



Internal/Female Condom Bibliography

December 1, 2021

The articles listed below represent a bibliography of research on the internal/female condom that was created by the Cervical Barrier Advancement Society (CBAS). To update the bibliography, we searched PubMed for the terms “internal condom” and “female condom” in titles and abstracts from articles published through December 1, 2021.

2021

Fenwick SE, Botfield JR, Kidman P, McGeechan K, Bateson D. Views and experiences of the female condom in Australia: An exploratory cross-sectional survey of cisgender women. Plos one. 2021 Feb 19;16(2):e0246664.

Background: The female condom is the only female-initiated form of protection against unintended pregnancy and sexually transmissible infections (STIs). However, use of this method in Australia is low. To better understand women's views and experiences of the female condom, we conducted an interventional cross-sectional study.

Methods: Cisgender women ≥ 16 years, heterosexually active and living in New South Wales were recruited through social media advertisements and email invitations to clients of a family planning service. Eligible participants were provided with three female condoms and invited to complete a follow-up survey. Survey responses for women who attempted to use at least one female condom were summarised using counts and proportions.

Results: We recruited 556 women; few (30/556) had used the female condom before the study. There were 284 women who used, or attempted to use, a female condom during the study and completed the follow-up survey. Fifty-one percent (104/205) reported experiencing some difficulty in insertion, although only 46% (130/284) had seen an instructional demonstration. Approximately half (105/204) of women rated the sensation and comfort of the female condom as the same or better than the male condom, and 66% (137/204) reported that it provided the same or better lubrication. Approximately half of women said they would consider using the female condom again for STI prevention (51% (133/260)) or contraception (40% (103/260)), or would recommend to others (43% (112/260)).

Conclusion: Findings highlight the need for increased health promotion and education regarding use of the female condom. To increase access it will be important to address method cost and availability in Australia. Future research should explore other perspectives of this method, including among the LGBTIQ+ community.

Botfield JR, Cucuzza S, Kidman P, Fenwick SE, Bateson D. The female condom: What do Australian women say?. Health Promotion Journal of Australia. 2021 Jan 31.

Background: The female condom is a barrier method for the prevention of sexually transmissible infections and unintended pregnancy. Uptake of this method remains low in Australia, although little research has been undertaken to explore this.

Methods: An interventional cross-sectional study was undertaken in 2019 to explore the views and experiences of women in New South Wales. After trying the female condom, they were invited to complete an online survey and/or structured interview. Training in the use of the female condom was not provided. This paper reports on qualitative findings from open-ended survey responses and interviews.



Results: In total, 284 participants completed the survey and 20 participated in an interview. Most were aware of the female condom prior to participating in the study, but few had used it previously. Four broad themes were identified from the data: (i) accessibility of the female condom, including cost and availability, (ii) supporting choice in different circumstances, (iii) aspects of empowerment and control and (iv) use of gendered language.

Conclusions: The female condom may be an acceptable option for many women in Australia. To support the choice of method and promote uptake, it will be important to increase the accessibility of the female condom by raising awareness and addressing the issues of cost and availability. Further exploration of issues regarding inclusive language and messaging in health promotion campaigns and marketing is warranted to ensure that this product is accessible for all people who may wish to use it, regardless of gender or sexuality. Similar research could be undertaken with men/partners and members of the LGBTQ+ community to explore their perspectives of the female condom. **SO WHAT?:** To support contraceptive choice and promote the uptake of the female condom for those who desire this method, it will be important to address the issues of cost and availability. Accessibility will also be enhanced through the consideration of inclusive language and messaging in health promotion campaigns and marketing of the female condom.

2020

Nel A, Malherbe M, van Niekerk N, Beksinska M, Greener R, Smit J, Frezieres R, Walsh T. Performance and Acceptability of the FC2 Female Condom When Used With and Without a Silicone Placebo Vaginal Ring-A Randomized, Crossover Trial. J Acquir Immune Defic Syndr. 2020 Sep 1;85(1):58-65. doi: 10.1097/QAI.0000000000002408.

BACKGROUND: The silicone Dapivirine Vaginal Ring 25 mg, has been developed to provide an additional HIV prevention option for women. If approved for use, women will always be counselled to use condoms when using the vaginal ring for maximum protection. This paper evaluates the compatibility of female condoms with the ring. **METHODS:** This was a 2-period crossover, randomized noninferiority trial. Couples in 2 sites in the United States of America were randomized to FC2 Female Condom (FC2) with and without a placebo silicone ring and asked to use 4 female condoms in each period. The primary noninferiority endpoint was the clinical failure rate during intercourse or withdrawal (self-reported clinical breakage, slippage, misdirection, and invagination). Frequencies and percentages were calculated for each failure mode and differences in performance of the 2 periods, using the female condom without the ring as reference. Noninferiority was defined using an 8% margin at the 5% significance level. Safety and tolerability were also assessed. **RESULTS:** Eighty-one couples were enrolled and 79 completed the trial using a total of 596 female condoms (297 and 299 with/without a ring inserted, respectively). Total female condom clinical failure was 14.1% and 15.7% in the presence and absence of a ring, respectively, with a difference of -2.1% (95% confidence interval: -7.8% to 3.6%), thereby demonstrating noninferiority when used with the ring. There were no differences in safety and tolerability between the 2 periods. **DISCUSSION:** Concurrent use of the placebo silicone vaginal ring had no significant effect on female condom functionality or safety outcomes.

Burton J, Bedford R, Graham C, Nadarzynski T. Perceived barriers and facilitators to female condoms among UK based healthcare professionals. Eur J Contracept Reprod Health Care. 2020 Aug;25(4):299-304. doi: 10.1080/13625187.2020.1777966. Epub 2020 Jun 22.

OBJECTIVES: The female condom (FC) is an effective strategy against sexually transmitted infections (STIs) in susceptible women and men who have sex with men. FCs are the only female-initiated dual protection method that protects against both STIs and unintended pregnancy. As healthcare professionals (HCPs) are a key element in the promotion of contraceptive use, it is important to examine attitudes towards FCs among this group. **Study participants:** 15 male and female HCPs aged between 22 and 57 years recruited from sexual and reproductive health settings located in Brighton, London, and Glasgow. **Sampling method:** Purposive sampling with targeted



advertisements (newsletters and bulletins). Study design: face-to-face and telephone interviews with sexual health HCPs. Main outcome measure: potential barriers and facilitators to FCs in the UK. Data were analysed thematically to identify common views and perspectives. RESULTS: FCs were thought to be unacceptable to most women due to stigma, design, negative visual appeal, insertion difficulties and lack of familiarity. The perceived unavailability and higher cost of FCs, in comparison to male condoms, are major barriers to their use. CONCLUSIONS: HCPs are reluctant to promote FCs, often due to the perceived social stigma surrounding FCs. Further education and promotion are needed to increase acceptability and correct usage. Future research needs to explore strategies to increase the acceptability of FCs among women, men who have sex with men and HCPs.

Beksinska M, Nkosi P, Mabude Z, Mantell JE, Zulu B, Milford C, Smit JA. Lessons from the evaluation of the South African National Female Condom Programme. PLoS One. 2020 Aug 13;15(8):e0236984.

Background: Understanding of the facilitators and challenges to female condom (FC) uptake has been limited due to lack of evaluation of national FC programmes.

Setting: The FC has been an integral component of South Africa's (SA) HIV prevention programme for 20 years and is the largest government-funded FC programme worldwide.

Methods: The national FC evaluation used a mixed-methods approach and consisted of key informant interviews and a telephone survey in a national sample of public and non-public sites. A sub-sample of sites participated in client and provider interviews, and a self-administered client survey. A review of distribution statistics from South Africa's District Health Information System was also conducted.

Results: All 256 public-sector and 28 non-public-sector facilities reported having ever distributed FCs. Less than 5% of these facilities reported stock-outs and less than 3% reported they had a supply of expired female condoms. Systems for male condom (MC) and FC distribution were complementary, with similar ordering, delivery and reporting processes. FC promotion by providers ($n = 278$) varied with regard to FC training, whether attitudes about FCs influenced providers offer of FCs, and how they counselled clients about FCs. Of the 4442 self-administered client surveys in 133 facilities, similar proportions of women (15.4%) and men (15.2%) had ever used FCs. Although FCs were available at almost all sites surveyed, only two-thirds of clients were aware of their availability.

Conclusion: Data highlight the role of providers as gatekeepers to FC access in public and non-public sectors and provide support for further FC programme expansion in SA and globally.

Mantell JE, Exner TM, Bai D, Leu CS, Beksinska M, Mabude Z, Hoffman S, Smit JA. Perceived male partner attitudes toward the female condom predict female university students' use of the female condom. Int J STD AIDS. 2020 Jul;31(8):753-762. doi: 10.1177/0956462420912986.

Female and male condoms are the only methods that prevent both sexually transmitted infections (STIs), including HIV, and unintended pregnancy. Despite continuing high STI rates, few studies investigate factors predicting whether women initiating female condom (FC) use sustain use. Using data from a randomized trial, we examined predictors of sustained FC use at five-month follow-up (FU2) among female university students in South Africa who participated in either a one-session, information-only, group-delivered Minimal Intervention or a two-session, group-delivered Enhanced Intervention. In the final multiple logistic regression model, believing one's partner holds positive attitudes toward the FC ($aOR = 1.40$; $p = 0.028$), and greater FC use for vaginal sex at previous assessment ($aOR = 1.19$; $p = 0.008$) were associated with greater odds of FC use at FU2. Excluding number of FC-protected occasions at FU1 from the analysis, discussing FC use with partner ($aOR = 2.89$; $p = 0.071$) and believing one's partner holds positive attitudes toward the FC ($aOR = 1.63$; $p < 0.001$) were associated with greater odds of use at FU2. The FC empowers women to protect themselves from both STIs and unintended pregnancy, but targeted interventions are needed to address men's negative attitudes toward the device. Engaging men as FC champions to support and promote FC use, along with marketing campaigns targeted to men, may expand FC coverage and enhance uptake.



Beksinska M, Wong R, Smit J. Male and female condoms: Their key role in pregnancy and STI/HIV prevention. Best Pract Res Clin Obstet Gynaecol. 2020 Jul;66:55-67. doi: 10.1016/j.bpobgyn.2019.12.001. Epub 2019 Dec 14.

Male and female condoms are the only available Multipurpose Prevention Technologies (MPTs) that can prevent unintended pregnancy and sexually transmitted infections including HIV. If used correctly and consistently, condoms can provide levels of pregnancy protection similar to many hormonal methods. Condoms remain one of the most common methods used at first sexual intercourse and are relied on as a current use of contraception by adolescents in many regions of the world. Male and female condoms are safe and require no prescription; in particular male condoms are generally easy to access at low cost. Female condoms are more expensive than male condoms and less accessible; however, they have the advantage of being a female-initiated method. Condom users may experience some common challenges; however, recent advances in condom technology have led to new designs and modifications of existing products to improve quality and make them more attractive, acceptable and pleasurable for consumers and increase its use.

Wiyeh AB, Mome RKB, Mahasha PW, Kongnyuy EJ, Wiysonge CS. Effectiveness of the female condom in preventing HIV and sexually transmitted infections: a systematic review and meta-analysis. BMC Public Health. 2020 Mar 12;20(1):319. doi: 10.1186/s12889-020-8384-7.

BACKGROUND: The effectiveness of female condoms for preventing HIV and sexually transmitted infections (STIs) remains inconclusive. We examined the effects of female condoms on the acquisition of HIV and STIs. **METHODS:** We searched four databases, two trial registries, and reference lists of relevant publications in October 2018 and updated our search in February 2020. We screened search output, evaluated study eligibility, and extracted data in duplicate; resolving differences through discussion. We calculated the effective sample size of cluster randomised trials using an intra-cluster correlation coefficient of 0.03. Data from similar studies were combined in a meta-analysis. We performed a non-inferiority analysis of new condoms relative to marketed ones using a non-inferiority margin of 3%. We assessed the certainty of evidence using GRADE. **RESULTS:** We included fifteen studies of 6921 women. We found that polyurethane female condoms (FC1) plus male condoms may be as effective as male condoms only in reducing HIV acquisition (1 trial, n = 149 women, RR 0.07, 95%CI 0.00-1.38; low-certainty evidence). However, the use of FC1 plus male condoms is superior to male condoms alone in reducing the acquisition of gonorrhoea (2 trials, n = 790, RR 0.59, 95%CI 0.41-0.86; high-certainty evidence) and chlamydia (2 trials, n = 790, RR 0.67, 95%CI 0.47-0.94; high-certainty evidence). Adverse events and failure rates of FC1 were very low and decreased during follow up. Although the functionality of newer female condoms (Woman's, Cupid, Pheonurse, Velvet, and Reddy) may be non-inferior to FC2, there were no available studies assessing their efficacy in preventing HIV and STIs. **CONCLUSION:** The use of female plus male condoms is more effective than use of male condoms only in preventing STIs and may be as effective as the male condom only in preventing HIV. There is a need for well conducted studies assessing the effects of newer female condoms on HIV and STIs. PROSPERO REGISTRATION NUMBER: CRD42018090710.

Hsu R, Tavrow P, Uysal J, Alterman AE. Seeking the female (internal) condom in retail pharmacies: Experiences of adolescent mystery callers. Contraception. 2020 Feb;101(2):117-121.

BACKGROUND:

Female (internal) condoms could be viable alternatives to male (external) condoms. Our objective was to describe barriers that adolescent mystery callers encountered when trying to access female condoms in U.S. pharmacies.

METHODS:

In mid-2016, university students seeking "condoms for girls" called retail pharmacies in Arizona, California, New Mexico and Utah. We evaluated differences in product availability and callers' experiences by pharmacy type.



RESULTS:

Of our final sample (n=1475), only eight outlets (0.5%), all national chains, definitely stocked female condoms. Of those not (or probably not) stocking female condoms, 11% tried to be helpful (e.g., offered to special order), 59% made no substantive comment, and 30% were unhelpful (e.g., dismissive, rude, gave wrong information). National chain employees were significantly more unhelpful (34% vs 22%, $p < .01$).

CONCLUSION:

Almost no pharmacies in four southwestern states stocked female condoms in mid-2016. Pharmacy staff frequently were unhelpful, which could deter adolescent use of female condoms even if new types become available.

2019

Pinchoff J, Boyer CB, Nag Chowdhuri R, Smith G, Chintu N, Ngo TD.

The evaluation of the Woman's Condom marketing approach: What value did peer-led interpersonal communication add to the promotion of a new female condom in urban Lusaka? PLoS One. 2019 Dec ;14(12):e0225832. doi: 10.1371/journal.pone.0225832.

During a mass media campaign accompanying the launch of the Maximum Diva Woman's Condom (WC) in Lusaka, Zambia, a cluster-randomized evaluation was implemented to measure the added impact of a peer-led interpersonal communication (IPC) intervention on the awareness and uptake of the new female condom (FC). The WC and mass media campaign were introduced simultaneously in 40 urban wards in April 2016; half of the wards were randomly assigned to the treatment (IPC intervention) with cross-sectional surveys conducted before ($n = 2,364$) and one year after ($n = 2,430$) the start of the intervention. A pre-specified intention-to-treat (ITT) analysis measured the impact of randomization to IPC at the community level. In adjusted ITT models, there were no statistically significant differences between intervention and control groups. Due to significant implementation challenges, we also conducted exploratory secondary analyses to estimate effects among those who attended an IPC event ($n = 66$) using instrumental variable and inverse probability weighting analyses. In addition to increases in FC identification (IPC attendees had higher reported use of any condom, improved perceptions of FC's, and were more likely to have discussed contraceptive use with their partner as compared to non-attendees). The introduction of a new FC product combined with an IPC intervention significantly increased general knowledge and awareness in the community as compared to media alone, but did not lead to detectable community level impacts on other primary outcomes of interest. Observational evidence from our study suggests that IPC attendance is associated with increased use and negotiation. Future studies should explore the intensity and duration of IPC programming necessary to achieve detectable community level impacts on behavior. Trial Registration: AEARCTR-0000899.

Gambir K, Pinchoff J, Obadeyi O, Ngo TD. Opportunities and challenges for the introduction of a new female condom among young adults in urban Zambia. Reprod Health. 2019 Dec;16(1):175. doi: 10.1186/s12978-019-0839-x.

BACKGROUND: Expanding contraceptive method choices for sexually active youth is critical to prevent STIs/HIV and unintended pregnancies. However, preferences and decision making around contraception among young adults are not well understood. A new female condom (FC), the Woman's Condom (WC), features an improved design and is marketed as a premium product at a higher price point. We conducted a qualitative study to examine the underlying knowledge, attitudes, and perceptions around the FC generally, the WC specifically, and to explore the opportunities and challenges of introducing the WC to young adults in urban Zambia. **METHODS:** Thirty focus group discussions comprised of 245 men and women aged 18-24 years were facilitated



by local moderators in Lusaka, Zambia between August and December 2016. Data were analyzed using thematic content analysis using ATLAS.ti (Version 7.5.17). RESULTS: While interest in the newly launched WC was high, few participants recognized it, so discussion was framed around FCs more generally. The decision to use a FC is challenged by misconceptions regarding safety and correct use, cost, and women's limited power over decision making in relationships. Participants also reported low availability of the product. Several opportunities for FC uptake were discussed, including the perception that FCs provide better sensation during intercourse compared with male condoms, and women reported enthusiasm for the opportunity to be the partner responsible for contraception. Some women expressed interest in the WC in order to ensure it was not tampered with by their partner, a practice commonly reported by both genders that reflects high levels of mistrust. CONCLUSIONS: Findings suggest the FC, including the new WC, has potential to increase gender equity by giving women a product they are comfortable buying and being able to control to ensure correct use; however, future programming should address high perceived cost of the WC and women's limited decision making power in relationships. Findings also highlight the need for interventions that include product demonstration and promote the WC as a method that provides better sensation during sex than male condoms. To increase voluntary uptake, the challenges identified here should be incorporated into future social marketing campaigns.

Walsh TL, Snead MC, St Claire BJ, Schwartz JL, Mauck CK, Frezieres RG, Blithe DL, Archer DF, Barnhart KT, Jensen JT, Nelson AL, Thomas MA, Wan LS, Weaver MA. Comparison of self-reported female condom failure and biomarker-confirmed semen exposure. Contraception. 2019 Nov;100(5):406-412

OBJECTIVE:

To investigate whether rates of self-reported Woman's Condom (WC) clinical failure and semen exposure from a functionality study are comparable to results from a contraceptive efficacy substudy.

STUDY DESIGN:

We structured our comparative analysis to assess whether functionality studies might credibly supplant contraceptive efficacy studies when evaluating new female condom products. Couples not at risk of pregnancy in the functionality (breakage/slippage/invagination/penile misdirection) study and women in the contraceptive efficacy study completed condom self-reports and collected precoital and postcoital vaginal samples for up to four uses of the WC. Both studies used nearly identical self-report questions and the same self-sampling procedures and laboratory for prostatic specific antigen (PSA), a well-studied semen biomarker. We compared condom failure and semen exposure proportions using generalized estimating equations methods accounting for within-couple correlation.

RESULTS:

Ninety-five (95) efficacy substudy participants used 334 WC and 408 functionality participants used 1572 WC. Based on self-report, 19.2% WC (64 condoms) clinically failed in the efficacy substudy compared to 12.3% WC (194 condoms) in the functionality study ($p=.03$). Of the 207 WC efficacy uses with evaluable postcoital PSA levels, 14.5% (30 uses) resulted in semen exposure compared to 14.2% (184 uses) of the 1293 evaluable WC functionality study uses.

CONCLUSIONS:

When evaluating the ability of an experimental condom to prevent semen exposure, the rate of clinical condom failure reported by participants risking pregnancy in an efficacy substudy was significantly higher than the rate reported by participants not risking pregnancy in a functionality study. The rate of semen exposure, assessed by an objective biomarker was nearly identical for the two studies.

IMPLICATIONS:



Our results suggest that an objective marker of semen exposure in functionality studies could provide a reasonable alternative to contraceptive efficacy studies in evaluating risk of unintended pregnancy and inferring protection from sexually transmitted infection than condom failure rates based on self-report.

Wu J, Zhang J, Li Y, Yang J, Zhou Y, Li Y, Xu S, Zhao R. Short-term acceptability of the Woman's Condom and influencing factors among internal migrants in China. BMC Public Health. 2019 Oct 29;19(1):1410.

BACKGROUND:

The Woman's Condom, a newly designed condom for women, has obtained market approval in China, but it remains relatively unfamiliar to the migrant population. The aim of this study is to evaluate the short-term acceptability of the Woman's Condom and influencing factors among internal migrants.

METHODS:

A longitudinal study was conducted among 1800 migrants in Beijing, Chongqing, and Shanghai in China between August 2013 and August 2014. Three-level model was implemented with the Statistical Analysis System software (v.9.4 SAS Institute) to analyze within-individual changes, between-individuals effects, and between-group effects.

RESULTS:

Three-level model analysis revealed statistically higher short-term acceptability of the Woman's Condom among subjects who lived in Shanghai ($\beta = 6.50$, $t = 2.76$, $p < 0.01$), unmarried and not in a cohabiting relationship ($\beta = 3.05$, $t = 2.76$, $p < 0.01$) than those who lived in Beijing, married and in a cohabiting relationship. Female ($\beta = -1.69$, $t = -7.55$, $p < 0.01$) and lower educational attainment ($\beta = -2.30$, $t = -1.94$, $p = 0.05$) were negatively related, while occupations of education, health, and civil staff ($\beta = 1.50$, $t = 2.92$, $p < 0.01$) were positively related to acceptability. It was predicted that migrants' acceptability of the Woman's Condom would significantly increase over time ($\beta = 1.09$, $t = 5.54$, $p < 0.01$).

CONCLUSIONS:

The findings indicate that the Woman's Condom enjoyed relatively high short-term acceptability among migrants in China. In order to popularize the Women's Condoms in migrants, more publicity, consultation and training in open and prosperous areas should be strengthened.

Beksinska M, Smit J, Mphili N, Greener R, Maphumulo V. The panty condom: a pilot study of the function and acceptability of an alternative female condom design. International journal of STD & AIDS. 2019 Sep: 0956462419845543.

New female condom (FC) products, different in design and materials that have the potential to lower cost and improve acceptability are being developed. A pilot study of the Panty Condom was conducted among experienced FC users in Durban, South Africa. This pilot function trial enrolled 19 women who were asked to use five Panty Condoms each and collect information on use in a condom diary at home, followed by one follow-up interview. Primary endpoints were total clinical failure and total female condom failure. Non-inferiority of component modes, clinical breakage, non-clinical breakage, slippage, misdirection, and invagination were also determined. Frequencies and percentages were calculated for each failure mode. The mean age of the participants was 27.8 years (SD 4.9). Safety and acceptability data were also assessed. In 95 condom uses nine failure events occurred in eight condoms. Clinical breakage occurred in 8.4% ($n = 8$) of condoms and slippage in one condom. Total FC failure was 8.4% of all condom uses. Of the eight breakage events there were two reports of the condom ripping during sex and six reports of the condom detaching from the panty. Fifteen women either liked very much or liked somewhat using the Panty Condom. Total clinical failure was approximately twice that seen in other FC functionality studies.



Probandari A, Setyani RA, Pamungkasari EP, Widyaningsih V, Demartoto A. Improving knowledge, acceptance, and utilization of female condoms among sex workers through a peer education: a mixed methods study in Surakarta Municipality, Central Java Province, Indonesia. Health Care for Women International. 2019 Aug 6:1-9.

Female sex workers (FSW) are high-risk for HIV infection. The authors conducted a quasi-experimental study by providing peer education on 110 FSWs, and routine HIV education on 120 controls, in Surakarta Indonesia. An additional qualitative study was performed to explain the contextual factors contributing to the effectiveness of peer education. The difference in difference approach showed that peer education improved knowledge, acceptance, and utilization of female condom. The improvements were related to the clients' perceptions, access, and available interactive communication with the peer educator. The peer education program should be enhanced to support the prevention of HIV/AIDS.

Walsh TL, Snead MC, Claire BJ, Schwartz JL, Mauck CK, Frezieres RG, Blithe DL, Archer DF, Barnhart KT, Jensen JT, Nelson AL. Comparison of self-reported female condom failure and biomarker-confirmed semen exposure. Contraception. 2019 Aug 2.

OBJECTIVE: To investigate whether rates of self-reported Woman's Condom (WC) clinical failure and semen exposure from a functionality study are comparable to results from a contraceptive efficacy substudy.

STUDY DESIGN: We structured our comparative analysis to assess whether functionality studies might credibly supplant contraceptive efficacy studies when evaluating new female condom products. Couples not at risk of pregnancy in the functionality (breakage/slippage/invagination/penile misdirection) study and women in the contraceptive efficacy study completed condom self-reports and collected precoital and postcoital vaginal samples for up to four uses of the WC. Both studies used nearly identical self-report questions and the same self-sampling procedures and laboratory for prostatic specific antigen (PSA), a well-studied semen biomarker. We compared condom failure and semen exposure proportions using generalized estimating equations methods accounting for within-couple correlation.

RESULTS: Ninety-five (95) efficacy substudy participants used 334 WC and 408 functionality participants used 1572 WC. Based on self-report, 19.2% WC (64 condoms) clinically failed in the efficacy substudy compared to 12.3% WC (194 condoms) in the functionality study ($p=.03$). Of the 207 WC efficacy uses with evaluable postcoital PSA levels, 14.5% (30 uses) resulted in semen exposure compared to 14.2% (184 uses) of the 1293 evaluable WC functionality study uses.

CONCLUSIONS: When evaluating the ability of an experimental condom to prevent semen exposure, the rate of clinical condom failure reported by participants risking pregnancy in an efficacy substudy was significantly higher than the rate reported by participants not risking pregnancy in a functionality study. The rate of semen exposure, assessed by an objective biomarker was nearly identical for the two studies.

IMPLICATIONS: Our results suggest that an objective marker of semen exposure in functionality studies could provide a reasonable alternative to contraceptive efficacy studies in evaluating risk of unintended pregnancy and inferring protection from sexually transmitted infection than condom failure rates based on self-report.

Ju L, Shi CX, Lv F, Tang H, Zeng G, Xu P, Chen W, He H, Ma L, Zhang L, Chen X. Female condom use and its acceptability among HIV-serodiscordant couples in China. J Assoc Nurses AIDS Care. 2019 Jul-Aug;30(4):428-439.

Intimate partners of people living with HIV are at risk of HIV infection. We assessed the acceptability of female condom use among 89 married, heterosexual, HIV-serodiscordant couples from Sichuan and Hunan provinces in



China for this prospective observational cohort study. Participants used female condoms for 3 months, reporting use and attitudes in written logs and questionnaires. At the end of the study, 58.4% of couples expressed willingness to continue using female condoms. Factors associated with willingness to use female condoms were (a) the female partner reporting having experienced forced sex by the male partner, (b) applying a lubricant to the penis, (c) understanding the correct application method, (d) being married more than 20 years, and (e) experiencing no difficulty during the first use. Most HIV-serodiscordant couples found female condoms to be acceptable. Increasing access to female condoms could be an acceptable alternative barrier method to male condoms for preventing HIV transmission.

Moraes AA, Suto CS, Oliveira EM, Paiva MS, Ferreira CS, Barreto MA. A look at female condoms from public school students. *Revista gaucha de enfermagem*. 2019 Jul;40:e20180277-.

OBJECTIVE: to find the social representations of female students about female condoms. **Methodology:** exploratory and descriptive study, with qualitative approach, based on the Theory of Social Representations.

METHOD: 94 students from high school students, technical courses, and adult education participated, all from public schools from a municipality in the countryside of Bahia/Brazil, and responded to the test of free word association. The evocations were submitted to the softwares EVOC and IRAMUTEQ.

RESULTS: students recognize that the female condom is a technology that provides autonomy, protects against sexually transmitted infections, and prevents pregnancy. In contrast, they reported that their reasons for not using the method are finding it uncomfortable and strange.

FINAL CONSIDERATIONS: Social representations point to the need for strategies that promote information exchange and stimulate practical knowledge about the female condom among public school students.

Beksinska M, Zulu B, Nkosi P, Mabude Z, Smit J. Offering choice in female condoms: The South African experience. *Int J STD AIDS*. 2019 Jul 8.

South Africa (SA) has an integrated male and female condom (FC) programme. Since 2014, the programme has introduced two new FC brands. This study evaluated the early introduction of the availability of new FCs. Twenty-three sites participating in the National SA Female Condom Evaluation were included. Providers and clients completed interviewer-administered questionnaires assessing FC brand availability, length of distribution, how clients are informed about new FCs and reactions to the choice of more than one FC. A total of 55 providers and 51 clients were interviewed. Although all 23 sites reported they had distributed new FCs, only one had all three types available. Almost all providers (96%) thought it was important to increase choice, although some (27%) worried that having different FCs may confuse clients. Almost all clients (96%) felt it was important to increase the choice of FCs, and most women (80%) felt that using one type of FC would make it easy to use another type. Providers called for more brand-specific Information, Education and Communication (IEC) training for themselves and the community. Providers and clients seem to be very positive about the choice of FCs. Providers recommended more support in the form of IEC materials and training to assist in the provision of the expansion of FC brands.

Zhou C, Hsieh E, Rou K, Tillman J, Dong W, Feng XX, Yang YZ, Yang YJ, Sun XG, Zang HJ, Wu YZ, Wu Z. Short-term acceptability of female condom use among low-fee female sex workers in China: a follow-up study. *BMC Womens Health*. 2019 Jun 14;19(1):77.

BACKGROUND: Low-fee female sex workers (FSW) lack power to effectively negotiate male condom use with clients. Female condoms (FCs) may provide an alternative strategy. This study was conducted to assess the acceptability of FC use among low-fee FSWs, and to identify appropriate candidates for future FC promotion. **METHODS:** A one-month follow-up study was conducted. At entry into the study, eligible participants completed a baseline questionnaire and were given 10 FCs. At the one-month follow up encounter, the number of used FC



packages were counted and each participant completed a follow-up questionnaire. Logistic regression was used to identify variables associated with more frequent use of FCs (> 2 times). RESULTS: A total of 312 low-fee FSWs were enrolled at baseline and all participants completed the follow-up evaluation. Among them, 123 (39.4%) participants had used more than two FCs. Participants who were illiterate or had completed at most primary school education (OR: 2.4, 95% CI: 1.4-7.2), charged ≤30 RMB per client (≤30 vs. 51-80 RMB, OR: 3.8, 95% CI: 1.9-7.6), or had consistently used condoms with regular clients in the past month (OR: 2.4, 95%CI: 1.4-4.2) were more likely to use FCs. CONCLUSION: Low-fee FSWs charging ≤30 RMB per client, and those who are less educated may be appropriate initial candidates for FC promotion in China. Strategies to consider include teaching FSWs tactics for negotiation of FC use that can initially be applied with regular clients, and providing education to maximize ease-of use, and minimize discomfort with FC usage.

Beksinska M, Greener R, Mphili N, Smit J, Kilbourne-Brook M, Coffey PS. Functional performance study of an adapted design of the woman's condom: a crossover, noninferiority, randomized clinical trial. The European Journal of Contraception & Reproductive Health Care. 2019 May 20:1-7.

Objectives: We aimed to assess the functional performance and safety of a modified Woman's Condom (WC2) against the existing FC2 female condom. Study design: This randomized clinical trial enrolled 287 women in one South African site. The primary outcome of the study was the rate of female condom failure. Participants were asked to use five of each female condom type and to collect information on use in a condom log at home and were interviewed after use of each FC type. Results: Noninferiority was demonstrated for the WC2 with respect to the reference condom FC2 for all condom functions. The WC2 was found to be superior to the FC2 reference condom for clinical failure ($p = .000$), total female condom failure ($p = .001$), misdirection ($p = .000$) and slippage ($p = .004$). Conclusion: The WC2 female condom performs as well as the FC2 female condom and offers good stability during use. Implications: Results from this study will inform further refinement of this female condom design, resulting in a new and potentially less expensive Woman's Condom.

Chen BA, Blithe DL, Muraguri GR, Lance AA, Carr BR, Jensen JT, Kimble TD, Murthy AS, Schreiber CA, Thomas MA, Walsh TL. Acceptability of the Woman's condom in a phase III multicenter open-label study. Contraception. 2019 Mar 6.

OBJECTIVE: This study aimed to evaluate the acceptability of the Woman's Condom (WC) over 6 months (183 days) and ≥6 menstrual cycles in a US-based multicenter open-label phase III contraceptive efficacy trial. STUDY DESIGN: We assessed acceptability via written questionnaire at visit 2 (after the third cycle) and visit 3 (after the sixth cycle or >183 days, or upon early discontinuation). Key domains included ease of use, comfort/lubrication, sexual satisfaction, male partner satisfaction and confidence in pregnancy and sexually transmitted infection (STI) prevention. We analyzed quantitative data using descriptive statistics. We conducted a content analysis to identify major themes from four open-ended questions. RESULTS: Most women [327/405 (81%)] had limited or no previous experience with female (internal) condoms. Of 405 evaluable women, 346 women completed questionnaires at visit 2 and 303 women at visit 3; 282 women attended both visits. Of women attending both visits, 165/282 (59%) reported at visit 2 that WC insertion was easy/very easy; this increased to 195/282 (69%) at visit 3 ($p = .03$). Many women [166/281 (59%)] preferred the WC [105/281 (37%)] or were neutral [61/281 (22%)], while 115/281 (41%) preferred male condoms. Women attending visit 3 felt confident that the WC could prevent pregnancy [246/303 (81%)] and STIs [217/303 (72%)]. Many women expressed empowerment with having control over their contraception; some disliked the design, esthetics and insertion process. Most women (254/299 (85%)) would recommend the WC to a friend. CONCLUSION: The WC's acceptability and ease of use is promising for wider dissemination as a female-controlled method that can protect against both pregnancy and STIs. IMPLICATIONS: The WC's overall acceptability and ease of use is promising for a new female-controlled barrier contraceptive option that can protect against both pregnancy and sexually transmitted infections.



Boraya JO, Githae C, Atandi TA, Gachau A. Social and psychological factors affecting utilization of female condom among youths in Migori County, Kenya. Health psychology open. 2018 Dec;5(2):2055102918815336.

The female condom is a dual protection tool for both prevention of HIV/AIDS transmission and conception of unwanted pregnancies. In Migori, HIV prevalence is 16 percent and utilization of female condom is at 0.3 percent. A descriptive cross-sectional study was conducted among 380 youths who were systematically and randomly sampled. Majority of youths (86.6%) were aged between 18 and 25 years with 83.9 percent being single, 95.3 percent were Christians, and 4.7 percent Muslim. There was a significant association between marital status, Men's role in negotiation of safe sex, incompetence in female condom insertion, and utilization of the female condom.

2018

Mokgetse M, Ramukumba MM. Female condom acceptability and use amongst young women in Botswana. Curationis. 2018;41(1):1-6.

BACKGROUND: The female condoms are a barrier method of contraception. The FC1 female condom is made from soft thin plastic called polyurethane and has been replaced by FC2 female condom, which is made of synthetic latex. The female condom is worn inside the vagina and acts as a barrier to prevent semen getting to the womb. It is about 75% - 82% effective with normal use. When used correctly all of the time, female condoms are 95% effective. Despite evidence of its effectiveness, the use of the female condom has continued to face resistance from both women and men. **OBJECTIVES:** The objectives of this study were to determine clients' level of knowledge of female condom, identify predominant methods of contraception, examine young women's views regarding the female condom and identify barriers to the use of female condoms by young women. **METHOD:** A simple random sampling approach was used to recruit young women between 15 and 34 years in Jwaneng, Botswana. Data were collected using self-administered structured questionnaire from women accessing healthcare services in the three health facilities in 2015. Descriptive statistics, exploratory factor analysis and the chi-square test techniques were applied using the Statistical Package for the Social Sciences (SPSS) statistical programme version 23 for Windows to analyse data. **RESULTS:** The findings based on factor loadings show low utilisation of the female condom and highlights the significant challenges about the material, size, shape and timing of insertion. Respondents had stronger views on the structure of the condom. There was no significant relationship between attitude and method of contraception. **CONCLUSION:** Acceptability of the female condom involves complex factors such as women position and decision-making power in a relationship, attitude and knowledge. Attitude, knowledge and power relations play a role in the extent to which women would want to try or use it. Various strategies need to be developed to effectively promote the female condom amongst young women.

Mome RK, Wiyeh AB, Kongnyuy EJ, Wiysonge CS. Effectiveness of female condom in preventing HIV and sexually transmitted infections: a systematic review protocol. BMJ Open. 2018 Aug 5;8(8):e023055.

INTRODUCTION: The HIV pandemic continues to evolve with young women being the most vulnerable group to acquire infection. The presence of sexually transmitted infections (STIs) further enhances HIV susceptibility and also leads to long-term complications such as infertility and cervical cancer. The female condom is a self-initiated method for STI and HIV prevention but there are controversies on its effects. We aim to assess the effectiveness, safety and acceptability of the use of female condoms for prevention of STI and HIV acquisition among women. **METHODS AND ANALYSIS:** We will search Cochrane Central Register of Controlled Trials, PubMed, EMBASE, Scopus, WHO International Clinical Trials Registry and reference lists of relevant publications for potentially eligible studies. We will screen search outputs, select eligible studies, extract data and assess risk of bias in duplicate; resolving discrepancies through discussion and consensus or arbitration. We will combine data from clinically homogenous studies in a fixed effect meta-analysis and assess the certainty of the evidence using the method for Grading of Recommendations Assessment, Development and Evaluation. We



registered the planned systematic review with the International Prospective Register of Systematic Reviews (PROSPERO) in March 2018 and will finalise the search strategy in August 2018; conduct the searches and select eligible studies between August and October 2018; and collect data, conduct statistical analyses and prepare and submit the manuscript for consideration by a peer-reviewed journal between November 2018 and April 2019. ETHICS AND DISSEMINATION: We will use publicly available data; hence no formal ethical approval is required for this review. We will disseminate the findings of this review through conference presentations and publication in an open-access peer-reviewed journal. PROSPERO REGISTRATION NUMBER: CRD42018090710.

Ting RS, Wong EL, Tnay JK. A pilot study on the functional performance and acceptability of an innovative female condom (Wondaleaf®) in Malaysia. Open access journal of contraception. 2018;9:11. BACKGROUND: Female condom (FC) has been available for over 30 years, but it still lacks wide acceptability. To overcome misdirection and invagination occurring in FC and to provide a wider area of protection, Wondaleaf® (WL), a new-generation adhesive FC, was recently invented. This pioneering study sought to assess the acceptability and functional performance of WL among Malaysian women. METHODS: A mixed method survey was conducted in three cities of Malaysia, recruiting sexually active heterosexual women, aged 18-50, by snowball sampling method. Participants were provided with WL and initially surveyed to rate its performance in five coital usages over 2 months. After that, the participants underwent a second survey to rate their satisfaction and acceptability toward WL. Descriptive statistics on clinical failure rates were tabulated with correlational analysis performed to identify major variables contributing to WL's functional performance and acceptability. RESULTS: Out of the 51 enrolled participants, 31 women completed the required surveys. WL's total clinical failure rate was 2.60% (out of 155 condom uses) with above-average ratings of functional performance. The ease of use significantly correlated with ratings of no slippage and no misdirection. The confidence in WL's safety features significantly correlated with a sense of empowerment and protection. CONCLUSION: WL has a relatively low risk of clinical failures and an overall favorable acceptability among Malaysian women. However, this study also showed that its future usage largely depends on partner acceptability. It may have the potential of complementing the existing barrier toward contraceptive use. Further studies are needed to understand the global acceptability of WL.

2017

Bowling J, Dodge B, Bindra N, Dave B, Sharma R, Sundarraman V, Thirupathur Dharuman S, Herbenick D. Female condom acceptability in urban India: Examining the role of sexual pleasure. J Health Psychol. 2017 Dec 1;1359105317745963. doi: 10.1177/1359105317745963.

This qualitative study examined the acceptability of female condoms in urban India, with a focus on sexual pleasure. We conducted focus group discussions with 50 women and 19 men, as well as a small number of individual interviews with women (n = 3), in Chennai and New Delhi. Perceived benefits of female condoms included protection against unintended pregnancy and sexually transmitted infections, increased sense of empowerment for women, and simple clean up. The most common drawback was reduced sensation. Participants suggested structural changes to the female condom to ease insertion and use. Consent and privacy were discussed as increasing sexual pleasure. Pleasure should be acknowledged in design and education efforts to increase female condom use.



Obembe T, Adebowale A, Odebunmi K. Perceived confidence to use female condoms among students in Tertiary Institutions of a Metropolitan City, Southwestern, Nigeria. BMC Res Notes. 2017;10(1):398.

BACKGROUND: Latex condoms for men have been documented to offer high efficacy as both a contraceptive and protection against sexually transmitted diseases. This equally establishes the importance of continued research on female condoms. This study aims to investigate the perceived confidence to use the female condoms amongst undergraduate female students from selected tertiary institutions from Ibadan Southwestern Nigeria. **METHODS:** The study was a descriptive cross-sectional survey involving 388 female undergraduate students selected through a multistage sampling technique. The survey was carried using pre-tested semi-structured questionnaires. Quantitative data were analyzed using the Statistical Package for the Social Sciences to generate frequencies, cross tabulations of variables at 5% level of significance. **RESULTS:** Mean age of respondents 18.26 ± 3.45 with most students being 20-24 years (55.2%), single (92.8%), Yorubas (85.6%) and from the polytechnic institutions (41.0%). Only 10.8% had good perceived confidence to use a female condom. Perceived confidence was significantly higher amongst other ethnicities (19.59 ± 3.827) compared to Yoruba ethnicity (18.04 ± 3.337) ($F = 9.935$; $p < 0.05$). Likewise, students from the Polytechnic campuses exhibited significantly higher mean scores (18.81 ± 3.187) compared to others ($F = 3.724$; $p < 0.05$). Perception towards the condom was a significant factor that influenced the confidence to use a female condom ($F = 9.896$; $p < 0.000$). **CONCLUSIONS:** Concerted efforts are advocated to improve the low perception exhibited towards the use of female condoms and the low perceived confidence to its utilization. This would help to transfer the decision making and control to women thus contributing to their empowerment and increased protection from unplanned pregnancies and sexually transmitted diseases.

Witte SS, MacPhee C, Ginsburg N, Deshmukh N. Medicaid Reimbursement for the Female Condom. Am J Public Health. 2017;107(10):1633-1635.

OBJECTIVES: To examine state-level female condom use through Medicaid from 2004 to 2014, because in 2010, the Patient Protection and Affordable Care Act (ACA) allowed for expanded Medicaid coverage in many states, extending requirements for contraceptive care to more of the poorest women in the United States and to most women with private insurance. **METHODS:** We collected data via brief survey of Medicaid offices in all 50 states between March 2015 and March 2016. **RESULTS:** The number of states providing Medicaid reimbursement for the female condom increased 33% (from 25 to 36) since 2007. Twenty-nine states provided data showing low numbers of claims for female condoms but high rates of reimbursement. **CONCLUSIONS:** This period of heightened access demands that the public health community seize the moment to increase awareness about and promote the female condom among health care professionals and consumers. The pending repeal of the ACA may thwart important gains in access; policies promoting women's reproductive health must be implemented immediately.

2016

Cavanaugh C, Mial K, Tulloch D. Assessing and Mapping the Availability of the Female Condom in the Philadelphia Metropolitan Area. AIDS Behav. 2016;20(12):2845-2849.

This study assessed and mapped the availability of the female condom in relation to the male condom and HIV prevalence in the Philadelphia metropolitan area, which has a high density of HIV. One percent of the 1228 service providers contacted sold/provided the female condom and 77 % sold/provided the male condom. The lack of availability of the female condom suggests this product will have no public health impact on reducing HIV and



that interventions that promote use of the female condom are not sustainable in this high-risk area. Our findings may help policy makers increase female condom availability in this area.

Martin J, de Lora P, Rochat R, Andes KL. Understanding Female Condom Use and Negotiation Among Young Women in Cape Town, South Africa. *Int Perspect Sex Reprod Health*. 2016;42 (1):13-20.

CONTEXT: In most countries, female condoms are not widely available and uptake has been slow. More information is needed on how women and men successfully negotiate female condom use. **METHODS:** In-depth interviews were conducted at two sites in Cape Town, South Africa, with 14 women and 13 men who had used female condoms. A structured interview guide was used to elicit information on how women negotiate female condom use, and how male partners negotiate or respond to negotiations of female condom use. Thematic analysis was used to identify key patterns in the data. **RESULTS:** Participants reported that female condoms are easier for women to negotiate than male condoms, largely because the method is understood to be under a woman's control. The main barrier to use was lack of familiarity with the method; strong negative reactions from partners were not a major barrier. Personal comfort and tensions with partners usually improved after first use. Some male respondents preferred the method because it shifts responsibility for condom use from men to women. **CONCLUSIONS:** Findings suggest that female condoms empower women to initiate barrier method use, and that programs designed to educate potential users about female condoms and familiarize them with the method may be useful. That some men preferred female condoms because they wanted women to take responsibility for condom use is cause for concern, and suggests that counseling efforts should be directed toward men as well as women, and should include a discussion of gender dynamics and responsibility that emphasizes condom use as a choice that couples make together.

Mogale R, Mulaudzi FM, Peu MD, Mataboge MS, Ngunyulu R, Phiri SS. The constraints and concerns regarding the size and/or shape of the second generation female condom: The narratives from the healthcare providers. *Afr J Prim Health Care Fam Med*. 2016;8(2):e1-7.

BACKGROUND: Despite the redesigning of the Reality condom (FC) to a new version of the second generation female condom commonly known as (FC2), the users are persistently constrained and concerned about the size and shape of this new version. Condom use is aligned to the Millennium Development Goals (MDG) 3, 5 and 6, which address gender equality, improving maternal health and preventing HIV and AIDS. **AIM:** To explore and describe the constraints and concerns regarding the size and/or shape of the FC2. **SETTING:** The study was conducted at Tshwane health district in Gauteng province. **METHODS:** A qualitative exploratory descriptive design was used. Individual in-depth interviews that yielded narratives in a designated health district in South Africa were conducted. **RESULTS:** From the analysis of narratives three specific themes emerged. Firstly, the specific theme was that the size and shape of FC2 is undesirable for the health care providers, which may lead women to contract HIV and AIDS. The second theme was that the size and shape of FC2 and female genitals makes insertion complicated and predisposes women to be vulnerable in sexual relationships. The third was that the size and shape of FC2 results in pain and discomfort during coitus, exposing women to unwanted pregnancies and HIV and AIDS. **CONCLUSIONS:** The findings indicated the need for an evocative collaborative, interdisciplinary 'walk the talk' sexual health and AIDS education training programme for health care providers in primary health care facilities. Such programmes, if maintained, may assist health care providers to achieve the MDG 3, 5 and 6.

Moore L, Beksinska M, Rumphs A, Festin M, Gollub EL. Knowledge, attitudes, practices and behaviors associated with female condoms in developing countries: a scoping review. *Open Access Journal of Contraception* 2016; 6: 125-142.



Women in developing countries are at high risk of HIV, sexually transmitted infections, and unplanned pregnancy. The female condom (FC) is an effective dual protective method regarded as a tool for woman's empowerment, yet supply and uptake are limited. Numerous individual, socioeconomic, and cultural factors influence uptake of new contraceptive methods. We reviewed studies of FC knowledge, attitudes, practices, and behaviors across developing countries, as well as available country-level survey data, in order to identify overarching trends and themes. High acceptability was documented in studies conducted in diverse settings among male and female FC users, with FCs frequently compared favorably to male condoms. Furthermore, FC introduction has been shown to increase the proportion of "protected" sex acts in study populations, by offering couples additional choice. However, available national survey data showed low uptake with no strong association with method awareness, as well as inconsistent patterns of use between countries. We identified a large number of method attributes and contextual factors influencing FC use/nonuse, most of which were perceived both positively and negatively by different groups and between settings. Male partner objection was the most pervasive factor preventing initial and continued use. Importantly, most problems could be overcome with practice and adequate support. These findings demonstrate the importance of accounting for contextual factors impacting demand in FC programming at a local level. Ongoing access to counseling for initial FC users and adopters is likely to play a critical role in successful introduction.

Pinchoff J, Chowdhuri RN, Taruberekera N, Ngo TD. Impact of communication strategies to increase knowledge, acceptability, and uptake of a new Woman's Condom in urban Lusaka, Zambia: study protocol for a randomized controlled trial. *Trials*. 2016 Dec 13;17(1):596.

BACKGROUND: Globally, 220 million women experience an unmet need for family planning. A newly designed female condom, the Woman's Condom (WC), has been developed featuring an improved design. It is the first dual-protection, female-initiated contraceptive that is a premium, higher price point product. However, market availability alone will not increase uptake. In February 2016 the WC will be distributed with a strong media campaign and interpersonal communication (IPC) outreach intervention. The impact of these on knowledge, acceptability, and use of the WC will be measured. **METHODS/DESIGN:** A baseline survey of 2314 randomly selected 18- to 24-year-old sexually active men and women has been conducted. The WC and mass media will be introduced throughout 40 urban wards in and surrounding Lusaka, Zambia. The baseline survey will serve as a quasi-control arm to determine the impact of introducing the WC with mass media. Half of the wards will be randomly allocated to additionally receive the IPC intervention. A single-blind randomized controlled trial will determine the impact of the IPC intervention on knowledge, uptake, and use of the WC. After one year, another 2314 individuals will be randomly selected to participate in the endline survey. We hypothesize that (1) the distribution and media campaign of the WC will increase overall condom use in selected urban wards, and specifically use of the WC; (2) the IPC intervention will significantly impact knowledge, acceptability, and use of the WC. The primary outcome measures are use of the WC, use of any condom, and willingness to use the WC. Secondary outcomes include measures of knowledge, acceptability, and choice of contraception. Odds ratios will be estimated to measure the effect of the intervention on the outcomes with 95% confidence intervals. All analyses will be based on the intention-to-treat principle. **DISCUSSION:** Increasing uptake of dual prevention measures (such as the WC) may reduce incidence of sexually transmitted infections/HIV and unplanned pregnancies. It is important to ensure young, urban adults have access to new contraceptive methods; and, understanding how mass media and IPC impact contraceptive knowledge, acceptability, and use is critical to reduce unmet need.

Sanou Sobze M, Fokam J, Onohiol JF, Soung Iballa B, Djeunang B, Azeufack Nguoko Y, Mbida M, Ercoli L, Colizzi V, Russo G. Poor Acceptability of Female Condom by Young Cameroonians: An Unmet Programmatic Agenda for HIV Prevention. *Ig Sanita Pubbl*. 2016 May-Jun;72(3):191-201.

BACKGROUND: An important component of the response to the AIDS epidemic is the prevention of HIV infection and other sexually transmitted diseases through the use of condoms. In order to enhance HIV prevention programs and minimize the occurrence of unwanted pregnancies, female condoms have been introduced within



the community, with the ultimate goal of reducing vulnerability of women. The success of such a program depends on its acceptance by the target population. **METHODS:** A survey was conducted among 426 respondents from different regions of Cameroon, to evaluate their perception of HIV/AIDS and their level of acceptance of condom usage in general, and female condom use in particular. **RESULTS:** Respondents were young adults residing in seven regions of Cameroon (86.4% west, 6.5% Littoral, 3% Centre and 4.1% Adamawa, East, Far-North and North-West). Mean age was 22.6 years; 57% were male, 95% were single, and 77% were university educated. Overall, 76% of participants reported using condoms, though 48% complained of decreased sexual satisfaction. Interestingly, awareness regarding female condoms was 74.5% and 88.5% in men and women respectively, however only 8% and 9.9% respectively reported having ever used them. Respondents generally learnt about sexual education through broadcasting media (~90%). **CONCLUSION:** In this sexually active Cameroonian population, the rate of acceptance or use of female condom remains very low, even among women. Strategies to increase awareness of female condoms among young women, their benefits and correct use, are needed.

Schuyler AC, Masvawure TB, Smit JA, Bekinska M, Mabude Z, Ngoloyi C, Mantell JE. Building young women's knowledge and skills in female condom use: lessons learned from a South African intervention. *Health Edu Res* 2016; 31(2):260-72.

Partner negotiation and insertion difficulties are key barriers to female condom (FC) use in sub-Saharan Africa. Few FC interventions have provided comprehensive training in both negotiation and insertion skills, or focused on university students. In this study we explored whether training in FC insertion and partner negotiation influenced young women's FC use. 296 female students at a South African university were randomized to a one-session didactic information-only minimal intervention (n= 149) or a two-session cognitive-behavioral enhanced intervention (n= 147), which received additional information specific to partner negotiation and FC insertion. Both groups received FCs. We report the 'experiences of' 39 randomly selected female students who participated in post-intervention qualitative interviews. Two-thirds of women reported FC use. Most women (n= 30/39) applied information learned during the interventions to negotiate with partners. Women reported that FC insertion practice increased their confidence. Twelve women failed to convince male partners to use the FC, often due to its physical attributes or partners' lack of knowledge about insertion. FC educational and skills training can help facilitate use, improve attitudes toward the device and help women to successfully negotiate safer sex with partners. Innovative strategies and tailored interventions are needed to increase widespread FC adoption.

Terris-Prestholt F, Windmeijer F. How to sell a condom? The impact of demand creation tools on male and female condom sales in resource limited settings. *J Health Econ*.2016 Jul;48:107-20. Despite condoms being cheap and effective in preventing HIV, there remains an 8 billion shortfall in condom use in risky sex-acts. Social marketing organisations apply private sector marketing approaches to sell public health products. This paper investigates the impact of marketing tools, including promotion and pricing, on demand for male and female condoms in 52 countries between 1997 and 2009. A static model differentiates drivers of demand between products, while a dynamic panel data estimator estimates their short- and long-run impacts. Products are not equally affected: female condoms are not affected by advertising, but highly affected by interpersonal communication and HIV prevalence. Price and promotion have significant short- and long-run effects, with female condoms far more sensitive to price than male condoms. The design of optimal distribution strategies for new and existing HIV prevention technologies must consider both product and target population characteristics.

Wang X, Liu M, Cheng Y. Acceptability of Phoenurse female condom and second-generation Femidom female condom in Chinese women. *J Obstet Gynaecol Res*.2016 Nov;42(11):1567-1574.

AIM: To compare the acceptability of Phoenurse female condom (PFC) and second-generation Femidom female condom (FC2) among Chinese women. **METHODS:** A randomized, cross-over clinical trial was carried out in women aged 20-49 years seeking family service in Qingdao, China, between April and October 2013. Women were classified into two groups using a computer-generated randomized sequence. Participants completed



questionnaires at baseline and after using 10 of each type of female condom (FC). RESULTS: Of 290 women, 247 (85.2%) believed that FC could protect against sexually transmitted diseases and HIV. A total of 152 (52.5%) thought that the female condom (FC) contraceptive failure rate was higher, and 107 (36.9%) thought that FC could be reused before they participated in this study. After the study, 135 (46.6%) and 39 women (13.4%) would have been happy to use FC2 and PFC, respectively. Significant difference was noted between PFC and FC2 for the features color, lubrication and overall fit, rather than length, appearance, smell and application method. A total of 68 (23.5%) and 140 women (49.5%) liked FC2's color and lubrication better than PFC (44, 15.2%; 99, 34.6%). Also, 158 women (54.5%) preferred the overall fit of FC2 compared with PFC (143, 49.5%; $P < 0.05$). CONCLUSION: Participants did not have sufficient knowledge about the contraceptive effect and use of FC. Lubrication means the smooth degree of using FC. Length means the size of FC. Appearance means the users' overall impression of the FC.

Wu J, Huang Z, Coffey PS, Kilbourne-Brook M. Short-Term Acceptability of the Woman's Condom among Married Couples in Shanghai. *J Sex Transm Dis.* 2016;2016:6201421. Background. The Woman's Condom, a second-generation female condom designed for acceptability, is poised for introduction in China. Method. This single-arm study was conducted among 60 couples in China in 2010 to assess acceptability of the Woman's Condom. Results. Male participants reported that ease of handling, inserting, and removing the device improved significantly from first to fourth use. Female and male participants reported that comfort during insertion, feel of lubricant during insertion, comfort/fit of outer ring during use, and overall comfort improved significantly from first to fourth use. Further, at fourth use, female participants reported significant improvement in the comfort of the feel of the condom material and lubricant. Female and male participants reported that satisfaction with stability and sensation during sex and ability to achieve orgasm improved significantly from first to fourth use. At fourth use, female participants reported statistically significant improvement in sensation compared to using nothing. A majority of participants (78%) stated that they would use the Woman's Condom in the future, primarily due to its dual protection profile. Conclusion. This study has shown that, in China, the Woman's Condom appears to be acceptable to married couples. User experience contributes to improvement in many aspects of device acceptability.

2015

Andrade SS, Zaccara AA, Leite KN, Brito KK, Soares MJ, Costa MM, Pinheiro AK, Oliveira SH. Knowledge, attitude and practice of condom use by women of an impoverished urban area. *Rev Esc Enferm USP* 2015;49(3):364-71.

OBJECTIVE Assessing the adequacy of knowledge, attitude and practice of women regarding male and female condoms as STI/HIV preventive measures. METHOD An evaluative Knowledge, Attitude and Practice (KAP) household survey with a quantitative approach, involving 300 women. Data collection took place between June and August 2013, in an informal urban settlement within the municipality of João Pessoa, Paraíba, Northeast Brazil. RESULTS Regarding the male condom, most women showed inadequate knowledge and practice, and an adequate attitude. Regarding the female condom, knowledge, attitude and practice variables were unsatisfactory. Significant associations between knowledge/religious orientation and attitude/education regarding the male condom were observed. CONCLUSION A multidisciplinary team should be committed to the development of educational practices as care promotion tools in order to improve adherence of condom use.

Beksinska M, Greener R, Kleinschmidt I, Pillay L, Maphumulo V, Smit J. A randomized noninferiority crossover controlled trial of the functional performance and safety of new female condoms: an evaluation of the Velvet, Cupid2, and FC2. *Contraception* 2015;92(3):261-7.

OBJECTIVES: New designs of female condoms have been developed to lower cost and/or improve acceptability. To secure regulatory approvals, clinical studies are required to verify performance. We aimed to assess the functional performance and safety of two new female condom types - Velvet and Cupid2 female condom - against



the existing FC2 female condom. **STUDY DESIGN:** This was a three-period crossover, randomized noninferiority clinical trial with 300 women randomized to condom-type order in one South African site. Primary end points were total clinical failure and total female condom failure. Noninferiority of component modes, clinical breakage, nonclinical breakage, slippage, misdirection and invagination were also determined. Safety data were also assessed for each female condom. Participants were asked to use five of each female condom type and to collect information on use in a condom diary at home and were interviewed after use of each type. Frequencies and percentages were calculated by condom type for each failure mode, and differences in performance of the three female condoms using FC2 as reference, with 95% confidence intervals, were estimated using generalized estimating equation models. **RESULTS:** A total of 282 (94%) participants completed follow-up, using at least one condom of each type. Total clinical failure (clinical breakage, invagination, misdirection, slippage) was <5% for all female condoms: FC2 (4.50%), Cupid2 (4.79%) and Velvet (3.93%). Noninferiority was demonstrated for all condom failure modes for the two new female condoms with respect to FC2, within the margin of 3% difference in mean failure, at the 5% significance level. **CONCLUSION:** Noninferiority for the two new female condoms was demonstrated with respect to the marketed FC2. These data are used to support manufacturer dossiers for World Health Organization (WHO)/United Nations Population Fund (UNFPA) prequalification. **IMPLICATIONS:** Data from this study have been submitted to WHO/UNFPA and will contribute to the prequalification submission requirements for the Cupid2 and Velvet female condoms.

Beksinska M, Smit J, Greener R, Piaggio G, Joanis C. The female condom learning curve: Patterns of female condom failure over 20 uses. *Contraception* 2015;91(1):85-90.

BACKGROUND: Male and female condom (FC) functional performance failure declines with user experience. With the recent availability of a wider range of FCs, it is important to know if women with experience in using one type of FC are more proficient in using another type, even if the FC design is quite different. **STUDY DESIGN:** A randomized, noninferiority crossover clinical trial assessed the function of four FCs (FC2, Woman's Condom, Cupid and VA w.o.w) among 300 women in Durban, South Africa. FC functional failure (breakage, slippage, invagination and misdirection) by condom type and use period was investigated in women using five FCs of each type (20 FC uses in total). **RESULTS:** Of the 5364 condoms used during intercourse by 272 women, 200 clinical failures occurred in 195 condoms (190 condoms had one failure, and 5 had two failures). Total clinical failure was comparable across FC types. Of the 195 condoms in which failures occurred, the number of failures in the first condom use period was 103 (7.7%), decreasing to 43 events (3.2%) in the second, 33 (2.5%) in the third and 16 (1.2%) in the fourth. Only 2 failures were reported in the 20th use of an FC compared to 29 in the first use, irrespective of condom type. **CONCLUSIONS:** FC failure rates decreased markedly after use of the first five condoms regardless of FC type and continued to fall across the next three use periods. **IMPLICATIONS:** FC failure rates decrease over 20 uses, regardless of FC condom type used. The decrease is higher at the beginning of use, indicating that improvement is greatest after the first five uses.

Brandão Kde S, Lima BG, Travassos AG, de Brito Fde O, de Souza EX, Haguihara T, da Silva CA. [Dual contraception adherence among HIV-infected women]. *Rev Bras Ginecol Obstet* 2015;37(10):486-91.

PURPOSE: To determine adherence to dual contraception using depot-medroxyprogesterone acetate (DMPA) and condom among HIV-infected women. **METHODS:** A cross-sectional study carried out from December 2013 to September 2014 at a local reference center, with application of questionnaire elaborated after Delphi panel and content validation to 114 HIV(+) women aged 15 to 49 years, using DMPA plus condom for contraception. **RESULTS:** Mean age was 33.2 ± 7.2 years, mean time since HIV detection was 8.1 ± 5.2 years, mean time of antiretroviral use was 6.8 ± 5 years and mean CD4 cells/mm³ count was 737.6 ± 341.1 . Sexual HIV acquisition was reported by 98.2% (112/114), antiretroviral use by 85.9% (98/114), and 77.7% (84/114) had a CD4 > 500/mm³ count. Having a single sex partner was reported by 78.9% (90/114), with HIV serodiscordance in 41.2% (47/114) of couples, 21.9% did not know the serological status of their partner and in 37.7% of cases (43/114) the partner was unaware of the HIV(+) status of the woman. The last pregnancy was unplanned in 71.9% of cases (82/114) and 14.9% of the women had become pregnant the year before, with pregnancy being unplanned



in 70.5% (12/17) of cases. Current use of DMPA was reported by 64.9% (74/114), with genital bleeding in 48.2% (55/114) and weight gain in 67.5% (77/114). Use of a male condom was reported by 62.2% of the subjects (71/114). Three reported that they always used a female condom and ten that they eventually used it. Unprotected vaginal sex was reported by 37.7% (43/114) and unprotected anal intercourse was reported by 32.4% (37/114). Partner resistance to use a condom occurred in 30.7% of cases (35/114). Dual contraception using DMPA with condom was reported by 42.9% (49/114). A partner who resisted wearing a condom was associated with poor adherence (PR=0.3; 95%CI 0.2-0.7; p<0.001). A partner who was unaware that a woman was infected with HIV favored adherence (PR=1.8; 95%CI 1.2-2.7; p=0.013). **CONCLUSION:** The percentage of dual contraception using DMPA plus condom was 42.9%, maintaining unplanned pregnancies and unprotected sex. Resistance of partners to use a condom increased three times the chance of a woman not adhering to dual contraception, and the partner not knowing women's HIV infection almost doubled the chance to adhere to safe contraception. **GOALS:** to offer new hormonal contraceptives and to involve the partners in contraception and serologic detection tests.

Cavalcante LD, Oliveira GO, Almeida PC, Reboucas CB, Pagliuca LM. Assistive technology for visually impaired women for use of the female condom: A validation study. *Rev Esc Enferm USP* 2015;49(1):14-21.

OBJECTIVE To validate assistive technology for visually impaired women to learn how to use the female condom. **METHOD** a methodological development study conducted on a web page, with data collection between May and October 2012. Participants were 14 judges; seven judges in sexual and reproductive health (1st stage) and seven in special education (2nd stage). **RESULTS** All items have reached the adopted parameter of 70% agreement. In Stage 1 new materials were added to represent the cervix, and instructions that must be heard twice were included in the 2nd stage. **CONCLUSION** The technology has been validated and is appropriate for its objectives, structure / presentation and relevance. It is an innovative, low cost and valid instrument for promoting health and one which may help women with visual disabilities to use the female condom.

Koster W, Bruinderink MG, Janssens W. Empowering Women or Pleasing Men? Analyzing Male Views on Female Condom Use in Zimbabwe, Nigeria and Cameroon. *Int Perspect Sex Reprod Health* 2015;41(3):126-35.

CONTEXT: Usage rates of female condoms are low throughout Sub-Saharan Africa. Programs have traditionally presented female condoms as a means of women's empowerment. However, prevailing gender norms in Sub-Saharan Africa assign sexual decision making to men, suggesting that male acceptance is imperative for increased use. **METHODS:** In 2011, data on perceptions of and experiences with female condom use were collected from 336 men in Zimbabwe, Nigeria and Cameroon through 37 focus group discussions and six in-depth interviews; participants also completed pre-focus group discussion questionnaires. The data were analyzed by country, using thematic content analysis. Results were stratified by marital status and regularity of female condom use. **RESULTS:** Perceived advantages of female condoms over other protection methods were enhanced pleasure, effectiveness and lack of side effects. Single and married men preferred using female condoms with stable rather than casual partners, and for purposes of contraception rather than protection from infections. In Cameroon and Nigeria, where contraceptive rates are lower than in Zimbabwe, men favored female condoms as a contraceptive device. Its acceptability as a method of protection from HIV infection is greater in highly AIDS-affected Zimbabwe than in the other two countries. In Cameroon, some men did report regular use of female condoms in casual encounters. Initiation of female condom use by men's stable partners was not acceptable in any of the countries. **CONCLUSION:** The findings suggest the importance of accounting for local contexts and targeting both men and women in campaigns to promote female condom use.

Kramzer LF, Cohen J, Schubert J, Dezzutti CS, Moncla BJ, Friend D, Rohan LC. Assessing the potential of the Woman's Condom for vaginal drug delivery. *Contraception* 2015;92(3):254-60.

BACKGROUND: The Woman's Condom is a new female condom that uses a dissolvable polyvinyl alcohol capsule to simplify vaginal insertion. This preclinical study assessed the feasibility to incorporate an antiviral drug, UC781, into the Woman's Condom capsule, offering a unique drug delivery



platform. **STUDY DESIGN:** UC781 capsules were fabricated using methods from the development of the Woman's Condom capsules as well as those used in vaginal film development. Capsules were characterized to evaluate physical/chemical attributes, Lactobacillus compatibility, in vitro safety and bioactivity, and condom compatibility. **RESULTS:** Two UC781 capsule platforms were assessed. Capsule masses (mg; mean \pm SD) for platforms 1 and 2 were 116.50 \pm 18.22 and 93.80 \pm 8.49, respectively. Thicknesses were 0.0034 \pm 0.0004 in and 0.0033 \pm 0.0004 in. Disintegration times were 11 \pm 3 s and 5 \pm 1 s. Puncture strengths were 21.72 \pm 3.30 N and 4.02 \pm 0.83 N. Water content measured 6.98 \pm 1.17% and 7.04 \pm 1.92%. UC781 content was 0.59 \pm 0.05 mg and 0.77 \pm 0.11 mg. Both platforms retained in vitro bioactivity and were nontoxic to TZM-bl cells and Lactobacillus. Short-term storage of UC781 capsules with the Woman's Condom pouch did not decrease condom mechanical integrity. **CONCLUSIONS:** UC781 was loaded into a polymeric capsule similar to that of the Woman's Condom product. This study highlights the potential use of the Woman's Condom as a platform for vaginal delivery of drugs relevant to sexual/reproductive health, including those for short- or long-acting HIV prevention. **IMPLICATIONS:** We determined the proof-of-concept feasibility of incorporation of an HIV-preventative microbicide into the Woman's Condom capsule. This study highlights various in vitro physical and chemical evaluations as well as bioactivity and safety assessments necessary for vaginal product development related to female sexual and reproductive health.

Mahlalela NB, & Maharaj P. Factors facilitating and inhibiting the use of female condoms among female university students in Durban, KwaZulu-Natal, South Africa. *Eur J Contracept Reprod Health Care* 2015;20(5):379-86.

OBJECTIVES: The study aimed to explore the factors facilitating and inhibiting female condom use among female university students in South Africa. **METHODS:** This qualitative study drew on 15 individual, in-depth interviews with female university students in Durban, South Africa. **RESULTS:** The results of the study highlight several factors that facilitate and inhibit female condom use. Protection from sexually transmitted infections (including HIV/AIDS) and prevention of pregnancy facilitated use of the device among female students. In addition, students expressed positive attitudes towards the female condom and preferred it to hormonal contraceptives because it offered them dual protection. Absence of side effects and greater power and autonomy to initiate safer sex were other factors that facilitated use. Inadequate availability, partner objection, stigma, insertion difficulties and lack of awareness served as significant barriers to consistent female condom use. **CONCLUSIONS:** Although the female condom can protect female students from infections and pregnancy, there are several barriers to its use. Interventions should aim to increase availability of the female condom, and male involvement should be increased to facilitate consistent use of the method.

Maksut JL, Eaton LA. Female Condoms=Missed Opportunities: Lessons Learned from Promotion-centered Interventions. *Womens Health Issues* 2015;25(4):366-76.

INTRODUCTION: The female condom is a barrier contraceptive device that is underutilized despite its effectiveness at preventing both unintended pregnancy and sexually transmitted infections (STIs). Prior research has highlighted that the underuse of the female condom as a contraceptive option is owing in large part to social stigma, and lacking or incorrect information about the product. **METHODS:** In an attempt to better understand the discrepancy between the female condom's documented effectiveness and its general lack of uptake, we conducted a systematic search and qualitatively reviewed 20 published intervention studies that focus on efforts to promote the female condom. The strategies that each intervention used were coded and carefully examined. We obtained information regarding relevant characteristics of the studies, including intervention setting, sampling strategy, participant demographics, and methodology used. **RESULTS:** We found that the majority of the studies had significant positive findings concerning the female condom, for example, many were effective at demonstrating participant uptake as well as increasing the number of protected sex acts. Additionally, perceived ability to use the device was a significant predictor of female condom use in multiple studies. Finally, the studies tended to include younger women; only 10.0% (n=2) reported having participants with a mean age older than 30), meaning that older women generally have not been well-served by previous efforts to promote the use of the



female condom. **CONCLUSIONS:** We offer guidelines for improving female condom uptake and recommendations for future research that seeks to establish and utilize best practice promotional strategies for female condoms.

Mantell JE, Smit JA, Exner TM, Mabude Z, Hoffman S, Beksinska M, Kelvin EA, Ngoloyi C, Leu CS, Stein ZA. Promoting Female Condom Use Among Female University Students in KwaZulu-Natal, South Africa: Results of a Randomized Behavioral Trial. *AIDS Behav* 2015;19(7):1129-40. Relatively few interventions have tested the efficacy of female condom promotion either alone or in combination with other barrier methods. We evaluated the efficacy of a two-session (enhanced) cognitive-behavioral intervention (EI) (n = 147) against a one-session control (minimal) educational intervention (MI) (n = 149) to promote female condom (FC) use among female students aged 18-28 at a South African university. We assessed change from baseline to 2.5 and 5 months in number of vaginal intercourse occasions unprotected by male or female condoms in EI versus MI using generalized linear models with a log link function and GEE. Both groups reported significant reductions in number of unprotected vaginal intercourse occasions from baseline to each follow-up, with no significant difference between the two-session and single-session intervention. Introduction of a brief group-based MI FC promotion intervention with FC access holds promise for delivery in clinics and other community venues.

Marfatia YS, Pandya I, Mehta K. Condoms: Past, present, and future. *Indian J Sex Transm Dis* 2015;36(2):133-9.

Though many methods of prevention of STI/HIV are available, condoms remain of utmost importance. They have gone a long way from the oiled silk paper used by the Chinese and the hard sheaths made of tortoise-shell used by the Japanese to the latex condoms of today. The breakthrough came when the rubber vulcanization process was invented by Charles Goodyear and eventually the first rubber condom was made. The condom offers maximum protection (more than 90%) against HIV, Hepatitis B virus and N. Gonorrhoea. They also offer protection in scenarios when alternate sexual practices are adapted. The female condom is the only female driven contraceptive method available today. Graphene and Nano lubricated condoms are new in the market and others in futuristic approach may include wearable technology/Technology driven condom and invisible Condoms. Both Correct and Consistent use of condoms needs to be promoted for HIV/STI prevention.

Mvundura M, Nundy N, Kilbourne-Brook M, Coffey PS. Estimating the hypothetical dual health impact and cost-effectiveness of the Woman's Condom in selected sub-Saharan African countries. *Int J Womens Health* 2015;7:271-7.

BACKGROUND: Female condoms are the only currently available woman-initiated option that offers dual protection from pregnancy and sexually transmitted infections, including HIV. The Woman's Condom is a new female condom designed to provide dual protection and to be highly pleasurable and acceptable. **OBJECTIVE:** We sought to estimate the potential dual health impact and cost-effectiveness of a Woman's Condom distribution program in 13 sub-Saharan African countries with HIV prevalence rates >4% among adults aged 15-49 years. We used two separate, publicly available models for this analysis, the Impact 2 model developed by Marie Stopes International and the Population Services International disability-adjusted life years (DALY) calculator program. We estimated the potential numbers of pregnancies and DALYs averted when the Woman's Condom is used as a family planning method and the HIV infections and DALYs averted when it is used as an HIV prevention method. **RESULTS:** Programming 100,000 Woman's Condoms in each of 13 countries in sub-Saharan Africa during a 1-year period could potentially prevent 194 pregnancies and an average of 21 HIV infections in each country. When using the World Health Organization Choosing Interventions that are Cost-Effective (WHO-CHOICE) criteria as a threshold to infer the potential cost-effectiveness of the Woman's Condom, we found that the Woman's Condom would be considered cost-effective. **CONCLUSION:** This was a first and successful attempt to estimate the impact of dual protection of female condoms. The health impact is greater for the use of the Woman's Condom as an HIV prevention method than for contraception. Dual use of the Woman's Condom



increases the overall health impact. The Woman's Condom was found to be very cost-effective in all 13 countries in our sample.

Rodriguez K, Ventura-DiPersia C, LeVasseur MT, Kelvin EA. Inconsistencies on U.S. Departments of Health Websites Regarding Anal Use of the Female Condom. *AIDS Behav* 2015;19(7):1141-9.

The female condom (FC) is FDA approved to prevent pregnancy and sexually transmitted infections during vaginal intercourse, but not for use during anal intercourse. Studies suggest that a sizeable proportion of men who have sex with men use the FC for anal intercourse despite lack of safety and efficacy information. We reviewed Department of Health (DOH) websites for U.S. states (n = 50) and major municipalities (population >500,000; n = 29) regarding anal use of the FC. Forty-eight (60.8 %) websites mentioned the FC, of which only 21(45.8 %) mentioned anal use. Of those that mention anal use, 8 (38.1 %) supported, 13 (61.9 %) were neutral, and 1 (4.8 %) discouraged this use. Ten websites (47.6 %) provided instructions for anal use of the FC-ranging from removal of the inner ring, leaving the inner ring in place, and either option. In the absence of safety and efficacy data, U.S. DOH websites are providing different and often contradictory messages about the FC for anal sex.

Smit J, Mosery N, Pillay L, Beksinska M, Rambally-Greener L, Milford C, Kilbourne-Brook M, Coffey PS. A Mixed-Methods Evaluation of Potential Distribution Channels for the V Condom in South Africa. *Int J Womens Health Wellness*. 2015; 1:2.

BACKGROUND: Market tests in Durban, South Africa, assessed the feasibility of commercial and non-traditional public-sector distribution channels for the V Condom, a new female condom.**METHODS:** Between August 2014 and July 2015, data were collected from 119 women and 78 men who were potential and actual V Condom users (male and female students, male factory workers, and female and male sex workers) to assess uptake and acceptability across multiple distribution channels (a tertiary health service centre, a factory, and two nongovernmental organizations). This prospective evaluation included initial awareness-raising and distribution of currently available and V condoms to those interested. Baseline data collection included a quantitative survey and two focus group discussions. After one-month follow-up, V Condom use data were collected through self-completed condom logs and SMS text messages, four focus group discussions and three inventories, and in-depth interviews with three site coordinators.

RESULTS: The quantitative results indicated high V Condom usage during the study period. Most sex acts were protected, with participants using more V Condoms than male condoms or other female condoms. Many participants reported preferring the V Condom over male and other female condoms. Ideal distribution channels included tertiary institutions, factories, government facilities, pharmacies, shops/supermarkets, schools, entertainment places, and tuck shops. Factors influencing preferred distribution channels were ease of access, convenience, operating hours, users' previous experiences, and peer influences. Most participants were willing to pay for the V Condom due to the perception that paying ensured a quality product and that free products are not as trustworthy.

CONCLUSIONS: There is a non-public-sector market for V Condoms in Durban, and some women and men are willing to pay for the V Condom at a price approaching the estimated market price. This novel mixed-methods approach to understanding consumer interest in a new female condom provided data relevant for both programmatic planning and future market introduction.

Ventura-DiPersia C, Rodriguez K, Kelvin EA. Failure of many United States department of health websites to provide accurate information about the female condom. *Contraception* 2015;92(1):40-5.

Uptake of the female condom (FC) in the United States has historically been low; inadequate promotion may be one barrier faced by potential users. We performed a content analysis of state and municipal health department websites to describe how the FC is being promoted for pregnancy and disease prevention. We found that only a slim majority (60.8%) of health department websites mention the FC at all, and those that do include numerous



inaccuracies in their messaging. These inaccuracies may discourage uptake of the FC or have a detrimental impact on the experience when using the product for the first time.

Wang X, Xi M, Zhang L, Jia L, Wang Y, Cheng Y. Awareness of female condoms and failures reported with two different types in China. *Int J Gynaecol Obstet* 2015;128(2):152-6.

OBJECTIVE: To explore knowledge and use of female condoms in China, and to compare four modes of failure between the Phoenur female condom (PFC) and the second-generation Femidom female condom (FC2).

METHODS: In a randomized, crossover trial, sexually active women aged 20-49 years who attended a family planning service in Qingdao, China, were recruited between April and October, 2013. A computer-generated randomized sequence was used to assign participants (1:1) to group A (used 10 PFCs followed by 10 FC2s) or group B (used 10 FC2s followed by 10 PFCs). Study investigators and participants were masked to allocation. Participants completed questionnaires at baseline and after using the two types of FCs. They also kept coital logs.

RESULTS: At baseline, 30 (10.3%) of 290 participants understood female condoms, but only 1 (0.3%) had ever used one. Total failure rates were 3.6% (420/11 578) and 2.3% (265/11 594) for PFC and FC2, respectively ($P<0.001$). Slippage was the most common form of failure, affecting 6.9% of PFC uses and 5.0% of FC2 uses. Breakage, misdirection, and slippage were significantly more common with the PFC than with the FC2

($P\leq 0.002$). **CONCLUSION:** Understanding of female condoms is poor in China. Failure is more common with the PFC than with the FC2.

Weeks MR, Zhan W, Li J, Hilario H, Abbott M, Medina Z. Female condom use and adoption among men and women in a general low-income urban US population. *AIDS Behav* 2015;19(9):1642-54.

ABSTRACT HIV prevention is increasingly focused on antiretroviral treatment of infected or uninfected persons. However, barrier methods like male condoms (MC) and female condoms (FC) remain necessary to achieve broad reductions in HIV and other sexually transmitted infections (STI). Evidence grows suggesting that removal of basic obstacles could result in greater FC use and reduced unprotected sex in the general population. We conducted four annual cross-sectional surveys (2009–2012) of urban residents ($N = 1614$) in low-income neighborhoods of a northeastern U.S. city where prevalence of HIV and other STIs is high. Findings indicate slow FC uptake but also heterosexual men's willingness to use them. Factors associated with men's and women's FC use included positive FC attitudes, network exposure, and peer influences and norms. These results suggest that men can be supporters of FC, and reinforce the need for targeted efforts to increase FC use in both men and women for HIV/STI prevention.

2014

Chipfuwa T, Manwere A, Kuchenga MM, Makuyana L, Mwanza E, Makado E, et al. Level of awareness and uptake of the female condom in women aged 18 to 49 years in Bindura district, Mashonaland Central province, Zimbabwe. *Afr J AIDS Res* 2014;13:75-80.

Zimbabwe introduced the female condom in 1997, but acceptance was slow. A study was conducted to determine its level of awareness and uptake in women aged 18 to 49 years at Bindura Provincial Hospital, and at Chipadze and Chiwaridzo council clinics. A descriptive cross-sectional study design was used. A total of 242 eligible consenting respondents were selected using simple random sampling. Data were processed using the Statistical Package for Social Sciences (SPSS) software version 16. Data revealed that 81.4% of the respondents had heard about the method. Most respondents 88 (36.4%) had heard about female condoms from nurses. However, 53.3% had not received health education on the method from healthcare providers. Knowledge of the female condom was low at 36.3% and most respondents (83.5%) had not used it. The major reasons cited for failure to use the method were unavailability (19.8%) and partner refusal (17.8%). Of the 16.5% who used the female condom only 4.1% used it consistently. Female condom uptake was very low at 16.1%. Knowledge of the method was associated with its uptake ($\chi^2(2) = 86, p < 0.05$). Pearson's correlation was used to examine the relationship



between awareness and uptake of the method. It indicated a weak positive linear relationship ($r = 0.309$, $p < 0.01$). A regression coefficient ($R(2) = 0.095$, $p < 0.05$) showed that female condom awareness accounts for 9.5% of the variance in uptake. This study revealed that women with increased level of awareness on the method are likely to use it. Therefore, healthcare providers need to strengthen health education on female condoms and make them readily available.

Coman EN, Weeks MR, Yanovitzky I, Iordache E, Barbour R, Coman MA, Huedo-Medina TB. The impact of information about the female condom on female condom use among males and females from a US urban community. *AIDS Behav* 2013 Jul;17(6):2194-201.

This study investigates the impact of exposure to information about a relatively new prevention method, the female condom (FC), on actual FC use in a community of adults at risk of HIV/STI. A community-wide survey from a mid-size US city is used to estimate unbiased effects of information about the FC on FC use among sexually active men and women. To control for potential confounders we use propensity score matching (PSM) which matches the group exposed to FC information to participants who were not exposed, achieving a statistical quasi-randomization in terms of ten measured confounders. Comparisons of exposed to unexposed participants matched on their propensity scores conclude that information about the FC increases initiation of FC use, such that eleven percent more of the men and women who receive FC information reported ever using the FC. We demonstrate the use of PSM and illustrate some of its strengths and limitations.

Guerra FM, Simbayi LC. Prevalence of knowledge and use of the female condom in South Africa. *AIDS Behav* 2014 Jan;18(1):146-58.

Male condoms remain a key tool in preventing the spread of HIV and the female condom (FC) holds similar potential. Using data collected through a national cross-sectional population survey that was conducted in 2008, this report investigated the national prevalence of FC knowledge and use by sexually active males and females ($n = 7,727$) over the age of 15 years in South Africa, followed by a closer examination of the sexually active female population alone. Though knowledge of the FC among sexually active females over the age of 15 years ($n = 4,551$) was relatively high at 77.75 %, use was low at 7.16 %. The present study found statistically significant associations between knowledge or use of the FC and several demographic variables for females in South Africa. Having heard of the FC was consistently associated with locality, province, age, education level, marital status, and employment status. Use of the FC, however, was only associated with province and age group. Many demographic groups exhibited a high prevalence of knowledge but a low level of use; or conversely, a low prevalence of knowledge but a high level of use compared to their counterparts. Our findings support the need for a rigorous campaign to promote the use of FCs by women and also to increase their availability in public health sector facilities such as government clinics and hospitals in order to improve the chance of women using the FC, a cost-effective device that has the potential to protect both their rights and lives.

Kavinya T. Have Malawian women embraced the female condom? *Malawi Med J* Sep 2013; 25(3): 95.
No abstract available.

Masvawure TB, Mantell JE, Mabude Z, Ngoloyi C, Milford C, Beksinska M, Smit JA. "It's a different condom, let's see how it works": Young men's reactions to and experiences of female condom use during an intervention trial in South Africa. *J Sex Res* 2014;(8):841-51.

Although male partner cooperation is often essential for successful use of the female condom, only a few studies have directly assessed men's experiences of using the device. We examined barriers to and facilitators of female condom use via qualitative in-depth interviews with 38 young men (18 to 28 years) in South Africa whose partners, all university students, were enrolled in a female condom intervention trial. In all, 21 men used the female condom; the remaining 17 did not attempt use. The main facilitators to female condom use were convenience of use for men, curiosity to see how female condoms compared to male condoms, enhanced sexual sensation, and perceptions of better safety and comfort of the device compared to male condoms. The main



barriers were men's limited familiarity with the device, insertion difficulties, and men's concerns about loss of control over sexual encounters. We recommend that human immunodeficiency virus (HIV) prevention and condom promotion programs around the world target men directly for education on female condoms and that they also work with couples jointly around issues of safer-sex communication and negotiation.

Penman-Aguilar A, Macaluso M, Peacock N, Snead MC, Posner SF. A novel approach to mixing qualitative and quantitative methods in HIV and STI prevention research. *AIDS Educ Prev* 2014;26:95-108.

Mixed-method designs are increasingly used in sexually transmitted infection (STI) and HIV prevention research. The authors designed a mixed method approach and applied it to estimate and evaluate a predictor of continued female condom use (6+ uses, among those who used it at least once) in a 6-month prospective cohort study. The analysis included 402 women who received an intervention promoting use of female and male condoms for STI prevention and completed monthly quantitative surveys; 33 also completed a semi-structured qualitative interview. The authors identified a qualitative theme (couples' female condom enjoyment [CFCE]), applied discriminant analysis techniques to estimate CFCE for all participants, and added CFCE to a multivariable logistic regression model of continued female condom use. CFCE related to comfort, naturalness, pleasure, feeling protected, playfulness, ease of use, intimacy, and feeling in control of protection. CFCE was associated with continued female condom use (adjusted odds ratio: 2.8, 95% confidence interval: 1.4-5.6) and significantly improved model fit ($p < .001$). CFCE predicted continued female condom use. Mixed-method approaches for "scaling up" qualitative findings from small samples to larger numbers of participants can benefit HIV and STI prevention research.

Peters AJ, van Driel FT, Jansen WH. Silencing women's sexuality: Global AIDS policies and the case of the female condom. *J Int AIDS Soc* 2013 Jul 8;16(1):18452.

INTRODUCTION: The female condom is the only evidence-based AIDS prevention technology that has been designed for the female body; yet, most women do not have access to it. This is remarkable since women constitute the majority of all HIV-positive people living in sub-Saharan Africa, and gender inequality is seen as a driving force of the AIDS epidemic. In this study, we analyze how major actors in the AIDS prevention field frame the AIDS problem, in particular the female condom in comparison to other prevention technologies, in their discourse and policy formulations. Our aim is to gain insight into the discursive power mechanisms that underlie the thinking about AIDS prevention and women's sexual agency. **METHODS:** We analyze the AIDS policies of 16 agencies that constitute the most influential actors in the global response to AIDS. Our study unravels the discursive power of these global AIDS policy actors, when promoting and making choices between AIDS prevention technologies. We conducted both a quantitative and qualitative analysis of how the global AIDS epidemic is being addressed by them, in framing the AIDS problem, labelling of different categories of people for targeting AIDS prevention programmes and in gender marking of AIDS prevention technologies. **RESULTS:** We found that global AIDS policy actors frame the AIDS problem predominantly in the context of gender and reproductive health, rather than that of sexuality and sexual rights. Men's sexual agency is treated differently from women's sexual agency. An example of such differentiation and of gender marking is shown by contrasting the framing and labelling of male circumcision as an intervention aimed at the prevention of HIV with that of the female condom. **CONCLUSIONS:** The gender-stereotyped global AIDS policy discourse negates women's agency in sexuality and their sexual rights. This could be an important factor in limiting the scale-up of female condom programmes and hampering universal access to female condoms.

Rodriguez K, Ventura-DiPersia C, LeVasseur MT, Kelvin EA. Inconsistencies on US departments of health websites regarding anal use of the female condom. *AIDS Behav* 2015;19(7):1141-9.

The female condom (FC) is FDA approved to prevent pregnancy and sexually transmitted infections during vaginal intercourse, but not for use during anal intercourse. Studies suggest that a sizeable proportion of men who have sex with men use the FC for anal intercourse despite lack of safety and efficacy information. We reviewed Department of Health (DOH) websites for US states ($n = 50$) and major municipalities (population $>500,000$; $n =$



29) regarding anal use of the FC. Forty-eight (60.8 %) websites mentioned the FC, of which only 21 (45.8 %) mentioned anal use. Of those that mention anal use, 8 (38.1 %) supported, 13 (61.9 %) were neutral, and 1 (4.8 %) discouraged this use. Ten websites (47.6 %) provided instructions for anal use of the FC-ranging from removal of the inner ring, leaving the inner ring in place, and either option. In the absence of safety and efficacy data, US DOH websites are providing different and often contradictory messages about the FC for anal sex.

Tobin-West CI, Maduka O, Onyekwere VN, Tella AO. Awareness, acceptability, and use of female condoms among university students in Nigeria: Implications for STI/HIV prevention. *Int J Adolesc Med Health* 2014;26(2):259-65.

Background: Most university students in Nigeria are sexually active and engage in high risk sexual behaviors. The aim of this study was to assess the acceptability and use of female condoms in the context of HIV prevention in order to provide basic information that can stimulate female condom programming to promote sexually transmitted infection and HIV prevention among youths in tertiary institutions. **Materials and methods:** A descriptive, cross-sectional study was carried out among 810 undergraduate students of the University of Port Harcourt from October to November 2011, using a stratified sampling method and self-administered questionnaires. **Results:** Most of the students, 589 (72.7%) were sexually active; 352 (59.7%) reported having just one sexual partner, while 237 (40.3%) had multiple partners. The mean number of sexual partners in the past six months was 2.2 ± 0 . Consistent condom use was reported among 388 (79.2%) students, 102 (20.8%) reported occasional usage, while 99 (16.8%) did not use condoms at all. Only 384 (65.2%) of the students had ever been screened for HIV. Although 723 (89.3%) were aware of female condoms, only 64 (8.9%) had ever used one due to unavailability, high cost, and difficulty with its insertion. Nevertheless, 389 (53.8%) of the students expressed willingness to use them if offered, while 502 (69.4%) would recommend it to friends/peers. **Conclusion:** This study highlights significant challenges in the use of female condoms among university students. These include unavailability, high cost, and difficulty with insertion. Therefore, deliberate efforts using social marketing strategies, appropriate youth-friendly publicity, and peer education must be exerted to provide affordable female condoms and promote usage; such efforts should target vulnerable youths in Nigerian tertiary institutions.

2013

Beksinska ME, Piaggio G, Smit JA, Wu J, Zhang Y, Pienaar J, et al. Performance and safety of the second-generation female condom (FC2) versus the Woman's, the VA worn-of-women, and the Cupid female condoms: a randomised controlled non-inferiority crossover trial. *Lancet Glob Health* 2013;1:e146-52.

BACKGROUND: New designs of female condom have been developed to reduce costs and improve acceptability. To secure regulatory approvals, clinical studies are needed to verify performance. We aimed to assess the functional performance and safety of three new condom types-the Woman's Condom, the VA worn-of-women (wow) Condom Feminine, and the Cupid female condom-against the existing second-generation female condom (FC2). **METHODS:** We did a randomised controlled, non-inferiority, four-period crossover trial at three sites in Shanghai, China, and one site in Durban, South Africa, between May 1, 2011, and Jan 31, 2012. Participants aged 18-45 years who were sexually active, monogamous, not pregnant, and not sex workers, were eligible for inclusion if they were literate, had no known allergies to the study products; used a reliable, non-barrier method of contraception, and had no visible or reported sexually transmitted infections. We used a computer-generated randomisation sequence with a Williams square design of size four to assign patients (1:1:1:1) to the FC2 control device, or the Woman's, VA wow, or Cupid condoms, with 12 potential allocations. Randomisation was stratified by site. Participants were not masked to condom type, but allocation was concealed from study investigators. The primary non-inferiority endpoints were total clinical failure and total female condom failure, with a non-inferiority margin of 3%. Women were asked to use five of



each condom type and were interviewed after use of each type. We also assessed safety data for each type. We did both per-protocol and intention-to-treat analyses. We calculated frequencies and percentages for each failure event and estimated differences in performance with a generalised estimating equation model. This study is registered, number DOH-27-0113-4271. FINDINGS: 616 women were assessed for eligibility, of whom 600 were randomly assigned to condom-type order (30, 120, and 150 women in the three sites in China, and 300 women in the site in South Africa). 572 women completed follow-up, with at least one condom of each type. Total female condom failure was 3.43% for FC2, 3.85% for the Woman's Condom (difference 0.42%, 90% CI -1.42 to 2.26), 3.02% for VA wow (-0.42%, -1.86 to 1.32), and 4.52% for Cupid (1.09%, -0.60 to 2.78); total clinical failure was 2.88%, 3.05% (0.17%, -1.48 to 1.81), 2.49% (-0.25%, -1.75 to 1.26), and 3.87% (0.99%, -0.55 to 2.52), respectively. Only two (<1%) participants, in South Africa, reported serious adverse events, unrelated to use of the study products. INTERPRETATION: Non-inferiority was shown for all condom failure events for the three new devices versus the FC2, within the predefined margin.

Coffey PS, Kilbourne-Brook M, Junqing W, Yufeng Z, Hongxin Z, Bin W, et al. Initial reactions to the Woman's Condom by potential user groups in Shanghai, China. *J Fam Plann Reprod Health Care* 2013; 39(2): 111-20.

BACKGROUND: The Woman's Condom, a second-generation female condom, is currently being manufactured in China by the Shanghai Dahua Medical Apparatus Company. The manufacturer plans to launch the product in China. METHODS: A survey and focus group discussions were conducted with 73 women and 57 men from nine potential user groups in the Shanghai area to explore, on the basis of visual inspection of the Woman's Condom and product information, their perceptions and attitudes toward the Woman's Condom and lubricant. The potential user groups were male and female university students, male and female college-educated young people, married women and men, migrant women and men, and women working in the entertainment industry. RESULTS: Female condoms were a new concept for almost all study participants. Women (49%) and men (51%) reported that the Woman's Condom would make "some" or a "great" difference in their lives. Participants reported interest in using the Woman's Condom for sexually transmitted infection (STI) (50%) or dual protection (43%) rather than for pregnancy prevention alone (33%). Findings highlighted comfort, partner approval and lubricant as possible concerns. CONCLUSIONS: Product introduction activities should be oriented toward the most likely early adopter groups (i.e. university students, college-educated young people, migrant women and women working in the entertainment industry). Lack of interest in using the new device by married women/men and migrant men may indicate that they do not perceive a need for a dual protection product since they are already using a contraceptive method and/or do not perceive themselves at risk of STIs.

Gallo MF, Norris AH, Turner AN. Female condoms: new choices, old questions. *Lancet Glob Health* 2013;1:e119-20.

No abstract available.

Hoffman S. The female condom in the age of antiretroviral-based HIV prevention. *J Womens Health* 2013; 22(1): 7-8.

OBJECTIVES: The female condom (FC), an effective barrier method for HIV/sexually transmitted infection (STI) prevention, continues to be absent from most community settings, including reproductive health and treatment clinics. Reducing or eliminating basic barriers, including lack of awareness, knowledge of proper use, and access to free samples, may significantly increase use among those who want or need them. METHODS: A prospective cohort of 461 women in Hartford, Connecticut (2005-2008), was interviewed at baseline, 1 month, and 10 months about FC use and other personal, partner, peer, and community factors. All participants received brief demonstration of FC use and four free FC1 at baseline. Pairwise longitudinal tests and structural equation modeling were used to test predictors of initial (1 month) and sustained (10 month) FC use. RESULTS: Although only 29% of the sample reported ever having used FC at baseline, 73% of never users (51% of the returned 1-



month sample) had initiated FC use by 1 month after receiving the brief intervention. Additionally, 24% of the returned 10-month sample (30% of 10-month FC users) reported sustained use, measured as having used FC at baseline or 1 month and also in the prior 30 days. General latent variable modeling indicated that FC knowledge and attitudes predicted initiating FC use; male condom use, FC knowledge and attitudes, and network exposure to FC information predicted sustained use. **CONCLUSIONS:** Findings indicated that many women will potentially initiate and continue using FC when basic barriers are removed. Brief FC education with free trial samples should be built into standard clinical practice and public health programs.

Holt K, Blanchard K, Chipato T, Nhemachena T, Blum M, Stratton L, et al. A nationally representative survey of healthcare provider counselling and provision of the female condom in South Africa and Zimbabwe. *BMJ Open* 2013; 3(3).

OBJECTIVES: Female condoms are the only female-initiated HIV and pregnancy prevention technology currently available. We examined female condom counselling and provision among providers in South Africa and Zimbabwe, high HIV-prevalence countries. **DESIGN:** A cross-sectional study using a nationally representative survey. **SETTING:** All facilities that provide family planning or HIV/sexually transmitted infection (STI) services. **PARTICIPANTS:** National probability sample of 1444 nurses and physicians who provide family planning or HIV/STI services. **PRIMARY AND SECONDARY OUTCOME MEASURES:** Female condom practices with different female patients, including adolescents, married women, women using hormonal contraception and by HIV status. Using multivariable logistic analysis, we measured variations in condom counselling by provider characteristics. **RESULTS:** Most providers reported offering female condoms (88%; 1239/1415), but perceived a need for novel female barrier methods for HIV/STI prevention (85%; 1191/1396). By patient type, providers reported less frequent female condom counselling of adolescents (55%; 775/1411), women using hormonal contraception (65%; 909/1409) and married women (66%; 931/1416), compared to unmarried (74%; 1043/1414) or HIV-positive women (82%; 1161/1415). Multivariable results showed providers in South Africa were less likely to counsel women on female condoms than in Zimbabwe (OR=0.48, 95% CI 0.35 to 0.68, $p \leq 0.001$). However, South African providers were more likely to counsel women on male condoms (OR=2.39, 95% CI 1.57 to 3.65, $p \leq 0.001$). Nurses counselled patients on female condoms more frequently than physicians (OR=5.41, 95% CI 3.26 to 8.98, $p \leq 0.001$). HIV training, family planning training, location (urban vs rural) and facility type (hospital vs clinic) were not associated with greater condom counselling. **CONCLUSIONS:** Female condoms were integrated into provider counselling and care, although providers reported a need for new female-initiated multipurpose prevention technologies, suggesting female condoms do not meet all patient/provider needs or are not adequately well known or accessible. Providers should be included in HIV training efforts to raise awareness of new and existing products, and encouraged to educate all women.

Mullan Z. Empowerment and protection. *Lancet Glob Health* 2013;1:e116.

No abstract available.

Nie L, Liao S, Weeks MR, Wang Y, Jiang J, Zhang Q, et al. Promoting female condoms in the sex industry in 4 towns of southern China: Context matters. *Sex Transm Dis* 2013; 40(3): 264-70.

BACKGROUND: The female condom (FC) is an effective tool for dual protection, but it remains underused. Individual and contextual reasons need to be explored. **OBJECTIVE:** The aim of this study was to compare individual and contextual characteristics of FC multitime users, 1-time users, and nonusers among women in the sex industry of 4 study sites in China. **METHODS:** A standardized 1-year FC intervention along with male condoms was implemented through outreach to sex establishments. Three serial cross-sectional surveys were conducted at baseline and after each of two 6-month intervention phases. **RESULTS:** A total of 445, 437, and 290 eligible women were interviewed at 3 cross-sectional surveys, respectively. At the first and second postintervention surveys, 83.3% and 81.7% of women reported knowing about FC, and 28.8% and 36.6% had used FC at least once. Women who used FC multiple times reported less unprotected sex than nonusers in the last 30 days (3.0% vs. 17.2% at first and 3.2% vs. 16.8% at second postintervention survey, $P < 0.01$). Polytomous



logistic regression showed that both 1-time and multitime users were more likely to come from one particular site (approximately 3 times more than the reference site). Higher intervention scores (adjusted odds ratio, 1.8-4.0) and working in boarding houses (adjusted odds ratio, 3.4) were associated with FC use. **CONCLUSIONS:** Adding FC into male-condom-only intervention may reduce unprotected sex among women in sex establishments in rural and small urban areas of China. Adoption of FC may be related not only to intervention exposure but also to contextual factors associated with study site and type of sex establishments.

van Dijk MG, Pineda DL, Grossman D, Sorhaindo A, García SG. The female condom: A promising but unavailable method for Dominican sex workers, their clients, and their partners. *J Assoc Nurses AIDS Care* 2013;24(6):521-9.

Despite evidence of the potential of the female condom as a method that effectively protects against sexually transmitted infections (STIs), HIV, and pregnancy, it is still not widely available. We conducted in-depth interviews with 18 sex workers, 15 male clients, and seven partners in the Dominican Republic to assess the acceptability of the female condom. The majority of the sex workers found the female condom acceptable and welcomed the option of a female-controlled method. Clients and partners of the sex workers were also positive about the female condom and, particularly with regard to pleasure; almost all preferred it to the male condom. These findings suggest that the female condom offers an acceptable option for protection against HIV, STIs, and pregnancy. The positive attitudes of women and men could be developed into messages in marketing campaigns for the female condom, targeting not only vulnerable groups but also the general population.

Wang Y, Liao S, Jiang J, Weeks MR, Nie L, Li J, He B, Zhou Y, Li F, Dunn J, Zhang Q. Who are the preferential targets for intervention programs related to the female condom among sex workers in southern China? *AIDS Educ Prev* 2013;25(4):349-61.

The authors used a cluster analysis approach to investigate which female sex workers (FSW) are preferential targets for female condom (FC) intervention programs in southern China. Cross-sectional 6-month (N = 316) and 12-month (N = 217) post-intervention surveys of FSW were analyzed. Based on FC attitudes and beliefs, initially suggesting FC use to a partner, practicing insertion, total times ever used, and willingness to use in the future, cluster analysis apportioned women into two clusters, with 50.6% and 58.1% of participants in the likely future FC users group at 6 months and 12 months, respectively. Likely future FC users tended to be from boarding houses, older, currently or previously married, experienced with childbirth, with current multiple sex partners, longer history of sex work, and more unprotected sexual encounters. Focusing FC programs on sectors of the community with more FSW who are likely to use FC may be more cost-effective for enhancing FC acceptability and usage.

Weeks MR, Abbott M, Hilario H, Radda K, Medina Z, Prince M, Li J, Kaplan C. Structural issues affecting creation of a community action and advocacy board. *Health Educ Res* 2013;28(3):375-91.

The most effective woman-initiated method to prevent HIV/sexually transmitted infections is the female condom (FC). Yet, FCs are often difficult to find and denigrated or ignored by community health and service providers. Evidence increasingly supports the need to develop and test theoretically driven, multilevel interventions using a community-empowerment framework to promote FCs in a sustained way. We conducted a study in a mid-sized northeastern US city (2009-2013) designed to create, mobilize and build capacity of a community group to develop and implement multilevel interventions to increase availability, accessibility and support for FCs in their city. The Community Action and Advocacy Board (CAAB) designed and piloted interventions concurrently targeting community, organizational and individual levels. Ethnographic observation of the CAAB training and intervention planning and pilot implementation sessions documented the process, preliminary successes, challenges and limitations of this model. The CAAB demonstrated ability to conceptualize, plan and initiate multilevel community change. However, challenges in group decision-making and limitations in members' availability or personal capacity constrained CAAB processes and intervention implementation. Lessons from this experience could inform similar efforts to mobilize, engage and build capacity of community



coalitions to increase access to and support for FCs and other novel effective prevention options for at-risk women.

Weeks MR, Coman E, Hilario H, Li J, Abbott M. Initial and sustained female condom use among low-income urban US women. *J Womens Health* 2013; 22(1): 26-36.

OBJECTIVES: The female condom (FC), an effective barrier method for HIV/sexually transmitted infection (STI) prevention, continues to be absent from most community settings, including reproductive health and treatment clinics. Reducing or eliminating basic barriers, including lack of awareness, knowledge of proper use, and access to free samples, may significantly increase use among those who want or need them. **METHODS:** A prospective cohort of 461 women in Hartford, Connecticut (2005-2008), was interviewed at baseline, 1 month, and 10 months about FC use and other personal, partner, peer, and community factors. All participants received brief demonstration of FC use and four free FC1 at baseline. Pairwise longitudinal tests and structural equation modeling were used to test predictors of initial (1 month) and sustained (10 month) FC use. **RESULTS:** Although only 29% of the sample reported ever having used FC at baseline, 73% of never users (51% of the returned 1-month sample) had initiated FC use by 1 month after receiving the brief intervention. Additionally, 24% of the returned 10-month sample (30% of 10-month FC users) reported sustained use, measured as having used FC at baseline or 1 month and also in the prior 30 days. General latent variable modeling indicated that FC knowledge and attitudes predicted initiating FC use; male condom use, FC knowledge and attitudes, and network exposure to FC information predicted sustained use. **CONCLUSIONS:** Findings indicated that many women will potentially initiate and continue using FC when basic barriers are removed. Brief FC education with free trial samples should be built into standard clinical practice and public health programs.

You H, Lau JT, Gu J, Tsui HY, Wang Z, Kim JH. Awareness and acceptability of female condoms among monogamous Hong Kong Chinese female sexually transmitted infection patients. *AIDS Behav* 2013; 17(3): 1195-204.

Female condom is an effective means of HIV prevention. Monogamous female sexually transmitted infection (STI) patients are exposed indirectly to high risk of contracting HIV/STI via their sole male sex partners. There are few interventions to protect such women whilst female condom use is a potential means of self-protection. With informed consent, this cross-sectional study investigated the prevalence of awareness and acceptability of female condoms among 335 Chinese monogamous female STI patients attending a government STI clinic in Hong Kong. Among those who were aware of female condoms (66.9 % of the sample), 68.3 % were willing to use free female condoms. Awareness was associated with having the sex partner being a boyfriend (OR = 3.76, $P < 0.001$), knowledge about asymptomatic property of HIV (OR = 2.14, $P = 0.006$) and no immunity for STI (OR = 2.14, $P = 0.011$), experience of HIV antibody testing (OR = 2.21, $P = 0.004$) and unemployment (OR = 0.50, $P = 0.011$). Among those who had heard of female condoms, acceptability was associated with knowledge about possibility to contracting two STI concomitantly (OR = 2.26, $P = 0.03$) and perceived chance of contracting STI from the sex partner in the coming 6 months (OR = 2.27, $P = 0.04$). Awareness is relatively low but the prevalence of acceptability is encouraging. Female condoms have been underused and should be promoted among monogamous female STI patients as a means of empowerment as an option for sex protection.

2012

Alexander KA, Coleman CL, Deatrck JA, Jemmott LS. Moving beyond safe sex to women-controlled safe sex: A concept analysis. *J Adv Nurs* 2012; 68(8): 1858-69.

Aim: This paper is a report of a conceptual analysis of women-controlled safe sex. **Background:** Women bear disproportionate burdens from sexually related health compromising outcomes. Imbalanced societal gender and power positions contribute to high morbidities. The expression, women-controlled safe sex, aims to empower women to gain control of their sexual lives. Few researchers focus on contextualized socio-cultural definitions of



sexual safety among women. Data sources: The sample included scientific literature from Scopus, CINAHL, PubMed, PsychINFO and Sociological Abstracts. Papers were published 2000-2010. Review methods: Critical analyses of literature about women-controlled safe sex were performed in May 2011 using Rodgers' evolutionary concept analysis methods. The search focused on social and cultural influences on sexual practices aimed at increasing women's control over their sexual safety. Results: The analysis uncovered five attributes of women-controlled safe sex: technology; access to choices; women at-risk; 'condom migration' panic; and communication. Three antecedents included: male partner influence; body awareness; and self-efficacy. Consequences were categorized as positive or negative. Nine surrogate terms included: empowerment; gender power; female-controlled sexual barrier method; microbicides; diaphragm; sexual negotiation and communication; female condom; women-initiated disease transmission prevention; and spermicides. Finally, a consensus definition was identified: a socio-culturally influenced multi-level process for initiating sexual safety by women deemed at-risk for sexually related dangers, usually sexually transmitted infections and/or HIV/AIDS. Conclusion: This concept analysis described current significance, uses, and applications of women-controlled safe sex in the scientific literature. The authors clarified its limited nature and conclude that additional conceptual refinement in nursing is necessary to influence women's health.

Beksinska M, Smit J, Joanis C, Hart C. Practice makes perfect: Reduction in female condom failures and user problems with short-term experience in a randomized trial. *Contraception* 2012; 86(2): 127–31.

Background: Female condom (FC) failure (breakage, slippage, invagination and misdirection) declines with user experience. Participants in FC performance trials are commonly novice users, and failure rates may be inflated related to inexperience. Study design: This was a randomized, crossover study assessing preference, safety, acceptability and function of three new FCs (WC, FC2 and V-Amour) among 170 women in Durban, South Africa. FC failure by condom type use period was investigated in women using five FCs of each type. Results: Of the 2411 condoms used during intercourse, 96 failures (breakage, slippage, invagination and misdirection) occurred in 86 condoms (77 condoms had one failure, 8 condoms had two failures, and 1 condom had three failures). Total clinical failure was comparable across FC types. The number of failures in the first condom use period was 58 (7.0%), and this decreased to 21 events (2.6%) in the second and, finally, 17 (2.1%) in the last condom use period. No failures were reported in the last use of the FC in the final condom use period. Conclusions: FC failure rates decreased markedly after use of the first five condoms, regardless of FC type, and stabilized in the second and third use periods. Consideration should be given to the number of condoms used in trials to ensure that failure rates are not inflated by limiting the numbers of condoms used by novice users.

Beksinska M, Smit J, Joanis C, Potter W. New female condoms in the pipeline. *Reprod Health Matters* 2012; 20(40): 188-96.

Male and female condoms are currently the only effective dual protection methods against unintended pregnancy and transmission of STIs and HIV. In recent years, advocacy and support to female condom (FC) programmes and increased distribution have played a significant role in highlighting to donors, policy-makers and programme managers the importance of FCs as essential tools for dual prevention. Further, the emergence of new FC products, differing in design and materials, has the potential to lower cost and improve acceptability. There are hurdles in developing new FC products, by far the greatest being the clinical studies required for regulatory purposes. However, several new designs are now available in selected countries and some are progressing through the final stages of regulatory approval, after which they will be more widely available. The new FC designs, which may also be more affordable, will increase options and choice for couples who want to use FCs as their prevention method. Here, we review the FC products that are available now and those still in development which are expected to be available within the next two to five years.

Beksinska ME, Smit JA, Mantell JE. Progress and challenges to male and female condom use in South Africa. *Sex Health* 2012; 9(1): 51–8.



South Africa has responded to the sexually transmissible infection and HIV epidemic with a rapid expansion of its national-level public sector condom program. Male condoms are available widely at no cost in the public sector, with expanded access via social marketing and the private sector. The female condom program is one of the largest and best established globally. National surveys show progressive increases in rates of condom use at last sex. However, inconsistent and incorrect condom use and the likelihood that condoms are discontinued in longer-term partnerships are some of the challenges impeding the condom program's successes in the fight against sexually transmissible infections and HIV. This article reviews the current condom program, related guidelines and policies, and the existing data on male and female condom use, including distribution and uptake. We discuss the main challenges to condom use, including both user and service-related issues and finally how these challenges could be addressed.

Chatterjee K, Markham Shaw C. Media portrayals of the female condom. *J Health Commun* 2012; 17(10):1138-50.

This study examines newspaper and broadcast news depictions of the female condom from 1993 to 2009 in the three major television networks (ABC, CBS, and NBC), and in 8 of 10 top daily newspapers and 3 of 4 national newspapers published in the United States, according to circulation figures as of September 30, 2008. Given the high rates of sexually transmitted infections in the United States and their effect on women, particularly those between 15 and 24 years of age, it is important to examine media sources and the health information that the public is or is not receiving through these sources. This study (a) examines whether the female condom was depicted positively or negatively in broadcast and newspaper coverage, (b) determines the ways in which the female condom was compared with the male condom and with other contraceptives, and (c) identifies the sources used by journalists in female condom portrayals. The authors discuss the implications of the coverage of the female condom by broadcast and print news.

Exner TM, Tesoriero JM, Battles HB, Hoffman S, Mantell JE, Correale J, Adams-Skinner J, Shapiro DA, Rowe K, Cotroneo RA, Leu CS, Hunter J, Klein SJ. A randomized controlled trial to evaluate a structural intervention to promote the female condom in New York State. *AIDS Behav* 2012; 16(5): 1121-32.

We conducted a structural intervention to promote the female condom (FC), comparing 44 agencies randomized to a Minimal Intervention (MI) [developing action plans for promotion and free access] or an Enhanced Intervention (EI) [with the addition of counselor training]. Intervention effects were evaluated via surveys with agency directors, counselors and clients at baseline and 12 months. Agency-level outcomes of the FC did not differ between the two interventions at follow-up. Counselors in the EI showed significantly greater gains in FC knowledge and positive attitudes, although there was no difference in the proportion of clients counseled on the FC, which significantly increased in both conditions. There was a greater increase in intention to use the FC among clients in EI agencies. Intervention effects were stronger in medical agencies. Findings suggest that making subsidized FCs available and assisting agencies to formulate action plans led to increased FC promotion. Limitations and implications for future research and intervention efforts are discussed.

Gallo MF, Kilbourne-Brook M, Coffey PS. A review of the effectiveness and acceptability of the female condom for dual protection. *Sex Health* 2012; 9(1): 18-26.

The female condom remains the sole female-initiated method of dual protection against unintended pregnancy and sexually transmissible infections (STIs), including HIV. We reviewed published data on the effectiveness and acceptability of the female condom for protection against pregnancy and infection. Overall, use of the female condom is low and several barriers hinder the wider adoption of the use of the method. Research on effectiveness has focused on pregnancy, STIs and biological markers of semen exposure. Although the data available suggest that female condoms (or a mixture of female and male condoms) may provide similar degrees of protection against pregnancy and STIs as do latex male condoms alone, this conclusion has not been demonstrated and thus comparative research is urgently needed.



Haddad L, Gallo MF, Jamieson DJ, Macaluso M. Condom type may influence sexual behavior and ejaculation and complicate the assessment of condom functionality. *Contraception* 2012; 86(4): 391-6.

BACKGROUND: Studies that evaluate condom effectiveness are affected by factors related to how the condom was used, and these factors may not be consistent between different types of condoms. Also, subjective assessments of the sexual act may be unreliable. **STUDY DESIGN:** We performed a secondary data analysis of a randomized crossover trial of male and female condoms among 108 couples. **RESULTS:** Self-reported duration and activeness of coital acts were significantly different for uses of the male condom compared to uses of the female condom. Fewer individuals reported ejaculation occurring with the female condom. Reliability of self-reports of ejaculation compared to a biological marker of semen detected inside the used male and female condoms was not strong. **CONCLUSIONS:** We found that sexual behaviors appear to differ by the type of condom used for the coital act. Studies should consider sexual behavior when evaluating condom effectiveness. Furthermore, studies would be strengthened by the use of a biological marker of semen to determine whether ejaculation, and therefore a true risk of exposure, occurred.

Holtgrave DR, Maulsby C, Kharfen M, Jia Y, Wu C, Opoku J, West T, Pappas G. Cost-utility analysis of a female condom promotion program in Washington, DC. *AIDS Behav* 2012; 16(5): 1115–20.

A retrospective economic evaluation of a female condom distribution and education program in Washington, DC, was conducted. Standard methods of cost, threshold and cost-utility analysis were utilized as recommended by the US Panel on cost-effectiveness in health and medicine. The overall cost of the program that distributed 200,000 female condoms and provided educational services was \$414,186 (at a total gross cost per condom used during sex of \$3.19, including educational services). The number of HIV infections that would have to be averted in order for the program to be cost-saving was 1.13 in the societal perspective and 1.50 in the public sector payor perspective. The cost-effectiveness threshold of HIV infections to be averted was 0.46. Overall, mathematical modeling analyses estimated that the intervention averted approximately 23 HIV infections (even with the uncertainty inherent in this estimate, this value appears to well exceed the necessary thresholds), and the intervention resulted in a substantial net cost savings.

Marlow HM, Tolley EE, Weaver MA, Kohli R, Mehendale S. Changes in condom use during a microbicide clinical trial in Pune, India. *AIDS Care* 2012; 24(5): 539–43.

Researchers have raised concerns that microbicide use during clinical trials would displace condom use. We sought to understand whether condom use changed for participants in a microbicide clinical trial in Pune, India, to understand whether condom shifts were a legitimate concern. We hypothesize that women participating in a microbicide clinical trial in Pune, India, were more likely, on average, to report condom use at follow-up. We further hypothesize that men, whose female partners participated in a microbicide clinical trial were more likely, on average, to report condom use at follow-up. The outcome measure for reported condom use was a dichotomous variable to indicate whether or not the participant had used a male or female condom with a sexual partner since 2 months before enrollment or since the last survey, depending on the visit. Data are from semi-structured interviews at baseline, 2 months, 4 months, and 6 months with HPTN 059 clinical trial participants (100 women and 57 male partners). We used generalized estimating equations with a logit link function, exchangeable correlation, and a binomial family to model condom use. The odds of condom use for clinical trial women increased from baseline to 6 months by a factor of 3.7 (95% CI: 1.84-7.63) and the change in odds of condom use for clinical trial men from baseline to 6 months increased by a factor of 2.58 (95% CI: 1.37-4.85). We found concerns about microbicide use displacing condom use were not merited in this study population. The percent of participants reporting condom use declined from 4 to 6 months, suggesting that increases in condom use may only be during active study participation. Information about clinical trial factors that enabled these men and women to enact this important HIV prevention behavior is needed to develop interventions.



Mathenjwa T, Maharaj P. Female condoms give women greater control: A qualitative assessment of the experiences of commercial sex workers in Swaziland. *Eur J Contracept Reprod Health Care* 2012; 17(5): 383-92.

Objectives: To explore commercial sex workers' experiences with the female condom in Swaziland. Methods: This is a qualitative study that draws on two focus group discussions and ten individual in-depth interviews with female commercial sex workers in Lavumisa, Swaziland. Results: The findings suggest that the majority of female sex workers prefer to use the female condom with their clients because it offers them greater control over the sexual encounter. Other factors that facilitate its use include the absence of side effects, the enhancement of sexual pleasure and protection against the risk of STIs (including HIV). In addition, the women reported that the female condom is stronger and more resistant to breakage than the male condom. Moreover, the female condoms can be inserted well in advance of sexual intercourse. Difficulties of insertion, partner objection and limited product availability were some of the barriers to the use of the device. There was also a tendency to reuse the female condoms because of lack of product availability and privacy to insert it. Conclusion: Although female condom use involves negotiation with clients, the fact that it offers sex workers an independent method of protection gives them more power and also, increases their ability to control their sexual and reproductive health.

Nicolau AI, Ribeiro SG, Lessa PR, Monte AS, Bernardo EB, Pinheiro AK. Knowledge, attitude and practices regarding condom use among women prisoners: The prevention of STD/HIV in the prison setting. *Rev Esc Enferm USP* 2012; 46(3): 711-9.

The objective of this study was to evaluate the knowledge, attitude and practices of women prisoners regarding the use of female and male condoms as a means of prevention against STD/HIV. This quantitative and evaluative Knowledge, Attitude and Practice (KAP) study included 155 female prisoners. Data collection was performed between January and March 2010 at the State of Ceara Women's Penitentiary. Although the women had heard of and/or knew about the purposes of the use of condoms, only 35 (22.6%) had appropriate knowledge regarding male condoms, and 11 (7.1%) in regards to the use of female condoms. Their attitudes were less favorable regarding oral sex. Appropriate practice was not significantly representative, particularly regarding the female condom. Homo/bisexuality, gender issues, lack of knowledge, and the difficult access to condoms are obstacles that must be considered in the promotion of sexual health in the studied group.

No author listed. Female condom program shows success, cost savings. *AIDS Policy Law* 2012; 27(6): 3.
No abstract available.

Stockman JK, Morris MD, Martinez G, Lozada R, Patterson TL, Ulibarri MD, Vera A, Strathdee SA. Prevalence and correlates of female condom use and interest among injection drug-using female sex workers in two Mexico-US border cities. *AIDS Behav* 2012; 16(7): 1877-86.

Little is known about female condom use among female sex workers who inject drugs (FSW-IDUs) in Northern Mexico, where HIV/STI prevalence is high. We examined the prevalence and correlates of female condom use and interest in female condom use among FSW-IDUs aged >18 years in Tijuana and Ciudad Juarez, Mexico enrolled in a behavioral intervention designed to reduce high-risk sexual and injection behaviors. Of 621 FSW-IDUs, 8 % reported ever using female condoms, and 67.2 % expressed interest in trying female condoms. Factors independently associated with female condom use were having had a client become angry at the suggestion of using condoms and having engaged in unprotected vaginal sex with non-regular clients. Factors independently associated with interest in using female condoms were lifetime physical abuse and lifetime sexual abuse. Increasing the availability of female condoms and providing education on their use in the context of drug use and violence is recommended.

Urada LA, Morisky DE, Pimentel-Simbulan N, Silverman JG, Strathdee SA. Condom negotiations among female sex workers in the Philippines: Environmental influences. *PLoS One* 2012; 7(3): e33282.



BACKGROUND: Social and structural influences of condom negotiation among female sex workers (FSWs) remain understudied. This study assesses environmental and individual factors associated with condom negotiation among FSWs at high risk for acquiring HIV in a large urban setting of Metro Manila, Philippines. **METHODS:** Female bar/spa workers (N=498), aged 18 and over, underwent interview-led surveys examining their sexual health practices in the context of their risk environments. Data were collected from April 2009-January 2010 from 54 venues. Multiple logistic regressions were conducted to assess socio-behavioral factors (e.g., age, education, length of time employed as an entertainer, and alcohol/drug use) and socio-structural factors (e.g., venue-level peer/manager support, condom rule/availability, and sex trafficking) associated with condom negotiation, adjusting for individuals nested within venues. **RESULTS:** Of 142 FSWs who traded sex in the previous 6 months (included in the analysis), 24% did not typically negotiate condom use with venue patrons. Factors in the physical environment--trafficked/coerced into work (AOR=12.92, 95% CI=3.34-49.90), economic environment--sex without a condom to make more money (AOR=1.52, 95% CI 1.01-2.30), policy environment--sex without a condom because none was available (AOR=2.58, 95% CI=1.49-4.48), and individual risk--substance use (AOR=2.36, 95% CI=1.28-4.35) were independently associated with FSWs' lack of condom negotiation with venue patrons. **CONCLUSIONS:** Factors in the physical, economic, and policy environments, over individual (excepting substance use) and social level factors, were significantly associated with these FSWs' condom negotiations in the Philippines. Drawing upon Rhodes' risk environment framework, these results highlight the need for policies that support safer sex negotiations among sex workers in the context of their risk environments. Interventions should reduce barriers to condom negotiation for FSWs trafficked/coerced into their work, substance using, and impacted by economic conditions and policies that do not support condom availability.

Walsh T, Warner L, Macaluso M, Frezieres R, Snead M, Wraxall B. Prostate-specific antigen as a biomarker of condom failure: Comparison of three laboratory assays and self-reported condom use problems in a randomized trial of female condom performance. *Contraception* 2012; 86(1): 55–61.

BACKGROUND: Prostate-specific antigen (PSA), a biomarker for semen exposure, may provide a more objective measure of condom failure than subject self-reports. Methods for measuring PSA vary and their comparability with respect to assessing condom performance has not been adequately evaluated. This study compared results from three different PSA assays of vaginal samples collected by subjects in a randomized clinical trial which compared the performance of female condoms. **STUDY DESIGN:** We selected 30 pairs of pre- and post-coital vaginal samples from subjects who reported condom functionality problems or whose original PSA assay was positive. Samples were retested using three different PSA assays [quantitative enzyme-linked immunoassay (EIA), rocket immune-electrophoresis (RIE) and chromatographic immunoassay (CIA)]. We compared the proportion of condom uses where the post-coital PSA result indicated semen exposure for each of the three assays. **RESULTS:** Despite varying levels of sensitivity, the results from all three assays were remarkably consistent. Self-reported condom failures did not correlate well with positive PSA results, suggesting that exclusive reliance on either PSA or user self-report may be inadequate for assessing condom functionality. **CONCLUSION:** In combination with user self-report of condom failure, PSA testing provides a reliable, objective marker of condom functionality. Studies based on PSA testing may improve on conventional contraceptive clinical trials by offering a more direct assessment of a condom product's ability to prevent semen exposure.

Zirong H, Junqing W, Coffey PS, Kilbourne-Brook M, Yufeng Z, Wang C, Hongxin Z, Bin W, Yuyan L, Hongbo P. Performance of the woman's condom among couples in Shanghai, China. *Eur J Contracept Reprod Health Care* 2012; 17(3): 212–8.

BACKGROUND: The Woman's Condom, a second-generation female condom, is poised for introduction in China. **STUDY DESIGN:** This single-arm couples' use study was conducted in China in 2010 to assess performance and safety of the Woman's Condom and feasibility of mobile phone technology to record adherence data. **RESULTS:** Sixty couples were enrolled in this study, and 59 couples completed all four of the condom uses,



resulting in 234 condom uses. Two condoms were opened but not used. Total breakage was 0.85% (two non-clinical breakages). Misdirection (2%), invagination (0.85%) and slippage (1%) were consistent with data on condom failure from other studies. Total clinical failure was 4%. Fifteen mild and no serious adverse events were reported during the study. **CONCLUSIONS:** This study has shown that in China, the Woman's Condom performs well. Mobile phones cannot yet replace the use of a coital log and questionnaire. Further work on effectiveness is required.

Zhao J, Song F, Ren S, Wang Y, Wang L, Liu W, et al. Predictors of condom use behaviors based on the Health Belief Model (HBM) among female sex workers: A cross-sectional study in Hubei Province, China. *PLoS One* 2012; 7(11): e49542.

BACKGROUND: HIV infection related to commercial sexual contact is a serious public health issue in China. The objectives of the present study are to explore the predictors of condom use among female sex workers (FSWs) in China and examine the relationship between Health Belief Model (HBM) constructs.

METHODOLOGY/PRINCIPAL FINDINGS: A cross-sectional study was conducted in two cities (Wuhan and Suizhou) in Hubei Province, China, between July 2009 and June 2010. A total of 427 FSWs were recruited through mediators from the 'low-tier' entertainment establishments. Data were obtained by self-administered questionnaires. Structural equation models were constructed to examine the association. We collected 363 valid questionnaires. Within the context of HBM, perceived severity of HIV mediated through perceived benefits of condom use had a weak effect on condom use ($r=0.07$). Perceived benefits and perceived barriers were proximate determinants of condom use ($r=0.23$ and $r=-0.62$, respectively). Self-efficacy had a direct effect on perceived severity, perceived benefits, and perceived barriers, which was indirectly associated with condom use behaviors ($r=0.36$). **CONCLUSIONS/SIGNIFICANCE:** The HBM provides a useful framework for investigating predictors of condom use behaviors among FSWs. Future HIV prevention interventions should focus on increasing perceived benefits of condom use, reducing barriers to condoms use, and improving self-efficacy among FSWs.

2011

Beksinska M, Smit J, Joanis C, Usher-Patel M, Potter W. Female condom technology: New products and regulatory issues. *Contraception* 2011; 83(4): 316-321.

Like male condoms, female condoms (FCs) provide protection against unplanned pregnancy and most sexually transmitted infections including HIV. The first FC made by the Female Health Company was approved by the US Food and Drug Administration (USFDA) in 1993. Since 2000, several different types of FCs have become available or are in development to lower the cost and/or improve acceptability. Although similar in function, new FCs often differ in design and materials. Classified as Class III medical devices by the USFDA, FCs have a regulatory process that is more complex than that for male condoms. This, coupled with the lack of an international standard to verify the quality of new devices, has hindered new products gaining regulatory approvals and entering the market. We review the existing regulatory pathway for FCs, the progress made in developing standards specifically for FCs and the FCs available now or in development, including their current status regarding approval.

Campbell AN, Tross S, Hu MC, Pavlicova M, Kenney J, Nunes EV. Female condom skill and attitude: Results from a NIDA Clinical Trials Network gender-specific HIV risk reduction study. *AIDS Education and Prevention* 2011; 23(4): 329-340.

The female condom is effective in reducing unprotected sexual acts; however, it remains underutilized in the United States. This study examined whether a five-session HIV prevention intervention (Safer Sex Skills Building [SSB]), including presentation, discussion, and practice with female condoms, improved female condom skills and attitude among women in outpatient substance abuse treatment. Mixed-effects modeling was used to test the effect of SSB on skills and attitude over 3- and 6-month post-treatment among 515 randomized women. SSB was



significantly associated with increases in skills and attitude, and the female condom demonstration session was primarily responsible for skills improvement. Attitude was a partial mediator of the intervention effect in reducing unprotected sex. Findings emphasize the utility of integrating female condom messages targeting proximal behavioral outcomes into HIV prevention. The study supports the use of female condom skill instruction via brief, hands-on exercises, as well as further research to enhance attitudinal change to reduce sexual risk.

Chen B, Zhang M, Yang D, Wang X, Zheng Y. Acceptability of female condom use in money boys compared with other men who have sex with men in Chengdu, China: A comparative study. *Sexual Health* 2011; 8(2): 262-263.

We conducted a clinical trial to compare sexual behaviours and attitudes regarding female condoms among money boys and other men who have sex with men in Chengdu, China, with a particular focus on factors influencing use of female condoms.

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 Ment Health J* 2011; 47(2): 143-155.

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.

Exner TM, Mantell JE, Hoffman S, Adams-Skinner J, Stein ZA, Leu CS. Project REACH: A provider-delivered dual protection intervention for women using family planning services in New York City. *AIDS Care* 2011; 23(4): 467-75.

High rates of unintended pregnancies and sexually transmitted infection (STI), including HIV, highlight the importance of promoting dual protection (DP) - i.e., methods that offer concurrent protection against unintended pregnancies and STI - during contraceptive counseling. Using a Phase II quasi-experimental design, this study compared an individualized, clinic-based, nurse-delivered intervention designed to increase DP against standard of care among 101 HIV negative women accessing contraceptive services in medically under-served areas of New York City. Participants were evaluated at baseline, post-counseling, and six months later. Findings indicated that the intervention has possible benefit. At six-month follow-up, there was greater perceived susceptibility to STI and fewer condom-unprotected vaginal sex occasions in the intervention arm. Women in the intervention also had five times the odds of reporting female condom use. Results suggest that this intervention has the potential for a larger population impact and should be more rigorously evaluated in a Phase III trial.

Food and Drug Administration, HHS. Effective date of requirement for premarket approval for three class III preamendments devices. Final rule. *Federal Register* 2011; 76(158): 50663-50667.

The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following three class III preamendments devices: Ventricular bypass (assist) device; pacemaker repair or replacement material; and female condom. The Agency has summarized its findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. This action implements certain statutory requirements.



Joanis C, Beksinska M, Hart C, Tweedy K, Linda J, Smit J. Three new female condoms: Which do South-African women prefer? *Contraception* 2011; 83(3): 248-254.

Background: The widespread distribution of female condoms (FCs) in developing countries has been hindered by high unit cost, making new, less expensive devices a priority for donor agencies. Study design: Randomized, crossover study assessing product preference, safety, acceptability, and function of three new FCs (PATH Woman's Condom, FC2, and V-Amour) among 170 women in Durban, South Africa. A subsequent "simulated market" study provided participants with free choice of FCs and assessed condom uptake over three months. Results: Of the 160 women who used at least one FC of each type, 47.5% preferred the PATH Woman's Condom (WC), 35.6% preferred FC2, and 16.3% preferred V-Amour ($p<.001$). Women rated the WC better than FC2 and V-Amour for appearance, ease of use, and overall fit and better than V-Amour for feel. WC was rated worse than FC2 and V-Amour for lubrication volume. The simulated market demonstrated similar preferences. Total clinical failure rates (i.e., the types of failures that could result in pregnancy or STI) were low ($<4\%$), regardless of condom type. Conclusions: Three new FC types functioned similarly and were generally acceptable. Most participants preferred WC and FC2 over V-Amour, and WC was preferred over FC2 in several acceptability measures.

Kelvin EA, Mantell JE, Cendelario N, Hoffman S, Exner TM, Stackhouse W, Stein ZA. Off-label use of the female condom for anal intercourse among men in New York City. *Am J Pub Health* 2011; 101: 2233-2244.

We surveyed 111 male clients of an HIV/AIDS service organization in New York City in 2008 and 2009. Seventeen percent had used the female condom for anal intercourse; of these, 89.3% had used the female condom with male partners, 21.4% with female partners, and 10.7% with both. Users of the female condom for vaginal intercourse were more likely to use it for anal intercourse (odds ratio=12.7; 95% confidence interval=2.5, 64.9; $P=.002$). The safety and efficacy of the female condom for anal intercourse are unknown and should be evaluated.

Liao S, Weeks MF, Wang Y, Li F, Jiang J, Li J, Zeng X, He B, Dunn J. Female condom use in the rural sex industry in China: Analysis of users and non-users at post-intervention surveys. *AIDS Care* 2011; 23 (Suppl 1): 66-74.

Changes in sexual attitudes and behaviors and resurgence of the sex industry in China have increased concerns about HIV/AIDS and sexually transmitted infections (STI) epidemics. Little attention has been paid to the significant and growing sex industry in rural China. Promotion of barrier protection in this context is most effective to prevent STIs and pregnancy. The female condom (FC) is a barrier method that gives women more autonomy in its application, and has other advantages, but has been little promoted and tested in high risk contexts in China. The China/US Women's Health Project was designed to promote FC use in addition to male condoms (MC) through outreach intervention conducted in sex work establishments in rural and small urban towns in southern China, using the original prototype FC1. The study used quantitative and qualitative methods to document the pre-intervention context, intervention delivery process, and post-intervention outcomes of FC use. In this paper we compare post-intervention FC users and non-users in the first study sites, two rural towns in a single county in Hainan Province. Examination of cross-sectional six-month and 12-month surveys indicated that, despite relatively high MC use, about one-third of the women in sex work establishments in these rural towns had adopted FC at each post-intervention survey. Compared with non-users, FC users were more likely to be freelance women in boarding houses, more sexually experienced, married with children, more sexually active in the prior month, and more exposed to the intervention. The rural context hampered intervention implementation, particularly the significant limits in health and human resources available to manage prevention of HIV/STIs among women in the sex industry. These challenges highlight the need to better understand the context of the rural sex industry and capacity of local resources for better prevention efforts and the benefits that new prevention technologies like FC can offer.

Mantell JE, Smit JA, Beksinska M, Scorgie F, Milford C, Balch E, Mabude Z, Smith E, Adams-Skinner J, Exner TM, Hoffman S, Stein ZA. Everywhere you go, everyone is saying condom, condom. But are they



being used consistently? Reflections of South African male students about male and female condom use. *Health Education Research* 2011; 26(5): 859-871.

Young men in South Africa can play a critical role in preventing new human immunodeficiency virus (HIV) infections, yet are seldom targeted for HIV prevention. While reported condom use at last sex has increased considerably among young people, consistent condom use remains a challenge. In this study, 74 male higher education students gave their perspectives on male and female condoms in 10 focus group discussions. All believed that condoms should be used when wanting to prevent conception and protect against HIV, although many indicated that consistent condom use was seldom attained, if at all. Three possible situations for not using condoms were noted: (i) when sex happens in the heat of the moment and condoms are unavailable, (ii) when sexual partnerships have matured and (iii) when female partners implicitly accept unprotected sex. Men viewed it as their responsibility to have male condoms available, but attitudes about whose decision it was to initiate condom use were mixed. Almost all sexually active men had male condom experience; however, very few had used female condoms. Prevention initiatives should challenge traditional gendered norms that underpin poor condom uptake and continued use and build on the apparent shifts in these norms that are allowing women greater sexual agency.

Marrazzo JM, Cates W. Interventions to prevent sexually transmitted infections, including HIV infection. *Clin Infect Dis* 2011; 53 Suppl 3: S64-78.

The Centers for Disease Control and Prevention (CDC) Sexually Transmitted Disease (STD) Treatment Guidelines were last updated in 2006. To update the "Clinical Guide to Prevention Services" section of the 2010 CDC STD Treatment Guidelines, we reviewed the recent science with reference to interventions designed to prevent acquisition of STDs, including human immunodeficiency virus (HIV) infection. Major interval developments include (1) licensure and uptake of immunization against genital human papillomavirus, (2) validation of male circumcision as a potent prevention tool against acquisition of HIV and some other sexually transmitted infections (STIs), (3) failure of a promising HIV vaccine candidate to afford protection against HIV acquisition, (4) encouragement about the use of antiretroviral agents as preexposure prophylaxis to reduce risk of HIV and herpes simplex virus acquisition, (5) enhanced emphasis on expedited partner management and rescreening for persons infected with *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, (6) recognition that behavioral interventions will be needed to address a new trend of sexually transmitted hepatitis C among men who have sex with men, and (7) the availability of a modified female condom. A range of preventive interventions is needed to reduce the risks of acquiring STI, including HIV infection, among sexually active people, and a flexible approach targeted to specific populations should integrate combinations of biomedical, behavioral, and structural interventions. These would ideally involve an array of prevention contexts, including (1) communications and practices among sexual partners, (2) transactions between individual clients and their healthcare providers, and (3) comprehensive population-level strategies for prioritizing prevention research, ensuring accurate outcome assessment, and formulating health policy.

Mauck C, Joshi S, Schwartz J, Callahan M, Walsh T. Reddy female condom: Functional performance of a 90-mm shaft length in two clinical studies. *Contraception* 2011; 83(5): 466-471.

Background: We report on the functional performance, safety and acceptability of the 90-mm Reddy female condom in two clinical trials, one in Los Angeles, CA, and one in Pune, Maharashtra, India. Study Design: Both studies used a Phase I, crossover design involving 25 couples. Each couple used three condoms of each of two shaft lengths: in Los Angeles, shaft lengths of 150 and 90 mm were used; in Pune, shaft lengths of 120 and 90 mm were used. This paper focuses on the 90-mm condom since it is commercially available. The primary endpoint of each study was invagination, defined as the outer frame of the condom being pushed into the vagina during intercourse. Secondary functionality endpoints included non-clinical breakage, clinical breakage, penile misdirection and complete slippage. Results: Invagination occurred in 26.9% of uses in Los Angeles vs. 6.8% of uses in Pune. Penile misdirection and complete slippage were reported only in Pune during 4.0% and 9.5% of uses, respectively. There were two clinical breaks in Pune and none in Los Angeles. Total clinical failure was



26.9% in Los Angeles and 23.0% in Pune. Conclusions: Two clinical studies of the 90-mm Reddy female condom suggest that its functional performance is inferior to other female condoms.

Morisky DE, Urada LA. Organizational policy recommendations for control of STI/HIV among female sex workers in China: Regular examination of workers in social hygiene clinics. *AIDS Care* 2011; 23 Suppl 1: 83-95.

This article aims to address female sex workers at high risk for contracting HIV in China by recommending evidence-based socio-structural interventions and policies at the national level that have yielded effective outcomes in other countries. National governments such as the Philippines and Hong Kong have utilized the Social Hygiene Clinic (SHC) model. A similar national policy can be highly effective in China. Evidence-based research study results indicate significant reductions in STI and consistent condom use among female sex workers in both China and the Philippines. Consistent condom use in both countries continues to be significantly associated with interpersonal- and venue-level factors. Individuals who had higher appointment-keeping ratios in the Philippines had higher rates of consistent condom use (OR = 2.7, 95% CI = 1.6-3.7) and significantly lower rates of STI (OR = 0.43, 95% CI = 0.26-0.57). By beginning with provinces, which already have a good relationship between establishment venues and the local Health Department, China can develop city ordinances and establishment regulations that begin to require regular examinations of female sex workers and entertainers in the local STI clinic.

Todd CS, Nasir A, Stanekzai MR, Scott PT, Close NC, Botros BA, et al. HIV awareness and condom use among female sex workers in Afghanistan: Implications for intervention. *AIDS Care* 2011; 23(3): 348-56.

There is little information about HIV awareness or condom use among female sex workers (FSWs) in Afghanistan. The purpose of this cross-sectional study was to assess HIV awareness, knowledge, and condom use among FSWs in three Afghan cities. FSWs residing in Jalalabad, Kabul, and Mazar-i-Sharif were recruited through outreach programs and completed an interviewer-administered questionnaire and rapid tests for hepatitis B surface antigen, HIV, syphilis, and hepatitis C virus. Logistic regression identified factors associated with HIV awareness, comprehensive HIV knowledge (knowledge that HIV cannot be detected by sight, that condoms prevent HIV, and rejection of local misconceptions about HIV transmission), and consistent condom use (use with every sex act) with clients in the last six months. Of 520 participants, 76.9% had no formal education and 37.7% lived outside Afghanistan in the last five years. Nearly half (44.2%) were aware of HIV but, of these, only 17.4% (N = 40) had comprehensive HIV knowledge. There were significant differences by site; FSWs in Jalalabad were more likely to be aware of HIV but FSWs in Kabul were more likely to have correct HIV knowledge and use condoms consistently with clients. Consistent client condom use was reported by 11.5% (N = 60) and was independently associated with having more clients per month (AOR = 1.99, 95% CI: 1.04-3.81). In conclusion, comprehensive HIV knowledge and consistent condom use with clients are low among Afghan FSWs in these cities. Efforts to reach this population should focus on relaying accurate information and expanding condom use with clients.

Turner AN, Feldblum P, Hoke TH. Condom use and sexually transmitted infections among Malagasy sex workers. *International Journal of STD & AIDS* 2011; 22(10): 552-557.

We evaluated whether use of a short- or longer-term recall period for condom use was superior for assessing risk of acquisition of incident sexually transmitted infection (STI). Female sex workers (n = 1000) in Madagascar took part in a randomized trial comparing counselling strategies for male and female condom promotion. We explored associations between women's self-reported condom use with clients and non-paying partners and incident STI, examining both short-term recall (last sex act) and longer-term recall (over the past month and year). Self-reported condom use was generally not associated with reduced STI risk, whether measured at the last act or over longer time periods; with clients or non-paying partners; and through unadjusted and adjusted modelling. No condom use measure (short versus longer time periods, with one or both partner types) was strongly predictive of STI, suggesting poor validity.



Anny P, Jansen W, van Driel F. The female condom: The international denial of a strong potential. *Reproductive Health Matters* 2010; 18(35): 119-128.

The female condom has received surprisingly little serious attention since its introduction in 1984. Given the numbers of women with HIV globally, international support for women's reproductive and sexual health and rights and the empowerment of women, and, not least, due to the demand expressed by users, one would have expected the female condom to be widely accessible 16 years after it first appeared. This expectation has not materialised; instead, the female condom has been marginalised in the international response to HIV and AIDS. This paper asks why and analyses the views and actions of users, providers, national governments and international public policymakers, using an analytical framework specifically designed to evaluate access to new health technologies in poor countries. We argue that universal access to female condoms is not primarily hampered by obstacles on the users' side, as is often alleged, nor by unwilling governments in developing countries, but that acceptability of the female condom is problematic mainly at the international policy level. This view is based on an extensive review of the literature, interviews with representatives of UNAIDS, UNFPA and other organisations, and a series of observations made during the International AIDS Conference in Mexico in August 2008.

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.

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.

Mack N, Grey TG, Amsterdam A, Williamson N, Matta CI. Introducing female condoms to female sex workers in Central America. *International Perspectives on Sexual and Reproductive Health* 2010; 36(3): 149-156.

Female condoms have a potential role in reducing HIV infection among female sex workers in Central America.



Research on how to introduce female condoms to this population is warranted. Methods: Two rounds of focus groups with sex workers (115 in round one and 81 in round two) were conducted in El Salvador and Nicaragua in 2007–2008. In addition, we conducted structured interviews with 95 sex workers and direct observations of six health educators. Results: Women reported that the design of the female condom made insertion and removal difficult to learn. About one-third of participants reported inserting it for the first time alone. Most women reported practicing 2–10 times before feeling skilled enough to use it with partners. Positive perceptions included lubrication, size, comfort, and strength. Negative perceptions included the large package, initial physical discomfort, and the possibility that the device would scare clients away. The participants preferred to learn to use female condoms from an instructional brochure plus instructor-led training in their workplace. They cited lack of exposure to female condoms among men and women as a barrier to female condom use and recommended education for both men and women; they also recommended distribution of female condoms at places where male condoms are available. Conclusions: If provisions are made for instructing women on female condom use in places where women will not feel stigmatized, and if supplies are easily and consistently available, uptake of the female condom among female sex workers in Central America seems likely. Health educators' use of promotional tools such as checklists and standardized messages is strongly recommended.

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.

Weeks MR, Liao S, Li F, Li J, Dunn J, He B, He Q, Feng W, Wang Y. Challenges, strategies, and lessons learned from a participatory community intervention study to promote female condoms among rural sex workers in Southern China. *AIDS Education and Prevention* 2010; 22(3): 252-271.

China faces a rapidly emerging HIV epidemic and nationwide resurgence of sexually transmitted infections associated with a growing sex industry. Community empowerment and capacity building through community-based participatory research partnerships show promise for developing, testing, and refining multilevel interventions suited to the local context that are effective and appropriate to address these concerns. However, such efforts are fraught with challenges, both for community collaborators and for researchers. We have built an international team of scientists from Beijing and the United States and collaborating health policy makers, health educators, and care providers from Hainan and Guangxi Province Centers for Disease Prevention and Control and the local counties and towns where we are conducting our study. This team is in the process of testing a community-wide, multilevel intervention to promote female condoms and other HIV prevention within sex-work



establishments. This article presents lessons learned from our experiences in the first two study sites of this intervention trial.

Witte SS, Stefano K, Hawkins C. Can Medicaid reimbursement help give female condoms a second chance in the United States? *American Journal of Public Health* 2010; 100(10): 1835-1840.

The female condom is the only other barrier contraception method besides the male condom, and it is the only "woman-initiated" device for prevention of sexually transmitted infections. Although studies demonstrate high acceptability and effectiveness for this device, overall use in the United States remains low. The female condom has been available through Medicaid in many states since 1994. We provide the first published summary of data on Medicaid reimbursement for the female condom. Our findings demonstrate low rates of claims for female condoms but high rates of reimbursement. In light of the 2009 approval of a new, cheaper female condom and the recent passage of comprehensive health care reform, we call for research examining how health care providers can best promote consumer use of Medicaid reimbursement to obtain this important infection-prevention device.

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 use 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].



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, Wheelless 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, Taegtmeyer 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 infection. 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 11 179). Conclusions: The female condom has some potential for reducing unprotected sex among sex workers. However, given its high cost, and the marginal improvements seen here, governments should limit promotion of the female condom in populations that are already successfully using the male condom. More research is needed to identify effective methods of encouraging sex workers to practise safer sex with their boyfriends.

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®, etc. 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 microbicidal 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 (gonorrhea, 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, Kulczycki 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 gonorrhea 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, Sakondhavat C, Kiriwat O, Rugpao 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, Billingshurst 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, Wijgert 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.

Sakondhavit C, Weeravatrakul Y, Benette T, Pinitsoontorn P, Kuchaisit C, Kukieattikool 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 US (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 gonorrhea and chlamydia and vaginal trichomoniasis, to be repeated at 6 and 12 months. The study has 80% power to detect a 10% prevalence difference, assuming an aggregate STD prevalence of 20% with 25% loss to follow-up and intracluster correlation of 0.03. Results: Among 1929 women at baseline, the mean age was 33.1 years; 78% had never used a male condom. The prevalences of gonorrhea, chlamydia and trichomoniasis were 2.6%, 3.2% and 20.4%, respectively (23.9% overall). The intracluster correlation based on these data was near zero. 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 ($> 70\%$ 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 microbicidal products for HIV risk reduction. *AIDS Care* 2000; 12(5): 581-588.

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

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, Bhiraueus P, Rugpao 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 US 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.

