The articles listed below represent a bibliography of recent research on the diaphragm. The bibliography contains a list of citations in alphabetical order followed by an expanded list including abstracts. This bibliography builds on and follows the format set forth in the annotated bibliography presented at the 2002 Diaphragm Renaissance conference (see: http://www.rho.org/html/cont_diaphragm_renaissance.htm)

You may click on the article citation to access the full abstract cited later in the document.

Citations


Elias C, 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).


Expanded citation list, including abstracts


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.


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 postcoital test (PCT) the ability of the Lea's Shield used with spermicide or non-spermicidal lubricant to prevent sperm from entering midcycle 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 midcycle cervical mucus with or without the use of spermicide and is as effective as the standard diaphragm used with spermicide.

**Beckman LJ, 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.

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.


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.


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 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.

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.


Except for the female condom, which is not reusable and is therefore expensive for most women in developing countries, a female controlled method proven to reduce the risk of HIV and other sexually transmitted infections does not currently exist. The diaphragm is a widely accepted reusable form of contraception that has relatively low cost per use. Although a randomized trial has not been performed, case-control investigations support the efficacy of the diaphragm used with nonoxynol-9 to prevent Neisseria gonorrhoeae, Trichomonas vaginalis, and perhaps, Chlamydia trachomatis infection in women. Our research team in Nairobi, Kenya, recently initiated a randomized controlled trial of the diaphragm to prevent recurrent N. gonorrhoeae and C. trachomatis infection in women attending an STD clinic. Awaiting results from this and future controlled trials, the diaphragm used alone, or ideally, with a microbicide, would provide affordable protection for women choosing to limit their risk of acquiring sexually transmitted infections and HIV.


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.

**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.**

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.

**Elias C, 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).

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.


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.


Female barrier methods include the diaphragm, female condom and spermicides. A number of experimental devices and microbicidal products 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.

**In this issue**

*Microbicide Products Enter Human Trials*

Scientists are evaluating more than 50 experimental substances as possible vaginal microbicides to protect against HIV and other diseases. Experimental microbicides in or nearing human trials use a variety of mechanisms. Microbicide research faces challenges, including how to determine effectiveness. Meanwhile, research is also examining the possible use of commercially available spermicides as microbicides.

*How Effective Are Spermicides?*

While spermicides appeal to some women, users should not expect substantial protection against pregnancy or sexually transmitted diseases. Nevertheless, they are often available without a prescription or provider's help, and using them is easy and can sometimes be done without a partner's knowledge.

*New Devices May Be Easier to Use*

Future versions of cervical caps and diaphragms should be easier to insert and remove. Development of new contraceptive sponges seeks to reduce vaginal irritation by lowering spermicide doses.

*Female Condom Reuse Examined*

If a female condom can be used safely and effectively more than once, the method would be less expensive for people to use. Early research by FHI and University of the Witwatersrand in Soweto, South Africa, on reuse is encouraging. Meanwhile, a recent Zimbabwe project promotes female condom use, illustrating the limitations of generating widespread public interest in the device.

*User, Partner Attitudes Influence Barrier Use*

At a time when AIDS has become a devastating public health problem, the role of female barrier methods to prevent sexually transmitted diseases has taken on new importance. Scientists are examining how and why couples use barrier methods, and what they like or do not like about them. Promoting partner communication among users is one aspect of how barrier methods can be used more effectively.

**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.

**In this issue**

*The "ABC to Z" Approach*

Male condoms — when used consistently and correctly — are an effective means of preventing HIV infection and unplanned pregnancy among sexually active individuals who need to protect themselves. However, they are only one element in a comprehensive approach to the prevention of HIV and other sexually transmitted infections (STIs.) For example, the term "ABC approach" refers to the strategy of: abstinence, be faithful to one partner, or — if "A" or "B" cannot be achieved — use condoms. This ABC approach defines an appropriate role for condoms as an essential part of a larger armamentarium for HIV prevention. In fact, a broader "ABC to Z" model is suggested in this article to convey the full spectrum of prevention opportunities.

*Targeting Populations at Increased Infection Risk*

Traditionally, efforts to prevent HIV infection by promoting condom use — as part of a comprehensive array of risk reduction approaches — have targeted people at increased risk of infection. These include sex workers based in brothel establishments, as well as those based in non-brothel establishments (where condom use often is low), and men, since they often make the final decision on condom use in sexual settings. Campaigns with Uniformed Services Change Behaviors describes the success of 100 percent condom use programs implemented in brothels, while also recognizing the contribution of a uniformed services peer education program that promotes condom use and delivers other HIV prevention messages. Public Health Initiative Nearly Halves STI Rates explains the nature of a condom promotion initiative in the Dominican Republic. Finally, Measuring Condom Use Better explores why and how researchers are seeking ways to more accurately measure the consistency of condom use.

*Female Condom Reuse Issues Explored*

For female condom users, use of a new female condom for every act of sexual intercourse is recommended by the World Health Organization (WHO). However, reuse may be acceptable, feasible, and safe in some circumstances, leading WHO to state that "the final decision on whether or not to support reuse of the female condom must ultimately be taken locally." WHO recommends that, on the local level, program managers not recommend female condom reuse until they have adapted a female condom cleaning and handling protocol (retaining all procedural steps) to local conditions and then tested the protocol's feasibility, efficacy, and usefulness in their settings.
Dual Protection
Continuing research and discussion on the two major strategies for dual protection against both unplanned pregnancy and sexually transmitted infections (STIs) indicate that each strategy has distinct advantages and disadvantages, as depicted in the table Dual Protection Strategies, and that appropriate dual protection messages may differ according to individual circumstances. Emphasizing Dual Protection Messages describes how such messages are being integrated into reproductive health services in such locations as Nigeria, Ethiopia, South Africa, and Kenya. That consistency of condom use may depend at least as much on individual characteristics as on whether a condom-only or a dual method approach to dual protection is used is discussed in Dual Protection and Consistency of Condom Use.

After N-9, What Next?
More than 50 agents are being studied for their potential as microbicides that might be used topically as protective barriers against HIV and other sexually transmitted infections (STIs). While a microbicide is unlikely to reach the market until after 2010, six microbicide products are expected to enter effectiveness trials in 2003 and 2004. The ways in which those products act to prevent HIV and other STI pathogens from infecting cells is depicted in Microbicides Approaching Effectiveness Trials: How They Work. Meanwhile, although nonoxynol-9 (N-9) remains a moderately effective contraceptive option for women at low risk of HIV infection, N-9 Not for Women at High Risk of HIV Infection explains why N-9 spermicides should not be used by other individuals or for other purposes.

Will Diaphragms Protect against STIs?
The hypothesis that diaphragms might offer women some protection against sexually transmitted infections (STIs), including HIV, will soon be tested in several randomized controlled trials. Also to be explored soon is the question of whether diaphragms and microbicides would be more effective in preventing STIs if they were used together. The status of the Today contraceptive sponge — an alternative to the diaphragm — is discussed in Contraceptive Sponge Re-enters the Market.


Objective: The male condom is the most effective barrier method available for protection against sexually transmitted diseases (STDs), including HIV infection. There is an urgent need to develop and evaluate other prevention methods, such as the female condom. This study estimated the additional protection against STDs offered to sex workers by giving them the option of using the female condom when clients refused to use a male condom.
Methods: Sex establishments in four cities in Thailand were randomized into two study groups: one in which sex workers were instructed to use male condoms consistently (male condom group); and one in which sex workers had the option of using the female condom if clients refused or were not able to use male condoms (male/female condom group). Randomization was done by sex establishments, and not by individuals, to minimize sharing of female condoms across study groups. The proportion of unprotected sexual acts (defined as sexual acts in which condoms were not used, tore, or slipped in or out) and incidence rate of STDs (gonorrhoea, chlamydial infection, trichomoniasis and genital ulcer disease) were measured over a 24-week period and compared between the two study groups.

Findings: Results are available from 34 sex establishments (249 women) in the male/female condom group, and 37 sex establishments (255 women) in the male condom group. Condom use was very high in both groups (97.9 and 97.3 % of all sexual acts, respectively, P > 0.05). Male condom use was lower in the male/female condom group when compared with the male condom group (88.2 and 97.5%, respectively, P < 0.001). However, this reduction in male condom use was counterbalanced by the use of female condoms in 12.0% of all sexual acts in the male/female condom group, contributing to a 17% reduction in the proportion of unprotected sexual acts in this group when compared to the male condom group (5.9 versus 7.1%, respectively, P = 0.16). Female condom use was sustained over the entire study period. There was also a 24% reduction in the weighted geometric mean incidence rate of STDs in the sex establishments of the male/female condom group compared to the male condom group (2.81 versus 3.69 per 100 person-weeks, P = 0.18).


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.


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.


In the U.S., few contraceptive 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.


Background: The diaphragm is effective against some STIs; could protect against HIV; has advantages over other methods; and could be used with microbicides. We need a better understanding of obstacles to using physical barrier methods like the diaphragm.
Objectives: This study examines diaphragm perceptions and self-efficacy among current and former diaphragm users and young women at increased risk for HIV, and explores factors that increase diaphragm acceptability among high-risk women.

Methods:
Study 1: phone interviews with 215 current and 173 former diaphragm users
Study 2: focus groups with and questionnaires from 140 racially/ethnically diverse women at risk for HIV/STIs who never used the diaphragm

Summary and Conclusions:
Product characteristics and self-efficacy influenced acceptability among diaphragm users. Emphasis on the diaphragm’s positive attributes (e.g., non-hormonal, effectiveness) and counseling could minimize negative attributes. Acceptability of the diaphragm among at-risk women could increase substantially if the method protects against HIV.


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.


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.


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.

In a prospective study of 1122 women attending a sexually transmitted disease (STD) clinic in Alabama, consistent use of the male condom and vaginal microbicide/spermicides was promoted to reduce STD risk. This analysis evaluated: 1) baseline characteristics that may influence birth control method choice; and 2) the association of birth control method and other baseline characteristics with consistency of barrier use during follow up. Birth control method was associated with sociodemographic variables, sexual, and reproductive history.

Women who adopted user-independent methods (tubal ligation, implants, injectable hormones) appear to have completed their family plan.

Oral contraceptive users were of higher socioeconomic status and at lower STD risk. Barrier method users and women who used no method were young and at higher STD risk. Consistency of condom/spermicide use increased in all groups. Barrier method users were more likely than other women to use condoms and spermicides during the study. Women who used no birth control method at baseline experienced the largest increase in barrier use during follow up, although their barrier use rates were lower than in other groups. The synergism between the intention to prevent pregnancy and the intention to prevent STD should be considered in the design of interventions promoting condom use.


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.

www.guttmacher.org/pubs/journals/3507103.html

Context: Family planning providers can play an important role in helping women to identify their risk of HIV and other sexually transmitted diseases (STDs) and to adopt preventive measures. In-depth investigation of providers’ attitudes about approaches to STD risk assessment, contraceptive counseling and dual protection—concurrent protection from STDs and unintended pregnancy—has been limited.

Methods: In semistructured interviews conducted in 1998, 22 health care providers from a large New York City agency offering contraceptive and STD services described how they balanced STD and pregnancy concerns, viewed risk assessment and assessed various contraceptive methods.

Results: STD prevention was seen as an integral part of family planning counseling, and most providers believed that risk assessment should be conducted universally. Providers viewed dual protection as use of condoms along with an effective contraceptive; few advocated use of the male or female condom alone. The female condom was believed to be a disease prevention method of last resort and was considered appropriate only for specific groups of women. Although providers lacked understanding about the effectiveness of the female condom and how to counsel clients concerning its use, they expressed interest in learning more.

Conclusions: Training is needed to reduce providers’ negative perceptions of the female condom and to reinforce the importance of individualized counseling tailored to women’s specific circumstances. Studies are needed on how to encourage family planning providers to promote male and female condoms as effective contraceptive methods.

With growing recognition of the potential value of microbicides for HIV/STI prevention, the importance of the acceptability of this brand-new technology has been widely acknowledged. We review the current body of microbicide acceptability research, characterize the limitations in assessment approaches, and suggest strategies for improvement. Electronic databases and abstracts of recent meetings were searched for acceptability data regarding vaginal and rectal products that may be used for HIV prevention. Of the 61 studies reviewed, more than half assessed acceptability based primarily on the description of a hypothetical microbicide, or with the demonstration of a spermicide or lubricant. Physical characteristics of microbicidal products, their effects after insertion, and their effects on sensation during intercourse (for both partners) were the dimensions most frequently assessed (measured in 77%, 49% and 49% of studies, respectively). Attention to the social context of use was inadequate. As acceptability is likely to be a key determinant in the use-effectiveness of microbicides, in-depth understanding of the social processes that shape microbicide acceptability across diverse populations will become increasingly valuable. This includes exploring the effects that sexual partners, health care providers, and key opinion leaders have on the acceptability of microbicides among women and men, including youth and people living with HIV. Future research will benefit from studies of the acceptability of other contraceptive-barrier methods (especially the female condom), use of an agreed-upon operationalization of acceptability, use of acceptability assessments within clinical trials, expansion of measurement domains, and assessment of changes in perceptions of acceptability and use over time. Failure to understand the key factors associated with microbicide acceptability is likely to hinder the adoption and continued use of products that are effective in preventing HIV infection.


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 (noninferiority) 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.


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 midcycle 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 postcoital testing in which no device was used, followed by three test cycles in which Femcap with spermicide, Femcap with nonspermicidal 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 midcycle, then a midcycle cervical mucus specimen was examined to ensure midcycle 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 nonspermicidal 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 nonspermicidal lubricant, appears to be comparable with the diaphragm used with spermicide in preventing sperm from entering midcycle cervical mucus.


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.

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 others 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.


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.


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.


The objective of this study was to examine the relationship between contraceptive method choice, sexual risk and various demographic and social factors. Data were collected on 378, 15- to 24-year-old women, recruited from health clinics and through community outreach in Northern California. Logistic regression analysis was used to estimate the association of predictors with contraceptive method used at last sex. Asian and Latina women were less likely to use any method. Women who were raised with a religion, or thought they were infertile, were also less likely to use any method. Women with multiple partners were generally less likely to use any method, but were more likely to use barrier methods when they did use one. Few women (7%) were dual method users. Women appear to act in a rational fashion within their own social context and may use no methods at all or use methods that are less effective for pregnancy prevention but offer more protection from sexually transmitted infections.

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.


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.

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.


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 nonspermicide 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.

**Stein Z and Susser M. 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.


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.


Objective: We evaluated whether offering a choice of barrier methods can increase overall barrier method use without decreasing condom use in women using oral contraceptives (OCs) for contraception.

Study Design: We randomized 167 OC users at risk for sexually transmitted diseases (STDs) into two groups, one receiving male latex condoms only (Condom group), the other receiving both male latex condoms and nonoxynol-9 film (Choice group). All participants received similar hierarchical STD protection counseling. We assessed method use with daily diaries.

Results: The Choice group protected a significantly higher percentage of their coital acts with a barrier method (month 1 to 2: 29% vs. 22%; month 3 to 4: 33% vs. 21%; and month 5 to 6: 35% vs. 19%; adjusted P = 0.012). Condom use in the Choice group was higher as well (adjusted P = 0.036). When we used a transitional multilogistic regression approach to account for differential loss to follow-up in the two groups, results were similar.

Conclusions: Offering a choice of barrier methods increased overall barrier method use without decreasing condom use.


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.


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 U.S. 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.


This report describes attempts to expand contraceptive options in India by promoting diaphragms, among several other methods. In 1995, only a limited number of outlets supplied the diaphragm in India. International donors had sharply reduced the procurement of these supplies due to the explicit policy of the Indian government to exclude barrier methods other than the condom from the public program.

The Population Council provided several health organizations with diaphragms and spermicide, and in some cases, examples of anatomical and instructional models for fitting and insertion training, videos for clinicians and clients, educational materials on the diaphragm for clients, and technical materials. The Population Council also submitted technical information and samples of the diaphragms and spermicides to the Drug Controller of India for review and assessment. The Population Council also organized a workshop in April 1994, attended by twenty professionals from organizations with potential interest in the reintroduction of the diaphragm. In June of 1995, the Ministry of Health and Family Welfare communicated to the State Innovations in Family Planning Services Project Agency (SIFPSA) in Uttar Pradesh that all studies on the diaphragm had to have the approval of the Indian government, and that the distribution of supplies to NGOs was not
authorized until such permission was granted. The Council then attempted to clarify this position in light of future plans for the diaphragm in efforts to expand choices for contraception and disease 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.


Objectives: The purpose of this study was to determine the clinical and economic impact of alternative contraceptive methods.

Methods: Direct medical costs (method use, side effects, and unintended pregnancies) associated with 15 contraceptive methods were modeled from the perspectives of a private payer and a publicly funded program. Cost data were drawn from a national claims database and MediCal. The main outcome measures included 1-year and 5-year costs and number of pregnancies avoided compared with use of no contraceptive method.

Results: All 15 contraceptives were more effective and less costly than no method. Over 5 years, the copper-T IUD, vasectomy, the contraceptive implant, and the injectable contraceptive were the most cost-effective, saving $14,122, $13,899, $13,813, and $13,373 per person. Because of their high failure rates, barrier methods, spermicides, withdrawal, and periodic abstinence were costly but still saved from $8,933 to $12,239 over 5 years. Oral contraceptives fell between these groups, costing $1,784 over 5 years, saving $12,879, and preventing 4.1 pregnancies.

Conclusions: Contraceptives save health care resources by preventing unintended pregnancies. Up-front acquisition costs are inaccurate predictors of the total economic costs of competing contraceptive methods.

In this chapter, contraceptive efficacy is addressed as perfect use and typical use. Pregnancy rates during perfect use reflect how effective methods can be in preventing pregnancy when used consistently and correctly. Pregnancy rates during typical use reflect how effective methods are for the average person who does not always use methods correctly or consistently. Pregnancy rates during typical use of compliance-dependent methods generally vary widely among different groups using the same method, primarily due to differences in the propensity to use the method perfectly. The percentage of women experiencing an unintended pregnancy during the first year of typical use of the diaphragm was 20%. The percentage of nulliparous women experiencing unintended pregnancy with typical use of the sponge was 20%. This was also true for nulliparous users of the cap. As for parous users, 40% of women experienced unintended pregnancies with the cap and 40% with the sponge as well. This information is summarized in table 31-1 of this chapter.


Background: In Zimbabwe, where HIV prevalence is over 30%, alternative methods to male condoms are urgently needed. Female-controlled physical barriers like the diaphragm (DA) cover the cervix and may protect against STIs and HIV. There is no data on diaphragm acceptability from Southern Africa.

Objectives: Among Zimbabwean women who are inconsistent condom users, this study will assess diaphragm-KY jelly use following a brief intervention; assess acceptability of DA among women and their partners; and describe demographic and acceptability correlates of consistent (100%) diaphragm use four months post-intervention (at visit 3).

Methods: This is a two-phase study on a cohort of sexually active women recruited from FP and RH clinics in Harare, Zimbabwe, involving: a two-month condom run-in phase (n 405); inconsistent (<100%) users enroll into a six-month DA acceptability phase (n = 190). Behavioral data is collected every 2 months.

Summary: Nearly all (95%) of the women used the DA at least once at every follow-up visit, the majority used DA at least half the time. Despite unknown efficacy, DA was preferred over condoms by over half the women. 80% of women did not always tell their partner when they were using a DA. At visit 3, 100% DA use was associated with older age, DA preference, never telling P about DA use and never using condoms.
Conclusions: If proven effective against HIV/STIs, diaphragms used alone or in combination with a microbicides could provide an acceptable alternative to male condoms in sexually active Zimbabwean women.


The World Health Organization Global Program on AIDS and the Joint United Nations Program on HIV/AIDS (UNAIDS) sponsored a clinical trial of a gel containing N-9 to assess its effectiveness in protecting against HIV. Preliminary results from the study were presented in July 2000 at the 13th International AIDS Conference in Durban, South Africa, and showed, contrary to expectation, that the HIV incidence was higher in women using N-9 than in women using a comparison product. While a disappointment with regard to the rapid deployment of an effective microbicide, these results also raised questions about the safety of N-9 when used for its main indication, protection against unwanted pregnancy.

After presentation of the preliminary results from the study in July 2000, WHO was approached to provide assessment of the scientific information regarding the safety and effectiveness of N-9 when used for family planning purposes. Accordingly, the WHO Department of Reproductive Health and Research convened a Technical Consultation in October 2001, in partnership with the CONRAD Program, to review the available evidence and provide advice on the use of N-9. The Consultation included experts from developed and developing countries with experience in product development, safety assessment, and public health and representatives from collaborating agencies. Reviews of key issues were commissioned prior to the meeting and are summarized in this report.

The meeting also considered the submitted manuscripts from recently completed studies directly relevant to the safety and effectiveness of N-9. This report summarizes the evidence presented to the meeting on the safety of N-9 and its effectiveness for protection against pregnancy, sexually transmitted infections and HIV. The meeting concluded with recommendations on the use of N-9 and identified key areas of uncertainty where more research was urgently required.

Also included in this report are data on cervical barrier use and N-9. One conclusion is that limited evidence suggests that the contraceptive effectiveness of the diaphragm and cervical cap may be moderately more effective when used with a spermicide than without. Data quantifying the contraceptive effects of N-9 in various formulations and doses, used with and without barriers, are clearly needed and the report states that studies to address this deficit are currently under way.