

# Faculty of Sexual & Reproductive Healthcare Clinical Guidance



## Intrauterine Contraception

Clinical Effectiveness Unit

April 2015

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## DETAILS OF CHANGES TO ORIGINAL GUIDANCE DOCUMENT

The CEU has updated this guidance (which was first published online in April 2015) following receipt of feedback from Faculty Members. The only amendments made to the document are as follows:

June 2015 update:

- Section 10.1 on page 19 has been reworded
- Table 5 on page 29, the fourth recommendation listed for removal/replacement outside the licensed duration of use has been expanded
- Reference 221 on page 39 has been revised

October 2015 update:

- Table 4 on page 7, the timing of IUC insertion for switching from Cu-IUD to LNG-IUS has been further defined.

## 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 guideline group

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NICE has accredited the process used by the Faculty of Sexual & Reproductive Healthcare to produce its Intrauterine Contraception guidance. Accreditation is valid for 5 years from May 2011. More information on accreditation can be viewed at [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).

For full details on our accreditation visit: [www.nice.org.uk/accreditation](http://www.nice.org.uk/accreditation).

**ABBREVIATIONS USED**

ALOs	actinomyces-like organisms
BASHH	British Association for Sexual Health and HIV
BMD	bone mineral density
BV	bacterial vaginosis
CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraception/contraceptive
CI	confidence interval
COC	combined oral contraception/contraceptive
Cu-IUD	copper intrauterine device
DMPA	depot medroxyprogesterone acetate
EC	emergency contraception
EURAS	European Active Surveillance Study
FSRH	Faculty of Sexual & Reproductive Healthcare
GAS	group A streptococcus
GBS	group B streptococcus
HIV	human immunodeficiency virus
HMB	heavy menstrual bleeding
HPV	human papillomavirus
IM	intramuscular
IUC	intrauterine contraception
LA	local anaesthesia
LARC	long-acting reversible contraception/contraceptive
LNG	levonorgestrel
LNG-IUS	levonorgestrel intrauterine system
MI	myocardial infarction
NICE	National Institute for Health and Care Excellence
NSAID	non-steroidal anti-inflammatory drug
OR	odds ratio
PI	Pearl index
PID	pelvic inflammatory disease
RCT	randomised controlled trial
RR	relative risk
SC	subcutaneous
SPC	Summary of Product Characteristics
STI	sexually transmitted infection
UKMEC	<i>UK Medical Eligibility Criteria for Contraceptive Use</i>
UPA	ulipristal acetate
UPSI	unprotected sexual intercourse
USMEC	<i>US Medical Eligibility Criteria for Contraceptive Use</i>
VAS	Visual Analogue Scale
VTE	venous thromboembolism
VVC	vulvovaginal candida
WHO	World Health Organization
WHOMEC	<i>World Health Organization Medical Eligibility Criteria for Contraceptive Use</i>

## SUMMARY OF KEY RECOMMENDATIONS

### Eligibility

- ✓ Health professionals should be familiar with the UK Medical Eligibility Criteria for intrauterine methods.

### Efficacy

- B** Women should be advised of the very low failure rates associated with use of intrauterine contraception (IUC).
- A** The most effective methods of IUC are the levonorgestrel intrauterine system (LNG-IUS) methods and T-shaped copper intrauterine devices (Cu-IUDs) with at least 380 mm<sup>2</sup> copper and copper bands on the transverse arms.

### Insertion of IUC and duration of use

- C** A medical and sexual history should be carried out as part of the routine assessment for IUC to assess suitability for use of the method and need for STI testing.
- ✓ In asymptomatic women attending for insertion of IUC there is no need to wait for STI screening results or to provide antibiotic prophylaxis providing the woman can be contacted and treated promptly in the event of a positive result.
- C** Prophylactic antibiotics are not routinely required for the insertion or removal of IUC even in women with conditions where the risk of infective endocarditis may be increased.
- B** The 52 mg LNG-IUS can be used to provide endometrial protection in conjunction with estrogen therapy for up to 5 years (outside product licence).

### Health benefits and risks

- B** Use of a Cu-IUD may be associated with a reduced risk of endometrial cancer and cervical cancer.
- A** The 52 mg LNG-IUS may reduce pain associated with primary dysmenorrhoea, endometriosis or adenomyosis.
- A** The 52 mg LNG-IUS is effective in reducing menstrual blood loss and can be used in the management of heavy menstrual bleeding.
- C** Women considering the LNG-IUS can be informed that systemic absorption of progestogen occurs with these devices. The 13.5 and 52 mg LNG-IUS have similar side-effect profiles (such as acne, breast tenderness/pain and headache) and hormonal side effects often settle with time. Rates of discontinuation due to side effects are not significantly different from Cu-IUD users.

- B** Women should be advised that existing evidence fails to support a negative effect on libido associated with IUC use.
- B** Weight gain has been observed with use of IUC. There is no significant difference between hormonal and non-hormonal intrauterine methods and evidence to support a causal association is lacking.
- B** In the 3-6 months following IUC insertion women may experience irregular, prolonged or frequent bleeding but menstrual bleeding patterns tend to improve with time.
- B** At 1 year infrequent bleeding is usual with the LNG-IUS and some women will experience amenorrhoea.
- A** Discontinuation due to bleeding and pain are similar for different types of framed and unframed Cu-IUDs.
- B** Evidence does not support a link between breast cancer and use of the LNG-IUS.
- C** Non-hormonal contraception is most appropriate for women with a history of breast cancer. Any consideration of the LNG-IUS should be carried out in consultation with the woman's cancer specialist.
- B** Evidence suggests there is little or no increased risk of venous thromboembolism or myocardial infarction associated with the use of a LNG-IUS.

### Ectopic pregnancy

- B** The overall risk of ectopic pregnancy is reduced with use of IUC when compared to using no contraception.
- B** If pregnancy does occur with an intrauterine method *in situ*, the risk of an ectopic pregnancy occurring is increased and in some studies half of the pregnancies that occurred were ectopic.
- C** Data are insufficient to determine if the 13.5 mg LNG-IUS is associated with a greater risk of ectopic pregnancy than other IUC methods.
- IUC users should be informed about symptoms of ectopic pregnancy. The possibility of ectopic pregnancy should be considered in women with an intrauterine method who present with abdominal pain especially in connection with missed periods or if an amenorrhoeic woman starts bleeding. If a pregnancy test is positive an ultrasound scan is urgently required to locate the pregnancy.

### Complications of IUC

- B** The risk of expulsion with IUC is around 1 in 20 and is most common in the first year of use, particularly within 3 months of insertion.
- B** There is no need to delay insertion of an IUC post-abortion providing a woman has been informed of the small increased risk of expulsion.
- B** Although ovarian cysts may occur when using the LNG-IUS, most cysts are asymptomatic and resolve spontaneously.

- B** The rate of uterine perforation associated with IUC is up to 2 per 1000 insertions and is approximately six-fold higher in breastfeeding women.
- B** Return of fertility after IUC use is generally similar to fertility rates after discontinuation of oral contraceptives and barrier methods.
- C** Cu-IUD users with recurrent bacterial vaginosis or vulvovaginal candida may wish to consider an alternative method of contraception.

### At the time of insertion

- ✓** Valid consent should be given by women prior to both pelvic examination and IUC insertion or removal.
- ✓** An appropriately trained assistant who can monitor the condition of the woman and assist in an emergency should be present during insertion of IUC.
- A** There is no evidence from current trials to support the use of topical lidocaine, misoprostol or non-steroidal inflammatory drugs (NSAIDs) for improving ease of insertion or reducing pain during insertion of intrauterine methods.
- ✓** Local anaesthetic block administered by cervical injection is not routinely required for IUC insertion but should be offered when cervical dilatation is required or difficult IUC insertion or removal is anticipated/experienced.
- ✓** NSAIDs can be offered to women who experience pain after insertion of an intrauterine method.
- C** A bimanual pelvic examination should be performed on all women before inserting IUC.
- ✓** There is no evidence to suggest that cervical cleansing prior to IUC insertion reduces subsequent pelvic infection.

### Management of complications

- ✓** There is no evidence as to the most appropriate treatment option for women with unscheduled bleeding with the LNG-IUS. For women with unscheduled bleeding who wish to continue with the LNG-IUS and are medically eligible, a combined oral contraceptive could be tried for up to 3 months (this can be in the usual cyclic manner or continuously without a pill-free interval – unlicensed use).
- A** NSAIDs can be considered in the management of problematic bleeding with use of Cu-IUDs.
- C** Insertion or reinsertion of an intrauterine method can be carried out in asymptomatic women with actinomyces-like organisms (ALOs).
- C** There is no need to remove IUC in asymptomatic women with ALOs.
- B** IUC removal is not routinely required in women with pelvic inflammatory disease but it should be removed if there is no response to treatment (approximately 72 hours).



- ✓ Women should be offered instruction on how to check for the IUC and advised that if the threads cannot be felt the device may have perforated the uterus or been expelled. Additional contraception should be used until they seek medical advice.
- C Women should be advised to seek medical assistance at any time if they develop symptoms of pelvic infection, pain, abnormal bleeding, late menstrual period (IUD), non-palpable threads or can feel the stem of the IUC.

### Other issues to consider

- ✓ Women requesting intrauterine methods should be informed about the use of additional precautions for protection against STIs and advised about the appropriate timings of STI testing after an episode of unprotected sexual intercourse.
- ✓ Health professionals should inform women about the availability of EC and when it may be required with intrauterine methods.
- ✓ A routine follow-up visit can be advised after the first menses following insertion of IUC or 3–6 weeks later. However, it is not essential and it may be more important to advise women as to signs and symptoms of infection, perforation and expulsion, returning if they have any problems relating to their intrauterine method.
- C Mooncups and tampons do not appear to be associated with an increased risk of IUC expulsion.
- B Use of intrauterine methods should not be restricted based on parity or age alone.
- ✓ For women with cardiac disease the decision to use IUC should involve a cardiologist. The IUC should be fitted in a hospital setting if a vasovagal reaction presents a particularly high risk, for example, women with single ventricle circulation, Eisenmenger physiology, tachycardia or pre-existing bradycardia.





## 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 (April 2015) Intrauterine Contraception

(Revision due by April 2020)

## 1 Purpose and Scope

This guidance provides evidence-based recommendations and good practice points for health professionals on the use of intrauterine contraception (IUC) currently available in the UK. Intrauterine methods include copper intrauterine devices (Cu-IUDs) and levonorgestrel intrauterine systems (LNG-IUS). This document updates previous Faculty of Sexual & Reproductive Healthcare (FSRH) guidance published in 2007.<sup>1</sup> The key changes include:

- Inclusion of the 13.5 mg LNG-IUS (Jaydess<sup>®</sup>)
- Updated *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC)<sup>2</sup>
- Updated advice on sexually transmitted infection (STI) screening and timing of IUC insertion
- Updated advice on antibiotic prophylaxis for prevention of bacterial endocarditis
- Updated advice on interventions to ease IUC insertion
- New advice in relation to women presenting late for replacement of the 52 mg LNG-IUS (Mirena<sup>®</sup>)
- Advice on IUC use in women with cardiac disease.

This document focuses primarily on the use of intrauterine methods for contraception. A detailed analysis of non-contraceptive benefits is outside the scope of this guidance and is covered in other national guidelines.<sup>3,4</sup>

Recommendations are based on the available evidence and 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 in the CEU section of the FSRH website ([www.fsrh.org](http://www.fsrh.org)). The recommendations included in this document 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.

## 2 Background

IUC methods are long-acting reversible contraceptives (LARC) with licensed durations of use ranging between 3 and 10 years. IUC is more cost-effective than shorter-acting methods such as oral contraceptives because typical use failure rates of IUC methods are significantly lower,<sup>5,6</sup> and users need to visit contraceptive services less frequently.

The Cu-IUDs are non-hormonal and vary in size and shape. They consist of copper and plastic, with some types containing a core of silver or other noble metal, which helps to prevent corrosion by reducing copper fragmentation. In theory this may increase the longevity of the device, however no evidence was identified to confirm any clinical benefit over IUDs that only contain copper. Most of the Cu-IUDs licensed for use in the UK are radiopaque and contain barium.<sup>7</sup> In addition to ongoing contraception, the Cu-IUD can be used for emergency contraception (EC). Recommendations regarding the use of the Cu-IUD as EC are covered by separate FSRH guidance.<sup>8</sup>


The LNG-IUS is a T-shaped device with an elastomere core containing levonorgestrel (LNG). The 52 mg LNG-IUS (Mirena) releases approximately 20 µg LNG per day, reducing to approximately 10 µg per day after 5 years.<sup>9</sup> In addition to its use for contraception, the licensed indications for use of the Mirena LNG-IUS also include management of heavy menstrual bleeding (HMB) and endometrial protection during estrogen replacement therapy.<sup>9</sup> The 13.5 mg LNG-IUS (Jaydess) is licensed for contraception and has a release rate of approximately 14 µg per day for the first 24 days, decreasing to 5 µg per day after 3 years.<sup>10</sup> There is initially a faster release of LNG from the 13.5 mg LNG-IUS due to the open ends of its elastomer core. Despite this, the pharmacokinetic profile is similar to that of the 52 mg LNG-IUS and systemic exposure is not higher in the days following insertion.<sup>10</sup>

### 3 UK Medical Eligibility Criteria for Contraceptive Use

UKMEC<sup>2</sup> provides evidence-based recommendations on the use of contraceptive methods in the presence of different medical and social factors. Health professionals should ensure they are familiar with or refer to the most up-to-date version of this document when assessing a woman’s eligibility to use intrauterine methods ([www.fsrh.org](http://www.fsrh.org)). Unless specifically stated, UKMEC does not take account of multiple conditions. There is no agreed method for assessing multiple UKMEC categories. Assessing an individual’s eligibility in the presence of multiple medical and social factors requires clinical judgement. UKMEC categories apply only to contraceptive use and are not applicable when use is solely for medical indications, such as HMB.

The definitions of the UKMEC categories used in this guidance document are shown in Table 1.

The Summary of Product Characteristics (SPC) for both the 52 mg<sup>9</sup> and 13.5 mg<sup>11</sup> LNG-IUS state that hypersensitivity to the active substance or any of the excipients is a contraindication to use. The CEU would suggest that such a contraindication would also apply to Cu-IUDs.

 Health professionals should be familiar with the UK Medical Eligibility Criteria for intrauterine methods.

### 4 Mode of Action

Both pre- and post-fertilisation effects contribute to the effectiveness of IUC.<sup>12,13</sup> Whilst there is potential for IUC to interfere with implantation, reduced rates of blastocyst formation have been observed in IUC users compared with non-users, suggesting that pre-fertilisation effects predominate in terms of mode of action for both Cu-IUDs and LNG-IUS.<sup>12</sup>

A Cu-IUD is effective immediately following insertion. With use of the Cu-IUD, fertilisation is inhibited through the effect of copper on the ovum and sperm. Alterations in the copper content of cervical mucus also inhibit sperm penetration.<sup>14-16</sup> If fertilisation has already occurred, the endometrial inflammatory reaction has been shown to have an anti-implantation effect.

A foreign body effect may be a contributing factor of the LNG-IUS,<sup>17</sup> as has been observed with other intrauterine methods.<sup>16,18</sup> The LNG-IUS has little effect on the hypothalamic-pituitary-ovarian axis,<sup>19</sup> serum estradiol concentrations are not reduced,<sup>19</sup> and the majority (>75%) of

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

women continue to ovulate.<sup>10,20,21</sup> The incidence of anovulation is lower with the 13.5 mg LNG-IUS than with the 52 mg LNG-IUS, with data from a clinical trial reporting that in Years 1, 2 and 3, respectively, 97.1% (34/35), 96.2% (25/26) and 100% (26/26) of women ovulated.<sup>10</sup>

Progestogenic effects of the LNG-IUS on cervical mucus have been demonstrated<sup>22–24</sup> but it is not fully understood how quickly such changes are established. In a small descriptive study<sup>25</sup> cervical mucus remained penetrable by sperm for up to 5 days after mid-cycle insertion of a 52 mg LNG-IUS.

Prevention of implantation occurs via a progestogenic effect on the endometrium.<sup>13,26</sup> Within 1 month of insertion, high intrauterine concentrations of LNG induce endometrial atrophy.<sup>17,18,27–29</sup> In addition, distinct changes in the intercellular junctions between the endometrial epithelial and stromal cells<sup>26</sup> and an increase in endometrial phagocytic cells<sup>26,28,30</sup> may contribute to the contraceptive effect. The effects on the endometrium and cervical mucus are similar for the 13.5 and 52 mg LNG-IUS.

## 5 Contraceptive Efficacy and Duration of Use

A Cochrane Review concluded that the TCU380A<sup>®</sup> and TCU380S<sup>®</sup> were more effective than the other Cu-IUDs to which they were compared.<sup>31</sup> These IUDs are no longer available in the UK and have been replaced by the Copper T 380A<sup>®</sup>, TT 380 Slimline<sup>®</sup> and the T-Safe 380A<sup>®</sup> (Table 2). As there are now a number of similar devices available the CEU advise that the most effective Cu-IUDs are T-shaped IUDs containing 380 mm<sup>2</sup> copper with additional copper bands on the transverse arms (i.e. banded devices). Cumulative pregnancy rates for IUDs with copper content >300 mm<sup>2</sup> are noted as being between 0.1% and 1% after the first year of use and around 2.2% for the TCU380A after 12 years.<sup>31</sup> IUDs with the longest duration of use should ideally be used as they reduce the risk of infection, perforation and expulsion associated with reinsertion.

A Cochrane Review (including 23 000 woman-years of use) identified comparable failure rates for a framed (TCU380A) and a frameless device (GyneFix<sup>®</sup>).<sup>32</sup> The higher rates of expulsion associated with the frameless device (GyneFix) limit its effectiveness.<sup>32–34</sup>

A Cochrane Review from 2004 found insufficient evidence from randomised controlled trials (RCTs) to demonstrate any significant difference in pregnancy rates between 52 mg LNG-IUS users and users of IUDs containing >250 mm<sup>2</sup> copper.<sup>35</sup> However, the European Active Surveillance Study (EURAS) for Intrauterine Devices did find that the LNG-IUS was superior in terms of efficacy, although the failure rate was low with both types of device. This prospective cohort study in a typical population of over 61 000 users found an overall Pearl index (PI; pregnancies per 100 woman-years) of 0.06 [95% confidence interval (CI) 0.04–0.09] in the LNG-IUS cohort and 0.52 (95% CI 0.42–0.64) in the Cu-IUD users. There was a markedly different age distribution between the cohorts in the study (with the LNG-IUS users being significantly older) but when stratified for age the LNG-IUS still remained superior at all ages, except for women aged between 40 and 50 years.<sup>36</sup>

The 52 mg LNG-IUS (Mirena) is licensed for 5 years of use but there is evidence<sup>37–39</sup> to suggest that it may provide effective contraception for longer than 5 years. For IUS devices such as Mirena that initially release 20 µg LNG, studies have reported cumulative pregnancy rates of up to 1% at 5 years<sup>40–42</sup> and up to 1.1 at 7 years.<sup>37,39</sup> However, one study<sup>43</sup> used LNG-IUS devices that contained 60 mg LNG. The low pregnancy rates reported with long-term use could also be because of the small numbers of longer-term users who are likely to be relatively older and to have a well-positioned IUC.

Studies investigating serum levels of LNG with prolonged 52 mg LNG-IUS use have shown that serum levels are detectable beyond 5 years of use.<sup>43,44</sup> While systemic serum levels of LNG may be indicative of contraceptive effect, they cannot be relied upon as proof of efficacy, as much of the contraceptive action of the LNG-IUS is a local effect.<sup>43,44</sup> The fact that the release rate of the 52 mg LNG-IUS at 5 years is twice that of the new 13.5 mg LNG-IUS at 3 years suggests that it may be effective for some time beyond its 5 years' licensed indication.

An RCT reported a PI for the 13.5 mg LNG-IUS of 0.33 (95% CI 0.16–0.60) and a cumulative pregnancy rate of 0.9 per 100 women over 3 years.<sup>45</sup>

The CEU cannot specifically endorse use of IUC methods for longer than the durations stipulated in Table 2, although a review of the evidence does support extended use of many devices beyond the licensed duration.<sup>46</sup> The CEU does support extended use of a Cu-IUD fitted at age

40+ years or a 52 mg LNG-IUS inserted at the age of 45+ years.<sup>6,47</sup> Women should be advised to have their IUC removed when it is no longer effective or required.<sup>47</sup> Recommendations on the management of women who present late for IUC removal/replacement are detailed later (see Table 5 on page 29). As the risk of pregnancy remains low between 5 and 7 years after 52 mg LNG-IUS insertion, the FSRH advises that even if a woman has not been using additional contraception the device can be replaced immediately, providing a pregnancy test is negative. A further pregnancy test, no sooner than 3 weeks after the last episode of unprotected sexual intercourse (UPSI), should then be advised.

Not all women will continue to use their IUC for the totality of its permitted duration and may choose to discontinue the method. Reasons for 'early' discontinuation may relate to side effects.<sup>48-50</sup>

**B** Women should be advised of the very low failure rates associated with use of IUC.

**A** The most effective methods of IUC are the LNG-IUS methods and T-shaped devices with at least 380 mm<sup>2</sup> copper and copper bands on the transverse arms.

Table 2 provides examples of available methods of IUC. For more detailed information the CEU would advise checking the *British National Formulary* (BNF) and package insert. A number of generic IUC devices are available and the CEU supports their use. The insertion tube diameter and manufacturer's recommended uterocervical length are provided as a guide to the most appropriate device in each clinical situation. The information is not intended to mean that a device should never be used in a woman with a uterus that is shorter or longer than recommended.

Examples of devices available in the UK <sup>a</sup>	Copper surface area (mm <sup>2</sup> )	Manufacturer's licensed duration of use (years)	Manufacturer's recommended uterocervical length <sup>b</sup> (cm)	Diameter of insertion tube (mm)
<b>Levonorgestrel intrauterine system</b>				
Mirena <sup>®</sup>	Not applicable	5 (contraception and idiopathic menorrhagia)  4 (endometrial protection) <sup>c</sup>	Not specified	4.40
Jaydess <sup>®</sup>	Not applicable	3 (contraception only)	Not specified	3.80
<b>Copper devices (banded copper arms)</b>				
Copper T 380A <sup>®</sup>	380	10	6.5–9.0	4.75
TT380 Slimline <sup>®</sup>	380	10	6.5–9.0	4.75
MiniTT 380 Slimline <sup>®</sup>	380	5	≥5	4.75
T-Safe 380A <sup>®</sup> Quickload	380	10	6.5–9.0	4.75
T-Safe 380A <sup>®</sup> Capped <sup>d</sup>	380	10	6.5–9.0	4.50
Flexi-T 380 <sup>®</sup>	380	5	>6	4.75
<b>Copper devices (copper in stem only)</b>				
Nova-T 380 <sup>®</sup>	380	5	6.5–9.0	3.60
UT 380 <sup>®</sup>	380	5	6.5–9.0	
UT 380 short <sup>®</sup>	380	5	≥5	
Flexi-T 300 <sup>®</sup>	300	5	>5	4.75
Multiload Cu375 <sup>®</sup>	375	5	6–9	3.60
Multisafe 375 Short Stem <sup>®d</sup>	375	5	5–7	3.85
<b>Copper device (frameless)</b>				
GyneFix Viz 330 <sup>®</sup>	330	5	Any	4.00

<sup>a</sup>List not exhaustive; generic versions of the above devices are also available.  
<sup>b</sup>Distance measured with uterine sound from upper limit of the endometrial cavity to external cervical os.  
<sup>c</sup>FSRH guidance supports the use of the LNG-IUS (Mirena<sup>®</sup>) for 5 years for endometrial protection (see page 11).  
<sup>d</sup>Product not currently on National Health Service Drug Tariff.

## 6 When Can IUC be Safely Inserted?

Health professionals should consider the woman's safety and convenience when considering the timing of IUC insertion. Recommendations for insertion of IUC in specific circumstances (for example, postpartum, post-abortion and when switching from other methods of contraception) are outlined in Tables 3 and 4.

As a Cu-IUD is effective immediately after insertion it can be inserted at any time in the menstrual cycle if it is reasonably certain the woman is not pregnant (Box 1). A systematic review was identified that examined the effect of inserting IUC on different days of the menstrual cycle specifically in relation to expulsion, pregnancy rates and pain.<sup>51</sup> No studies were identified for the LNG-IUS; eight Cu-IUD studies were included.<sup>52-59</sup> Although the review had some limitations, the authors found reasonable quality evidence that timing of insertion of a Cu-IUD did not have a significant effect on longer-term or short-term outcomes such as continuation, pregnancy rates, expulsion, bleeding at insertion or pain at insertion<sup>51</sup> (page 20). There is therefore no need to only insert IUDs during menses, providing the risk of pregnancy can be appropriately excluded.

If a woman has had UPSI, a Cu-IUD can be inserted as a means of EC providing it is inserted before the process of implantation begins (i.e. within 120 hours of the first episode of UPSI in a cycle, or up to 5 days after the earliest estimated day of ovulation). It is not always possible to know when a woman has ovulated, particularly if she has been using hormonal contraceptives or taken EC. A Cu-IUD can be fitted in good faith to act as EC, providing appropriate steps have been taken to try and establish a woman's earliest estimated date of ovulation. The Cu-IUD should not be inserted if there is a risk of pregnancy outside these circumstances or where there is uncertainty about the earliest date of ovulation.

For the purposes of excluding pregnancy, the CEU would advise that hormonal, intrauterine and barrier contraceptive methods can be considered reliable providing they have been used consistently and correctly on every incidence of intercourse. This should be assessed on an individual basis.

There are insufficient data to indicate precisely how soon after insertion of the LNG-IUS contraceptive protection is established.<sup>51</sup> A systematic review examining the effect of inserting IUDs on different days of the menstrual cycle found no studies for the 52 mg LNG-IUS.<sup>51</sup> A study observed no early pregnancies when the 52 mg LNG-IUS was inserted up to Day 10 of the menstrual cycle;<sup>61</sup> however, the authors did not provide information on sexual intercourse before or after insertion.

The SPCs for Mirena and Jaydess state that the LNG-IUS can be inserted up to Day 7 of the menstrual cycle.<sup>9,11</sup> No advice is given regarding avoidance of UPSI before insertion or use of additional contraception after insertion, and there is no information on starting the method at

### Box 1 Criteria for excluding pregnancy (adapted from *UK Selected Practice Recommendations for Contraceptive Use*)<sup>60</sup>

Health professionals can be 'reasonably certain' that a woman is **not currently pregnant** if any one or more of the following criteria are met and there are no symptoms or signs of pregnancy:

- She has not had intercourse since last normal menses
- She has been correctly and consistently using a reliable method of contraception
- She is within the first 7 days of the onset of a normal menstrual period
- She is not breastfeeding and less than 4 weeks from giving birth
- She is fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months' postpartum
- She is within the first 7 days post-abortion or miscarriage.

A negative pregnancy test, if available, adds weight to the exclusion of pregnancy, but only if  $\geq 3$  weeks since the last episode of unprotected sexual intercourse (UPSI).

NB. In addition to the conditions mentioned above, health professionals should also consider whether a woman is **at risk of becoming pregnant** as a result of UPSI within the last 7 days.

any other time in the cycle. Thus, the SPCs suggest that the LNG-IUS can be safely inserted as late as Day 7 with no risk of pregnancy from UPSI earlier in the cycle or after insertion.

Advice from the FSRH and the World Health Organization (WHO) is consistent with that of the SPCs, stating that the LNG-IUS can be inserted up to Day 7 without the need for additional contraception, and that if an LNG-IUS is inserted later in the cycle additional contraceptive precautions are required for 7 days.<sup>1,60,62,63</sup>

An LNG-IUS can be inserted any time in the menstrual cycle if it is reasonably certain the woman is not pregnant or at risk of pregnancy (outside the terms of the product licence). The LNG-IUS should not be used for EC as unlike the Cu-IUD there is no evidence to demonstrate that it is effective immediately.

UKMEC indicates that postpartum insertion of an intrauterine method is UKMEC 3 between 48 hours and 4 weeks, after which time there is no restriction on use (UKMEC 1).<sup>2</sup> Updated UKMEC will include guidance on insertion during the first 48 hours postpartum as this is becoming more available in UK obstetric practice.<sup>2</sup> However, immediate postpartum insertion is undertaken in other countries<sup>64,65</sup> and WHO guidance<sup>66</sup> includes categories for the first 48 hours postpartum. In the first 48 hours insertion is a WHOMEK 1 for insertion of the Cu-IUD or LNG-IUS in non-breastfeeding women and insertion of the Cu-IUD in breastfeeding women. From birth until 4 weeks insertion of an LNG-IUS is a WHOMEK 3 in breastfeeding women.<sup>66</sup> More details on the timing of IUC insertion are outlined in Table 3.

**Table 3** Faculty of Sexual & Reproductive Healthcare advice on starting intrauterine contraception

Circumstance	Method inserted	Timing of insertion	Additional contraceptive precautions required
All circumstances	Cu-IUD	Any time in menstrual cycle if reasonably certain the woman is not pregnant or at risk of pregnancy (unless qualifies for use as EC)	No
	LNG-IUS	Any time in menstrual cycle if reasonably certain the woman is not pregnant or at risk of pregnancy (outside terms of product licence after Day 7)	Yes, required for 7 days unless inserted in the first 7 days of the menstrual cycle
Postpartum (including post-Caesarean section and breastfeeding)	Cu-IUD	Any time after 4 weeks postpartum and it is reasonably certain the woman is not pregnant or at risk of pregnancy (unless qualifies for use as EC)	No
	LNG-IUS	Any time after 4 weeks postpartum and it is reasonably certain the woman is not pregnant or at risk of pregnancy (outside product licence which says 6 weeks)	Yes, required for 7 days unless inserted in the first 7 days of menstrual cycle or if fully meeting LAM criteria
Following abortion (all induced or spontaneous abortions <24 weeks' gestation)	Cu-IUD	Post-surgical abortion IUC: ideally should be inserted at the end of the procedure  Post-medical abortion IUC: can be fitted any time after completion of the second part of the abortion (i.e. passage of products of conception confirmed by clinical assessment and/or local protocols)	No
	LNG-IUS	Post-surgical abortion IUC: ideally should be inserted at the end of the procedure  Post-medical abortion IUC: can be fitted any time after completion of the second part of the abortion (i.e. passage of products of conception confirmed by clinical assessment and/or local protocols)	If an LNG-IUS is fitted after Day 7 post-abortion, additional precautions are required for 7 days
Following administration of oral EC	Cu-IUD	Within the first 5 days (120 hours) following first UPSI in a cycle or within 5 days from the earliest estimated day of ovulation	No additional precautions required
		Outside of the above criteria Cu-IUD should not be inserted following administration of oral EC until pregnancy can be excluded by a pregnancy test no sooner than 3 weeks after the last episode of UPSI	Not applicable
	LNG-IUS	Should <b>not</b> be inserted following administration of oral EC until pregnancy can be excluded as above	Not applicable

Cu-IUD, copper intrauterine device; EC, emergency contraception; LAM, lactational amenorrhoea method; LNG-IUS levonorgestrel intrauterine system; UPSI, unprotected sexual intercourse.



**Table 4** Faculty of Sexual & Reproductive Healthcare advice on switching to intrauterine contraception

IUC method switching to	Contraceptive method switching from	Timing of IUC insertion	Need for additional precautions	Additional information
Cu-IUD	All methods of contraception	Cu-IUD can be inserted at any time if another method of contraception has been used consistently and correctly and it is reasonably certain that the woman is not pregnant or at risk of pregnancy (except in those circumstances that would qualify for use as an EC)	No additional precautions required	Ideally if switching from an LNG-IUS to a Cu-IUD additional contraceptive precautions are advised in the 7 days before changing in case the new method cannot be inserted
LNG-IUS	CHC	Week 2 or 3 of CHC cycle or Day 1 of the hormone-free interval	No additional precautions required, providing CHC used correctly for 7 days prior to insertion	There is evidence to suggest that taking hormonally active pills for 7 consecutive days prevents ovulation <sup>67</sup>
		After Day 1 of the hormone-free interval or in Week 1 of CHC cycle	Continue CHC or use other additional contraception for 7 days	Advice for switching during the hormone-free interval may be overcautious but there is a theoretical risk that ovulation may occur as early as Day 10 after stopping CHC, before the LNG-IUS is fully effective <sup>68</sup>
	POP	At any time	Yes, continue POP or use other additional contraception for 7 days	
	Progestogen-only implant	Up to 3 years post-insertion	No	
		From 3 years post-insertion	Yes (7 days)	If it is reasonably certain the woman is not pregnant or at risk of pregnancy
	Progestogen-only injectable	≤14 weeks post-IM or SC injection	No	
		>14 weeks since last IM or SC injection	Yes (7 days)	If it is reasonably certain the woman is not pregnant or at risk of pregnancy
	Barrier methods	Days 1–7 of the menstrual cycle	No	
		After Day 7 of the menstrual cycle	Yes, 7 days	If it is reasonably certain the woman is not pregnant or at risk of pregnancy
	Cu-IUD	Any time	Yes (7 days)	If sex has occurred in the last 7 days advise to leave Cu-IUD for a further 7 days from that episode and use extra precautions before change to LNG-IUS

CHC, combined hormonal contraception; Cu-IUD, copper intrauterine device; EC, emergency contraception; IM, intramuscular; IUC, intrauterine contraception; LNG-IUS levonorgestrel intrauterine system; POP, progestogen-only pill; SC, subcutaneous.

## 7 What Should Health Professionals Assess When a Woman is Considering IUC?

### 7.1 Clinical assessment

A full medical history should be taken and, if necessary, health professionals should check UKMEC to assess an individual woman's eligibility.<sup>2</sup> If a woman attends to discuss IUC in advance of the procedure, pelvic examination is not required unless indicated by the clinical history.

Additional investigations such as full blood count, pelvic ultrasound scan and endometrial biopsy may be indicated prior to or at the same time as IUC insertion in women with HMB, particularly if other treatments for HMB have not been effective or if a woman has risk factors for gynaecological disease. Clinicians should be guided by national<sup>3</sup> and local guidelines on management of HMB.

### 7.2 STI risk assessment

A sexual history must be taken in order to identify women at risk of STI.<sup>62</sup> The British Association for Sexual Health and HIV (BASHH) has guidance on sexual history taking.<sup>69</sup> Risk factors include:

- Being sexually active and aged <25 years
- Having a new sexual partner in the last 3 months
- Having more than one sexual partner in the last year
- Having a regular sexual partner who has other sexual partners
- A history of STIs
- Attending as a previous contact of STI
- Alcohol/substance abuse.

An STI screen should be offered to all women who are identified as being at risk of STIs when requesting IUC.<sup>70,71</sup> If STI testing is indicated *Chlamydia trachomatis* testing should be performed as a minimum requirement. In most settings a single vulvovaginal or endocervical swab can be sent for combined *C. trachomatis* and *Neisseria gonorrhoeae* testing by nucleic acid amplification techniques.<sup>71-73</sup> Vulvovaginal swabs may be self-taken if preferred. Urine specimens are no longer recommended for STI testing in women.<sup>71-73</sup> Syphilis and HIV testing should also be offered routinely.

There is no indication to screen for other lower genital tract organisms in asymptomatic women considering IUC. If bacterial vaginosis or candidal infection is diagnosed or suspected the infection should be treated and the method inserted without delay. A high vaginal swab is not routinely indicated in women with vaginal discharge and should only be taken in specific circumstances defined in FSRH guidance on *Management of Vaginal Discharge in Non-Genitourinary Medicine Settings*.<sup>74</sup>

## 8 When Should IUC Insertion be Delayed or Antibiotic Prophylaxis Given?

### 8.1 Women diagnosed with, or at risk of, STI

Where possible, screening for STIs in advance of IUC insertion will allow infection to be treated before or at the time of insertion. Following a positive chlamydia or gonorrhoea result, an intrauterine method can be inserted if the woman is asymptomatic and has completed antibiotic treatment. In a woman with asymptomatic chlamydia in an emergency situation, the IUC could be inserted on the same day as treatment was instituted.

There has been uncertainty with regard to insertion of IUC before STI results are available. A Cochrane Review<sup>75</sup> examined the effectiveness of prophylactic antibiotic administration, before IUD insertion, in reducing IUD-related complications and discontinuations within 3 months of insertion. It concluded that the risk of IUD-related infections was low, with or without antibiotic prophylaxis. There were possible benefits in terms of reducing unscheduled return visits but there was limited evidence to suggest such an intervention was cost-effective.

A large retrospective cohort study<sup>76</sup> compared the incidence of pelvic inflammatory disease (PID) in women who were and were not screened for gonorrhoea and chlamydia in advance of IUC insertion. In the 57 728 women undergoing IUC insertion the overall risk of PID within the first 90 days was 0.54% (95% CI 0.0048–0.0060). There was no association between screening and a reduced risk of PID. Same-day screening was associated with a similar risk to pre-screening even when age and race were taken into account.<sup>76</sup>

The CEU would therefore suggest that if a woman has been screened for STIs on or before the day of IUC insertion and the results are unavailable, an IUC can be inserted without prophylactic antibiotic treatment, providing the woman is asymptomatic and can be contacted and treated promptly when the results are known.

Women who have symptoms of possible STI infection and/or PID should ideally delay IUC insertion until test results are available, until PID or confirmed STI infection have been treated, and until symptoms have resolved. A bridging contraceptive method should be offered if necessary. Women diagnosed with an STI or PID should be advised to abstain from intercourse until they and any current sexual partner(s) have finished treatment or for 1 week after treatment with single-dose azithromycin.<sup>77</sup>

Antibiotic prophylaxis for chlamydia (and gonorrhoea if local prevalence or individual risk factors warrant) can be considered for women who require an emergency IUD and who are symptomatic or at high risk of STI (e.g. if their partner is known to be infected).



A medical and sexual history should be carried out as part of the routine assessment for IUC to assess suitability for use of the method and need for STI testing.



In asymptomatic women attending for insertion of IUC there is no need to wait for STI screening results or to provide antibiotic prophylaxis providing the woman can be contacted and treated promptly in the event of a positive result.

## 8.2 Streptococcal bacteria

In asymptomatic women routine screening for bacterial infection is not recommended prior to IUC insertion. However, cases of group A streptococcus (GAS) infection have been reported post-IUD insertion.<sup>78–80</sup> Such cases are rare but can include life-threatening septicaemia, invasive GAS (e.g. necrotising fasciitis) and streptococcal toxic shock syndrome.<sup>81</sup> Therefore, it is important that women found to be infected with GAS in the vagina are treated and IUC insertion delayed. In addition, women using IUC should be advised to seek medical advice if they experience signs or symptoms of infection. Guidance on the management of GAS infections in community and acute health care and maternity settings is available.<sup>82,83</sup>

Because GAS is a  $\beta$ -haemolytic streptococcus there is potential for it to be confused with group B streptococcus (GBS). GBS is a commensal organism which if detected does not usually require treatment except in pregnant or symptomatic women and neonates. There is no need to delay treatment or treat asymptomatic women who have been identified as having GBS.

## 8.3 Antibiotic prophylaxis for bacterial endocarditis

A review by the National Institute for Health and Care Excellence (NICE)<sup>84</sup> found no evidence to link level, frequency and duration of bacteraemia with the development of infective endocarditis. Risk factors for infective endocarditis are outlined in FSRH guidance on *Contraceptive Choices for Women with Cardiac Disease*.<sup>85</sup> NICE considered that for people who are at risk of infective endocarditis:

- There is insufficient evidence to determine whether antibiotic prophylaxis in those at risk of developing infective endocarditis reduces the incidence of infective endocarditis when given before a defined interventional procedure (both dental and non-dental).
- There is little evidence to support offering antibiotics routinely as a preventative measure to people at risk of infective endocarditis undergoing interventional procedures.

The NICE guideline<sup>84</sup> recommends that antibiotic prophylaxis is no longer offered routinely for defined interventional procedures. However, it should be noted that the NICE guideline does not exclude consideration of antibiotic prophylaxis on a case-by-case basis and states that if there is a suspected infection at a site of the genitourinary procedure, an antibiotic that covers organisms that cause infective endocarditis should be considered (see page 31 for more information on IUC use by women with cardiac disease).



Prophylactic antibiotics are not routinely required for the insertion or removal of IUC even in women with conditions where the risk of infective endocarditis may be increased.

## 9 Health Benefits, Side Effects and Concerns/Risks

Choosing between a Cu-IUD and an LNG-IUS will likely be determined by any benefits for the individual, for example, changes to menstrual bleeding patterns, duration of use, any side effects or perceived concerns. The cost-effectiveness of LARC methods in the UK is affected by discontinuation rates;<sup>5</sup> therefore it is important that women are adequately informed before initiating their chosen method and offered appropriate information and management about any side effects or concerns during use.

### 9.1 Benefits

#### 9.1.1 Endometrial and other cancer protection

The 52 mg LNG-IUS has been shown to provide endometrial protection from the stimulatory effects of estrogen<sup>86–90</sup> and is licensed in the UK for protection from endometrial hyperplasia during estrogen replacement therapy for up to 4 years.<sup>9</sup> The FSRH supports use of the 52 mg LNG-IUS for up to 5 years (outside product licence) for this purpose.<sup>47</sup> A systematic review<sup>91</sup> that sought to review how effective the 52 mg LNG-IUS was at preventing endometrial pathology concluded that while in selected groups of women there was evidence that it counters endometrial proliferation and causes regression and prevention of endometrial hyperplasia, there is currently insufficient evidence to recommend its use as the treatment for endometrial hyperplasia or use solely as a preventative method in high-risk groups. However, other studies and reviews have suggested that the 52 mg LNG-IUS is no less effective than oral progestogens and indeed may actually provide more favourable outcomes in women with complex or atypical hyperplasia.<sup>92,93</sup>

Tamoxifen, used in the management of breast cancer, is known to stimulate the endometrium,<sup>94</sup> increasing the risk of endometrial hyperplasia and malignancy. A Cochrane Review reported that in breast cancer patients taking tamoxifen, use of the 52 mg LNG-IUS over 1 year reduced the risk of endometrial polyps.<sup>95</sup> However, the authors indicated that more studies are required to establish the effect of 52 mg LNG-IUS use on endometrial hyperplasia and cancer in such women.<sup>95</sup>

A systematic review, of case-control studies, reported that use of a Cu-IUD may be associated with a reduced risk of endometrial cancer [relative risk (RR) 0.51, 95% CI 0.3–0.8]<sup>96</sup> and a meta-analysis of 10 studies suggested that there may be a decreased risk associated with IUD use.<sup>97</sup> A pooled analysis of 26 epidemiological studies reported that ever-use of IUDs was associated with a decreased risk of cervical cancer compared to never-users [odds ratio (OR) 0.55, 95% CI 0.42–0.70,  $p < 0.0001$ ]. This protective association was apparent for squamous-cell carcinoma (OR 0.56, 95% CI 0.43–0.72,  $p < 0.0001$ ), adenocarcinoma and adenosquamous carcinoma (OR 0.46, 95% CI 0.22–0.97,  $p = 0.035$ ). However, a protective effect was not observed amongst those women who were found to be human papillomavirus (HPV)-positive (OR 0.68, 95% CI 0.44–1.06,  $p = 0.11$ ). Amongst those without cervical cancer, IUD use was not reported to be associated with detection of cervical HPV DNA.<sup>98</sup> There are few data on risk of ovarian cancer and use of IUDs, but one cohort study reported a small increased risk,<sup>99</sup> while a large case-control study<sup>100</sup> observed that using the Cu-IUD for 4 years or less conferred a protective benefit against ovarian cancer.

**B** The 52 mg LNG-IUS can be used to provide endometrial protection in conjunction with estrogen therapy for up to 5 years (outside product licence).

**B** Use of a Cu-IUD may be associated with a reduced risk of endometrial cancer and cervical cancer.

### 9.1.2 Dysmenorrhoea/pelvic pain

One randomised<sup>101</sup> and two non-randomised trials<sup>102,103</sup> suggested that the 52 mg LNG-IUS reduced primary dysmenorrhoea. Available evidence also suggests that the 52 mg LNG-IUS reduces pain associated with endometriosis and adenomyosis.<sup>104-112</sup> A Cochrane Review<sup>113</sup> of three RCTs and a retrospective chart review, of adolescent women with endometriosis, suggested that insertion of a 52 mg LNG-IUS at the time of surgery reduced the recurrence of symptoms. The 52 mg LNG-IUS is a recommended treatment option for pain associated with endometriosis.<sup>114</sup>

**A** The 52 mg LNG-IUS may reduce pain associated with primary dysmenorrhoea, endometriosis or adenomyosis.

### 9.1.3 Heavy menstrual bleeding

The 52 mg LNG-IUS is very effective in reducing menstrual blood loss<sup>115-120</sup> and has been shown to be more effective at improving quality of life than other medical treatments for HMB.<sup>121</sup> The Mirena LNG-IUS is licensed for the management of HMB and is one of the recommended pharmaceutical treatments within NICE guidelines.<sup>6</sup> Various 'hybrid' generic LNG-IUS are licensed products for treatment of HMB in the UK but are not currently licensed for contraception.<sup>122</sup>

The 13.5 mg LNG-IUS (Jaydess) is not licensed for treatment of HMB. The 13.5 mg LNG-IUS does reduce menstrual bleeding and there is a significant increase in the number of women who experience amenorrhoea with time. However, the proportion of women experiencing amenorrhoea at the end of 3 years in an RCT was less amongst those who used the 13.5 mg LNG-IUS compared to the 52 mg LNG-IUS (12.7% vs 23.6%).<sup>123</sup>

**A** The 52 mg LNG-IUS is effective in reducing menstrual blood loss and can be used in the management of HMB.

## 9.2 Hormonal side effects

Undesirable effects are more prevalent in the first few months after insertion of the LNG-IUS but decrease with prolonged use.<sup>9</sup> Side-effect profiles for the 13.5 and 52 mg LNG-IUS have been reported as being similar.<sup>123</sup>

### 9.2.1 Acne, breast tenderness/pain, headaches and mood changes

The SPC<sup>9</sup> for the 52 and 13.5 mg LNG-IUS<sup>11</sup> lists acne, breast tenderness/pain, headache and mood changes as common ( $\geq 1/100$  to  $< 1/10$ ) undesirable effects reported by users. A systematic review<sup>124</sup> identified no significant differences in overall side effects between using a 52 mg LNG-IUS or an IUD.

**C** Women considering the LNG-IUS can be informed that systemic absorption of progestogen occurs with these devices. The 13.5 and 52 mg LNG-IUS have similar side-effect profiles (such as acne, breast tenderness/pain and headache) and hormonal side effects often settle with time. Rates of discontinuation due to side effects are not significantly different from Cu-IUD users.

### 9.2.2 Libido

Identifying a causal relationship between use of contraceptives and libido is difficult due to the impact of other potential influences, such as psychological and/or partner problems. Due to the limitations of observational research, an effect on libido with IUC use cannot be completely excluded, however existing evidence fails to support a negative association.<sup>125–129</sup>

**B**

Women should be advised that existing evidence fails to support a negative effect on libido associated with IUC use.

### 9.2.3 Weight

It is difficult to assess the 'true' impact of contraceptives on body weight due to a number of potential confounding factors.

Weight gain has been observed with use of both Cu-IUDs and the 52 mg LNG-IUS.<sup>40,111,130</sup> A 5-year RCT of a 46 mg LNG-IUS with the Nova T (200 mm<sup>2</sup> Cu) reported that at 5 years the mean weight in both groups had increased to 64.4 kg from a baseline of 62.0 kg and 61.9 kg, respectively.<sup>40</sup> A small prospective study<sup>130</sup> evaluating body weight and composition in users of the 52 mg LNG-IUS and the TCu380A observed an increase of body weight in both groups 1 year after insertion. Although the mean gain body weight among the 52 mg LNG-IUS users was significantly increased, there was no significant difference when comparing 52 mg LNG-IUS and Cu-IUD users. The 52 mg LNG-IUS users also demonstrated a significant increase in fat mass, whilst Cu-IUD users demonstrated a non-significant loss. There were no significant differences in body composition between the two groups at 12 months. There is no known biological mechanism for weight gain with a Cu-IUD, suggesting that weight gain with IUC use is likely to be a consequence of confounding factors such as increasing age.

**B**

Weight gain has been observed with use of IUC. There is no significant difference between hormonal and non-hormonal intrauterine methods and evidence to support a causal association is lacking.

## 9.3 Health concerns/risks

Altered menstrual bleeding patterns are a common reason for discontinuation of Cu-IUDs and the 52 mg LNG-IUS.<sup>6,41,49,131,132</sup> Discontinuation rates for the 52 mg LNG-IUS and Cu-IUD are similar,<sup>35</sup> as are discontinuation rates due to bleeding for different types of framed devices.<sup>31</sup>

The aetiology of bleeding associated with the 52 mg LNG-IUS is complex.<sup>18,133,134</sup> Infrequent bleeding is common after the first year of 52 mg LNG-IUS use.<sup>135</sup> Amenorrhoea is more common with the 52 mg LNG-IUS than a Cu-IUD.<sup>135</sup>

Some women will have normal bleeding patterns after insertion of an intrauterine method, however some will experience longer and more frequent bleeding.<sup>136</sup>

There is some evidence to suggest that bleeding patterns in IUD and LNG-IUS users tend to improve/settle with time after insertion (>3 months);<sup>135,136</sup> however, irregular bleeding may be present in around 20% of women at 1 year of use of intrauterine methods.<sup>135</sup> One study<sup>137</sup> reported that although improvements with menstrual bleeding and dysmenorrhoea were generally observed over a 12-month period, there were no changes in complaints of other pelvic pain and spotting episodes. Similar trends in patterns of bleeding have been observed with insertion following an abortion.<sup>135</sup>

Postpartum bleeding patterns have been studied following the immediate fitting of IUC during elective Caesarean sections.<sup>138</sup> In one study, women fitted with a Cu-IUD compared to controls with no IUC had a significantly longer duration of postpartum bleeding but the heaviness of bleeding was comparable. Insertion of an 52 mg LNG-IUS was associated with significantly

shorter and lighter puerperal bleeding, longer duration of amenorrhoea, and shorter and lighter menstrual periods than women in the control or Cu-IUD group.<sup>138</sup>

During the first year of 52 mg LNG-IUS use infrequent bleeding and amenorrhoea become more common. Studies of women who had a replacement 52 mg LNG-IUS, after approximately 5 years of use, have found that there is an initial slight increase in bleeding/spotting after replacement but that there is an overall decrease in bleeding episodes and increase in amenorrhoea during use of a second 52 mg LNG-IUS.<sup>38,139</sup> Data from trials suggest that users of the 13.5 mg LNG-IUS have a lower rate of amenorrhoea than users of the 52 mg LNG-IUS, although there is still a trend towards less bleeding with time (i.e. a temporal relationship).<sup>123</sup> While less amenorrhoea may appeal to some woman, it may equally be perceived as a disadvantage by others (see page 23 for management of bleeding).

**B** In the 3–6 months following IUC insertion women may experience irregular, prolonged or frequent bleeding but menstrual bleeding patterns tend to improve with time.

**B** At 1 year infrequent bleeding is usual with the LNG-IUS and some women will experience amenorrhoea.

**A** Discontinuation due to bleeding and pain are similar for different types of framed and unframed Cu-IUDs.

### 9.3.1 Bone mineral density

Studies investigating bone mineral density (BMD) with use of IUC have found no significant differences in BMD at the mid-shaft of the ulna<sup>140,141</sup> or the distal radius<sup>141</sup> when comparing 52 mg LNG-IUS users and Cu-IUD users. In a comparative trial of two low-dose LNG-IUS devices, no effect on BMD was observed and no reduction in estradiol levels was reported in a pooled pharmacokinetic and pharmacodynamic analysis of Phase II and III studies.<sup>10</sup>

### 9.3.2 Breast cancer

The Collaborative Group on Hormonal Factors in Breast Cancer undertook a re-analysis of 54 studies to investigate the relationship between breast cancer and hormonal contraceptives.<sup>142</sup> Progestogen-only methods (oral and injectable) were used by less than 3% of the women studied. The quantity of information available was therefore limited but for oral progestogens the results were broadly similar to those found for combined oral contraceptives (COCs). The study reported a slightly increased risk of breast cancer associated with current or recent use of hormonal contraceptives and found there was no evidence of an increased risk 10 or more years after stopping use.<sup>142</sup>

A limited number of studies have examined the risk specifically associated with the 52 mg LNG-IUS.<sup>143–145</sup> Two of these studies<sup>144,145</sup> reported no increased risk of breast cancer, although both acknowledged that an increased risk could not be excluded because of the methodological limitations of observational research. A case-control study<sup>143</sup> evaluating the association between postmenopausal hormone therapy and the risk of breast cancer, in recently postmenopausal Finnish women, reported an increased risk of breast cancer in women who used the 52 mg LNG-IUS on its own or in conjunction with estradiol. The authors themselves stated that this was a surprising finding and that bias and confounding could not be excluded.

There is limited evidence of the effect of 52 mg LNG-IUS on breast cancer recurrence. A retrospective case-controlled cohort study<sup>146</sup> that compared 79 breast cancer patients using the 52 mg LNG-IUS to a control group of 120 breast cancer patients with no history of 52 mg LNG-IUS use was identified. Overall the authors did not observe an increased risk of breast cancer recurrence associated with use of the 52 mg LNG-IUS. A subgroup analysis was carried out in which women who developed breast cancer and continued to use the 52 mg LNG-IUS were shown to have a higher risk of recurrence; however, it was of borderline statistical

significance.<sup>146</sup> This study was again limited by its retrospective design, and potential confounding factors were identified by the authors.

In women with current breast cancer, UKMEC<sup>2</sup> advises that it is a condition which represents an unacceptable health risk if the method is used (UKMEC 4). For those with a past history and no evidence of disease recurrence for 5 years or more, UKMEC advises that the theoretical or proven risks of using the LNG-IUS generally outweigh the advantages. The provision of the LNG-IUS to women with a history of breast cancer 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 3). Currently these categories apply to all breast cancer cases irrespective of receptor status.

**B** Evidence does not support a link between breast cancer and use of the LNG-IUS.

**C** Non-hormonal contraception is most appropriate for women with a history of breast cancer. Any consideration of the LNG-IUS should be carried out in consultation with the woman's cancer specialist.

### 9.3.3 Cardiovascular health

Few studies have been large enough to evaluate the risk of venous thromboembolism (VTE) with progestogen-only contraception. Data have thus far generally suggested that there is little or no risk of VTE associated with progestogen-only contraception.<sup>147–150</sup>

No increased risk of myocardial infarction (MI) (OR 1.07, 95% CI 0.62–1.84) was reported with use of progestogen-only contraception by a meta-analysis<sup>151</sup> of six case-control studies. The results were similar regardless of the route of administration (i.e. implant, injectable or oral). The authors felt further research was required, especially among women at high risk of MI.

Specific studies<sup>152–154</sup> examining the effect of 52 mg LNG-IUS on cardiovascular risk factors, such as lipids, are reassuring although more research is required; particularly in higher-risk populations. For women with either multiple risk factors for cardiovascular disease, stroke, current or history of ischaemic heart disease, or a history or current VTE there is no restriction for the use of the Cu-IUD (UKMEC 1).<sup>2</sup> The advantages of initiating a LNG-IUS in women with any of these conditions generally outweigh the risks (UKMEC 2). Continuing to use the LNG-IUS in a woman who develops ischaemic heart disease or has a stroke is a UKMEC 3.

Women with systemic lupus erythematosus are at increased risk of a number of cardiovascular conditions such as ischaemic heart disease, stroke and VTE. It is for this reason that greater caution is advised amongst women with positive or unknown antiphospholipid antibodies compared to women who have a history of VTE.<sup>2</sup> A UKMEC Category 3 does not exclude use of the method, but the provision requires expert clinical judgement and/or referral to a specialist contraceptive provider since use is not usually recommended unless other more appropriate methods are not available or not acceptable (also see section on cardiac disease on page 31).

**B** Evidence suggests there is little or no increased risk of VTE or MI associated with the use of a LNG-IUS.

### 9.3.4 Ectopic pregnancy

In users of IUC the absolute risk of ectopic pregnancy is reduced because they are such effective methods of contraception overall. The absolute risk of ectopic pregnancy is lower than among women not using any contraception.<sup>155–157</sup> A meta-analysis of case-control studies reported no increased risk of ectopic pregnancy with current IUD use when cases were compared to non-pregnant controls with past IUD use (pooled OR 1.06, 95% CI 0.91–1.59).<sup>158</sup> NICE<sup>6</sup> recommends that women are informed that the overall risk of ectopic pregnancy when



using an IUC is very low, at about 1 in 1000 at 5 years. The EURAS-IUD study reported an ectopic pregnancy rate for the 52 mg LNG-IUS of 0.02 per 100 woman-years (95% CI 0.01–0.003) and for the Cu-IUD a rate of 0.08 per 100 woman-years (95% CI 0.04–0.13).<sup>36</sup>

While the absolute risk of ectopic pregnancy is not increased by use of IUC, should a pregnancy occur with an intrauterine method *in situ*, the likelihood of it being ectopic is greater than if a pregnancy were to occur with no IUC *in situ*. An early prospective study from the UK reported that among 90 unintended pregnancies in women using IUC, 8.9% were ectopic.<sup>159</sup> In a cross-sectional study<sup>160</sup> of 52 mg LNG-IUS users (17 360 users, totalling 58 600 woman-years) there were 64 pregnancies reported with a 52 mg LNG-IUS *in situ*. The risk of pregnancy was therefore low (5-year cumulative pregnancy rate of 0.5 per 100 users). However, of the 64 pregnancies, approximately half (53%) were ectopic. In the more recently reported EURAS-IUD study, 52 mg LNG-IUS users appeared to experience fewer ectopic pregnancies than Cu-IUD users, but when pregnancy did occur, 5/13 (38.6%) were ectopic compared with 10/56 (17.9%) in Cu-IUD users.<sup>36</sup>

Data from a meta-analysis<sup>158</sup> of case-control studies also suggested that a past history of IUC use is a risk factor for ectopic pregnancy (OR 1.4, 95% CI 1.23–1.59). The strength of association is small and may be the result of confounding or bias.

As with other intrauterine methods, the absolute risk of an ectopic pregnancy is reduced with use of the 13.5 mg LNG-IUS. In a phase III study the absolute ectopic pregnancy rate for the 13.5 mg LNG-IUS was reported as 0.10 per 100 woman-years (95% CI 0.02–0.29).<sup>45</sup> However, as with other intrauterine methods, when pregnancy does occur it is more likely to be ectopic. There was one ectopic pregnancy out of two pregnancies in phase II studies of the 13.5 mg LNG-IUS,<sup>123</sup> and three ectopic pregnancies out of seven failures in a phase III study.<sup>45</sup> It is difficult to compare ectopic pregnancy rates for the 13.5 and 52 mg LNG-IUS due to the small number of studies involving the 13.5 mg LNG-IUS.<sup>45,161</sup> Furthermore, the ectopic pregnancy rates for the 13.5 mg LNG-IUS are expressed as woman-years, preventing direct comparison with the rates quoted in the literature for 52 mg LNG-IUS (1 in 1000 at 5 years and 0.1% per year).<sup>9</sup>

A previous ectopic pregnancy is not a contraindication to use of intrauterine methods of contraception (UKMEC 1).<sup>2</sup>

- B** The overall risk of ectopic pregnancy is reduced with use of IUC when compared to using no contraception.
- B** If pregnancy does occur with an intrauterine method *in situ*, the risk of an ectopic pregnancy occurring is increased and in some studies half of the pregnancies that occurred were ectopic.
- C** Data are insufficient to determine if the 13.5 mg LNG-IUS is associated with a greater risk of ectopic pregnancy than other IUC methods.
- IUC users should be informed about symptoms of ectopic pregnancy. The possibility of ectopic pregnancy should be considered in women with an intrauterine method who present with abdominal pain especially in connection with missed periods or if an amenorrhoeic woman starts bleeding. If a pregnancy test is positive, an ultrasound scan is urgently required to locate the pregnancy.

### 9.3.5 Expulsion

A Cochrane systematic review<sup>31</sup> observed little difference in expulsion rates between the devices studied. The review reported a small significant excess in expulsions with Multiload Cu375<sup>®</sup> compared to TCu380A in the fourth and subsequent years. In Years 1 and 4, the TCu380S was reported as being associated with more expulsions than the TCu380A. Fewer partial expulsions were observed with the NovaT380 in comparison to the TCu380S, but no significant difference was observed in the overall expulsion rate.

Problems with early expulsion have been reported in trials of the frameless device (GyneFix).<sup>162-164</sup> A subsequent study<sup>165</sup> using a modified inserter observed no significant difference in expulsion rates between the frameless device and the TCu380A at 1 year. However, a Cochrane Review<sup>32</sup> examining whether or not the frameless IUD GyneFix reduced the risk of expulsion, pregnancy, problems of bleeding and pain necessitating early removal concluded that there was insufficient evidence to suggest that the modified inserter had helped to overcome problems of early expulsion.

A Cochrane Review<sup>31</sup> has indicated that the 52 mg LNG-IUS has a statistically significantly higher rate of expulsion at 5 years than for users of IUDs containing >250 mm<sup>2</sup> copper. However, a multicentre retrospective chart review,<sup>166</sup> that included data for 2138 women aged 13–35 years, reported more expulsions in women using a Cu-IUD than a 52 mg LNG-IUS (hazard ratio 1.62, 95% CI 1.06–2.50).

It has been estimated that expulsion of IUC occurs in approximately 1 in 20 women and is most common in the first 3 months after insertion and often occurs during menstruation.<sup>61,167</sup> Anecdotal evidence suggests that a past history of IUC expulsion increases the risk of future/subsequent expulsions.

**B**

The risk of expulsion with IUC is around 1 in 20 and is most common in the first year of use, particularly within 3 months of insertion.

### 9.3.6 Post-abortion insertion

Royal College of Obstetricians and Gynaecologists guidance on *The Care of Women Requesting Induced Abortion*<sup>168</sup> recommends that any chosen method of contraception may be initiated immediately after abortion. WHO guidance on *Safe Abortion: Technical and Policy Guidance for Health Systems*<sup>169</sup> states that for medical abortion, hormonal contraception can be started by the woman after taking the first pill of a medical abortion regimen, but confirmation that the abortion is complete should precede insertion of an IUD or sterilisation.

There is consensus in the literature that offering LARC concomitantly with first-trimester abortion increases insertion rates<sup>170-173</sup> and reduces the number of subsequent unwanted pregnancies and repeat abortions.<sup>172-174</sup> There is consistent evidence reporting high non-attendance rates for follow-up appointments for interval insertion of IUC or the initiation of other LARC methods.<sup>170,173,175-177</sup>

An RCT<sup>177</sup> sought to assess the expulsion rate of IUC following insertion soon after medical abortion (5–9 days after the procedure) and delayed insertion (3–4 weeks after the procedure). The study reported that there was no difference in the expulsion rate between early (9.7%) and delayed (7.4%) intrauterine contraceptive insertion or in adverse other events.

A cohort study that examined the safety and adverse reactions associated with the immediate insertion of a Cu-IUD, following surgical abortion, compared to interval insertion (after the next menstrual bleed) reported that there was no difference in terms of either contraceptive efficacy or side effects between the two groups.<sup>178</sup> A multicentre RCT<sup>179</sup> randomised participants to receive one of three different IUDs (two copper, UCu200 or TCu380A, and one LNG-IUS) following vacuum aspiration and followed up participants for 1 year. The study reported that no pregnancies were observed during follow-up. The expulsion rate for the UCu200 was 4.13 per 100 women (95% CI 0.83–5.75), 5.16 per 100 women (95% CI 0.92–6.96) for the TCu380A and 2.73 per 100 women (95% CI 0.67–4.05) for the LNG-IUS.<sup>179</sup> Another RCT<sup>173</sup> randomised participants to either immediate IUD insertion or delayed insertion (2–6 weeks) following aspiration for induced or spontaneous abortion. The study reported that the 6-month expulsion rate for immediate insertion was 5% (13/258 women) and 2.7% (6/226 women) for delayed insertion (absolute difference 2.3%, 95% CI 1.0–5.8). The RCT reported that no pregnancies were observed at 6 months' follow-up for the immediate treatment arm and that five pregnancies were observed in the delayed treatment arm ( $p=0.07$ ). A retrospective cohort study<sup>175</sup> reported that there was no difference in complications between a group comprised of participants with immediate IUC insertion in comparison to a group with delayed insertion following surgical abortion.

Individual studies suggest a trend towards higher expulsion rates with immediate or early insertion in comparison to interval insertion following both medical and surgical abortion. A systematic review<sup>180</sup> concluded that the insertion of IUC immediately after abortion is not associated with an increased risk of adverse outcomes when compared to other contraceptive methods or no contraception. Furthermore, the review stated that IUD expulsions were low but are higher for later first-trimester abortions in comparison to early first-trimester abortions. A meta-analysis<sup>171</sup> of three RCTs concluded that following sub-analysis, higher expulsion rates were observed for post-abortion insertions when compared to interval insertions. Despite this, the authors concluded that the insertion of IUC immediately after abortion is safe and practical but expulsion rates appear to be higher when compared to interval insertions.

**B** There is no need to delay insertion of an IUC post-abortion providing a woman has been informed of the small increased risk of expulsion.

### 9.3.7 Postpartum insertion

The evidence comparing immediate postpartum insertion (within 10 minutes of placental delivery) with other insertion times following birth is limited but appears to suggest that it is associated with higher expulsion rates than with interval (6–8 weeks after birth) insertion.<sup>181</sup> A prospective cohort study<sup>65</sup> examining immediately post-placental placement of a CuT380A at Caesarean delivery found no self-reported expulsions in the 48% of women who returned for 6-week follow-up. The study was limited by high attrition rates. Larger studies, which also include insertion of the 52 mg LNG-IUS, are required. A systematic review<sup>182</sup> of 26 articles on event rates in interval and post-placental IUD insertion following Caesarean section reported expulsion rates of 5–15 per 100 woman-years of use. At 6+ weeks (interval insertion) following Caesarean section, insertion of an IUD was associated with a higher expulsion rate (≥5%) predominantly with use of older-type devices.

### 9.3.8 Ovarian cysts and use in women with ovarian cancer

Cu-IUDs have not been found to be associated with the development of functional ovarian cysts.<sup>183</sup>

An increased incidence of benign functional ovarian cysts has been observed in 52 mg LNG-IUS users.<sup>184</sup> No correlation has been identified between the presence of ovarian cysts and age or bleeding pattern. The majority of cysts occurring in LNG-IUS users are asymptomatic and resolve spontaneously. In an RCT comparing different dose LNG-IUS devices, ovarian cysts were observed more frequently with the 52 mg LNG-IUS than with a 19.5 mg LNG-IUS or the 13.5 mg LNG-IUS.<sup>123</sup>

Women should be informed that functional ovarian cysts are reported to be a common (1/100 to <1/10) possible undesirable effect of LNG-IUS use.<sup>9</sup> Ovarian pathology should be considered in the differential diagnosis of abdominal pain in LNG-IUS users.<sup>185</sup> There is no restriction on the use of IUC (LNG-IUS or Cu-IUD) in women with a history of ovarian cysts (UKMEC 1)<sup>2</sup> and there is no need to remove the method unless requested by the woman.

No data have been identified on the safety of using IUC in women with ovarian cancer.<sup>186</sup> UKMEC guidance on initiation and continuation of IUC in the presence of ovarian cancer is being updated. The Centres for Disease Control's *US Medical Eligibility Criteria for Contraceptive Use (USMEC)*<sup>187</sup> gives use of IUC in women with ovarian cancer a Category 1 (i.e. no restrictions). This decision was taken in the light of new treatments that can preserve the ovaries and fertility, whereas previously the ovaries would have been removed. In addition, the American group was unable to identify any evidence or theoretical concerns that insertion of IUC could worsen the condition.

**B** Although ovarian cysts may occur when using the LNG-IUS, most cysts are asymptomatic and resolve spontaneously.

### 9.3.9 Pelvic pain

In a large cohort study<sup>49</sup> of LARC users, pelvic pain or cramping was the most commonly reported reason for discontinuation of IUC at 6 months' follow-up. Of the 200 women who had discontinued IUC, and for whom data was available, 28% of 52 mg LNG-IUS discontinuers and 35% of Cu-IUD discontinuers reported pain/cramping as the reason for discontinuation; the difference was not statistically significant ( $p=0.38$ ).

### 9.3.10 Pelvic inflammatory disease

Evidence examining a link between IUC use and PID is subject to limitations, confounding and bias, and good evidence is lacking.<sup>188</sup>

A large retrospective cohort study<sup>76</sup> of 57 728 insertions found an overall risk of PID within the first 90 days of 0.54% (95% CI 0.0048–0.0060); the study included women who were and were not screened for gonorrhoea and chlamydia in advance of insertion.

In IUC users, PID appears to be most strongly related to the insertion procedure and to the background risk of STIs. A review of 12 randomised and one non-randomised trial (22 908 insertions and more than 51 399 woman-years of follow-up) identified low rates of PID (1.6 per 1000 woman-years).<sup>189</sup> A six-fold increase in the risk of PID was reported in the 20 days after insertion, after adjusting for confounding factors, but the overall risk was low. After this time the risk was low and remained low unless there was exposure to STIs. A systematic review<sup>190</sup> designed to establish timeframes for appropriate follow-up following initiation of specific contraceptive methods, including intrauterine methods, found that compared to women starting depot medroxyprogesterone acetate (DMPA) and 52 mg LNG-IUS or COCs, the incidence of PID was similar for women starting a Cu-IUD. The findings are somewhat restricted by the limitations of the included studies.

One multicentre RCT<sup>191</sup> reported that the cumulative rate of PID was higher after 36 months of use amongst women using a Cu-IUD (Nova T 200 mm<sup>2</sup>) as compared with women using the 52 mg LNG-IUS. Differences were also observed after 60 months of use amongst the youngest women in a 5-year study.<sup>40</sup> However, in another RCT<sup>192</sup> that compared a 52 mg LNG-IUS to the Copper T 380Ag IUD, cumulative PID rates did not differ between the two methods. No significant differences in discontinuation rates due to PID were observed between different Cu-IUDs or when the 52 mg LNG-IUS has been compared to Cu-IUDs in randomised trials.<sup>191,192</sup>

### 9.3.11 Perforation

The rate of uterine perforation associated with IUC use is very low.<sup>6,193–195</sup> No significant differences were identified in the perforation rates with differed framed Cu-IUDs.<sup>31</sup> A Cochrane Review has indicated that it is not known if the perforation rate for framed devices differs from frameless devices but only one perforation was noted with GyneFix in the studies reviewed (approximately 3000 insertions) compared to none with the framed device.<sup>32</sup>

The rate of perforation reported with the 52 mg LNG-IUS in a large observational cohort study was 0.9 per 1000 insertions.<sup>196</sup> A randomised trial comparing the 52 mg LNG-IUS and a TCU380A IUD reported similarly low perforation rates at 7 years.<sup>192</sup>

Findings from observational studies suggest an association between IUD perforation rates and breastfeeding.<sup>195,197,198</sup> Findings from the large EURAS comparative prospective cohort study<sup>199</sup> suggest that while perforation rates with use of IUC are low, around 1 in 1000 insertions, there was an increased relative risk of total uterine perforation amongst breastfeeding women (RR 6.1, 95% CI 3.6–10.1). Summaries of product information for Mirena<sup>9</sup> and Jaydess<sup>11</sup> highlight that the risk of perforation is increased in breastfeeding women and may be increased in postpartum insertions (see page 26 for management of suspected perforation and page 25 for management of pregnancy).

#### **B**

The rate of uterine perforation associated with IUC is up to 2 per 1000 insertions and is approximately six-fold higher in breastfeeding women.

### 9.3.12 Return to fertility

Concerns about IUC affecting fertility have been cited as a reason for discontinuation of IUC<sup>200</sup> and women's wariness of long-acting contraception.<sup>201</sup> Many reports show no delay in return of fertility among mainly parous women using the Cu-IUD.<sup>202-204</sup> One study of nulliparous women in the UK suggested that longer-term Cu-IUD use for 78 months or more was associated with lower fertility rates after discontinuation than use of oral contraceptives or barrier methods.<sup>205</sup> The difference in fertility remained after adjusting for age and history of gynaecological illness. The authors advise caution extrapolating these findings to current-day practice because of improvements in STI screening since the time of the study.

There are fewer data available on return of fertility after use of the 52 mg LNG-IUS. Reviews of the evidence suggest no delay.<sup>6,206</sup>

**B** Return of fertility after IUC use is generally similar to fertility rates after discontinuation of oral contraceptives and barrier methods.

## 9.4 Vasovagal reaction

Cervical stimulation during the insertion of intrauterine methods can cause a vasovagal reaction, bradycardia and other arrhythmias.<sup>207-209</sup> In healthy women vasovagal incidents usually resolve with simple resuscitation measures; rarely bradycardia persists and requires treatment with intravenous or intramuscular atropine<sup>85,210,211</sup> (see page 22).

## 9.5 Vulvovaginal candida and bacterial vaginosis

The Cu-IUD has been identified as a possible risk factor for acute or recurrent vulvovaginal candida (VVC).<sup>212</sup> There is some evidence to demonstrate that yeasts adhere to IUDs and produce biofilm<sup>213,214</sup> that could possibly facilitate recurrent VVC by protecting yeasts from antifungal agents. There is, however, no consistent evidence of an association between use of a Cu-IUD and VVC, and although cervical cytology slides from LNG-IUS users have shown increased presence of candida with time from insertion, rates of symptomatic infection are not significantly changed.<sup>215,216</sup>

Bacterial vaginosis (BV) is associated with use of the Cu-IUD<sup>217</sup> and FSRH guidance recommends that women with a Cu-IUD who experience recurrent BV may wish to consider switching to an alternative method of contraception.<sup>74</sup> The association between BV and use of the LNG-IUS is unclear. Advice on the management of vaginal discharge is available from the FSRH<sup>74</sup> and guidance on the management of BV<sup>218</sup> and VVC<sup>219</sup> is available from BASHH.

**C** Cu-IUD users with recurrent BV or VVC may wish to consider an alternative method of contraception.

# 10 How Can Safe Insertion of IUC be Facilitated?

## 10.1 Training

Health professionals offering IUC should hold the appropriate FSRH Letter of Competence in Intrauterine Techniques or have achieved equivalent recognised competencies and show evidence of recertification/reaccreditation.<sup>220</sup> The risk of perforation is related to the competence of the health care professional. In one study, doctors who performed fewer than 10 IUD insertions in a 10-year period reported significantly more perforations than doctors fitting between 10 and 99 devices in the same study period.<sup>221</sup> To ensure health professionals are able to maintain competence they should be able to show evidence of at least two continuing professional development (CPD) credits relevant to intrauterine techniques, completion of

e-SRH Module 18 or other approved distance-learning course, basic life support and anaphylaxis update, and a minimum of 12 insertions with at least two different types of intrauterine method in conscious women undertaken during a 12-month period within 24 months of recertification. The FSRH website ([www.fsrh.org](http://www.fsrh.org)) contains information about training requirements and recertification. No formal training as such is required for removal of IUDs but health professionals should have basic gynaecological skills and sufficient contraceptive knowledge to identify and appropriately manage any risk of pregnancy at the time of IUC removal, and to advise on ongoing contraceptive needs.

## 10.2 Valid consent

Valid consent should be obtained before examining, taking an STI screen, or starting treatment for a patient.<sup>220,222</sup> Detailed information can be found in the *FSRH Service Standards for Sexual and Reproductive Healthcare*.<sup>220</sup> Women should be given appropriate information about the contraceptive method and the procedure in order to give valid consent. Oral consent is sufficient for a non-anaesthetised woman.



Valid consent should be given by women prior to both pelvic examination and IUC insertion or removal.

## 10.3 Assistants and chaperones

All women should be offered a chaperone. An appropriately trained assistant should be present during cervical instrumentation procedures. This person may be required to call for additional assistance, monitor the condition of the woman, or perform basic life support.<sup>210</sup>



An appropriately trained assistant who can monitor the condition of the woman and assist in an emergency should be present during insertion of IUC.

## 10.4 Interventions to ease IUC insertion

Factors that predict pain during insertion of intrauterine methods include nulliparity or no history of vaginal delivery, anxiety, and length of time since last pregnancy or last menses.<sup>57,223–225</sup> In a non-randomised prospective study<sup>226</sup> of nulligravid women undergoing IUC insertion, severe dysmenorrhoea was identified as a predictor of painful insertion, and shorter uterine length and steeper flexion angle were associated with difficult insertion. However, the majority of fittings were uneventful irrespective of individual anatomy.<sup>226</sup>

### 10.4.1 Cervical priming agents

Various agents have been investigated for their potential to prime (soften) the cervix. The cervical priming agent misoprostol has been extensively studied with regard to ease of insertion and pain.<sup>227–230</sup> A Cochrane Review<sup>231</sup> concluded that none of the cervical priming agents investigated reduced IUC insertion pain. Side effects associated with using misoprostol were reported in several of the studies.

Gels containing the smooth muscle dilating drugs nitroprusside<sup>232</sup> and nitroglycerin<sup>233</sup> have also been used to ripen the cervix prior to IUC insertion but have had no effect on ease of insertion or pain.

### 10.4.2 Prophylactic oral analgesia

Oral ibuprofen administered at doses up to 600 mg and at different intervals before insertion has not been shown to reduce pain at the time of IUC insertion.<sup>59,224,234–238</sup> There is limited evidence suggesting that other non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. naproxen and mefenamic acid) may relieve post-insertion pain.

### 10.4.3 Bladder filling

A study of 200 women reported no difference in ease of insertion between groups randomised to IUD insertion with the woman's bladder filled or when emptied immediately prior to the procedure.<sup>239</sup>

### 10.4.4 IUC design

Ease of insertion and pain may vary with the insertion of different devices. A Cochrane Review<sup>31</sup> reported that RCTs found no difference between the framed Cu-IUDs studied in relation to ease of insertion or pain during insertion. In a placebo-controlled study<sup>225</sup> examining the effects of lidocaine gel, insertion of a 52 mg LNG-IUS was associated with greater pain than insertion of a Cu-IUD (Paragard®). In a clinical trial of the smaller-framed 13.5 mg LNG-IUS<sup>123</sup> health professionals were significantly more likely to report placement as 'easy' compared with insertion of a 52 mg LNG-IUS. Clinical trials of the 13.5 mg LNG-IUS failed to use a validated measure of pain.<sup>45,123</sup> Subjects were asked to rate pain during placement as 'none', 'mild', 'moderate' or 'severe'. Pain relief and cervical dilation were provided at the physician's discretion with no randomisation. A significantly higher proportion of women using lower-dose LNG-IUS devices (13.5 and 19.5 mg) reported no or mild pain compared with those in the 52 mg LNG-IUS group.<sup>123</sup> However, subsequent to these studies, a narrower, more ergonomic inserter has been introduced to aid insertion of the 52 mg LNG-IUS, and therefore the observed difference may no longer exist.

### 10.4.5 Tissue forceps

Application of tissue forceps (volsellum) to the cervix facilitates IUC insertion by stabilising the cervix and reducing the flexion angle of the uterus. Forceps are available with a single-tooth (tenaculum) or multi-tooth design. Some multi-tooth forceps are termed 'atraumatic' because they grasp only the superficial tissue layers. Slow application of forceps over a few seconds and distraction techniques are commonly practised to reduce pain. There is insufficient evidence to recommend any particular type of forceps or application technique.

### 10.4.6 Local anaesthetic

There is wide variation in clinical practice with regard to administration of local anaesthetic prior to IUC insertion. A survey of UK clinicians reported that approximately one-quarter ( $n=129$ ) of health professionals who undertook the survey routinely used local anaesthetic for IUC insertion, with around one-quarter of health professionals never, or rarely, offering it, and the remainder doing so sometimes.<sup>240</sup>

A Cochrane Review<sup>231</sup> concluded that none of the included trials showed an effect of topical local anaesthetic on insertion pain, although the authors acknowledged that there may be a case for further investigation of topical lidocaine. However, further RCTs have not shown any benefit, even when applied and left for 3 minutes prior to insertion.<sup>225,241,242</sup>

The two main techniques for cervical local anaesthesia (LA) are paracervical and intracervical block using a dental syringe and fine-gauge needle. The local anaesthetic drugs prilocaine, lidocaine or mepivacaine may be used with or without a vasoconstrictor. Use of the mepivacaine product Scandonest® is outside the product licence as it is currently licensed for dental use only. There is wide variation in how cervical block techniques are described in the literature. Further information is available via the FSRH e-learning Module 18 on Intrauterine Techniques.

There is evidence that cervical LA block effectively reduces the pain associated with gynaecology procedures,<sup>243-246</sup> and it is generally advised for any procedure that requires dilatation of the cervix. There is limited evidence regarding the routine use of cervical block for IUC insertion. In a small randomised trial<sup>247</sup> using 1% lidocaine paracervical block, perceived pain during IUC insertion was less in the paracervical block group [median Visual Analogue Scale (VAS) score 24.0 mm] than women receiving no anaesthetic (median VAS score 62.0 mm). The median VAS score associated with the LA block itself was 40.0 mm. Another small randomised study<sup>248</sup> with a placebo injection arm reported that paracervical block with 1%

lidocaine was associated with significantly lower pain scores at tenaculum placement, IUC insertion, and 5 minutes after the procedure when compared to placebo saline injection or no injection. Pain experienced during injection was not reported. Further studies are required to fully evaluate the use of LA cervical block for straightforward IUC insertion.

**A** There is no evidence from current trials to support the use of topical lidocaine, misoprostol or NSAIDs for improving ease of insertion or reducing pain during insertion of intrauterine methods.

**✓** Local anaesthetic block administered by cervical injection is not routinely required for IUC insertion but should be offered when cervical dilatation is required or difficult IUC insertion or removal is anticipated/experienced.

## 10.5 Post-procedure analgesia

NSAIDs such as ibuprofen effectively reduce pain after IUC insertion, although evidence suggests that treatment is unlikely to improve discontinuation rates in women who cite pain as a reason for removal.<sup>59,249</sup>

**✓** NSAIDs can be offered to women who experience pain after insertion of an intrauterine method.

## 10.6 Emergency management for problems at IUD insertion

Any invasive procedure in a non-anaesthetised woman, including IUC fitting, can trigger a vasovagal response. It is recommended that all staff involved with IUC insertion should undergo training and regular updates in resuscitation. For further information health professionals should refer to the FSRH *Service Standards for Sexual and Reproductive Health Services*<sup>220</sup> and *Service Standards for Resuscitation*.<sup>210</sup>

All significant adverse clinical events should be recorded and reported according to local policies, and should be discussed with individuals and a process put in place for the whole team to learn from them.

## 10.7 Practical procedures for intrauterine insertions

### 10.7.1 Bimanual examination

A bimanual pelvic examination should be performed prior to inserting IUC to allow health professionals to assess the position, size, shape and mobility of the uterus.

**C** A bimanual pelvic examination should be performed on all women before inserting IUC.

### 10.7.2 Measurement of pulse rate and blood pressure

Practice in the UK varies around the measurement of pulse rate and blood pressure before and after insertion of IUC. The clinical picture should guide clinicians in the appropriate measurement and documentation of pulse rate and blood pressure before, during and/or after inserting IUC.

### 10.7.3 Cervical cleansing

Although a study found that a high number of doctors reported cleaning the cervix prior to insertion of IUC,<sup>250</sup> no studies were identified that suggested such practice reduced post-insertion pelvic infection. None of the standard cleansing agents are effective bacteriocidally against chlamydia or gonorrhoea. Health professionals may choose to remove any mucus or debris from the cervix prior to insertion.

**✓** There is no evidence to suggest that cervical cleansing prior to IUC insertion reduces subsequent pelvic infection.



### 10.7.4 Sterile gloves

Gloves should be worn on both hands for pelvic examination.<sup>251</sup> There is no recommendation regarding the use of sterile gloves when fitting IUC particularly if a 'no touch' or aseptic technique is used (i.e. one whereby anything that is to be inserted into the uterine cavity remains sterile). Gloves should be changed after the pelvic examination and before proceeding to uterine instrumentation to avoid cross-contamination.

### 10.7.5 Use of forceps and assessment of the uterine cavity

Application of tissue forceps to the cervix has been recommended to ease insertion and reduce the risk of perforation. Evidence for the routine application of tissue forceps is lacking but use of forceps is advised in IUC manufacturers' instructions. In individual clinical circumstances an experienced clinician may choose not to use tissue forceps if the risks (e.g. from bleeding) are judged to outweigh the benefits. A uterine sound should be used to assess the length of the uterine cavity, reducing the risk of perforation and facilitating fundal placement of the device.<sup>251,252</sup>

## 10.8 Documentation

Recommendations for record-keeping specific to intrauterine insertion are available within FSRH *Service Standards for Record Keeping*.<sup>253</sup>

## 11 Managing Problems Associated with IUC

### 11.1 Unscheduled bleeding

While bleeding patterns can be irregular with IUC, STIs represent a common cause of problematic bleeding in women of reproductive age. Women with intermenstrual, postcoital or unscheduled bleeding while using these methods should be assessed to identify their individual risk of STI. Consideration should also be given to other causes of bleeding, such as concurrent gynaecological pathology, pregnancy, and other infections. Details are provided in *The Management of Unscheduled Bleeding in Women Using Hormonal Contraception*.<sup>254</sup>

Bleeding is common in the initial months of using any progestogen-only method and often settles without treatment. If treatment encourages women to continue with the method, it may be considered. Evidence for appropriate treatment options is lacking with regard to the LNG-IUS. An RCT<sup>255</sup> of 187 women who received a 52 mg LNG-IUS and were then randomised to receive tranexamic acid (500 mg), mefenamic acid (500 mg) or placebo three times daily during episodes of bleeding or spotting found that compared with placebo neither of these options was effective at 'treating' nuisance bleeding. A double-blind placebo-controlled trial,<sup>256</sup> designed to evaluate the effect of intermittent ulipristal acetate (UPA) on unscheduled bleeding in the first 4 months following insertion, found that although initially beneficial (first 28 days after treatment) the effect then reversed. In the absence of evidence, the FSRH recommend that as a short-term empirical treatment, a COC (30–35 µg ethinylestradiol with LNG or norethisterone) may be considered for up to 3 months continuously or in the usual cyclical regimen (outside product licence) in eligible women experiencing unscheduled bleeding with the 52 mg LNG-IUS. This may help settle bleeding in some women.<sup>254</sup>

A Cochrane Review<sup>249</sup> of RCTs reported that NSAIDs can reduce the pain and bleeding associated with IUDs and that if ineffective, antifibrinolytics (tranexamic acid) can be considered for bleeding issues. A systematic review,<sup>257</sup> which included 17 studies of varying quality, similarly reported that there may be some benefit associated with the use of NSAIDs.



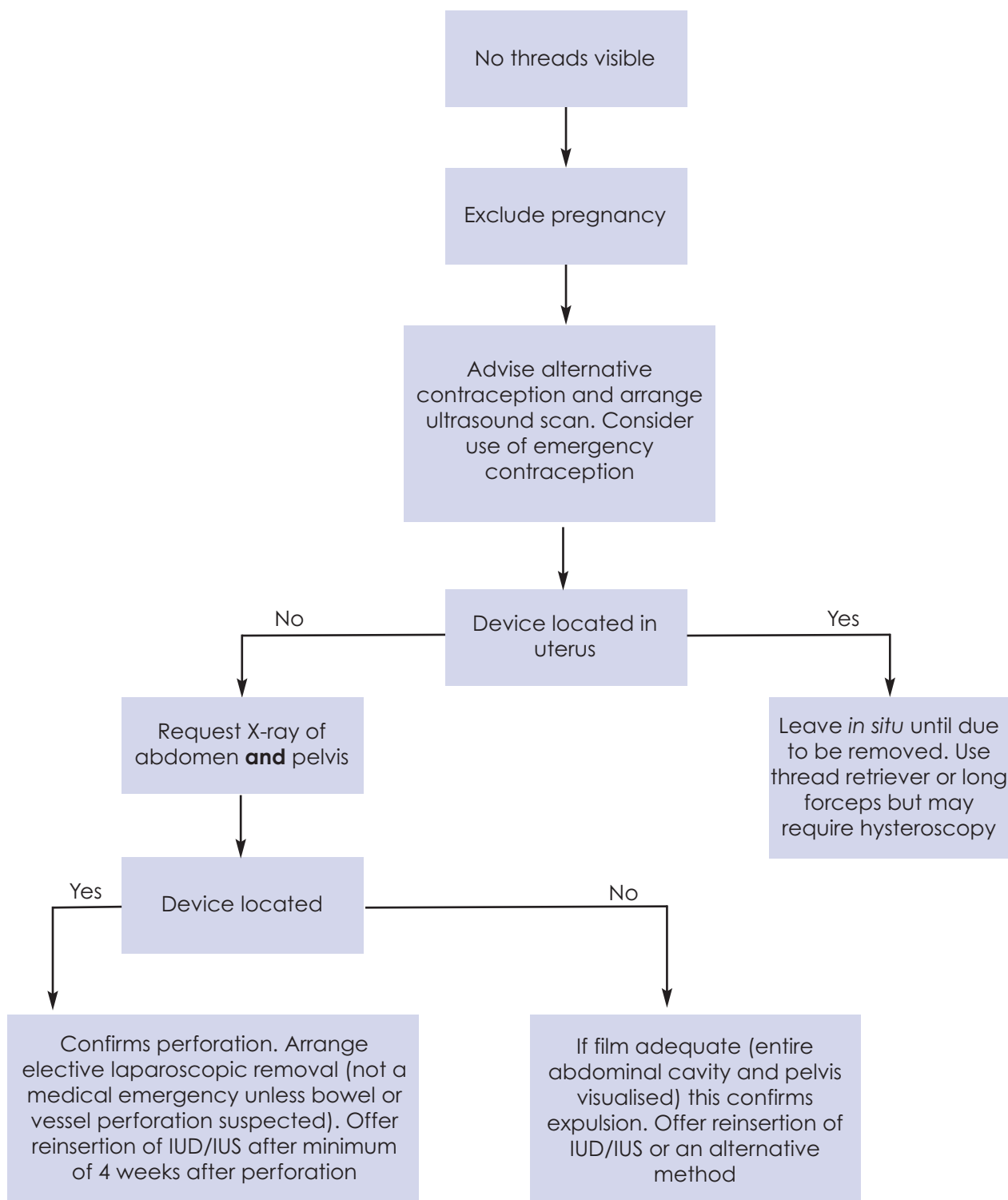
There is no evidence as to the most appropriate treatment option for women with unscheduled bleeding with the LNG-IUS. For women with unscheduled bleeding who wish to continue with the LNG-IUS and are medically eligible, a COC could be tried for up to 3 months (this can be in the usual cyclic manner or continuously without a pill-free interval – unlicensed use).



NSAIDs can be considered in the management of problematic bleeding with use of Cu-IUDs.

## 11.2 Non-visible threads

IUC threads may not be visible in the vagina as a consequence of IUD expulsion, perforation or pregnancy, but often the cause is retraction of the threads into the cervical canal or uterus. If no threads are visible on speculum examination pregnancy should be excluded, additional precautions advised, and an ultrasound scan undertaken to locate the device (Figure 1).



**Figure 1** Management of women with no intrauterine contraceptive threads visible on speculum examination. IUD, intrauterine device; IUS, intrauterine system.

If the IUC device is confirmed to be within the uterine cavity, the woman can be reassured and the device left *in situ*. If the device is to be removed, then thread retrievers (such as Retrievette® or Emmett) or Spencer Wells forceps can be used to facilitate this process.<sup>258</sup>

It is not advisable to use a thread retriever or forceps blindly without first confirming the intrauterine location of the device and excluding pregnancy.

If the IUC device cannot be removed easily, individuals should be referred for specialist review and then for removal using IUD removal forceps under local anaesthetic. Ultrasound guidance may be helpful and hysteroscopic removal is occasionally required.

When an IUC device is due to be removed or replaced, in general it should not be left *in situ* because of 'lost threads'. Cases of actinomyces-like organisms (ALOs) and pyometra have very occasionally occurred in postmenopausal women with IUDs. Careful discussion is required to balance the risks of surgical removal against the risks of infection from retained IUC, or if the woman refuses to have the IUC removed.

### 11.3 Non-fundally placed IUC

There is limited evidence to allow recommendations to be made about management of non-fundally placed intrauterine methods. It is believed that correct IUC insertion to the fundus may be necessary for maximum efficacy and that incorrect placement may increase the risk of expulsion.

In theory the efficacy of the LNG-IUS may be less affected by its position in the uterine cavity, because of the local release of progestogen hormone. However, one study<sup>259</sup> suggested that intracervical placement of a specially designed intracervical IUS was associated with less uniform endometrial suppression and more days of bleeding and spotting than fundal placement of a standard IUS. Another study<sup>260</sup> ( $n=298$ ) comparing the small intracervical IUS with an intrauterine IUS showed that there was no difference in the number of pregnancies in the two groups. However, it was not clear whether this study was powered to demonstrate equivalence. There is currently insufficient evidence to confirm whether efficacy is reduced or maintained when intrauterine methods are non-fundally placed. Repositioning of malpositioned 52 mg LNG-IUS devices was attempted in a small study<sup>261</sup> of 18 women. At follow-up 2–3 months later, the 52 mg LNG-IUS was still in place in 14/17 cases in which repositioning was possible.

Overall, the guideline group were of the opinion that contraceptive efficacy of a non-fundally placed IUC cannot be guaranteed, especially if it is more than 2 cm from the fundus on ultrasound measurement. The decision to remove and replace a device is a matter of individual clinical judgement following discussion with the woman and consideration of her individual circumstances (e.g. history of expulsion, age and type of device). Timing of removal may be dictated by recent sexual intercourse. EC may need to be considered in certain circumstances. If removed, immediate replacement or an alternative contraception should be initiated

### 11.4 Pregnancy

A systematic review<sup>262</sup> of observational studies concluded that compared to women who conceive without an IUC *in situ*, those who do are at greater risk of adverse pregnancy outcomes such as spontaneous abortion, preterm delivery, septic abortion and chorioamnionitis. From the limited available evidence it appears that removal of the IUC early in pregnancy may help to improve outcomes, although it will not necessarily eliminate the risks.

If a woman does become pregnant while using IUC, the site of the pregnancy should be determined by ultrasound scan and advice given regarding appropriate removal of the intrauterine method, where possible, before 12 weeks' gestation. The SPC for the 52 mg LNG-IUS<sup>9</sup> suggests that in case of an accidental pregnancy with the device *in situ*, ectopic pregnancy should be excluded and the IUS must be removed and termination of the pregnancy should be considered. There is limited evidence of pregnancy outcomes with a 52 mg LNG-IUS *in situ* but to date there is no evidence of birth defects.<sup>9</sup>

If it has not been possible to remove an IUD or confirm its location during pregnancy and the IUD is not found at the time of delivery or abortion, it is important to exclude uterine perforation by arranging an abdominal X-ray (see page 24).

### 11.5 Presence of actinomyces-like organisms

*Actinomyces israelii* is a commensal of the female genital tract.<sup>263–265</sup> Actinomyces-like organisms (ALOs) have been identified in women with and without IUC,<sup>267–271</sup> although it is acknowledged that the level is thought to be low and that actinomycosis is rare.<sup>272</sup> The role of ALOs in infection in women using IUC is unclear.<sup>273,274</sup> No evidence was identified as to whether or not an IUD should be inserted in women who have ALOs identified prior to IUD use.

If ALOs are identified and the woman presents with symptoms of pelvic pain, then removal of IUC may be considered. Treatment involves high-dose antibiotics for at least 8 weeks and health professionals should consult with a microbiologist. Other more common causes of pain (including STIs) should be excluded. It has been suggested that asymptomatic women with positive ALOs on a cervical smear are more likely to be colonised by ALOs than infected,<sup>272</sup> with the IUD potentially providing a good surface for the development of biofilm *in vivo*.<sup>275</sup> There is no need to remove IUC in asymptomatic women with ALOs. For women who require a replacement device but have ALOs identified there is some evidence to suggest that immediate reinsertion or a short delay of 3–5 days is safe.<sup>276</sup>

**C** Insertion or reinsertion of an intrauterine method can be carried out in asymptomatic women with ALOs.

**C** There is no need to remove IUC in asymptomatic women with ALOs.

### 11.6 Suspected pelvic infection

If a woman diagnosed with pelvic infection wishes to continue to use IUC there is no need for routine removal and appropriate antibiotic treatment can be initiated.<sup>62</sup> BASHH guidance<sup>77</sup> suggests that there may be better short-term clinical outcomes from IUD removal, and that the decision to remove an IUD in women PID needs to be balanced against the risk of pregnancy in those women who may have had sex in the preceding 7 days. A systematic review<sup>277</sup> of three studies, two RCTs and one prospective cohort suggested that there was no advantage to Cu-IUD removal and that clinical or laboratory outcomes for women who were hospitalised for PID tended to be similar or better for those who retained their device. No studies examining the LNG-IUS were identified by the systematic review. Oral EC may need to be considered in women requesting or having their IUC removed and advice should be provided about avoidance of sex/additional precautions. The CEU supports the continued use of IUC and appropriate antibiotic treatment if PID is suspected.

Follow-up of women with pelvic infection is advised 72 hours after starting treatment.<sup>77</sup> Further follow-up may be warranted 2–4 weeks after treatment.<sup>77</sup>

**B** IUC removal is not routinely required in women with PID but it should be removed if there is no response to treatment (approximately 72 hours).

### 11.7 Suspected uterine perforation

Although some uterine perforations are identified at the time of insertion, there can be a delay before perforation is identified.<sup>194,198,278</sup> For those women in whom perforation is identified at the time of insertion, the procedure should be stopped, the IUC removed, and vital signs (blood pressure and pulse rate) and level of discomfort monitored until stable.

Mild lower abdominal pain, 'lost threads', changes in bleeding (LNG-IUS) and a history of pain at the time of insertion may indicate uterine perforation.<sup>197,198,278,279</sup> The threads may remain in the vagina and may break off at attempted removal if an IUC has become embedded in the uterine wall or has perforated the cervix.

If there is any possibility of perforation at the time of insertion or later, an ultrasound scan and then, if indicated, a plain abdominal and pelvic X-ray should be arranged as soon as possible in order to locate the device. Women should be advised to use additional contraceptive precautions in the interim (see Figure 1).

## 12 What Information Should be Given to Women About Ongoing Use of IUC and Follow-up?

### 12.1 Information about the device

Women should be informed about what device has been inserted and when it needs to be removed and/or replaced. In addition to oral information, women should be given/directed to appropriate sources of information (e.g. leaflets, websites and apps).

### 12.2 Checking threads and device

Information should be offered on how to check for the threads of the IUC after each menstruation (or alternatively at regular intervals). If a woman's bleeding pattern changes from what might be expected with their chosen method (e.g. amenorrhoea to bleeding) or a period is missed when using the Cu-IUD, women should consider returning to have their IUC checked. If threads are present and menstruation has not been missed or has not changed from the usual pattern, an IUC can be assumed to be normally placed. If threads are not present women should be advised to use condoms or abstain from intercourse until the location of the IUC can be confirmed. Hormonal EC may be indicated if there is a risk of pregnancy.

Women should be advised to seek medical advice if the IUC causes discomfort to her or her partner during sexual intercourse. The threads can be cut shorter or flush within the cervical os if they cause irritation to a partner's penis.



Women should be offered instruction on how to check for the IUC and advised that if the threads cannot be felt the device may have perforated the uterus or been expelled. Additional contraception should be used until they seek medical advice.

### 12.3 Symptoms requiring medical attention

Women should be advised that the risk of pelvic infection is greatest in the first few weeks following IUC insertion and to look out for symptoms of pelvic infection as well as symptoms associated with pregnancy or uterine perforation.



Women should be advised to seek medical assistance at any time if they develop symptoms of pelvic infection, pain, abnormal bleeding, late menstrual period (IUD), non-palpable threads or can feel the stem of the IUC.

### 12.4 Sexually transmitted infections

IUC methods do not provide protection against STIs. Women requesting these methods should be informed about safer sex and that the consistent and correct use of condoms provides an effective means of protecting against STIs including the human immunodeficiency virus (HIV).<sup>280</sup>

Individuals with concerns about STIs, HIV or other blood-borne viruses, whether symptomatic or

not, should have a risk assessment and an appropriate medical and sexual history taken.<sup>71</sup> The minimum tests that in combination constitute an STI check (often called an STI screen) are those for chlamydia, gonorrhoea, syphilis and HIV.<sup>70,71</sup>

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 detect chlamydia and gonorrhoea acquired at the time of potential risk exposure. Serological tests for HIV, hepatitis and syphilis will require individuals to wait longer to allow for seroconversion.

- ✓ Women requesting intrauterine methods should be informed about the use of additional precautions for protection against STIs and advised about the appropriate timings of STI testing after an episode of UPSI.

### 12.5 Emergency contraception

EC may need to be considered if recent intercourse has occurred and the IUC is to be removed or in those who do not take additional precautions, when indicated, after an LNG-IUS is fitted. Additionally, EC may be required if the IUC is used for longer than its licensed duration.

The Cu-IUD can be used for EC and for ongoing contraception thereafter. All eligible women presenting between 0 and 120 hours of UPSI or within 5 days of expected ovulation should be offered a Cu-IUD because of the low documented failure rate.<sup>8</sup> Women requesting a Cu-IUD for EC and ongoing contraception should ideally be fitted with a device with at least 380 mm<sup>2</sup> copper and banded copper on the arms of the device.<sup>8</sup>

It is not appropriate to 'quick start' a LNG-IUS following administration of oral EC.<sup>281</sup> The Cu-IUD can be inserted after administration of oral LNG or UPA only if it is within 5 days of UPSI or within 5 days after the earliest expected ovulation.

- ✓ Health professionals should inform women about the availability of EC and when it may be required with intrauterine methods.

### 12.6 Routine follow-up

Following IUC fitting a follow-up visit after the first menses (or 3–6 weeks) has traditionally been advised to exclude infection, perforation or expulsion;<sup>62</sup> however, many women do not return for such appointments. The CEU would therefore suggest greater emphasis is placed on ensuring women are informed about how to check their own threads and to be aware of problems that might occur with IUC such as side effects, infection or irregular bleeding. Women should be advised to return at any time if they have any concerns, cannot locate their threads, or if they want to change their contraceptive method.<sup>62</sup>

- ✓ A routine follow-up visit can be advised after the first menses following insertion of IUC or 3–6 weeks later. However, it is not essential and it may be more important to advise women as to signs and symptoms of infection, perforation and expulsion, returning if they have any problems relating to their intrauterine method.

### 12.7 Timing of removal/replacement

Advice for removal and replacement of IUC is given in Table 5. If a device is inadvertently inserted after the expiry date stated on the packaging the woman should be advised that if the device has only recently expired this is unlikely to affect contraceptive efficacy. The risk of infection from loss of microbiological sterility is likely to be lower than the risk of infection from replacement of the device; consequently the device does not necessarily need to be removed unless requested by the woman. The error should be managed according to local clinical governance policies.

**Table 5** Recommendations for removal/replacement of intrauterine contraception

Reason for removal	Recommendation for removal
For a planned pregnancy	Offer pre-pregnancy advice regarding lifestyle, diet, folic acid, rubella immunity, vitamin D, then remove at any time in the menstrual cycle when the woman is ready to conceive
When removal is within the licensed duration of use and an alternative method is chosen	<p>Women using Cu-IUDs can have their method removed up to Day 3 after the onset of menstruation without the need for additional precautions</p> <p>Women having a Cu-IUD removed after Day 3 and women having an LNG-IUS removed at any time should be advised to avoid intercourse or use another method of contraception for at least 7 days before removal. Advise contraception thereafter</p>
When replacement is within the licensed duration of use	Advise condoms for at least 7 days before the procedure in case reinsertion is not possible
When removal/replacement are outside the licensed duration of use	<p>A Cu-IUD (containing <math>\geq 300</math> mm<sup>2</sup> copper ) inserted at or after the age of 40 years can be retained until 1 year after the last menstrual period if this occurs when the woman is over the age of 50 years (2 years if under 50 years)</p> <p>Women who wish replacement of a Cu-IUD outwith the licensed duration of use (excluding those detailed above) should have pregnancy reliably excluded prior to the replacement or fit the criteria for an emergency IUD</p> <p>Women who had their 52 mg LNG-IUS inserted for contraception and/or heavy menstrual bleeding at the age of 45 years or over can use the device for 7 years or if amenorrhoeic until the menopause,* after which the device should be removed</p> <p>Women who were under the age of 45 years at the time of 52 mg LNG-IUS insertion and who present for replacement of the device between 5 and 7 years after insertion may have immediate replacement if a pregnancy test is negative and another pregnancy test is advised no sooner than 3 weeks after the last episode of UPSI</p> <p>If a woman is under 45 years at the time of 52 mg LNG-IUS insertion and more than 7 years have elapsed since insertion, replacement should be delayed until the woman has a negative pregnancy test at least 3 weeks after the last UPSI</p> <p>Women who retain their 13.5 mg LNG-IUS for more than 3 years should be advised to use additional precautions until pregnancy can be excluded, after which time a replacement device can be inserted</p>

\*See FSRH guidance on *Contraception for Women Aged Over 40 Years*.<sup>47</sup>

Cu-IUD, copper intrauterine device; LNG-IUS levonorgestrel intrauterine system; UPSI, unprotected sexual intercourse.

## 12.8 Vibrating gym plates

Some gym product information advises that women using IUC consult a health professional before using vibrating gym plates. This is because of theoretical concerns about an increased risk of expulsion caused by the vibrations and contractions that occur during use. The CEU found no evidence of any adverse effect; however, precautionary advice has been to avoid such activity in the first few weeks following insertion. Women should be reminded about how to check threads and to use additional precautions if they have any concerns until a device can be checked.

## 12.9 Magnetic resonance imaging

Most Cu-IUDs are composed of plastic with copper wire or fitted with copper bands, while some also have a central core of silver to prevent copper fragmentation. Theoretically as none of these materials are magnetic, no magnetic force should be experienced with magnetic resonance imaging (MRI).

An *in vitro* study<sup>282</sup> was conducted to determine if MRI using a Signa 1.5T system would create movement, torque or heating of a Copper T 380A IUD placed within the magnetic field. No

significant temperature changes were seen and, additionally, there was no static deflection of the IUD and no turning motion with different gradient pulses of MRI. The authors concluded that these findings were to be expected because the IUD has no magnetic or magnetisable components. They recommended that screening women for the presence of an IUD prior to an MRI scan is unnecessary, and that removal of the device before the scan is unjustified.

The safety of using some Cu-IUDs has been shown at static magnetic field strengths of 1.5<sup>283</sup> and 3 Tesla<sup>284</sup> under test conditions. Nevertheless, most diagnostic centres ask women to inform them if they have any metallic object in their body, including an IUD. Some have policies stating that the IUD should be removed prior to an MRI scan and the CEU suggests checking with the local radiology department. However, the CEU would suggest that IUD removal is not required when a static magnetic field of up to 3 Tesla is used.

There is no reason for either the 13.5 or 52 mg LNG-IUS to be removed at any strength of magnetic field.

## 12.10 Mooncups and tampons

The manufacturer of the Moon Cup<sup>®</sup> recommends waiting for 6 weeks following the insertion of IUC before using the menstrual cup.<sup>285</sup> They also state that the Moon Cup should be placed low in the vagina with an adequate seal, which should be broken before the cup is removed. The manufacturer also recommends checking for IUC threads after each menses. If the threads cannot be located, or if a woman thinks her Cu-IUD has moved or if a woman experiences pain, the manufacturer recommends using additional contraception and consulting with an appropriate health care professional.<sup>285</sup>

A retrospective chart review<sup>286</sup> was identified which examined the risk of IUC device expulsion associated with the use of tampons, menstrual cups and sanitary towels. The study retrospectively reviewed the medical records of 1050 women with 743 meeting the eligibility criteria. A total of 135 women used a menstrual cup, 469 used tampons and 293 used sanitary towels. The study reported that at between 6 and 8 weeks' post-insertion that there were five expulsions (3.7%, 95% CI 1.6–8.4) in the menstrual cup cohort, 11 expulsions (2.4%, 95% CI 1.3–4.2) in the tampon cohort and 11 expulsions (3.8%, 95% CI 2.1–6.6) in the sanitary towel cohort. As the confidence intervals overlap, the authors concluded that there was no evidence to suggest that the use of menstrual cups or tampons was associated with increased early IUC expulsion.

**C** Mooncups and tampons do not appear to be associated with an increased risk of IUC expulsion.

## 13 IUC in Specific Populations

### 13.1 Nulliparous and adolescent women

Health professionals may present a possible barrier to the use of IUC in nulliparous women due to their own misconceptions about the difficulties associated with insertion and risks.<sup>287</sup>

A systematic review<sup>288</sup> of six cohort studies and seven case-series indicated that there is a lack of data on the use of IUC in young people but that existing data are generally reassuring. A retrospective cohort study conducted using health insurance claims reported that serious complications occurred in less than 1% of women regardless of age or IUD type.<sup>289</sup>

To date there is no evidence from RCTs to suggest that any of the IUC devices available in the UK is better for nulliparous women.<sup>31,290</sup>

UKMEC would suggest that the advantages of using IUC in women under the age of 20 years generally outweigh any theoretical or proven risks providing there are no other factors that would affect use. The CEU further suggests that there is no restriction on the use of IUC in young women based on parity.<sup>2</sup>

**B** Use of intrauterine methods should not be restricted based on parity or age alone.



### 13.2 Perimenopausal women

In women using the LNG-IUS, bleeding patterns cannot be used to determine menopausal status. Guidance on the menopause and stopping contraception in women using IUC can be found in FSRH guidance on *Contraception for Women Aged Over 40 Years*.<sup>47</sup> The LNG-IUS offers protection against the stimulatory effects of estrogen as part of hormone replacement therapy (see page 10). It is also helpful in reducing HMB (see page 11), which women may experience during the perimenopause. In women over the age of 45 years for whom medical treatment such as the LNG-IUS has failed, an endometrial biopsy should be considered.<sup>3</sup>

### 13.3 Women with cardiac disease

Vasovagal reaction represents a particularly serious risk for women with cardiac conditions such as single ventricle (e.g. Fontan circulation) or Eisenmenger physiology. These women may also be at particularly high risk if they become pregnant, therefore the risk of IUD/IUS insertion must be balanced against the risks associated with pregnancy. Women with arrhythmias can also experience vasovagal collapse because the heart rate is too fast to allow ventricular filling or too slow to facilitate adequate outflow.

Women with cardiac disease may not respond to standard treatment measures in the same way. Therefore, those at increased risk from vasovagal reaction should have IUC fitted in a hospital setting. More detailed guidance on contraception for women with cardiac disease can be found in separate FSRH guidance.<sup>85</sup>



For women with cardiac disease the decision to use IUC should involve a cardiologist. The IUC should be fitted in a hospital setting if a vasovagal reaction presents a particularly high risk, for example, women with single ventricle circulation, Eisenmenger physiology, tachycardia or pre-existing bradycardia.

### 13.4 Women who are immunosuppressed/taking immunosuppressants

No evidence was identified on the risk of infection with IUC for women immunocompromised due to the use of drugs that affect the immune system. Any inflammatory changes in the endometrium as a result of a Cu-IUD may possibly be attenuated by immunosuppressant drugs. In theory this could reduce the efficacy of the Cu-IUD. Use of NSAIDs does not reduce the efficacy of the Cu-IUD.<sup>291</sup> The CEU would advise there is no evidence to support a reduction in IUC efficacy with immunosuppressant drugs.

A small retrospective case review investigating use of the 52 mg LNG-IUS in renal transplant patients found no documented cases of pelvic infection. Prospective data have suggested comparable rates of pelvic infection among HIV-positive and HIV-negative women using the Cu-IUD.<sup>293</sup> A conference poster abstract<sup>294</sup> outlining a small 5-year follow-up study reported that long-term use of the 52 mg LNG-IUS was safe in women with HIV and no cases of pelvic infection occurred among users. When compared to hormonal contraceptives IUC has not been shown to adversely affect progression of HIV,<sup>295</sup> increase significant genital shedding of HIV<sup>296,297</sup> or increase risk of transmission to sexual partners.<sup>298,299</sup>

### 13.5 Long-term corticosteroid users

Long-term corticosteroid treatment suppresses the adrenal response to stress. Consequently, women on steroid replacement therapy for Addison's disease or on long-term corticosteroids for other indications may be at greater risk of cardiovascular collapse during IUC insertion. Advice should be sought from the woman's physician regarding the need for increased steroid treatment prior to IUC insertion.

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## APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

### GUIDELINE DEVELOPMENT GROUP

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### Declared Interests

Dr Karin Piegsa has received lecture fees for delivering non-promotional update sessions to general practice. Her department has received payment from Bayer and Merck, Sharp and Dohme towards training fees for subdermal implant training.

Administrative support to the CEU team was provided by **Mr John Matthews**.

### Patient Consultation

A questionnaire on the proposed guidance content was completed by a sample of potential users.

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 specialities, 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 (1996–2014); EMBASE (1996–2014); PubMed (1996–2014); The Cochrane Library (to 2014) and the US National Guideline Clearing House. The Cochrane Library is searched for relevant systematic reviews, meta-analyses and controlled trials relevant to intrauterine contraception. 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. Summary evidence tables are available on request from the CEU. The process for development of CEU guidance is detailed in the CEU section of the FSRH website ([www.fsrh.org](http://www.fsrh.org)). The methods used in development of this guidance (CEU Process Manual Version 2.0) have been accredited by NHS Evidence.

## Questions for Continuing Professional Development

The following questions have been developed for continuing professional development (CPD).

The answers to the questions and information on claiming CPD points can be found in the 'members-only section' of the FSRH website ([www.fsrh.org](http://www.fsrh.org)), which is accessible to all Diplomates, Members, Associate Members and Fellows of the FSRH.

- 1 Intrauterine contraception (IUC) works primarily by:**

  - a. Destroying developing embryos
  - b. Inhibiting ovulation
  - c. Preventing fertilisation
  - d. Preventing implantation
  
- 2 The daily release rate of the 52 mg levonorgestrel intrauterine system (LNG-IUS) is:**

  - a. 5 µg
  - b. 14 µg
  - c. 20 µg
  - d. 52 µg
  
- 3 In women aged over 45 years, the CEU recommends use of the 13.5 µg LNG-IUS for:**

  - a. 3 years
  - b. 4 years
  - c. 7 years
  - d. Until the menopause
  
- 4 A woman presents with heavy menstrual bleeding (HMB). What is the single most appropriate advice to give in relation to use of an LNG-IUS?**

  - a. The LNG-IUS is not recommended for HMB
  - b. The LNG-IUS has no effect on HMB
  - c. The 13.5 mg LNG-IUS is licensed to manage HMB
  - d. The 52 mg LNG-IUS is licensed to manage HMB
  
- 5 A woman who wishes to use IUC for long-term contraception presents reporting multiple episodes of unprotected sexual intercourse (UPSI) since her last period. The earliest episode was 10 days ago and the most recent 3 days ago. She is on Day 18 of a regular 28-day cycle. What is the single most appropriate advice to offer her from the list below?**

  - a. Advise that it is too late to use emergency contraception (EC) and to return when she has her period
  - b. Advise that it is too late to use EC and offer a bridging method
  - c. Advise that she can have a copper intrauterine device (Cu-IUD) inserted for EC and ongoing contraception
  - d. Advise that she can have an LNG-IUS inserted for EC and ongoing contraception
  
- 6 A woman presents requesting to start the LNG-IUS. She is on Day 19 of a 28-day cycle. She received ulipristal acetate 5 days ago for a single episode of UPSI. She has had no further episodes. What is the single most appropriate management from the list below?**

  - a. Do not insert the LNG-IUS, advise her to return when her period starts
  - b. Insert the LNG-IUS and advise a pregnancy test if she has no period
  - c. Insert the LNG-IUS and advise additional precautions for 7 days
  - d. Offer a bridging method until pregnancy can be excluded
  
- 7 A woman presents enquiring about the risk of ectopic pregnancy associated with IUC. What is the single most appropriate advice to offer her?**

  - a. Compared to no contraception, IUC increases the risk of ectopic pregnancy
  - b. Copper intrauterine devices (Cu-IUDs) decrease the risk of ectopic pregnancy when a pregnancy occurs
  - c. The LNG-IUS decreases the risk of ectopic pregnancy when a pregnancy occurs
  - d. Overall the risk is decreased with IUC but the risk is increased if a pregnancy occurs

- 8 **A woman presents enquiring about use of the LNG-IUS for contraception. She is keen to know how it will affect her bleeding patterns. What is the single most appropriate piece of information to give her?**
- a. Bleeding patterns can be irregular but by 1 year infrequent bleeding is usual
  - b. Following insertion, bleeding patterns will remain regular throughout use
  - c. Following insertion, bleeding patterns are likely to regular and heavy
  - d. Following insertion, infrequent bleeding is usual until the last year of use
- 9 **A woman with a Cu-IUD *in situ* presents with pelvic inflammatory disease. She wants to know if she should have the device removed. What is the single most appropriate advice according to CEU guidance?**
- a. Clinical outcomes are much worse if the device is removed
  - b. She can choose to keep her IUD whilst receiving treatment
  - c. Long-term clinical outcomes are better if the device is removed
  - d. Removal is recommended unless sex has occurred in the last 7 days
- 10 **A woman presents requesting an LNG-IUS. She is currently using a norethisterone progestogen-only pill (POP). What is the single most appropriate advice to offer her in relation to switching?**
- a. She can start immediately with no additional precautions required
  - b. She can start immediately and should continue the POP for 2 days
  - c. She should delay starting until her next menstrual bleed
  - d. She can start immediately and should continue the POP for 7 days

**What learning needs did this guidance address and how will it change your practice? (Please write below)**

## Auditable Outcomes for Intrauterine Contraception

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

### Auditable Outcomes

- 1 The proportion of sexually active women offered sexually transmitted infection screening requesting intrauterine contraception (IUC). [Auditable standard 97%]
- 2 The proportion of women who had a pelvic assessment either by bimanual examination or ultrasound scan before insertion of IUC. [Auditable standard 97%]
- 3 An appropriately trained assistant should be present during insertion of IUC. [Auditable standard 97%]







## **COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE**

All comments on published guidance can be sent directly to the Faculty of Sexual & Reproductive Healthcare (FSRH) at **[mail@fsrh.org](mailto:mail@fsrh.org)**.

The FSRH is unable to respond individually to all feedback. However, the FSRH 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.

