

Faculty of Sexual & Reproductive Healthcare Clinical Guidance



Barrier Methods for Contraception and STI Prevention

Clinical Effectiveness Unit

August 2012

(Updated October 2015)

ABBREVIATIONS USED

AIN	anal intraepithelial neoplasia
BASHH	British Association for Sexual Health and HIV
BBV	blood-borne virus
BHIVA	British HIV Association
BNF	<i>British National Formulary</i>
BV	bacterial vaginosis
CEU	Clinical Effectiveness Unit
CIN	cervical intraepithelial neoplasia
EC	emergency contraception
FSRH	Faculty of Sexual & Reproductive Healthcare
HIV	human immunodeficiency virus
HPV	human papillomavirus
HSV	herpes simplex virus
LARC	long-acting reversible contraception
MSM	men who have sex with men
N-9	nonoxinol-9
PEP	post-exposure prophylaxis (for HIV)
PEPSE	post-exposure prophylaxis after sexual exposure (to HIV)
POP	progestogen-only pill
PrEP	pre-exposure prophylaxis (for HIV)
SPC	Summary of Product Characteristics
STI	sexually transmitted infection
TSS	toxic shock syndrome
TV	<i>Trichomonas vaginalis</i>
UKMEC	<i>UK Medical Eligibility Criteria for Contraceptive Use</i>
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UPA	ulipristal acetate
UPSI	unprotected sexual intercourse
VIN	vulval intraepithelial neoplasia
WHO	World Health Organization
WHOMEK	<i>World Health Organization Medical Eligibility Criteria for Contraceptive Use</i>

GRADING 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

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NHS Evidence has accredited the process used by the Faculty of Sexual and Reproductive Healthcare of the Royal College of Obstetricians and Gynaecologists to produce guidelines. Accreditation is valid for five years from May 2011 and is applicable to guidance produced using the processes described in the Faculty of Sexual and Reproductive Healthcare: Clinical Effectiveness Unit Framework for Guidance Development (May 2011). More information on accreditation can be viewed at www.evidence.nhs.uk

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DETAILS OF CHANGES TO ORIGINAL GUIDANCE DOCUMENT

The CEU has updated this guidance (which was first published online in August 2012) following receipt of feedback from Faculty Members. The only amendment made to this document is as follows:

October 2015 update:

- Section 6.2 on page 10, the first paragraph has been reworded regarding the use of oil-based lubricants with newer condom brands.

SUMMARY OF KEY RECOMMENDATIONS

How to use barrier methods

- ✓ Men and women requesting a barrier method should be informed of the efficacy of the method, including the failure rate relative to other methods such as long-acting reversible contraception. Information should be provided on correct use, factors affecting efficacy, and when sexually transmitted infection (STI) testing, emergency contraception (EC) and post-exposure prophylaxis after sexual exposure to HIV (PEPSE) may be required.
- C A diaphragm or cervical cap can be inserted with spermicide any time before intercourse.
- C Spermicide should be reapplied if sex is to take place and the diaphragm or cap has been *in situ* for ≥ 3 hours or if sex is repeated with the method in place.
- C A diaphragm or cervical cap should not be removed until at least 6 hours after the last episode of intercourse.

Efficacy of barrier methods: pregnancy prevention

- B Male condoms are 98% effective and female condoms are 95% effective at preventing pregnancy but only when used consistently and correctly.
- B Pregnancy rates are similar for latex and non-latex condoms.
- C When used consistently, correctly and with spermicide, diaphragms and cervical caps are estimated to be between 92% and 96% effective at preventing pregnancy.

Efficacy of barrier methods: STI prevention

- * Sexually active men and women can be informed that the consistent and correct use of condoms (including with sex toys) is the most efficient means of protecting against HIV and other STIs. (*Grades of evidence vary: see text for specific infection/type of condom.)
- C Women using a diaphragm or cervical cap should be aware that there is little evidence that these methods reduce the risk of HIV/STI transmission or development of cervical intraepithelial neoplasia.
- ✓ Individuals should be informed that dams are available as a means of reducing risk of exposure to STIs and blood-borne viruses during cunnilingus and/or oro-anal contact.

Factors affecting efficacy

- C Women using a diaphragm or cap should be advised to use the method with spermicide.
- B The use of condoms lubricated with nonoxinol-9 is not recommended.
- B When using lubricant with latex condoms, diaphragms and caps a water- or silicone-based preparation is recommended.

Factors affecting efficacy

- B** The use of lubricant is recommended for anal sex to reduce the risk of condom breakage.
- C** In terms of condom safety, there is insufficient evidence to routinely advise additional lubricant for vaginal sex, but its use can be considered for those experiencing condom breakage.
- B** Men and women should be informed that adding lubricant to the inside of condoms or to the outside of the penis before using condoms is associated with an increased risk of slippage.
- C** Ill-fitting condoms can be associated with breakage and incomplete use. Individuals should be informed that different shapes and sizes of condoms are available.
- C** Condom breakage rates are similar for standard and thicker condoms and therefore there is no requirement to recommend thicker condoms for anal sex.
- C** Advice on condoms should be supported by demonstration of correct use.

HIV/STI transmission and the law

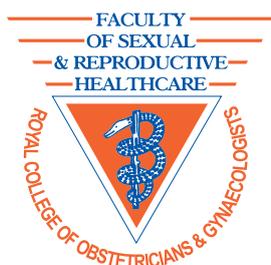
- Health professionals should keep up to date with the important legal issues regarding HIV/STI transmission and advise patients appropriately as regards partner notification, disclosure and condom use.

Other considerations

- Men and women can be made aware of post-exposure prophylaxis after sexual exposure to HIV (PEPSE). The decision to initiate PEPSE can only be made after consideration of the risks of exposure and likelihood of side effects and compliance with treatment.
- Health professionals should utilise opportunities such as presentation for EC, PEPSE or STI testing to discuss pregnancy and STI risk reduction strategies.
- Health professionals should inform women about the availability of EC and when it can be used. Advance supply may be considered but there is no evidence to support routine provision.

Medical eligibility

- C** For women living with HIV or at high risk of HIV infection the use of either a diaphragm or cervical cap is a UK Medical Eligibility Criteria (UKMEC) Category 3.
- C** Women with sensitivity to latex proteins should avoid the use of latex barrier contraceptives and may use a silicone diaphragm, cervical cap, non-latex male or female condoms, or deproteinised latex male condoms.
- C** For women with a history of toxic shock syndrome (TSS) the use of the diaphragm, cervical cap or contraceptive sponge is UKMEC Category 3.
- C** Women with a history of TSS may use male or female condoms.
- Caps and diaphragms should not be left *in situ* for longer than recommended by the manufacturer or used during menstruation.



Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit

A unit funded by the FSRH and supported by NHS Greater Glasgow & Clyde to provide guidance on evidence-based practice

FSRH Guidance (August 2012)

Barrier Methods for Contraception and STI Prevention

(Update due by August 2017)

1 Purpose and Scope

This Faculty of Sexual & Reproductive Healthcare (FSRH) guidance document is an update of two previous FSRH guidance documents on *Male and Female Condoms*¹ and *Female Barrier Methods*² published in 2007. The document provides evidence-based recommendations and good practice points for health professionals on the use of barrier methods to prevent pregnancy and/or reduce the risk of sexually transmitted infections (STIs), including the human immunodeficiency virus (HIV). The term 'barrier method' is used in the document to refer predominantly to male and female condoms, diaphragms and the contraceptive cap.

The main changes from previous guidance are updated information on the range of barrier methods available, reference to updated guidance on post-exposure prophylaxis after sexual exposure to HIV (PEPSE), and signposting to information on reckless transmission of STIs.

Recommendations are based on the evidence available at the time of writing and on consensus opinion of experts. A key to the Grading of Recommendations, based on levels of evidence, is provided on the inside front cover of this document. Details of the methods used by the Clinical Effectiveness Unit (CEU) in developing this guidance are outlined in Appendix 1 and on the FSRH website (www.fsrh.org). The recommendations should be used to guide clinical practice but they are not intended to serve alone as a standard of medical care or to replace clinical judgment in the management of individual cases.

For additional advice we recommend that readers refer to the *UK National Guidelines on Safer Sex Advice* that were published by the British Association for Sexual Health and HIV (BASHH) as this guidance document went to press.³

2 Background

Barrier methods discussed include:

- Male condoms (latex, non-latex and deproteinised latex varieties)
- Female condoms (nitrile or latex)
- Diaphragms (latex, silicone)
- Cervical cap (silicone)
- Dams (latex, non-latex).

Male and female condoms provide a barrier to the ejaculate, pre-ejaculate and to cervico-vaginal secretions. Condoms can be used as a primary method of contraception or as an additional method either in the short term, for example, when starting hormonal contraception, or in the long term to provide double protection. They can also be used for STI and HIV prevention. Data have suggested that the male condom is a commonly used method of contraception in the UK.^{4,5}

Diaphragms and caps provide a physical barrier to sperm reaching the cervix. As only the cervix is covered by these methods, they do not prevent exposure of the vaginal mucosa to semen or exposure of the penis to cervico-vaginal secretions. In 2008/2009, a survey found that less than 1% of women reported using this contraceptive method.⁴ Contraceptive sponges and spermicidal pessaries are no longer available in the UK.

Dams are not a contraceptive but they can be used to protect against STIs. A dam is a thin film of material that provides a barrier between the mouth and cervico-vaginal secretions during cunnilingus or between the mouth and anus during oro-anal contact. Hand-free varieties are available.

3 How to Use Barrier Methods

Men and women requesting barrier methods should be given information on how to use the method correctly. Leaflets are available from a variety of sources (Appendix 2).

3.1 Condoms (male and/or female)

Users should be advised to check condom packaging for the relevant safety markings and the 'use by' date. A new condom should be used for each episode of sexual intercourse or if applied incorrectly. No more than one condom should be worn simultaneously by one person, and the male and female condom should not be used simultaneously for the same act of intercourse.

Male condoms should not be unrolled until placed on an erect penis. The condom should be rolled down to the base of the penis before there is genital contact. After ejaculation, men should withdraw before the penis goes soft. Removal of the condom from the penis should occur away from the vagina, anus or genital area.

There are several female condoms available on the market. They are lubricated sheaths that are inserted into the vagina before sex. Female condoms can have a ring or sponge within the closed end of the sheath. The open end of the sheath, which remains outside the vagina, is formed either by a larger ring or flexible 'V' frame.

Care should be taken when handling condoms as sharp objects such as fingernails, teeth or jewellery can tear them. If there is any possibility of a condom failure (e.g. break, slip, leak, put on too late and/or removed too early) there may be a risk of pregnancy and/or infection. Consideration may need to be given to emergency contraception (EC) and/or testing for STIs. In some cases PEPSE may also need to be considered (see section on pages 13–14).



Men and women requesting condoms should be informed of the efficacy of condoms including their failure rate relative to other methods, such as long-acting reversible contraception (LARC). Information should be provided on correct use, factors affecting efficacy, and when STI testing, EC and PEPSE may be required.

3.2 Diaphragms and caps

The following advice on the use of diaphragms and caps is based on expert consensus due to the paucity of good-quality evidence in this area.

In the UK it has been recommended that a spermicidal agent be used with diaphragms and the cervical cap.² Diaphragms and caps can be inserted with spermicide any time before intercourse. The spermicide is held against the cervix by the diaphragm or cap and provides a chemical barrier to sperm. Diaphragms are usually inserted dome down but some types can be inserted dome up (see page 11). Approximately two 2 cm strips of spermicide should be applied to the upper surface of the diaphragm. Some spermicide can be applied to the leading edge of the rim to ease insertion. When using a cap the inside of the cap should be filled about a third with spermicide. Spermicide should not be put on the rim of a cervical cap

as it may stop it staying in place. Additional spermicide should be applied before sex is repeated or if the diaphragm or cervical cap has been *in situ* for 3 hours or more before sex takes place. The diaphragm or cervical cap should not be removed to reapply 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 can remain *in situ* for a maximum of 30 hours. The silicone cervical cap can remain *in situ* up to 48 hours.

Nurses and doctors can provide the initial fitting of a diaphragm/cervical cap. Health professionals who fit diaphragms or cervical caps should have appropriate training and recognised competencies for contraceptive counselling and female examination. Women must be offered a chaperone during an intimate examination.^{6,7}

A diaphragm should be positioned so that the rim fits comfortably and not too loosely or tightly into the vaginal fornices. Ideally the anterior rim should sit in the groove behind the pubic bone. The cap should fit over the cervix. The woman should be shown how to apply spermicide and insert and remove the diaphragm/cap. Before leaving the clinic with a trial diaphragm/cap the woman must be able to remove the diaphragm/cap herself.

Before the woman relies on the method for contraception she should be asked to return wearing the diaphragm/cap. A vaginal examination should be repeated to ensure that the diaphragm/cap has been inserted correctly and is covering the cervix.

If there is any suspicion of diaphragm/cap failure (e.g. removed too early) there may be a risk of pregnancy and EC may need to be considered or used. STI testing may also be appropriate (see section on page 13).

- C** A diaphragm or cervical cap can be inserted with spermicide any time before intercourse.
- C** Spermicide should be reapplied if sex is to take place and the diaphragm or cap has been *in situ* for ≥ 3 hours or if sex is repeated with the method in place.
- C** A diaphragm or cervical cap should not be removed until at least 6 hours after the last episode of intercourse.

4 How Effective are Barrier Methods at Preventing Pregnancy?

Factors that affect the efficacy of barrier methods are outlined in the section on pages 10-12.

4.1 Condoms

Data from the USA have suggested that with perfect (i.e. correct and consistent) use there is a 5% failure rate with the female condom and a 2% failure rate with the male condom.⁸ With typical use (which includes incorrect and inconsistent use) the failure rates are 21% and 18%, respectively⁸ (Table 1).

Many factors other than correct and consistent condom use may influence the efficacy of condoms in the prevention of pregnancy (e.g. background fertility, coital frequency and EC use when condoms fail).

A study that looked at semen exposure following condom failure suggested that even when condoms break or slip, the risk of pregnancy may be reduced in comparison to no method.⁹ Although condom studies often report clinical breakage and slippage rates, these are not considered valid surrogate endpoints of pregnancy.¹⁰

Table 1 Percentage of women experiencing unintended pregnancy within the first year of use of barrier contraceptive methods in the USA⁸

Method	Percentage of women experiencing an unintended pregnancy within the first year of use (%)	
	Typical use ^a	Perfect use ^b
Spermicides ^c	28	18
Female condom ^d	21	5
Male condom ^d	18	2
Diaphragm ^e	12	6

^aAmong typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides and the diaphragm are taken from the 1995 National Survey of Family Growth (NSFG) corrected for underreporting of abortion; estimates for fertility awareness-based methods, withdrawal, the male condom, the pill and Depo-Provera[®] are taken from the 1995 and 2002 NSFG corrected for underreporting of abortion.

^bAmong couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

^cFoams, creams, gels, vaginal suppositories and vaginal film.

^dWithout spermicides.

^eWith spermicidal cream or jelly.

A Cochrane review designed to evaluate non-latex male condoms in comparison with latex condoms found that although non-latex condoms performed well in terms of acceptability, they were associated with significantly higher clinical breakage (breakage during intercourse or withdrawal).¹¹ However, two randomised trials¹² (Nelson *et al.*, 2001, unpublished data) reported no differences in pregnancy rates for latex and non-latex condoms. No data on the efficacy of deproteinised latex condoms (see section on latex sensitivity on page 16) in pregnancy prevention were identified. However, as this type of condom carries the BSI Kitemark and meets the requirements of ISO 4074, it is expected to perform as least as well as other Kitemarked condoms.

With typical use, long-acting reversible methods of contraception (LARCs) have lower failure rates than shorter-acting methods such as the contraceptive pill or condoms.⁸ It has been recommended that increasing the uptake of LARC methods will reduce the number of unintended pregnancies.¹³ However, condoms should not be forgotten for STI prevention (see section on page 9).

B Male condoms are 98% effective and female condoms are 95% effective at preventing pregnancy but only when used consistently and correctly.

B Pregnancy rates are similar for latex and non-latex condoms.

4.2 Diaphragms and caps

Data have suggested that with perfect use 6% (range 4.3–8.4%) of women using the diaphragm with spermicidal cream or jelly experience an unintended pregnancy within the first year of use.⁸ With typical use the percentage increases to 12% (Table 1).⁸

In a comparative study, the only contraceptive cap available in the UK was found to be less effective at preventing pregnancy than the diaphragm to which it was compared.^{14,15} The unadjusted typical-use probability of pregnancy at 6 months use was 13.5% for contraceptive cap users and 7.9% for diaphragm users.¹⁵ The adjusted risk of pregnancy at 6 months use was 1.96 times higher than among diaphragm users.¹⁵

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

5 How Effective are Barrier Methods at Preventing Transmission of STIs and Blood-borne Viruses?

STIs including HIV can be transmitted via vaginal/anal/oral sex, as well as the sharing of sex toys and digital penetration. BASHH has a leaflet for patients on how to make sex safer (Appendix 2).

5.1 Condoms

Laboratory studies show that condoms (male latex, male and female non-latex) protect against STIs including HIV.^{16–28} Data from other studies suggest female condoms may be as effective as male condoms in the prevention of STIs from vaginal intercourse (*Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and genital ulcer disease).^{20,29}

Evidence on condom effectiveness outside of laboratory studies comes from observational studies. It is therefore limited due to potential biases such as self-reported condom use, the population being studied, difficulties isolating the risk associated with specific activities, incorrect use not being evaluated or the use of different definitions (e.g. slippage). A lack of 'good' evidence in relation to condoms (male and female) and specific STIs does not necessarily equate to lack of protection.

There is high-level evidence on the use of condoms in particular groups for specific types of sex [e.g. use of male latex condoms for anal sex by men who have sex with men (MSM)]. For the purpose of this guidance document the evidence for the male condom has been generalised to men and women for vaginal and anal sex. The Grade of Recommendation has been reduced to reflect indirect evidence.

Although there is evidence that female condoms are used for anal sex among heterosexual couples and MSM,³⁰ little evidence was found looking at the effectiveness of female condoms in relation to anal sex. Therefore recommendations relating to the female condom apply to vaginal sex only.

The CEU supports the World Health Organization (WHO), Joint United Nations Programme on HIV/AIDS (UNAIDS) and United Nations Population Fund (UNFPA) Position Paper³¹ on condoms and HIV, which states that the male latex condom is the single most efficient, available technology to reduce the sexual transmission of HIV and other STIs. (See pages 6–9 for grades of evidence for specific infection/type of condom.)



Sexually active men and women can be informed that the consistent and correct use of condoms (including with sex toys) is the most efficient means of protecting against HIV and other STIs. (*Grades of evidence vary: see pages 5–9 for specific infection/type of condom.)

5.1.1 HIV

There is strong evidence that condoms are effective in reducing sexually transmitted HIV.^{32–34} Consistent condom users are estimated to be 10 to 20 times less likely to become infected with HIV when exposed to the virus than inconsistent or non-users.³⁵

The risk of an individual acquiring HIV is dependent on the type of exposure, the infectivity of the person with HIV (e.g. viral load, other STIs, bleeding) and the susceptibility of the person at risk (e.g. presence of an STI).³⁶ Table 2 outlines the estimated risk of HIV transmission following exposure from a known HIV-positive individual. More detailed information can be found in the BASHH UK National Guideline for the Use of Post-Exposure Prophylaxis Following Sexual Exposure³⁶ (see also page 14).

Table 2 The risk of HIV transmission following sexual exposure to a known HIV-positive individual³⁶ (adapted from the UK National Guideline for the Use of Post-Exposure Prophylaxis Following Sexual Exposure with permission from BASHH)

Type of sexual exposure	Estimated median (range) risk of HIV transmission per exposure
Receptive anal intercourse	1.11% (0.042–3.0%)
Insertive anal intercourse	0.06% (0.06–0.065%)
Receptive vaginal intercourse	0.1% (0.004–0.32%)
Insertive vaginal intercourse	0.082 (0.011–0.38%)
Receptive oral sex (fellatio)	0.02% (0–0.04%)
Insertive oral sex (receiving fellatio)	0%

Although unprotected oral sex is associated with a lower risk of HIV transmission than unprotected anal or vaginal sex, it is implicated as a route for other STIs including gonorrhoea, *C. trachomatis* and syphilis.^{37–39} The frequency of oral sex in some groups may increase its relative contribution to overall HIV transmission rates.⁴⁰

In order to reduce their risk of HIV transmission some individuals choose to serosort [i.e. the practice of choosing sexual partners based on their HIV status, often to engage in unprotected sexual intercourse (UPI)]. Serosorters may still be at risk of transmitting other undiagnosed STIs and HIV-negative individuals may still be at risk of acquiring HIV as around a quarter of people with HIV are unaware of their HIV status.⁴¹ For two individuals who are seroconcordant for HIV, UPI may put them at risk of superinfection (i.e. infection with a different strain of HIV that may alter response to treatment).

- A** The consistent and correct use of male latex condoms is recommended to reduce the risk of HIV transmission.
- C** The consistent and correct use of female condoms and non-latex male condoms may be recommended to reduce the risk of HIV transmission.
- C** The use of male condoms can be advised for oral sex as a means of reducing the risk of HIV transmission.
- B** Individuals living with HIV should be advised to use condoms to prevent onward transmission of HIV, superinfection with different HIV strains, and acquisition of other STIs.

5.1.2 *Chlamydia trachomatis*

Chlamydia trachomatis can be transmitted in vaginal or seminal fluids through vaginal, anal or oral intercourse. Prevalence of infection in partners of those diagnosed with chlamydia is up to 75%.^{42–46} Available evidence supports the use of condoms to reduce the risk of *C. trachomatis*,^{47–58} including rectal chlamydia infection.⁵⁹ It has been suggested that the female condom may be as effective as male condoms in the prevention of chlamydia transmission.^{20,29}

- B** The consistent and correct use of male or female condoms is recommended to reduce the risk of chlamydia transmission.
- C** The use of male condoms can be advised for oral sex as a means of reducing the risk of chlamydia transmission.

5.1.3 *Neisseria gonorrhoeae*

Neisseria gonorrhoeae is transmitted via vaginal or seminal fluids and is easily transmitted through vaginal, anal or oral sexual activity. There is evidence that the consistent use of male condoms reduces the risk of *N. gonorrhoeae*^{32,47,49–52,54,56–58,60–64} and it has been suggested that the female condom may be as effective as male condoms in the prevention of *N. gonorrhoeae*.^{20,29} Increased use of condoms in female sex workers for oral sex resulted in a decreased incidence of pharyngeal gonorrhoea.⁶⁵

B The consistent and correct use of male and female condoms is recommended to reduce the risk of *N. gonorrhoeae* transmission.

C The use of male condoms can be advised for oral sex as a means of reducing the risk of *N. gonorrhoeae* transmission.

5.1.4 *Trichomonas vaginalis*

Trichomonas vaginalis (TV), can be isolated from the vagina and urethra in infected women and the urethra in infected men.⁶⁶ It is not transmitted through anal or oral sex.

Self-reported consistent male condom use has been associated with a reduced risk of incidence of urethral STIs (chlamydia, gonorrhoea and/or TV).⁵⁸ Other data support a reduced risk of TV in women using male latex condoms.⁶⁷

In a study of young African women, a positive test for TV was more common among inconsistent condom users when compared to consistent users.⁴⁸ Inconsistent users of female condoms have been shown to be more likely to be reinfected with TV compared to consistent users, although the finding was not statistically significant.⁶⁸ Reinfection with TV did not occur in consistent female condom users.⁶⁸

B The consistent and correct use of condoms is recommended to reduce the risk of *T. vaginalis* transmission.

5.1.5 Syphilis

Treponema pallidum can be transmitted through sexual intercourse or direct contact with syphilitic sores. There have been a number of syphilis outbreaks particularly among MSM. Unprotected oral sex was identified as a key contributing factor.^{69–73}

A systematic review⁷⁴ of epidemiological studies assessing condom use and risk of syphilis identified that significant methodological limitations have hindered the ability to estimate the measure of effect across these studies. However, within the review, the two most rigorously designed studies provided evidence to support a reduced risk of syphilis transmission with consistent use of male condoms.⁷⁴

B The consistent and correct use of male condoms is recommended to reduce the risk of syphilis transmission.

✓ The consistent and correct use of female condoms may be advised to reduce the risk of syphilis transmission.

C The use of male condoms can be advised for oral sex as a means of reducing the risk of syphilis transmission.

5.1.6 Human papillomavirus

There are more than 100 different sub-types of human papillomavirus (HPV). Some of these sub-types are associated with genital warts and others are linked to cervical, vulval and anal intraepithelial neoplasia (CIN, VIN and AIN, respectively). At least 50% of sexually active men and women acquire genital HPV infection at some point in their lives and may develop genital warts. Ano-genital warts are mainly transmitted through sexual contact. However, they can also be transmitted perinatally and later through direct contact with warts.⁷⁵ Most ano-genital warts are benign and caused by HPV types 6 and 11.⁷⁵ Persistent infection with high-risk HPV types (e.g. 16 and 18) is a risk factor for squamous cancer of the cervix, anus and oropharynx.

Some studies have reported that condoms do not reduce the transmission rate of HPV.^{51,76-79} A meta-analysis concluded that whilst they may not prevent HPV infection, they may protect against genital warts, CIN II or III and invasive cervical cancer.⁸⁰ Other studies, however, have reported that male condoms do protect against HPV transmission, and are associated with lower prevalence or promote clearance of cervical HPV.⁸¹⁻⁸⁹ There is no evidence in relation to female condoms.

In the UK there is currently an HPV vaccination programme. From September 2012, the programme will use a vaccine that helps protect against four strains of HPV (two strains that cause the majority of cases of cervical cancer and two that cause the majority of cases of genital warts). Although this programme will go some way to offering protection against infection with these four HPV strains, the programme is currently only available to young women and does not offer protection from other strains of HPV or other STIs. Men and women need to be advised about the use of condoms to reduce the transmission of the different HPV strains and other STIs including HIV.

B/C The consistent and correct use of male (Grade B) and female condoms (Grade C evidence) is recommended to reduce the risk of transmission of genital HPV.

B Male latex condoms, when used consistently and correctly, can increase the rate of HPV clearance and CIN regression.

C The use of male condoms can be advised for oral sex as a means of reducing the risk of HPV transmission.

5.1.7 Herpes simplex infection

Transmission of herpes simplex virus (HSV) can occur with unprotected sex (vaginal, anal and oral). In addition to sexual transmission, it can also occur as a result of direct contact with genital ulcers, or in the absence of clinical lesions when the virus is shed in asymptomatic men and women. There is an especially high risk of transmission when a person has an active genital sore or an active oral lesion at the time of contact.⁹⁰

Evidence on the benefit of condoms in reducing transmission risk is conflicting with some studies supporting condom use⁹¹⁻⁹³ and others reporting that condom use offered no protection from HSV transmission.^{51,54,94} A pooled analysis⁹⁵ of prospective studies found that consistent condom use (used 100% of the time) was associated with a 30% lower risk of laboratory defined HSV-2 acquisition compared with those who never used condoms. No differences by gender were found.

The 2001 report by the National Institute of Allergy and Infectious Diseases³² indicated that due to limitations with the available evidence they were unable to form conclusions about the effectiveness/ineffectiveness of correct and consistent condom use.

C The consistent and correct use of male condoms is recommended to reduce the risk of transmission of HSV.

✓ The consistent and correct use of female condoms may be advised to help reduce the risk of transmission of HSV.

C Individuals can be informed that whilst condoms offer some protection against HSV, avoidance of sex (vaginal, anal and oral) during symptomatic episodes may be advisable and that transmission can still occur by viral shedding even when there are no symptoms.

5.1.8 Viral hepatitis

Evidence on the use of condoms (male or female) in the prevention of viral hepatitis is limited.

The hepatitis B virus can be passed via seminal and vaginal fluids. Sexual transmission of hepatitis B among MSM (unvaccinated and non-immune) has been found to correlate with multiple partners, unprotected anal sex and oro-anal sex.⁹⁶ Transmission of hepatitis B via heterosexual contact has also been observed^{97–100} with infection rates of around 18% quoted for regular partners of those with acute hepatitis. A study found that female sex workers who consistently used male condoms were less likely to be hepatitis B core antibody-positive than inconsistent condom users.⁵⁴

The hepatitis C virus can be transmitted through seminal and vaginal fluids but the risk of sexual transmission is low.^{101–103} Exact risk estimates are therefore difficult to establish because of the high study numbers required. BASHH quotes figures of <1% per year of relationship or about 2% of spouses in long-term relationships.¹⁰¹ Rates of infection increase if the index patient is also infected with HIV.

Hepatitis A is spread via the faecal-oral route but this is usually via food, water or by close (non-sexual) contact. Hepatitis A may be spread through sexual contact via oro-anal sex and digital-rectal contact, and there have been outbreaks reported in MSM. BASHH recommends individuals avoid UPSI until considered non-infectious.¹⁰¹

- B** The consistent and correct use of male condoms is recommended to reduce the risk of hepatitis B transmission.
- C** The use of male condoms for oral sex may reduce the risk of hepatitis B transmission.
- ✓ The consistent and correct use of male condoms is recommended to reduce the risk of hepatitis C transmission.
- ✓ There is insufficient evidence to determine the efficacy of condoms in preventing the risk hepatitis A during sexual activity. The use of dams is recommended for oral-anal contact.

5.2 Diaphragms and caps

Data from a small case control study of women attending a genitourinary medicine clinic suggested that diaphragm use may protect against STI pathogens such as *N. gonorrhoeae* and *T. vaginalis*.¹⁰⁴ A subsequent randomised controlled trial¹⁰⁵ sought to examine the effect of the diaphragm and lubricant gel on the incidence of chlamydial and gonococcal infections among women at risk of HIV and STI infections. For ethical reasons the intervention group had to use condoms and were compared to controls who also used condoms. This meant only the benefit in addition to condoms could be assessed. The study found no difference by study arm in the rate of acquisition of these two infections suggesting no additional benefit in addition to condoms, although there was some suggestion that it may have helped to reduce acquisition of gonorrhoea among the small number of women who used the diaphragm 100% of the time.

A case-control study found that the risk of CIN II and III may be reduced in women who use a diaphragm with spermicide.¹⁰⁶ However subsequent studies have failed to confirm these observations.^{107,108}

- C** Women using a diaphragm or cervical cap should be aware that there is little evidence that these methods reduce the risk of HIV/STI transmission or development of CIN.

5.3 Dams

A growing body of evidence suggests a link between bacterial vaginosis (BV) and sexual behaviour^{109–112} including oral sex.³⁷ No evidence was identified on the effectiveness of dams used for cunnilingus or oro-anal contact in the prevention of HIV or STI transmission or BV. In

theory the use of dams should reduce exposure to infections and thus any potential transmission. However, a study of women identified as having sex with women found that dams were not commonly used for oral sex.¹¹³ No data were found in relation to heterosexual couples or MSM.

- ✓ Individuals should be informed that dams are available as a means of reducing risk of exposure to STIs and blood-borne viruses during cunnilingus and/or oro-anal contact.

6 Factors Affecting the Efficacy of Barrier Methods

6.1 Spermicides

A Cochrane review concluded that there was insufficient evidence to draw conclusions as to whether the efficacy of diaphragms is improved with use of spermicide compared to diaphragm use without spermicide. However, it was also noted that there was no evidence to change the current practice of using spermicide with diaphragms.¹¹⁴

There is no evidence that condoms lubricated with spermicide provide additional protection against pregnancy or STIs compared with condoms lubricated with a non-spermicidal lubricant.¹¹⁵

The main spermicide available in the UK contains nonoxinol-9 (N-9). N-9 is a surfactant that disrupts cell membranes. In human and animal models epithelial disruption in the vagina and rectum has been identified with N-9 use.^{115,116} Repeated and high-dose use of N-9 is associated with an increased risk of genital lesions, which may in turn increase the risk of HIV acquisition (see section on page 15).

- C Women using a diaphragm or cap should be advised to use the device with spermicide.

- B The use of condoms lubricated with N-9 is not recommended.

6.2 Lubricants

Water- or silicone-based lubricants are recommended when using latex condoms. Oil-based products (such as baby oil and petroleum jelly) can damage latex and may increase the risk of breakage of latex condoms.¹¹⁷⁻¹¹⁹ *The British National Formulary* (BNF) (www.bnf.org) and the Summary of Product (SPC) characteristics (www.medicines.org.uk/emc/) for vaginal and topical preparations containing econazole, miconazole, isoconazole, fenticonazole or clotrimazole warn that these products may damage latex contraceptives. Oil-based lubricants should not be used with newer condoms brands made from polyisoprene (Skyn®) or lamb intestine (Naturalamb®).

Male latex condoms are less likely to break during anal sex if a suitable lubricant is used. A study showed that with additional lubricant 3% of condoms broke during anal sex compared with 21.4% when no lubricant was used.¹²⁰ When an unsuitable lubricant was used breakage rates increased (7.7% broke with oil-based lubricant and 10.8% broke when saliva was used).¹²⁰ Concerns have been raised about the lack of data on the safety of personal lubricants and the possible effect their use may have on facilitation of STI transmission^{121,122} More research is needed in this area.

Results vary in relation to the use of water-based lubricants with condoms for vaginal sex. Some studies have suggested reduced condom breakage¹²³ while others have found that use of lubricant with condoms during vaginal sex increased rates of slippage^{124,125} or had no impact on breakage or slippage.¹²⁶ The authors of a large cross-over study¹²⁷ that examined condom failure rates with and without additional spermicide amongst heterosexual couples found no evidence of slippage. They found evidence of reduced clinical failures (breaks, tears, condom slips occurring after initial penetration but before complete withdrawal) amongst couples who had previously experienced failures.¹²⁷ They also found lower total and clinical failure rates with additional spermicide use.¹²⁷ The authors believed that the reduced failure rates were related to the lubricating effect of the spermicide rather than the spermicidal effects.

Gel charging is the practice of adding a small amount of lubricant to the inside of condoms to increase sensation. Additional lubricant applied under condoms (e.g. to the tip or all over the penis) has been shown to be associated with increased rates of slippage. When additional lubricant was only applied to the outside of condoms, slippage rates were reduced compared to no additional lubricant at all.¹²⁰

- B** When using lubricant with latex condoms, diaphragms and caps a water- or silicone-based preparation is recommended.
- B** The use of lubricant is recommended for anal sex to reduce the risk of condom breakage.
- C** In terms of condom safety, there is insufficient evidence to routinely advise additional lubricant for vaginal sex, but its use can be considered for those experiencing condom breakage.
- B** Men and women should be informed that adding lubricant to the inside of condoms or to the outside of the penis before using condoms is associated with an increased risk of slippage.

6.3 Size, shape and thickness of barrier methods

Diaphragms are available in different diameters ranging from 55 to 95 mm in 5 mm increments. The flat spring diaphragm tends to be the most commonly used (usually dome up).¹²⁸ Some women may find a coil spring diaphragm more comfortable because it is softer, and an arcing diaphragm may be required if the position of the cervix makes other types more difficult to fit.¹²⁸ Women with poor muscle tone or prolapse may find that a cervical cap fits better than a diaphragm. FemCap® is currently the only cap available in the UK. It is made in 22, 26 and 30 mm sizes.

For efficacy it is important that the diaphragm or cervical cap covers the cervix. A vaginal examination by a competent health professional is essential to ensure a diaphragm or cervical cap is a suitable method and is the correct size.^{129,130} Using information such as parity, body weight, height, body mass index (BMI), age and day of cycle has not been shown to improve the prediction of diaphragm size. Women may need to be refitted for a device after pregnancy. A single size, non-latex diaphragm is available outside of the UK. Magnetic resonance imaging has shown that following simulated intercourse, the single size diaphragm remained in position covering the cervix in a small number of women with varying parity and BMI.¹³¹

The condom brands commonly supplied in the UK vary from 80 mm to 240 mm in length and from 41 mm to 69 mm in width. Condoms fitted to self-measured penile dimensions are available to buy via the Internet. The range of lengths and widths is similar to that of standard condoms but there are more size options within the range.

Ill-fitting condoms have been associated with condom breakage and incomplete use in a number of studies.^{132–134} In one study, ill-fitting condoms were associated with self-reported difficulties in reaching orgasm (self and partners); reduced sexual pleasure, as well as erectile issues.¹³³ A study of men and women using different sizes and shapes of condoms found that perceptions of differences between straight, flared, contoured and narrower condoms influenced user preference.¹³⁵

A randomised cross-over study¹³⁶ comparing failure rates of standard-sized condoms to condoms fitted to a man's penile length and circumference found no significant difference in overall failure rates between the two condom types for vaginal and anal sex. Subgroup analysis suggested that among men with larger penile dimensions fitted condoms may be associated with reduced breakage rates during vaginal and anal sex. However, among men with medium-sized penile dimensions fitted condoms were associated with increased slippage during vaginal sex.

Thicker ('extra strong') condoms have been traditionally recommended for anal sex. However, a study found that condom breakage rates were similar for standard and thicker condoms.¹²⁰ Use of lubricant, duration of sex and penis size were more likely to be associated with breakage than with condom thickness.¹²⁰

C Ill-fitting condoms can be associated with breakage and incomplete use. Individuals should be informed that different shapes and sizes of condoms are available.

C Condom breakage rates are similar for standard and thicker condoms and therefore there is no requirement to recommend thicker condoms for anal sex.

6.4 Knowledge/familiarity with the method

Incorrect condom use has been shown to be associated with an increased likelihood of condom breakage.¹³⁴ A randomised clinical trial¹³⁷ examining the efficacy of male and female condoms as barriers to semen found that measurements of prostate-specific antigen in vaginal fluid (a marker of condom failure) decreased as the number of female condoms used by women increased, suggesting that increasing familiarity reduces method error. Advice on the use of condoms including a condom demonstration significantly reduced self-reported condom breakage among men attending an STI clinic in Jamaica.¹³⁸

C Advice on condoms should be supported by demonstration of correct use.

6.5 Duration of intercourse

Duration of intercourse has been shown to be a significant risk factor for condom breakage among MSM.¹²⁰ There was a strong association between breakage and sex lasting more than 45 minutes. Amongst those who experienced a breakage, the mean duration of intercourse at which the breakage happened was 28 minutes. No study was identified looking at the effect of vaginal intercourse duration on condom breakage.

7 Improving Condom Use

Whilst health services are encouraged to promote LARC as the most effective means of preventing an unintended pregnancy, it is also important to encourage condom use for STI prevention. Some of the factors affecting condom use such as size, shape, and familiarity have already been discussed. However, a great many social and behavioural factors influence use of contraceptives and condoms such as self-esteem, parental relationships and relationship status. Recommendations on how these wider influences should be addressed are outlined in national strategies.^{139,141} Recently published BASHH guidance on safer sex³ provides advice on interventions to influence condom use and other safer sex behaviours.

Sexual health services have a role in ensuring free access to condoms and providing information/education on their use including the benefits of use. Health professionals should avoid making assumptions as to who may benefit from information about condoms based on factors such as age or relationship status alone.

8 HIV/STI Transmission and the Law

There have been several prosecutions in the UK relating to the transmission of HIV and other STIs. In England and Wales, to be successfully prosecuted, transmission of HIV has to occur. However, in Scotland the common law offence of 'Culpable and Reckless Conduct' is used to prosecute. This means that individuals can potentially be prosecuted irrespective of whether or not the virus has been transmitted. However, these cases are extremely rare. This is a relatively new area, and legal practice is evolving as more cases come to court.

Advice for professionals is available from BHIVA and BASHH.¹⁴² Further useful information on HIV/STI and criminalisation is available on the Terence Higgins Trust, AVERT and Aidsmap websites (Appendix 2). Concerned individuals can also access helplines for information on HIV and sexual health and guidance from the Crown Prosecution Service¹⁴³ (England and Wales) and the Crown Office and Procurator Fiscal Service¹⁴⁴ (Scotland) (Appendix 2).

Health professionals should keep up to date with the important legal issues regarding HIV/STI transmission, and their responsibilities as to the duty of care of patients, confidentiality and public health concern.¹⁴²



Health professionals should keep up to date with the important legal issues regarding HIV/STI transmission and advise patients appropriately as regards partner notification, disclosure and condom use.

9 Considerations Following Barrier Method Failure

9.1 Emergency contraception

Health professionals should discuss the potential need for EC with women who use barrier contraception. EC may be indicated in the following situations (list not exhaustive):

- Diaphragm or cap is dislodged or removed within 6 hours of sex
- Diaphragm has been left in for longer than 3 hours before sex and no additional spermicide applied
- Condom splitting/breaking
- Condom slippage
- Failure to use condoms as advised when starting or switching contraception
- If enzyme-inducing drugs are being used alongside hormonal contraception (combined hormonal contraception, POP and implant) and condoms are not used during or for 28 days after.

If, following administration of EC, a woman chooses to immediately start a hormonal method of contraception, the CEU advises that condoms are required for 7 days [2 days progestogen-only pill (POP), 9 days estradiol valerate/dienogest pill (Qlaira®)]. If the woman has used ulipristal acetate (UPA), additional precautions are advised for 14 days (9 days POP, 16 days estradiol valerate/dienogest pill). If waiting until their next menstrual period before starting a hormonal method, women should be advised to avoid sexual intercourse or use a barrier method.

Detailed guidance on the use of EC and also quick starting contraception is available from the FSRH.^{145,146}

9.2 Testing for STIs

Individuals with concerns about STIs, HIV or other blood-borne viruses (BBV), whether symptomatic or not, should have a risk assessment and an appropriate medical and sexual history taken.¹⁴⁷ The minimum tests that in combination constitute an STI check (often called an STI screen) are those for chlamydia, gonorrhoea, syphilis and HIV.^{147,148} All services offering STI testing should meet the standard of 100% offer of an HIV test, and the minimum standard of at least 60% uptake by those offered, at a person's first STI screen.^{140,147} Where this cannot occur, referral should be made to an appropriate service.

Although an STI screen can be offered immediately following sexual activity, this may only identify pre-existing infection. An STI screen 2 weeks after sexual activity is recommended to allow detection of infections acquired at the time of potential risk exposure. In general, serological tests for HIV, hepatitis and syphilis will require individuals to wait longer to allow for seroconversion. BASHH guidance¹⁴⁹ advises that individuals attending for HIV testing who identify a specific risk occurring more than 4 weeks previously should not be made to wait 3 months (12 weeks) before HIV testing. They should be offered a combined test for HIV antibody and p24 antigens (fourth-generation laboratory HIV test) and be advised that a negative result at 4 weeks post-exposure is very reassuring/highly likely to exclude HIV infection.¹⁴⁹ An additional HIV test should be offered to all persons at 3 months (12 weeks) to definitively exclude HIV infection. Patients at lower risk may opt to wait until 3 months to avoid the need for HIV testing twice.¹⁴⁹

Table 3 Indications for post-exposure prophylaxis after sexual exposure to HIV (PEPSE) (adapted with permission from BASHH from the UK national guideline on PEPSE³⁶)

Sexual exposure	Partner status			
	HIV-positive/ viral load detectable	HIV-positive/ viral load undetectable	Unknown high prevalence group/area ^a	Unknown low prevalence group/area
Receptive anal sex	Recommended	Recommended	Recommended	Not recommended
Insertive anal sex	Recommended	Not recommended	Consider ^a	Not recommended
Receptive vaginal sex	Recommended	Not recommended	Consider ^a	Not recommended
Insertive vaginal sex	Recommended	Not recommended	Consider ^b	Not recommended
Fellatio with ejaculation	Consider	Not recommended	Not recommended	Not recommended
Fellatio without ejaculation	Not recommended	Not recommended	Not recommended	Not recommended
Splash of semen into eye	Consider	Not recommended	Not recommended	Not recommended
Cunnilingus	Not recommended	Not recommended	Not recommended	Not recommended

^aHigh prevalence groups within this recommendation are those where there is a significant likelihood of the source individual being HIV positive. Within the UK at present this is likely to be MSM and individuals who have immigrated to the UK from areas of high HIV prevalence (particularly sub-Saharan Africa).

^bMore detailed knowledge of local prevalence of HIV within communities may change these recommendations from consider to recommended in areas of particularly high HIV prevalence.

9.3 Post-exposure prophylaxis for HIV

Post-exposure prophylaxis (PEP) is a course of medication administered after potential exposure to HIV. It is only recommended where the individual presents within 72 hours of risk of exposure. Evidence for the efficacy of PEPSE is lacking. A risk versus benefit analysis should be undertaken for every individual presenting following any potential exposure and the decision to initiate PEP made on a case-by-case basis.³⁶ UK national guidance on the use of PEPSE is available from BASHH.³⁶ Table 3 summarises when PEPSE should be considered.

- ✓ Men and women can be made aware of PEPSE. The decision to initiate PEPSE can only be made after consideration of the risks of exposure and likelihood of side effects and compliance with treatment.

9.4 Pre-exposure prophylaxis for HIV and advance provision of emergency contraception

Pre-exposure prophylaxis (PrEP) is the administration of antiretroviral therapy in advance of potential exposure to HIV. Clinical trials have been undertaken and more are underway looking at the effectiveness of PrEP in the reduction of HIV transmission. The UK position statement on this is that while further evidence relevant to the UK setting is being gathered, validated behavioural interventions, regular HIV testing, STI diagnosis and treatment, and intensive health promotion activities (i.e. risk reduction strategies) should be implemented in preference to PrEP.¹⁵⁰

Advance provision of EC has not been shown to reduce pregnancy rates when compared to conventional provision.¹⁵¹ However, the World Health Organization (WHO) recognises that in certain circumstances an advance supply of EC is appropriate and acceptable.¹³⁰

- ✓ Health professionals should utilise opportunities such as presentation for EC, PEPSE or STI testing to discuss pregnancy and STI risk reduction strategies.
- ✓ Health professionals should inform women about the availability of EC and when it can be used. Advance supply may be considered but there is no evidence to support routine provision.

Table 4 Summary of UK Medical Eligibility Criteria (UKMEC) categories as they apply to different barrier methods

Medical condition	UKMEC Category	
	Condoms	Diaphragms/caps
Complicated valvular and congenital heart disease (e.g. with pulmonary hypertension, atrial fibrillation, history of subacute bacterial endocarditis)	1	2
High risk of HIV	1	3
HIV infected/not using antiretroviral or using antiretrovirals	1	3
AIDS (using antiretrovirals)	1	3
History of toxic shock syndrome	1	3
Parity (parous women)	1	2
Urinary tract infection	1	2
Sensitivity to latex proteins (applies to latex condoms and diaphragms only)	3	3

UK Medical Eligibility Criteria (UKMEC) Categories

UKMEC 1: A condition for which there is no restriction for the use of the contraceptive method.

UKMEC 2: A condition where the advantages of using the method generally outweigh the theoretical or proven risks.

UKMEC 3: A condition where the theoretical or proven risks generally outweigh the advantages of using the method. The provision 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 more appropriate methods are not available or not acceptable.

UKMEC 4: A condition that represents an unacceptable health risk if the contraceptive method is used.

10 Medical Eligibility

The *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC)¹⁵² provides evidence-based recommendations on the use of contraceptive methods in the presence of different medical and social factors. A Category of 1 to 4 is assigned to guide practitioners on the suitability of the method. The definitions of the UKMEC Categories used in this Guidance document are listed as a footnote to Table 4. There are few restrictions on the use of barrier methods for the majority of women. The cap should not be used in women with CIN or cervical cancer. The diaphragm cannot be used in certain cases of prolapse and the cap is not appropriate for women with markedly distorted cervical anatomy. An individual assessment of STI risk should inform decisions about the appropriateness of these methods and need for additional use of male condoms and STI testing. Women with conditions that make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention may not be appropriate for those who cannot use them consistently and correctly because of their relatively higher typical use failure rates. Table 4 highlights medical conditions for which a UKMEC Category 2 or 3 applies to the use of barrier methods.

10.1 HIV

The use of a diaphragm or cervical cap by women at high risk of HIV or living with HIV is a UKMEC Category 3¹⁵² due to the recommendation for these methods to be used with spermicide, which can be associated with the development of genital lesions and thus a potential increased risk of HIV acquisition/transmission.

An alternative spermicide is available to buy in the UK that does not contain N-9. However the UKMEC recommendation for women at high risk or living with HIV remains unchanged. There are currently no clinical data relating to this product.



For women living with HIV or at high risk of HIV infection the use of either a diaphragm or cervical cap is a UKMEC Category 3.

10.2 Sensitivity to latex proteins

The presence of a positive skin test to latex allergens or the demonstration of specific immunoglobulin E antibodies in serum is described when there is sensitivity to latex. Latex allergy is the occurrence of immediate type I symptoms when a latex-sensitive person comes in contact with latex.

For individuals who have a sensitivity to latex proteins or latex allergy, silicone diaphragms, caps or non-latex condoms can be used. Evidence suggests that the use of deproteinised latex condoms can be used in individuals with latex allergy¹⁵³ although this may be contradictory to the manufacturer's advice for these types of condoms.

If symptoms of genital irritation appear to be associated with barrier contraception use a clinical history should be taken to identify any potential causes. Enquiry should be made about discharge or dysuria, other skin conditions (such as eczema and dermatitis) and the type of method used and any spermicide. Referral for further investigation may be warranted.

C Women with sensitivity to latex proteins should avoid the use of latex barrier contraceptives and may use a silicone diaphragm, cervical cap, non-latex male or female condoms, or deproteinised latex male condoms.

10.3 Toxic shock syndrome

Toxic shock syndrome (TSS) is an extremely rare but potentially life-threatening condition often associated with tampon use and linked to bacterial infections, in particular *Staphylococcus aureus*.¹⁵⁴ There is a small amount of evidence from case control studies to suggest that diaphragm and sponge use may be associated with an increased risk of non-menstrual TSS.^{155,156}

Diaphragms and caps should be avoided during menstruation. Condoms can be used during this time. There is no reported association between female condom use and TSS. For women with a history of TSS who wish to use a barrier method condoms should be advised.

C For women with a history of toxic shock syndrome (TSS) the use of the diaphragm, cervical cap or contraceptive sponge is a UKMEC Category 3.

C Women with a history of TSS may use male or female condoms.

✓ Caps and diaphragms should not be left *in situ* for longer than recommended by the manufacturer or used during menstruation.

10.4 Postpartum, parous and breastfeeding women

There is no restriction on the use of male or female condoms following childbirth.¹⁵²

Diaphragms and caps are unsuitable for women who are less than 6 weeks postpartum.^{152,157} A different size of diaphragm or cap may be required for postpartum women who may have used this method prior to pregnancy. Another method of contraception should be used from Day 21 until the woman is able to insert and remove a correctly fitted diaphragm or cap.¹⁵⁷ The failure rates for cervical caps (but not diaphragms) may be increased for parous women.¹⁵⁸

There is no evidence that N-9 is teratogenic in humans but use in lactating women has not been studied.^{159,160}

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APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

GUIDELINE DEVELOPMENT GROUP

Dr Louise Melvin – Director, Clinical Effectiveness Unit

Ms Julie Craik – Researcher, Clinical Effectiveness Unit

Dr Soe Nyunt Aung – FSRH Clinical Standards Committee representative; Specialty Trainee in Community Sexual and Reproductive Health, Leeds Community Health Care NHS Trust

Dr Angela Ford – General Practitioner, Specialty Doctor, Sandyford, Glasgow

Mr Justin Gaffney – Genitourinary Nurse Association Chairman, Metrosexual Health, London

Mrs Lynn Hearton – FSRH Clinical Effectiveness Committee representative; Helpline & Information Services Manager, Family Planning Association, London

Dr David Hicks – Divisional Medical Director, Barnsley Hospital NHS Foundation Trust, South Yorkshire

Ms Jane Morel – Area Manager, Terrence Higgins Trust Scotland, Glasgow

Mr Martin Murchie – President of the Society of Sexual Health Advisors, Sandyford, Glasgow

Dr Indhu Prabakhar – Subspecialty Registrar in Sexual and Reproductive Health, Liverpool

Dr Helen Ribbans – Consultant in Sexual and Reproductive Health, Burnley General Hospital, Burnley

Ms Clodagh Ross – Senior Nurse, Chalmers Sexual Health Service, NHS Lothian and Lecturer, School of Nursing, Midwifery & Social Care, Edinburgh Napier University

Administrative support to the CEU team was provided by **Ms Janice Paterson** and **Miss Jennifer Lyle**.

INDEPENDENT PEER REVIEWERS

Dr Barbara Hollingworth – Consultant, Sexual Health, Queens Hospital, Barking, Havering & Redbridge University Hospital Trust

Dr Chris Mauck – Consultant in Obstetrics and Gynaecology, CONRAD, Arlington, Virginia, USA

Declared Interests

Dr Chris Mauck consults for CONRAD and the Population Council. Dr David Hicks has received payment for consultancy work for Reckitt Benkinser, producers of Durex® condoms.

Clinical Effectiveness Unit (CEU) Guidance is developed in collaboration with the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (FSRH). 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 specialties, and user representation. In addition, the aim is to include a representative from the FSRH CEC, the FSRH Meetings Committee and FSRH Council in the multidisciplinary group.

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2012); EMBASE (1996–2012); PubMed (1996–2012); The Cochrane Library (to 2012) 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 relevant systematic reviews, meta-analyses and controlled trials relevant to barrier contraceptive methods. Previously existing guidelines from the FSRH (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched. All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded as in the table on the inside front cover of this document 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. The process for the development of CEU guidance is outlined in the table on the inside back cover of this document and is detailed on the FSRH website (www.fsrh.org). The methods used in the development of this guidance have been accredited by NHS Evidence.

APPENDIX 2: USEFUL SOURCES OF INFORMATION

INFORMATION LEAFLETS ON CONDOMS, DIAPHRAGMS AND CAPS, AND MAKING SEX SAFER

Family Planning Association (FPA): <http://www.fpa.org>

Patient.co.uk: <http://patient.org.uk>

Terrence Higgins Trust: <http://www.tht.org.uk/sitemap/>

British Association for Sexual Health and HIV (BASHH): <http://www.bashh.org/guidelines>

HIV CRIMINALISATION

Crown Office and Procurator Fiscal Service (Sexual Transmission or Exposure to Infection – Prosecution Policy): <http://www.crownoffice.gov.uk/Publications/2012/05/Sexual-Transmission-or-Exposure-Infection-Prosecution-Policy>

Crown Prosecution Service (Intentional or Reckless Sexual Transmission of Infection): http://www.cps.gov.uk/legal/h_to_k/intentional_or_reckless_sexual_transmission_of_infection_guidance/index.html

Terrence Higgins Trust (THT): <http://www.myhiv.org.uk/Telling-people/Law>

AVERT (AVERTing HIV and AIDS): <http://www.avert.org/criminal-transmission.htm>

Aidsmap: <http://www.aidsmap.com/Criminalisation-of-HIV-transmission/page/1693735/>

HELPLINES

National AIDS Helpline: 0800 012 322

Free 24-hour confidential helpline offering telephone counselling, information and referral for those with or affected by HIV.

THT Direct Helpline: 0808 802 1221

Confidential information and support on HIV and sexual health. Open 10.00am–10.00pm weekdays, 12.00 noon–6.00pm weekends. Free from UK landlines and most mobiles.

Sexual Health Information Line (Scotland): 0800 22 44 88

Free 24-hour helpline.

Sexual Health Wales helpline: 0800 567 123

Free 24-hour helpline.

FPA Helpline (England): 0845 122 8690

9.00am–6.00pm Monday to Friday.

FPA Helpline (Northern Ireland): 0845 122 8690

9.00am–6.00pm Monday to Friday.

Brook helpline (for those aged under 25 years): 0808 802 1234

Free helpline 9.00am–7.00pm Monday to Friday (closed Thursdays from 2.00–3.30pm).

Discussion Points for Barrier Methods for Contraception and STI Prevention

The following discussion points have been developed by the FSRH Meetings Committee.

Discussion Points	
1	A woman presents having experienced condom failure 24 hours previously. What needs to be considered and how would you counsel this woman?
2	How would you counsel a man who presents reporting lack of sensation whilst using condoms and frequent condom breakage during sex?
3	How would you advise someone who is worried about contracting herpes from their partner?

Questions for Barrier Methods for Contraception and STI Prevention

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

<i>Indicate your answer by ticking the appropriate box for each question</i>	True	False
1 Latex diaphragms can remain <i>in situ</i> for a maximum of 40 hours.	<input type="checkbox"/>	<input type="checkbox"/>
2 A diaphragm or cervical cap should not be removed until at least 6 hours after the last episode of intercourse.	<input type="checkbox"/>	<input type="checkbox"/>
3 Thicker condoms are recommended for anal sex.	<input type="checkbox"/>	<input type="checkbox"/>
4 Women at high risk of HIV can use the diaphragm or cap without restriction.	<input type="checkbox"/>	<input type="checkbox"/>
5 Spermicide should be reapplied if a diaphragm or cap has been <i>in situ</i> for more than 3 hours before sex.	<input type="checkbox"/>	<input type="checkbox"/>
6 In England you have to have transmitted HIV to another person in order to be prosecuted.	<input type="checkbox"/>	<input type="checkbox"/>
7 Some topical and vaginal medicines have the potential to reduce the efficacy of latex contraceptives.	<input type="checkbox"/>	<input type="checkbox"/>
8 The efficacy of all female condoms is reduced by use of oil-based lubricants.	<input type="checkbox"/>	<input type="checkbox"/>
9 Spermicide is recommended with diaphragm use.	<input type="checkbox"/>	<input type="checkbox"/>
10 Condoms lubricated with spermicide provide additional protection against pregnancy or sexually transmitted infections compared with condoms lubricated with a non-spermicidal lubricant.	<input type="checkbox"/>	<input type="checkbox"/>

Answers

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

Auditable Outcomes from Barrier Methods for Contraception and STI Prevention

The following auditable outcomes have been developed by the FSRH Clinical Standards Committee.

Auditable Outcomes

- 1 Record keeping when counselling for use of barrier methods of contraception should include failure rate relative to other methods, advice on correct use and factors affecting their efficacy. [Target 100%]
- 2 Advice that consistent and correct use of condoms (safe sex education) is the most efficient means of protecting against HIV and other sexually transmitted infections (STIs) should be recorded. [Target 100%]
- 3 Record keeping should include that information on when STI screening may be required has been provided. [Target 100%]
- 4 Information on when emergency contraception and/or post-exposure prophylaxis after sexual exposure to HIV (PEPSE) may be required should be recorded as appropriate. [Target 100%]

STEPS INVOLVED IN THE DEVELOPMENT OF THIS GUIDANCE DOCUMENT

- Appointment of a multidisciplinary group (MDG) by invitation to main stakeholders.
- Revision of key questions by the Clinical Effectiveness Unit (CEU) and MDG.
- Systematic literature review, critical appraisal and development of evidence tables by the CEU researcher.
- Draft one guidance document is written by the CEU.
- Peer review by the MDG (written feedback and one-day meeting).
- Preparation of draft two guidance document by the MDG, the Faculty of Sexual & Reproductive Healthcare (FSRH), Clinical Effectiveness Committee (CEC) and two independent peer reviewers.
- Preparation of draft three guidance document based on written feedback.
- The MDG reviews the guidance and recommendations using a formal consensus process.
- Preparation of draft four guidance document.
- Draft four document is published on the Faculty website for up to 1 month for public consultation. Stakeholders are informed of this consultation process.
- All feedback comments are reviewed by the CEU, MDG, FSRH CEC and peer reviewers.
- The final draft is prepared and the CEU's response to consultation comments is posted on the FSRH website.
- The final document is published by the FSRH.
- Printed copies are mailed to FSRH members and an electronic version is made available on the FSRH website.
- Post-publication feedback is reviewed by the CEC and the web version is amended as and when necessary.

COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

All comments on published guidance can be sent directly to the Clinical Effectiveness Unit (CEU) at **ceu.members@ggc.scot.nhs.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) 141 232 8459/8460] or e-mail (**ceu.members@ggc.scot.nhs.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 are reviewed by the Clinical Effectiveness Committee and any necessary amendments made.

