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Editorial
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Adding to the menu of modern methods – the diaphragm

Wendy Holmes

Macfarlane Burnet Institute for Medical Research and Public Health, Melbourne, Vic. 3004, Australia.
Email: holmes@burnet.edu.au

As a prying adolescent I one day opened my mother's hidden, shell-like, plastic case and found her carefully washed and powdered diaphragm, smelling slightly of rubber. I marvelled that she could be sufficiently well organised to safely store and use this device to prevent babies. I now better understand her strength of motivation – and the value there must have been for her of being in control of contraception, given my father's Catholic faith.

For decades the diaphragm was used successfully as a method of contraception by millions of women in developed countries. With the advent of the highly convenient Pill in the 1960s its popularity waned – and the diaphragm never became well established as an option in developing countries. In this issue, Coffey and Kilbourne-Brook contend that the use of the diaphragm in low-income settings should be reconsidered.[1] They present findings from their acceptability study about the ways that women in the Dominican Republic, South Africa and Thailand were able to use, clean and store a diaphragm. Their findings support the idea that motivated women in low-income settings would find ways to use and care for the device appropriately.

In recent years the diaphragm has received renewed attention because of hope that it might enable women to protect themselves against sexually transmissible infections (STIs) and HIV.[2] It is plausible that the diaphragm could be protective because it covers the cervix, which is more susceptible to infection with HIV, chlamydia and gonorrhoea than the vaginal mucosa. Early observational studies suggested that the diaphragm prevents STIs,[3,4] although diaphragm users may have been at lower risk for other reasons.

A randomised controlled efficacy study, the 'Methods for Improving Reproductive Health in Africa' (MIRA) trial of the diaphragm and Replens® lubricant gel (Lil' Drug Store Products Inc., Cedar Rapids, IA, USA) was carried out in South Africa and Zimbabwe from 2003 to 2006.[5] Such studies are difficult to conduct. There is an ethical imperative to provide both groups of women with counselling and condoms, and to detect and treat any STIs. They are then likely to have lower incidence of new infections than the population from which they are drawn, so sample sizes must be very large to be able to detect any difference in incidence between the groups.

Disappointingly, like other recent studies of potential women-controlled HIV prevention methods, the study did not find evidence of efficacy in preventing HIV infection.[5] The incidence of HIV infection was no lower among women provided with counselling, condoms and the diaphragm compared with those who received only counselling and condoms. The study could not determine whether use of a diaphragm provides any protection compared with no intervention but demonstrates that it cannot be recommended as a public health intervention. The trial also found no additional protection from diaphragm use against gonorrhoea and chlamydia.[6] However, there was some evidence that women who used the diaphragm consistently were protected against gonococcal infection, and although the women who were provided with the diaphragm used condoms less than the other group they had no higher incidence of HIV, suggesting that there may be some protective effect. The 'Duet', a diaphragm-like device loaded with an acidic buffer gel, is currently being evaluated as an HIV prevention method.[7]

There has also been some concern that diaphragm use might increase susceptibility to HIV. It is possible that frequent insertion and removal could cause small abrasions of the vaginal mucosa, or the spermicide could cause inflammation. The spermicide nonoxynol-9 was found to increase susceptibility to HIV.[8] Subsequent studies found that nonoxynol-9 and other detergent spermicides have toxic effects on vaginal mucosa (but the acidic spermicide, Buffergel, does not).[9] These concerns have led to advice that women at high risk of HIV infection should avoid using diaphragms.[10]

It would be a pity if the renewed interest in the diaphragm now declines because of the lack of evidence of protective efficacy against HIV. Many women in the developing world are at very low risk of infection with HIV but remain at high risk of unintended pregnancy. An estimated 25–50% of pregnancies are unintended, a huge burden which contributes to preventable deaths from unsafe abortion and in childbirth. Access to and uptake of modern contraceptive methods remains unacceptably low. No contraceptive method is perfect – each has a different profile of advantages and drawbacks. Women of reproductive age have varied circumstances and needs. Consistent and correct use of the diaphragm with spermicide provides 94% protection against pregnancy.[11] As more commonly used we might expect ~16 pregnancies per 100 women per year.[11] The diaphragm is not suitable for all women, but is likely to be a good option for many. Coffey and Kilbourne-Brook set out the benefits, but there is a further significant advantage in resource-poor settings. It is a reversible method that women can control with little dependence on the health care system. Once she has a diaphragm, has been shown how to use and store it, and has a supply of spermicide, the woman is able to manage her own fertility control. Increasing the choice of contraceptive methods is an important strategy to

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achieve the second target of Millennium Development Goal 5: 'universal access to reproductive health'. With the repeal last year of the Mexico City Policy or 'global gag rule' in the USA, funding for family planning services is increasing, which should enable support for the diaphragm as an option for women in developing countries.

Coffey and Kilbourne-Brook suggest that one of the reasons the diaphragm has not been made more widely available is an unwillingness to allocate the human resources necessary for counselling and support. However, that counselling and support are needed should not necessarily be viewed as a problem. Health care providers need training in communication and counselling skills to help women and couples to choose and use any appropriate contraceptive method consistently and correctly. Health care providers need to feel confident to talk about sensitive issues and this will help them to be more effective in many aspects of their work, increasing their interest and satisfaction in their jobs.[12]

The evaluation of the diaphragm as a potential female-controlled HIV prevention method has led to several acceptability studies that can inform a reinvigorated promotion of the diaphragm as a contraceptive.[13,14] Coffey and Kilbourne-Brook's findings help to build a picture of the feasibility of diaphragm use in low-income settings. Their study used the new SILCS diaphragm, developed by Program for Appropriate Technology in Health (PATH). This differs from previous diaphragms because one size fits most women so a pelvic examination for fitting the correct size is not necessary. Other key improvements that need research include how efficacy is affected when the diaphragm is worn continuously except for removal for washing every 24 h, when it is removed earlier than the currently recommended 6 h after sex, and when it is used without spermicide.[15]

Marketing is a field in which there have been huge advances since the decades when the diaphragm was popular. There is a great need for what we think of as the old-fashioned, rather icky diaphragm to have an image makeover – and, please, a new name.[16]

References

1 Coffey PS, Kilbourne-Brook M. Wear and care of the SILCS diaphragm: experience from three countries. *Sex ,Health* 2010; 7: 159–64. doi:10.1071/SH09049

2 Harvey SM, Bird ST, Branch MR. A new look at an old method: the diaphragm. *Perspect Sex Reprod Health* 2003; 35: 270–3. doi:10.1363/3527003

3 Rosenberg MJ, Davidson AJ, Chen JH, Judson FN, Douglas JM. Barrier contraceptives and sexually transmitted diseases in women: a comparison of female-dependent methods and condoms. *Am J Public Health* 1992; 82: 669–74. doi:10.2105/AJPH.82.5.669

4 Magder LS, Harrison HR, Ehret JM, Anderson TS, Judson FN. Factors related to genital *Chlamydia trachomatis* and its diagnosis by culture in a sexually transmitted disease clinic. *Am J Epidemiol* 1988; 128: 298–308.

5 Padian NS, van der Straten A, Ramjee G, Chipato T, de Bruyn G, Blanchard K, *et al*. MIRA Team. Diaphragm and lubricant gel for prevention of HIV acquisition in southern African women: a randomised controlled trial. *Lancet* 2007; 370: 251–61. doi:10.1016/S0140-6736(07)60950-7

6 Ramjee G, van der Straten A, Chipato T, de Bruyn G, Blanchard K, Shiboski S, *et al*. MIRA team. The diaphragm and lubricant gel for prevention of cervical sexually transmitted infections: results of a randomized controlled trial. *PLoS One* 2008; 3: e3488. doi:10.1371/journal.pone.0003488

7 Montgomery E, Musara P, Chandipiswa A, Chipato T, van der Straten A, Moench T, *et al.* Safety of the Duet used continuously or pre-coitally in Zimbabwean women. Abstract: LBPEC02. 5th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention; 2009 July 19–22; Cape Town, South Africa. Geneva: IAS; 2009. Available online at: http://www.ias2009.org/pag/PosterExhibition.aspx [verified March 2010].

8 Van Damme L, Ramjee G, Alary M, Vuylsteke B, Chandeying V, Rees H, *et al*. COL-1492 Study Group. Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-1 transmission in female sex workers: a randomised controlled trial. *Lancet* 2002; 360: 971–7. doi:10.1016/S0140-6736(02)11079-8

9 Cone RA, Hoen T, Wong X, Abusuwwa R, Anderson DJ, Moench TR. Vaginal microbicides: detecting toxicities *in vivo* that paradoxically increase pathogen transmission. *BMC Infect Dis* 2006; 6: 90. doi:10.1186/1471-2334-6-90

10 IPPF Contraception: Diaphragm. Available online at: www.ippf.org/en/Resources/Contraception/Diaphragm.htm [verified March 2010].

11 Johns Hopkins Bloomberg School of Public Health, USAID, WHO. Family planning: a global handbook for providers. Baltimore: Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs and World Health Organization; 2007. Available online at: http://info.k4health.org/globalhandbook [verified March 2010].

12 Margarita Diaz M, Rogow D, Barzelatto J. Quality No. 6. The Coletivo: A Feminist Sexuality and Health Collective in Brazil. New York: The Population Council; 1995. Available online at: http://www.popcouncil.org/pdfs/qcq/qcq06.pdf [verified March 2010].

13 Okal J, Stadler J, Ombidi W, Jao I, Luchters S, Temmerman M, *et al*. Secrecy, disclosure and accidental discovery: perspectives of diaphragm users in Mombasa, Kenya. *Cult Health Sex* 2008; 10: 13–26. doi:10.1080/13691050701519730

14 Bulut A, Ortayli N, Ringheim K, Cottingham J, Farley TM, Peregoudov A, *et al*. Assessing the acceptability, service delivery requirements, and use-effectiveness of the diaphragm in Colombia, Philippines, and Turkey. *Contraception* 2001; 63: 267–75. doi:10.1016/S0010-7824(01)00204-9

15 Grossman D, Ellertson C, Abuabara K, Blanchard K, Rivas FT. Barriers to contraceptive use in product labeling and practice guidelines. *Am J Public Health* 2006; 96: 791–9. doi:10.2105/AJPH.2004.040774

16 Mills A. Barrier contraception. *Clin Obstet Gynaecol* 1984; 11: 641–60.

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