Is "Just as Good" good enough? Sexually Transmitted Diseases. 2003;30(5):440-442.

USE BY MEN WHO HAVE SEX WITH MEN (MSM): Renzi C, Tabet SR, Stucky JA, et al. Safety and acceptability of the Reality condom for anal sex among men who have sex with men. AIDS. 2003;17(5):727-731.

IV. NEGOTIATION WITH PARTNERS

Beksinska M, Smit J, Mabude Z, et al. Male partner involvement and assistance in female condom use. The European Journal of Contraception and Reproductive Health Care. 2008;13(4):400-403.

The objective of this study was to investigate how males assist their partners in using the female condom. A multi-site, randomized, cross-over trial was conducted to test the performance and acceptability of the Reality® female condom compared to a prototype similar in design and appearance but made of synthetic latex (FC2). In this study women were asked about male partner assistance in FC use. Partner assistance in FC use was similar across FC type. Of the women who returned for the first follow-up visit (n = 233), just over a third (35.2%) reported that the male partner assisted in the insertion compared to 26.4% of the 201 women who returned for the second visit. In most cases where the partner assisted, the devise was inserted using the inner ring, as recommended in the instructions for use. A small number (6%) mentioned that partners assisted in removal. Men have a role to play in the use of the female condom and are willing to assist their partners in using it.

Choi KH, Gregorich SE. Social network influences on male and female condom use among women attending family planning clinics in the United States. Sexually Transmitted Diseases. 2009;36(12):1-6.

Research has shown that social networks play an important role in determining health behaviors. However, little is known about their influence on male and female condom use among women. We analyzed data obtained from 157 sexually-active women who enrolled in the Female Condom Intervention Trial from June 2003 to November 2004 in Northern California and completed an audio computer-assisted self interview at baseline and 3-months. At the 3-month assessment, the mean number of male and female "conversation" network members (i.e., nonspouse/sex partner people with whom respondents had discussed male and female condoms in the past 3 months) was 1.62 and 1.03, respectively. Results of multiple logistic regression analyses showed that male and female condom use was higher among women with at least 1 network member who encouraged using the male condom (OR, 3.39; 95% CI, 1.52, 7.56) and the female condom (OR, 6.03; 95% CI, 1.95, 18.61), respectively. Female condom use was also associated with having "dense" female condom conversation networks (i.e., at least 2 of respondents' network members knew one another; OR, 8.42; 95% CI, 3.05, 23.29). The significant association between conversation network characteristics and male and female condom use suggests that more research is needed to better understand the role of conversation networks in affecting condom use among women.

Choi KH, Wojcicki J, Valencia-Garcia D. Introducing and negotiating the use of female condoms in sexual relationships: Qualitative interviews with women attending a family planning clinic. AIDS and Behavior. 2004;8(3):251-261.

Safe sex skills training often teach women to be assertive in condom use negotiations. However, it has been suggested that assertiveness training may be inappropriate for women who lack power in their sexual relationship. Our qualitative study of 62 women attending a family planning clinic explored various communication styles they used to introduce and negotiate female condom use in their sexual relationships. We further examined how different introduction and negotiation styles were related to actual use of the device. The device was introduced using a direct, semidirect, indirect, or nonverbal communication approach. Use of the female condom was negotiated by avoiding sex, using humor, discussing the possibility of using the condom, or being argumentative with partners. The outcome of introducing and negotiating female condom use was often mediated by other factors including partner characteristics, relationship power dynamics, situational context, and use of additional discourse strategies (e.g., describing the female condom as a sexual toy or taking the opportunity to educated partners about the female condom). Less direct approaches appeared to be as effective in facilitating use of the female condom as more direct approaches. Female condom introduction and negotiation styles that continued to engage their partners by using additional discourse strategies led to more frequent use of the device. Implications of our findings for HIV risk reduction program development are discussed.

Penman-Aguilar A, Hall J, Artz L, et al. Presenting the female condom to men: A dyadic analysis of effect of the woman's approach. Women and Health. 2002;35(1):37-51.

Although male partner resistance to female condom use has been reported, little is understood about circumstances under which partners will agree to female condom use. This study documents the experiences of couples who have worked together to achieve female condom use. As part of a prospective female condom efficacy study, female participants (age 18-34) received a behavioral intervention and an assortment of take-home items. Selected women and their partners were recruited for a qualitative interview focusing on their experience with the female condom. Interviews were transcribed, double-coded, and verified using a standard retrieval coding system. Twenty-six pairs of linked interviews were analyzed dyadically: 9 couples who used the female condom "consistently," 12 "experimenters," and 5 "non-users." Women who successfully promoted the female condom to their partners used multiple presentation strategies. Initial male partner reaction did not predict continued use beyond the first trial. In conclusion, employment of multiple strategies facilities successful introduction of the female condom into a sexual partnership.

Rivers K, Aggleton P, Elizondo J, et al. Gender relations, sexual communication and the female condom. Critical Public Health. 1998;8(4):273-290.

An exploratory multi-site study supported by the World Health Organization and UNAIDS was conducted in Costa Rica, Indonesia, Mexico and Senegal to examine the

extent to which women's capacity to negotiate safer sex might be enhanced by the introduction of the female condom. Data were first collected on prevailing gender relations, sexual communications and negotiation. This was followed by the distribution of the female condom and a locally designed intervention devised to develop women's knowledge and confidence in relation to their bodies, health and sexuality. In each of the four research sites, two groups of women were involved: one consisted of women engaged in sex work, the other of women from a range of backgrounds which varied across the sites. The introduction of the female condom was particularly successful in enhancing sexual communication between sex workers and clients, in couples where the man was already supportive of family planning, in a context where men were reassured that acceptance was high among peers, where the male condom was already in use but unpopular, and where the female condom was able to be eroticized and introduced into sex play.

V. PROMOTION (INCLUDES STUDIES OF BEHAVIORAL, COUNSELING AND EDUCATIONAL INTERVENTIONS)

Adeokun L, Mantell JE, Weiss E, et al. Promoting dual protection in family planning clinics in Ibadan, Nigeria. International Family Planning Perspectives. 2002;28(2):87-95.

Integration of efforts to prevent HIV and sexually transmitted infections (STIs) and of condom promotion into family planning services is urgently needed because of the escalating HIV epidemic in Sub-Saharan Africa. Counseling on dual protection – concurrent protection from unintended pregnancy and HIV and other STIs—and provision of the female condom were introduced in six family planning clinics in Ibadan, Nigeria. Structured observations of interactions between clients and service providers, clinic service statistics, provider interviews, and other qualitative and quantitative methods were used to assess family planning providers' promotion of dual protection. Following intensive training, providers delivered dual-protection counseling to a majority of clients and demonstrated the female condom to 80% of the new clients observed. Discussion of the sexual behavior of clients and their partners, of the relative ability of various contraceptives to protect against HIV infection and of how to negotiate condom use increased significantly, as did STI assessment. Providers' internalization of the importance of HIV/AIDS prevention was crucial to promoting and sustaining the dual-protection initiative. Condom purchases increased from a baseline of 2% of all family planning visits in 1999 to 9% in January-June 2001. This increase came mainly from acceptance of the female condom, used either alone or in conjunction with another contraceptive. Integrating dual-protection counseling and female condom provision into family planning services appears feasible, as is service providers' acceptance of dual-protection objectives. While providers and clients are key to transforming family planning to dual-protection services, the attitudes and behaviors of clients' male partners must be considered in gauging the success of the dual-protection intervention.

Agha S. Consumer intentions to use the female condom in a population to which it has been mass-marketed. Population Services International. 1999;26:1-16.

This article examines intentions to use the female condom among men and women in Lusaka, Zambia. The female condom had been mass-marketed in Lusaka for about a year when this study was conducted. A social marketing program distributed female condoms, which were sold in more than 300 retail outlets in Lusaka. Through a subsidy, the female condoms were sold at a price comparable to that of the subsidized male condom (also distributed by the social marketing project). This study uses data from a representative sample of consumers at outlets that sell/distribute the female condom to determine the correlates of consumer intentions to use the female and the male condom. About 40% of sexually experienced respondents at retail outlets that sell the female condom intend to use it. In comparison, 72% of respondents intend to use the male condom. Younger respondents are more interested in using the female condom than older respondents. Both men and women report similar intentions to use the female condom. Unmarried respondents who have regular partners are more likely to use the

female condom than others. The relationships between intentions to use the female condom and socio-demographic variables are similar to the relationships between sociodemographic variables and intentions to use the male condom. Of consumers who used both the male and the female condom in the last year, 58% report an intention to use the female condom and 90% report an intention to use the male condom. Ever-users of the female condom who do not intend to use the female condom in the future cite difficulties with its insertion, dislike for the method and a preference for the male condom as the main reasons for future non-use of the female condom. These findings show that there are substantial barriers to adoption of the female condom in Lusaka, where the female condom has been mass-marketed. More intensive counseling/education about the female condom, especially about insertion, is likely to be extremely important in sustaining women's intentions to use the method and in motivating them to use it. Mass-marketing programs such as the one in Zambia could benefit by having peer education/promotion sessions (currently being conducted in public settings such as supermarkets, pharmacies, bars and nightclubs) supplemented by counseling sessions in more intimate settings.

Agha S. Intention to use the female condom following a mass-marketing campaign in Lusaka, Zambia. American Journal of Public Health. 2001;91(2):307-310.

This report examines intention to use the female condom among men and women in Lusaka, Zambia, who were exposed to mass-marketing of the female condom. The study used data from a representative sample of consumers at outlets that sell or distribute the female condom and the male condom. In spite of a high level of awareness of the female condom, use of this method in the last year was considerably lower than use of the male condom. Intention to use the female condom in the future was highest among respondents who had used only the female condom in the last year. The female condom is likely to be most important for persons who are unable or unwilling to use the male condom.

Agha S. Patterns of use of the female condom after one year of mass marketing. AIDS Education and Prevention. 2001;13(1):55-64.

The female condom is an effective new contraceptive method that can reduce HIV transmission. This study examines use of the female condom after 1 year of its mass marketing and compares this with use of the male condom. It is based on exit interviews conducted among a random sample of male and female customers visiting outlets that sell the female condom. Compared with reported use of the male condom, which was five to eight times as high in nonmarital as in marital partnerships, reported use of the female condom varied less by partnership type (it was twice as high in nonmarital compared with marital partnerships). In marital and regular partnerships, use of the female and the male condom increased with socioeconomic status (SES). In casual partnerships, use of the male condom increased with SES, but use of the female condom was higher for those with lower SES. Men reported higher levels of male condom use than women, but there were no gender differences in use of the female condom. These findings suggest that the largest contribution to HIV protection through use of the female condom may be within

marital partnerships and among low SES men and women who engage in casual sex. The absence of gender differentials in use of the female condom suggests that women are able to exert greater control over the use of the female condom than they are over the use of the male condom. However, the overall low levels of female condom use among relatively affluent persons at outlets that sell the female condom indicate that the introduction of the female condom will be resource intensive.

Agha S, Van Rossem R. Impact of mass media campaigns on intentions to use the female condom in Tanzania. International Family Planning Perspectives. 2002; 28(3):151-158.

Mass media campaigns have been used in social marketing programs designed to prevent HIV infection by changing sexual behavior. More information is needed about the effectiveness of these campaigns and the mechanisms through which they influence behavior. Data on 2,712 sexually experienced men and women in Tanzania, collected in an exit survey at outlets that sell the female condom, were used to determine if a mass media campaign promoting the female condom had an impact on women's and men's intentions to use this method. Respondents were asked about their exposure to the mass media campaign, to peer education and to explanation of the female condom by a medical provider. They were also asked about their intention to use the female condom in the future. Path analysis was used to determine the impact of the three exposure factors on respondents' intentions to use the female condom. About 6% of respondents had been exposed to peer education and 6% had been given an explanation by a provider on the use of the female condom. In contrast, about 38% of respondents had been exposed to the mass media campaign promoting the female condom. Mass media exposure significantly increased the likelihood that a man or a woman would discuss use of the female condom with a partner. In turn, discussion of the female condom with a partner strongly influenced the intention to use the female condom in the future. Peer educators and providers had limited coverage, but they had a stronger impact than the mass media on an individual's intention to use the female condom. Although mass media campaigns do not have as strong an impact on a particular individual's motivation to use the female condom as do peer educators or providers, such campaigns have a substantial impact at the population level because of their considerably greater reach.

Artz L, Macaluso M, Brill I, et al. Effectiveness of an intervention promoting the female condom to patients at sexually transmitted disease clinics. American Journal of Public Health. 2000;90(2):237-244.

This study evaluated a behavioral intervention designed to promote female condoms and reduce unprotected sex among women at high risk for acquiring sexually transmitted diseases (STDs). The effect of the intervention on barrier use was evaluated with a pretest-posttest design with 1159 female STD clinic patients. Among participants with follow-up data, 79% used the female condom at least once and often multiple times. More than one third of those who completed the study used female condoms throughout follow-up. Use of barrier protection increased significantly after the intervention, and high use was maintained during a 6-month follow-up. To account for attrition, the use of

protection by all subjects was projected under 3 conservative assumptions. The initial visit and termination visit projections suggest that use increased sharply after the intervention and declined during follow-up but remained elevated compared with the baseline. Many clients of public STD clinics will try, and some will continue, to use female condoms when they are promoted positively and when women are trained to use them correctly and to promote them to their partners. A behavioral intervention that promotes both female and male condoms can increase barrier use.

Artz L, Macaluso M, Kelaghan J, et al. An intervention to promote the female condom to sexually transmitted disease clinic patients. Behavior Modification. 2005;29(2):318-369.

This article describes a 1-hour behavioral intervention designed to promote female condoms and safer sex to women at a high risk for sexually transmitted diseases (STDs). The intervention includes a promotional videotape; a skills-oriented counseling session with a nurse clinician; assorted take-home items, including a videotape for men; and free supplies of female and male condoms. Designed for women ages 18 to 34 attending public STD clinics, the intervention is developed using a systematic process of formative evaluation influenced by principles of social marketing and drawing on the social cognitive theory. The effect of the intervention on female and male condom use is evaluated using a pretest-posttest design with 1,159 women. Most elements of the intervention could be replicated in settings other than STD clinics and delivered by persons other than nurse clinicians.

Bull SS, Cohen J, Ortiz C, et al. The POWER campaign for promotion of female and male condoms: Audience research and campaign development. Health Communication. 2002;14(4):475-491.

In this study, we conducted and content analyzed 12 focus groups with women aged 15-25 living in inner city Denver, as a process of audience research to develop a male and female condom promotion campaign. We recruited 89 women from school and community sites in central Denver neighborhoods to discuss their knowledge, attitudes, and practices regarding both male and female condoms, then solicited opinions about how to increase knowledge about and familiarity with female condoms, increase positive attitudes toward both male and female condoms, and how to increase access to and use of both male and female condoms. Opinions on these topics drove the development of a targeted media campaign promoting condom use in this population. We report here on the general findings from focus groups and provide details about the campaign the participants helped to develop.

Bull SS, Posner SF, Ortiz C, et al. POWER for reproductive health: Results from a social marketing campaign promoting female and male condoms. Journal of Adolescent Health. 2008;43(1):71-78.

The purpose of this study was to evaluate effects of a 6-month social marketing campaign on awareness of, attitudes toward and use of female as well as male condoms for 15-25

year-old-women. Using a time-space sampling methodology, we conducted a cross-sectional survey of 3407 women at pre-campaign in 12 western U.S. neighborhoods on female and male condom awareness, attitudes, and use. Six of the 12 study neighborhoods were randomly selected to receive the POWER social marketing campaign designed to impact condom knowledge, attitudes, and use. The campaign was followed with another cross-sectional survey of 3,003 women in all 12 study neighborhoods on condom knowledge, attitudes, use and awareness of POWER materials. We compared pre- and post-campaign surveys to determine the efficacy of POWER and conducted post hoc analyses on post-campaign data to determine if exposure to POWER was related to higher levels of positive condom attitudes and norms and condom use. We found no differences between neighborhoods with and without the POWER campaign with regard to our primary outcomes. To diagnose reasons for this null effect, we examined outcomes post hoc examining the influence of POWER exposure. Post hoc analyses show some evidence that exposure to POWER was associated with condom use. In the context of the nested trial, this raises concerns that post test only evaluations are limited. Establishing the efficacy of a social marketing campaign is challenging. This group randomized trial showed a null effect. Social marketing campaigns may need to have more media channels and saturation before they can show behavioral effects. Using a nested design with randomization at the community level and probability sampling introduces rigor not commonly seen in evaluations of social marketing campaigns.

Busza J, Baker S. Protection and participation: An interactive programme introducing the female condom to migrant sex workers in Cambodia. AIDS Care. 2004;16(4):507-518.

The female condom has received much attention for its potential to empower users in negotiating safer sex. Studies demonstrate that the process used to introduce the method can influence subsequent use rates, resulting in calls for comprehensive documentation of introduction activities. This paper details an intervention study introducing the female condom to Vietnamese sex workers in Cambodia. Part of a wider community mobilization approach to reducing HIV/AIDS transmission, the intervention emphasized informed debate, group skills building and collective support. Research methods included both quantitative and qualitative data collection to evaluate the introduction's effect on sex workers' negotiation skills and social support networks. The findings show that approximately 16% of sex workers tried the female condom. Ever-use was significantly associated with participation in intervention workshops, and with indicators of both individual and community empowerment. Sex workers who incorporated the female condom into their work were also more likely to feel a sense of community identity. Introduced through an appropriate process, the female condom can serve as an 'entry point' to building community capacity. It can support sex workers in achieving protected sex and developing cooperative relationships, even in severely restrictive settings.

Cates W, Steiner MJ. Dual protection against unintended pregnancy and sexually transmitted infections. Sexually Transmitted Diseases. 2002;29(3):168-174.

In the midst of the global epidemics of both unintended pregnancy and sexually transmitted infection, contraceptive options that provide dual protection are ideal. However, those contraceptives with the best record of preventing pregnancy under typical use conditions (sterilization, hormonal methods, intrauterine devices) provide little if any protection against sexually transmitted infection. Alternatively, barrier contraceptive methods (specifically, condoms), which can reduce risks of many sexually transmitted infections, are associated with relatively higher pregnancy rates for most users than other contraceptives. This situation has produced a dilemma for those wishing to promote dual protection: whether to advocate use of two methods (one primarily to prevent pregnancy and the other primarily to prevent infections) or whether to emphasize use of condoms for both purposes. Data comparing these two approaches are limited and often contradictory. We discuss the underlying concepts of exposure to both pregnancy and infection, provide a broad overview of the effectiveness of contraceptive methods against these two conditions, present approaches to optimize dual protection, and propose several new directions for necessary research. In the absence of evidence-based recommendations, we believe clinicians should assist clients in assessing their likelihood of exposure to infection, either by prevalence of sexually transmitted infection in the community or by the specific risk factors of the client. If exposure is likely, particularly to the more serious infections such as human immunodeficiency virus, the one-method approach should be given greater weight. However, in settings where unintended pregnancy is the greater concern, emphasizing the two-methods approach as a first option may be appropriate.

Gollub EL, Brown EL, Savouillan M, et al. A community-based safer-sex intervention for women: Results of a pilot study in south-eastern France. Culture, Health and Sexuality. 2002;4(1):21-41.

This study tested the feasibility and short-term acceptability of a public health intervention for women aimed at reducing HIV/STD risk through counseling on a variety of protection methods, including the female condom, spermicides and diaphragms. Women from diverse community groups in Marseille, France participated in a five-session group intervention seeking to educate women about their bodies, teach protection skills, develop solidarity, and prompt community diffusion of information and new norms. Intervention sessions were held weekly, and included visual and hands-on demonstration materials and free protection supplies. Knowledge scores on protection methods improved over the course of the study, and 56% of respondents reported having tried the female condom at least once. The intervention was very highly rated, with the best-liked aspect (50%) being the group process. Women of African or French territories' origin rated the female condom more positively than women born in continental France or Europe. Evidence suggests that the approach used is feasible and well-liked by women of diverse cultural backgrounds in south-eastern France. Longer follow-up is required to assess behavioural change.

Gollub EL, French P, Latka M, et al. Achieving safer sex with choice: Studying a women's sexual risk reduction hierarchy in an STD clinic. Journal of Women's Health and Gender-Based Medicine. 2001;10(8):771-783.

A flexible, risk-reduction approach, as compared with a single method approach, may increase sexually transmitted disease (STD)/HIV protection for women attending STD clinics. A brief intervention was tested in an observational study of 292 STD clinic patients in three distinct cohorts. These included subjects counseled on (1) the "women's safer sex hierarchy of prevention methods" (hierarchy cohort, n = 118), including the female condom (FC), male condom (MC), diaphragm, cervical cap, and spermicides, (2) MC only (n = 62), or (3) FC (n = 112) only. We evaluate method use and level of protection achieved at 6-month follow-up among the women in the hierarchy cohort and compare the level of unprotected sex across the three cohorts, using ordinal logistic regression analyses and an imputation procedure to account for attrition. In the hierarchy cohort, the MC, FC, spermicidal film, foam, suppository, and diaphragm were used with main partners by 80%, 46%, 37%, 28%, 17%, and 5% of women, respectively. Spermicides were used frequently, mainly in conjunction with condoms. As compared with hierarchy subjects, both MC cohort subjects (OR = 2.3, p = 0.01) and FC cohort subjects (OR = 1.6, p = 0.11) were more likely to report 100% unprotected sex. The tendency for subjects to move toward higher levels of protection was observed most strongly in the hierarchy group. Hierarchical-type counseling, compared with single method counseling, leads to increased protection during sex among women at high risk of STD/HIV infection and should be implemented in STD clinics.

Gollub EL, French P, Loundou A, et al. A randomized trial of hierarchical counseling in a short, clinic-based intervention to reduce the risk of sexually transmitted diseases in women. AIDS. 2000;14(9):1249-1255.

Effective public health interventions to reduce the incidence of sexually transmitted disease (STD), including HIV, among women are urgently needed. A randomized trial among STD clinic patients of two types of counseling regarding methods to reduce disease transmission: a 'hierarchical' message (HP), with counseling on male condoms, female condoms, diaphragms, cervical caps, and spermicides (three formulations) and a single method message (SM) covering male condoms only or female condoms only. For this analysis, 1591 subjects received one of three educational messages at the central public STD clinic in Philadelphia. Disease incidence data for up to 6 months following the index visit were extracted from the clinic's electronic database. The primary outcome was STD reinfection: laboratory-confirmed trichomonas infection and/or clinical diagnoses of at least one of four STD. Rates were based on the full sample of randomized women (full sample) and on the subset who spontaneously returned between 22 days and 183 days following their initial visit (returners). Rates of trichomonas infection (SM 2.5% full sample and 12.9% returners versus HP 2.4% full sample and 11.5% returners) and clinical diagnoses (SM 6.3% full sample and 39.7% returners versus HP 6.9% full sample and 41.2% returners) did not differ across the two arms of the randomized trial, both as a straight percentage and in survival analysis (P = .81). At

least in this single-session intervention trial, increasing choices in protection for women did not produce a change in disease risk compared with single-method approaches.

Hardwick D. The effectiveness of a female condom intervention on women's use of condoms. The Canadian Journal of Human Sexuality. 2002;11(2):63-76.

This paper reports the findings of an evaluation of a female condom promotion intervention delivered to 109 socio-economically disadvantaged women at high risk for STI/HIV living in Toronto, Canada, who had never used female condoms in the past. The intervention was designed to introduce the female condom to participants and to increase the frequency of their use of either the female or male condom. The percentage of sexual intercourse events protected by either a female or male condom significantly increased from 48.9% at baseline to 70.7% at one-month follow up and 70.5% at two-month follow-up. Use of the female condom increased from 0% at baseline to 44.7% at one-month and then decreased slightly to 42.3% at the two-month follow-up. Women aged 25 and older, those who were comfortable inserting the female condom, and those who reported liking the female condom were more likely to use it. At the two-month follow-up, 37.5% of participants reported a preference for access to female condoms, 33.7% preferred both male and female condoms, and 28.9% preferred male condoms. This is the first published report on the impact of a female condom promotion intervention conducted in Canada, and, consistent with previous research from the U.S.A., the findings suggest that female condom focused interventions can significantly increase condom use among women at high risk for STI/HIV.

Hoffman S, Exner TM, Leu CS, et al. Female-condom use in a gender-specific family planning clinic trial. American Journal of Public Health. 2003;93(11):1897-1903.

The authors evaluated female-condom use among women participating in an HIV/STD intervention designed to reduce unprotected sex and expand prevention strategies. Women (n=360) were recruited from a family-planning clinic and were randomized into an 8- or 4-session intervention group or a control group. We conducted follow-up interviews at 1, 6, and 12 months. At 1 month, the odds ratios of first-time female-condom user were 9.49 (95% confidence interval [CI] = 4.01, 22.20) in the 8-session group and 4.39 (95% CI = 1.84, 10.49) in the 4-session group relative to controls. Repeated use (n=21) was predicted by perceived ability to use, by self and partner satisfaction, by dislike of male condoms, and by previous diaphragm use. Gender sensitive cognitive-behavioral interventions can influence women to try the female condom. To increase long-term use, interventions may need to include self-insertion practice and involvement of male partners.

Hoke TH, Feldblum PJ, Van Damme K, et al. Randomised controlled trial of alternative male and female condom promotion strategies targeting sex workers in Madagascar. Sexually Transmitted Infections. 2009;83(6):448-453.

The objectives of this study was to assess whether individual clinic-based counseling as a supplement to peer education for male and female condom promotion leads to greater use of protection and lower STI prevalence among sex workers in Madagascar already exposed to intensive male condom promotion. In two public dispensaries in Madagascar, a total of 901 sex workers were randomly allocated between two alternative male and female condom promotion interventions: peer education only, or peer education supplemented with individual clinic-based counseling. Participants were followed for 12 months. Every 2 months they made clinic visits, where they were interviewed on condom use. Peer educators counseled all participants on condom use as they accompanied their assigned participants to study visits. Participants assigned to receive the supplemental intervention were counseled by a trained clinician following study interviews. Participants were tested and treated for Chlamydia, gonorrhoea and trichomoniasis every 6 months. We used logistic regression to assess whether the more intensive intervention was associated with reduced STI prevalence. Use of protection with clients and non-paying partners was assessed by study arm, site, and visit. There was no statistically significant association between study arm and aggregated STI prevalence. No substantial differences in levels of reported protection were noted between study groups. This study found little evidence for gains from more thorough clinical counseling on male and female condom use. These findings suggest that less clinically intensive interventions such as peer education could be suitable for male and female condom promotion in populations already exposed to barrier method promotion.

Jones DL, Ross D, Weiss SM, et al. Influence of partner participation on sexual risk behavior reduction among HIV-positive Zambian women. Journal of Urban Health: Bulletin of the New York Academy of Medicine. 2005;82(3):iv92-iv100.

Sexual risk behavior interventions in sub-Saharan Africa focus predominantly on individual and couples counseling. This cognitive-behavioral group intervention was adapted from an urban US context to urban Zambia. Preliminary data analyses assessed the influence of partner participation on sexual risk behavior among HIV-positive Zambian women. Female participants (n=180) attended four group intervention sessions and received sexual behavior skill training and male and female condoms; male partners (n=152) were randomly assigned to high- or low-intensity gender-concordant group intervention sessions. Sexual risk behavior, strategies, attitudes, and knowledge were assessed at baseline, 6, and 12 months. At baseline, 19% of males reported using alcohol before sex, 10% reported using alcohol to cope, and negative coping was associated with sexual risk behavior. In contrast, 1% of women reported using alcohol before sex, and 15% used alcohol as an HIV-coping strategy. Consistent barrier use was reported by 48% of women and 74% of men. After intervention, female high intensity participants reported higher rates of condom use (F=5.68, P=.02), more positive condom attitudes, safer sex intentions, and less alcohol use. These findings highlight the influence of male partners in implementation of effective risk reduction interventions.

Jones DL, Weiss SM, Bhat GJ, et al. Influencing sexual practices among HIV-positive Zambian women. AIDS Care. 2006;18(6):629-634.

This study assessed and compared the efficacy of culturally tailored behavioral interventions to increase use and acceptability of sexual barrier products among HIV-positive women in Zambia. It also sought to evaluate cultural preferences as facilitators or impediments to potential use of vaginal chemical barriers for sexual risk reduction within the Zambian context. Women (N = 240), recruited from the University Teaching Hospital HIV Voluntary Counseling and Testing Center, were randomized into group or individual intervention arms. Participants attended a baseline assessment, three intervention sessions and follow up assessments at six and 12 months. All participants increased use and acceptability of female condoms and vaginal products and maintained male condom use at six and 12 months. Preliminary data indicated that group participants increased male condom use at six months and trial use and acceptability of female condoms and lubricants predicted their use in the group condition. Results support group interventions to increase sexual barrier use and acceptability in HIV-positive women within the Zambian context. From a public health standpoint, groups may represent a cost-effective and culturally congruent intervention.

Jones DL, Weiss SM, Malow R, et al. A brief sexual barrier intervention for women living with AIDS: Acceptability, use, and ethnicity. Journal of Urban Health: Bulletin of the New York Academy of Medicine. 2001;78(4):593-604.

Interventions aimed at reducing sexual transmission of human immunodeficiency virus/sexually transmitted diseases (HIV/STDs) have focused primarily on male condom use among seronegative men and women. However, female-controlled sexual barriers (female condoms and vaginal microbicides) offer women living with acquired immunodeficiency syndrome (AIDS) alternative methods to protect themselves and others from disease transmission. A pilot behavioral intervention was conducted to increase sexual barrier use and enhance and assess factors related to acceptability. Participants (N = 178) were drawn from the Stress Management and Relaxation Training with Expressive Supportive Therapy (SMART/EST) Women's Project, a multisite phase III clinical trial for women living with AIDS (Miami, FL; New York City, NY; Newark, NJ). Intervention participants (n = 89) were matched for age and ethnicity with control condition participants (n=89). Women were African American (52%), Haitian (15%), Hispanic (19%), Caucasian (10%), and other ethnicities (4%). The intervention condition received barrier products (male and female condoms and spermicides based on nonoxynol-9 in the form of vaginal gel, film, and suppositories) during three sessions held over 3 months. Data on barrier use and acceptability were analyzed at baseline and 3 and 9 months postintervention. Use of N-9 spermicides on a trial basis increased significantly by 3 months in the intervention conditions (22% - 51%, P<.05). Cultural differences in acceptability were greatest between Haitian women and women in other ethnic groups. Exposure to this pilot behavioral intervention was associated with increased acceptability and use of chemical barriers without decreased use of male condoms.

Kaler A. The female condom in North America: Selling the technology of 'empowerment'. Journal of Gender Studies. 2004;13(2):139-152.

In this paper, I examine the selling of the female condom and the predominantly negative response it garnered in the North American media during the 1990s. I situate the female condom as a technology that emerged at the convergence of the twentieth century women's health movement and the much more recent HIV-prevention movement, both of which stressed ideals of individual self-control and empowerment for women as the keys to sexual health. However, the female condom was constructed in media accounts as a joke or an insult. The idea of women's empowerment embodied in the device was taken as an unwelcome reminder of the dangers and risks of heterosexuality in the age of AIDS – thus, the female condom was perceived as more depressing than emancipating. It has since found a substantial market and receptive users in HIV-prevention programmes in Asia and Africa. I conclude that the episode of the female condom complicates the narrative of the women's health movement as a drive towards women's empowerment, by pointing out that empowerment is an ambiguous concept which can evoke an ambivalent response from its intended audience.

Kalichman SC, Williams E, Nachimson D. Brief behavioural skills building intervention for female controlled methods of STD-HIV prevention: Outcomes of a randomized clinical field trial. International Journal of STD and AIDS. 1999; 10(3):174-181.

The need for female controlled methods for preventing HIV infection is well recognized and women have been found to accept the female condom for these purposes. Women (n=105) were randomly assigned to receive either (a) a 3-h behavioural skills building intervention that concentrated on educating women about the female condom, motivating female condom use, and building behavioural skills relevant to using the female condom, or (b) a time-matched broadly defined women's health education intervention. Women who received the female controlled skills building intervention used the female condom to a greater extent than did women in the health education condition. Importantly, the effects of the behavioural skills intervention were most pronounced for women who reported only one male sex partner in the previous 6 months compared to women with multiple sex partners. However, female condom use was modest, with only one in 5 vaginal intercourse acts being protected by female condoms among women with one partner who received skills training. Interventions are needed to further enhance use of the female condom and new female controlled methods are needed for the majority of women at risk who did not adopt the female condom.

Kerrigan D, Mobley S, Rutenberg N, et al. The female condom: Dynamics of use in urban Zimbabwe. The Population Council, 2000.

In July 1997, Population Services International (PSI), at the request of the Zimbabwe National AIDS Coordination Programme (NACP), launched a social marketing program for the female condom in Zimbabwe. To avoid stigma associated with condoms and STI

prevention, the female condom was marketed as a family planning product or "contraceptive sheath" under the brand name *care*™. The female condom was initially sold through selected pharmacies and clinics at a heavily subsidized retail price of US $0.24 for a box of two; distribution has since expanded to other urban outlets, including large supermarkets and convenience stores. Approximately one year after the start of the female condom social marketing program, the Horizons Project and PSI conducted a descriptive, cross-sectional study of female condom users, male condom users, and non-users of either barrier method. The goal of this research is to increase understanding of the patterns and dynamics of female condom use in order to inform policymakers and program planners involved in decisions about promotion and distribution of the female condom in Zimbabwe. The study used a combination of quantitative and qualitative methods. An intercept survey was conducted with women and men exiting urban sales outlets that carry both *Protector Plus*™ male condoms and *care*™ female condoms. In total, 493 female condom users, 633 male condom users, and 624 non-users are included in the analyses upon which this report is based. Male and female users of the female condom also participated in in-depth interviews and focus groups.

Latka M, Gollub E, French P, et al. Male-condom and female-condom use among women after counseling in a risk-reduction hierarchy for STD prevention. Sexually Transmitted Diseases. 2000;27(8):431-437.

A concern with hierarchy messages, which promote male condoms and female-controlled barrier methods along a prevention continuum, is that they may discourage condom use. To measure male-condom and female-condom use among women who received hierarchy counseling and compare this with women counseled about condoms only. Three observational cohorts that correspond to prevention message received were assembled, and consisted of female sexually transmitted disease clinic patients who were counseled about male condoms, female condoms, or a hierarchy message. The hierarchy message promoted male and female condoms, the diaphragm and cervical cap, spermicides, and withdrawal, in descending order of effectiveness against sexually transmitted diseases. After counseling, women were interviewed and returned for follow-up visits at 2 weeks, 4 months, and 6 months. The outcome was the mean proportion of male condom- or female condom-protected coital acts at each follow-up visit in the hierarchy cohort. The outcome was dichotomized as high (> = 70% of coital acts protected) or low (< 70%), and generalized estimating equations were used to compare observed follow-up condom use with baseline within the hierarchy cohort and observed follow-up condom use between cohorts. It was assumed that condom use in persons not present at 6 months was equal to baseline levels, and condom use estimates were calculated for each full cohort that was initially enrolled. The mean proportion of condom-protected coital acts in the hierarchy cohort was significantly increased from baseline at each follow-up visit. There were no differences in observed condom use during follow up between the hierarchy cohort and either the male-condom or the female-condom cohort. However, when the full cohort initially enrolled was considered, 6-month condom use was significantly higher in the hierarchy cohort than in the male-condom cohort. Hierarchy counseling was associated with a significant increase in

condom use. Our findings suggest that offering a choice of male and female condoms results in increased protection over counseling in male condoms alone.

Macaluso M, Demand M, Artz L, et al. Female condom use among women at high risk of sexually transmitted disease. Family Planning Perspectives. 2000;32(3):138-144.

Whereas the female condom has been evaluated in many hypothetical acceptability or short-term use studies, there is little information about its suitability for the prevention of sexually transmitted diseases (STDs) or HIV over extended periods of time. As part of a six-month prospective follow-up study of 1,159 STD clinic patients, clients were interviewed during their initial visit, exposed to a behavioral intervention promoting condoms, given a physical examination and provided with instructions on completing a sexual diary. Potential predictors of trying the female condom were evaluated using logistic regression, and three condom-use groups (exclusive users of female condoms, exclusive users of male condoms and users of both types of condoms) were compared using multinomial regression. Among 895 women who reported having engaged in vaginal intercourse during the study period, one-half had sex with only one partner, while one-quarter each had two partners or three or more partners. A total of 731 women reported using the female condom at least once during the follow-up period – 85% during the first month of follow-up. Multiple logistic regression analyses indicated that employed women and those with a regular sexual partner at baseline were significantly more likely to try the female condom. By the end of the follow-up period, 8% of participants had used the female condom exclusively, 15% had used the male condom exclusively, 73% had used both types of condom and 3% had used no condoms. Twenty percent of women who tried the female condom used it only once and 13% used it twice, while 20% used 5-9 female condoms and 32% used 10 or more. Consistent condom users (N=309) were predominantly users of both types of condom (75%), and were less often exclusive users of the male condom (18%) or the female condom (7%). According to a multivariate analysis, women who used the female condom exclusively or who mixed condom types were more likely to be black, were more likely to be employed and were more likely to have a regular partner than were users of the male condom. Women at risk of STDs find the female condom acceptable and will try it, and some use it consistently. Mixing use of female condoms and male condoms may facilitate consistent condom use. The female condom may improve an individual's options for risk reduction and help reduce the spread of STDs.

Mantell JE, Scheepers E, Karim QA. Introducing the female condom through the public health sector: experiences from South Africa. AIDS Care. 2000;12(5):589-601.

The successful implementation of new public health policy is influenced by provider preparedness and user acceptability of the new intervention. This paper describes the development and implementation of a participatory Training of Trainers (TOT) programme as a precursor to launch the South African government's female-initiated HIV prevention strategies in public health clinics. Three hundred peer-trainees from

throughout South Africa were trained through a comprehensive, modular and interactive three-day workshop. The workshop content included: HIV/AIDS knowledge, beliefs and attitudes; values clarification regarding HIV infection and sexuality; sexual desensitization; 'hands-on' training in the use of and introduction of the female condom; and counseling, communication and programme planning skills. The TOT generated a cadre of knowledgeable health care workers for training others and provided a support structure at the service delivery level for ensuring potential users' access to the female condom within each province. Qualitative assessments of the training and trainer debriefing sessions suggest that the training was successful in increasing knowledge and promoting positive attitudes about female condoms. In addition, the expanded repertoire of problem-solving approaches left providers feeling confident about recommending this method to clients.

Miller LC, Murphy ST, Clark LF, et al. Hierarchical messages for introducing multiple HIV prevention options: Promise and pitfalls. AIDS Education and Prevention. 2004;16(6):509-525.

In battling HIV, many interventionists advocate the use of hierarchical messages that present multiple prevention options in order of decreasing effectiveness. The purpose of the present study was to determine if hierarchical messages provide women with additional prevention options without reducing the perceived efficacy of and willingness to use the primary method mentioned (in this case, male condoms). African American and Mexican American women between 18 and 32 years of age (n = 112) at risk for HIV were randomly assigned to receive either a male-condom-only message (use male condoms) or a hierarchical message (use male condoms; if not, use female condoms; if not, use spermicide). Compared with women in the male-condom-only condition, a significantly smaller percentage of women who received the hierarchical message perceived male condoms as highly effective against HIV. Women currently not using male condoms who received the hierarchical, rather than the male-condom-only, message were less likely to consider using the male condoms in the future. Among current male condom users, however, the hierarchical message did not influence intent to use male condoms. These data point to the need for examining both the intended and unintended effects of hierarchical health care messages.

Mung'ala L, Kilonzo N, Angala P, et al. Promoting female condoms in HIV voluntary counseling and testing centres in Kenya. Reproductive Health Matters. 2006;14(28):99-103.

Promotion of male condoms and voluntary counseling and testing for HIV (VCT) have been cornerstones of Kenya's fight against the HIV epidemic. This paper argues that there is an urgent need to promote the female condom in Kenya through VCT centres, which are rapidly being scaled-up across the country and are reaching increasingly large numbers of people. Training of counselors using a vaginal demonstration model is needed, as well an adequate supply of free female condoms. In a study in five VCT centres, however, counselors reported that most people they counseled believed female condoms were "not as good" as male condoms. In fact, many clients had little or no

knowledge or experience of female condoms. Counsellors' knowledge too was largely based on hearsay; most felt constrained by lack of experience and had many doubts about female condoms, which need addressing. Additional areas that require attention in training include how to re-use female condoms and the value of female condoms for contraception. VCT counselors in Kenya already promote male condoms as a routine part of risk reduction counseling alongside HIV testing. This cadre, trained in client-centred approaches, has the potential to champion female condoms as well, to better support the right to a healthy and safe sex life.

Musaba E, Morrison CS, Sunkutu MR, et al. Long-term use of the female condom among couples at high risk of human immunodeficiency virus infection in Zambia. Sexually Transmitted Diseases. 1998;25(2):260-264.

Few studies have measured female condom use for more than a 6-month period or among persons at high risk of STD. To measure long-term use of the female condom among couples at high risk of HIV infection and to evaluate the effect of female condom use on unprotected coital acts. Ninety-nine Zambian couples with symptomatic sexually transmitted diseases (STD) received female condoms, male condoms, and spermicides and were counseled to use either condom plus spermicide for each coital act. Couples were followed up at 3-, 6- and 12-month visits. Barrier contraceptive use was measured prospectively by coital log. Among the 99 couples enrolled, 51, 38, and 30 couples were successfully followed up for 3, 6, and 12 months, respectively. Female condoms were reportedly used in 24%, 27%, and 23% of coital acts and by 86%, 79%, and 67% of the returning couples during each time interval. Higher-level female condom users used male condoms less often but had fewer unprotected coital acts (5% vs 14%; $p < 0.05$) than lower-level female condom users. A majority of couples at high risk of HIV infection used the female condom in conjunction with other barrier methods over a 1-year period. The addition of female condoms accompanied by appropriate counseling to the barrier method mix may reduce unprotected sex among couples at high-risk of HIV infection.

Nokes KM, Brown J. Teaching about the female condom. Holistic Nursing Practice. 1997;11(2):1-8.

Reality female condoms became available for over-the-counter purchase in the fall of 1994. Because the female condom is a new sexual barrier device, women need to learn how to use it correctly. Health care providers must also be knowledgeable about the correct use of the female condom so that they can teach women how to use it as a barrier method. To facilitate learning about the female condom, a curriculum was developed that included a quiz on knowledge about the female condom. Content validity was established through a content validity index completed by six content experts. This quiz was used to evaluate educational sessions offered to 42 persons in an urban college setting and 18 women in a community setting. The article describes the female condom along with the curriculum that was developed to teach its correct use and the reactions of potential users of the female condom.

Posner SF, van der Straten A, Kang MS, et al. Introducing diaphragms into the mix: What happens to male condom use patterns? AIDS and Behavior. 2005; 9(4):443-449.

The objective of this analysis was to assess the effect of introducing the diaphragm on condom use patterns. Participants included one hundred eighty nine women attending family planning clinics in Harare, Zimbabwe who reported less than 100% condom use. The proportion of acts where at least one method was used significantly increased over using follow-up; male condom use remained stable. A diaphragm was used with 50% to 54% of acts; male condoms were also used about 50% of the time. The proportion of acts where a female condom was used decreased. Women who used both male and female condoms were more likely to use diaphragms than those who reported not using female condoms. Introducing the diaphragm increased the overall proportion of protected acts. The proportion of acts where a male condom was used did not change. Female condoms use declined because concurrent use with the diaphragm is not possible.

Raphan G, Cohen S, Boyer AM. The female condom, a tool for empowering sexually active urban adolescent women. Journal of Urban Health: Bulletin of the New York Academy of Medicine. 2001;78(4):605-613.

Adolescent women are at high risk of sexually transmitted diseases/human immunodeficiency virus (STDs/HIV) because of physiologic susceptibility and risky sexual behavior. The latter may be related to the "personal factors" of self-efficacy, sexual knowledge, self-esteem, and ability to communicate/negotiate. In the current study, near-peers attempted to have an impact on these factors by using the female condom as a negotiating tool for safer sex in a group of 100 urban adolescent women recruited from an adolescent health center waiting room. This pilot study consisted of a questionnaire, a workshop on how to use the female condom and negotiate its use, and follow-up interviews at 1 and 4 months. Demographics of the study sample define a multiethnic (40% black, 33% Hispanic) group in late adolescence (average age 18 years) completing high school. At baseline, 18% evidenced depression, 62% had moderate-to-low self-esteem, 91% had an internal locus of control. At baseline, male condom use in the prior 6 months was 28% always, 51% inconsistently, 21% never. When baseline and follow-up scores were compared, there was a statistically significant increase in sexual knowledge and self-efficacy, together with the suggestion of improved negotiating skills. At 1 month, 50% (20/40) had tried the female condom, and 17 of these women planned to use it in the future. Total percentage of protected sex acts increased significantly during the follow-up period through increased use of both the male and female condoms. The data suggest that adolescent women will accept the female condom and can be empowered to protect themselves from STDs/HIV through its application or through the using of it as a negotiating tool.

Stein Z, Saez H, El-Sadr W, et al. Safer sex strategies for women: The hierarchical model in methadone treatment clinics. Journal of Urban Health: Bulletin of the New York Academy of Medicine. 1999;76(1):62-72.

Women clients of a methadone maintenance treatment clinic were targeted for an intervention aimed to reduce unsafe sex. The hierarchical model was the basis of the single intervention session, tested among 63 volunteers. This model requires the educator to discuss and demonstrate a full range of barriers that women might use for protection, ranking these in the order of their known efficacy. The model stresses that no one should go without protection. Two objections, both untested, have been voiced against the model. One is that, because of its complexity, women will have difficulty comprehending the message. The second is that, by demonstrating alternative strategies to the male condom, the educator is offering women a way out from persisting with the male condom, so that instead they will use an easier, but less effective, method of protection. The present research aimed at testing both objections in a high-risk and disadvantaged group of women. By comparing before and after performance on a knowledge test, it was established that, at least among these women, the complex message was well understood. By comparing baseline and follow-up reports of barriers used by sexually active women before and after intervention, a reduction in reports of unsafe sexual encounters was demonstrated. The reduction could be attributed directly to adoption of the female condom. Although some women who had used male condoms previously adopted the female condom, most of those who did so had not used the male condom previously. Since neither theoretical objection to the hierarchical model is sustained in this population, fresh weight is given to emphasizing choice of barriers, especially to women who are at high risk and relatively disempowered. As experience with the female condom grows and its unfamiliarity decreases, it would seem appropriate to encourage women who do not succeed with the male condom to try to use the female condom, over which they have more control.

Thomsen SC, Ombidi W, Toroitich-Ruto C, et al. A prospective study assessing the effects of introducing the female condom in a sex worker population in Mombasa, Kenya. Sexually Transmitted Infections. 2006;82(5):397-402.

The objective of this study was to assess the impact and costs of adding female condoms to a male condom promotion and distribution peer education programme for sex workers in Mombasa, Kenya. A 12 month, prospective study of 210 female sex workers. We interviewed participants about their sexual behaviour every 2 months for a total of seven times and introduced female condoms after the third interview. We also collected cost data and calculated the cost and cost effectiveness of adding the female condom component to the existing programme. Introduction of the female condom in an HIV/AIDS prevention project targeting sex workers led to small, but significant, increases in consistent condom use with all sexual partners. However, there was a high degree of substitution of the female condom for male condoms. The cost per additional consistent condom user at a programme level is estimated to be $2,160. The female condom has some potential for reducing unprotected sex among sex workers. However, given its high cost, and the marginal improvements seen here, governments should limit

promotion of the female condom in populations that are already successfully using the male condom. More research is needed to identify effective methods of encouraging sex workers to practice safer sex with their boyfriends.

Van Devanter N, Gonzales V, Merzel C, et al. Effect of an STD/HIV behavioral intervention on women's use of the female condom. American Journal of Public Health. 2002;92(1):109-115.

This study assessed the effectiveness of a sexually transmitted disease (STD)/HIV behavior change intervention in increasing women's use of the female condom. A total of 604 women at high risk for STDs and HIV in New York City, Baltimore, MD, and Seattle, Wash, enrolled in a randomized controlled trial of a small-group, skills-training intervention that included information and skills training in the use of the female condom. In a logistic regression, the strongest predictors of use were exposure to the intervention (odds ratio [OR] = 5.5; 95% confidence interval [CI] = 2.8, 10.7), intention to use the female condom in the future (OR = 4.5; 95% CI = 2.4, 8.5), having asked a partner to use a condom in the past 30 days (OR = 2.3; 95% CI = 1.3, 3.9), and confidence in asking a partner to use a condom (OR = 1.9; 95% CI = 1.1, 3.5). Clinicians counseling women in the use of the female condom need to provide information, demonstrate its correct use with their clients, and provide an opportunity for their clients to practice skills themselves.

Vieira EM, Machado AA, Duarte G, et al. The use of the female condom by women in Brazil participating in HIV prevention education sessions. Pan American Journal of Public Health. 2004;15(6):373-379.

To study HIV-positive women and women at risk of becoming infected with HIV who attended HIV prevention education group sessions at a university hospital in Brazil and to compare the use of the female condom and the male condom by these two groups of women. The study subjects were 165 women participating in HIV prevention education group sessions at the Medical School Hospital of Ribeirao Preto of the University of Sao Paulo, in the city of Ribeirao Preto, Sao Paulo, Brazil. Women could be enrolled in the study from August 2000 to June 2001, and the follow-up observation time period was from August 2000 to July 2001. Male condoms and female condoms were freely distributed to all the participants at the end of each educational session and also at the end of each follow-up visit that the participants made. Each woman took part in an initial interview and was asked to return monthly. At each follow-up visit an additional short interview was carried out in order to investigate use of the male condom and of the female condom. Variables that were examined for the study included age, education, ethnic group, marital or relationship status, number of children, the women's use of male condoms and female condoms, commercial sex (whether the women had ever had sex in exchange for money, gifts, or favors), and previous knowledge of the female condom. The 165 women studied fell into the following three categories: 132 of them (80.0%) were HIV-positive, 26 of them (15.8%) had a sexually transmitted disease (STD) other than HIV and did not have an HIV-positive partner, and 7 of them (4.2%) had an HIV-positive partner but did not have HIV or any other STD. The women ranged in age from

15 to 64 years, with a mean of 30.3 years. Of the women in the study, 69.7% of them were married or were cohabitating, and 90.9% of them had a sexual partner. Just over two-thirds of the women had seven years of formal schooling or less. Out of the 163 women, a total of 31 of them (19.0%) had never used the male condom with a partner, and 49 of 163 (30.1%) had not used a male condom at the time of last sexual intercourse. Out of the 165 women, 74 of them (44.8%) returned for at least one follow-up visit. Of these 74 women, 58 of them (78.3%) reported using the female condom between the initial interview and the first follow-up visit. The majority of the 74 women who returned for a visit liked using the female condom, and the women reported that their partners also generally accepted the female condom. In comparison to women at risk of HIV, HIV-positive women were more likely to have used the male condom with a partner before the initial interview. Women who continued returning over a longer follow-up period were more likely to have used the female condom at the time of last sexual intercourse. No association was found between female condom use at the time of last sexual intercourse and the woman's HIV infection status. In comparison to the women at risk of HIV, the HIV-positive women in our study were more likely to use male condoms with their partners, to return for follow-up visits, and to have a longer follow-up period. The acceptance of the female condom among HIV-positive women in this study, as reported at their first follow-up visit, appears to be similar to the acceptance of the female condom among women in general in Brazil.

Warren M, Philpott A. Expanding safer sex options: Introducing the female condom into national programmes. Reproductive Health Matters. 2003;11(21):130-139.

Although the female condom has been introduced into over 90 countries since 1997, it has only been accepted in sexual and reproductive health programmes as a mainstream method in a few. This paper describes introductory strategies developed by Ministries of Health and non-governmental organizations in Brazil, Ghana, Zimbabwe and South Africa, supported by UNAIDS, and the manufacturers of the female condom, which have significantly expanded the number of female condoms being used. These projects have several key similarities: a focus on training for providers and peer educators, face-to-face communication with potential users to equip them with information and skills, an identified target audience, a consistent supply, a long assessment period to gauge actual use beyond the initial novelty phase, and a mix of public and private sector distribution. Female condom programmes require the sanction, leadership and funding of governments and donors. However, the non-governmental and private sectors have also played a major role in programme implementation. To ensure successful introduction of the female condom, it is crucial to involve a range of decision-makers, programme managers, service providers, community leaders and women's and youth groups. The rising cost of inaction and unprotected sex in the spread of HIV and AIDS force us to recognize the high cost of not providing female condoms alongside male condoms in family planning and AIDS prevention programmes.

Welsh MJ, Feldblum PJ, Kuyoh MA, et al. Condom use during a community intervention trial in Kenya. International Journal of STD and AIDS. 2001;12 (7):469-474.

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

Witte SS, El-Bassel N, Gilbert L, et al. Promoting female condom use to heterosexual couples: Findings from a randomized clinical trial. Perspectives on Sexual and Reproductive Health. 2006;38(3):148-154.

The female condom remains the only female-initiated method for preventing pregnancy and STDs, including HIV. Innovative methods for promoting its use, and for involving male partners in its use, are needed. A sample of 217 women and their main male sexual partners were randomly assigned to one of the three study conditions: a six-session relationship-based STD prevention intervention provided to the couple together, the same intervention provided to the woman only or a single-session education control provided to the woman only. Assessments were conducted at baseline and three months postintervention. Contrast coding was used to examine whether the effects of the two active interventions differed from those of the control intervention, and whether the effects of the two active interventions differed from each other. Regression analyses were used to estimate treatment effects. During follow-up, participants in either active intervention were more likely to use a female condom with their study partner and with all partners, and used female condoms at a higher rate with all partners, than individuals assigned to the control intervention; at the end of three months, they were more likely to intend to use the condom in the next 90 days. No significant differences in outcomes were found between the active intervention groups. Focusing on both a woman and her main male sexual partner is efficacious in increasing female condom use and intention to use among heterosexual couples at risk for HIV and other STDs.

World Health Organization and the Joint United Nations Programme on HIV/AIDS. The Female Condom: A guide for planning and programming, 2000.

This new document -- *The Female Condom: A guide for planning and programming* – aims to complement the *Information Pack* by providing guidance on how to plan for integrating the female condom into already existing activities as well as how to effectively promote it and train providers to adequately educate potential users about it. Its aim is to help programme managers in public and private sector health systems and non-governmental (CBOs) who are interested in developing or expanding programmes to include the female condom and to address some of its more operational and promotional aspects. This document is intended to help design, implement and monitor programmes that incorporate the female condom in a range of different settings. It is based on real experiences from projects from all over the world. Because the female condom is still a relatively new method, the way in which it is introduced is essential to its acceptance by policy-makers, programme managers, service providers, non-governmental organizations and potential users.

Yimin C, Zhaohui L, Xianmi W, et al. Introductory study on female condom use among sex workers in China. Contraception. 2002;66(3):179-185.

There is lack of barrier method use among sex workers (SWs) in China. Our objective was to find new ways to introduce female condoms (FCs) among SWs, and to increase knowledge of, support for, and use of this method in this population. We used the intervention study method and provided the SWs of experimental groups with information, education, and communication on FCs and provided them with FCs. We recuited 330 SWs as the participants of the study in Enping City, China. The selected 330 SWs were randomly divided into the experimental group (165 SWs to use female condom) and the others into the reference group (165 SWs to use male condom). Questionnaires were used to evaluate the intervention study. At the end of our study, 15 SWs were lost of follow-up, so only 315 were included in the analysis. After intervention, about 97% of SWs in the intervention group expressed that they would use FC in the future. The rate of SWs who reported liking FC increased from 60% at pre-intervention to 94% at post-intervention. The rate of SWs who considered their clients could accept FC increased from 27% to 92%, and the rate of SWs who were willing to recommend FC to others increased from 19% to 70%. In comparison with the first several uses, during last several uses about 80% of SWs expressed that it became easier to use FC. Our intervention increased knowledge of, positive attitudes towards, and correct use of FC in this population of SWs.

Yimin C, Zhaohui L, Xianmi W, et al. Use of the female condom among sex workers in China. International Journal of Gynecology and Obstetrics. 2003; 81(2):233-239.

To introduce the female condom (FC) among sex workers (SWs) in China. We adopted the intervention study method. The 315 participating SWs were randomly assigned to an intervention group (155 SWs) or a control group (160 SWs). The rate of SWs who

reported liking FC increased from 60.0% pre-intervention to 93.5% post-intervention, and the rate of SWs who considered that their clients could accept FC increased from 27.1% to 92.3%. After the intervention, 93.5% expressed that their sexual satisfaction had increased with their familiarity with FC and 97.4% expressed that they would use it in the future. The understanding and use of FC can be greatly improved through active intervention – i.e. medical workers providing SWs with FC.

See Also:

COMMENTARY/LITERATURE REVIEWS: Kaler A. The future of female-controlled barrier methods for HIV prevention: Female condoms and lessons learned. Culture, Health and Sexuality. 2004;6(6): 501-516.

COMMENTARY/LITERATURE REVIEWS: Sakondhavat C. Challenges to female condom integration into condom programming. International Journal of STD and AIDS. 2002;13(7):444-448.

EFFICACY: Feldblum PJ, Kuyoh MA, Bwayo JJ, et al. Female condom introduction and sexually transmitted infection prevalence: Results of a community intervention trial in Kenya. AIDS. 2001;15(8):1037-1044.

EFFICACY: French PP, Latka M, Gollub EL, et al. Use-effectiveness of the female versus male condom in preventing sexually transmitted disease in women. Sexually Transmitted Diseases. 2003;30(5):433-439.

EFFICACY: Galvao LW, Oliveira LC, Diaz J, et al. Effectiveness of female and male condoms in preventing exposure to semen during vaginal intercourse: a randomized trial. Contraception. 2005;71(2):130-136.

VI. RE-USE

Beksinska ME, Rees HV, Dickson-Tetteh KE, et al. Structural integrity of the female condom after multiple uses, washing, drying, and re-lubrication. Contraception. 2001;63(1):33-36.

Establishing the safety of re-using the female condom could significantly increase women's access to barrier methods especially in poorer countries. In this study, the structural integrity of female condoms was tested (n = 295) after multiple acts of vaginal intercourse. Fifty women were recruited to the study. Each woman re-used one condom up to eight times and washed, dried, and re-lubricated between each use. Structural integrity was measured using standard quality control testing; water-leakage, air-burst, and seam tensile strength. All results were compared to the United States Food and Drug Administration (US FDA) standards for an unused female condom. The results of the structural integrity tests for all cycles were above the FDA minimum standards for seam strength and burst tests. There was no deterioration detected in condoms used 8 times when compared to new female condoms in these tests. Five holes were detected by the water leakage test across all cycles, of which three were detected by the subjects themselves and reported to the investigators, therefore, giving a breakage rate of 1.7%. The holes were not associated with increased number of uses. This study provides further evidence that suggests the structural integrity of the female condom after multiple use is still within FDA minimum standards, although random holes resulting from handling occur infrequently with the re-use procedure.

Joanis C, Latka M, Glover LH, et al. Structural integrity of the female condom after a single use, washing, and disinfection. Contraception. 2000;62(2):63-72.

The Reality® female condom is approved for use during a single act of intercourse, but is expensive relative to other barrier methods. Re-use is a potential strategy to reduce its per-use cost. We tested the structural integrity of female condoms (n = 318) after a single act of vaginal intercourse. We also measured the impact of laboratory washing (1, 5, or 10 times) with and without disinfection on the structural integrity of unused condoms. Structural integrity was measured via 5 tests: seam tensile strength, water leakage, air-burst, tear propagation, and device dimensions. No degradation in device structural integrity occurred after a single use when compared to control for seam tensile (16.0 vs. 15.7 mPa; $p = 0.558$); water leakage (1.9% vs. 0.9%; $p = 0.618$); air burst (3.9 vs. 3.6 kPa; $p < 0.0010$; or tear propagation (344.6 vs. 336.8 psi; $p = 0.313$). Mean length was slightly increased [single use vs. control (177.9 vs. 172.5 mm; $p < 0.001$)]. No consistent pattern of structural degradation emerged across all wash/disinfection groups. Our data suggest the structural integrity of the female condom remains intact after a single use and cleaning.

Pettifor AE, Beksinska ME, Rees HV, et al. The acceptability of reuse of the female condom among urban South African women. Journal of Urban Health: Bulletin of the New York Academy of Medicine. 2001;78(4):647-657.

This study assessed whether reuse of the female condom was acceptable among two groups of women in central Johannesburg, South Africa, who were taking part in two separate studies of female condom reuse. The first group consisted of women (aged 17 to 43 years) attending a family planning/sexually transmitted infections (STIs) clinic who were participating in a cross-sectional survey of the acceptability of female condoms reuse (n = 100). The second group included women (aged 18-40 years) at high risk for STI (80% self-declared sex workers) who were taking part in an ongoing cohort study to investigate the safety of reuse of the female condom through a structural integrity and microbial retention study (n = 50). Among women participating in the acceptability study, 83% said that they would be willing to reuse the female condom, and 91% thought the idea of reuse of the female condom was acceptable. All women taking part in the safety of reuse study and who reused the female condom up to seven times (n = 49) reported that the steps involved in reusing the device were easy to perform and acceptable. All 49 women said they would reuse the female condom at least once, while 45% said they would use it a maximum of seven or eight times. From the results of the interviews with both study groups, it can be concluded that, among women in a South African urban environment who have used a male and/or female condom, the concept of reuse of the female condom is acceptable and thought to be a good idea.

Philpott A. Re-use of the female condom: Now for the practical realities. Reproductive Health Matters. 2003;11(22):185-186.

Female condoms are being re-used in programmes where women do not have access to or cannot afford new ones, or there is not a consistent supply. This has led to research into the safety of re-use of female condoms. Clinical guidelines on re-use of the female condom were released by the World Health Organization (WHO) in July 2002. The WHO protocol states that while a new condom is best with each act of intercourse, in situations where they are not available or affordable, evidence suggests that the structural integrity of the female condom allows it to be used at least five times, if the WHO guidelines are followed.

Potter B, Gerofi J, Pope M, et al. Structural integrity of the polyurethane female condom after multiple cycles of disinfection, washing, drying and relubrication. Contraception. 2003;67(1):65-72.

The female condom provides an important alternative means of protection against HIV and other sexually transmitted infections for women, particularly in situations where partners are reluctant or refuse to use male condoms. The relatively high cost of the device, however, is a barrier to its use in resource-poor environments. This has led to some reuse of the product and two studies have demonstrated that female condoms can withstand a limited level of reuse without an excessive loss of structural integrity when washed with soap and water. A consultation on female condom reuse convened by the

World Health Organization and the Joint United Nations Programme on AIDS in June 2000 recommended that all used female condoms should be disinfected immediately after use, before washing. The effect of such treatments on the female condom was not known. This study was undertaken to assess the effect of the disinfection, washing, drying and relubrication on the properties of the condom. Samples from three batches of female condoms were subjected to seven treatment cycles before being tested for structural integrity. In all cases the batches of condoms complied with the manufacturer's release specification for the product after treatment. Some minor changes in properties were seen but these were not considered important. There was evidence of a small increase in the number of condoms with holes following repeated disinfection and washing cycles, suggesting that excessive or rough handling can damage the condom. Condoms should therefore be handled carefully and inspected thoroughly for signs of damage after washing and drying before being stored with the intention of subsequently reusing the device.

Smith JB, Nkhama G, Trottier DA. Female condom reuse in Lusaka, Zambia: Evidence from 12 cases. Journal of Urban Health: Bulletin of the New York Academy of Medicine. 2001;78(4):638-646.

Female condom reuse could address one of the principal barriers to use, namely, cost; however, the safety of reuse has not been established. Recent reports have provided information related to reuse safety under carefully specified research study conditions. Still, little is known about reuse outside a research study context, and there are outstanding questions related to feasibility of reuse among general populations. This study reports on naturally occurring reuse from a small, purposive sample of self-identified women who, prior to the study, had reused the female condom of their own volition without reuse instruction. Three types of reuse were identified. Most women attempted to clean devices between removal and reinsertion. A number of agents, including water (only), bath soap, laundry detergent, Dettol, and beer were used for cleaning. A number of agents were used for relubrication, including Reality® lubricant, various kinds of cooking oil, and Vaseline. Perception of the strength and integrity of female condoms making them suitable for reuse were influenced by both provider advice and product packaging. Most participants reported no problems with reuse. Some women, faced with barriers to single use of a female condom or use of an acceptable alternative, will resort to reuse and rely on their own "common sense" notions to implement reuse. Providers and purveyors have opportunities to shape responses to reuse for the better, and the research community is obligated to provide a solid scientific base regarding reuse safety.

World Health Organization. Considerations regarding re-use of the female condom: Information update, 10 July 2002. Reproductive Health Matters. 2002;10 (20);182-186.

The World Health Organization (WHO) recommends use of a new male or female condom for every act of intercourse where there is a risk of unplanned pregnancy and/or sexually transmitted infection, including HIV. Since access to female condoms may be

limited and re-use of female condoms has been reported. WHO has convened two consultations to address considerations regarding such re-use. Based on these consultations, WHO does not recommend or promote re-use of female condoms. Recognizing the urgent need for risk-reduction strategies for women who cannot or do not access new condoms, the consultation developed a draft protocol for safe handling and preparation of female condoms intended for re-use. This protocol, outlined in this paper, is based on the best available evidence, but has not yet been extensively studied for safety or evaluated for efficacy in human use. Given the diversity of cultural and social contexts and personal circumstances under which female condom re-use may be acceptable, feasible and safe, and since the balance of risks and benefits varies according to individual settings, the final decision on whether or not to support re-use of the female condom must ultimately be taken locally. WHO continues to support research on female condom re-use and will disseminate relevant information, study results and guidelines for policy makers as additional data on re-use become available.

World Health Organization. The safety and feasibility of female condom reuse: Report of a WHO Consultation, January 28-29, 2002.

Many women face difficulties in negotiating the use of male condoms. The female condom may therefore be an important option to assist women in protecting themselves and their partners from both unwanted pregnancy and sexually transmitted infections (STI). Some women have reported using the same female condom for multiple sex acts, a behaviour said to be motivated by the high cost or limited availability of the device as well as by its perceived strength. Such practices may expose women or their partners to pathogens during washing or subsequent reuse of the female condom, especially for populations living in areas of high STI/HIV prevalence.

VII. USE BY MEN WHO HAVE SEX WITH MEN (MSM)

Gibson S, McFarland W, Wohlfeiler D, et al. Experiences of 100 men who have sex with men using the Reality® condom for anal sex. AIDS Education and Prevention. 1999;11(1):65-71.

A self-administered, anonymous questionnaire examining opinions and experiences of using Reality®, the "female" condom, for anal sex was completed by a convenience sample of 100 men who have sex with men (MSM). Eighty-six percent of respondents said they would use Realty® again; 54% would rather use Reality® than penile condoms. Acceptability was higher among MSM who were HIV positive, in nonmonogamous relationships, or who had serodiscordant partners. Negative experiences included: difficulty inserting (33%), irritation (17%), bunching up (12%), unpleasant texture (10%), and noise (9%). Breakage was reported three times in 334 episodes of use. Although no available data compare preferences and efficacy of Reality® to penile condoms, Reality® is a welcome alternative for some MSM who have difficulty consistently using penile condoms and probably reduces HIV transmission compared with unprotected anal sex. Research to more definitively assess Reality as a risk reduction method for MSM is greatly needed.

Gross M, Buchbinder SP, Holte S, et al. Use of Reality "Female Condoms" for anal sex by US men who have sex with men. American Journal of Public Health. 1999;89(11):1739-1741.

This study assessed use of Reality "female condoms" for anal sex by HIV-seronegative men who have sex with men and are at high risk for HIV infection. Self-administered questionnaires were completed by 2277 participants in a 6-city prospective cohort study. Of the 1084 (48%) men who had heard of using the female condom for anal sex, 145 (13%) reported using it in the prior 6 months. Users were at greater risk than nonusers: 47 receptive and 35 insertive users reported problems, including bleeding by the receptive partner (4). Redesign of the female condom could increase acceptability and use by men who have sex with men and could address possible safety concerns.

Mantell JE, Kelvin EA, Exner TM, et al. Anal use of the female condom: does uncertainty justify provider inaction? AIDS Care. 2009;21(9):1185-1194.

Despite limited safety data and the absence of efficacy data, several studies have reported that the female condom is being used for anal sex by men who have sex with men. We describe providers' awareness of female condom use during anal sex among their clients and their experiences in counseling clients. We conducted semi-structured interviews with 78 health-care providers recruited from various health-care delivery systems in New York City: a family planning agency, a sexually transmitted infections agency, a hospital-based obstetrics and gynecology clinic, and two community-based AIDS service organizations. While two-thirds of providers reported that they were uncertain as to whether the female condom could or should be used for anal intercourse, nearly one-third believed that anything is better than nothing to prevent HIV/sexually transmitted

infections during anal sex. Few providers had actually talked with clients about anal use of the female condom, and clients themselves had seldom mentioned nor asked for information about such use. Our findings highlight providers' uncertainty about anal use of the female condom. Lacking guidelines regarding the safety and efficacy of female condom use during anal sex, health-care providers are left to make their own well-intentioned recommendations (or not) to potential users. The dearth of information on female condom use during anal sex could encourage individuals to use the female condom for anal sex, which may increase HIV transmission risk or represent a missed opportunity for protecting non-condom users. There is a need for a series of harm-reduction safety, acceptability, and efficacy studies and, in the interim, for the development of a carefully qualified set of guidelines regarding anal use of the female condom for health-care providers.

Renzi C, Tabet SR, Stucky JA, et al. Safety and acceptability of the Reality condom for anal sex among men who have sex with men. AIDS. 2003;17(5):727-731.

To assess safety and acceptability of Reality condoms for anal sex among men who have sex with men. Crossover study among HIV-seroconcordant (33 HIV-negative and 5 HIV-positive) monogamous male couples, randomized to latex male and Reality condom use with anal sex. Slippage with removal was reported more frequently with Reality than male latex condoms [odds ratio (OR), 2.7; 95% confidence interval (CI), 1.2 – 5.8 for receptive partners and OR, 34.1; 95% CI, 13.8 – 84.1 for insertive partners]. Receptive partners more frequently reported pain or discomfort (OR, 5.0; 95% CI, 2.6 – 9.4) and rectal bleeding (OR, 1.9; 95% CI, 0.9 – 4.1) with Reality condoms than male condoms. Over 20% reported willingness to use the Reality condom in the future with a partner of unknown HIV status; willingness was associated with past problems with male condoms and no problems with Reality condoms among receptive partners, and with past use of Reality condoms and HIV seropositivity among insertive partners. Men reported more frequent problems with Reality condoms than male latex condoms used for anal intercourse, particularly slippage, discomfort, and rectal bleeding. Design modifications, training, and research on the clinical significance of safety outcomes are needed for use of Reality condoms with anal sex.