FACULTY OF FAMILY PLANNING & REPRODUCTIVE HEALTH CARE
ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS

Faculty of Family Planning & Reproductive Health Care Clinical Guidance

Female Barrier Methods

Clinical Effectiveness Unit
June 2007

ISSN 1755-103X

Published by the Faculty of Family Planning and Reproductive Health Care
Registered in England No. 2804213 and Registered Charity No. 1019969

First published June 2007

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A unit funded by the FFPRHC and supported by the University of Aberdeen to provide guidance on evidence-based practice

FFPRHC Guidance (June 2007) Female Barrier Methods

(Date for planned revision June 2010)

Purpose and scope

This Guidance document provides evidence-based recommendations and good practice points for clinicians on the use of female barrier methods to prevent pregnancy and/or reduce the risk of sexually transmitted infections (STIs). In this Guidance, female barrier methods include the diaphragm, cervical cap and female condom. More detailed information on the female condom is included in the CEU Guidance document *Male and Female Condoms*.[1] For completeness, some information is provided on the contraceptive sponge, which is a delivery system for spermicide and may have some barrier actions. Limited information on dams has been provided. The use of spermicide alone is not included as this is not generally accepted as an effective method of contraception in UK clinical practice.[2] Unless otherwise stated, the use of diaphragms and cervical caps is with spermicide.

This document is not intended to serve alone as a standard of medical care, as this should be determined individually based on available clinical information. This Guidance has been systematically developed using the standard methodology outlined in the Appendix to this document. Learning points on female barrier methods are outlined in Box 1.

Background

Before the introduction of hormonal and intrauterine contraception, female barrier methods (diaphragms and cervical caps) were a common method used by one in eight couples in the UK.[3,4] The Office for National Statistics collects information about contraceptive use in Great Britain from the Omnibus Survey.[5] The survey in 2005/2006 included a stratified random sample of 3025 respondents (1696 men aged 16–69 years and 1329 women aged 16–49 years). Diaphragms and cervical caps are used by 1% of women aged 16–49 years surveyed. The majority of users are aged 30–49 years.[5]

Female condoms provide a barrier to the ejaculate, pre-ejaculate and cervico-vaginal secretions. Diaphragms and cervical caps provide a physical barrier and a chemical barrier due to concurrent use of spermicide to prevent sperm reaching the cervix. In the UK it is recommended that diaphragms and cervical caps are used with spermicide.[6,7] Diaphragms and cervical caps act as a reservoir to hold spermicide against the cervix. No barrier is provided to the ejaculate and pre-ejaculate secretions or cervico-vaginal secretions between the vaginal mucosa and the penis. The vaginal sponge acts as a delivery system for spermicide and may act as a barrier.

If used consistently and correctly, female barrier methods are effective in preventing pregnancy.[8–15] Evidence on the effectiveness of female barrier methods in preventing STIs is limited. There is evidence of some protection against cervical human papillomavirus (HPV) and cervical intra-epithelial neoplasia (CIN) with use of female barrier methods.[16]

The user acceptability of female barrier methods can be variable and satisfaction with the diaphragm for example varies between 29% and 79%.[17–19] However, discontinuation rates for diaphragms and contraceptive sponges can be high.[20] No significant differences in the discontinuation rate between women using a diaphragm with spermicide versus without a spermicide was noted over a 1-year period of use.[6]

Advantages of female barrier methods are that there are no serious side effects, use is under the woman's control, they need only be used during sex, they can be inserted at a convenient time before sex and may provide some protection against STIs.[21–23] Perceived disadvantages include: messiness, problems with insertion/removal, irritation (with diaphragm and cervical caps used with spermicide), lack of sexual spontaneity[24] and noisiness (female condom).[19,21] Diaphragms and cervical caps should be initially assessed for correct size and type by a competent health professional. Other female barrier methods (female condom and sponge) do not need initial assessment for sizing and can be used without fitting.

Assessing which women can use female barrier methods

Medical Eligibility Criteria for Contraceptive Use

The World Health Organization *Medical Eligibility Criteria for Contraceptive Use* (WHOMEC)[25] provides evidence-based recommendations to ensure women can select the most appropriate method of contraception without imposing unnecessary restrictions. The UK *Medical Eligibility Criteria* (UKMEC) was developed from the WHO

Box 1: Learning points on female barrier methods

- May provide a physical and/or a chemical barrier.
- With the exception of the female condom and contraceptive sponge, female barrier methods should initially be fitted by a competent health professional.
- With the exception of a female condom, the other barrier methods need to remain *in situ* for at least 6 hours after the last episode of intercourse.
- They provide limited protection against sexually transmitted infections.

Table 1 *UK Medical Eligibility Criteria for Contraceptive Use categories for use of female barrier methods*[2]

UKMEC Category	Definition of category
1	A condition for which there is no restriction for the use of the contraceptive method.
2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
3	A condition where the theoretical or proven risks usually outweigh the advantages of using the method.[a]
4	A condition which represents an unacceptable health risk if the contraceptive method is used.

[a]Use of the method requires expert clinical judgement and/or referral to a specialist contraceptive provider since use of the method is not usually recommended unless other methods are not available or not acceptable.[2]

document in 2005 and is available on the Faculty of Family Planning and Reproductive Health Care (FFPRHC) website (www.ffprhc.org.uk).[2] A chapter on barrier methods includes female condoms, diaphragms and cervical caps. The UKMEC categories are used in this Guidance document (Table 1). There are no absolute contraindications to the use of female barrier methods. There are some medical conditions that require caution for use of female barrier methods in certain groups of women (Table 2). Conditions where there is a theoretical or proven risk that usually outweighs the advantages of using the method receive a UKMEC Category 3 (Table 1). Provision of a method to a woman with a Category 3 condition requires expert clinical judgement since use of that method is not usually recommended unless other more appropriate methods are not available or not acceptable. Conditions where a UKMEC Category 3 is given are outlined here.

Table 2 *Medical conditions for which the risks associated with use of contraceptive methods may outweigh the benefits*

Medical condition	Diaphragms/ cervical cap	Female condoms
High risk of HIV/AIDS	UKMEC 3[a]	UKMEC 1[b]
HIV infected (with and without use of antiretroviral therapy)	UKMEC 3	UKMEC 1
AIDS and using HAART	UKMEC 3	UKMEC 1
(Evidence of repeated high-dose use of the spermicide nonoxynol-9 is associated with increased risk of genital lesions, which may increase the risk of acquiring HIV)		
History of toxic shock syndrome	UKMEC 3	UKMEC 1
(Case-control study suggests a possible association between diaphragm and non-menstrual TSS)		
Sensitivity to latex proteins	UKMEC 3	UKMEC 3[c]
(Does not apply to non-latex condoms or diaphragms)		

[a]UKMEC 3 (Risks usually outweigh benefits). The use of the method requires expert clinical judgement and/or referral to a specialist contraceptive provider since use of the method is not usually recommended unless other methods are not available or not acceptable.[2]
[b]UKMEC 1 (Unrestricted use).
[c]UKMEC 3 Category is given but this refers to all condoms, which includes latex male condoms. For female polyurethane condoms the benefits would outweigh the risks.
AIDS, acquired immune deficiency syndrome; HAART, highly active antiretroviral therapy; HIV, human immunodeficiency virus; TSS, toxic shock syndrome.

HIV/AIDS

Little is known about the effectiveness of female barrier methods in preventing the sexual acquisition of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS). It is recommended that diaphragms and cervical caps are used with spermicide. Nonoxynol-9 (N-9) is the only spermicide available in the UK.[26] Evidence on N-927–36 was reviewed in the *WHO/CONRAD Technical Consultation on Nonoxynol-9*.[37] N-9 is a surfactant, which disrupts cell membranes. Epithelial disruption in the vagina and rectum has been identified in association with N-9 use in human and animal models.[37–39] Repeated and high-dose use of the spermicide N-9 is associated with increased risk of genital lesions, which may increase the risk of HIV acquisition.[37–40] The WHO therefore recommends that women at high risk of HIV infection should not use N-9[37] (Level III evidence). The risks of using a diaphragm or cervical cap (with N-9) by women with a high risk of HIV, with HIV or AIDS generally outweigh the benefits (UKMEC 3).[2]

No studies have directly investigated whether female condoms prevent HIV transmission. Nevertheless, laboratory studies suggest that polyurethane condoms (male and female) protect against STIs.[41–53]

1 The use of a diaphragm, cervical cap or contraceptive sponge (all with nonoxynol-9) by women who have HIV or AIDS, or who are at high risk of HIV infection, is not generally recommended (Grade C).

2 The consistent and correct use of female condoms may reduce the risk of HIV transmission (Good Practice Point).

Sensitivity to latex proteins

The presence of a positive skin test to latex allergens or the demonstration of specific immunoglobulin E (IgE) antibodies in serum is described as sensitivity to latex. Latex allergy is the occurrence of immediate Type I symptoms when a latex-sensitive person comes into contact with latex.[54] The diagnosis of a true latex allergy is difficult to make. Repeat exposure may increase the risk of a reaction.[55] Most reactions due to latex allergy are clinically mild and localised to the penis or vulva (Type IV hypersensitivity). Other symptoms can include pruritis, oedema of the skin, mucous membranes or subcutaneous tissues, and abdominal symptoms (cramp, nausea, vomiting, and diarrhoea). Symptoms usually develop 24–48 hours after exposure in a sensitised person. The most serious clinical syndrome (Type I hypersensitivity) can manifest with symptoms as above but the onset is quicker. People with Type I latex allergy are at risk of anaphylaxis.

Direct evidence on the use of female barrier methods in women with sensitivity to latex proteins is limited. The UKMEC recommends that in women with sensitivity to latex proteins the risks of using a latex diaphragm or cervical cap generally outweigh the benefits (UKMEC 3).[2] Silicone diaphragms and cervical cap or a polyurethane female condom can be used by women who themselves, or whose partners, have sensitivity to latex proteins.

3 Women with sensitivity to latex proteins can use a silicone diaphragm or cervical cap or a polyurethane female condom (Grade C).

Toxic shock syndrome

Toxic shock syndrome (TSS) is an extremely rare inflammatory response syndrome often associated with tampon use and linked to bacterial infections, in particular *Staphylococcus aureus*.[56–58] The incidence of TSS in the UK is 40 cases per year with half the cases occurring in menstruating women.[58] The risk of TSS associated with female barrier method use is very low (an estimated 2.25 cases per 100 000 users per year and 0.18 deaths per 100 000 users per year).[59] A small case-control study suggested that use of a female barrier method (diaphragm, cervical cap or contraceptive sponge) was associated with an increased risk of non-menstrual TSS [odds ratio (OR) 14.9, 95% CI 4.3–52.2][59] (Level IIa evidence). Nine reported cases of TSS are thought to have been directly associated with contraceptive sponge use. Data from surveillance programmes indicate that the risk of TSS on non-menstrual days for contraceptive sponge users is 7.8 to 40 times greater than for non-users (risk of 0.2 to 1 per 100 000 woman-years)[60] (Level III evidence). There is no evidence of an association between female condom use and TSS.

Manufacturers recommend that a diaphragm, cervical cap or contraceptive sponge should not be left *in situ* for more than the recommended time especially during menstruation and indeed use during menstruation should be avoided (Table 3).[24,61–63]

4 For women with a history of toxic shock syndrome the use of a diaphragm, cervical cap or contraceptive sponge is not generally recommended (Grade C).

5 Women with a history of toxic shock syndrome may use a female condom (Grade C).

6 A diaphragm, cervical cap or contraceptive sponge should not be left *in situ* longer than recommended by the manufacturer (Good Practice Point).

Other conditions that may need to be considered individually when counselling about the use of female barrier methods

Women considering use of a diaphragm or cervical cap should be assessed by clinical history and vaginal examination individually to determine if use is appropriate for them.

The failure rate for cervical caps and the contraceptive sponge (but not for diaphragms or female condoms) may be increased for parous women.[15] It is unclear if this is related to anatomical changes in the cervix or if it reflects different motivation for use of the method (e.g. family spacing). A UKMEC Category 2 is given (benefits outweigh the risks) for use of diaphragms and cervical caps by parous women.[2]

Diaphragm use has been linked to urinary tract infection (UTI).[64–71] However, this risk of UTI was

Table 3 *Female barrier methods available or likely to be available soon in the UK*

Type of barrier method	Material	Description
Diaphragms		Available in different sizes from 60 to 95 mm (in 5 mm increments). Initial fitting by a competent health professional is required. Maximum duration of use recommended after insertion is 30 hours
Coil spring	Latex	Has a soft flexible rim, which does not form an arc when folded. This diaphragm may be used for women with average vaginal muscle tone
Arcing spring	Latex	Has a firm rim, which causes the diaphragm to fold at two hinged points, and form an arc. The firm rim makes it easier to place the diaphragm in the posterior fornix. It can be used in women with a retroverted uterus, a rectocele, cystocele or lax vaginal muscle tone
Flat spring	Latex	Has a more delicate and thinner rim than the coil spring diaphragm. It may be used in women with firm muscle tone
Arcing spring or coil spring types	Silicone	Wide seal rim diaphragm has flexible flange attached to the inner edge of the rim. The flange is approximately 1.5 cm wide and intended to hold spermicide in place inside the diaphragm and to create a better seal between the diaphragm and the vaginal wall
Cervical caps		Available in different sizes as noted below. Initial fitting by a competent health professional is required. Maximum duration of use recommended after insertion is 30 hours (48 hours for a silicone cervical cap)
Dumas®, Vimule®, Prentif®	Latex	Dumas in sizes 1 to 5; Vimule in sizes 1 to 3; Prentif in sizes 22, 25, 28 and 31 mm. Attach to the cervix by suction
FemCap®	Silicone	Shaped like an American sailor's hat. It has a dome, which covers the cervix. The circular rim fits into the fornices of the vaginal vault. The posterior brim adheres to the walls of the vagina and it is designed to funnel ejaculate into a groove between the dome and the brim. This also acts as a reservoir for spermicide. Available in three sizes: 22 mm for nulliparous women, 26 mm for parous women who have not had a vaginal delivery and 30 mm for parous women who have had at least one vaginal delivery. The second generation of FemCap has a strap to facilitate removal
Female condom Femidom® (no fitting required)	Polyurethane	This is a loose-fitting sheath with two flexible polyurethane rings one at either end. It sits within the vagina. At the closed end of the tube the ring is not fixed but facilitates insertion and acts as an internal anchor. At the open end the flexible ring lies outside the vagina. The Femidom is lubricated with non-spermicidal lubricant
Contraceptive sponge		Maximum duration of use recommended is 30 hours
Today® (no fitting required)	Polyurethane	6 cm in diameter and 1.5 cm thick, impregnated with nonoxynol-9 spermicide. It is fitted into the vagina prior to sexual intercourse and works by occluding the cervix, releasing spermicide, and absorbing semen. The sponge requires being wetted (with water) to activate the spermicide. It is inserted into the vagina digitally, with an indentation on one side helping to ensure placement against the cervix. There is a retrieval loop for ease of removal following sexual intercourse. The sponge may be inserted up to 24 hours before sex and removed any time after 6 hours post-intercourse

unrelated to the type of diaphragm used[64,66] or the duration of use each time.[64,66] Sexual intercourse itself is a risk factor for UTI.[64,65,72] A diaphragm should be chosen that will ensure a correct fit but which does not put undue pressure on or obstruct the urethra.

There is no evidence on use of female barrier methods by women with cervical or vaginal abnormalities, poor vaginal muscle tone or an awkwardly positioned cervix. These conditions are not highlighted in UKMEC.[2]

7 Women considering use of a diaphragm or cervical cap should be assessed individually to determine if use is appropriate for them (Good Practice Point).

What types of female barrier methods and spermicide are currently available?

There are a variety of diaphragms and cervical caps available in the UK (Table 3). At the time of developing this Guidance the contraceptive sponge (Today®) had not received marketing approval in Europe although this is expected in 2007. Other contraceptive sponges such as Protectaid® cannot be obtained in the UK. There is one type of female condom available in the UK (Femidom®).[1] The only spermicide available in the UK contains N-9. At the time of writing this Guidance, N-9 preparations include a cream (Ortho-Creme®) and pessaries (Orthoforms®).[73–75]

How effective are female barrier methods at preventing pregnancy?

With consistent and correct use, latex diaphragms and cervical caps (with spermicide) are estimated to be between 92% and 96% effective in preventing pregnancy.[12,15,,24,76] Female condoms are estimated to be 95% effective in preventing pregnancy.[77,78] Exact point estimates for failure rates vary between studies and are outlined below. Data can be presented either as failure rates or efficacy. Data on efficacy of female condoms and contraceptive sponge are also included here.[15,79,80] Studies investigating efficacy of female barrier methods are limited by inherent biases, for example, although consistent use is determined correct use is not, data may only be recorded for a short time frame, and efficacy may be influenced by age and background fertility.

Diaphragms

A re-analysis of data from two clinical studies that randomly assigned women to use the contraceptive sponge or diaphragm, or the cervical cap or diaphragm, found first-year probabilities of failure for the diaphragms during typical use of 13–17% and *for perfect use* of 4–8%.[15,81] The *method failure rate* for diaphragms (with spermicide) in the first year of use is estimated to be 6%.[12] The *typical use failure rate* (method failure plus user failure) for diaphragms (with spermicide) in the first year of use is estimated to be 16%.[12] Differences between method and user failure may be attributed to incorrect and/or inconsistent use. When used consistently and correctly, latex diaphragms (with spermicide) are between 92% and 96% effective in preventing pregnancy.[24] No differences in efficacy for diaphragm use was identified between parous and nulliparous women.[15]

A Cochrane Review found that a diaphragm (with spermicide) was more effective in preventing pregnancy than a contraceptive sponge[80] (Level Ib evidence). However, a Phase II/III trial was unable to identify differences in the failure rate for a diaphragm (with spermicide) and a silicone cervical cap (FemCap®) at 6 months use[14] (Level IIb evidence).

Cervical caps

Data from a clinical study in which women were randomly assigned to the cervical cap or diaphragm found first-year probabilities of failure for the cervical cap during *typical use* of 18% and for *perfect use* of 10–13%.[15] Significant differences in failures rates were noted in association with parity for cervical cap users.[13,15,82] The probability of failure during perfect use was higher among parous women (26–27%) than nulliparous women (8–10%).[15]

In the first year of use, the *true failure rate* (method failure) for parous women was 20% while for nulliparous women it was 9%. The *typical use failure rate* (method failure plus user failure) is estimated to be 32% for parous women and 16% for nulliparous women.[13,82] When used consistently and correctly, latex cervical caps (with spermicide) are between 92% and 96% effective in preventing pregnancy.[24]

Early Phase I studies in 1221 women found that a silicone cervical cap (FemCap) with spermicide prevented 95% of pregnancies (Pearl index, 5 per 100 woman-years)[83] (Level III evidence). A Phase II/III trial that compared a silicone cervical cap (FemCap) with a traditional diaphragm (Ortho All-Flex®) with spermicide found the unadjusted typical-use probability of pregnancy at 6 months use (13.5%) for FemCap users was higher than that for diaphragm users (7.9%).[14] The trial suggests that the efficacy of a silicone cervical cap is lower than that for conventional diaphragms[84] (Level IIb evidence).

8 When used consistently and correctly and with spermicide, diaphragm and cervical caps are estimated to be between 92% and 96% effective at preventing pregnancy (Grade C).

Female condoms

With consistent and correct use the *method failure rate* for female condoms is 5% (i.e. 95% effective) while the *typical use failure rate* is 21%.[12,77] A clinical trial reported seven unplanned pregnancies during 437 months of use giving a use-effectiveness failure rate (by life table) of 15% at 12 months (95% CI 3.5–26%)[10] (Level III evidence). Gross cumulative pregnancy rates of 12.4% (USA) and 22.2% (Latin America) at 6 months were found in a large multicentre study.[11] Higher contraceptive efficacy rates were identified in a Japanese study.[78] Breakage rates for female condoms are very low (<1 in 100 female condoms used).[85,86] The slippage rate (slipping out of the vagina or pushed into the vagina) for female condoms is 5.6%.[86] A randomised trial found a total clinical failure rate (breakage during sex, turned completely or partially inside out, slipped completely out, outer ring displacement, misplaced penetration by the penis) of 5.24%[87] (Level Ib evidence).

9 When used consistently and correctly, female condoms are 95% effective at preventing pregnancy (Grade C).

Contraceptive sponge

A systematic review of two randomised trials suggests that pregnancy rates are higher with contraceptive sponge use than with diaphragm use.[80] The review included two randomised controlled trials.[20,89] The 12-month cumulative life table rate of pregnancy per 100 women (USA) for the contraceptive sponge was 17.4 compared to 12.8 for the diaphragm (OR 1.5, 95% CI 1.1–2.1).[80] UK figures were 24.5 for the contraceptive sponge and 10.95 for diaphragm (OR 2.6, 95% CI 1.3–5.4)20 (Evidence Level Ib). The first-year method failure rate for the contraceptive sponge was estimated to be between 8.2% and 19%.[15,20,79,88]

10 When used consistently and correctly, the contraceptive sponge is estimated to be between 80% and 90% effective (Grade C).

Is the contraceptive efficacy of a diaphragm or cervical cap increased with use of spermicide?

A Cochrane Review investigated women of reproductive age using diaphragms (with and without spermicide) as the only method of contraception[6] (Level Ia evidence). One small randomised controlled trial was included in the review[89] (Level Ib evidence). The randomised trial was designed to include 144 women for each arm of the trial and would have been powered to detect a 14% absolute difference in pregnancy rates.[89] Eighty-four women were recruited into each arm of the study. Although there was a trend towards higher pregnancy rates in women using a diaphragm without spermicide, the study was underpowered to detect differences in pregnancy rates between the two groups.[89] No significant differences in the discontinuation rate between the two groups were noted over a 1-year period of use. The use of spermicide with diaphragm is recommended.[6] No studies investigating pregnancy rates for cervical cap use with and without spermicide use were identified. Nevertheless, it is recommended that a cervical cap is used with spermicide.

11 Women using a diaphragm should be advised to use it with spermicide (Grade B).

12 Women using a cervical cap should be advised to use it with spermicide (Good Practice Point).

Do female barrier methods provide any protection against STIs?

The transmission of STIs is influenced by many factors (Table 4).[90–95] CIN is linked to the sexual transmission of certain types of HPV.

Female condoms

Laboratory studies suggest condoms (male latex, male and female polyurethane) provide significant protection against STIs[41–53] (Level IIb evidence). Even with consistent and correct use, however, even condoms may not completely eliminate the risk of STI transmission.[95] Two randomised controlled trials suggest female condoms are as effective as male condoms in the prevention of *Chlamydia trachomatis* transmission[43,96] (Level II evidence). There is more evidence to support the use of male condoms to protect against the transmission of STIs than female condoms.[1]

13 In general, evidence supports the use of female condoms to reduce the risk of STIs. However, even with consistent and correct use, transmission may occur and male condoms provide better protection (Grade C).

Diaphragm, cervical caps and contraceptive sponge

There is a lack of good quality evidence to support the use of diaphragm, cervical cap or contraceptive sponge to protect against the transmission of STIs. A small case-control study of women attending a genitourinary medicine clinic suggested that the risk of *Neisseria gonorrhoeae* and *Trichomonas vaginalis* was reduced with use of a diaphragm or contraceptive sponge[97] (Level IIa evidence). When adjusted for age, race, number of sexual partners in the previous month and history of previous

Table 4 *Factors that influence transmission of sexually transmitted infections (STIs)*

Factors influencing transmission of STI other than condom use	Description
Organism	Average transmission rate for *Neisseria gonorrhoeae* is one for every two exposures and for HIV is one in every 1000 exposures[54,56]
Asymptomatic disease or asymptomatic viral shedding	The absence of symptoms may not alert individuals to the presence of disease and the need to abstain or use condoms
Health of the individual or his/her partner	Specific and non-specific immunity and susceptibility to infection
Gender	Women are more susceptible to *N. gonorrhoeae* and *Chlamydia trachomatis* than men (e.g. the risk of acquiring gonorrhoea with one act of unprotected sexual intercourse is approximately 1 in 5 for men and ≥1 in 2 for women)
Age	Prevalence of most STIs highest in younger age groups <25 years
Type of sex	Receptive sex (anal or vaginal) is more likely to transmit HIV than insertive sex or oral sex. This may be due to an increased risk of mucosal damage
Number of sexual contacts	There is a risk of transmission for STI with every episode of sex

STI, the OR for *N. gonorrhoeae* was 0.32 (90% CI 0.16–0.65) and for *T. vaginalis* was 0.24 (90% CI 0.12–0.48) for diaphragms users. The OR for *N. gonorrhoea* was 0.31 (90% CI 0.11–0.81) and OR for *T. vaginalis* was 0.29 (90% CI 0.11–0.76) for contraceptive sponge users. Nevertheless, the findings from this study are limited by its small size and short time period (1 month). It is unclear whether diaphragm users were also using spermicide. No information was obtained on the consistency of contraceptive use.

No evidence was identified on use of a cervical cap in the prevention of STIs.

A case-control study found that the risk of CIN II and III may be reduced in women who use a diaphragm with spermicide[16] (Level IIa evidence).

No evidence was identified on the effectiveness of dams used for oral sex in the prevention of STI transmission.

14 In general there is little evidence to support the use of a diaphragm or cervical cap (with spermicide) or a contraceptive sponge to reduce the risk of STIs (Grade C).

15 There is limited evidence that a diaphragm may reduce the risk of CIN (Grade C).

What should health professionals assess at the initial fitting and follow-up of women using a diaphragm or cervical cap?

No fitting by a health professional is required for the female condom or a contraceptive sponge. When considering use of a diaphragm or cervical cap, health professionals should enable the woman to make an informed choice about using the method.

Clinical history taking

A medical history (including a sexual history) should be taken from women considering the use of a diaphragm or cervical cap. An individual assessment of STI risk should inform decisions about the appropriateness of the method, the need for use of male condoms in addition if STI risk is higher, and appropriate testing for STIs.[98]

16 A medical history (including a sexual history) should be taken from women considering the use of a diaphragm or cervical cap (Good Practice Point).

17 An individual assessment of STI risk should inform decisions about the appropriateness of diaphragm and cervical cap use, the need for use of male condoms in addition if STI risk is higher, and appropriate testing for STIs (Good Practice Point).

Vaginal examination at initial visit and follow-up

Diaphragms are available in a variety of sizes (Table 3). A study found that one-third of women need a 70 mm diaphragm.[99] Using information such as parity, body weight, height, body mass index, age and day of cycle did not improve the prediction of diaphragm size.[99] A vaginal examination by a competent health professional is necessary to ensure a diaphragm or cervical cap is a suitable method and is of the correct size. The WHO *Selected Practice Recommendations for Contraceptive Use*[100] and the UK version of this document[101] recommend that a vaginal examination is required for the safe and effective use of cervical caps and diaphragms.

There are no recognised training requirements for health professionals regarding fitting diaphragms and cervical caps. Nurses and doctors can provide the initial fitting of a diaphragm or cervical cap. This should be done within recognised competencies. Skills should be maintained. As a minimum the health professional should be competent in:

- Counselling about the use of diaphragms and cervical caps
- Performing a vaginal examination to identify the appropriate size of diaphragm or cervical cap
- Ensuring that the cervix is covered by the method chosen
- Selecting the most appropriate method depending on the examination findings.

Women need time to practise using a diaphragm or cervical cap before relying on it as the only method of contraception. During this practice time another reliable method of contraception should be used.

Women should be asked to re-attend for review after using the diaphragm or cervical cap as a secondary method of contraception. Women should be asked to re-attend wearing the diaphragm or cervical cap. A vaginal examination should be repeated with the diaphragm or cervical cap *in situ* to ensure the woman has been able to insert the diaphragm or cervical cap correctly (covering the cervix). The health professional can check again that it is the correct size. In addition, at this follow-up appointment health professionals should ensure women are:

- Comfortable while using the method for the duration of its use, including during intercourse
- Able to check the position of a diaphragm or cervical cap before and after intercourse and recognise if it is correctly positioned
- Able to tolerate keeping it in overnight if sex occurs in the evening
- Able to tolerate the use of spermicide.

18 A vaginal examination by a competent health professional at initial fitting and follow-up is mandatory to ensure the safe and effective use of a diaphragm or cervical cap (Grade C).

19 Women having a vaginal examination for fitting a diaphragm or cervical cap should be offered a chaperone and this should be documented in the case notes (Grade C).

20 As a minimum, health professionals should be competent in counselling about the correct use of the method, choosing the most appropriate method and ensuring that the cervix is covered (Good Practice Point).

21 After the initial fitting, all women should be asked to re-attend the clinic for review after using the diaphragm or cervical cap as a secondary method of contraception (Good Practice Point).

22 At first follow-up, the health professional should check the woman can insert the diaphragm or cervical cap correctly to cover the cervix; that the method used is the correct size; that the woman is comfortable while using the method for the duration of its use, including during intercourse; and that she can tolerate the use of spermicide (Good Practice Point).

Emergency contraception

Health professionals should discuss the potential need for emergency contraception with women who use a diaphragm or cervical cap. Emergency contraception may be indicated, for example, if a diaphragm or cervical cap is dislodged or removed within 6 hours of sex. The FFPRHC supports the provision of an advance supply of emergency hormonal contraception for women relying on female barrier methods.[102] Advance supply of emergency hormonal contraception does not increase sexual risk-taking behaviour but can increase the likelihood of early use if required.[103,104]

23 Health professionals should consider the advance provision of emergency hormonal contraception to women who use a diaphragm or cervical cap (Grade C).

What information should be given to women on the use of a diaphragm or cervical cap?

Information about correct use (i.e. insertion and removal, use of spermicide and need for emergency contraception)

The fpa leaflet, *Diaphragms and Caps*, provides women with information about use of diaphragms and cervical caps[24] (Box 2). Women should also be given the patient information leaflets that accompany specific types of diaphragms and cervical caps. Women using a diaphragm or cervical cap should be informed that:

- The method can be inserted with spermicide any time before intercourse.
- Additional spermicide (either cream via an applicator or a pessary) can be applied if sex is to be repeated or if the diaphragm or cervical cap has been *in situ* for 3 or more hours. [NB. The diaphragm or cervical cap should not be removed to re-apply spermicide.]
- The diaphragm or cervical cap must be left *in situ* for at least 6 hours after the last episode of intercourse. (Sperm in the lower reproductive tract are unlikely to be alive after 6 hours.)
- Latex diaphragms and cervical caps can remain *in situ* for a maximum of 30 hours (Table 3) but women should refer to the patient information leaflet for recommended duration of use for specific diaphragms and cervical caps.

24 A diaphragm or cervical cap can be inserted with spermicide any time before intercourse but additional spermicide should be applied if sex is to take place and the method has been *in situ* for ≥3 hours or if sex is repeated with the method in place (Grade C).

Box 2: Instructions for women on use of a diaphragm or cervical cap (adapted from fpa leaflet[24])

DIAPHRAGM USE

1 A health professional will show you how to fit your diaphragm.

2 A diaphragm can be inserted any time with spermicide before sex. It must remain in place for at least 6 hours after the last episode of sex. More spermicide may need to be applied if sex is to take place and ≥3 hours have elapsed since the method was inserted or if sex is repeated while the method is in place. DO NOT remove your diaphragm to do this; use a pessary or an applicator with spermicide cream.

3 With clean hands apply two strips of spermicide about 2 cm long on both sides of the diaphragm. A little spermicide on the rim can make inserting it easier.

4 Put your index finger on top of the diaphragm and squeeze it between your thumb and other fingers. Slide the diaphragm into your vagina towards the small of your back. This makes sure that the diaphragm covers your cervix. Some women squat while putting in the diaphragm others lie down or stand with one foot up on a chair. You will need to find out which position is easiest for you.

5 Always check that the cervix is covered. The cervix feels like the end of your nose. If the cervix is not covered take the diaphragm out by hooking your finger under the rim or loop (if there is one) and pulling downwards and try again.

6 You must keep the diaphragm in place for at least 6 hours after the last time you had sex. You can leave it in for longer but don't leave it for longer than the recommended time. For latex diaphragms this is 30 hours including the minimum 6 hours.

7 Wash the diaphragm in warm water with a mild, unperfumed soap and allow to air dry. Keep it in its container in a cool dry place. Check diaphragm regularly for tears, holes or cracks.

CAP USE

1 Instructions about use will come with your cap.

2 Fill one-third of the cap with spermicide but don't put any around the rim as this can stop the cap from staying in place (If you are using a Femcap there is a groove between the dome and the rim and spermicide can be placed there.)

3 Squeeze the sides of the cap together and hold it between your thumb and first two fingers.

4 The cap must fit over your cervix. Always check that the cervix is covered. The cervix feels like the end of your nose. If the cervix is not covered remove the cap and try again.

5 You must leave the cap in place for at least 6 hours after the last episode of sex. You can leave it for longer but don't leave a cap in for longer than the recommended time. For most latex types this is 30 hours including the minimum 6 hours after sex. (NB. For FemCap this is 48 hours including the minimum 6 hours.)

6 Take out the cap by gently hooking your finger under the rim, loop or strap and pulling downwards.

Notes

1 Diaphragms and cervical caps should not be used during your period.

2 Latex diaphragms and caps can be damaged by oil-based products (e.g. some vaginal creams and pessaries) and these should be avoided when using the method or an alternative contraceptive used.

3 Water can wash away spermicide so if bathing after insertion opt for a shower rather than a bath.

4 You should see a doctor or nurse if you have any questions or concerns about use, if you have gained or lost >3 kg (7 lb) in weight or if you have had a pregnancy.

5 *Emergency contraception* can be used to reduce the risk of pregnancy and should be taken as soon as possible after a female barrier method accident. The emergency contraceptive pill is available free of charge from family planning clinics, sexual health clinics, walk-in centres (England), general practices, some pharmacies and some accident and emergency departments. A copper intrauterine device may also be used as emergency contraception.

6 *Tests for sexually transmitted infections* can be performed if you are worried about infection.

25 Women using a diaphragm or cervical cap should be informed that the method must be left in place for at least 6 hours after the last episode of intercourse (Grade C).

26 Latex diaphragms and cervical caps can remain in place for a maximum of 30 hours but women should refer to the patient information leaflet for recommended duration of use for specific diaphragms and cervical caps (Grade C).

27 Women using a diaphragm or cervical cap should be advised in what circumstances emergency contraception may be indicated (such as if a diaphragm or cervical cap is dislodged during sex or removed within 6 hours of sex) (Good Practice Point).

Factors that may influence contraceptive efficacy

Many factors can potentially reduce the contraceptive efficacy of diaphragms and cervical caps: tears, holes or cracks; incorrect use (not covering the cervix, removed less than 6 hours after the last episode of intercourse, failure to apply and re-apply spermicide); and inconsistent use. Diaphragms and cervical caps can be damaged, and therefore contraceptive efficacy potentially impaired, by inappropriate cleaning (e.g. boiling, or the use of disinfectant, detergent or talcum powder). Latex diaphragms and cervical caps may be damaged by the use of oil-based products (e.g. baby oil, petroleum jelly).[24,61–63] No evidence was identified that colour changes or a small change in outer ring shape has an effect on contraceptive efficacy.

There is no evidence that inserting the diaphragm with dome up or dome down influences efficacy. The most important point is that the diaphragm should cover the cervix after insertion.

28 Women should be advised to check the diaphragm or cervical cap regularly for tears, holes or cracks (Grade C).

29 Oil-based products can damage latex and women should be advised to avoid their use when using latex diaphragms or cervical caps (Grade C).

30 Women should be advised to follow the manufacturers' instructions regarding cleaning and caring for a diaphragm or cervical cap (Good Practice Point).

31 Women using diaphragms can be advised that there is no evidence that colour changes or a small change in outer ring shape has an effect on contraceptive efficacy (Good Practice Point).

32 There is no evidence that inserting the diaphragm dome up or dome down influences efficacy, however the woman should check that the diaphragm covers the cervix after insertion (Good Practice Point).

When should women attend for advice

There are no recommendations regarding routine follow-up and replacement of diaphragms or cervical caps. Women should be advised to attend for advice if they have any problems with use of the diaphragm or cervical cap (e.g. discomfort with use, pain, vaginal discharge or urinary tract infection).

A small retrospective study found no relationship between weight change and need for a different size of diaphragm.[105,106] No studies investigated contraceptive efficacy and weight change. Nonetheless, the Clinical Effectiveness Unit continue to support current practice in the UK, which is to review and reassess women if they have gained or lost more than 3 kg (7 lb) in weight.[24] In addition, women should be offered a review of contraception following any pregnancy (full-term, miscarriage or abortion).[24] Re-assessment for correct size or a change in method may be appropriate on an individual basis.

33 Women using a diaphragm or cervical cap should be advised to attend for a contraceptive review if they have any problems with the method, if they have lost or gained over 3 kg (7lb) in weight, or if they have had any pregnancy (Grade C).

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APPENDIX: DEVELOPMENT OF CEU GUIDANCE

This Guidance was developed by the Clinical Effectiveness Unit (CEU) (Dr Susan Brechin, Unit Director; Ms Lisa Allerton and Ms Gillian Stephen, Research Assistants) on behalf of the Faculty of Family Planning and Reproductive Health Care (FFPRHC) with a multidisciplinary group of health professionals (in attendance) comprising: Dr Audrey Brown (Consultant in Family Planning, The Sandyford Initiative, Glasgow/Representative of the FFPRHC Clinical Effectiveness Committee); Ms Lorraine Forster (Nurse Practitioner and Clinical Governance Co-ordinator, The Sandyford Initiative, Glasgow); Dr Asha Kasliwal (Clinical Director and Consultant in Community Gynaecology, Paladine Centre, Manchester/Representative of the FFPRHC Clinical Standards Board); Dr Louise Massey (Consultant in Public Health, Wolverhampton); Dr Anjana Oswal (Associate Specialist in Family Planning and Reproductive Health, Central Middlesex Hospital, London/Representative of the FFPRHC Education Committee); Dr Ros Tolcher (Clinical Director and Consultant in Family Planning, Southampton City Primary Care Trust, Southampton); Ms Maddy Ward (Clinical Nurse Specialist in Reproductive and Sexual Health, Westside Contraceptive Services, London). Written feedback was received from: Ms Toni Belfield (Director of Information, fpa, London); Mrs Walli Bounds (Former Research Co-ordinator at The Margaret Pyke Centre, London/Principal Research Fellow, Department of Obstetrics and Gynaecology, University College London, London (now retired); Dr Helen Ribbans (Consultant in Community Gynaecology, Burnley General Hospital, Burnley); Dr Sarah Randall (Consultant in Sexual and Reproductive Health, Portsmouth and Medical Advisor, National Chlamydia Screening Programme, Health Protection Agency, London). In addition, this Guidance document was independently peer reviewed by Ms Kelly Blanchard (President, Ibis Reproductive Health).

No competing interests were noted by members of the multidisciplinary group. Administrative support to the CEU team is provided by Mrs Tracey Chiverton

CEU Guidance is developed in collaboration with the Clinical Effectiveness Committee of the FFPRHC. The CEU Guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic area and typically includes clinicians working in family planning, sexual and reproductive health care, general practice, other allied specialities and user representation. In addition, the aim is to include a representative from each of the FFPRHC Clinical Effectiveness Committee, the FFPRHC Education Committee and FFPRHC Council in the multidisciplinary group.

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2006); EMBASE (1996–2006); PubMed (1996–2006); The Cochrane Library (to 2006) and the US National Guideline Clearing House. The searches are performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library is searched for systematic reviews, meta-analyses and controlled trials relevant to female barrier methods for contraception and in the prevention of sexually transmitted infections. Previously existing guidelines from the FFPRHC, the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization and the British Association for Sexual Health and HIV, and reference lists of identified publications, are also searched. Similar search strategies have been used in the development of other national guidelines. Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Clinical Excellence (NICE). All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded as in the table below, using a scheme similar to that adopted by the RCOG and other guideline development organisations. The clinical recommendations within this Guidance are based on evidence whenever possible. Summary evidence tables are available on request from the CEU. An outline of the Guidance development process is given in the table on the inside back cover of this Guidance document. Feedback on Guidance documents should be directed to the CEU via e-mail (ceu.guidance@abdn.ac.uk).

Level of evidence	Evidence
Ia	Evidence obtained from meta-analysis of randomised trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study, without randomisation
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies, correlation studies and case studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

	Grades of Recommendations
A	Evidence based on randomised controlled trials
B	Evidence based on other robust experimental or observational studies
C	Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities
✓	Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

Discussion Points for Female Barrier Methods

The following discussion points have been developed by the FFPRHC Education Committee.

Discussion Points

1 Female barrier methods offer holistic sexual health protection. Discuss.

2 How can a family planning service ensure that professionals are trained and competent to fit diaphragms and cervical caps?

3 Discuss how the limited choice of spermicide impacts on the use of female barrier methods.

Questions for Female Barrier Methods

The following questions and answers have been developed by the FFPRHC Education Committee.

Indicate your answer by ticking the appropriate box for each question	***True***	***False***
1 Femidoms are lubricated with spermicide.	☐	☐
2 Polyurethane condoms can be used by couples who are allergic to latex.	☐	☐
3 Sperm can survive in the vagina for up to 6 hours.	☐	☐
4 The breakage rate of female condoms is very low.	☐	☐
5 A contraceptive sponge should be left *in situ* for at least 6 hours after intercourse.	☐	☐
6 Risk of using a diaphragm or cervical cap by women at high risk of HIV or AIDS generally outweighs benefits.	☐	☐
7 Spermicide should be added if intercourse occurs more than 3 hours after the diaphragm has been inserted.	☐	☐
8 All female barrier methods need assessment and initial sizing by a competent clinician.	☐	☐
9 All spermicides available in the UK contain nonoxynol-9.	☐	☐
10 Advance supply of emergency contraception does not increase risk-taking behaviour.	☐	☐

Answers

1 False, 2 True, 3 True, 4 True, 5 True, 6 True, 7 True, 8 False, 9 True, 10 True

KEY POINTS: FEMALE BARRIER METHODS

EFFICACY

- When used consistently and correctly and with spermicide, *diaphragms* and *cervical caps* are estimated to be between 92% and 96% effective at preventing pregnancy.
- When used consistently and correctly, *female condoms* are 95% effective at preventing pregnancy and the *contraceptive sponge* is estimated to be between 80% and 90% effective at preventing pregnancy.

REDUCING THE RISK OF SEXUALLY TRANSMITTED INFECTIONS (STIs)

- There is limited evidence on the use of diaphragms, cervical caps or contraceptive sponge in reducing the risk of STIs. There may be some protection against cervical intra-epithelial neoplasia (CIN) with diaphragms.
- In general, evidence supports the use of female condoms to reduce the risk of STIs. However, even with consistent and correct use, transmission may occur. Evidence on use of male condoms suggests they offer better protection against STIs than female barrier methods.

ELIGIBILITY FOR USE

- Women with sensitivity to latex proteins can use a silicone diaphragm or cervical cap or a polyurethane female condom.
- The use of a diaphragm, cervical cap or contraceptive sponge by women who have or at high risk of HIV or AIDS is not generally recommended.
- For women with a history of toxic shock syndrome the use of diaphragms, cervical caps and contraceptive sponge is not generally recommended.

INSTRUCTIONS FOR USE

- Initial assessment of diaphragm and cervical caps should be done by a competent health professional.
- All methods can be inserted any time before intercourse.
- The use of spermicide is recommended when using diaphragms and cervical caps.
- If intercourse is repeated or occurs ≥3 hours after insertion more spermicide is required and should be inserted with an applicator or as a pessary without removing the diaphragm or cervical cap.
- The diaphragm or cervical cap must be left *in situ* for at least 6 hours after the last episode of intercourse. Sperm in the lower reproductive tract are unlikely to be alive after 6 hours.
- Oil-based lubricants can damage latex and women should be advised to avoid their use when using latex diaphragms or cervical caps.
- Women should be advised to check their diaphragm or cervical cap regularly for tears, holes or cracks.
- There is no evidence that a colour change or change in shape of the outer ring of a diaphragm reduces efficacy.
- Women should be advised on the use of emergency contraception should female barrier methods be used incorrectly.

FOLLOW-UP

- Women should be advised to attend for a review of contraception if they have:
  - any problems with the method
  - lost or gained more than 3 kg (7 lb) in weight
  - had a pregnancy

EMERGENCY HORMONAL CONTRACEPTION

- An advance provision of emergency hormonal contraception can be offered to women relying on female barrier methods for contraception.

STEPS INVOLVED IN THE DEVELOPMENT OF CEU GUIDANCE

STEP	TIME TAKEN
Formulation of **key clinical questions** by the Clinical Effectiveness Unit (CEU). **Systematic literature review** involving searching electronic, bibliographic databases by CEU researchers. **Obtaining and reviewing** copies of the full papers of all relevant publications identified through the searches. **Formal, critical appraisal** of key papers and development of short evidence tables.	This process must be completed in a maximum of 8 weeks.
Draft One Guidance document is written, providing recommendations and good practice points based on the literature review.	The CEU has overall responsibility for writing the Guidance document. The Multidisciplinary Group and other peer reviewers should highlight inconsistencies and errors or where the text is incomprehensible.
Multidisciplinary Group Meeting comprising stakeholders and including service user representation, representation from the Faculty of Family Planning and Reproductive Health Care (FFPRHC) Education Committee and, where possible, representation from the FFPRHC Clinical Effectiveness Committee and FFPRHC Council.	A one-day meeting held in Aberdeen with the Multidisciplinary Group to discuss the Draft One Guidance document.
Preparation of Draft Two Guidance document based on discussion at the Multidisciplinary Group.	The Multidisciplinary Group meeting is held at least 2 months before the Guidance deadline to allow time for development of further drafts.
Peer Review of Draft Two Guidance document by the Multidisciplinary Group and the FFPRHC CEU.	
All **written feedback on the Draft Two Guidance document** is tabulated and the CEU response to these comments outlined.	
Draft Three Guidance document is prepared based on written feedback and is sent to the Multidisciplinary Group and the FFPRHC CEU. In addition, two independent peer reviewers are identified by the CEC to provide feedback at this stage.	Only minor comments can be accepted at this stage.
The **Final Guidance document** is published by the FFPRHC.	Proofreading of the Guidance document is then performed by three members of the CEU team independently and comments collated and sent back by the Unit Director. A pdf version of the Guidance is available on the FFPRHC website.

COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

All comments on published Guidance can be sent directly to the Clinical Effectiveness Unit (CEU) via e-mail **(ceu.guidance@abdn.ac.uk)**.

You will receive an automated acknowledgment on receipt of your comments. If you do not receive this automated response please contact the CEU by telephone [+44(0)1224 553623] or e-mail **(ffp.ceu@abdn.ac.uk)**.

The CEU is unable to respond individually to all feedback. However, the CEU will review all comments and provide an anonymised summary of comments and responses which, after review by the Clinical Effectiveness Committee, will be posted on the Faculty website **(www.ffprhc.org.uk)**.