Annotated Bibliography
Diaphragm Renaissance Conference
September 9th &10th Seattle, WA

1. Bounds, W., Guillebaud, J., Dominik, R., & Dalberth, B. T. (1995). The diaphragm with and without spermicide. A randomized, comparative efficacy trial. *Journal of Reproductive Medicine*, 40, 764-74.

Abstract: To determine the relative contraceptive efficacy of a diaphragm used with spermicide as compared to one used without.
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.
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.
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.

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

Abstract: 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.

3. Cohen, C. (2002). *The Diaphragm: A Female Controlled Method to Prevent HIV and Other Sexually Transmitted Infections?* Paper presented at the Microbicides Conference, Antwerp, Belgium.

Abstract: 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 *Neiserria 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. gonnorrhoeae* 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.

4. Gollub, E. L., French, P., Latka, M., Rogers, C., & Stein, Z. (2001). 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*, 10(8), 771-83.

Abstract: 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.

5. Harvey, S. M., Thorburn Bird, S., Maher, J., & Beckman, L. J. (2002). *Acceptability of the Vaginal Diaphragm Among a Sample of Women in the US: Comparing Current and Former Diaphragm Users*. Paper presented at the Microbicides Conference, Antwerp, Belgium.

Abstract: Multiple HIV/STI prevention methods are needed so that women have options that fit with their personal preferences, life circumstances, and socio-cultural contexts. Of particular importance are female-controlled methods that can be used without the male partner's cooperation or knowledge. These methods are not intended to replace the male condom, but would provide women with an alternative method of protection if condoms are not an option. Research on the vaginal diaphragm suggests that this method is effective in preventing some STIs, could potentially help protect against HIV, and has advantages over other female-controlled contraceptive methods. In addition, the diaphragm could serve as a device to hold in place microbicidal products currently under development. Diaphragm use, however, has declined over the last 20 years and very few women now use the diaphragm. This study is part of a larger project that examines the acceptability of the diaphragm for HIV/STI prevention among a sample of women in the U.S. In this presentation, we will compare current and former diaphragm users with respect to their background characteristics, their perceptions of the importance of method characteristics, and their perceptions of the diaphragm's characteristics. Telephone interviews were conducted with 215 current diaphragm users, 173 former diaphragm users, and 378 women who use other contraceptive methods. Analysis of preliminary data from current diaphragm users and former diaphragm users indicates that significant differences between former and current diaphragm users exist. For example, former diaphragm users more highly rated the importance of a birth control method being easy to use, not messy, and a method that their partner likes than did current users. Furthermore, current diaphragm users more strongly agreed that the diaphragm is easy to use, is not messy to use, is a method that they can control, can be used without their partner knowing, and is a method their partner likes. Additional results will be presented and the implications of findings for HIV and STI prevention will be discussed.

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

Abstract: 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.

7. Ravindran, T. K. S., & Rao, S. S. (1997). 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* (pp. 78-88). London, England: Reproductive Health Matters.

Abstract: 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.

8. Roy, S. (1994). Vaginal anatomy and physiology as they relate to sexual intercourse. In C. K. Mauck, M. Cordero, H. L. Gabelnick, J. M. Spieler, & R. Rivera (Eds.), *Barrier contraceptives: Current status and future prospects* (pp. 77-89). New York, New York: Wiley-Liss.

Abstract: 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 sypmtomatic 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.

9. Smith, C., Gaston, F., Feldblum, P. J., & Spence, A. (1995). Effectiveness of the non-spermicidal fit-free diaphragm. *Contraception*, 51, 289-291.

Abstract: 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.

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

Abstract: 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.

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

Abstract: 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 became 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.

12. Stewart, F. (1998). Vaginal barriers. In Hatcher, R.A., Trussell, J., Stewart, F., Cates, W. Jr., Stewart, G. K., Guest, F., & Kowal, D. (Eds.), *Contraceptive Technology* (17th Rev. ed.). (pp. 371-404). New York, New York: Ardent Media.

Abstract: The chapter addresses mechanisms of action; effectiveness; cost; advantages and indications; disadvantages and cautions; method provision; managing problems and follow-up; and instructions for use. The methods included are the diaphragm, contraceptive sponge, cervical cap, and female condom.

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

Abstract: 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.

14. Townsend, J. W. (1995). *Technical assistance for expanding contraceptive choice in India* (Final Report). New Delhi, India: The Population Council. http://www.popcouncil.org/pdfs/aneorta/pdfs/india/fr/ifr10.pdf

Abstract: This report describes the Population Council's efforts in the ANE OR/TA Project in India. One of the roles of this project was to participate in the policy dialogues with national counterparts, both in the public sector and among NGOs, about expanding contraceptive choices and to provide technical assistance to facilitate changes in service delivery procedures.

This report discusses many of the issues revolving around expanding contraceptive choice in India. Constraints and barriers to women's use of the diaphragm are discussed along with

measures and steps taken to increase access to and use of the diaphragm in India. At the time of the study, only a limited number of outlets supplied the diaphragm in India, and the pharmaceutical industry had discontinued the manufacture and distribution of spermicides. International donors also sharply reduced the procurement of these supplies due to the explicit policy of the Government of India to exclude barrier methods other than the condom from the public program. The more traditional family planning service organizations were skeptical about the diaphragm's acceptance and impact.

In April 1994, the Council organized a workshop on the diaphragm, attended by twenty professionals from organizations with potential interest in the reintroduction of the diaphragm. As a follow-on to this workshop, the Council imported 1200 Milex diaphragms with spermicide for the NGO sector. The Council also developed a proposal with RUWSEC to examine the feasibility of diaphragm services in an urban slum of Madras. (See abstract number seven).

Essentially, the project demonstrated some demand for the diaphragm, particularly among young low parity women and never users. Community education and outreach probably played a major role in adoption.

15. Trussell, J. (1998). Contraceptive efficacy. In Hatcher, R.A., Trussell, J., Stewart, F., Cates, W. Jr., Stewart, G. K., Guest, F., & Kowal, D. (Eds.), *Contraceptive Technology* (17th Rev. ed.). (pp. 779-844). New York, New York: Ardent Media.

Abstract: 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.

16. Van der Straten, A., Posner, S. F., Mapfumo, O., Khumalo-Sakutukwa, G., Chipato, T., Callahan, M., & Padian, N. *Diaphragms are Well Accepted in Sexually Active Zimbabwean Women.* Paper presented at the Microbicides Conference, Antwerp, Belgium.

Abstract: In Zimbabwe, where HIV prevalence is over 30%, alternative methods to condoms are urgently needed. This is an ongoing cohort study to assess acceptability and use over time of diaphragms with KY jelly among women who are inconsistent condom users. Methods: Women first enroll in a 2-month condom intervention phase. Inconsistent condom users are then enrolled into the diaphragm acceptability phase and receive a diaphragm educational session (including information about its unknown efficacy against HIV/STI), followed by a booster session 2 months later. Women are followed every 2 months for a total of 6 months. Demographic, behavioral, and medical assessments and free condom distribution occurred at every visit. Results: 156 women have entered the diaphragm acceptability phase, and follow- up is ongoing. At this time, 131, 89, and 38 women have been seen at 2, 4, and 6 months, respectively. Mean age is 29 (range:17-46), 54% have completed secondary education, 97% are married, and 70% have one lifetime partner. Prior to entering the study, only 1% had ever used diaphragms. Diaphragm uptake was almost universal following the intervention and stayed high over time. Consistent use (>1/2 time) was reported by close to half the sample. KY jelly was used almost universally with diaphragms and 69% of the sample reported using diaphragms both for disease and pregnancy prevention. Conclusions: Virtually no studies have examined the acceptability of diaphragms in sub-Saharan Africa. When provided with appropriate counseling and education, a majority of women in our study were willing to use the diaphragm in spite of its unknown efficacy. If proven effective against HIV/STI, diaphragms used alone or in combination with microbicides may provide a viable woman-controlled alternative to condoms.

17. *WHO/CONRAD technical consultation on Nonoxynol–9*. (2001). (Summary Report.) Geneva, Switzerland: World Health Organization.

Abstract: 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 and 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.