



Cervical Barriers Bibliography

March 2017

The articles listed below represent a bibliography of research on cervical barriers that was created by the Cervical Barrier Advancement Society (CBAS). To update the bibliography, we searched in PubMed and Google Scholar for the terms “diaphragm,” “cervical cap,” and “cervical barrier” in titles and abstracts from articles published through March 15, 2017.

2016

Gollub EL, Dévieux J, Michele JG, Pierre Ste-Rose S, Neptune S, Pelletier V. “This Method, I Think, Can Shed New Light” Haitian-American Women's Reflections on Risk, Culture, and Family Planning Decisions From a Short-Term Trial of a Cervical Barrier (Femcap™). *Int Q Community Health Educ.* 2016 Jul;36(4):253-63.

Improving the reproductive health of immigrant populations requires understanding the specific context of risk and need. As part of a field trial of the FemCap™, a woman-initiated cervical barrier contraceptive, we conducted postintervention focus group discussions (FGDs) with 20 women (five FGDs) of Haitian background, the majority of whom were born in Haiti and spoke Haitian Créole at home, at a community health center in south Florida. Participants discussed the role of religion and inequitable gender norms in Haitian traditions about family planning decisions and provided important insights into the gender-power nuances of their partnership dynamics vis à vis the use of female barrier methods. Encouraged by more equitable gender norms in the United States, participants were eager to serve as health education agents, with strong altruistic sentiments toward other Haitian girls and women who they felt could be encouraged to negotiate for greater reproductive decision-making power.

2015

Gollub EL, Cyrus E, Devieux JG, Jean-Gilles M, Neptune S, Pelletier V, et al. 'Men don't need to know everything': A field trial of a discreet, female-initiated, contraceptive barrier method (FemCap) among Haitian-American women. *Cult Health Sex* 2015; 17(7):842-58.

Worldwide, women report the need for safe, non-hormonal, woman-initiated methods of family planning. Cervical barriers provide such technology but are under-researched and under-promoted. In the USA, there are few studies of cervical barriers among women at high unmet need for contraception. A feasibility study of the FemCap was conducted among US women of Haitian origin. Participants were heterosexual and seeking to avoid pregnancy. At first visit, participants completed baseline assessments, underwent group counselling and were fitted with FemCap. Women were asked to insert or use the cap at home. The second visit (2-3 weeks) included an interviewer-administered questionnaire and a focus-group discussion. Participants (n = 20) were Haitian-born (70%), married (55%) and parous (85%). Their mean age was 32.6 years. Seventy percent reported recent unprotected sex. All women inserted the device at home and 9 women used it during intercourse, including 5 without prior partner negotiation. Of 20 women, 11 liked FemCap very much or somewhat; 7 considered it 'OK'; 2 disliked it. Best-liked attributes were comfort, discreet wear and reusability. Difficulties with removal abated over time. Qualitative data revealed a high value placed on lack of systemic side effects. Use of FemCap was feasible and acceptable, supporting expansion of research, particularly among relevant populations with unmet need.



Lépine A, Nundy N, Kilbourne-Brook M, Siapka M, Terris-Prestholt F. Cost-Effectiveness of Introducing the SILCS Diaphragm in South Africa. *PLoS One* 2015;10(8):e0134510.

BACKGROUND: Though South Africa has high contraceptive use, unintended pregnancies are still widespread. The SILCS diaphragm could reduce the number of women with unmet need by introducing a discreet, woman-initiated, non-hormonal barrier method to the contraceptive method mix. **METHODS:** A decision model was built to estimate the impact and cost-effectiveness of the introduction of the SILCS diaphragm in Gauteng among women with unmet need for contraception in terms of unintended and mistimed pregnancies averted, assuming that the available contraceptives on the market were not a satisfying option for those women. Full costs were estimated both from a provider's and user's perspective, which also accounts for women's travel and opportunity cost of time, assuming a 5% uptake among women with unmet contraceptive need. The incremental cost-effectiveness ratio is computed at five and 10 years after introduction to allow for a distribution of fixed costs over time. A probabilistic sensitivity analysis was conducted to incorporate decision uncertainty. **RESULTS:** The introduction of the SILCS diaphragm in Gauteng could prevent an estimated 8,365 unintended pregnancies and 2,117 abortions over five years, at an annual estimated cost of US\$55 per woman. This comes to a cost per pregnancy averted of US\$153 and US\$171 from a user's and provider's perspectives, respectively, with slightly lower unit costs at 10 years. Major cost drivers will be the price of the SILCS diaphragm and the contraceptive gel, given their large contribution to total costs (around 60%). **CONCLUSIONS:** The introduction of the SILCS diaphragm in the public sector is likely to provide protection for some women for whom current contraceptive technologies are not an option. However to realize its potential, targeting will be needed to reach women with unmet need and those with likely high adherence. Further analyses are needed among potential users to optimize the introduction strategy.

Schwartz JL, Weiner DH, Lai JJ, Frezieres RG, Creinin MD, Archer DF, et al. Contraceptive efficacy, safety, fit, and acceptability of a single-size diaphragm developed with end-user input. *Obstet Gynecol* 2015;125(4):895-903.

OBJECTIVE: To estimate contraceptive efficacy, safety, acceptability, and fit of a single-size diaphragm used with contraceptive gel. **METHODS:** We conducted a multicenter trial in which 450 couples used the single-size diaphragm, 300 randomized to acid-buffering gel and 150 to nonoxynol-9, for at least 190 days and six menstrual cycles. Visits were at enrollment and after menstrual cycles 1, 3, and 6. Study outcomes included pregnancy probability, safety, acceptability, and fit. Pregnancy and safety were compared with an historical control group who used a standard diaphragm with these gels. **RESULTS:** Most (439/450 [98%]) women could be fitted with the single-size diaphragm. A total of 421 of 450 (94%) provided follow-up. The 35 study pregnancies yielded 6-month Kaplan-Meier cumulative typical use pregnancy probabilities per 100 women with 95% confidence intervals (CIs) of 10.4 (6.9-14.0) for all users and 9.6 (5.5-13.6) and 12.5 (5.4-19.5) with acid-buffering gel and nonoxynol-9, respectively. Historical control analysis yielded a propensity score-adjusted estimate of this pregnancy probability for the single-size diaphragm of 11.3 compared with 10.7 per 100 women for the standard diaphragm ([rounded] difference 0.7, 95% CI -3.6 to 4.9). Approximately half (51%) reported at least one urogenital event but compared favorably to the standard diaphragm in historical control analysis. Most (282/342 [82%]) liked the diaphragm. Results suggest that if provided by a clinician, 94% (95% CI 92-96%) could insert, correctly position, and remove the diaphragm. **CONCLUSION:** The single-size diaphragm was safe, as effective as a standard diaphragm, and acceptable when used with contraceptive gel.

2014

Kyamwanga IT, Turyakira E, Kilbourne-Brook M, Coffey PS. Potential for revitalisation of the diaphragm for family planning in Uganda: A rapid assessment of the feasibility of introducing the SILCS Diaphragm. *Afr J Reprod Health* 2014;18:77-86.



This health systems assessment evaluated the feasibility of introducing a new contraceptive device, the SILCS single-size diaphragm, into the existing family planning method mix in Uganda. A total of 26 focus group discussions with 201 female and 77 male potential users and 98 key informant interviews with policymakers and providers were conducted between June and August 2010. Potential users, providers, and policymakers recognised that the SILCS Diaphragm could fill a gap in the method mix and expressed eagerness to make the SILCS Diaphragm available, particularly because it is nonhormonal and woman initiated. The diaphragm was viewed by all stakeholders as a method that would increase choice and could improve women's reproductive health in Uganda. Like many countries, Uganda's family planning programme is financially stretched, and clear support for the SILCS Diaphragm by end-users will need to be demonstrated before the product will be considered for public-sector introduction.

2013

Major I, Boyd P, Kilbourne-Brook M, Saxon G, Cohen J, Malcolm RK. A modified SILCS contraceptive diaphragm for long-term controlled release of the HIV microbicide dapivirine.

Contraception 2013;88(1):58-66.

BACKGROUND: There is considerable interest in developing new multipurpose prevention technologies to address women's reproductive health needs. This study describes an innovative barrier contraceptive device--based on the SILCS diaphragm--that also provides long-term controlled release of the lead candidate anti-HIV microbicide dapivirine. **STUDY DESIGN:** Diaphragm devices comprising various dapivirine-loaded polymer spring cores overmolded with a nonmedicated silicone elastomer sheath were fabricated by injection molding processes. In vitro release testing, thermal analysis and mechanical characterization were performed on the devices. **RESULTS:** A diaphragm device containing a polyoxymethylene spring core loaded with 10% w/w dapivirine provided continuous and controlled release of dapivirine over a 6-month period, with a mean in vitro daily release rate of 174 mcg/day. The mechanical properties of the new diaphragm were closely matched to the SILCS diaphragm. **CONCLUSIONS:** The study demonstrates proof of concept for a dapivirine-releasing diaphragm with daily release quantities potentially capable of preventing HIV transmission. In discontinuous clinical use, release of dapivirine may be readily extended over 1 or more years.

Naidoo S, Wand H. Prevalence and incidence of *Trichomonas vaginalis* infections in women participating in a clinical trial in Durban, South Africa. *Sex Transm Infect* 2013;89(6):519-22.

BACKGROUND AND OBJECTIVES: *Trichomonas vaginalis* is known to be the most common, curable, sexually transmitted infection among sexually active women and may be associated with the acquisition and transmission of HIV. The purpose of this analysis is to determine the prevalence and incidence of T vaginalis and assess risk factors associated with T vaginalis infection in a cohort of women participating in a clinical trial. **METHODS:** We analysed data from women participating in a phase III vaginal diaphragm trial conducted in two communities in Durban, South Africa from 2003 to 2006. A total of 3492 women were screened and 1485 women meeting the respective study eligibility criteria were enrolled. T vaginalis infection was determined at the initial screening visit and at quarterly visits among the enrolled women. Sexual behaviour and sociodemographic data were collected as per the study protocol. Combined data were analysed using STATA V.10.0. **RESULTS:** At baseline, prevalence of infection was 6.5%. The overall incident rate was estimated to be 8.6/100 women-years. Prevalent T vaginalis infection was associated with having a concurrent chlamydial infection and incident



infections were associated with increased number of sex partners. CONCLUSIONS: T vaginalis infection was found to be relatively high among this cohort of women. Given the association of this infection with HIV, there is an evident need for T vaginalis screening and treatment in populations at risk for both infections.

Pentlicky S, Rosen M, Coffey PS, Kilbourne-Brook M, Shaunik A, Schreiber CA, et al. An exploratory, randomized, crossover (MRI) study of microbicide delivery with the SILCS diaphragm compared to a vaginal applicator. *Contraception* 2013; 87(2): 187-92.

BACKGROUND: Microbicide gels studied for HIV prevention often are delivered via a single-use vaginal applicator. Using a contraceptive diaphragm such as the SILCS diaphragm for gel delivery could have advantages, including lower cost and additional pregnancy prevention. STUDY DESIGN: We performed an exploratory, nonblinded, randomized, crossover study among healthy, sexually active, nonpregnant women. Using BufferGel, we evaluated three microbicide delivery methods for gel distribution and retention: SILCS single-sided gel delivery, SILCS double-sided gel delivery and a vaginal applicator (without SILCS). Magnetic resonance images were taken at baseline, after gel insertion, and immediately and 6 h after simulated intercourse. Three women completed all gel delivery methods described in this article. RESULTS: Magnetic resonance imaging analysis indicated similar gel spread in the vagina among all three methods. SILCS single-sided gel application resulted in the most consistent longitudinal coverage; SILCS double-sided gel application was the most consistent in the transverse dimension. CONCLUSIONS: Gel coverage was similar with all three methods. These results suggest that the SILCS microbicide delivery system is comparable to vaginal applicators for delivery of gel products intravaginally.

2012

Frezieres RG, Walsh T, Kilbourne-Brook M, Coffey PS. Couples' acceptability of the SILCS diaphragm for microbicide delivery. *Contraception* 2012; 85(1): 99-107.

Background: Disposable plastic applicators used in microbicide gel studies are expensive and have a negative environmental impact. The SILCS diaphragm is a barrier contraceptive that could offer a reusable delivery system. Study design: Thirty-six couples in this randomized, cross-over study evaluated single- and double-sided gel delivery from a SILCS diaphragm compared with gel from an applicator. Couples used each gel scenario during two acts of intercourse and completed acceptability questionnaires after each. Results: All three scenarios received favorable ratings for ease of application, acceptability and perceived effectiveness. Both female and male participants tended to rate the gel applicator significantly more favorably than either SILCS gel delivery scenarios for all attributes except messiness/leakage and effectiveness. Additionally, about 60% of female participants and about half of male participants preferred the gel applicator to either of the gel delivery systems using SILCS. The preference for the SILCS scenario for pregnancy protection was statistically significant for both sexes. Male participants were also significantly more likely to prefer the SILCS single-sided delivery system to the gel applicator for protection from sexually transmitted infection. Conclusions: In this study population, participants found the gel applicator to be more acceptable than either single- or double-sided gel delivery from a SILCS diaphragm. Further research of the SILCS as a microbicide delivery system should be implemented to assess its acceptability among study populations that reflect diverse potential user groups such as women and men from both low and high HIV prevalence settings including HIV-positive populations and with and without experience using female barrier methods.

Kacanek D, Dennis A, Sahin-Hodoglugil NN, Montgomery ET, Morar N, Mtetwa S, Nkala B, Phillip J, Watadzaushe C, van der Straten A, the MIRA Team. A qualitative study of obstacles to diaphragm and condom use in an HIV prevention trial in Sub-Saharan Africa. *AIDS Education and Prevention* 2012; 24(1): 54-67.



Consistent condom use and the substitution of condoms with potential HIV prevention methods of lower or unknown effectiveness are important concerns in the development of new prevention technologies. This qualitative study explored obstacles to consistent condom use with the diaphragm in MIRA, an HIV prevention trial in South Africa and Zimbabwe. We conducted 26 focus group discussions (FGDs) with 206 women and 7 FGDs and 10 in-depth interviews with 41 male partners of intervention-arm women. The belief that the diaphragm/gel prevented HIV, women's difficulties negotiating condom use, and men's unawareness that using the products together was recommended were obstacles to consistent condom use with the diaphragm/gel. Concerns about protection from HIV and pregnancy, recognition that the diaphragm was not yet proven to prevent HIV or sexually transmitted infections, and the trial context were facilitators. Understanding selective study product use in HIV prevention trials may inform improved adherence counseling and male involvement strategies.

van der Straten A, Montgomery E, Mavedzenge S, Musara P, Cheng H, Lutnick A, Woodsong C. Preference between precoital and daily use of Duet((R)) and BufferGel in Zimbabwe. *AIDS Behav* 2012; 16(7): 1799-1807.

Duet((R)) is a microbicide-delivery system and cervical barrier for use daily or precoitally. We conducted a crossover study among 80 Zimbabwean women to explore factors associated with use-regimen preference. Women were assigned in random order to 14 days of precoital and 14 days of daily Duet and BufferGel use. About 51 % of women preferred precoital use, 39 % preferred daily use, and 10 % liked both equally. Overall product adherence during sex was similar for both use-regimens. In multivariable analysis, diaphragm experience was associated with preference for precoital use (AOR 2.80, 95 % CI 1.01-7.76). Reasons for preferring precoital use included use only when needed, cleanliness, and discomfort with daily use. Daily use preference included convenience, discreetness, and being prepared for "sex-on-demand." Different personal and life circumstances may result in varying use-regimen preferences. Methods that can accommodate both coitally-related and daily use may be advantageous by providing more choice to users.

2011

de Bruyn G, Shiboski S, van der Straten A, Blanchard K, Chipato T, Ramjee G, Montgomery E, Padian N, The MIRA Team. The effect of the vaginal diaphragm and lubricant gel on acquisition of HSV-2. *Sexually Transmitted Infections* 2011; 87(4): 301-305.

Background: In the context of a multisite HIV prevention trial in Southern African women, we examined the effectiveness of the Ortho All-Flex Diaphragm, lubricant gel (Replens) and condoms compared to condoms alone on the incidence of herpes simplex virus type 2 (HSV-2) infections. Methods: We analysed data from 2016 sexually active women in Zimbabwe and South Africa. Women were followed quarterly, and specimens obtained at the closing visit from previously HSV-2 seronegative women were retested for HSV-2 antibodies using Focus HerpeSelect Elisa. The first visit at which the participant tested positive for HSV-2 was defined by back-testing. We compared the incidence of HSV-2 after randomisation between study arms in both intent-to-treat (ITT) and per-protocol populations. Results: 210 women acquired HSV-2 during study participation (HSV incidence: 6.8 cases/100 women years). Allocation to the intervention arm was found to offer no benefit in reduction of HSV-2 by modified ITT (HR 1.03, 95% CI 0.78 to 1.35; p=0.85) or per protocol analysis (HR 0.87, 95% CI 0.61 to 1.24; p=0.45). Conclusions: HSV-2 infection was common in the study population as detected by type-specific Elisa testing. Provision of diaphragm and lubricant gel offered no additional protection against HSV-2 acquisition over male condoms alone.

Montgomery ET, van der Straten A, Chidanyika A, Chipato T, Jaffar S, Padian N. The importance of male partner involvement for women's acceptability and adherence to female-initiated HIV prevention methods in Zimbabwe. *AIDS and Behavior* 2011; 15(5): 959-969.



Enlisting male partner involvement is perceived as an important component of women's successful uptake of female-initiated HIV prevention methods. We conducted a longitudinal study among a cohort of 955 Zimbabwean women participating in a clinical trial of the effectiveness of a female-initiated HIV prevention method (the diaphragm and lubricant gel) to: (a) describe the extent to which women involved their male partners in the decision to use the study products, and (b) measure the effect perceived male partner support had on their acceptability and consistent use of these methods. Reported levels of male partner involvement in discussions and decisions regarding: joining the study, study activities, the outcome of HIV/STI test results, and product use were very high. In multivariate analyses, regular disclosure of study product use and partner approval for the diaphragm and gel were significantly associated with women's acceptability and consistent use of the products; an essential component for determining efficacy of investigational prevention methods. These results support the need for more sophisticated measurement of how couples interact to make decisions that impact study participation and investigational product use as well as more rigorous adaptations and evaluations of existing strategies to involve male partners in female-initiated HIV prevention trials.

Sahin-Hodoglugil NN, Montgomery E, Kacanek D, Morar N, Mtetwa S, Nkala B, Philip J, Ramjee G, Cheng H, van der Straten A, The MIRA Team. User experiences and acceptability attributes of the diaphragm and lubricant gel in an HIV prevention trial in southern Africa. *AIDS Care* 2011; 23(8): 1026-1034.

Methods for Improving Reproductive Health in Africa (MIRA), a phase III HIV prevention trial, was conducted among 5039 Zimbabwean and South African women to test the Ortho All-Flex diaphragm and Replens lubricant gel. Among the 2418 intervention group participants, 105 women who had completed the trial and 41 male partners participated in focus group discussions and in-depth interviews about the acceptability of the diaphragm and gel and their experiences using the study products. Women who participated in the qualitative study had exited the trial in the prior nine months, were HIV negative, and used the diaphragm and gel for 12-24 months. The comprehensive and flexible conceptual framework was applied to investigate the salient attributes for acceptability of the products as potential HIV prevention methods, and emerging themes for acceptability were framed within three categories of attributes (product, relationship, and sexual intercourse attributes). Both diaphragm and gel were found to be highly acceptable in the study group, and the gel was popular due to its effect of enhancing sexual pleasure. Some of the important product attributes influencing acceptability as reported by users were convenience, ease of use, dual use potential for contraception and disease prevention, and being female-initiated. It was also noted that some elements (such as sexual pleasure, couple communication, and the necessity of diaphragm negotiation) could be more important than others in terms of influencing product acceptability and use. Acceptability attributes reflective of the broader contextual environment (beliefs generated in the trial community suggesting preventive efficacy - preventive method optimism - and gendered norms favoring male superiority in sexual decision making) also emerged as important themes. The high level of acceptability of the diaphragm and gel among MIRA trial participants and their male partners is an indicator of the continued need for an effective female-initiated product.

2010

Coffey PS, Kilbourne-Brook M. Wear and care of the SILCS diaphragm: Experience from three countries. *Sexual Health* 2010; 7: 59-164.

Women have been regularly underestimated in their ability to care for and wear cervical barrier devices such as diaphragms appropriately. Methods: Data from two non-randomised, non-blinded, non-significant risk acceptability studies of a novel cervical barrier device, the SILCS diaphragm, conducted in the Dominican Republic (n = 20), South Africa (n = 21) and Thailand (n = 20), are used to provide insights into the fundamental question of how women actually use an intravaginal device within the constraints of low-resource settings. In all



sites, couples not at risk of pregnancy and at low risk of sexually transmissible infections used the SILCS diaphragm four times and provided feedback on acceptability, care and use of the device via product use questionnaires and gender-specific debriefing interviews. Results: Data from user acceptability studies in these three countries provide an intimate view of how women care for and store the SILCS diaphragm, and both female and male perceptions about handling and re-using it. Results support the view that women are able to wear and care for diaphragms successfully in a variety of settings. In general, male partners were also supportive of care and reuse of the diaphragm. Conclusions: While the results from these studies indicate that women are able to find ways to cope successfully with the logistics of wearing and caring for an intravaginal device, further supportive evidence from a woman-centred perspective is crucial for reproductive health policymakers and program managers. The authors contend that it is time to reassess perceived constraints to barrier protection.

Holmes W. Adding to the menu of modern methods – the diaphragm. *Sexual Health* 2010; 7: 101-102.

Editorial summary: Although not suitable for all, many women in low-income settings could benefit if they were able to choose the diaphragm, especially a one-size-fits-all version. Research is needed to establish efficacy when the diaphragm is used continuously and without spermicide.

Kulczycki A, Qu H, Bosarge PM, Shewchuk RM. Barriers to diaphragm use: The views of advanced nurses. *Journal of Family Planning and Reproductive Health Care* 2010; 36(2): 79-82.

Background and Methodology: Women have used the contraceptive diaphragm for decades. Although use has recently declined, the diaphragm may find a new role in STI/HIV and dual prevention programmes when microbicides become available. We developed a questionnaire to examine seven provider issues identified as possible barriers to diaphragm use among advanced practice nurses (APNs) specialising in women's health. The perceived degree to which each issue represented a barrier was examined. Non-parametric correlations were calculated between diaphragm fitting history, demographic and practice characteristics, and the response ratings for each issue. Results: Responses were analysed for 204 APNs who averaged 15 years' experience in women's health care; 87% had fitted a diaphragm at least once, but 40% had not prescribed one in the past year. The degree to which each issue was perceived as a barrier varied. Based on respondents' ratings of a 'more than moderate barrier,' diaphragm non-promotion by women's health providers, effectiveness doubts, unfamiliarity and lack of access to educational materials were more often perceived as impeding diaphragm use. Other results indicated that APNs with recent diaphragm fitting history perceived five of the seven issues to be less of a barrier: nonpromotion by women's health providers, lack of access to educational materials and to a fitting set, unfamiliarity, and inadequate reimbursement. Discussion and Conclusions: Formulation of successful strategies to reintroduce the diaphragm will depend on better identification and understanding of provider-perceived barriers. This paper offers new insights about such barriers and guidance for the development of strategies for diaphragm reintroduction.

Montgomery ET, Cheng H, van der Straten A, Chidanyika AC, Lince N, Blanchard K, Ramjee G, Nkala B, Padian NS, and The MIRA team. Acceptability and use of the diaphragm and Replens® lubricant gel for HIV prevention in Southern Africa. *AIDS and Behavior* 2010; 14(3): 629-638.

The acceptability and use of the diaphragm and lubricant gel were assessed as part of a large randomized controlled trial to determine the effectiveness of the methods in women's HIV acquisition. 2,452 intervention-arm women were enrolled at five Southern African clinics and followed quarterly for 12-24 months. Acceptability and use data were collected by face-to-face interviews at Month 3 and Exit. Participants were "very comfortable" with the physical mechanics of diaphragm use throughout the trial, and approval of the gel consistency, quantity, and the applicator was high. At Exit, consistent disclosure of use (AOR 1.97, 95% CI: 1.10-3.55); an overall high diaphragm rating (AOR 1.84, 95% CI: 1.45-2.34); and perception of partner approval (AOR 1.75, 95% CI: 1.35-2.26) were the most significant acceptability factors independently associated with consistent use. Despite being female-initiated, disclosure of use to male partners and his perceived approval of the products were factors significantly associated with their consistent use.



Njoroge B, Gallo MF, Sharma A, Bukusi EA, Nguti R, Bell AJ, Jamieson DJ, Williams D, Eschenbach DA. Diaphragm for STI and HIV prevention: Is it a safe method for women at high risk? *Sexually Transmitted Diseases* 2010; 37(6): 382-385.

Female sex workers (n = 140) were enrolled in a six-month acceptability trial of the diaphragm. We randomized a subset (n = 40) to receive colposcopies after one month of diaphragm use or after one month of observation before commencing diaphragm use. Adverse events were mild in nature. Frequency of colposcopic findings did not differ between women randomized to immediate versus delayed diaphragm use (P = 0.25).

Shihata A, Brody S. HIV prevention by enhancing compliance of Tenofovir microbicide: Using a novel delivery system. *HIV&AIDS Review* 2010; 9(4): 105-108.

Background: CAPRISA 004 (Centre for the AIDS Programme of Research in South Africa) revealed that women who had high self-reported adherence with Tenofovir microbicide application achieved a 54% reduction in HIV seroconversion in comparison to placebo. Conversely, there was only a 28% reduction in the poor compliance group. Materials and Methods: To enhance the adherence of Tenofovir application, we investigated an alternative to the vaginal applicator which was used before and after intercourse in CAPRISA study. The FemCap contraceptive device has a unique delivery system for microbicides on its cervical and vaginal sides to ensure better coverage, and retention of gel on the cervix and vagina. To evaluate this delivery system, 20 women compared the use of the vaginal applicator to deliver a vaginal lubricant before and after intercourse versus the FemCap to deliver the same lubricant once before intercourse. Results: Forty percent of women missed the application of the lubricant with the vaginal applicator before intercourse and 10% missed it after intercourse. Of the FemCap users, 10% missed application of the vaginal lubricant before intercourse and both inserted it after intercourse. The gel was better retained over the cervix by single application with the FemCap versus two applications with the applicator. Conclusions: Participants preferred the FemCap, due to elimination of leakage and the single application, versus two applications with the vaginal applicator. The increased adherence and retention of gel over the cervix by using the FemCap may potentially increase the efficacy of Tenofovir.

van der Straten A, Sahin-Hodoglugil N, Clouse K, Mtetwa S, Chirenje MZ. Feasibility and potential acceptability of three cervical barriers among vulnerable young women in Zimbabwe. *J Fam Plann Reprod Health Care* 2010; 36(1): 13-19.

Background: We explored the potential acceptability of three cervical barriers (CB) (Ortho All-Flex® diaphragm, SILCS® diaphragm, FemCap™ cervical cap) among sexually experienced Zimbabwean young women. Methods: Forty-five young women (aged 16–21 years) received an individual CB educational session. Participants were then randomly assigned to one of the three CBs in a 1:1:1 ratio, and practised insertion and removal of their device at the clinic. Next, participants were interviewed on their practice experiences, and their post-practice attitudes towards CB. Results: All 45 young women were willing and able to insert their assigned device. The majority reported “easy” insertion and removal and 93% “liked” the device they tried. All showed interest in participating in future CB studies: when asked which device they would like to try in the future, over half (58%) chose SILCS, regardless of the device they had tried. The majority felt comfortable touching their genitals to insert/remove the CB and most participants favoured methods’ attributes associated with female-control and non-interference with sex. Over half the participants said they would prefer to use a CB continuously compared to episodic use. Two-thirds of them expressed interest in CB for dual protection. Conclusion: The concept of CB, and initial insertion experience, were well accepted in this selected, small group of Zimbabwean young women. Evaluating CB in larger studies seems feasible in this population.

van der Straten A, Cheng H, Minnis AM. Change in condom and other barrier method use during and after an HIV prevention trial in Zimbabwe. *Journal of the International AIDS Society* 2010; 13(39): 1-11.



Background: We examined the use of male condoms and the diaphragm following completion of a clinical trial of the diaphragm's HIV prevention effectiveness. In the trial, called Methods for Improving Reproductive Health in Africa (MIRA), women were randomized to a diaphragm group (diaphragm, gel, and condoms) or a condom-only control group. At trial exit, all women were offered the diaphragm and condoms. Methods: Our sample consisted of 801 Zimbabwean MIRA participants who completed one post-trial visit (median lapse: nine months; range two to 20 months). We assessed condom, diaphragm, and any barrier method use at last sex act at enrolment, final MIRA, and post-trial visits. We used multivariable random effects logistic regression to examine changes in method use between these three time points. Results and Discussion: In the condom group, condom use decreased from 86% at the final trial visit to 67% post trial (AOR = 0.20; 95% CI: 0.12 to 0.33). In the diaphragm group, condom use was 61% at the final trial visit, and did not decrease significantly post trial (AOR = 0.77; 95% CI: 0.55 to 1.09), while diaphragm use decreased from 79% to 50% post trial (AOR = 0.18; 95% CI: 0.12 to 0.28). Condom use significantly decreased between the enrolment and post-trial visits in both groups. Use of any barrier method was similar in both groups: it significantly decreased between the final trial and the post-trial visits, but did not change between enrolment and the post-trial visits. Conclusions: High condom use levels achieved during the trial were not sustained post trial in the condom group. Post-trial diaphragm use remained relatively high in the diaphragm group (given its unknown effectiveness), but was very low in the condom group. Introducing —new|| methods for HIV prevention may require time and user skills before they get adopted. Our findings underscore the potential benefit of providing a mix of methods to women as it may encourage more protected acts.

von Mollendorf CE, Van Damme L, Moyes JA, Rees VH, Callahan MM, Mauck CK, Puren AJ, Tweedy K, Taylor D. Results of a safety and feasibility study of the diaphragm used with ACIDFORM Gel or K-Y® Jelly. *Contraception* 2010; 81(3): 232-239.

New strategies are needed for preventing HIV infection in women. One potential approach is female-initiated use of an effective topical microbicide in combination with a cervical barrier such as the diaphragm. Study design: Randomized, placebo-controlled safety and feasibility trial of diaphragm with vaginal gel during 6 months of use among 120 HIV-negative sexually active women in Johannesburg, South Africa. Results: Pelvic event rates were 338.3 and 247.1 per 100 women-years in the ACIDFORM gel (plus diaphragm) and K-Y® Jelly (plus diaphragm) groups, respectively, with a rate ratio of 1.37 (95% CI: 0.89-2.11). Most women found diaphragm with gel use acceptable. Conclusion: There was a trend towards more safety events in the ACIDFORM plus diaphragm group, although no primary comparisons achieved statistical significance. Adding an effective microbicide gel to a mechanical barrier may still prove to be an important and acceptable combination method to help prevent pregnancy and HIV/sexually transmitted infection transmission.

2009

Anderson DJ, Williams DL, Ballagh S, Barnhart K, Creinin MD, Newman DR, Bowman FP, Politch JA, Duerr AC, Jamieson DJ. Safety analysis of the diaphragm in combination with lubricant or acidifying microbicide gels: Effects on markers of inflammation and innate immunity in cervicovaginal fluid. *American Journal of Reproductive Immunology* 2009; 61(2): 121-129.

Objective: Diaphragms are being considered for use with vaginal microbicide gels to provide enhanced protection against sexually transmitted pathogens. The purpose of this study was to determine whether use of a diaphragm with microbicide or placebo gel causes cervicovaginal inflammation or perturbations in cervicovaginal immune defense. Method of study: Eighty-one non-pregnant women were randomized into three groups and instructed to use Milex® (CooperSurgical, Inc., Trumbull, CT, USA) diaphragms overnight for 14 days in combination with one of the two acid-buffering microbicide gels [ACIDFORM2122 (Instead Inc., La Jolla, CA, USA) or



BufferGel2122 (BG; ReProtect Inc., Baltimore, Maryland)] or placebo gel (K-Y Jelly®; Personal Products Inc., Raritan, NJ, USA). Cervicovaginal lavages (CVLs) were performed prior to study entry and on days 8 and 16. Nine soluble mediators of vaginal inflammation or immune defense were measured in CVLs by Bio-Plex or ELISA. Results: Use of diaphragms with placebo or microbicide gel was not associated with increased levels of inflammation markers. Concentrations of secretory leukocyte protease inhibitor (SLPI) were markedly reduced in the BG group. Conclusion: Daily use of a diaphragm with placebo or acidifying microbicide gel did not cause cervicovaginal inflammation. However, diaphragm/BG use was associated with markedly reduced levels of SLPI, an important mediator of innate immune defense. Further studies are warranted to establish the safety of diaphragm/microbicide gel combinations.

Averbach S, Sahin-Hodoglugil N, Musara P, Chipato T, van de Straten A. Duet® for menstrual protection: A feasibility study in Zimbabwe. *Contraception*. 2009; 79(6): 463-468.

Background: Managing menses is a challenge for women in developing countries. Duet® is a cervical barrier being developed for contraception and STI prevention. We explored the hypothetical acceptability of using Duet as a menstrual cup, among Zimbabwean women. Study Design: A survey and focus group discussions (FGD) were conducted with 43 women aged 18–45 years to gain information about their menstrual practices and attitudes regarding the use of Duet for menstrual protection. Results: All 43 women reported that if Duet were available, they would “definitely” try it, and that it was “very important” that Duet is low cost and easy to clean; 86% reported that using it would make a difference in their lives. FGD findings highlighted unhygienic practices due to the lack of affordable options for menstrual management and a genuine interest in Duet, including its potential use for multiple purposes (contraception, disease prevention and menstrual protection). Conclusions: Accessing affordable and hygienic menstrual protection was a problem for these Zimbabwean women. Duet appeared acceptable and it would be feasible to conduct a user-acceptability study of Duet as a menstrual cup in Zimbabwe.

Bukusi EA, Gallo MF, Sharma A, Njoroge B, Jamieson DJ, Nguti R, Bell AJ, Eschenbach DA. Adherence to diaphragm use for infection prevention: A prospective study of female sex workers in Kenya. *Infectious Diseases in Obstetrics and Gynecology* 2009; 2009:1-11.

Objective: To assess adherence to and acceptability of the diaphragm among 140 female sex workers in Kenya in a six-month prospective study. Methods: At baseline and bimonthly visits, participants were interviewed on diaphragm knowledge, attitude, and practices. We used principal component analysis and logistic regression to identify predictors of consistent use. Results: At 50% of 386 bimonthly visits, women reported consistently using a diaphragm with all partners during the preceding two weeks. Consistent use was significantly higher at the six-month than the two-month visit. Women reported less covert use with "helping" (regular sex partners to whom she could go for help or support) than with "other" partners. Perceptions that diaphragms are easier to use than condoms and that their lack of coital interruption is important were associated with consistent diaphragm use with both partner types. Partner support of diaphragm use is correlated with consistent use with "helping" partners only while higher parity, consistent condom use, and perceived lack of need of condoms as a benefit of diaphragms were associated with consistent use with "other" partners. Conclusions: Diaphragm acceptance among female sex workers in Nairobi was high. Future studies should distinguish between partner types when evaluating diaphragm adherence.

Khan MR, Turner AN, Pettifor A, Van Damme K, Rabenja NL, Ravelomanana N, Swezey T, Williams D, Jamieson D, Behets F. Unmet need for contraception among sex workers in Madagascar. *Contraception* 2009; 79(3): 221-227.

Background: The study was conducted to investigate past and future pregnancy preferences and contraceptive need among Malagasy sex workers. Study Design: We analyzed data on pregnancy and contraceptive use collected during the baseline visit of a randomized, prospective formative trial which assessed diaphragm and



microbicide acceptability among sex workers. To be eligible, women could not be pregnant or planning pregnancy for the next 2 months. Results: Women (N=192) from four cities (Antananarivo, Antsiranana, Mahajanga and Toamasina) reported a median of 10 sex acts per week. Fifty-two percent reported a prior unwanted pregnancy, 45% at least one induced abortion and 86% that preventing future pregnancy was moderately to very important. During the last sex act, 24% used a hormonal method, 36% used a male condom, 2% used a traditional method and 38% used no method. Nearly 30% of participants reported that pregnancy prevention was moderately or very important but used no contraception at last sex; these women were categorized as having "unmet need" for contraception. In multivariable binomial regression analyses, factors associated with unmet need included low knowledge of contraceptive effectiveness [age- and site-adjusted prevalence ratio (PR): 2.1; 95% confidence interval (CI): 1.4-3.0] and low self-efficacy to negotiate condom use (age- and site-adjusted PR: 2.0; 95% CI: 1.4-3.0). Conclusions: Among these women, prior unwanted pregnancy and induced abortion were common and preventing future pregnancy was important, yet gaps in contraceptive use were substantial. Contraceptive knowledge and self-efficacy should be improved to promote contraceptive use by sex workers.

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

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

Turner AN, Van Damme K, Jamieson DJ, Khan MR, Pettifor AE, Swezey TA, Bell AJ, Newman DR, Penman-Aguilar A, Raharinivo MS. Predictors of adherent use of diaphragms and microbicide gel in a four-arm, randomized pilot study among female sex workers in Madagascar. *Sexually transmitted diseases* 2009; 36(4):249-257.

Background: Participants' protocol adherence may influence assessments of the effectiveness of new female-controlled methods for sexually transmitted infection prevention. Methods: In 2005 we conducted a randomized pilot study among female sex workers (FSWs) in Madagascar in preparation for sexually transmitted infection prevention trial of diaphragms and a vaginal microbicide. Participants (n = 192) were randomized into 4 arms: diaphragm plus microbicide (Acidform), diaphragm plus placebo gel hydroxyethyl cellulose (HEC), Acidform alone, or HEC alone. FSWs were seen weekly for 4 weeks. Using multivariable regression with generalized estimating equations, we assessed predictors of adherent product use during all sex acts in the last week. We collapsed the gel-diaphragm arms together and the gel-only arms together for this analysis. Results: Between 43% and 67% of gel-diaphragm users (varying by visit) reported using study products during all sex acts in the last week, compared with 20% to 45% of gel-only users. Adherence increased with follow-up [visit 4 vs. visit 1 risk ratio (RR) for gel-diaphragm users: 1.55, $P < 0.01$; for gel-only users, RR: 1.58, $P = 0.01$]. Gel-diaphragm users whose casual partners were never aware of products (RR: 2.02, $P = 0.03$) and who had experienced partner violence after requesting condom use (RR: 1.45, $P < 0.01$) were more adherent. Gel-only users reporting lower sexual frequency (1-9 weekly acts vs. ≥ 10 acts, RR: 1.98, $P < 0.01$) and no sex with primary partners in the past week (RR: 1.54, $P = 0.02$) were more adherent. Conclusions: Gel-diaphragm users had better adherence than gel-only users, and predictors of adherence differed between groups. Addressing modifiable factors during counseling sessions may improve adherence.



van der Straten A, Shiboski S, Montgomery ET, Moore J, Bruyn GD. Patterns and predictors of adherence to diaphragm use in a phase III trial in Sub-Saharan Africa: A trajectory analysis. *JAIDS Journal of Acquired Immune Deficiency Syndromes* 2009; 50(4): 419.

Background: We examined diaphragm adherence among 2429 women randomized to the intervention arm (diaphragm + gel + condoms) in Methods for Improving Reproductive Health in Africa, a phase III trial of the diaphragm for HIV prevention in Zimbabwe and South Africa. Methods: Women were followed for a median of 7 quarterly visits (range: 1-8 quarterly visits) during which diaphragm adherence was assessed. We conducted trajectory analyses to identify behavioral groups associated with specific diaphragm adherence patterns. Multivariate multinomial logistic regression was used to identify baseline characteristics associated with higher probability of being in a particular trajectory group. Results: Diaphragm uptake was very high (3.1% never used diaphragms). However, diaphragm adherence was reported at only 49% of visits. Women were clustered into 4 diaphragm adherence groups based on their highest estimated group membership probability: low adherers (31.0%), decreasing adherers (28.9%), increasing adherers (9.3%), and high adherers (30.8%). Women classified as high adherers (as compared with low adherers) were more likely to be older [adjusted odds ratio (AOR) = 1.09, 95% confidence interval (CI): 1.07 to 1.11] and to report baseline condom adherence (AOR = 2.00, 95% CI: 1.47 to 2.71). They were less likely to have high-risk behavior (AOR = 0.51; 95% CI: 0.37 to 0.71) and to have high-risk partners (AOR = 0.58; 95% CI: 0.43 to 0.78). They were most likely to be from the Zimbabwe site (AOR = 2.82; 95% CI: 1.89 to 4.20) and least likely to be from the Johannesburg site (AOR = 0.51; 95% CI: 0.37 to 0.77). Conclusion: This analytic approach could help to identify high compliers for enrollment in future HIV prevention trials or the types of participants who may need intensive adherence counseling during follow-up.

2008

Ballagh SA, Brache V, Mauck C, Callahan MM, Cochon L, Wheelless A, Moench TR. A Phase I study of the functional performance, safety and acceptability of the BufferGel® Duet(TM). *Contraception* 2008; 77(2): 130-137.

Background: The purpose of this study was to assess the functional performance of the BufferGel® Duet(TM), a buffering microbicide and spermicide gel applied to the cervix and vagina by a novel applicator that also serves as a mechanical barrier. Study Design: This was a noncomparative Phase I safety trial in 30 healthy couples, aged 20-50 years, at low risk for sexually transmitted infections, who agreed to use the gel-device combination twice in 1 week and respond to detailed questionnaires about their experience. The female participants were examined with colposcopy before and 6-18 h after using the second device. Results: Based on written instructions alone, 25 women successfully placed and 28 women successfully removed the device. Three women reported feeling the device dislodge around the time of intercourse. The product was equally acceptable to both men and women. Most users concluded that intercourse was the same or better with the device than with no product. About 73% would choose Duet over male condoms, and no one preferred the standard diaphragm. Colposcopic findings were noted in 79% of women with external genital findings (9) or cervicovaginal peeling (18) predominating. Only one finding breached the epithelium. Most product-related adverse events were mild (10/11) and confined to the genitourinary tract. Conclusions: The successful placements and acceptability suggest that further product development is warranted and could target over-the-counter use. During increased duration of use or more frequent dosing, cervicovaginal monitoring is advised based on the extent of peeling and external colposcopic findings in this short-term study.

Behets FM, Van Damme K, Turner AN, Rabenja NL, Ravelomanana N, Raharinivo M, Zeller KA, Rennie SM, Swezey TA. Evidence-based planning of a randomized controlled trial on diaphragm use for prevention of sexually transmitted infections. *Sexually Transmitted Diseases* 2008; 35(3): 238.



Objectives: We conducted formative research to evaluate the acceptability and feasibility of continuous diaphragm use among low-income women highly exposed to sexually transmitted infections (STIs) in Madagascar. **Goal:** To identify potential obstacles to researching the effectiveness of diaphragm use for STI prevention in a randomized controlled trial. **Study Design:** Mixed methods to collect complex information. In a quantitative pilot study, women were asked to use diaphragms continuously (removing once daily for cleaning) for 8 weeks and promote consistent male condom use; they were interviewed and examined clinically during follow-up. Focus group discussions (FGDs) were conducted pre-/postpilot study. Audiotaped FGDs were transcribed, translated, coded, and analyzed. **Results:** Ninety-three women participated in prepilot FGDs, 91 in the pilot study, and 82 in postpilot FGDs. Diaphragm use was acceptable and feasible, but participants reported lower condom use in FGDs than during interviews. Most participants reported in interviews that they used their diaphragms continuously, but FGDs revealed that extensive intravaginal hygiene practices may impede effective continuous diaphragm use. Despite counseling by study staff, FGDs revealed that participants believed the diaphragm provided effective protection against STIs and pregnancy. **Conclusions:** Mixed methods formative research generated information that the prospective pilot study alone could not provide and revealed contradictory findings. Results have methodological and ethical implications that affect trial design including provision of free hormonal contraceptives, and additional instructions for vaginal hygiene to avoid displacing the diaphragm. Mixed methods formative research should be encouraged to promote evidence-based study design and implementation.

Behets FM, Turner AM, Van Damme K, Rabenja NL, Ravelomanana N, Swezey TA, Bell AJ, Newman DR, D'Nyce LW, Jamieson DJ. Vaginal microbicide and diaphragm use for sexually transmitted infection prevention: A randomized acceptability and feasibility study among high-risk women in Madagascar. *Sexually Transmitted Diseases* 2008; 35(9): 818.

Background: In preparation for a randomized controlled trial (RCT), we conducted a pilot RCT of the acceptability and feasibility of diaphragms and candidate vaginal microbicide for sexually transmitted infection prevention among high-risk women in Madagascar. **Methods:** Participants were randomized to four arms: (1) diaphragm (worn continuously) with Acidform(TM) applied in the dome; (2) diaphragm (worn continuously) with placebo gel hydroxyethylcellulose (HEC) in the dome; (3) HEC applied intravaginally before sex; (4) Acidform applied intravaginally before sex. All women were given condoms. Participants were followed weekly for 4 weeks. We fit unadjusted negative binomial regression models with robust variance estimators to generate the proportion of sex acts with casual partners where condoms and experimental study products were used. **Results:** Retention was 98% among 192 participants. Experimental product use with casual partners was high, reported in 85%, 91%, 74%, and 81% of sex acts for women in the Acidform-diaphragm, HEC-diaphragm, HEC-alone, and Acidform-alone arms, respectively. However, the proportion reporting product use during 100% of acts with casual partners over the full follow-up period was much lower: 28% to 29% in the gel-diaphragm arms and 6% to 10% in gel-alone arms. Women used condoms in 62% to 67% of sex acts with casual partners, depending on the randomization arm. Participants found diaphragms easy to insert (97%) and remove (96%). Acidform users (with or without the diaphragm) reported more genitourinary symptoms than HEC users (14% vs. 5% of visits). **Conclusions:** A sexually transmitted infection prevention RCT of candidate microbicide with and without the diaphragm appears acceptable and feasible in this population.

Chersich M. Secrecy, disclosure and accidental discovery: Perspectives of diaphragm users in Mombasa, Kenya. *Culture, Health & Sexuality* 2008; 10(1): 13-26.

The diaphragm is receiving renewed attention as a promising female-controlled method of preventing HIV and other sexually-transmitted infections. It is anticipated that female-controlled technologies will reduce women's biological susceptibility and assist in counteracting their sociocultural vulnerability to HIV. Understanding the subjective experiences of diaphragm users in different settings has the potential to inform the development and promotion of such methods. This paper explores the perspectives of female sex workers and women attending



sexual and reproductive health services in Mombasa, Kenya. Data are reported from focus group discussions and in-depth interviews with women and men, following a prospective study investigating diaphragm continuation rates over six months. Discussions highlighted covert use of the diaphragm, during sex work or with casual partners, and coital independence as favourable attributes. These features were especially pronounced compared with male condoms. Few difficulties with diaphragm use were reported, although its insertion and removal occasionally presented problems. Many women-especially those in long term partnerships-wished to disclose its use but found the disclosure process highly problematic. Accidental discovery often resulted in partner conflict. Although future uptake of the diaphragm may be high in this setting, its use may be limited to certain types of relationships and relationship context.

Coffey PS and Kilbourne-Brook M. Comparative acceptability of the SILCS and Ortho ALL-FLEX® diaphragms among couples in the Dominican Republic. *Contraception* 2008; 78(5): 418-423.

Background: The SILCS diaphragm is a new, single-size contraceptive diaphragm. The objective of this crossover pilot study was to assess the fit and acceptability of the SILCS diaphragm compared to the Ortho ALL-FLEX® diaphragm to validate the product design among parous women in a low-resource setting. Study Design: Sexually active couples not at risk of pregnancy and at low risk of sexually transmitted infection were recruited and randomly assigned to one of two groups to determine order of device use. Couples used each device four times and provided feedback on key performance indicators via product-use questionnaires, a simple coital log and a gender-specific debriefing interview. Results: Twenty couples provided data on a total of 160 product uses (80 for each device). Couples indicated that both diaphragms were acceptable with respect to ease of use, comfort and satisfaction with sex. At the end of the study, 19 of 20 women and 15 of 20 men reported preferring the SILCS diaphragm over the Ortho diaphragm ($p < .01$ for both). Conclusion: Short-term acceptability of the SILCS and Ortho diaphragms during use was comparable, although overall both women and men preferred the SILCS diaphragm over the Ortho diaphragm. Acceptance of diaphragms in general, and the SILCS diaphragm in particular, is likely among couples willing to use a barrier method.

Coffey PS, Kilbourne-Brook M, Beksinska M, Thongkrajai E. Short-term acceptability of a single-size diaphragm among couples in South Africa and Thailand. *Journal of Family Planning and Reproductive Health Care* 2008; 34: 233-236.

Background: The SILCS diaphragm is a new, reusable, single-size cervical barrier device that is designed to offer the same barrier protection as a standard diaphragm with improved user acceptability. Methods: This non-randomised, non-blinded, non-significant risk, multi-site pilot study assessed the short-term acceptability of the SILCS diaphragm among women with no previous diaphragm experience. Sites in South Africa and Thailand recruited couples not at risk of pregnancy and at low risk of sexually transmitted infections. Couples used the SILCS diaphragm four times and provided feedback on the ease of handling, comfort, and sensation during sex. Data were collected via detailed product-use questionnaires, simple coital logs and gender-specific debriefing interviews. Results: A total of 41 couples completed the study, providing data from 164 product uses. The SILCS device fits women representing a range of diaphragm sizes, parity and body mass index. Women from both sites reported that the SILCS diaphragm was easy to use and provided good comfort and sensation in over 80% of all product uses. Men from both sites reported good comfort and sensation in over 60% of all product uses. Conclusion: The SILCS diaphragm appears to be acceptable to women and men in low-resource settings. These data suggest that the SILCS design should be tested in broader populations to assess effectiveness and acceptability.

Harvey SM, Branch MR, Thorburn S, Warren J, Casillas A. Exploring diaphragm use as a potential HIV prevention strategy among women in the United States at risk. *AIDS Education & Prevention* 2008; 20(2): 135-147.

Given the immediate need for physical cervical barrier methods like the diaphragm to protect against HIV/STIs,



understanding what factors influence the acceptability of these products and how to overcome obstacles to their use is important. We explored perceptions of the diaphragm and factors that might enhance its acceptability in 25 focus groups with racially/ethnically diverse young women in the US at risk for HIV/STIs (N = 140). Women believed the diaphragm has positive attributes, and most indicated they would be more likely to use the diaphragm if they were confident they could use it correctly and it protected against HIV. They also considered it messy to use and difficult to insert or remove. Findings suggest that the diaphragm could be a desirable option for pregnancy and disease prevention for some women at risk for HIV/STIs. Although disadvantages to diaphragm use were identified, many could be eliminated through changes in product design and provider intervention.

Kulczycki A and Shewchuk RM. Using Internet-based nominal group technique meetings to identify provider strategies for increasing diaphragm use. *Journal of Family Planning and Reproductive Health Care* 2008; 34(4): 227-231.

Background and methodology: The diaphragm, once the most commonly used female contraceptive method, is being re-evaluated for prevention against some sexually transmitted infections (STIs), including HIV. However, provider views about this prescription-based method are poorly understood. Using expert panels, this study aimed to identify facilitative strategies to increase diaphragm use. The nominal group technique (NGT) was employed using a novel web-based interface to systematically elicit and prioritise responses to a specific question about what can be done to encourage providers to recommend diaphragm use. Two NGT sessions were convened with 15 geographically dispersed panellists who had extensive knowledge and experience with the diaphragm. Participants were identified using purposeful and snowball sampling. Results: Panel 1 identified 22 strategies for encouraging providers to recommend diaphragm use, with seven perceived as relatively more important (67% of the total available votes). Panel 2 identified 31 strategies, nine of which accounted for 77% of the votes. Both sessions highlighted that to make the diaphragm a more plausible option, educational materials and tools are needed to better inform providers and patients about the method and its specific advantages. Conclusions: The enhanced, Internet-based NGT offers the family planning and reproductive health care field a powerful and inexpensive tool for systematically collecting and analysing expert opinion. Results are being used to develop a questionnaire to further examine strategies that may help promote diaphragm use and to refine ideas for intervention design. This will facilitate method reintroduction, if the diaphragm is proven effective against STIs/HIV, especially when used with a microbicide.

Okal J, Stadler J, Ombidi W, Jao I, Luchters S, Temmerman M, Chersich MF. Secrecy, disclosure and accidental discovery: Perspectives of diaphragm users in Mombasa, Kenya. *Culture, Health & Sexuality: An International Journal for Research, Intervention and Care* 2008; 10(1): 13-26.

The diaphragm is receiving renewed attention as a promising female-controlled method of preventing HIV and other sexually-transmitted infections. It is anticipated that female-controlled technologies will reduce women's biological susceptibility and assist in counteracting their sociocultural vulnerability to HIV. Understanding the subjective experiences of diaphragm users in different settings has the potential to inform the development and promotion of such methods. This paper explores the perspectives of female sex workers and women attending sexual and reproductive health services in Mombasa, Kenya. Data are reported from focus group discussions and in-depth interviews with women and men, following a prospective study investigating diaphragm continuation rates over six months. Discussions highlighted covert use of the diaphragm, during sex work or with casual partners, and coital independence as favourable attributes. These features were especially pronounced compared with male condoms. Few difficulties with diaphragm use were reported, although its insertion and removal occasionally presented problems. Many women—especially those in long term partnerships—wished to disclose its use but found the disclosure process highly problematic. Accidental discovery often resulted in partner conflict. Although future uptake of the diaphragm may be high in this setting, its use may be limited to certain types of relationships and relationship context.



Ramjee G, van der Straten A, Chipato T, de Bruyn G, Blanchard K, Shiboski S, Cheng H, Montgomery E, Padian N. The diaphragm and lubricant gel for prevention of cervical sexually transmitted infections: Results of a randomized controlled trial. *PLoS ONE* 2008; 3(10): e3488.

Background: We evaluated the effectiveness of the Ortho All-Flex Diaphragm, lubricant gel (Replens®) and condoms compared to condoms alone on the incidence of chlamydial and gonococcal infections in an open-label randomized controlled trial among women at risk of HIV/STI infections. Methods: We randomized 5045 sexually-active women at three sites in Southern Africa. Participants who tested positive for curable STIs were treated prior to enrollment as per local guidelines. Women were followed quarterly and tested for *Chlamydia trachomatis* (CT) or *Neisseria gonorrhoeae* (GC) infection by nucleic-acid amplification testing (Roche Amplicor®) using first-catch urine specimens. STIs detected at follow-up visits were treated. We compared the incidence of first infection after randomization between study arms in both intent-to-treat (ITT) and per-protocol populations. Findings: Baseline demographic, behavioral and clinical characteristics were balanced across study arms. Nearly 80% of participants were under 35 years of age. Median follow-up time was 21 months and the retention rate was over 93%. There were 471 first chlamydia infections, 247 in the intervention arm and 224 in the control arm with an overall incidence of 6.2/100 woman-years (wy) (relative hazard (RH) 1.11, 95% Confidence Interval (CI): 0.93-1.33; p=0.25) and 192 first gonococcal infections, 95 in the intervention arm and 97 in the control arm with an overall incidence of 2.4/100wy (RH 0.98, 95%CI: 0.74-1.30; p=0.90). Per protocol results indicated that when diaphragm adherence was defined as “always use” since the last visit, there was a significant reduction in the incidence of GC infection among women randomized to the intervention arm (RH 0.61, 95%CI: 0.41-0.91, P=0.02). Interpretation: There was no difference by study arm in the rate of acquisition of CT or GC. However, our per-protocol results suggest that consistent use of the diaphragm may reduce acquisition of GC.

Sawaya Gf, Chirenje MZ, Magure MT, Tuveson JL, Ma Y, Shiboski SC, Da Costa MM, Palefsky JM, Moscicki AB, Mutasa RM. Effect of diaphragm and lubricant gel provision on human papillomavirus infection among women provided with condoms. *Obstetrics & Gynecology* 2008; 112: 990-7.

Objective: To estimate the effect of providing women with a latex diaphragm, lubricant gel, and male condoms (intervention) compared with condoms alone (control) on human papillomavirus (HPV) incidence and clearance. Methods: Participants were 2,040 human immunodeficiency virus (HIV)-negative Zimbabwean women enrolled in a randomized trial estimating the effect of the intervention on HIV acquisition. Clinicians collected cervical samples for HPV testing at baseline, 12 months, and exit. L1 consensus polymerase chain reaction primers were used to determine HPV presence and type. Results: We found no differences in the following outcomes: HPV prevalence at the time of the first post enrollment HPV test (intention-to-treat analysis, relative risk [RR] 1.02, 95% confidence interval [CI] 0.90-1.16); HPV incidence at 12 months among women HPV-negative at baseline (RR 0.95, 95% CI 0.80-1.14); and HPV clearance at 12 months among women HPV-positive at baseline (RR 0.80, 95% CI 0.61-1.05). Clearance of HPV type 58 was lower in the intervention group at 12 months (RR 0.67, 95% CI 0.48-0.92), but not at exit (RR 0.93, 95% CI 0.75-1.16); clearance of HPV type 18 was lower in the intervention group at exit (RR 0.55, 95% CI 0.33-0.89), but not at 12 months (RR 0.55, 95% CI 0.29-1.05). Women reporting diaphragm/gel use at 100% of prior sex acts had a lower likelihood of having one or more new HPV types detected at 12 months (RR 0.75, 95% CI 0.58-0.96) and exit (RR 0.77, 95% CI 0.59-0.99). Conclusion: Among women receiving risk reduction counseling and condoms in an HIV prevention program, diaphragm plus lubricant gel provision did not affect HPV incidence or clearance.

Schwartz JL, Ballagh SA, Creinin MD, Rountree RW, Kilbourne-Brook M, Mauck CK, Callahan MM. SILCS diaphragm: post-coital testing of a new single-size contraceptive device. *Contraception* 2008; 78(3): 237-244.

Background: This study was conducted to compare the effectiveness of a new, single-size silicone contraceptive diaphragm used with either spermicide [2% nonoxynol-9 (N-9)] or lubricant in preventing sperm from penetrating mid-cycle cervical mucus. Study design: A crossover post-coital test (PCT) in healthy, sexually active women not



at risk for pregnancy due to tubal occlusion was conducted. Couples had a baseline PCT without a device to verify normal fertility parameters. Qualified couples underwent up to two test cycles using the SILCS diaphragm with a metal spring. A subgroup of couples underwent a third test cycle with the SILCS polymer spring diaphragm used with N-9 gel. Results: Fifteen couples completed a baseline cycle and were randomized to order of study gel. Of these, 14 couples completed a baseline cycle and at least one test cycle, 12 couples completed a baseline cycle and two test cycles and 8 couples completed a third test cycle with the polymer spring prototype. Sperm was detected in the vaginal pool in all completed test cycles. The SILCS metal spring diaphragms used with N-9 gel reduced the average number of progressively motile sperm per high power field in the cervical mucus from a baseline of 12.5 to 0, while use of this device with lubricant reduced the number to 0.5. The SILCS polymer spring diaphragm used with N-9 performed the same as the metal spring used with N-9. Conclusion: The SILCS diaphragm used with N-9 gel performed well. It is likely that the SILCS diaphragm will give acceptable results in a contraceptive effectiveness study but that adjunctive use of a chemical barrier such as N-9 gel will be necessary for it to be most effective.

van der Straten A, Moore J, Napierala S, Clouse K, Mauck C, Hammond N, Padian N. Consistent use of a combination product versus a single product in a safety trial of the diaphragm and microbicide in Harare, Zimbabwe. *Contraception* 2008; 77(6): 435-443.

Background: We examined the use and acceptability of a combination product (diaphragm and gel) compared to a single product (gel) during a 6-month safety trial in Zimbabwe. Study Design: Women were randomized to the use of a diaphragm with gel or the use of gel alone, in addition to male condoms. Ever use and use of study product on the last act of sexual intercourse were assessed monthly by Audio Computer-Assisted Self-Interviewing. Acceptability, correct use and consistent use (use at every sexual act during the previous 3 months) were measured on the last visit by face-to-face interview. Predictors of consistent use were examined using multivariate logistic regression analyses. Results: In this sample of 117 sexually active, monogamous, contracepting women, rates of consistent use were similar in both groups (59.7% for combination method vs. 56.4% for gel alone). Product acceptability was high, but was not independently associated with consistent use. Independent predictors of consistent use included age [adjusted odds ratio (AOR)=1.08; 95% confidence interval (95% CI)=1.01-1.16], consistent condom use (AOR=3.85; 95% CI=1.54-9.63) and having a partner who approves of product use (AOR=2.66; 95% CI=1.10-6.39). Conclusions: Despite high reported acceptability and few problems with the products, the participants reported only moderate product adherence levels. Consistent use of condoms and consistent use of products were strongly associated. If observed in other studies, this may bias the estimation of product effectiveness in future trials of female-controlled methods.

2007

Barnhart K, Rosenberg MJ, MacKay HT, Blithe DL, Higgins J, Walsh T, Wan L, Thomas M, Creinin MD, Westhoff C. Contraceptive efficacy of a novel spermicidal microbicide used with a diaphragm. *Obstetrics & Gynecology* 2007; 110: 577-86.

Objective: Women need products that protect against both pregnancy and sexually transmitted infections, including human immunodeficiency virus (HIV). The acid buffering gel is a non-detergent spermicide that may provide this dual protection by reinforcing normal vaginal acidity to inactivate both sperm and acid-sensitive sexually transmitted pathogens. The objective of this study was to assess the gel's contraceptive effects, safety, and acceptability. Methods: We conducted a multicenter, randomized, double-masked, non-inferiority study at 11 centers, comparing 621 women who used an acid buffering gel plus diaphragm with 300 women who used a



nonoxynol-9 spermicide plus diaphragm for 6 months. A double-masked study extension followed 234 women for an additional 6 months of use. Results: The 6-month pregnancy rate per hundred women was 10.1% (95% confidence interval [CI] 7.1-13.1%) for acid buffering gel and 12.3 (95% CI 7.7-16.9) for nonoxynol-9 spermicide users. The difference in rates was -2.2% with a 95% CI -7.7 to 3.3%. Consistent and correct use 6-month pregnancy rates were 4.7% for acid buffering gel and 6.1% for nonoxynol-9 spermicide users, calculated from those cycles where diary entries indicated such use. Adverse events and acceptability were similar between the two groups. Pregnancy probabilities were similar between groups participating in the 12-month study extension. Conclusion: An acid buffering gel used with a diaphragm is a safe, acceptable contraceptive with efficacy comparable to that of a common commercial spermicide with diaphragm.

Bateson D and Weisberg E. Comparison of diaphragm and combined oral contraceptive pill users in the Australian family planning setting. *The European Journal of Contraception & Reproductive Health Care* 2007; 12(1): 24-29.

To determine the number of women fitted with a diaphragm or cervical cap at family planning clinics across the Australian State of New South Wales (NSW) from 2000 to 2005. To compare the demographic characteristics of women fitted with this form of contraceptive with women prescribed the combined oral contraceptive pill (COCP). An audit of women presenting for contraceptive services between 2000 and 2005 was undertaken. The demographic characteristics of women fitted with a barrier method or prescribed the COCP between 1st April, 2002, and 31st October, 2004, were obtained from the Family Planning NSW Activity Data Set (FADS). Results: The proportion of women fitted with a diaphragm or cap remained constant between 2001 and 2005 at approximately 5%. During the 31 months that the study period lasted, 793 women were fitted with a diaphragm or cervical cap compared with 8047 women prescribed the COCP during the same time frame (including 76 women who received both a diaphragm and COCP prescription during this period). Women fitted with the barrier contraceptive were significantly more likely to be older, to have received a tertiary level education and to have private health insurance than their counterparts prescribed the COCP. They were less likely to come from a non-English speaking background. Discussion: The diaphragm and cervical cap are viable contraceptive methods for a specific group of older, well-educated women. The possible benefits of female-controlled barrier devices in the prevention of sexually transmissible infections may result in a wider demographic use in the future.

D'nyce L, Newman DR, Ballagh SA, Creinin MD, Barnhart K, Weiner DH, Bell AJ, Jamieson DJ. Phase I safety trial of two vaginal microbicide gels (Acidform or BufferGel) used with a diaphragm compared to KY Jelly used with a diaphragm. *Sexually Transmitted Diseases* 2007; 34(12): 977.

Objectives: To assess the safety and acceptability of 2 vaginal microbicide gels (Acidform and BufferGel) used with a diaphragm compared to KY Jelly used with a diaphragm among low-risk, sexually abstinent women. Study Design: Eighty-one women enrolled in a randomized, masked, phase I safety study using a diaphragm with Acidform, BufferGel, or KY Jelly for 6 to 10 hours nightly for 14 nights. Physical examination, colposcopy, and lab studies were performed after 1 and 2 weeks of use. Diaries and questionnaires were used to assess user acceptability. Results: Sixty-nine participants (85%) completed the study. Safety and acceptability appeared similar among the 3 study groups and no serious adverse events related to the study products were reported. Adverse events were mild and anticipated. Conclusions: Acidform and BufferGel compared to KY Jelly, when used with diaphragm daily for 14 days, appeared to be safe and acceptable in a small study of low-risk abstinent women.

Guest G, Johnson L, Burke H, Rain-Taljaard R, Severy L, von Mollendorf C, Van Damme L. Changes in sexual behavior during a safety and feasibility trial of a microbicide/diaphragm combination: An integrated qualitative and quantitative analysis. *AIDS Education & Prevention* 2007; 19(4): 310-320.

If proven effective, vaginal microbicides and diaphragms will likely be part of a larger HIV prevention model that includes condoms and other prevention strategies. It is, therefore, important to understand how introducing new



prevention methods may affect overall patterns of sexual risk behavior. Data presented were collected as part of a safety and feasibility study of ACIDFORM gel with a diaphragm among 120 women in South Africa. Interviews were administered at enrollment and months 1, 3, 5, and 6 of the trial. Focus groups were conducted at trial exit. Frequency of sex increased significantly after enrollment. This increase appears to be owing to perceived protection from HIV and greater sexual pleasure afforded by the gel. Male condom use was high overall but increased significantly from enrollment. Data suggest this is because of increased partner involvement, increased negotiating power afforded by study participation, and provision of free condoms perceived to be of high quality.

Guest G, Severy L, Mollendorf C, Damme LV. Overcoming recruitment challenges: Lessons learned from a safety and feasibility study of a diaphragm/microbicide combination in South Africa. *JAIDS Journal of Acquired Immune Deficiency Syndromes* 2007; 45(4): 481-482.

No abstract available

Hardy E, Hebling E, Sousa MH, Almeida AF, Amaral E. Delivery of microbicides to the vagina: Difficulties reported with the use of three devices, adherence to use and preferences. *Contraception* 2007; 76(2): 126-131.

Purpose: A crossover study was carried out in 405 couples to compare women's difficulties with three different devices that could be used to administer a microbicide and to evaluate adherence to use and preference for any one of the devices. Methods: Couples used a single size diaphragm, a vaginal ring or disposable applicators for 1 month each in a randomly assigned order. Results: Few women reported difficulty using the applicators or the ring; however, almost two-thirds reported difficulty using the diaphragm. Approximately 5%, 10% and 40% of the women and a similar but slightly lower percentage of their partners reported incorrect use of the applicator, vaginal ring and diaphragm, respectively. About half the women preferred the vaginal ring, while around half the men preferred the applicator. Conclusion: The release of microbicides from a vaginal ring is a lead worth pursuing. The diaphragm is the only one of the three devices that also offers mechanical protection, but it requires greater investment in patient education to ensure adherence to use.

Kang MS, Buck J, Padian N, Posner S, Khumalo-Sakutukwa G, van der Straten A. The importance of discreet use of the diaphragm to Zimbabwean women and their partners. *AIDS and Behavior* 2007; 11(3): 443-451.

We conducted a 6-month acceptability study of diaphragms as a potential HIV/STI prevention method among Zimbabwean women. We examined partner involvement in diaphragm use, and importance of discreet use (use without partner awareness). Of the 181 women who completed the study, 45% said discreet use was very or extremely important and in multivariate logistic regression, women were more likely to value discretion if their partners: had other partners; drank alcohol; or were believed to prefer condoms to diaphragms. Qualitative data confirmed these findings. Both women and their partners reported that diaphragms can be used discreetly and saw this as advantageous, for both sexual pleasure and female control. However, many were concerned that use without partner approval could lead to marital problems. Discreet use should be considered in development of barrier methods and in diaphragm promotion, if proven effective against HIV/STI.

Luchters S, Chersich MF, Jao I, Schroth A, Chidagaya S, Mandaliya K, Temmerman M. Acceptability of the diaphragm in Mombasa Kenya: A 6-month prospective study. *The European Journal of Contraception & Reproductive Health Care* 2007; 12(4): 345-353.

Objectives: If proven acceptable, safe and effective, the diaphragm could be used as a female-controlled method of preventing both sexually-transmitted infections (STIs) and pregnancy. This study's aim was to assess the acceptability and safety of the diaphragm among sexually-active women in Mombasa, Kenya. Methods: We conducted a 6-month prospective study among female sex workers (FSWs), and women attending sexual and reproductive health services. Diaphragm acceptability was assessed using continuation rates and factors



associated with acceptability. Safety evaluations included colposcopy findings and incidence of urinary tract infections (UTIs) and STIs. Results: Half the 185 participants were FSWs who had less schooling and were less likely to be married than other women. After 6 months, 55% (56/102) of sexually-active women reported having used the diaphragm each sex act during the preceding month. Women liked using the diaphragm (95%, 104/109), and 96% (125/130) reported willingness to continue using it. Colposcopy did not reveal significantly more vaginal or cervical lesions. Use of the diaphragm was not associated with an increase in bacterial vaginosis or UTIs. A pregnancy rate of 12 per 100 women/years was observed. Conclusion: After 6 months of diaphragm use in this setting, continuation rates were sustained, user satisfaction was high and adverse effects were few.

Padian NS, van der Straten A, Ramjee G, Chipato T, de Bruyn G, Blanchard K, Shiboski S, Montgomery ET, Fancher H, Cheng H, Rosenblum M, van der Laan M, Jewell N, McIntyre J. Diaphragm and lubricant gel for prevention of HIV acquisition in southern African women: A randomised controlled trial. *The Lancet* 2007; 370(9583): 251-261.

Summary/Background: Female-controlled methods of HIV prevention are urgently needed. We assessed the effect of provision of latex diaphragm, lubricant gel, and condoms (intervention), compared with condoms alone (control) on HIV seroincidence in women in South Africa and Zimbabwe. Methods: We did an open-label, randomised controlled trial in HIV-negative, sexually active women recruited from clinics and community-based organizations, which were followed up quarterly for 12-24 months (median 21 months). All participants received an HIV prevention package consisting of pre-test and post-test counseling about HIV and sexually transmitted infections, testing, treatment of curable sexually transmitted infections, and intensive risk-reduction counseling. The primary outcome was incident HIV infection. This study is registered with ClinicalTrials.gov, number NCT00121459. Findings: Overall HIV incidence was 4.0% per 100 woman-years: 4.1% in the intervention group (n=2472) and 3.9% in the control group (n=2476), corresponding to a relative hazard of 1.05 (95% CI 0.84-1.32, intention-to-treat analysis). The proportion of women using condoms was significantly lower in the intervention than in the control group (54% vs 85% of visits, $p < 0.0001$). The proportions of participants who reported adverse events (60% [1523] vs 61% [1529]) and serious adverse events (5% [130] vs 4% [101]) were similar between the two groups. Interpretation: We observed no added protective benefit against HIV infection when the diaphragm and lubricant gel were provided in addition to condoms and a comprehensive HIV prevention package. Our observation that lower condom use in women provided with diaphragms did not result in increased infection merits further research. Although the intervention seemed safe, our findings do not support addition of the diaphragm to current HIV prevention strategies.

Schroth A, Luchters S, Chersich MF, Jao I, Temmerman M. Use of self home-made diaphragm for protection against pregnancy and sexually-transmitted infections: Case report. *East African Medical Journal* 2007; 84(1): 35.

This is a case report of a 44-year-old woman who used a home-made diaphragm for 16 years to protect herself from pregnancy and sexually-transmitted infections. The woman stitched a piece of cloth with folded polythene inside. This case report provides a vivid illustration of the limitations of available methods of protection for women. It consists of an introduction to the topic, a description of her experiences using her home-made diaphragm and a discussion of the significance of the case. This report supports the need for additional research on female-controlled methods of protection against sexually-transmitted infections, methods that can be used without male knowledge and co-operation, such as vaginal microbicides and cervical barriers against infection, including the diaphragm.

van der Straten A, Napierala S, Cheng H, Mauck C, Depineres T, Dhlakama P, Thompson M, Chipato T, Hammond N, Padian N. A randomized controlled safety trial of the diaphragm and cellulose sulfate microbicide gel in sexually active women in Zimbabwe. *Contraception* 2007; 76(5): 389-399.

Background: Cellulose sulfate (CS) is an antimicrobial and contraceptive agent. We assessed its safety when used



alone or with the diaphragm in Harare, Zimbabwe. Study Design: This was a randomized controlled safety trial with three arms: diaphragm with 6% CS gel vs. diaphragm with KY gel vs. CS gel alone. Participants were instructed to use their study products before every sex act for a period of 6 months. Safety end points were assessed monthly by questionnaires and urinalysis and bimonthly by clinical examinations, colposcopy, wet mounts and gram stains. Results: One hundred nineteen monogamous women were enrolled (28% HIV+) and 105 (88%) completed the study. No urinary tract infections were diagnosed during the study; 81.4% women had symptoms and/or signs of genital irritation considered at least possibly related to the gel or device, and 41.5% had changes in vaginal flora. There were no statistically significant differences between treatment groups in safety end points. All six women with deep epithelial disruption were diaphragm users, and all such findings were on the external genitalia. Of those, 4 had herpetic ulcers which were unrelated to products use. Conclusions: Cellulose sulfate appeared safe when used for 6 months alone or with a diaphragm.

Yang CC, Maravilla KR, Kilbourne-Brook M, Austin G. Magnetic resonance imaging of SILCS diaphragm: Anatomical considerations and corroboration with clinical fit. *Contraception* 2007; 76(3): 238-244.

Background: We performed a pilot study to evaluate in vivo the fit of the new SILCS diaphragm, a single-size cervical barrier, using magnetic resonance imaging (MRI) in a group of women varying in body mass and parity. Study Design: Two healthy premenopausal women were recruited for each of the following groups: body mass index (BMI)<25, BMI=25-30 and BMI>30. One woman in each group was nulliparous and one was multiparous. Subjects were instructed on the placement of the SILCS diaphragm. Each subject underwent three MRI scans: baseline, with the SILCS diaphragm in place and after placement of intravaginal contrast and simulated intercourse. Results: The SILCS diaphragm was easily identified on MRI. In all subjects, the diaphragm covered the cervix. The position of the diaphragm did not change after simulated intercourse. The appropriate position of the diaphragm, as assessed by the subjects and the practitioner, was corroborated by the MR images. The intravaginal contrast was not readily visible on the images, precluding assessment of the diaphragm's barrier properties. Conclusion: MRI confirms the anatomic position of the SILCS diaphragm in vivo, among a sample of women varying in body mass and parity.

2006

Bagga R, Raghuvanshi P, Gopalan S, Das SK, Baweja R, Suri S, Malhotra D, Khare S, Talwar GP. A polyherbal vaginal pessary with spermicidal and antimicrobial action: Evaluation of its safety. *Transactions of the Royal Society of Tropical Medicine and Hygiene* 2006; 100(12): 1164-1167.

A polyherbal vaginal pessary (Praneem) has been formulated that has antimicrobial properties against genital pathogens in addition to spermicidal action. Thus, it has dual potential as a barrier method for contraception and for providing protection against some sexually transmitted infections. The present study reports the findings of a multicentre trial that was conducted to evaluate the safety of this product. Trials were carried out in 23 women in three centres in India: the Postgraduate Institute of Medical Education and Research, Chandigarh; Safdarjang Hospital, New Delhi; and Kamla Nehru Memorial Hospital, Allahabad. Thorough clinical and pelvic examinations were carried out as well as cervical cytology, blood biochemistry and haematology before and after use of the polyherbal pessary intravaginally once daily for 7 consecutive days. No toxicity was observed on clinical examination or by laboratory investigations. Daily intravaginal use of this pessary for 7 days had no adverse effects on cervical cytology or on metabolic and organ functions.

Beckman LJ, Harvey SM, Thorburn S, Maher JE, Burns KL. Women's acceptance of the diaphragm: The role of relationship factors. *Journal of Sex Research* 2006; 43(4): 297.



The vaginal diaphragm is a candidate for a female-controlled method of reducing risk of HIV/STI acquisition. We examined the association between relationship and partner factors and three measures of diaphragm acceptability: current use, consistency of use, and satisfaction with use. We conducted a telephone survey with 448 female members of a managed care organization, aged 18-49, who currently used contraception (including 140 diaphragm users, 187 pill users, and 121 male condom users). Use of a specific contraceptive was significantly associated with relationship length, condom-use negotiation self-efficacy, importance of covert use, perceived motivation of partner to prevent HIV/STIs, and perceived satisfaction of partner with current method. In addition, among diaphragm users, communication about HIV/STIs and perceived partner motivation to use a diaphragm were related to consistent use. These results suggest that acceptability of contraceptive methods among women is influenced by their perceptions of their male partner and relationship factors.

Dominik R and Chen P-L. Day-specific pregnancy probability estimation in barrier contraceptive effectiveness trials. *Paediatric and Perinatal Epidemiology* 2006; 20(s1): 38-42.

We apply an extension of a statistical model developed in the fertility research setting to the barrier contraceptive trial setting to obtain estimates of the probability of pregnancy per cycle day in the presence or absence of barrier use among participants of a randomised trial of female barrier contraceptives. The per cycle day pregnancy curve for the barrier trial participants was similar to previously published results from a fertility study that included a precise indicator of ovulation day. In addition, our analysis showed strong contraceptive effects for the diaphragm. The proposed modelling approach should allow evaluation of the effects of other coitus-specific exposures on the chance of pregnancy in other prospective studies, including fertility studies.

Mantell JE, Dworkin SL, Exner TM, Hoffman S, Smit JA, Susser I. The promises and limitations of female-initiated methods of HIV/STI protection. *Social Science & Medicine* 2006; 63(8): 1998-2009.

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

Mauck CK, Weiner DH, Creinin MD, Archer DF, Schwartz JL, Pymar HC, Ballagh SA, Henry DM, Callahan MM. FemCap™ with removal strap: Ease of removal, safety and acceptability. *Contraception*. 2006; 73: 59-64.

Objectives: FemCap™ is a silicone–rubber barrier contraceptive approved for marketing in the United States. To address reported problems with removal and dislodgment, the device's developer added a strap to the device and increased the height of the brim. This trial assessed whether the new design reduced removal difficulties and had any effects on dislodgment, genital pain/discomfort, safety, and acceptability. Methods: Women used the strapped device for 8 weeks with follow-up visits at 2 and 8 weeks. Outcome measures were obtained through diary cards, questionnaires, and naked eye examination. Data from these 120 women were compared with data from 419 women who used the unstrapped FemCap in a previous contraceptive effectiveness study. Results: The strapped device was not significantly easier for users to remove than the unstrapped device. Similar odds of dislodgment



and cervical/vaginal irritation were seen with the two devices. Both female and male participants were significantly more likely to report pain/discomfort with use of the strapped device. Female users of the strapped device were significantly more likely to say they disliked their device. In six weeks, two pregnancies were observed, but pregnancy was not an endpoint in the study and no conclusions should be drawn regarding pregnancy rates. Conclusions: The modifications to the FemCap did not significantly improve the ease of device removal and appears to have resulted in significantly more female and male partner pain/discomfort and decreased acceptability, compared with the unstrapped device.

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

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

Schwartz JL, Mauck CK, Rountree RW, Ballagh SA, Creinin MD, Kilbourne-Brook M. SILCS Diaphragm: Postcoital testing of a new single-size contraceptive diaphragm. *Obstetrics & Gynecology* 2006; 107: S12.

Objective: To compare the effectiveness of a new, single size silicone contraceptive diaphragm developed by PATH used with either spermicide or petroleum jelly to prevent sperm from penetrating midcycle cervical mucus. Methods: A crossover postcoital testing in 33 healthy, sexually active women not at risk for pregnancy due to previous bilateral tubal ligation or salpingectomy was conducted at Eastern Virginia Medical School and University of Pittsburgh Medical Center. Qualified participants underwent up to 2 test cycles using the SILCS diaphragm (metal spring) with either N-9 or petroleum jelly. Some participants underwent a third test cycle using the SILCS diaphragm (polymer spring) with N-9. Results: The SILCS diaphragm (metal or polymer spring) with N-9 reduced the average number of progressively motile sperm per high power field from a baseline of 12.5 to 0. The SILCS diaphragm (metal spring) with petroleum jelly reduced the number of progressively motile sperm per high power field to 0.5. Conclusion: Results from this most recent postcoital testing indicate that the current SILCS diaphragm design with the polymer spring and used with N-9 performed well and is acceptable for contraceptive effectiveness testing.

Sharma A, Bukusi E, Posner S, Feldman S, Ngugi E, Cohen CR. Sex preparation and diaphragm acceptability in sex work in Nairobi, Kenya. *Sexual Health* 2006; 3(4): 261-268.

Background: Women in sex work stand to benefit if the contraceptive diaphragm alone or combined with a microbicide proves to be an effective barrier method against HIV and sexually transmissible infection (STI). Currently, contraceptive diaphragm users are advised to leave the diaphragm in situ without concomitant use of other intravaginal substances for at least 6 h after intercourse. Methods: We conducted in-depth interviews on sexual behaviour including post-coital intravaginal practices with 36 women in sex work and 26 of their clients and held two focus-group discussions, each with 10 women. Results: The women described adapting several potentially harmful substances, such as cloth and soapy water, for post-coital vaginal use to ensure personal



hygiene, disease prevention and client pleasure. Some wanted to clean themselves and remove the diaphragm early, fearing exposure to HIV infection for themselves and their subsequent clients. Clients indicated their desire for “dry sex”, vaginal cleanliness and reduced risk of infection through vaginal cleaning. Conclusions: The diaphragm as a female-controlled barrier method for HIV/STI prevention may have limited acceptability among women in sex work if its effectiveness depends on a 6-h post-coital wait before removal, along with avoidance of concomitant use of intravaginal substances. In keeping with the beliefs of the female sex workers and their needs and practices, alternative intravaginal substances and modes of insertion that will not disrupt vaginal flora, injure vaginal epithelium, damage the diaphragm or counteract potentially beneficial effects of microbicides are needed. The possibility of removing the diaphragm sooner than the recommended for contraception should be further studied.

Smith-McCune KK, Tuveson JL, Rubin MM, Da Costa MM, Darragh TM, Shiboski SC, Van Der Pol B, Moscicki AB, Palefsky JM, Sawaya GF. Effect of Replens Gel used with a diaphragm on tests for human papillomavirus and other lower genital tract infections. *Journal of Lower Genital Tract Disease* 2006; 10(4): 213.

Objective: Little is known about effects of vaginal lubricants with barrier contraceptives on detection of sexually transmissible infections. We hypothesized that Replens gel used with a diaphragm would neither inhibit human papillomavirus (HPV) detection in cervical samples and chlamydia (CT) and gonorrhea (GC) detection in urine samples, nor affect cervical cytology quality. Materials and Methods: After a clinician-collected cervical sample and a self-collected vaginal sample for HPV detection ("pregel" specimens), women placed a diaphragm containing Replens gel into the vagina. Participants (n = 77) removed the diaphragm after 6 hours and performed vaginal HPV self-sampling at several time points thereafter. Clinicians performed cervical cytology sampling and HPV testing ("postgel" specimens) 24 hours after diaphragm removal. Pregel and postgel specimens were analyzed with and without added SiHa cells (source of defined numbers of HPV16 genomes). HPV was detected by polymerase chain reaction using MY09/11 primers. Urine samples were obtained for CT and GC testing. Proportions of samples testing positive were compared using relative risk (RR) regression models. Results: Proportions with detectable HPV in the clinician-collected cervical pregel and postgel samples were not statistically different for samples with added SiHa cells (88.3% vs 93.2%, RR = 1.06, 95% confidence interval = 0.96-1.14) or for native HPV infection (32.9% vs 28.2%, RR = 0.87, 95% confidence interval = 0.71-1.06). In self-collected vaginal postgel samples, there was no trend for decreased HPV detection after gel exposure. Gel affected neither urine tests for CT and GC nor cytological quality. Conclusions: Recent Replens gel use with a diaphragm does not inhibit cervical HPV testing, urine testing for CT and GC, or cervical cytology quality.

Thorburn S, Harvey SM, Tipton J. Diaphragm acceptability among young women at risk for HIV. *Women & Health* 2006; 44(1): 21-39.

The purpose of this study was to increase understanding of acceptability of the diaphragm among young women at risk for HIV and other sexually transmitted infections (STIs) in the US Methods: A total of 140 young (aged 18-25 years) women who had never used the diaphragm and who were at risk for HIV and other STIs completed questionnaires that included questions about the diaphragm and other sexual and reproductive health topics. These women were participants in a focus group study. Results: The majority of participants perceived that the diaphragm had several characteristics (e.g., is a method they can control, is effective in preventing pregnancy, will not cause side effects, does not decrease sexual pleasure) considered important when selecting a birth control method. However, most were not confident in various aspects of diaphragm use, including their ability to use the method correctly, without breaking the mood, or when sexually excited. In multivariate analyses, intention to use the diaphragm was significantly higher among participants who were less motivated to avoid pregnancy and those with greater perceived self-efficacy to use a diaphragm in different contexts (e.g., when sexually excited). Conclusion: The diaphragm has characteristics that some women consider desirable, suggesting that it could be an acceptable HIV prevention method for some at-risk women.



Behets F, Turner AN, Van Damme K, Rabenja NL, Ravelomanana N, Zeller K, Rasolofomanana JR. Acceptability and feasibility of continuous diaphragm use among sex workers in Madagascar. *Sex Transm Infect* 2005; 81(6): 472-476.

Objectives: The diaphragm, a woman controlled, reusable contraceptive device, might prevent some sexually transmitted infections (STIs). We assessed the acceptability and feasibility of use of silicone Wide-Seal Arcing Diaphragms (Milex Products, Chicago, IL, USA) by sex workers in Madagascar. Methods: Over 8 weeks, we evaluated method acceptability by examining patterns of and problems with women's diaphragm use. We also evaluated several measures of study feasibility, including recruitment and follow up methods. Results: 91 women from three cities (Antananarivo, Tamatave, and Mahajanga) participated, and 87 (96%) completed follow up. At enrolment, participants reported a median of six sex acts with five clients in the previous week. During the follow up period, participants reported a median of three sex acts with three clients during the previous 2 days, and self reported continuous diaphragm use during the previous day increased from 87% to 93%. Seven women became pregnant (incidence 53 pregnancies per 100 woman years). Self reported use of male condoms and diaphragms was fairly constant over the study period: women reported condom use in 61% to 70% of acts and diaphragms in 95% to 97% of acts. The number of participants reporting diaphragm problems decreased from 15 (16%) at the first visit to six (7%) at the final visit. 20 women (22%) needed replacement devices during follow up because their original diaphragms were lost, were the wrong size, or became seriously damaged. Conclusions: Given the high use and steady decrease in reported problems during the study, we believe diaphragms are acceptable and feasible in this resource poor, low education sex worker population.

Buck J, Kang MS, 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.

Mauck C, Creinin M, Rountree W, Callahan M, Hillier S. Lea's Shield®: Colposcopic and microbiological testing during 8 weeks of use. *Contraception*. 2005; 72: 53-59.

Objectives: The aims of this study were to assess the effects of Lea's Shield® plus nonoxynol-9 spermicide on signs and symptoms of female genital irritation and cervical and vaginal microflora during 8 weeks of use with intercourse and to analyze problems associated with the use of the device. Methods: In this open-label, single-arm study, participants were evaluated by pelvic examination, colposcopy and vaginal and cervical cultures. Results: About 13% of women (4/30) reported symptoms of irritation, and minor product-related colposcopic findings were seen in about one third (11/30). Although average colony counts for enterococcus, *Escherichia coli* and anaerobic gram-negative rods increased during product use, no clinical diagnoses of infection were made. Most users reported at least one problem using Lea's Shield. Conclusion: Lea's Shield, when used for 8 weeks during



intercourse, is associated with evidence of genital irritation in a minority of users and with changes in vaginal microflora that do not appear to correlate with clinical infections.

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

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

Posner S, van der Straten A, Kang M-S, 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.

van der Straten A, Kang MS, Posner SF, Kamba M, Chipato T, Padian NS. Predictors of diaphragm use as a potential sexually transmitted disease/HIV prevention method in Zimbabwe. *Sexually transmitted diseases* 2005; 32(1): 64.

Background: Women who are the most vulnerable to sexually transmitted diseases/HIV are often unable to consistently use condoms. One potential alternative method currently under investigation is the diaphragm. Goals: The goals of this study were to assess diaphragm uptake and use over time in Zimbabwe and to identify factors associated with self-reported consistent diaphragm use. Study: Women attending family planning clinics who were inconsistent condom users received a diaphragm intervention and were followed for 6 months. Results: Of the 186 participants, 99% ever reported using the diaphragm, and, at study exit, 96% had used it in the previous 2 months. Consistent diaphragm use since the previous visit was reported by 13% to 16% of the women, and in multivariate regression analysis, it was significantly associated with never using condoms (adjusted odds ratio,



24.08; 95% confidence interval, 6.71-86.34). Other factors included discreet use, preferring diaphragms to condoms, timing of insertion, domestic violence, and contraception. Conclusion: Diaphragms were well accepted among women at risk for sexually transmitted diseases/HIV.

2004

Allen RE. Diaphragm fitting. *American Family Physician* 2004; 69(1): 97-100.

When used with a spermicide, the diaphragm can be a more effective barrier contraceptive than the male condom. The diaphragm allows female-controlled contraception. It also provides moderate protection against sexually transmitted diseases and is less expensive than some contraceptive methods (e.g., oral contraceptive pills). However, diaphragm use is associated with more frequent urinary tract infections. Contraindications to use of a diaphragm include known hypersensitivity to latex (unless the wide seal rim diaphragm is used) or a history of toxic shock syndrome. A diaphragm is fitted properly if the posterior rim rests comfortably in the posterior fornix, the anterior rim rests snugly behind the pubic bone, and the cervix can be felt through the dome of the device. The diaphragm should not be left in the vagina for longer than 24 hours. When the diaphragm is the chosen method of contraception, patient education is key to compliance and effectiveness. An extended visit with the physician or a nurse may be required for a woman to learn proper insertion, removal, and care of the diaphragm.

Bird ST, Harvey SM, Maher JE, Beckman LJ. Acceptability of an existing, female-controlled contraceptive method that could potentially protect against HIV: A comparison of diaphragm users and other method users. *Women's Health Issues* 2004; 14(3): 85-93.

Objective: The diaphragm, an internal barrier contraceptive device, is a candidate for a female-controlled method for preventing human immunodeficiency virus (HIV) and other sexually transmitted infections (STIs). This study's objective was to examine how women who use the diaphragm differ from women using the pill and/or condoms with respect to factors hypothesized to influence the acceptability of contraceptive methods. Our goal was to increase understanding of who finds the diaphragm acceptable and why. Methods: We conducted a cross-sectional telephone survey with selected female members of a managed care organization. For this analysis, we limited the sample to 585 women currently using the diaphragm (n = 196), pill (n = 200), condoms (n = 132), or pill and condoms (n = 57). We conducted bivariate analyses and multinomial logistic regression analyses to assess the associations between selected characteristics and diaphragm use. Results: Diaphragm use was significantly associated with several variables. Of particular interest, placing less importance on hormonal method characteristics was significantly associated with diaphragm use (versus use of the pill, condoms, or both). Placing more importance on barrier method attributes was significantly associated with diaphragm use (versus pill use, alone or with condoms). In addition, lower condom use self-efficacy was significantly associated with diaphragm use (versus condom use, alone or with pill). Lack of motivation to avoid HIV/STIs was significantly associated with using the diaphragm versus condoms (only). Conclusion: These results have important implications for future research, interventions, counseling strategies for providers, and product development. Our findings suggest that if the diaphragm protects against HIV, it could be a desirable option for some women.

Cates W Jr and Stewart F. Vaginal barriers. In Hatcher RA, Trussell J, Stewart F, et al. (Eds.), *Contraceptive Technology* (18th Rev. ed). New York, New York: Ardent Media. 2004. Pp. 365-89.

The chapter addresses mechanisms of action; effectiveness; cost; advantages and indications; disadvantages and cautions; method provision; managing problems and followup; and instructions for use. The methods included are the female condom, diaphragm, contraceptive sponge, cervical cap, Lea's Shield and Femcap.



Cook L, Nanda K, Grimes D. Diaphragm versus diaphragm with spermicides for contraception (Cochrane Review). In: The Cochrane Library, Issue 3, 2004. Chichester, UK: John Wiley & Sons, Ltd.

Background: The diaphragm is usually used with a spermicide. However, some practitioners have suggested that spermicides offer no additional contraceptive protection and have advocated alternative guidelines for the use of diaphragms. Objectives: The objective of this review was to compare the effectiveness, safety and acceptability of the diaphragm with and without spermicide. Search Strategy: We searched MEDLINE, EMBASE, POPLINE, CINAHL, the Cochrane Controlled Trials Register, and reference lists of relevant articles. In addition, we contacted experts in the field to identify unpublished studies. Selection Criteria: Randomized controlled trials comparing women of reproductive age using the diaphragm with and without spermicide as the sole contraceptive method that reported clinical outcomes. Data collection and analysis: Two reviewers independently extracted data on outcomes and trial characteristics and any discrepancies were resolved by consensus or by consultation with the third reviewer. The results of one identified study are presented descriptively. Main results: We identified only one study. No significant difference was found in the pregnancy rates (with typical use or consistent use) or discontinuation rates between the diaphragm-with-spermicide and diaphragm-without-spermicide groups. There was a trend towards higher pregnancy rates in the diaphragm-without-spermicide group. However, this study failed to recruit the planned number of participants and was consequently underpowered. Reviewers' conclusions: As only one underpowered study was identified, we cannot distinguish between the contraceptive effectiveness of the diaphragm with and without spermicide. We cannot draw any conclusion at this point, further research is needed. However, the study provides no evidence to change the commonly recommended practice of using the diaphragm with spermicide.

Gallo MF, Grimes DA, Schulz KF. Cervical cap versus diaphragm for contraception (Cochrane Review). In: The Cochrane Library, Issue 3, 2004. Chichester, UK: John Wiley & Sons, Ltd.

Background: The cervical cap and the diaphragm are vaginal barrier contraceptive methods that prevent pregnancy by covering the cervix. The two devices also act as a reservoir for spermicide. The cervical cap is smaller and can remain in place longer than the diaphragm. Two types of cervical caps, the Prentif cap and the FemCap, have been compared to the diaphragm in randomized controlled trials. Objectives: The review seeks to evaluate the contraceptive efficacy, safety, discontinuation, and acceptability of the cervical cap with that of the diaphragm. Search Strategy: We searched MEDLINE, Popline, Cochrane Controlled Trials Register, EMBASE, and LILACS for randomized controlled trials of cervical caps, and we reviewed the references of the included publications. Also, we wrote to the manufacturers and known investigators to request information about any other published or unpublished trials not found in our search. Selection Criteria: All randomized controlled trials in any language comparing a cervical cap with a diaphragm were eligible for inclusion. Data collection and analysis: All titles and abstracts located in the literature searches were assessed, and articles identified for inclusion were independently abstracted by two reviewers. Data were entered and analyzed with RevMan 4.1, and a second reviewer verified the data entered. Outcome measures include contraceptive efficacy, safety, discontinuation, and acceptability. Outcomes were calculated as Peto odds ratios with 95 percent confidence intervals using women as the denominators. Life-table and Kaplan-Meier cumulative rate ratios for selected measures were also presented in "Additional Tables." Main Results: The Prentif cap was comparable to the diaphragm in preventing pregnancy, but the FemCap was not as effective in preventing pregnancy as its comparison diaphragm. The curves for the life-table cumulative pregnancy rates through 24 months for the Prentif cap and the diaphragm were not statistically significantly different (p-value of 0.39). However, the six-month Kaplan-Meier cumulative pregnancy rates for the FemCap and the diaphragm did not meet the a priori definition of clinical equivalence. The Prentif cap had a higher proportion of Class I to Class III cervical cytologic conversions at the three-month visit than the diaphragm; the odds ratio was 2.3 (95% CI, 1.0-5.1). The FemCap trial did not find differences in Papanicolaou smear results between the cap and diaphragm groups. Prentif cap users had a lower odds ratio of vaginal ulcerations or lacerations (0.3; 95% CI, 0.1-0.7) than diaphragm users. FemCap users had a higher odds ratio of blood in the device on removal (2.3; 95% CI, 1.3-4.1), but a lower odds ratio of urinary tract infections (0.6; 95%



CI, 0.4-1.0) than those in the diaphragm group. In the FemCap trial, similar proportions of women reported liking their assigned device "somewhat" or "a lot" at the two-week interview. However, FemCap users were less likely than the diaphragm users to state that they were "probably" or "definitely" likely to use the device alone after completing the trial (odds ratio of 0.5; 95% CI, 0.3-0.7) or that they would recommend it to a friend (odds ratio of 0.5; 95% CI, 0.3-0.8). Reviewers' conclusions: The Prentif cap was as effective as its comparison diaphragm in preventing pregnancy, but the FemCap was not. Both cervical caps appear to be medically safe.

Kaler A. The future of female-controlled barrier methods for HIV prevention: Female condoms and lessons learned. *Culture, Health and Sexuality* 2004;6(6):501-16.

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

Maher JE, Harvey SM, Bird ST, Stevens VJ, Beckman LJ. Acceptability of the vaginal diaphragm among current users. *Perspectives on Sexual and Reproductive Health* 2004; 36(2): 64-71.

Context: Interest in the diaphragm has been growing, in part because it is a female-controlled method that might protect against HIV and other sexually transmitted diseases (STDs). A better understanding of diaphragm acceptability is needed. Methods: In 2001–2002, female members of a managed care organization were interviewed by telephone. The 215 participants, aged 19–49, who reported diaphragm use during the past three months were asked about their experience with the method and background characteristics. Characteristics associated with women's satisfaction with and consistent use of the diaphragm were identified through multiple logistic regression analysis. Results: Most participants had a low risk for HIV and other STDs. The mean duration of diaphragm use was 8.5 years. Although only 42% of participants reported consistent use in the past three months, most were satisfied with the method (79%) and planned to use it at next vaginal intercourse (85%). Satisfied users had significantly higher diaphragm use self-efficacy and more positive perceptions of the method than those not satisfied. Consistent use was significantly associated with older age and having had some college education rather than none. More than half of women cited dissatisfaction with previous methods (72%) and provider recommendation (61%) as moderately to extremely important in their decision to begin diaphragm use. When asked what they would change about the diaphragm, 32% mentioned concerns related to inserting or removing it. Conclusion: From an acceptability point of view, the diaphragm appears to be a viable candidate for a female-controlled method for prevention of HIV and other STDs. Our findings have important implications for the reintroduction of the traditional diaphragm and development of new diaphragm-like products.

Mauck C, Lai JJ, Schwartz J, Weiner DH. Diaphragms in clinical trials: Is clinician fitting necessary? *Contraception* 2004; 69: 263-6.

Background: The need for fitting a contraceptive diaphragm has recently been questioned in the context of upcoming trials in which the ability of the diaphragm to prevent sexually transmitted infections will be tested. Being able to provide the same size device to all women would greatly simplify supplying the device and training the clinicians, provided that it does not compromise effectiveness. Methods: Data from studies of Lea's Shield and FemCap, in which all women were sized for a standard diaphragm and half were randomized to use it during the studies, were reanalyzed to determine if it was feasible to give all women in a barrier study the same size diaphragm or, alternatively, to determine if diaphragm size could be predicted using an algorithm of one or more



parameters. Results: If all women received a size 70 diaphragm, rather than being fitted by a clinician, 33.2% would receive the same size that they would have received if they had been fitted by a clinician. If the definition of a “correct” fit were broadened to include one size larger or smaller than what the clinician would have prescribed, 78.0% would be “correctly” fitted. Using an algorithm that considered parity, body weight and other factors did not improve results. Conclusion: It would be acceptable to conduct a trial in which all women receive a size 70 diaphragm, provided that all women are sized; that safety, effectiveness and acceptability are closely monitored and that study results are stratified by the diaphragm size determined by clinician fitting. It would also be informative to use sized diaphragms as the comparator in studies of new single-size devices.

Shihata AA. New FDA approved woman-controlled, latex-free barrier contraceptive device “FemCap”. In S Daya, J Gunby and R Pierson (Eds.). *Research Papers in Fertility and Reproductive Medicine – Proceedings of the 18th World Congress on Fertility and Sterility (IFFS 2004) held in Montreal, Canada, between 23 and 28 May 2004*. Elsevier, 2004. Pp. 303-306.

Objectives: To provide a woman-controlled vaginal barrier contraceptive device that not only prevents pregnancy, but also protects against sexually transmitted infections (STIs). Methods: The FemCap is designed to cover and protect the cervix completely –the portal of entry for sperm, bacteria and viruses– and the site of chemokine co-receptors for the HIV virus (CCR-5 and CXCR-4). The FemCap is an FDA approved cervical barrier device that is designed with a unique delivery system that stores and delivers any microbicide on the vaginal side. This ensures immediate contact of the microbicide with invading microorganisms and the HIV virus. Results: Many microbicides, even soap and water, lemon juice, and Nonoxynol-9, can destroy the fragile HIV virus in the lab; none have proven yet to be effective in the vagina. In fact, Nonoxynol-9 increases HIV transmission if applied over the cervix. This is due to the disruption of the microbicides to the fragile columnar cervical and uterine epithelium. Conclusion: To minimize the transmission of STIs/HIV it is critical to use: A mechanical cervical barrier with a microbicide reservoir on the vaginal side such as the FemCap. This ensures immediate contact of the microbicide with the HIV virus upon deposition into the vagina.

2003

Ellertson C and Burns M. Re-examining the role of cervical barrier devices. *Outlook* 2003; 20(2): 1-8.

Cervical barriers are contraceptive methods that are woman-initiated, simple to use, low-cost, non-hormonal, and reasonably effective. Researchers are currently examining the possibility that cervical barriers may provide “dual protection,” that is, protection against STIs, including HIV, as well as pregnancy. At the Diaphragm Renaissance Meeting in 2002, experts re-examined the role of cervical barriers in STI protection, and discussed clinical studies, acceptability studies, attention to regulatory issues, and coordination of resources. Currently available cervical barriers include diaphragms, cervical caps and sponges; female condoms are another effective and acceptable woman-initiated method. In the future, microbicides, such as gels, creams, foams, or films, may offer protection against STIs, especially in combination with a barrier method. Risks associated with cervical barriers are minimal, and side effects are rare. Some evidence suggests that custom fitting of the diaphragm, as currently required by most family planning guidelines, is not necessary, and modifying fitting requirements would help product developers bring the method to developing countries. Acceptability studies from around the world show that the diaphragm can be very successful family planning method, and new research indicates that the cervix may be a primary site of STI and HIV infection. Covering the cervix with a diaphragm or other cervical barrier may therefore reduce transmission of HIV and other STIs. Research on this topic is currently underway.



Harvey SM, Bird ST, Branch MR. A new look at an old method: The diaphragm. *Perspectives on Sexual and Reproductive Health* 2003; 35(6): 270-273.

In the US, few contracepting women currently use the diaphragm, a method that has the potential to play an important role in preventing unintended pregnancy and sexually transmitted infections (STIs), including HIV. The method is female-controlled, allowing women to protect themselves with or without their partner's knowledge or cooperation. In addition, the diaphragm is safe, has limited side effects, does not interfere with natural hormones, can be inserted up to six hours prior to sex, and is unlikely to interfere with intimacy and sexual pleasure. In the future, it may be used to hold microbicidal products in place. Data suggests that the existence of a variety of contraceptive method choices increase women's ability to find a method suitable to their preferences, and also empowers women to negotiate condom use with their partners, which is currently seen as the best method to prevent STIs. While the diaphragm is not a perfect "magic bullet," multiple methods, including the diaphragm, should be promoted rather than waiting for a perfect solution that may never arrive. The successful reintroduction of the diaphragm will depend on changing current perceptions of and increasing knowledge about the diaphragm among women, men and family planning providers.

Harvey SM, Bird ST, Maher JE, Beckman LJ. Who continues using the diaphragm and who doesn't: implications for the acceptability of female-controlled HIV prevention methods. *Women's Health Issues* 2003; 13(5): 185-193.

Objectives: This study examines the acceptability of the diaphragm with the aim of facilitating the development of female-controlled human immunodeficiency virus (HIV) prevention methods. More specifically, we assess associations between being a current (vs. former) diaphragm user and characteristics that are hypothesized to influence the acceptability of contraceptive methods; and explore reasons for discontinuing use of the diaphragm among former diaphragm users. **Design:** The study involved a cross-sectional telephone survey with women who were members of a nonprofit health maintenance organization and who were either a current (n=215) or former (n=172) diaphragm user. **Methods:** Participants were interviewed about the importance of contraceptive attributes; perceptions for the diaphragm; diaphragm use self-efficacy; perceived risk of and motivation to avoid pregnancy, HIV, and other sexually transmitted infections; and demographic characteristics, sexual, and contraceptive behavior. **Results:** The likelihood of being a current diaphragm user (vs. former) increased with age, greater confidence in being able to use the diaphragm, greater perceived risk of pregnancy and more positive perceptions of the diaphragm. Women who valued attributes of hormonal contraceptives were less likely to be current users. Former diaphragm users reported that the following reasons were moderately to extremely important in their decision to stop using the diaphragm: difficulty inserting or removing the diaphragm (50.8%), dislike of leaving the diaphragm inside the vagina (46.8%), and wanting a more effective method for preventing pregnancy (44.2%). **Conclusions:** The findings suggest that specific characteristics of a product influence continued use and have implications for improving the acceptability of existing and new female-controlled HIV prevention methods.

Kuyoh MA, Toroitich-Ruto C, Grimes DA, Schulz KF, Gallo MF. Sponge versus diaphragm for contraception: A Cochrane review. *Contraception* 2003; 67: 15-18.

The contraceptive vaginal sponge was developed as an alternative to the contraceptive diaphragm. Unlike the diaphragm, the sponge can be used for more than one coital act within 24 h without the insertion of additional spermicide, and it does not require fitting or a prescription from a physician. We conducted a systematic review of randomized controlled trials that compared the vaginal contraceptive sponge with the diaphragm used with a spermicide in order to evaluate the efficacy and continuation rates of the two devices. The sponge was statistically significantly less effective in preventing overall pregnancy than was the diaphragm in the two trials that met our inclusion criteria. The 12-month cumulative life table termination rates per 100 women for overall pregnancy were 17.4 for the sponge versus 12.8 for the diaphragm in the larger US trial, and 24.5 for the sponge and 10.9 for the diaphragm in the UK trial. Similarly, discontinuation rates at 12 months were higher with the sponge than with the diaphragm [odds ratio 1.3; 95% confidence interval (CI) 1.1–1.6]. Allergic-type reactions were more



common with the sponge in both trials, although the frequency of discontinuation for discomfort differed in the two trials. Other randomized controlled trials will be needed to resolve the role of spermicides in preventing sexually transmitted infections or in causing adverse effects.

Stuart GS, Castano PM. Sexually transmitted infections and contraceptives: selective issues. *Obstetrics and Gynecology Clinics of North America* 2003; 30(4): 795-808.

It is important to examine the successful completed research and use it to move forward in practice to halt the almost 50% unintended pregnancy rate in the United States and the continued worldwide epidemic of HIV and other STIs. A significant development has been the evidence supporting the IUD as a valuable contraceptive option available to many women, including women who are HIV infected, with no increased risks of infertility or PID. Evidence exists that OCPs may increase chlamydial infection acquisition and cervicitis, but it is unlikely that OCP use is associated with PID. The lack of female-controlled dual method protection remains a void, but with the introduction of products such as FemCap and Reality condom and the continuing progress of microbicides and spermicides, the future is brighter. Clearly research into the interactions of STIs and contraceptives must continue to discern how best to approach a resolution to these public health concerns that affect women and the global population.

2002

Family Health International. Barrier methods. *Network* 2002; 22(4).

The actual and potential use of various barrier methods for contraception and prevention of sexually transmitted infections (STIs) is the focus of this issue of *Network*. Male condoms — when used consistently and correctly — are an effective means of preventing HIV infection, gonorrhea (in men) and unplanned pregnancy among people who are sexually active and need to protect themselves. In various settings, promotion of 100 percent condom use has contributed to marked reductions in STI rates. However, accurate messages about condoms must build on (and not substitute for) a wide range of STI risk-avoidance and risk-reduction approaches. The issue also discusses female condom reuse issues and various strategies that offer dual protection against both unplanned pregnancy and STIs. Another highlight is an overview of the status of research on various microbicides that might be used topically as protective barriers against HIV and other STIs. Finally, the issue explores the soon-to-be tested hypothesis that diaphragms offer women some protection against STIs.

2001

Bulut A, Ortayli N, Ringheim K, Cottingham J, Farley TMM, Peregoudov A, Joanis C, Palmore S, Brady M, Diaz J, Ojeda G, and Ramos R. Assessing the acceptability, service delivery requirements, and use-effectiveness of the diaphragm in Colombia, Philippines, and Turkey. *Contraception* 2001; 63: 267-275.

The diaphragm is not available in many countries, despite the recommendations of numerous authors that it has important advantages as a woman-controlled method that offers some protection against sexually transmitted diseases, and one that is safe and free of side effects. An interagency team collaborated to introduce the diaphragm in Colombia, the Philippines, and Turkey, using the same protocol to assess the acceptability, service delivery requirements, and use-effectiveness of the method. Eighteen public and private sector service 2 delivery sites were involved, and a total of 550 women were enrolled in the study. Provider training aimed to improve the quality of care with which all methods were delivered and included counseling about sexuality and reproductive health risks. The cumulative 12-month pregnancy rate of 10.1 (SE 1.7) per 100 woman-years is on the low end of previous studies of the diaphragm, and the 12-month continuation rate (57.2 [SE 2.4] per 100) compares favorably with that for oral contraceptives and the intrauterine device. Focus group discussions conducted with clients and



providers indicated that the method was an important alternative for some women, particularly those who had experienced health problems with other methods or were unable to negotiate condom use with their partners. Provider biases diminished as they observed the strategic niche that the diaphragm filled for their clients. While providing the diaphragm requires training and good client-provider interaction, the requirements are consistent with those called for in the Programme of Action of the International Conference on Population and Development (ICPD, 1994). With proper attention to quality of care, the diaphragm can be successfully offered in resource-poor settings.

Elias C and Coggins C. Acceptability research female-controlled barrier methods to prevent heterosexual transmission of HIV: Where have we been? Where are we going? *Journal of Women's Health and Gender Based Medicine* 2001; 10(2): 163-173.

Acceptability research is an important component of any product development process. As researchers move into a new, accelerated phase of vaginal microbicides development, it is important to take stock of the acceptability research conducted to date and determine future research priorities. In this paper, we review findings from acceptability research conducted to date in four categories: hypothetical product acceptability research, existing product research (spermicide acceptability studies), acceptability research within the context of clinical trials, and postmarketing acceptability research conducted around the female condom. Finally, we highlight areas where additional research is needed in light of recent progress in microbicides development and discuss a possible framework for the introduction and acceptability of new sexually transmitted disease (STD) prevention technologies.

Gollub EL, French P, Latka M, Rogers C, Stein Z. Achieving safer sex with choice: Studying a woman's sexual risk reduction hierarchy in an STD clinic. *Journal of Women's Health and Gender Based Medicine* 2001; 10(8): 771-83.

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 "woman'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.

Moench TR, Chipato T, Padian N. Preventing disease by protecting the cervix: The unexplored promise of internal vaginal barrier devices. *AIDS* 2001; 15(13): 1595-1602.

In the absence of an effective vaccine or treatment, contraceptive methods capable of preventing sexual transmission of HIV as well as other sexually transmitted diseases (STDs) are vital for protecting the health of a woman. As such, vaginal microbicides may provide such an alternative to women-controlled methods. Although many of these new microbicides show robust activity against HIV and other STD pathogens, and some also appear to be less toxic, achieving reliable protection with microbicides remains a significant challenge. Hence, in this paper the authors contend that the likelihood of success of such products could be greatly increased by



combining microbicide with an internal barrier that protects the cervix. Like condoms, these devices (diaphragms, caps, and other novel designs) create a physical barrier that covers the cervix. Yet because they are worn completely inside the vagina, they avoid the obtrusiveness that limits the acceptability of male and female condoms. Moreover, microbicide should not only be applied on the cervical side, as has been traditional for contraceptive use, but also on the vaginal side of the device to mix directly with semen and help protect the vaginal epithelium. Nevertheless, in spite of its potential efficacy, as with any new method of prevention, its efficacy will only be as good as its use, which is ultimately determined by acceptability.

Tone A. A Medical Fit. In *Devices and Desires*. New York, New York: Hill and Wang. 2001. Pp. 117-149.

This chapter chronicles the rise and fall of the diaphragm in America and the successes and failures of Margaret Sanger to improve access to such methods among the poor and under served in society. The chapter describes how by 1944 the diaphragm had become the number one prescribed form of birth control by doctors in the US, and how the medicalization of birth control gave it legitimacy in the eyes of US policy makers. While this helped increase women's access, it began the portrayal of birth control not as woman's right, but as a medical prerogative. This gave fuel to the argument that birth control was useful and necessary in cases where pregnancy might endanger the life of the mother, and increased its popularity in medical circles. Unfortunately this also gave rise to the idea that the diaphragm was too complicated, expensive and required too much medical expertise to be viable for marginal groups in society.

2000

Family Health International. Female barrier methods. *Network* 2000; 20(2).

Female barrier methods include the diaphragm, female condom and spermicides. A number of experimental devices and microbicides are under development. In general, female barrier methods are not as effective in preventing pregnancy as other modern methods, but provide a degree of protection against sexually transmitted diseases. Correct and consistent use of the male latex condom offers the best barrier protection against infections.

Ortayli N, Bulut A, Nalbant H, Cottingham J. Is the diaphragm a viable option for women in Turkey? *International Family Planning Perspectives* 2000; 26(1): 36-42.

Context: In Turkey, where contraceptive prevalence is about 65%, a large number of couples rely on withdrawal and the IUD. Although the country has had a national family planning program for 35 years, the diaphragm has not been introduced as a contraceptive option. Methods: Diaphragms were offered to women as a contraceptive option during counseling sessions at four family planning clinic sites in western Turkey: two public-sector clinics (one in Çapa, Istanbul, the other in Izmir) and two private-sector clinics (one in Incirli, Istanbul, the other in Denizli). Women who chose the diaphragm were interviewed at enrollment and were invited for follow-up visits with a physician at two weeks and at any time thereafter. Demographic information was also collected from an additional 740 women who chose another contraceptive method, and focus-group discussions were conducted with diaphragm users and their partners, with users of other methods and with service providers. Results: Overall, 166 women selected the diaphragm, and 161 enrolled in the study. Initial acceptance rates were higher at the two private clinics (14% and 6%) than at the public clinics (3% and 1%). At the public-sector clinics, diaphragm users were better educated and more likely to be professionally employed than were women who selected other contraceptive methods. In Çapa, 42% of women who chose the diaphragm were university graduates, compared with 7% of those who chose another method. Despite differences between the two private clinics in clients' educational levels, no such differences existed between diaphragm acceptors and users of alternative methods at each site. Among women who chose the diaphragm, 47% said they had sex four times or more per week, compared with 29% of those using another contraceptive. More than half of the women who selected the diaphragm (59%) cited safety and freedom from side effects as the reason for their choice of contraceptive. A



similar percentage of clients who used other methods (58%) cited effectiveness. Fifty percent of diaphragm users had discontinued by six months, and 66% had done so by 12 months. Conclusion: A small proportion of clients in both private- and public-sector clinics were interested in using the diaphragm and found it acceptable. In less-developed countries, the diaphragm may be a viable contraceptive option when providers are able to provide adequate information and support.

1999

Mauck C, Callahan M, Weiner DH, Dominik R. A comparative study of the safety and efficacy of FemCap, a new vaginal barrier contraceptive, and the Ortho All-Flex diaphragm. *Contraception* 1999; 60: 71-80.

The FemCap is a new silicone rubber barrier contraceptive shaped like a sailor's hat, with a dome that covers the cervix, a rim that fits into the fornices, and a brim that conforms to the vaginal walls around the cervix. It was designed to result in fewer dislodgments and less pressure on the urethra than the cervical cap and diaphragm, respectively, and to require less clinician time for fitting. This was a phase II/III, multicenter, randomized, open label, parallel group study of 841 women at risk for pregnancy. A subset of 42 women at one site underwent colposcopy. Women were randomized to use the FemCap or Ortho All-Flex contraceptive diaphragm, both with 2% nonoxynol-9 spermicide, for 28 weeks. The objectives were to compare the two devices with regard to their safety and acceptability and to determine whether the probability of pregnancy among FemCap users was no worse than that of the diaphragm (meaning not more than 6 percentage points higher). The 6-month Kaplan-Meier cumulative unadjusted typical use pregnancy probabilities were 13.5% among FemCap users and 7.9% among diaphragm users. The adjusted risk of pregnancy among FemCap users was 1.96 times that among diaphragm users, with an upper 95% confidence limit of 3.01. Clinical equivalence (non-inferiority) of the FemCap compared with the diaphragm, as defined in this study, would mean that the true risk of pregnancy among FemCap users was no more than 1.73 times the pregnancy risk of diaphragm users. Because the observed upper 95% confidence limit (and even the point estimate) exceeded 1.73, the probability of pregnancy among FemCap users, compared with that among diaphragm users, did not meet the definition of clinical equivalence used in this study. The FemCap was believed to be safe and was associated with significantly fewer urinary tract infections. More women reported problems with the FemCap with regard to insertion, dislodgement, and especially removal, although their general assessments were positive. The two devices were comparable with regard to safety and acceptability, but a 6-point difference in the true 6-month pregnancy probabilities of the two devices could not be ruled out. Further studies are needed to determine whether design modifications can simplify insertion and removal.

1998

Stein Z and Susser M. Annotation: Prevention of HIV, other sexually transmitted diseases, and unwanted pregnancy –testing physical barriers available to women. *American Journal of Public Health* 1998; 88(6): 872.

Although the male and female condom, vaginal diaphragm, and cervical cap have been approved for contraceptive purposes, these barrier methods have not been tested fully for protection against sexually transmitted diseases (STDs), including HIV. Such evaluation requires consideration of three issues. First, there is a need to bypass tests of efficacy (impossible, given the need to render subjects blind to the nature of the physical barrier and ensure randomization) and move directly to tests of use effectiveness. Effectiveness testing addresses matters such as acceptability, adherence to advice, and implementation. The second issue concerns the interventions to be offered to the experimental group. Many maintain that, for ethical reasons, all trial participants must be offered the male condom. Since the male condom cannot be used in tandem with



the female condom, the experimental intervention should provide a choice between a hierarchy of methods. Third, given the epidemic nature of HIV/AIDS, the study design should be focused at the group rather than the individual level.

1997

Mauck CK, Baker JM, Barr SP, Johanson W, Archer DF. A phase I study of Femcap used with and without spermicide: Post-coital testing. *Contraception* 1997; 56(2): 111-5.

The objectives of the study were to assess the ability of the Femcap, a new vaginal contraceptive device made of silicone and designed to fit snugly around the cervix to prevent the penetration of sperm into mid-cycle cervical mucus when used with and without spermicide; and to compare it with the standard contraceptive diaphragm used with spermicide. Eight women underwent two baseline cycles of post-coital testing in which no device was used, followed by three test cycles in which Femcap with spermicide, Femcap with non-spermicidal lubricant (K'Y gel) or the Ortho All-Flex diaphragm with spermicide was used. The sequence of testing cycles was randomized. In each cycle, condoms were used prior to mid-cycle, then a mid-cycle cervical mucus specimen was examined to ensure mid-cycle characteristics and the absence of sperm. Each woman then had intercourse using either no device (baseline cycles) or the prescribed device (test cycles) and returned 2-3 h afterwards. Cervical mucus was again assessed for adequacy and the presence of spermatozoa. The average number of progressively motile sperm seen per high power field was as follows: first baseline cycle, 18.0; second baseline cycle, 17.8; test cycle with Femcap used with non-spermicidal lubricant, 0.1; test cycle with Femcap used with spermicide, 0.2; and test cycle with the diaphragm used with spermicide, 0.0. There was no significant difference between baseline cycles or among test cycles in the average number of progressively motile sperm seen ($p > 0.05$). The average number of progressively motile sperm seen in each test cycle did, however, differ significantly from the average number seen in either baseline cycle ($p < 0.05$). Femcap, used with either a spermicidal lubricant or a non-spermicidal lubricant, appears to be comparable with the diaphragm used with spermicide in preventing sperm from entering mid-cycle cervical mucus.

Ravindran TKS and Rao SS. Is the diaphragm a suitable method of contraception for low-income women: A user perspectives study, Madras, India. In World Health Organization [WHO], Beyond acceptability: users' perspectives on contraception London, England: Reproductive Health Matters. 1997. Pp. 78-88.

Women's experiences with the vaginal diaphragm were investigated in a qualitative study of 97 low-income women from Madras, India, who received the device from non-governmental family planning clinics. Most of the women intended to use the diaphragm for 18-24 months—for spacing their next pregnancy or until they underwent sterilization. The lack of other acceptable contraceptive options for low-income Indian women contributed to a high level of motivation among study participants to use the method correctly. In the overwhelmingly provider-controlled context of India's family planning services, women appreciated the ability to control the use and discontinuation of this method. The absence of negative health effects was the most important advantage of use. Women were comfortable inserting the diaphragm and removed the device for washing at the time of their morning bath. Since sexual intercourse was infrequent in the study group, women preferred a coitus-related method. Spousal opposition to the diaphragm was not reported. The extent of women's positive responses to the diaphragm as a contraceptive method of choice exceeded the researchers' expectations. The diaphragm is no longer available in India. However, these findings suggest that its reintroduction to the national family planning program would represent a valuable expansion of contraceptive choice for low-income women.

1996



Beckman LJ and Harvey SM. Factors affecting the consistent use of barrier methods of contraception. *Obstetrics & Gynecology* 1996; 88(3): 65S-71S.

Objective: To discuss the major issues involved in the consistent and effective use of barrier methods of contraception. Data sources: Major research and review articles on barrier methods published within the last 10 years were considered. One major source of articles was Family Planning Perspectives. Methods of study selection: This paper is a focused review and integration of recent literature rather than a comprehensive literature review. Only selected articles published since 1986 that are pertinent to the issues raised are included. Tabulation, Integration and Results: All barrier methods have common characteristics that influence their patterns of use. The correct and consistent use of such methods is determined by the methods themselves, characteristics of users, and the situational context. Method characteristics include the extent of interference with sexual spontaneity and enjoyment, the amount of partner cooperation required, and the ability of the method to protect against human immunodeficiency virus and other sexually transmitted diseases. User characteristics include motivation to avoid unintended pregnancy, ability to plan, comfort with sexuality, and previous contraceptive use. Stage of sexual career, relationship characteristics, and physical and sexual abuse are important situational influences. Conclusions: Even though most barrier methods can be obtained without a prescription from a provider, clinicians have an extremely important role in promoting effective and consistent method use. Four major ways to improve the use of barrier methods currently available include: 1) improve method characteristics and the distribution systems; 2) change consumers' perceptions of method attributes; 3) train consumers to use methods correctly and overcome perceived negative characteristics of the methods; and 4) change values about the perceived importance of method characteristics. There also is an urgent need for the development of better barrier methods.

Mauck C, Glover LH, Miller E, Allen S, Archer DF, Blumenthal P, Rosenzweig BA, Dominik R, Sturgen K, Cooper J, Fingerhut F, Peacock L, Gabelnick HL. Lea's Shield: a study of the safety and efficacy of a new vaginal barrier contraceptive used with and without spermicide. *Contraception* 1996; 53: 329-35.

The purpose of this study was to evaluate the safety, efficacy and acceptability of Lea's Shield, a new vaginal contraceptive barrier device, when used with either spermicidal or non-spermicidal lubricant. One-hundred-eighty-five (185) women enrolled at six centers. Half were randomized to use the device with spermicide and half with a non-spermicidal lubricant. To be eligible, volunteers had to be 18-40 years old (inclusive), in good health with regular menses, sexually active in an on-going relationship and at risk for pregnancy, and willing to use Lea's Shield as their sole means of contraception for six months. Participants were seen at admission, one week, one month, three months and six months. Gross cumulative life table rates were calculated for pregnancy and other reasons for discontinuation. Adverse experiences and responses to an acceptability questionnaire were evaluated. One-hundred-eighty-two (182) volunteers contributed data to the analysis of safety and 146 to that of contraceptive efficacy. The unadjusted six-month life table pregnancy rate was 8.7 per 100 women for spermicide users and 12.9 for non-spermicide users ($p = 0.287$). After controlling for age, center, and frequent prior use of barrier methods, the adjusted six-month life table pregnancy rate was 5.6 for spermicide users and 9.3 for non-spermicide users ($p = 0.086$), indicating that use of spermicide lowered pregnancy rates, although not significantly, during typical use. For purposes of comparison, it is important to note that this study differed from the cap/diaphragm and sponge/diaphragm studies in that a high percentage (84%) of volunteers were parous. For reasons that are unclear, pregnancy rates among parous women using barrier contraceptives tend to be higher than among nulliparous women. Indeed, in this study there were no pregnancies among nulliparous users of Lea's Shield. Standardization of parity of this study population on those of the cap/diaphragm and sponge/diaphragm studies suggests that unadjusted pregnancy rates for this device would have been considerably lower (2.2 and 2.9 per 100 users of spermicide and non-spermicide, respectively) had the study been done using the populations of earlier studies. Since no directly comparative study has been done, these figures provide a tentative estimate of the relative efficacy of Lea's Shield compared with the sponge, cap, and diaphragm. There were no serious adverse experiences attributed to the use of Lea's Shield. Acceptability was very good. Seventy-five percent (75%) of



women responded to an end-of-study questionnaire; 87% of these reported that they would recommend Lea's Shield to a friend. Lea's Shield is a new vaginal contraceptive that does not require clinician fitting. Pregnancy rates in this study compare favorably with other studies of barrier contraceptive methods including the cervical cap, diaphragm, and sponge, even though this study was done with greater rigor and with a greater percentage of parous women than previous barrier studies. Lea's Shield appears to be safe and very acceptable to study volunteers.

1995

Archer DF, Mauck CK, Viniegra-Sibal A, Anderson FD. Lea's Shield: a phase I post-coital study of a new contraceptive barrier device. *Contraception* 1995; 52(3): 167-73.

Lea's Shield is a new vaginal barrier contraceptive that may offer advantages over existing methods. It is made of silicone which is resistant to petroleum-based lubricants, does not absorb odors, and does not cause allergic reactions in users with latex sensitivity. It has an anterior loop for ease of insertion and removal and a one-way flutter valve. Its novel design has sufficient volume to fill the posterior fornix, which helps keep it in place and prevent sperm from entering the cervical os. This study evaluated with a standard post-coital test (PCT) the ability of the Lea's Shield used with spermicide or non-spermicidal lubricant to prevent sperm from entering mid-cycle cervical mucus. Ten sterilized women underwent four PCT cycles: one cycle in which no contraceptive barrier was used (a baseline cycle) and 3 cycles in which one of the following was used: Lea's Shield with spermicide, or with non-spermicidal lubricant, or the contraceptive diaphragm used with spermicide. All volunteers demonstrated more than 5 progressively motile sperm per high power field in the cervical mucus after intercourse in the baseline cycle. No motile sperm were found in the cervical mucus in any cycle in which Lea's Shield or the diaphragm was used with spermicide. No motile sperm were found in cervical mucus in 9 of 10 cycles in which Lea's Shield was used without spermicide. Only two progressively motile sperm were present in the cervical mucus of one volunteer who used the shield with non-spermicidal lubricant. This volunteer used a smaller Lea's Shield which is no longer manufactured. There were no serious adverse experiences in any volunteer. This study suggests that the Lea's Shield can prevent the passage of motile sperm into mid-cycle cervical mucus with or without the use of spermicide and is as effective as the standard diaphragm used with spermicide.

Bounds W, Guillebaud J, Dominik R, and Dalberth BT. The diaphragm with and without spermicide. A randomized, comparative efficacy trial. *Journal of Reproductive Medicine* 1995; 40: 764-74.

Objective: To determine the relative contraceptive efficacy of a diaphragm used with spermicide as compared to one used without. Study design: Two hundred sixteen women entered the study between September 1985 and December 1990. Of these, 84 were randomly assigned to the diaphragm-only group and 80 to the diaphragm-with-spermicide group as their primary method of contraception. In addition, a spermicide-only group was planned originally to serve as a control group to assess the contribution to efficacy made by a spermicide alone. Thirty-nine women were randomly assigned to this group, and 13 selected themselves for it. All were followed for a maximum of 12 months. The primary outcome variable was accidental pregnancy. The statistical difference between the two diaphragm groups was analyzed. Results: The 12-month "typical use" failure rates for the diaphragm-only group were 28.6 per 100 women, and for the diaphragm-with-spermicide group, 21.2. The 12-month cumulative consistent-use failure rates were 19.3 per 100 women for the diaphragm-only group as compared to 12.3 per 100 women for users of a diaphragm with spermicide. Conclusion: Although the consistent use rates were not significantly different, this study had low statistical power and hence gives no support to the hypothesis that adjunctive spermicide use fails to improve the effectiveness of the diaphragm method, especially in view of the magnitude and direction of the difference observed. Unless a study with sufficient power proves that the use of a diaphragm alone is statistically as effective as use of a diaphragm with spermicide, use of a spermicide in conjunction with the diaphragm continues to be the appropriate clinical recommendation.



Di Giacomo do Lago T, Barbosa RM, Kalckmann S, Villela WV, Gohiman S. Acceptability of the diaphragm among low-income women in São Paulo, Brazil. *International Family Planning Perspectives* 1995; 21(3): 114-118.

A study of the acceptability of the diaphragm among low-income women in São Paulo, Brazil, found that about 11% of 1,723 women who sought a method in one of five public health clinics opted for the diaphragm following a contraceptive educational session on all methods. The main reason they gave for doing so was because it was physically harmless. Women who chose the diaphragm were older and better educated than those who chose the pill, and were more likely than IUD users to want to space births rather than limit them. However, 46% of the women who selected the method were no longer using it three months later, compared with 29% of women who chose the condom and 16% who chose the pill. Although low-income women appear willing to use the diaphragm, providers may need further training to assist women in resolving difficulties that appear in the first few months of diaphragm use.

Smith C, Gaston F, Feldblum PJ, Spence A. Effectiveness of the non-spermicidal fit-free diaphragm. *Contraception* 1995; 51: 289-291.

Standard instructions for diaphragm use call for an individually sized latex diaphragm, used in conjunction with spermicide jelly. However, some investigators have reported that the diaphragm can be effective without a spermicide. A non-randomized trial designed to measure the contraceptive effectiveness of the diaphragm used without spermicide was conducted. A total of 110 self-selected women were enrolled to use a non-spermicide fit-free (60 mm) diaphragm for a period of one year. They were advised to wear the diaphragm continuously, removing it once each day for washing but not within six hours after intercourse. Product-related problems related to insertion, retention, and removal were few at both the 6- and 12-month follow-up visits, most commonly odor. The 12-month life table accidental pregnancy rate during typical use was 24.1 per 100 women (29.5 per 100 women without female barrier experience). Over 85% of the women who returned for follow-up visits reported using the diaphragm during every act of intercourse. Until better data refute the traditional recommendations, users should be advised to add spermicide to fitted latex diaphragms.

1994

Roy S. Vaginal anatomy and physiology as they relate to sexual intercourse. In CK Mauck, M Cordero, HL Gabelnick, JM Spieler, and R Rivera (Eds.). Barrier contraceptives: Current status and future prospects. New York, New York: Wiley-Liss. 1994. Pp. 77-89.

This chapter includes a review of the embryology and anatomy of the vagina followed by a consideration of its physiology with special reference to issues that relate to vaginal contraceptive development. Many women of reproductive age have anatomical changes as a consequence of parity including symptomatic cystocele, rectocele, uterine descensus or procidentia. These anatomic factors should be considered in the development of vaginal contraceptives. Another consideration is coital position, in that vaginal contraceptives should be effective in non-traditional positions. Extremes of vaginal lubrication or semen volume should be considered in the design and testing of vaginal contraceptives. Although the sources of fluids have been identified, the expected volumes, especially of vaginal transudation, are not well studied or understood.

1993



Stein Z. HIV prevention: An update on the status of methods women can use. *American Journal of Public Health* 1993; 83(10): 1379-82.

Since 1990, advocates have increasingly called for the development of prophylactic methods women can use to protect themselves from HIV infection. The risk of heterosexual transmission of HIV is enhanced by the presence of other sexually transmitted diseases caused by ulcerative (Ducrey's bacillus) and non-ulcerative (gonococcus) organisms. Therefore, both microbicides and barrier methods (chemical and physical) are needed to provide protection from HIV transmission. Whereas chemical methods, specifically nonoxynol-9, have been shown to provide protection in low doses, much remains to be learned through human trials about their mechanism of action and how they vary in different individuals in different circumstances. The diaphragm and cervical cap can be used by women independently of cooperation from men. While they only protect the cervix, recent evidence gives weight to the theory that the cervix plays a role in HIV transmission. The female condom may become the method of choice in protection against HIV, despite the unenthusiastic greeting it received from the popular press. In general, however, much remains to be discovered about the behavioral and social determinants of the use of barrier methods. Health professionals also wonder if presenting women within a range of options is confusing rather than helpful; however, women have the right to education in these matters. Discovering whether HIV is transferred by sperm alone or by somatic cells in the semen alone will determine whether contraception or application of a virucide is necessary for prevention. This will have social, moral, and biological consequences as well as practical implications. Whereas some populations have instituted behavioral changes to achieve AIDS prevention, it remains urgent to emphasize methods women can use to complement other approaches. While awaiting the development of long-term microbicides or vaccines, the largely untested efficacy of barrier methods for prevention needs to be moved from the area of speculation to a central position in research studies. Despite their imperfections, barrier methods may have a positive impact on prevention.

Trussell J, Strickler J, Vaughan B. Contraceptive efficacy of the diaphragm, the sponge and the cervical cap. *Family Planning Perspectives* 1993; 25(3): 100-5 & 135.

A reanalysis of data from two clinical studies--in which 1,439 women were randomly assigned to use either the contraceptive sponge or the diaphragm and 1,394 women were randomly assigned to use either the cervical cap or the diaphragm--found first-year probabilities of failure during typical use of 17% for the sponge, 18% for the cervical cap and 13-17% for the diaphragm. The first-year probabilities of failure during perfect use are 11-12% for the sponge, 10-13% for the cervical cap and 4-8% for the diaphragm. The probability of failure during perfect use is significantly higher among women who have given birth than among those who have not for users of the sponge (19-21% vs. 9-10%) and users of the cervical cap (26-27% vs. 8-10%), but not for users of the diaphragm.

