



Female Condom Bibliography
Chronological Order
June 2010

The articles listed below represent a bibliography of research on the female condom. We searched in PubMed for the term “female condom” in titles and abstracts from articles published before May 15, 2010. This version of the bibliography contains citations and abstracts in chronological order by year; please see the other version of the bibliography for a list of studies in alphabetical order.

2010

Batár I, Sivin I. State-of-the-art of non-hormonal methods of contraception: I. Mechanical barrier contraception. *The European Journal of Contraception and Reproductive Health Care*. 2010; 15: 67–88.

Mechanical barriers, specifically male condoms, command renewed interest and are used today by more people. The worldwide prevalence rate of male condoms was about 6% in 2007 corresponding to 65 million cohabiting couples. The prevalence of female barrier methods, including diaphragms, cervical caps and female condoms has declined to less than 1% of women in North America and in north-west Europe. Even smaller percentages use female barriers elsewhere. First-year life table pregnancy probabilities of mechanical barrier methods range from 4 to 19 per hundred in clinical trials. The male condom is the only proved preventive tool against several sexually transmitted infections (STIs), especially HIV. The effectiveness of the diaphragm and cervical caps in this regard appears limited. Further research is needed to measure the efficacy of female condoms in disease prevention. Sponges are not known to protect against STIs. Because of their ease of use and availability, low short term costs, relative freedom from side effects, and usefulness in combating STIs, mechanical barrier methods, especially condoms, will continue to be used on a large scale. For our literature search we used personal files, search engines such as Popline, Medline, PubMed and Google, and data bases of WHO, FHI and Cochrane Library.

Collins PY, von Unger H, Putnins S, Crawford N, Dutt R, Hoffer M. Adding the Female Condom to HIV Prevention Interventions for Women with Severe Mental Illness: A Pilot Test. *Community Mental Health Journal* 2010; published online March 25, 2010.

We evaluated the efficacy of a gender-specific intervention to reduce sexual risk behaviors by introducing female-initiated methods to urban women with severe mental illness. Seventy-nine women received 10 sessions of an HIV prevention intervention or a control intervention. The primary outcome was unprotected oral, anal, or vaginal intercourse, expressed using the Vaginal Episode Equivalent (VEE) score. Knowledge and use of the female condom were also assessed. Women in the HIV prevention intervention showed a three-fold reduction in the VEE score at the 3-month follow-up compared to the control group, but the difference was not significant. These women were significantly more likely to know about female condoms, have inserted one and used it with a sexual partner at the 3-month follow-up and to have inserted it at 6 months compared to controls. The female condom may be a useful addition, for a subset of women with SMI, to comprehensive HIV prevention programs.

Hou LY, Qiu HY, Zhao YZ, Zeng XS, Cheng YM. A crossover comparison of two types of female condom. *International Journal of Gynaecology and Obstetrics* 2010;108(3):214-8.



OBJECTIVE: To compare the performance and acceptability of 2 types of female condoms (FCs) among female sex workers (FSWs) in China. **METHODS:** The present crossover survey trial was conducted in Enping City between September and December 2007. **RESULTS:** 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. **CONCLUSION:** There were no statistically significant differences in performance between the 2 types of FCs tested, and most participants would accept using either in the future.

Weeks MR, Li J, Coman E, Abbott M, Sylla L, Corbett M, Dickson-Gomez J. Multilevel Social Influences on Female Condom Use and Adoption Among Women in the Urban United States. *AIDS Patient Care and STDS* 2010; 24(5): 297-309.

Heterosexually transmitted HIV remains of critical concern in the United States and around the world, especially among vulnerable and disadvantaged women, complicated by socioeconomic circumstances, gender power, addiction, and experiences of abuse, among other conditions. Effective woman-initiated HIV prevention options, such as the female condom (FC), are needed that women can use in different sexual relationship contexts. We conducted a behavioral and attitudinal survey with 461 primarily African American and Latina (especially Puerto Rican) women in Hartford, Connecticut, to measure factors on the individual, partner relationship, peer, and community levels influencing their initial and continued use of FC (using the prototype FC1) for disease prevention. We used multivariate analyses and structural equation modeling to assess effects of multiple level factors on FC use and unprotected sex with primary, casual, and paying partners. Initial, recent, and continued FC use was associated with factors on the individual level (education, marital status, drug use, child abuse experiences, HIV status), partner level (number of sex partners, paying sex partner, relationship power), and peer level (more or influential peers saying positive things about FC). Community level factors of availability and support were consistently poor across all sectors, which limited overall FC use. Patterns differed between African American and Latina women in stages and contexts of FC use and unprotected sex. FC can make a valuable contribution to reducing heterosexually transmitted HIV among women in many circumstances. The greatest barrier to increased FC use is the lack of a supportive community environment for its promotion and use.

2009

Bisika T. Female controlled methods of contraception and sexually transmitted infections including HIV in Malawi: examining the role of the female condom and microbicides. *East African Journal of Public Health* 2009;6(2):223-5.

No abstract available.

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):757-62.

BACKGROUND: 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. **METHODS:** 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. **RESULTS:** 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). CONCLUSIONS: 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.

Kelvin EA, Smith RA, Mantell JE, Stein ZA. 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.

Lara DK, Grossman DA, Muñoz JE, Rosario SR, Gómez BJ, García SG. Acceptability and use of the female condom and diaphragm among sex workers in Dominican Republic: Results from a prospective study. *AIDS Education and Prevention* 2009;21(6):538-551.

To assess the acceptability and use of the female condom and diaphragm among female sex workers in the Dominican Republic, 243 participants were followed for 5 months. Participants received female and male condoms and a diaphragm along with proper counseling at monthly visits. Seventy-six percent reported used of female condom at least once during the final month of the study, compared with 50% that used the diaphragm with male condoms and 9% that used the diaphragm alone. The proportion of women reporting every sex act protected with some barrier method increased from 66% at first month to 77% at final month ($p < 0.05$). Participants reported higher acceptability and use of the female condom than the diaphragm. The introduction of female-controlled barrier methods resulted in the use of a wide range of prevention methods and a significant reduction in unprotected sex.

MacPhail C, Terris-Prestholt F, Kumaranayake L, Ngoako P, Watts C, Rees H. Managing men: women's dilemmas about overt and covert use of barrier methods for HIV prevention. *Culture, Health & Sexuality* 2009; 11(5): 485 - 497.

Women in sub-Saharan Africa are at high risk of HIV infection and may struggle to negotiate condom use. This has led to a focus on the development of female-controlled barrier methods such as the female condom, microbicides and the diaphragm. One of the advantages of such products is their contribution to female empowerment through attributes that make covert use possible. We used focus groups to discuss covert use of barrier methods with a sample of South African women aged 18-50 years from Eastern Johannesburg. Women's attitudes towards covert use of HIV prevention methods were influenced by the overarching themes of male dislike of HIV and pregnancy prevention methods, the perceived untrustworthiness of men and social interpretations of female faithfulness. Women's discussions ranged widely from overt to covert use of barrier methods for HIV prevention and were influenced by partner characteristics and previous experience with contraception and HIV prevention. The discussions indicate that challenging gender norms for HIV prevention can be achieved in quite subtle ways, in a manner that suits individual women's relationships and previous



experiences with negotiation of either HIV or pregnancy prevention.

Mantell JE, Kelvin EA, Exner TM, Hoffman S, Needham S, Stein ZA. 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 infection 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, acceptability, and efficacy studies and, in the interim, for the development of a carefully qualified safety set of guidelines regarding anal use of the female condom for health-care providers.

Mauck CK, Weaver MA, Schwartz JL, Walsh T, Joanis C. Critical next steps for female condom research -- report from a workshop. *Contraception* 2009; 79(5): 339-344.

No abstract available [workshop report].

Wadhams N. Uganda to reintroduce female condoms. *The Lancet* 2009;374(9685):190.

No abstract available [world report].

2008

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

Objective: To investigate how males assist their partners in using the female condom. Methods: 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. Results: 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 device was inserted using the inner ring, as recommended in the instructions for use. A small number (6%) mentioned that partners assisted in removal. Conclusion: 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, Hoff C, Gregorich SE, Grinstead O, Gomez C, Hussey W. 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.

Objectives: We evaluated the efficacy of skills training designed to increase female condom use among women. **Methods:** We conducted a 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. **Results:** 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. **Conclusions:** Outcomes suggest that skills training can increase female condom use and protected sexual acts without reducing male condom use among women.

Holmes L, Ogungbade GO, Ward DD, Garrison O, Peters RJ, Kalichman SC, Lahai-Momohe J, Essein EJ. Potential markers of female condom use among inner city African-American Women. *AIDS Care: Psychological and Socio-medical Aspects of AIDS/HIV* 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.

Jones DL, Weiss SM, Chitalu N, Mumbi M, Shine A, Vamos S, Villar O. Acceptability and Use of Sexual Barrier Products and Lubricants among HIV-Seropositive Zambian Men. *AIDS Patient Care & 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 Therapeutics, 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.

Lameiras Fernandez M, Failde Garrido JM, Castro YR, Núñez Mangana AM, Carrera Fernandez MV, Foltz ML. Assessing female condom acceptability among heterosexual Spanish couples. *The European Journal of Contraception & Reproductive Health Care* 2008; 13(3): 255-263.

Objective: To assess the acceptability of the female condom in a sample of young heterosexual Spanish couples. Methods: 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 three stages: pre-trial, post-trial, and follow-up (one year later). Results: 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. Conclusion: This study reveals that although the female condom is considered to be a useful method, it is still largely unknown and requires further promotion if it is to be used by young couples.

Latka MH, Kapadia F, Fortin P. The Female Condom: Effectiveness and Convenience, Not Female Control, Valued by US Urban Adolescents. *AIDS Education & 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.

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

Objective: To determine contraceptive use among HIV infected women attending Comprehensive Care Centre at Kenyatta National Hospital. Design: Hospital based cross-sectional descriptive study. Setting: Comprehensive Care Centre (CCC), Kenyatta National Hospital. Subjects: 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 pretested interviewer administered questionnaire. Consecutive women willing to participate in the study were interviewed. Main Outcome Measures: Current contraceptive use, contraceptive methods, source of contraception, reproductive intention and unmet need of family planning. Results: 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. Conclusion: 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, Padian N, van der Straten A. Female condom uptake and acceptability in Zimbabwe. *AIDS Education & 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.

Schwartz JL, Barnhart K, Creinin MD, Poindexter A, Wheeless A, Kilbourne-Brook M, Mauck CK, Weiner DH, Callahan MM. Comparative crossover study of the PATH Woman's Condom and the FC Female Condom®. *Contraception* 2008; 78(6): 465-473.

Background: 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. Study Design: 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 substudy 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 substudy. Acceptability of each given condom type was measured by questionnaire. Results: 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. Conclusions: 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.

2007

Barbosa RM, Kalckmann S, Berquo E, Stein Z. Notes on the female condom: experiences in Brazil. *International Journal of STD & 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 a 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 M, Joanis C, Manning J, Smit J, Callahan M, Deperthes B, Usher-Patel M. 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.

Chen MP, Macaluso M, Blackwell R, Galvao L, Kulczycki A, Diaz J, Jamieson DJ, Duerr A. Self-reported mechanical problems during condom use and semen exposure: Comparison of two randomized trials in the United States of America and Brazil. *Sexually Transmitted Diseases* 2007; 34(8): 557.

Objectives/Goal: To compare self-reported condom use problems and objectively determined semen exposure in 2 populations. Study Design: 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 precoital and postcoital samples of



vaginal fluid. Prostate-specific antigen (PSA) was detected by immunoassay. Results: 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. Conclusions: 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.

Hoke TH, Feldblum PJ, Damme KV, Nasution MD, Grey TW, Wong EL, Ralimamonjy L, Raharimalala L, Rasamindrakotroka A. Randomised controlled trial of alternative male and female condom promotion strategies targeting sex workers in Madagascar. *Sexually Transmitted Infections* 2007; 83(6): 448-453.

Objectives: To assess whether individual clinic-based counselling 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. Methods: 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 counselling. Participants were followed for 12 months. Every 2 months they made clinic visits, where they were interviewed on condom use. Peer educators counselled all participants on condom use as they accompanied their assigned participants to study visits. Participants assigned to receive the supplemental intervention were counselled 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. Results: 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. Conclusions: This study found little evidence for gains from more thorough clinical counselling 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.

Hoke TH, Feldblum PJ, Van Damme K, Nasution MD, Grey TW, Wong EL, Ralimamonjy L, Raharimalala L, Rasamindrakotroka A. Temporal trends in sexually transmitted infection prevalence and condom use following introduction of the female condom to Madagascar sex workers. *International Journal of STD & 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.

Mukandavire Z, Garira W. Sex-structured HIV/AIDS model to analyse the effects of condom use with application to Zimbabwe. *Journal of Mathematical Biology* 2007; 54(5): 669-699.



We present a sex-structured model for heterosexual transmission of HIV/AIDS in a community. The model is formulated using integro-differential equations, which are shown to be equivalent to delay differential equations with a time delay due to incubation period. The sex-structured HIV/AIDS model divides the population into a two sex-structure consisting of females and males. The threshold and equilibria for the model are determined and stabilities are examined. We extend the model to focus on the effects of condom use as a single-strategy approach in HIV prevention in the absence of any treatment. Initially we model the use of male condoms and further extend the model to incorporate the use of both female and male condoms. The model includes two primary factors in condom use to control HIV that are condom efficacy and compliance. The exposure risk of infection after each intervention is obtained. Basic reproductive numbers for these models are computed and compared to assess the effectiveness of male and female condom use in a community. The models are numerically analysed to assess the effectiveness of condom use on the transmission dynamics of HIV/AIDS using demographic and epidemiological parameters for Zimbabwe. The study demonstrates the use of sex-structured HIV/AIDS models in assessing the effectiveness of female and male condom use as a preventative strategy in a heterosexually active population.

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

Background: This study describes the outcome of a postabortion care intervention aimed at introducing the female condom as a means of preventing women from having unwanted pregnancies and sexually transmitted infections (STIs)/HIV. Methods: Postabortion 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 male or female condom. In total, 521 (95%) women accepted contraception. Results: 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. Conclusion: Postabortion 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.

Spizzichino L, Pedone G, Gattari P, Luzi AM, Gallo P, Valli R, Rezza G. The female condom: knowledge, attitude, and willingness to use. The first Italian study. *Annali dell'Istituto superiore di sanità* 2007; 43(4):419-24.

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 counselling. 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.

2006

Beksinska M, Smit J, Mabude Z, Vijayakumar G, Joanis C. 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.

Objective: 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. Method: In total, 276 women were enrolled and 201 women completed the study. Altogether, 1910 FC1 condoms and 1881 FC2 condoms were used. Results: 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. Conclusion: The FC1 and FC2 performed comparably within this trial.

Boudaya S, Masmoudi A, Meziou TJ, Bouassida S, Marrakchi S, Mseddi M, Turki H, Zahaf A. Acceptability of the female condom among prostitutes in Tunisia. *Annales de dermatologie et de vénéréologie* 2006; 133(2):185-187.

No abstract available [article in French].

Coffey PS, Kilbourne-Brook M, Austin G, Seamans Y, Cohen J. 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

Objective: To evaluate the cost-effectiveness and potential impact of expanded female condom distribution. Design: 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. Results: 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, 9577 (5-95th percentiles, 6539-13 270) infections could be averted, at \$985 (5-95th percentiles, 633-1412) 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 \$1503 (5-95th percentiles, 1245-1769) in South Africa, indicating potential cost savings. The incremental cost of expanded distribution would be reduced to \$8930 (5-95th percentiles, 5864-13 163) 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. Conclusions: 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.



Mung'ala L, Kilonzo N, Angala P, Theobald S, Taegtmeier M. Promoting Female Condoms in HIV Voluntary Counselling and Testing Centres in Kenya. *Reproductive Health Matters* 2006; 14(28): 99-103.

Promotion of male condoms and voluntary counselling 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 counsellors using a vaginal demonstration model is needed, as well as an adequate supply of free female condoms. In a study in five VCT centres, however, counsellors reported that most people they counselled 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 counsellors in Kenya already promote male condoms as a routine part of risk reduction counselling 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.

Narrigan D. Women's Barrier Contraceptive Methods: Poised for Change. *Journal of Midwifery & Women's Health Special Continuing Education Issue - Topics in Gynecology and Reproductive Health* 2006; 51(6): 478-485.

Over the past 20 years, the number of women in the United States choosing a cervical barrier contraceptive method has dramatically declined. By 2002, fewer than 3% of women reported using any woman-initiated barrier method, including the diaphragm, female condom, or cervical cap. At the same time, however, research in infectious diseases indicates that cervical barriers may effectively prevent the transmission of several sexually transmitted infections. This possibility has fueled the recent development of two novel devices. This article examines the seven devices currently available in the United States, comparing their characteristics, efficacy, benefits, and drawbacks. Compared to the diaphragm, the new devices do not offer improved odds of pregnancy prevention, and evidence for their efficacy is sparse. Reasons for the limited acceptance of these methods as contraceptives on one hand--and for interest in their potential for limiting sexually transmitted infections on the other--will also be reviewed. Despite the limited acceptance of cervical barrier methods, midwives and other clinicians should promote their availability as an alternative to other reversible contraceptives.

Okunlola MA, Morhason-Bello IO, Owonkioko KM, Adekunle AO. 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 among 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 learnt 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 practises and its sequelae in a country like Nigeria that is male dominated.

Smit J, Beksinska M, Vijayakumar G, Mabude Z. 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.**

Purpose: 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. Methods: In total, 276 women were enrolled and 1910 FC1 condoms and 1881 FC2 condoms were used by 218 and 216 women, respectively. Results: 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%). Conclusion: The acceptability of FC1 and FC2 was comparable, and women who find FC1 acceptable to use should also find FC2 acceptable.

Telles Dias P, Souta K, Page-Shafer K. Long-term Female Condom Use Among Vulnerable Populations in Brazil.
***AIDS and Behavior* 2006; 10(0): 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.

Thomsen SC, Ombidi W, Toroitch-Ruto C, Wong EL, Tucker HO, Homan R, Kingola N, Luchters S. 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.**

Objective: To assess the impact and costs of adding female condoms to a male condom promotion and distribution peer education programme for sex workers in Mombasa, Kenya. Design: A 12 month, prospective study of 210 female sex workers. Methods: We interviewed participants about their sexual behaviour every 2 months for a total of seven times and introduced female condoms after the third interview. We also collected cost data and calculated the cost and cost effectiveness of adding the female condom component to the existing programme. Results: Introduction of the female condom in an HIV/AIDS prevention project targeting sex workers led to small, but significant, increases in consistent condom use with all sexual partners. However, there was a high degree of substitution of the female condom for male condoms. The cost per additional consistent condom user at a programme level is estimated to be \$2160 (£1169, €1711) (95% CI: 1338 to 11179). Conclusions: The female condom has some potential for reducing unprotected sex among sex workers. However, given its high cost, and the marginal improvements seen here, governments should limit promotion of the female condom in populations that are already successfully using the male condom. More research is needed to identify effective methods of encouraging sex workers to practise safer sex with their boyfriends.



Vijayakumar G, Mabude Z, Smit J, Beksinska M, Lurie M. A review of female-condom effectiveness: patterns of use and impact on protected sex acts and STI incidence. *International Journal of STD & 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.

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, Gilbert N, Wu E, Mingway C, Hill J. 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 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.

2005

Artz L, Macaluso M, Kelaghan J, Austin H, Fleenor M, Robey L, Hook EW, Brill I. 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.

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.

Rates of HIV/AIDS have increased at an alarming rate among minority women, especially African-American women. Suggestions that have been presented to decrease HIV/AIDS transmission among African-American women include promoting abstinence and the use of the male condom. Little recognition and support have been given for promoting the female condom as a viable solution to combating the HIV/AIDS epidemic.

Buck J, Kang M-S, van der Straten A, Khumalo-Sakutukwa G, Posner S, Padian N. 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.

Galvão LW, Oliveira LC, Diaz J, Kim D-J, Marchi N, van Dam J, Castilho RF, Chen M, Macaluso M. Effectiveness of female and male condoms in preventing exposure to semen during vaginal intercourse: a randomized trial. *Contraception* 2005; 71(2): 130-136.

Objectives: 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. Design: Randomized crossover trial. Methods: 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). Results: 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, >1 ng/mL; 22%) than with MC use (15%); the difference, however, was small and nonsignificant for high PSA levels (≥ 150 ng/mL; 5.1% for FC vs. 3.6% for MC). Conclusions: 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.

McNaught J, Jamison MA. Barrier and Spermicidal Contraceptives in Adolescence. *Adolescent Medicine Clinics* 2005; 16(3): 495-515.

This article describes both barrier and spermicide methods of contraception including the male and female condom, diaphragm, contraceptive sponge, Lea Shield, cervical cap and multiple spermicide options. Their efficacy, differences and proper use are discussed with an emphasis on the adolescent user.

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

Context: 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. Methods: 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. Results: 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. Conclusions: 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.

Muula AS. Acceptability and technical problems of the female condom in Malawi. *Tropical Doctor* 2005; 35(2): 122.

No abstract available.

Posner S, van der Straten A, Kang MS, Padian N, Chipato T. 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.

Prudhomme M, Boucher J, Delberghe P, Christman H, Leroux M-C. Female condom or male condom: offer a choice! *Gynécologie Obstétrique & Fertilité* 2005; 33(11): 891-897.

Objectives: As in the entire Ile-de-France, the Val-de-Marne is facing an increase in female contamination by HIV, a clear increase in STI and furthermore the number of legal abortions is still high. Various recent studies have emphasized the decrease in condom use since 1998. Can the possibility of proposing another condom, more specifically controlled by women, boost condom use? Patients and methods: The conseil général (local government authority) thus initiated a study in the general population, from January 1st 2001 to December 31st 2001, in order to study the criteria of acceptability of the female condom (FC). Results: Although the women coming to consultation had no specific requests a quarter finally tested the female condom during sexual intercourse. Among them 4 out of 10 are ready to use it again. Curiosity was the primary motivation of those who accepted to test the female condom (77 %). Women who were more at ease with their sexuality were twice more likely to test the female condom. Three main advantages were put forward by the women who tested the FC: the strength of the FC, the fact that insertion was possible prior to the sexual act and the possibility of postponing removal, the latter being considered a supplementary advantage. The disadvantages most frequently cited before use were its appearance and difficult insertion process. The frequency of utilisation of the FC was multiplied by three when women practised putting the condom in place in a non-sexual context. However, even when they recognized one or several disadvantages women accepted to test it. In addition, whenever a woman finds at least one advantage before use she is twice more likely to test it. This is where counselling by professionals in charge of presenting the FC becomes a deciding factor. Discussion and conclusions: The chance of using at least one sort of condom is increased when a choice of condoms is available. When both male and female condoms are available, the responsibility for prevention is better balanced within the couple: each partner can then be in charge of his or her own health. However the adoption of a barrier method such as the condom, means that the individual is conscious of such a need and finds that there are benefits mainly staying in good health. However the insufficient number of prevention and health promotion campaigns in France does not favour such an awareness. The availability of inexpensive female condoms in pharmacies, supermarkets as well as free distribution by certain institutions remains an unresolved question. [article in French]

Smita J, Neelam J, Rochelle DY, Kumar BK, Callahan M, Suniti S, Sanjay M. 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.

Objective: 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. Methods: 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. Results: 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. Conclusions: Female condoms are being introduced in India. This study has generated data that is suggestive of optimism for this female controlled option.

Smith J, Joglekar N, D'Souza YR, Kumar BK, Callahan M, Suniti S, Sanjay M. Female condom reuse in Lusaka, Zambia: Evidence from 12 cases. *Journal of Urban Health* 2005; 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.

Valappil T, Kelaghan J, Macaluso M, Artz L, Austin H, Fleenor ME, Robey L, Hook III EW. Female condom and male condom failure among women at high risk of sexually transmitted diseases. *Sexually Transmitted Diseases* 2005; 32(1): 35.

Objective: The objective of this study was to study the frequency and determinants of breakage and slippage during female and male condom use. Goal: The goal of this study was to determine condom breakage and slippage rate. Study: We 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. Results: 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). Conclusions: Both condoms may provide good protection against sexually transmitted diseases. Experience determines success with either condom.

2004

Busza J, Baker S. Protection and participation: an interactive programme introducing the female condom to migrant sex workers in Cambodia. *AIDS Care: Psychological and Socio-medical Aspects of AIDS/HIV* 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.

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 educate 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.

Hoffman S, Mantell J, Exner T, Stein Z. The future of the female condom. *International Family Planning Perspectives* 2004; 30(3): 139-146.

No abstract available [viewpoint].

Kulczycki A, Dhong-Jin K, Duerr A, Jamieson DJ, Macaluso M. 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.

Saul J, Moore J, Murphy ST, Miller LC. 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 microbicial product may be the preferred alternative for this group of women and their male partners.

Vieira EM, Machado AA, Duarte G, de Souza RHB, Rodrigues Júnior AL. The use of the female condom by women in Brazil participating in HIV prevention education sessions. *Revista Panamericana de Salud Publica/Pan American Journal of Public Health* 2004; 15: 373-379.

Objectives: 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. Methods: The study subjects were 165 women participating in HIV prevention education group sessions at the Medical School Hospital of Ribeirão Preto of the University of São Paulo, in the city of Ribeirão Preto, São 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. Results: 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 163 women, a total of 31 of them (19.0%) had never used the male condom with a partner, and 49 of the 163 (30.1%) had not used a male condom at the time of the 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 the 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. Conclusions: 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 the 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.

2003

Bull S, Posner S, Ortiz C, Thomas E. Knowledge of, attitudes toward, and stage of change for female and male condoms among Denver inner-city women. *Journal of Urban Health* 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 R, Posner S, Macaluso M, Artz LM, Johnson C, Pulley LV. Do main partner conflict, power dynamics, and control over use of male condoms predict subsequent use of the female condom? *Women & 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 no 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.

Choi KH, Gregorich S, Anderson K, Grinstead O, Gomez CA. Patterns and predictors of female condom use among ethnically diverse women attending family planning clinics. *Sexually Transmitted Diseases* 2003; 30(1):91.

Background: The female condom is a viable option for women to protect themselves from HIV infection and other sexually transmitted diseases. Goal: 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. Study Design: 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). Results: 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 condoms. Conclusion: 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.

Francis-Chizororo M, Natshalaga NR. The female condom: acceptability and perception among rural women in Zimbabwe. *African Journal of Reproductive Health* 2003; 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%).

French PP, Latka M, Gollub EL, Rogers C, Hoover DR, Stein ZA. Use-effectiveness of the female versus male condom in preventing sexually transmitted disease in women. *Sexually Transmitted Diseases* 2003; 30(5): 433.

Background: Data are limited on the female condom's effectiveness against STDs. Goal: The goal was to compare STD rates between women given small-group education on, and free supplies of, either female or male condoms. Study Design: Female patients at an STD clinic (n = 1442) were randomly assigned to condom type and followed via medical records for STDs (gonorrhoea, chlamydia, early syphilis, or trichomoniasis). Results: 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]). Conclusion: 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.

Hatzell T, Feldblum PJ, Homan RK, Gmach RD. The Female Condom: Is "Just as Good" Good Enough? *Sexually Transmitted Diseases* 2003; 30(5): 440.

No abstract available [editorial].

Hirky AE, Kirshenbaum SB, Melendez RM, Rollet C, Perkins SL, Smith RA. The female condom: attitudes and experiences among HIV-positive heterosexual women and men. *Women & 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.

Hoffman S, Exner TM, Leu CS, Ehrhardt AA, Stein Z. Female-Condom Use in a Gender-Specific Family Planning Clinic Trial. *American Journal of Public Health* 2003; 93(11): 1897-1903.

Objectives: We evaluated female-condom use among women participating in an HIV/STD intervention designed to reduce unprotected sex and expand prevention strategies. Methods: 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. Results: At 1 month, the odds ratios of first-time female-condom use 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. Conclusions: 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.

Lawson ML, Macaluso M, Duerr A, Hortin G, Hammond KR, Blackwell R, Artz L, Bloom A. 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 increased 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; 147-148.

No abstract available [digest].

Macaluso M, Blackwell R, Jamieson DJ, Kulcycki A, Chen MP, Akers R, Kim DJ, Duerr A. 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* 2003; 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 included 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 (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 (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, Demand MJ, Artz L, Hook III EW. Partner type and condom use. *AIDS* 2003; 15(4): 537-546.

Objectives: To examine the association between type of sexual partnership and condom use consistency. **Design:** A prospective follow-up study of women attending two urban clinics for sexually transmitted diseases (STD). **Methods:** 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. **Results:** 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. **Conclusions:** 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, Demand MJ, Artz LM, Hook III EW. 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.

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.

Background: 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. Goal: The goal was to evaluate associations between measures of acceptability and use of existing over-the-counter barrier methods. Study Design: In the San Francisco Bay Area, 510 females aged 15 to 30 years were recruited from reproductive health clinics for this longitudinal study. Results: 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. Conclusion: 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.

Philpott A. Re-use of the Female Condom: Now for the Practical Realities. *Reproductive Health Matters* 2003; 185-186.

No abstract available [letter].

Potter B, Gerofi J, Pope M, Farley T. 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.

Preussler G, Micheletti VC, Pedro EN. Female condom: A possibility for autonomy in HIV-positive women. *Revista Brasileira de Enfermagem* 2003; 56(6): 699.

In this article, the authors report an experience developed in the Specialized Care Service on STD/AIDS from Porto Alegre, where one of them works. It approaches adult women, emphasizing sexuality, reproduction and vulnerability concerning STDs, mainly HIV infection. The methodology used is a data survey starting from the return to the service in order to receive female condoms within one year. Subjects are HIV-positive women linked to the service. Results show that the use of this method is incipient and that its adoption demands a change in behaviour from women already in an early stage of their development, prior to adult age, and that there is a huge importance of raising awareness among professionals, either in Education or Health fields. [article in Portuguese]

Renzi C, Tabet SR, Stucky JA, Eaton N, Coletti AS, Surawicz CM, Agoff SN, Heagerty PJ, Gross M, Celum CL. Safety and acceptability of the Reality™ condom for anal sex among men who have sex with men. *AIDS* 2003; 17(5): 727-731.

Objectives: To assess safety and acceptability of Reality™ condoms for anal sex among men who have sex with men. Methods: 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. Results: 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. Conclusions: 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.

Salabarria-Pena Y, Lee JW, Montgomery SB, Hopp HW, Muralles AA. 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.

Yimin C, Zhaohui L, Xianmi W, Shiyong W, Lingzhi H, Yueying X, Xiaolan H, Lifan X, Yunzhen W, Shaolan Z, Yulian L. Use of the female condom among sex workers in China. *International Journal of Gynecology & Obstetrics* 2003; 81(2): 233-239.

Objectives: To introduce the female condom (FC) among sex workers (SWs) in China. Methods: 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). Results: 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. Conclusions: The understanding and use of FC can be greatly improved through active intervention-i.e. medical workers providing SWs with FC.

Zachariah R, Harries AD, Buhendwa L, Spielman MP, Chantulo A, Bakali E. Acceptability and technical problems of the female condom amongst commercial sex workers in a rural district of Malawi. *Tropical Doctor* 2003; 33(4): 220.

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 reuse of the device with consecutive clients, 6% after having washed it, and 2% without any washing or rinsing. The most common discomfort 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.

2002

Artz L, Demand M, Pulley LV, Posner SF, Macaluso M. 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.

Bull S, Cohen J, Ortiz C, Evans T. 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.

Marshall S, Giblin P, Simpson P, Backos A. 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 and 2]. The study assesses the acceptability of the FC to adolescent girls, and examines whether experience with other vaginal products affects its use.

Neilands TB, Choi KH. A Validation And Reduced Form Of The Female Condom Attitudes Scale. *AIDS Education & Prevention* 2002; 14(2): 158.

Assesses the validity and reliability of the Female Condom Attitudes Scale (FCAS) in measuring women's attitude toward the female condom. Factors hindering acceptance and use of the female condom; Measurement of internal reliability; Factor correlations of the FCAS with the condom self-efficacy, sexual comfort and female condom usage.

Penman-Aguilar A, Hall J, Artz L, Crawford MA, Peacock N, van Olphen J, Parker L, Macaluso M. Presenting the female condom to men: a dyadic analysis of effect of the woman's approach. *Women & 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 facilitates successful introduction of the female condom into a sexual partnership.

Sehonou J, Gresenguet G, Tokunaga M, Keou FX, Favier C. Acceptability of the female condom in Bangui, Central African Republic: results from a prospective study [letter]. *International Journal of STD and AIDS* 2002; 13(9): 649-651.

No abstract available [letter].

Van Devanter N, Gonzales V, Merzel C, Parikh NS, Celantano D, Greenberg J. 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.

Objectives: This study assessed the effectiveness of a sexually transmitted disease (STD)/HIV behavior change intervention in increasing women's use of the female condom. Methods: 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. Results: 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). Conclusions: 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.

Yimin C, Zhaohui L, Xianmi W, Shiyong W, Lingzhi H, Yueqing X, Xiaolan H, Lifan X, Yunzhen W, Zheng S, Yulian L. 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 recruited 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.

2001

Beksinska ME, Rees HV, McIntyre JA, Wilkinson D. 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.

Objective: To assess the acceptability of the female condom to different groups of women and their partners in South Africa. Design: Descriptive, cross-sectional study. Setting: Multicentre study conducted in five sites.



Subjects: The study recruited 678 women from five centres to an acceptability trial of the female condom. **Acceptability and successful use** varied between the centres. **Outcome Measures:** Factors affecting successful use and willingness and intention to use the method again. **Results:** 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%). **Conclusions:** 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.

Beksinska ME, Rees HV, Dickson-Tetteh KE, Mqoqi N, Kleinschmidt I, McIntyre JA. 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.

Feldblum PJ, Kuyoh MA, Bwayo JJ, Omari M, Wong EL, Tweedy KG, Welsh MJ. Female condom introduction and sexually transmitted infection prevalence: results of a community intervention trial in Kenya. *AIDS* 2001; 15:8, 1037-1044.

Objective: To measure the impact on sexually transmitted infection (STI) prevalence of a female condom introduction and risk-reduction program at Kenyan agricultural sites. **Design:** We conducted a cluster-randomized trial to determine whether a replicable, community-level intervention would reduce STI prevalence. **Methods:** 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 gonorrhoea and chlamydia by ligase chain reaction on urine specimens, and vaginal trichomoniasis by culture, at baseline, 6 and 12 months. **Results:** 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. **Conclusions:** 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.



Gollub EL, French P, Latka M, Rogers C, Stein Z. Achieving safer sex with choice: studying a women's sexual risk reduction hierarchy in an STD clinic. *Journal of Women's Health & 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.

Green G, Pool R, Harrison S, Hart GJ, Wilkinson J, Nyanzi S, Whitworth J. Female control of sexuality: illusion or reality? Use of vaginal products in south west Uganda. *Social Science & 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.

Jivasak-Apimas S, Saba J, Changing V, Sakondhvat C, Kiriwat O, Ruggao S, Rojanapithakorn W, Fontanet AL. Acceptability of the Female Condom Among Sex Workers in Thailand: Results From a Prospective Study. *Sexually Transmitted Diseases* 2001; 28(11): 648-654.

Background : The female condom may provide women with the first female-controlled barrier method that is effective against sexually transmitted diseases, including HIV infection. Goal : This study evaluated the acceptability of the female condom among sex workers in Thailand. Study Design : Data on use and acceptability of the female condom were collected using a structured questionnaire during an 8-week follow-up. Results : 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. Conclusion : 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.

Latka M, Joanis C, Glover L. Acceptability of the reality® female condom and a latex prototype. *Journal of Urban Health* 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.

Mantell J, Hoffman S, Weiss E, Adeokun L, Delano G, Jagha T, Exner T, Stein Z, Karim Q, Scheepers E, Atkins K, Weiss E. The acceptability of the female condom: Perspectives of family planning providers in New York City, South Africa, and Nigeria. *Journal of Urban Health* 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 about 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.

Marseille E, Khan JG, Billingham K, Saba J. Cost-effectiveness of the female condom in preventing HIV and STDs in commercial sex workers in rural South Africa. *Social Science & 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 Mpumalanga 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. Choice of female-controlled barrier methods among young women and their male sexual partners. *Family Planning Perspectives* 2001; 28-34.

Context: 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. Methods: 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. Results: 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). Conclusions: 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.



Pettifor A, Beksinska M, Rees H, Mqoqi N, Dickson-Tettell K. The acceptability of reuse of the female condom among urban South African women. *Journal of Urban Health* 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 time (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.

Raphan G, Cohen S, Boyer A. The female condom, a tool for empowering sexually active urban adolescent women. *Journal of Urban Health* 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.

Ray S, Wiggert J, Mason P, Ndowa F, Maposhere C. Constraints faced by sex workers in use of female and male condoms for safer sex in urban Zimbabwe. *Journal of Urban Health* 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.

Sakondhavat C, Weeravatrakul Y, Benette T, Pinitsoontorn P, Kuchaisit C, Kukiattikool P, Pongsatra K. Consumer preference study of the female condom in a sexually active population at risk of contracting AIDS. *Journal of the Medical Association of Thailand* 2001; 84(7): 973.

To determine the acceptability of the female condom among commercial sex workers in Khon Kaen, Thailand. Twenty sex workers from a massage parlor and 21 from a brothel were trained in the use of the female condom. The voluntary participants were instructed about the risk of HIV and advised that they could use the female condom as an alternative method to the male condom for protection. The female condom was used in 28.4 per cent and 17.8 per cent episodes of sex in each site during the two weeks. Continuation of use of the female condom increased from 0 per cent in the first group to 43 per cent in the second group. The reasons for discontinuing its use were that it was inconvenient and because of their partners' objection. More users said they liked the female condom even though more thought it was difficult to insert and it did cause pain. However, they would recommend it to others and most felt that other women would want to try it. The participants also saw the advantage of the female condom as a back-up method in case of clients' refusal to use the male condom but all preferred the male condom if there was a choice.

Steiner MJ, Hertz-Picciotto I, Taylor D, Schoenbach V, Wheelless A. Retrospective vs. Prospective Coital Frequency and Menstrual Cycle Length in a Contraceptive Effectiveness Trial. *Annals of Epidemiology* 2001; 11(6): 428-433.

Purpose: To determine how well information at enrollment would predict coital frequency and menstrual segment length during a prospective contraceptive effectiveness trial. Methods: We compared retrospective reports of monthly coital frequency and menstrual segment (cycle) length with prospective information for women participating in a contraceptive trial of the Reality® female condom. Results: Participants reported slightly higher mean monthly coital frequency and slightly longer menstrual segments prior to the study than during the study (12.6 acts vs. 12.0 acts per month and 30.8 days vs. 28.4 days). We examined the actual distribution of differences between the retrospective and prospective measures and found considerable variability. Among the 195 participants studied, parous women were less likely to predict accurately menstrual segment length (OR 0.4; 95% CI 0.3-0.9), while older women were more likely to predict accurately coital frequency (OR 1.9; 95% CI 0.9-3.3). Conclusions: Coital frequency and menstrual segment length vary considerably over time. Hence, prospective data collection is essential to accurately characterize these variations and to properly interpret results from contraceptive trials and other studies concerned with fecundability and hazards of reproduction.

Welsh MJ, Feldblum PJ, Kuyoh MA, Mwarogo P, Kungu D. Condom use during a community intervention trial in Kenya. *International Journal of STD & 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.

2000

Artz L, Macaluso M, Brill I, Kelaghan J, Austin H, Fleenor M, Robey L, Hook EW. 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.

Objectives: 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). **Methods:** The effect of the intervention on barrier use was evaluated with a pretest-posttest design with 1159 female STD clinic patients. **Results:** 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. **Conclusions:** 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.

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 with 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.

Choi KH, Roberts KJ, Gomez C, Grinstead O. Facilitators and barriers to use of the female condom: Qualitative interviews with women of diverse ethnicity. *Women & Health* 2000; 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.

Feldblum PJ, Bwayo JJ, Kuyoh M, Welsh M, Ryan KA, Chen-Mok M. The Female Condom and STDs: Design of a Community Intervention Trial. *Annals of Epidemiology* 2000; 10(6): 339-346.

Objectives: 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. **Methods:** 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 gonorrhoea 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. **Results:** Among 1929 women at baseline, the mean age was 33.1 years; 78% had never used a male condom. The prevalences of gonorrhoea, 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. **Conclusions:** 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 M, Omari M, Ryan KA, Bwayo JJ, Welsh M. Baseline STD prevalence in a community intervention trial of the female condom in Kenya. *Sexually Transmitted Infections* 2000; 76(6): 454-456.

Objective: We present baseline sexually transmitted disease (STD) prevalence rates from an ongoing intervention trial at Kenyan agricultural sites. **Methods:** 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. **Results:** 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. Conclusions: 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.

Haignere CS, Gold R, Maskovsky J, Ambrosini J, Rogers CL, Gollub E. High-risk adolescents and female condoms: knowledge, attitudes, and use patterns. *Journal of Adolescent Health* 2000; 26(6): 392-398.

Purpose: To explore data on high-risk male and female adolescents' attitudes towards female condoms, compared with male condoms. Methods: 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. Results: 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. Conclusions: 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.

Joanis C, Latka M, Glover H, Hamel S. 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 < 0.001); 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.

Kalichman SC, Rompa D, Cage M. Factors associated with female condom use among HIV-seropositive women. *International Journal of STD & 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.

Latka M, Gollub E, French P, Stein Z. 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.

Background: 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. Goal: To measure male-condom and female-condom use among women who received hierarchy counseling and compare this with women counseled about condoms only. Study Design: 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 (> or = 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.

Macaluso M, Demand M, Artz L, Fleenor M, Robey L, Kelaghan J, Cabral R, Hook III EW. Female condom use among women at high risk of sexually transmitted disease. *Family Planning Perspectives* 2000; 138-144.

Context: 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. Methodology: 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. Results: 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. Conclusions: 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.

Malow R, Ziskind D, Jones DL. Use of female controlled microbicial products for HIV risk reduction. *AIDS Care* 2000; 12(5): 581-588.

Many over-the-counter microbicial contraceptive methods reduce the risk of acquiring sexually transmitted diseases. This pilot project compared the use of female controlled barrier methods in an extremely high-risk population of low-income drug abusing women following an intervention designed to promote HIV risk reduction and barrier use. An HIV transmission risk reduction interactive intervention emphasizing self-esteem, assertiveness and sexual negotiation was offered to 41 drug dependent women. Participants were randomly assigned to one of two conditions, a male and female condom condition or a male and female condom plus N-9 products (vaginal suppositories, film, gel) condition. Results from the three-month follow-up period suggest that there may be a synergistic effect of availability of multiple protective methods on the overall rate of protective behaviours. The use of the male condom for penile/vaginal sex increased from 19% at study entry to 27% during the three-month follow-up period. The total protected sexual episode rate, calculated to include use of the other protective barriers distributed, was 60%. Thus, the condom use rate was not found to decrease because of the availability of alternative methods of protection. Future research should address the use of microbicial products to empower women to prevent STD/HIV transmission.

Murphy ST, Miller LC, Moore J, Clark LF. 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.

Objectives: This study assessed interest in female-controlled methods of HIV and sexually transmitted disease (STD) prevention. Methods: 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. Results: 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. Conclusions: Female control may be of less interest to women most at risk for HIV and other STDs. This underscores the need to take the priorities and preferences of women into consideration when developing new prevention methods.

Pettifor AE, Rees HV, Beksinska ME, Kleinschmidt I, McIntyre J. In vitro assessment of the structural integrity of the female condom after multiple wash, dry, and re-lubrication cycles. *Contraception* 2000; 61(4): 271-276.

Since the introduction of the female condom in the early 90s, there have been numerous reports of reuse of the device. In response to these reports, studies were undertaken to evaluate the safety of female condom reuse. If reuse were shown to be safe, then programmatic costs of introduction of the female condom would be reduced allowing it to be more widely available. This article outlines the results of in vitro structural integrity testing of the female condom after multiple wash, dry, and re-lubrication cycles. Devices were tested up to 10 washes using water leakage, burst, and tensile seam testing. 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 6 washing procedures examined in this study were above the FDA minimum standards for seam strength and burst tests. For the water leakage test, 3 of 6 washing procedures tested passed the required FDA minimum standards (no holes detected). From the results of the study, it seems that washing, drying, and re-lubricating the female condom up to 10 times leads to some deterioration in the structural integrity of the device for specified washing procedures. Further studies are currently being conducted to establish the safety of



female condom reuse with respect to microbial retention, structural integrity after in vivo use, and viral permeability.

Pool R, Hart G, Green G, Harrison S, Nyanzi S, Whitworth J. Men's attitudes to condoms and female controlled means of protection against HIV and STDs in south-western Uganda. *Culture, Health & 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, Mbonye AK, Harrison S, Wilkinson J, Hart GJ. An acceptability study of female-controlled methods of protection against HIV and STDs in south-western Uganda. *International Journal of STD & 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.

Witte SS, Wada T, El-Bassel N, Gilbert L, Wallace J. Predictors of Female Condom Use Among Women Exchanging Street Sex in New York City. *Sexually Transmitted Diseases* 2000; 27(2): 93-100.

Background: 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.



Objective: To describe predictors of female condom use among 96 women exchanging sex for money and drugs on the streets of New York City. Study Design: 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. Results: 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. Conclusions: 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.

1999

Cecil H, Pinkerton SD. 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.

Feldblum PJ, Chen-Mok M, Bwayo JJ, Omari M, Kuyoh M, Ruan KA. Intracluster correlation of STD prevalence in a community intervention trial in Kenya. *The Lancet* 1999; 354(9187): 1356-1357.

Summary: This study is a cluster-randomised, community intervention trial to measure the impact of female condom introduction on STD prevalence among Kenyan agricultural workers. The intracluster correlation coefficient of baseline STD prevalences at the 12 sites was 0.0011.

Gibson S, McFarland W, Wohlfeiler D, Scheer K, Katz MH. Experiences of 100 men who have sex with men using the Reality condom for anal sex. *AIDS Education and Prevention* 1999; 11(1): 65.

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 Reality 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.

Gollub EL. Women need HIV prevention approaches that maximize choice. *Sexual Health Exchange* 1999;



(1)12.

The Philadelphia Women's Health Sister Studies examined protective options against HIV and sexually transmitted diseases with women. A total of 292 women participating in the study were subdivided into a male condom arm, a female condom arm, and a hierarchy arm. Findings showed that the percentage of women retained in the study was poorest for the single message arm; about 51% for the female condom arm, 58% for the male condom arm, and 75% for the hierarchy arm. Moreover, most women were satisfied using the female condom. Well-liked aspects were high level of protection, natural feel, and female control; dislikes were related to insertion, appearance, and the inner ring. This study has important implications for women's prevention interventions.

Gross M, Buchbinder SP, Holte S, Celum CL, Koblin BA, Douglas JM. Use of reality "female condoms" for anal sex by US men who have sex with men. HIVNET Vaccine Preparedness Study Protocol Team. *American Journal of Public Health* 1999; 89(11): 1739-1741.

Objectives: 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. Methods: Self-administered questionnaires were completed by 2277 participants in a 6-city prospective cohort study. Results: 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). Conclusions: Redesign of the female condom could increase acceptability and use by men who have sex with men and could address possible safety concerns.

Hart GJ, Pool R, Green G, Harrison S, Nyanzi S, Whitworth JAG. Women's attitudes to condoms and female-controlled means of protection against HIV and STDs in South-Western Uganda. *AIDS Care: Psychological and Socio-medical Aspects of AIDS/HIV* 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 microbicide 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.

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 & 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.

Klein H, Eber M, Crosby H, Welka DA, Hoffman JA. The acceptability of the female condom among substance-using women in Washington, DC. *Women & 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 reinterviewed 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.

Nkhama G, Feters T. Female condom acceptability in Zambia. *Sexual Health Exchange* 1999; (1):14.

This article discusses a female condom that offers Zambian women another option to control their own fertility and sexual health. A cross-sectional study was conducted in three public sector clinics in Lusaka City. The findings revealed interest, even excitement, in the female condom. Most of the women and men welcomed the female condom as a method of choice in Lusaka. Moreover, attitudes toward the female condom are sometimes based on gender beliefs. The strongest reason for discontinuation was the unwillingness of the male partner. Thus, its introduction should be accompanied by an education campaign to combat social stigma associated with male and female condoms.

No author listed. Research affirms female condom's effectiveness. *Contraceptive Technology Update* 1999; 20(2): 18-19.

A recent study of the female condom was conducted in 190 Japanese women aged 20-40 who reported coital frequency of at least 4 times per month. Of the 11 women who did not complete the 6-month study, 6 became pregnant, and, of these, only 1 pregnancy occurred despite consistent and correct use. Thus, results this study's results of 3.2% probability of pregnancy during typical use and 0.8% during perfect use were better than those found in a study in the UK that resulted in a 12-month life table probability of 15% during typical use or in a multinational trial that found 6-month typical use rates of 12.4% in the US and 22.2% in Latin America (with perfect use rates of 2.6% and 9.5%, respectively). The fact that most of the Japanese women found the female



condom acceptable may open the door to a very significant market because 85% of Japanese couples rely on barrier methods of contraception. The mean ages of the women in all three studies was similar, but the mean coital frequency was 59% lower in the Japanese trial than among US women, and this may have contributed to the reduced risk of pregnancy.

Pool R. Acceptability of the female condom and vaginal spermicidal products in Uganda. *Sexual Health Exchange* 1999; 1: 5-7.

The Medical Research Council's Program on AIDS assessed the acceptability of the female condom and vaginal spermicidal products in Masaka, Uganda. The interviews and focus group discussions revealed that women are more likely to practice safer sex with female controlled methods that can be used secretly. The most popular formulations were the sponge and foaming tablets, followed by the female condom and foam. Age, level of education and location did not affect their choices. Expanding the range of choice among these women may improve the means of preventing HIV and sexually transmitted diseases. However, the possibility of secrecy, particularly female ownership of the product, was an important issue for women.

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

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 a 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.

Witte SS, El-Bassel N, Wada T, Gray O, Wallace J. Acceptability of female condom use among women exchanging street sex in New York City. *International Journal of STD & AIDS* 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.

Xu J, Wu Y, Cao Q. Contraceptive efficacy of Sino-female condom: comparison with condom. *Zhonghua fu chan ke za zhi* 1999; 34(1): 33.

Objective: To compare the contraceptive efficacy of Sino-female condom with condom. Methods: 603 volunteer couples were randomly divided into two groups: 304 couples using female condom for contraception, and 299



using condom. Using lifetable method and log rank test, we compared the pregnancy rates and other discontinuation rates after follow-up for 6 months in two groups. Results: No abnormal findings of cervical and vaginal smears were detected before and after this clinical trial in all 603 women. The follow-up rates at 6 months were 99.01% and 99.67% in the female condom group and condom group, respectively. The 6-month gross cumulative pregnancy rates were 1.06 and 1.69 per 100 women and the discontinuation rates due to allergy were 1.39 and 0.34, respectively. No difference was statistically significant ($P > 0.05$). However, the discontinuation rate for other causes in the female condom group was significantly higher than that in the condom group ($P < 0.01$). The main cause was that more than half of subjects were used to applying condom before this study. Conclusion: The contraceptive efficacy of Sino-female condom is as same as that of condom, and its clinical use is quite safe. [article in Chinese]

Zimmers E, Privette G, Lowe RH, Chappa F. Increasing use of the female condom through video instruction. *Perceptual and Motor Skills* 1999; 88(3 Pt 2): 1071.

The female condom is effective in preventing sexually transmitted diseases and when used properly reduces risk of HIV infection among women. This field experiment evaluated the effect of a video presentation on reported use of and satisfaction with the female condom. Participants were 100 women tested for HIV infection in a community agency. Ages ranged from 17 to 62 years, and one fifth of the sample were African American or Hispanic. The 23 women who viewed an instructional video were significantly more likely than 13 of the control group of 50 to try the condom and report to the researcher. Video viewing was unrelated to liking the product and future intent to use. Almost three quarters of those who used the condoms reported they liked and would use them.

1998

El-Bassel N, Krishnan SP, Schilling RF, Witte S, Gilbert L. Acceptability of the female condom among STD clinic patients. *AIDS Education and Prevention* 1998; 10(5): 465.

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 that 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 S, Witte S, Schilling RF, Catan V, Pollin S. Correlates of intention to use the female condom among women taking methadone. *Womens Health Issues* 1998; 8(2): 112-22.

The correlates of high-risk women's intentions to use the female condom were investigated in a descriptive study involving 148 sexually active women from 3 US methadone clinics. 51% of women were Latina and 38% were African-American; the mean age was 39 years. Male condoms, douching, sterilization, and withdrawal were the most frequently used contraceptive methods in the 90 days preceding the study. 56% had heard of the female condom, but only 6% had used it. Of the 139 women who had never used the female condom, 32% indicated they intended to use it in the future. Such intention was significantly, positively correlated with age



under 39 years, African-American ethnicity, and the belief the female condom offers users a sense of personal control over their sexuality. Those who intended to use the female condom were more likely to have previously used male condoms, believe their partners would be supportive of the device, think female condom use could be erotic and fun, feel confident in their ability to negotiate safer sex, and to welcome an additional option for practicing safer sex. They were also less likely than their counterparts, who did not intend to use a female condom, to believe use of this method would imply they had a sexually transmitted disease or were too eager to have sex. Compared with women who did not intend to use the female condom, those who did were more likely to discuss the device with at least 1 member of their social network. These findings confirm the necessity of considering gender relations and social networks in the design of female condom promotion strategies.

Fontanet A, Saba J, Chandelying V, Sakondhavat C, Bhiraleus P, Ruggpao S, Chongsomchai C, Kiriwat O, Tovanabutra S, Dally L. 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.

Background: 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. **Methods:** 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 (gonorrhoea, chlamydial infection, trichomoniasis and genital ulcer disease) were measured over a 24-week period and compared between the two study groups. **Findings:** 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, $P = 0.18$). **Interpretation:** The replacement of male condoms by female condoms in a proportion of sexual acts in the male/female condom group suggests that some sex workers and/or their clients preferred using the female condom. This switch in barrier method was accompanied by non-significant reductions in the proportion of unprotected sexual acts and in the incidence rate of STDs in the women of the male/female condom group. Special attention should be paid to a potential risk of slippage of the female condom in inexperienced users.

Hicks D. The female condom: the African perspective. *Africa Health* 1998; 20(3): 18.

The female condom is a soft, pliable, prelubricated polyurethane pouch which is inserted into the vagina prior to having sexual intercourse. A flexible polyurethane ring encircles the condom's open end to prevent the entire pouch from entering the vagina during intercourse and to cover the vulva while allowing an entryway for the penis. A smaller flexible ring inside of the condom helps to position and hold the condom within the vagina.



Studies have found the female condom to be as effective as male condoms or other female controlled barrier methods in preventing pregnancy. Moreover, the female condom is theoretically better than the male latex condom because of its lower leakage and slippage rates. A recent study in Thailand has shown that accessibility of the female condom can lead to a reduction in STIs among prostitutes, while Trussel et al. estimate that perfect use of the device may reduce the annual risk of acquiring HIV by more than 90% among women who have sexual intercourse twice weekly with an infected male. Women participants in several studies in Africa, however, have complained that the female condom is too long, and over-lubrication has been a reported problem in areas where dry sex is preferred. On the other hand, some users have found sexual intercourse using the female condom to convey the same level of physical sensitivity in the genital region as intercourse without using a barrier method. Evidence suggests that the female condom may be acceptable to men and women in certain types of sexual relationships, but unacceptable in others.

Madrigal J, Schifter J, Feldblum PJ. Female condom acceptability among sex workers in Costa Rica. *AIDS Education and Prevention* 1998; 10(2): 105.

This study measured short-term female condom acceptability among 51 female sex workers in San José, Costa Rica. Each woman was trained in use of the female condom and was asked to use the device if clients refused to use male condoms during a 2-week study period (male condoms were also distributed). Two follow-up visits with short interviews were scheduled, including questions on general reaction to the female condom by the participants and their clients, ease and comfort of use, and preferences for male or female devices. At the first follow-up visit, 51% of the women reported they "liked the female condom very much" and 45% reported they "liked it somewhat." Similar results were reported after the second follow-up phase. Sixty-seven percent of the participants preferred the female condom over the male condom, and, according to the the women, over half of their clients liked the female condom "very much" or "somewhat." The most common problems during the first phase were difficulty to insert (61%) and discomfort (43%). However, during the second study phase a reduction in these problems (22% and 25%, respectively) and other use-related problems were noted. Although this new method is not yet available throughout Costa Rica, these results should encourage sexually transmitted diseases and HIV service organizations to make this method accessible to women.

Musaba E, Morrison CS, Sunkutu MR, Wong EL. Long-term use of the female condom among couples at high risk of human immunodeficiency virus infection in Zambia. *Sexually Transmitted Diseases* 1998; 25(5): 260.

Background: Few studies have measured female condom use for more than a 6-month period or among persons at high risk of STD. Objective: 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. Study Design: 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. Results: 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. Conclusion: 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.



Rivers K, Aggleton P, Elizondo J, Hernandez G, Herrera G, Mane P, Niang CI, Scott S, Setiadi B. 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.

Sinpisut P, Chandeying V, Skov S, Uahgowitchai C. Perceptions and acceptability of the female condom [Femidom] amongst commercial sex workers in the Songkla province, Thailand. *International Journal of STD & AIDS* 1998; 9(3): 168-172.

In a prospective descriptive study on the perceptions and acceptability of the female condom in a group of Thai commercial sex workers (CSWs) in the Songkla province, we invited CSWs from selected brothels to participate. Those who used the female condom were interviewed after one week and 16 weeks of use. Focus group discussions were also conducted at the end of the study period to obtain additional information. The group comprised 56 CSWs. Only 34% of them had heard of the female condom prior to this study and none had ever used one. A high proportion of CSWs reported positive experiences and perceptions. There were no significant changes in perceptions and experiences during the study. Eighty per cent of participants said they were satisfied with the female condom and would use it again in the future and would recommend it to their friends. However, the female condom was used in only 29% of the total number of sexual acts reported, and 98% of CSWs said they would prefer to use a male condom for sex work. Many of the women were concerned that the physical appearance of the condom would reduce its acceptability to their clients. This was the most frequently cited reason for not using the female condom in the future. While a promising device, the female condom must also become more acceptable to men if it is to enable women to be in control of their own protection from pregnancy and STD/HIV.

Surratt HL, Wechsberg WM, Cottler LB, Luekefeld CG, Klein H, Desmond DP. 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.



Torres MI, Lyon-Callo S, Hernandez CM. Focused Female Condom Education and Trial: Comparison of Young African American and Puerto Rican Women's Assessments. *International Quarterly of Community Health Education* 1998; 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.

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 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.

Xu JX, Leeper MA, Wu Y, Zhou X-B, Chen T, Yang X-L, Zhuang L-Q. 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 child-bearing 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.

1997

Deniaud F. Dynamics of female condom acceptability among prostitutes and young women in Abidjan, Ivory Coast. *Contraception, fertilité, sexualité* 1997; 25(12): 921.

Objective: To assess the acceptability of the female condom among 2 groups of women in Côte d'Ivoire. Design: Trial of use. Setting: Abidjan, non-medical structures. Participants: 114 women accepted initial interview: 52 commercial sex workers (CSWs), 62 young women. 103 women volunteered for the trial of use. Interventions:



20 female condoms given to the CSWs, 10 given to the young women; adapted instructions for use, counselling on AIDS, STDs and genital anatomy provided before and all along the trial. Main Outcome Measures: Qualitative assessment with some quantitative measures. Results: The female condom aroused a general interest from all participants. 90% accepted to use it; 75% of 103 volunteers completed the trial. Approximately 1,200 utilizations were recorded. Prevalence of misuses was low (approx. 2% of the total); prevalence of discomforts was much higher. All the users except two wanted to use it in the future. Conclusion: Safe protection and dual protection (against HIV/STDs, pregnancies) were the two main sources of interest; CSWs quickly appropriated this new tool. Considering these data, the HIV infection rate among young women in Côte d'Ivoire, and evidence of changing attitudes towards birth spacing, a low-price distribution programme of female condoms for all women is recommended, with an educational component and the community participation. [article in French]

No author listed. Peer support groups boost use of female condom. *Contraceptive Technology Update* 1997; 18(9): 109-110.

Preliminary research findings from Brazil and Kenya indicate that, when women are provided with female condoms and peer group support, traditional obstacles to safe sex practices can be overcome. In these countries, as well as many others, women face cultural barriers to negotiating condom use with male partners. The study, conducted by the Women's Health Initiative of Family Health International's AIDS Control and Prevention Project, involved 106 Kenyan and 103 Brazilian women. A female focus group was held at the beginning of the study, followed by two peer support group meetings, with another focus group at the end of the study. Group support was an essential element in the acceptance process. Women who were afraid or unsuccessful with initial use were encouraged by other group members to try different, non-threatening approaches to the negotiation of female condom use and given suggestions for overcoming difficulties with insertion and lubrication. Some of these strategies included laying the female condom on the bed so the male partner raises the subject of its use and telling the partner the doctor had recommended the method to avoid the negative side effects associated with the pill. When female condom use is presented as a form of pregnancy prevention, the association of condoms with infidelity is overcome.

Roberts KL, Cahill S. Condom use in a group of Aboriginal women. *Australian Journal of Rural Health* 1997; 5(1): 43-47.

This exploratory study investigated the attitudes of Aboriginal women in Darwin to the use of condoms to prevent HIV and other sexually transmitted diseases. An Aboriginal research assistant interviewed twelve women regarding their usage of and attitudes to the male condom and their attitude to the possibility of using a female condom. These women, like their ethnic minority counterparts in Africa and North America, had a fair level of knowledge about HIV, a low level of perceived risk of HIV and other sexually transmitted diseases, infrequent usage of male condoms with their partner, and negative attitudes to the male condom. Their attitude to the female condom was more positive. Educational programs and further research into the attitudes of women in remote communities are recommended.

Sly DF, Quadagno D, Harrison DF, Eberstein IW, Riehman K. Factors associated with use of the female condom. *Family Planning Perspectives* 1997; 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 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.

1996

Ruminjo JK, Steiner M, Joanis C, Mwathe EG, Thagana N. Preliminary comparison of the polyurethane female condom with the latex male condom in Kenya. *East African Medical Journal* 1996; 73(2): 101.

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.

1995

Ashery RS, Carlson RG, Falck RS, Siegal HA, Wang J. Female condom use among injection drug-and crack cocaine-using women. *American Journal of Public Health* 1995; 85: 736-737.

No abstract available [letter to the editor].

Gollub EL, Stein Z, El-Sadr W. Short-term acceptability of the female condom among staff and patients at a New York City hospital. *Family Planning Perspectives* 1995: 155-158.

An acceptability study of the female condom undertaken at New York's Harlem Hospital between August 1993 and February 1994 enrolled 52 women aged 18-57, 41 of whom (79%) used the female condom at least once. Of these, one-half used the female condom at least three times and 40% used it once; on average, women used it 2.4 times. Two-thirds of users liked the female condom either very much or somewhat, 20% were neutral and 15% stated that they did not like it. One-half of the women reported that their partner liked the device, while 17% said he felt neutral about it and approximately one-quarter said he disliked it. Seventy-three percent of respondents and 44% of their partners preferred the female condom to the male condom.

Sapire K. The female condom (Femidom): a study of user acceptability. *South African Medical Journal* 1995; 85(Suppl 10): S1081-S1084.

Objective: To determine the acceptability of the female condom (Femidom). Design: Questionnaire survey



following the use of the Femidom during sexual intercourse. Setting: Groote Schuur and Somerset Hospitals, Cape Town. Participants: Nurses, secretaries, doctors and domestic staff of Groote Schuur and Somerset Hospitals who volunteered-61 women were recruited, 8 did not use any female condoms, and 1 did not return. Many women refused, mainly because of the unaesthetic appearance of the Femidom and the fact that they had to continue using their regular contraceptive and they did not think their partners would co-operate. Outcome Measures: Sexual responsivity compared with that without Femidom; acceptability of the method; women's and their partners' enjoyment of using the method; comparison with the male condom; awareness of HIV-AIDS and protective measures that can be used. Results: Of the 52 participants, 23 used all 10 Femidoms issued to them. Thirteen women and 18 of their partners did not enjoy using the method and 9 had problems with it. Sex with the Femidom was the same or better in 51.9%. The Femidom was unacceptable in 32.7%, acceptable in 52% and very acceptable in 13.4%. Compared with the male condom, 50% of women and 44.2% of men considered the Femidom as good or better. Of the 61 women, 59 had heard of AIDS, and awareness of protective measures was good. Conclusion: There was resistance to accepting the Femidom, mainly because of its unaesthetic appearance and because women were participating for altruistic reasons. Acceptance and ease of application improved with use. Comments regarding problems and subjects' and their partners' enjoyment varied from extremely positive to extremely negative; 65.4% considered sex using the Femidom acceptable or very acceptable. It is important to inform and obtain co-operation from the male partner. The female condom has been developed as an alternative for women to use if their partners refuse or dislike using male condoms. Perfect use of the Femidom may reduce the annual risk of acquiring HIV by more than 90% in women who are sexually active with an infected male. The efficacy of the female condom has been described as equal to that of the diaphragm. The Femidom will increase the range of choices of contraceptives and prophylactic methods available for protective sex. It should become accepted as a method of contraception and an adjunct to other contraceptive methods as a prophylactic against sexually transmitted diseases and AIDS, particularly in relationships that are not mutually monogamous.

1994

Farr G, Gabelnick H, Sturgen K, Dorflinger L. Contraceptive efficacy and acceptability of the female condom. *American Journal of Public Health* 1994; 84: 1960-1964.

Objectives: The purpose of the study was to determine the contraceptive efficacy of the female condom and to provide data about the device to the US Food and Drug Administration. Methods: The clinical trial was conducted at six US sites and three sites in Latin America. Eligible subjects were in mutually monogamous relationships and agreed to use the female condom as their only means of contraception for 6 months. Results: A total of 328 subjects contributed to the analysis of contraceptive efficacy. Twenty-two US subjects and 17 Latin American subjects became pregnant, yielding 6-month gross cumulative accidental pregnancy rates of 12.4 and 22.2, respectively. During perfect (consistent and correct) use of the method, the 6-month accidental pregnancy rates were 2.6 and 9.5 for the US and Latin American centers, respectively. There were no serious adverse events related to the use of the method. Conclusions: The female condom provides contraceptive efficacy in the same range as other barrier methods, particularly when used consistently and correctly, and has the added advantage of helping protect against sexually transmitted diseases.

Trussell J, Sturgen K, Strickler J, Dominik R. Comparative contraceptive efficacy of the female condom and other barrier methods. *Family Planning Perspectives* 1994; 66-72.

Because the research design for the clinical trial establishing the contraceptive efficacy of the female condom--a six-month life-table probability of failure of 15% (12% in the United States vs. 22% in Latin America)--did not include randomization with another method of contraception, no definite conclusion about its comparative



efficacy is possible. Comparisons using other female barrier methods as historical controls, however, provide evidence that, among women in the United States, the contraceptive efficacy of the female condom during typical use is not significantly different from that of the diaphragm, the sponge or the cervical cap. The six-month probability of failure during perfect use of the female condom is 2.6% among U.S. women, similar to rates for the diaphragm and the cervical cap but significantly lower than that for the sponge. Meaningful comparisons with the male condom are not possible because of the lack of data from carefully controlled prospective clinical trials. Extrapolations from the results on contraceptive efficacy suggest that perfect use of the female condom may reduce the annual risk of acquiring the human immunodeficiency virus by more than 90% among women who have intercourse twice weekly with an infected male.

1993

Shervington DO. The acceptability of the female condom among low-income African-American women. *Journal of the National Medical Association* 1993; 85(5): 341.

Among women, African Americans are at the highest risk for contracting the human immunodeficiency virus (HIV). Unfortunately, the majority of African-American women do not perceive themselves to be at risk nor perceive the need to engage in safe-sex practices. Given the alarming rate of increase of HIV disease among African-American women, more in-depth information about the sociocultural factors influencing these nonhealth-promoting beliefs and behaviors is needed immediately in order to design effective Information, Education, Communication campaigns. As part of such an effort, a premarketing study of the recently developed female condom, Reality (Wisconsin Pharmacal, Jackson, Wisconsin), was used as an opportunity to assess not only acceptance and relevance of the product, but also knowledge, attitudes, and practices among a group of African-American women in New Orleans. The methodology chosen was focus group discussions. The main finding from these discussions is that the previously reported low-risk perception of HIV disease among African-American females is also true among this group. The discussions suggest that cultural norm of female submission and passivity in sexual negotiation is a major barrier to preventive actions among these African-American women, ie, insistence on condom use during sexual intercourse [corrected]. The second important finding from these focus group discussions is that the women enthusiastically endorsed the female condom because they felt this condom allowed them control over safe-sex practices without having to challenge the power of their male partners. This study also demonstrates that the dynamics of universality and interpersonal learning inherent to insight-oriented or support groups can also be present.

Soper DE, Shoupe D, Shangold GA, Shangold MM, Gutmann J, Mercer L. Prevention of vaginal trichomoniasis by compliant use of the female condom. *Sexually Transmitted Diseases* 1993; 20(3): 137.

Background: Several case-control studies suggest that the male condom protects women against some sexually transmitted diseases. The female condom is the first barrier device under the woman's control that may be effective in the prevention of sexually transmitted diseases. Goal Of This Study: To determine if appropriate use of the female condom decreased the rate of recurrent vaginal trichomoniasis in previously diagnosed and treated women. Study Design: One hundred and four sexually active women with vaginal trichomoniasis were treated with metronidazole and assigned to a group using the female condom or a control group during a 45-day period of continued sexual activity. Fifty women served as controls, and 54 women were assigned to use the female condom. Results: Only 20 women used the female condom each time they had sexual intercourse. Reinfection with trichomonas occurred in 7/50 (14%) controls, in 5/34 (14.7%) noncompliant users, and in 0/20 compliant users of the female condom. Conclusion: The compliant use of the female condom is effective in preventing recurrent vaginal trichomoniasis.



1992

Ford N. Female condom improves with use. *Entre nous* 1992; 20(14).

A preliminary quantitative analysis of couples' experiences with the new female condom, Femidom, suggests that the acceptability of this method improves with duration of use. The analysis, conducted by the Institution of Population Studies at UK's University of Exeter, involved a sample of 51 couples who were provided with 15 female condoms. 36 couples returned the after-1st-use questionnaire and 29 couples completed the after-10th-use form. Responses revealed substantial initial concern about the large size of the sheath and proper insertion. Although these condoms diminished after 1st use, a small number of female respondents felt that the condom's visibility during use detracted from their sexual attractiveness. In most cases, the latter perception seemed conditioned by the response of the male partner. The finding that over half of the couples in the survey used the female condom at least 10 times is a positive indicator of the method's potential acceptability in the general population. Given the female condom's ability to protect against both pregnancy and sexually transmitted diseases, it is a valuable addition to the contraceptive marketplace.

1991

Schilling RF, El-Bassel N, Leeper MA, Freeman L. Acceptance of the female condom by Latin-and African-American women. *American Journal of Public Health* 1991; 81(10): 1345.

No abstract available [letter to the editor].

Soper DE, Brockwell NJ, Dalton HP. Evaluation of the effects of a female condom on the female lower genital tract. *Contraception* 1991; 44(1): 21-29.

The purposes of this study were to determine if use of the female condom (Reality™) was traumatic to the vaginal mucosa and/or vulvar skin and to determine its effect on resident vaginal bacterial flora. Thirty subjects were randomly assigned to utilize the female condom or diaphragm during the study period. Initially and during 3 follow-up visits, each subject underwent colposcopic examination of the vagina, cervix, and vulva with photographic record, and qualitative fungal, aerobic and anaerobic cultures of the vagina. The two groups were compared with respect to the frequency of abnormal physical findings determined by both macroscopic and colposcopic examination. Visits were compared within each contraceptive group with respect to changes in resident vaginal flora. There was no evidence of significant trauma associated with the use of either contraceptive device during the study period. The resident vaginal flora did not significantly change during the three follow-up visits in patients using the female condom. In diaphragm users, lactobacilli were less frequently isolated at the third and fourth follow-up visits when compared to the initial visit. In addition, aerobic gram-negative rods were more frequently isolated during the fourth visit when compared to the first visit. We conclude that neither the female condom (Reality™) nor the diaphragm is associated with trauma to the lower genital tract. Subjects using the diaphragm undergo a significant change in vaginal bacterial flora, becoming more likely to be colonized with coliform microorganisms and less likely to maintain lactobacilli colonization.

1990

Drew W, Blair M, Miner RC, Conant M. Evaluation of the virus permeability of a new condom for women. *Sexually Transmitted Diseases* 1990; 17(2): 110.

The authors tested a polyurethane women's condom for permeability to the human immunodeficiency virus (HIV) and cytomegalovirus (CMV) using an artificial intercourse model. They did not detect viral leakage in three trials for each virus. Use of this device, which can be controlled by the woman, may reduce HIV and CMV



infection.

1989

Kulig JW. Adolescent contraception: nonhormonal methods. *Pediatric Clinics of North America* 1989; 36(3): 717.

A comparison of the advantages, disadvantages, and costs of each method is presented in Table 1. Barrier methods of contraception offer adolescents protection against both pregnancy and STDs, but innovative approaches are needed to enhance availability and acceptability. Condom use in conjunction with a vaginal spermicide would provide optimal protection. The "female condom" may prove to be an effective alternative. Diaphragms and cervical caps can be prescribed for well-educated, highly motivated adolescents comfortable with insertion and removal. The vaginal contraceptive sponge provides many of the advantages of the diaphragm and cap without the need for an examination and fitting and also may be used as a backup method with the condom. Vaginal spermicides used alone are significantly less effective than in combination with a mechanical barrier. The IUD is not considered appropriate for most adolescents due to its association with an increased risk of pelvic infection. Periodic abstinence requires accurate identification of the fertile period, extensive education, and partner cooperation. Sterilization is rarely considered an option in adolescents. Alternate forms of sexual expression are available to adolescents who choose to abstain from intercourse.

