The Faculty of Sexual & Reproductive Healthcare

FSRH Guideline
Intrauterine Contraception

March 2023 (Amended Jan 2025) I FSRH

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Abbreviations used

ALO	actinomyces-like organisms
BASHH	British Association for Sexual Health and HIV
BMD	bone mineral density
BMI	body mass index
BNF	British National Formulary
BV	bacterial vaginosis
CEU	Clinical Effectiveness Unit
CI	confidence interval
COC	combined oral contraception/contraceptive
CT	computed tomography
Cu-IUD	copper intrauterine device
DMPA	depot medroxyprogesterone acetate
EC	emergency contraception
EMA	early medical abortion
ENG	etonogestrel
FSH	follicle-stimulating hormone
FSRH	Faculty of Sexual & Reproductive Healthcare
GDG	guideline development group
GTD	gestational trophoblastic disease
hCG	human chorionic gonadotropin
HCP	healthcare practitioner
HMB	heavy menstrual bleeding
HR	hazard ratio
HRT	hormone replacement therapy
IRR	incident rate ratio
IUC	intrauterine contraception
IUD	intrauterine device
LARC	long-acting reversible contraception/contraceptive
LLETZ	large loop excision of the transformation zone
LNG	levonorgestrel
LNG-IUD	levonorgestrel intrauterine device
MHRA	Medicines and Healthcare products Regulatory Agency
MRI	magnetic resonance imaging
NICE	National Institute for Health and Care Excellence
NSAID	nonsteroidal anti-inflammatory drug
OR	odds ratio
PI	Pearl Index
PID	pelvic inflammatory disease
POP	progestogen-only pill
PoTS	postural orthostatic tachycardia syndrome
PPIUC	postpartum intrauterine contraception/contraceptive
RCT	randomised controlled trial
RR	relative risk
SRH	sexual and reproductive healthcare
STI	sexually transmitted infection
TGD-AFB	transgender and gender-diverse individuals assigned female at birth
UKMEC	United Kingdom Medical Eligibility Criteria
UPSI	unprotected sexual intercourse
USS	ultrasound scan
VAS	visual analogue scale
VTE	venous thromboembolism
VVC	vulvovaginal candidiasis

Grading of recommendations

Refer to **Appendix 1** for a full explanation of the classification of evidence level and grading of recommendations.

A	**At least one meta-analysis, systematic review or randomised controlled trial (RCT) rated as 1++, and directly applicable to the target population;** ***or*** **A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results.**
B	**A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results;** ***or*** **Extrapolated evidence from studies rated as 1++ or 1+.**
C	**A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results;** ***or*** **Extrapolated evidence from studies rated as 2++.**
D	**Evidence level 3 or 4;** ***or*** **Extrapolated evidence from studies rated as 2+.**
✓	**Good Practice Point based on the clinical experience of the guideline development group.**

Details of changes to original guidance document

Subsequent to the publication of this guideline in March 2023 the following amendments has been made.

Date	Revision
10 July 2023	**Section 8.1 Breast cancer** updated to reflect newly published evidence
21 January 2025	**Text throughout** updated to reflect 8-year licence for all 52 mg LNG-IUDs **Text throughout** updated to reflect association between higher BMI and increased risk of expulsion.

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Executive summary of recommendations

Intrauterine contraception

Key information

✓	**Intrauterine contraception (IUC) methods are long-acting reversible contraceptives (LARCs) with licensed durations of use ranging between 3 and 10 years.**
✓	**There are two types of IUC available in the UK: copper intrauterine devices (Cu-IUDs) and levonorgestrel intrauterine devices (LNG-IUDs).**
C	**A Cu-IUD is a highly effective method of contraception or emergency contraception.**
C	**A 13.5 mg, 19.5 mg or 52 mg LNG-IUD is a highly effective method of contraception.**
C	**A 52 mg LNG-IUD has additional potential gynaecological benefits including management of heavy menstrual bleeding (HMB) and dysmenorrhoea.**
D	**A Cu-IUD is effective immediately following insertion.**
D	**An LNG-IUD is effective 7 days after insertion.**
D	**Pre-fertilisation effects are the main mode of action for both the Cu-IUD and the LNG-IUD.**

Clinical recommendations

✓	**Any 52 mg LNG-IUD inserted at age <45 years can be used for contraception for 8 years.**
✓	**Any 52 mg LNG-IUD inserted at age ≥45 years can be used for contraception until age 55 years.**
✓	**Any Cu-IUD with copper surface area ≥300 mm^2 inserted at age ≥40 years can be used for contraception until menopause. It can be removed 1 year after the final menstrual period if this occurs after age 50 years.**
✓	**Any 52 mg LNG-IUD can be used for 5 years as endometrial protection as part of hormone replacement therapy (HRT).**

Effectiveness

Key information

C	**The contraceptive failure rate for a Cu-IUD in the first year of use has been estimated at 0.8% (typical use) and 0.6% (perfect use).**
C	**The contraceptive failure rate for a 52 mg LNG-IUD in the first year of use has been estimated at 0.2% for both typical and perfect use. Studies suggest that contraceptive failure during licensed use is around 0.3% for the 19.5 mg and 13.5 mg LNG IUD devices.**

Suitability in specific populations

Young people, individuals who have never been pregnant and individuals who have never been sexually active

Key information

D	**IUC can be used by young people, individuals who have never been pregnant and individuals who have never been sexually active.**

After pregnancy

Key information

B	**Immediate postpartum IUC (within 48 hours of childbirth) is safe, effective, convenient and associated with high continuation rates.**
✓	**When inserted within 48 hours of childbirth, the insertion technique is different to that of standard IUC insertion and clinicians need to be appropriately trained in this technique.**
B	**Interval IUC insertion (from 48 hours after childbirth) is associated with an increased risk of uterine perforation, particularly if the user is breastfeeding. Despite this, the risk of uterine perforation from 28 days after childbirth remains small.**
C	**Expulsion rates are higher when IUC is inserted within 48 hours after childbirth compared with interval insertion. Expulsion rates are higher when IUC is inserted after vaginal birth compared with caesarean section.**
B	**IUC insertion after abortion is convenient and acceptable and has been associated with high continuation rates and reduced likelihood of another abortion within the next 2 years.**
D	**After medical abortion, or medical or expectant management of miscarriage, IUC can be inserted any time after expulsion of the pregnancy, providing there is no clinical suspicion of sepsis and no new risk of pregnancy.**
A	**IUC can be inserted immediately after surgical abortion or surgical management of miscarriage or ectopic pregnancy, providing there is no clinical suspicion of sepsis.**

Clinical recommendations

B	**If >48 hours have passed since childbirth, insertion should be delayed until 28 days after childbirth (interval insertion). The risks of insertion from 48 hours until 28 days after childbirth generally outweigh the benefits (UKMEC3).**

Perimenopause

Clinical recommendations

✓	**Additional investigations may be indicated prior to or at the same time as IUC insertion in individuals with abnormal uterine bleeding, or if an individual has risk factors for gynaecological disease.**
✓	**The FSRH supports the use of any 52 mg LNG-IUD for endometrial protection as part of HRT for 5 years.**

Uterine malformation

Key information

D	**For individuals with known distortion of the uterine cavity, risks associated with IUC insertion generally outweigh the benefits (UKMEC3).**

Clinical recommendations

✓	**The decision to insert an IUC in an individual with uterine cavity distortion should be made on an individualised basis, considering the degree of distortion, uterine cavity size, the accuracy of imaging available, the indication for use and other suitable alternatives, the type of device being inserted and the potential consequence of complications for that particular individual.**
✓	**IUC insertion for an individual with uterine cavity distortion due to fibroids or uterine malformation should be undertaken in a specialist setting with access to concurrent ultrasound or hysteroscopy.**
✓	**The uncertainty around the safety and contraceptive effectiveness of IUC in individuals with uterine cavity distortion should be explained to the individual, with advice on how and when to seek review.**
✓	**The decision to insert IUC at an interval following endometrial ablation should be made on an individualised basis, considering the indication for IUC insertion, the need for a reliable concurrent endometrial biopsy, and the ultrasound appearance of the endometrium.**
✓	**If IUC insertion is considered for an individual who has previously undergone endometrial ablation, the procedure should be undertaken in a specialist setting, with ultrasound or hysteroscopic assessment of the cavity to determine suitability.**

After large loop excision of the transformation zone (LLETZ) procedure

Clinical recommendations

✓	**If an IUC is removed during LLETZ and not immediately reinserted, alternative contraception should be provided and emergency contraception (EC) considered.**

Risk of infection

Key information

D	**Current pelvic inflammatory disease, postpartum or post-abortion sepsis, known gonorrhoea infection, symptomatic chlamydial infection, and purulent cervicitis are all contraindications to IUC insertion (UKMEC4).**

Clinical recommendations

✓	**If IUC insertion has to be delayed due to infection, bridging contraception should be offered.**
✓	**A sexual history should be taken prior to IUC insertion and screening offered to individuals at risk of sexually transmitted infections. Screening can be performed at the time of insertion.**

Immunosuppression

Key information

D **The contraceptive effectiveness of Cu-IUD does not appear to be reduced in individuals who are immunosuppressed/on immunosuppressants.**

Clinical recommendations

✓ **Where an immunosuppressed individual is having an IUC procedure, the use of prophylactic antibiotics should be discussed with the individual's lead clinician in order to assess the suitability for that individual.**

Adrenal insufficiency

Key information

C **Individuals with adrenal insufficiency are advised to increase their steroid dose at times when an adrenal crisis may be provoked.**

Clinical recommendations

✓ **Individuals at risk of an adrenal crisis should ideally have their IUC procedure scheduled for early morning.**

✓ **Individuals at risk of an adrenal crisis will usually need to increase their steroid dose prior to, and for 24 hours after, IUC insertion.**

Ehlers–Danlos syndrome (EDS)

Key information

D **Some types of Ehlers–Danlos syndrome (EDS) are associated with an increased risk of uterine rupture in pregnancy and/or joint hyperlaxity, both of which may be relevant to IUC procedures.**

Clinical recommendations

✓ **Suitability of IUC and the most appropriate setting for IUC insertion should be discussed with the individual's EDS specialist.**

✓ **Clinicians should be guided by the individual with EDS as to their most appropriate/ comfortable positioning during IUC insertion.**

Cardiac disease

Key information

C **Antibiotic prophylaxis is not routinely recommended when an individual at increased risk of developing infective endocarditis has an IUC procedure.**

D **There is a small risk of vasovagal reaction during IUC procedures.**

✓ **The majority of IUC insertions in individuals with postural orthostatic tachycardia syndrome (PoTS) should be straightforward and low risk, providing precautions (adequate hydration, salt intake and postural awareness) are in place.**

Clinical recommendations

✓ **Contraception choice for individuals with cardiac disease will often require a multidisciplinary approach and discussion with the individual's cardiologist is recommended.**

✓ **For individuals with pre-existing arrhythmia, Eisenmenger physiology, single ventricle (or Fontan) circulation, long QT syndrome or impaired ventricular function a vasovagal reaction could pose a serious risk of a significant cardiac event and therefore IUC procedures should be undertaken in a hospital setting.**

✓ **If an individual with PoTS has a history of postural syncope, advice should be sought from their cardiologist as it may be recommended that insertion should be undertaken in a hospital setting.**

✓ **IUC insertion for an individual who is anticoagulated should be undertaken by an experienced clinician, with consideration given to the timing of the procedure, as well as ensuring availability of haemostatic agents/equipment.**

Inherited bleeding disorders

Clinical recommendations

✓ **When an individual with an inherited bleeding disorder requests IUC insertion, clinicians should take advice from the individual's haematologist as to the appropriateness of the method, where the procedure should be undertaken and whether any additional precautions are required.**

Allergy and sensitivity

Clinical recommendations

D **Use of IUC is contraindicated if there is a known or suspected allergy or hypersensitivity to any of the components of the device.**

Wilson's disease and copper toxicity

Clinical recommendations

✓ **Cu-IUD use is not recommended for individuals with Wilson's disease.**

Health risks associated with IUC use

Breast cancer

Key information

D **The available evidence suggests a possible association between current or recent use of hormonal contraception (including LNG-IUDs) and a small increase in risk of breast cancer; absolute risk remains very small.**

Ovarian cysts

Key information

D	**Although incidence of ovarian cysts may be elevated during LNG-IUD use, this does not appear to be clinically significant.**
D	**Presence of (or history of) ovarian cysts or polycystic ovary syndrome is not a contraindication to IUC use.**

Bone mineral density

Key information

D	**The limited evidence available suggests that IUC use has no significant effect on serum estradiol levels or bone mineral density.**

Side effects associated with IUC use

Bleeding patterns

Key information

C	**Cu-IUD use is associated with an increase in menstrual blood loss and intermenstrual bleeding compared with natural menstrual cycles in individuals without Cu-IUD.**
D	**Increased menstrual bleeding associated with Cu-IUD use will often decrease over time.**
C	**Altered bleeding patterns are common after LNG-IUD insertion.**
C	**With the LNG-IUD there is a trend towards decreased bleeding over time.**

Clinical recommendations

✓	**Individuals should be informed about the expected changes in bleeding pattern with an IUC.**

Hormonal side effects

Key information

D	**Acne, breast tenderness, headache and mood changes are reported by some individuals using LNG-IUD. However, evidence is too limited to confirm or exclude a causative effect. When present these symptoms appear to be more prevalent in the first few months after insertion but decrease with time.**

IUC insertion

Insertion checklist

Clinical recommendations

✓	**Prior to insertion of their chosen IUC, individuals should be advised about contraceptive effectiveness, duration of use, potential bleeding patterns and side effects, any non-contraceptive benefits, the procedure (including associated risks), analgesia options, checking threads and when to seek review. The clinician should answer any questions the user has about the method.**
✓	**The clinician should confirm the type of device with the individual and assistant prior to IUC insertion.**
✓	**The expiry date on the IUC ± anaesthetic/analgesia should be checked prior to use.**

Facilitating safe insertion

Clinical recommendations

✓	**Clinicians offering IUC insertion should hold the appropriate FSRH Letter of Competence in Intrauterine Techniques or have achieved equivalent recognised competencies and show evidence of recertification/reaccreditation.**
✓	**The insertion procedure for immediate postpartum intrauterine contraception (PPIUC) is different to that for standard IUC insertion and should only be performed by those who have been trained in this technique.**
✓	**An appropriately trained assistant should be present during all uterine instrumentation procedures.**

Practical aspects

Clinical recommendations

✓	**A bimanual pelvic examination should be performed prior to inserting IUC.**
✓	**To reduce the risk of perforation and facilitate fundal placement of the device, tissue forceps should usually be used to stabilise the cervix and straighten the uterine cavity during IUC insertion, and a uterine sound should be used to assess the cavity length prior to insertion.**

Pain

Key information

D	**Experiences vary for individuals having IUC inserted, and clinicians may underestimate the pain and anxiety users experience.**
D	**Discomfort and pain may be experienced with any of the stages of IUC insertion: speculum insertion, tenaculum placement, uterine sounding and device placement.**
C	**Paracervical block, intracervical local anaesthetic injection, 10% lidocaine spray or cream containing 2.5% lidocaine plus 2.5% prilocaine appear to be beneficial in reducing insertion-related pain.**

Clinical recommendations

✓	**Individuals should be advised that most IUC insertions are associated with mild-to-moderate pain or discomfort, but that pain can range from none to severe.**
✓	**Clinicians should support and encourage users to tell them if they are experiencing pain or discomfort and reassure them that the procedure can be paused or stopped at any time.**
✓	**An assistant should be present to support the individual during the IUC procedure and monitor the patient for any signs of pain or distress.**
✓	**Analgesia options should be discussed and offered to all individuals having IUC inserted.**
✓	**Referral processes should be in place for circumstances where an individual requests an analgesia option that the clinician is unable to provide.**

Emergency management for problems at IUC insertion

Clinical recommendations

✓	**All staff involved with IUC insertion should undergo training and regular updates in resuscitation.**

Aftercare advice and follow-up

Clinical recommendations

✓	**After IUC insertion, individuals should be given information on the device inserted, including the name of the device, its mode of action, duration of use and time to become effective.**
✓	**Where IUC has been inserted outside of product licence or as EC, information about how and when to perform a pregnancy test should be given.**
✓	**With the exception of PPIUC, routine post-insertion check-ups with a clinician are not required.**
✓	**When IUC has been inserted within 48 hours of a vaginal or caesarean birth (PPIUC), an IUC check-up with a clinician 4–6 weeks after insertion is recommended.**
✓	**IUC users should be advised to feel for their threads within the first 4–6 weeks after insertion and then at regular intervals (e.g. monthly or after menses).**

Managing problems associated with IUC

Unscheduled bleeding

Clinical recommendations

D	**Tranexamic acid or nonsteroidal anti-inflammatory drugs (NSAIDs) can be offered for management of HMB during use of IUC.**
✓	**A 3-month trial of combined oral contraception can be offered to medically eligible individuals with problematic bleeding during use of IUC.**

New-onset pelvic pain

Clinical recommendations

✓	**New-onset pelvic pain in an IUC user should be assessed, and pregnancy should be excluded.**

Pregnancy

Key information

C	**The risk of any pregnancy, including ectopic pregnancy, during use of IUC and after insertion of a Cu-IUD for EC is very low.**
C	**If a pregnancy occurs with IUC in situ, the likelihood of it being ectopic is greater than if a pregnancy was to occur without IUC in situ.**
D	**A previous ectopic pregnancy is not a contraindication to use of intrauterine methods of contraception.**

Clinical recommendations

✓	**If an individual with an IUC in situ has a positive pregnancy test, local early pregnancy assessment pathways should be followed to determine the location of the pregnancy.**
D	**When an intrauterine pregnancy is less than 12 weeks' gestation, the IUC should usually be removed, if the threads are visible, as this could improve later pregnancy outcomes.**

Infection

Key information

C	**The risk of pelvic infection appears to increase in the first 3 weeks after IUC insertion, but overall the risk is very low (<1%).**
D	**The evidence pertaining to effect of IUC use on risk of vulvovaginal candidiasis (VVC) and/or bacterial vaginosis is limited and conflicting.**
D	**Pelvic actinomycosis is a very rare, chronic bacterial pelvic infection that is associated with long-term IUC use.**

Clinical recommendations

D	**Individuals with pelvic inflammatory disease (PID) and IUC in situ should be given antibiotic treatment, managed in accordance with BASHH guidance and reviewed after 48–72 hours.**
D	**Individuals with mild-to-moderate PID and IUC in situ, whose clinical condition is improving over the first 48–72 hours, can retain their IUC.**
D	**Individuals whose clinical condition does not improve after 48–72 hours of antibiotics should usually have their IUC removed, but this decision should be considered alongside any potential risk of pregnancy if there has been unprotected vaginal sex within the preceding 7 days. EC and follow-up pregnancy testing should be considered if indicated.**

D	**IUC users with symptomatic, recurrent VVC or bacterial vaginosis not controlled by standard treatment may wish to switch to an alternative method of contraception.**
D	**Asymptomatic individuals with positive actinomyces-like organisms on cervical cytology are more likely to be colonised than infected, and there is no need to remove the IUC or to commence antibiotic treatment.**
D	**If actinomycosis is suspected, further investigation and management should be discussed on an individual basis with local radiology, microbiology and/or gynaecology teams.**

Malpositioned IUC

Key information

D	**Correct IUC position at the fundus may be necessary for maximum contraceptive effectiveness and incorrect placement may be associated with increased risk of contraceptive failure.**
D	**The published evidence is too limited to predict failure rates of malpositioned IUC.**
D	**There is insufficient evidence to definitively guide whether a malpositioned IUC should be left in situ or removed and replaced, and clinicians should consider each case on an individual basis.**

Clinical recommendations

✓	**The guideline development group (GDG) suggests that as a general guide any of the following findings would usually be an indication to suggest that the IUC is removed and replaced: IUC >2 cm from the fundus; IUC within the cervical canal (fully or partially); or IUC user experiencing symptoms that may be related to malpositioned IUC (e.g. pain or bleeding).**
D	**Clinicians should consider the need for EC and follow-up pregnancy testing when an IUC is found to be malpositioned.**

Expulsion

Key information

C	**The overall risk of IUC expulsion is approximately 1 in 20 and expulsion appears to be most common in the first year of use, particularly within 3 months after insertion.**
C	**Expulsion rates are higher when inserted immediately postpartum compared with interval postpartum insertion or insertion in individuals who have not had a recent pregnancy.**
D	**Expulsion rates may be higher in adolescents, those who have IUC inserted after late first-trimester or second-trimester surgical abortions, individuals with fibroids and HMB, individuals with uterine cavity distortion, individuals concurrently using a menstrual cup with IUC, those who have had a previous expulsion, and individuals with a BMI over 25.**

Clinical recommendations

✓ **If there have been ≥2 IUC expulsions, a pelvic ultrasound to assess the uterine cavity may be helpful prior to insertion of a further IUC.**

✓ **Post-insertion ultrasound scan (USS) is not predictive of the likelihood of further expulsion but can provide immediate confirmation of correct positioning.**

Perforation

Key information

C **The rate of uterine perforation associated with IUC use is very low, with an overall risk of perforation in the general population of 1–2 in 1000.**

C **Postpartum interval IUC insertion (from 48 hours after childbirth) is associated with an increased risk of uterine perforation, particularly if the user is breastfeeding.**

D **Uterine perforation may be identified at the time of insertion or at a later date.**

D **Lower abdominal pain, non-visible threads or changes in bleeding may indicate uterine perforation.**

Clinical recommendations

✓ **If perforation is suspected, an ultrasound scan ± plain abdominal and pelvic X-ray should be arranged as soon as possible in order to locate the device. EC and pregnancy testing should be considered, and ongoing contraception provided.**

✓ **Following confirmed or suspected uterine perforation, the GDG suggests waiting at least 6 weeks before inserting a subsequent IUC. Referral to a specialist service, where ultrasound is available, is suggested for the subsequent insertion.**

Thread problems

Key information

D **IUC threads may not be visible in the vagina as a result of IUC expulsion, perforation or pregnancy, or the device being correctly sited but with threads within the cervical canal or uterus.**

D **The prevalence of non-visible threads may be as high as 18% (standard IUC insertion), 30% (IUC insertion within 48 hours of vaginal birth) and 50% (IUC insertion at the time of caesarean section).**

Clinical recommendations

✓ **If no threads are visible on speculum examination, pregnancy should be excluded, EC considered, alternative contraception provided, and an USS (± abdominal and pelvic X-ray) undertaken to locate the device.**

✓ **If the IUC is confirmed to be correctly sited within the uterine cavity, the user can be reassured and the device left in situ.**

✓	**The uterus should only be instrumented by a clinician with appropriate training to do so, and it is not advisable to instrument the uterine cavity without first confirming the intrauterine location of the device and excluding pregnancy.**
D	**As threads may descend into the vagina after PPIUC insertion, they may need to be trimmed at a subsequent IUC check.**

IUC removal

Timing of removal/replacement

Clinical recommendations

D	**Individuals who do not wish to become pregnant should be advised to avoid unprotected sexual intercourse (UPSI) for 7 days prior to IUC removal.**
✓	**Individuals should be advised to avoid UPSI for 7 days prior to IUC removal and replacement in case it is not possible to insert the new device.**

Unexpected findings

Clinical recommendations

✓	**On removal the IUC should be checked to ensure it is intact and is the expected device.**

Difficult removals

Clinical recommendations

✓	**When there is difficulty in removing an IUC a referral should be made to an experienced provider.**

FSRH Guideline (March 2023)
Intrauterine Contraception

(Revision due by March 2028)

1 Purpose and scope

This document updates previous Faculty of Sexual & Reproductive Healthcare (FSRH) guidance and aims to summarise the available evidence and expert opinion on intrauterine contraception (IUC). The guideline is intended for use by healthcare practitioners (HCPs) providing IUC care and advice.

2 Identification and assessment of the evidence

This guideline was developed in accordance with standard methodology for developing FSRH clinical guidelines. The recommendations made within this document are based on the best available evidence and the consensus opinion of experts and the guideline development group (GDG). The methodology used in developing this guideline and a list of GDG members and other contributors can be found in **Appendix 1**.

The recommendations included should be used to guide clinical practice but are not intended to serve alone as a standard of medical care or to replace clinical judgement in the management of individual cases.

3 Introduction

Intrauterine contraception (IUC) is a highly effective, reversible method of contraception used by approximately 159 million users worldwide.[1] This guideline provides information and recommendations on IUC and considers the two categories of IUC available in the UK at the time of publication: copper intrauterine devices (Cu-IUDs) and levonorgestrel intrauterine devices (LNG-IUDs).

The guideline is designed to enable clinicians to support individuals to make informed decisions about choosing and using IUC. It includes information on assessing suitability of IUC use for contraception, the risks and benefits of IUC and guidance for IUC procedures, complications and follow-up.

4 Summary including changes to existing guidance

Intrauterine devices (IUDs) are long-acting, reversible, highly effective methods of contraception. In the UK there are two types of IUD available: copper IUDs (Cu-IUDs) and levonorgestrel-releasing IUDs (LNG-IUDs). All Cu-IUDs in the UK have a copper surface area ≥300 mm^2. Three different doses of LNG-IUD are currently available in the UK containing 52 mg, 19.5 mg or 13.5 mg of levonorgestrel (LNG).

The LNG-IUDs were formerly referred to in FSRH guidelines as intrauterine systems (IUSs), but the terminology used in this guideline has been updated to align with that used by other international organisations, and LNG devices are now referred to as LNG-IUDs.

Effectiveness

Contraceptive effectiveness of IUDs is high and is not affected by enzyme-inducing drugs or weight/body mass index (BMI). However, higher BMI is associated with an increased risk of IUC expulsion[401].
The overall contraceptive failure rates are approximately 0.6%–0.8% in the first year of use for the Cu-

IUDs, 0.2% for the 52 mg LNG-IUD in the first year of use and 0.3% for the 13.5 mg and 19.5 mg LNG-IUDs during their licensed durations of use.

Duration of use

Cu-IUDs: Cu-IUDs can be used for contraception for 5 or 10 years (device dependent). If a Cu-IUD is inserted when the individual is ≥40 years old, the FSRH supports extended use of the device, and the Cu-IUD can be used for contraception until menopause. Cu-IUDs are also highly effective emergency contraception (EC) that can be retained to provide ongoing contraception.

LNG-IUDs*:** The 13.5 mg LNG-IUD can be used for 3 years, the 19.5 mg LNG-IUD can be used for 5 years and the 52 mg LNG-IUD can be used for 8 years for contraception if the user is <45 years old at the time of insertion. Individuals who have ***any 52 mg LNG-IUD inserted when they are ≥45 years old can use the device for contraception until age 55 years, after which time contraception is no longer required.

This guideline supports use of ***any*** 52 mg LNG-IUD for up to 5 years for endometrial protection in individuals using estrogen as part of hormone replacement therapy (HRT).

Assessing suitability

There are few medical conditions that contraindicate use of IUC (see UKMEC (2016)[2]) and no investigations are routinely required prior to insertion. Whilst the majority of IUD insertions will be straightforward and can be undertaken in primary care and community settings, there will be additional considerations for some individuals, for example, pre-insertion investigations, alterations to current medication dosage/timing, discussion with the individual's usual care provider or a requirement to insert the IUD in a specialist setting. Information and guidance can be found in **Section 7.1**: Suitability of IUC in specific populations.

Health risks

The available evidence suggests that there may be an association between current or recent hormonal contraception use (including LNG-IUDs) and breast cancer; however, any potential increased risk appears to be small. LNG-IUD use may be associated with an increased incidence of ovarian cysts; however, this does not appear to be clinically significant.

The risk of pregnancy (including ectopic pregnancy) is very low during use of IUC. A previous ectopic pregnancy is not a contraindication to IUC use.

Individuals considering IUC use should be made aware of the potential complications during IUD insertion, which include pelvic infection (<1%), uterine perforation (1–2 per 1000 insertions in the general population but higher in individuals who are postpartum, particularly if they are also breastfeeding – see **Section 7.1.3.1**: After childbirth) and pain/discomfort.

Side effects

***Bleeding patterns*:** IUC users often experience altered bleeding patterns. Although Cu-IUD users continue to have natural menstrual cycles, and the Cu-IUD does not affect the frequency of menses, Cu-IUD use is associated with an increase in menstrual blood loss compared with natural menstrual cycles in individuals without a Cu-IUD. Conversely, whilst the frequency of bleeding is less predictable with an LNG-IUD, LNG-IUDs are associated with a decrease in menstrual blood loss, with increasing rates of infrequent bleeding and amenorrhoea over time.

***Hormonal side effects*:** Acne, breast tenderness, headache and mood changes are reported by some individuals using LNG-IUDs; however, evidence is too limited to confirm or exclude a causative effect.

***Other side effects*:** Studies do not suggest that IUC use is associated with a negative effect on libido or that IUC use is associated with weight gain.

Timing of IUD insertion

IUC can be inserted at any time during the menstrual cycle, providing that pregnancy can be reasonably excluded – see **Box 1**: Criteria for reasonably excluding pregnancy. Recommendations for starting or switching to IUC can be found in **Table 15**: Starting intrauterine contraception and **Table 16**: Switching to intrauterine contraception from a hormonal contraceptive method.

A Cu-IUD can be used for EC if inserted within 5 days after the first episode of unprotected sexual intercourse (UPSI) that cycle, or within 5 days of the earliest expected date of ovulation.

A Cu-IUD is effective immediately following insertion. An LNG-IUD is effective 7 days after insertion.

Insertion checklist

See **Section 10.3**: Insertion checklist and **Box 2**: Intrauterine contraception pre-insertion checklist for the minimum criteria that should be met prior to insertion.

Safe insertion

Clinicians offering IUC insertion should be appropriately trained to do so. Note that the insertion technique for immediate postpartum IUC (PPIUC) insertion is different to that for standard IUC insertion. An appropriately trained assistant should be present during all intrauterine instrumentation procedures and clinicians should be familiar with the guidance in FSRH Service Standards for Resuscitation in Sexual and Reproductive Healthcare.[3]

Insertion pain

Potential IUC users should be advised that whilst most insertions are associated with mild or moderate pain or discomfort, pain can range from none to severe. Analgesia options should be discussed and offered to all individuals having IUC inserted, and an assistant should be present to support the individual during the insertion procedure and to monitor them for any signs of pain or distress. Whilst there is no one 'best' anaesthetic/analgesia option for IUD insertions, paracervical block, intracervical local anaesthetic injection, 10% lidocaine spray or a cream containing 2.5% lidocaine plus 2.5% prilocaine applied to the cervix appear to be beneficial in reducing insertion-related pain.

Aftercare advice

With the exception of IUDs inserted within 48 hours of childbirth, routine post-insertion checks are not required. However, users should be advised to self-check their threads 4–6 weeks after insertion and then at regular intervals (e.g. monthly or after menses).

When IUC is inserted within 48 hours of childbirth, an IUC check-up with a clinician 4–6 weeks after insertion is recommended as PPIUC is associated with an increased risk of expulsion and with long or non-

visible threads. See **Appendix 2**: Example pathway for postpartum intrauterine contraception (PPIUC) follow-up and **Appendix 3**: Aftercare following immediate postpartum intrauterine device (PPIUC) insertion – guidance for clinicians.

Managing complications

The management of problems associated with IUC insertion and IUC use are discussed in **Section 14: Managing problems associated with IUC.**

IUC removal

Section 15 contains links to FSRH resources that support clinicians who remove IUC. Recommendations regarding the timing of IUC removal and replacement can be found in **Table 18**: Recommendations for timing of intrauterine contraception removal/replacement. Guidance on the management of unexpected findings at IUC removal, such as a broken or incomplete device, can be found in **Section 15.3: Unexpected findings at IUC removal.**

5 What is intrauterine contraception (IUC)?

Key information

✓	**IUC methods are long-acting reversible contraceptives (LARCs) with licensed durations of use ranging between 3 and 10 years.**
✓	**There are two types of IUC available in the UK: copper intrauterine devices (Cu-IUDs) and levonorgestrel intrauterine devices (LNG-IUDs).**
C	**A Cu-IUD is a highly effective method of contraception or emergency contraception.**
C	**A 13.5 mg, 19.5 mg or 52 mg LNG-IUD is a highly effective method of contraception.**
C	**A 52 mg LNG-IUD has additional potential gynaecological benefits including management of heavy menstrual bleeding (HMB) and dysmenorrhoea.**
D	**A Cu-IUD is effective immediately following insertion.**
D	**An LNG-IUD is effective 7 days after insertion.**
D	**Pre-fertilisation effects are the main mode of action for both the Cu-IUD and the LNG-IUD.**

Clinical recommendations

✓	**Any 52 mg LNG-IUD inserted at age <45 years can be used for contraception for 8 years.**
✓	**Any 52 mg LNG-IUD inserted at age ≥45 years can be used for contraception until age 55 years.**

✓ **Any Cu-IUD with copper surface area ≥300 mm² inserted at age ≥40 years can be used for contraception until menopause. It can be removed 1 year after the final menstrual period if this occurs after age 50 years.**

✓ **Any 52 mg LNG-IUD can be used for 5 years as endometrial protection as part of hormone replacement therapy (HRT).**

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

5.1 Copper intrauterine device (Cu-IUD)

The Cu-IUDs are non-hormonal and vary in size and shape (Table 1). They consist of copper and plastic and may contain barium for radio-opacity. Some types contain a core of silver or other inert metal, which helps to maintain the integrity of the wire. In theory, this could increase the longevity of the device; however, no evidence was identified to confirm this.

In addition to regular contraception, the Cu-IUD can be used for emergency contraception (EC), if inserted within 5 days after the first episode of unprotected sexual intercourse (UPSI) that cycle, or within 5 days of the earliest expected date of ovulation. Recommendations regarding the use of the Cu-IUD as EC are covered by the FSRH Clinical Guideline Emergency Contraception.[4]

5.2 Levonorgestrel intrauterine device (LNG-IUD)

The LNG-IUD is a T-shaped device with an elastomere core containing the progestogen levonorgestrel (LNG). At the time of guideline publication there are five LNG-IUDs available in the UK: Benilexa®, Levosert®, Mirena®, Kyleena® and Jaydess® (Table 2).

The 52 mg LNG-IUD releases approximately 20 mcg LNG per day, reducing to approximately 6.5[66,398] to 7[397] mcg per day at the end of licensed use. The 19.5 mg LNG-IUD has an initial release rate of 17.5 mcg LNG per day, reducing to approximately 7.4 mcg per day after 5 years. The 13.5 mg LNG-IUD has a release rate of approximately 14 mcg per day for the first 24 days, decreasing to 5 mcg per day after 3 years.

5.3 Types of IUC

Table 1: Types of copper intrauterine device listed in the British National Formulary*

Device	Copper content (mm^2)	Uterine length (cm)	Licensed use duration (years)	Frame size (W x L) (mm)	Loading tube width (mm)
Framed, banded copper arms					
Copper T380 A®	380	6.5–9	10	31.9 x 35.9	4.75
T-Safe® 380A QL	380	6.5–9	10	31.9 x 35.9	4.75
T-Safe® 380 A	380	6.6–9	10	31.9 x 35.9	4.5
TT 380® Slimline	380	≥7	10	31.6 x 36.2	4.75
Flexi-T®+ 380	380	≥6	5	28 x 32	3.5
Mini TT380® Slimline	380	5–7	5	23.2 x 29.5	4.75
Framed, copper in stem only					
Nova-T® 380	380	6.5–9	5	32 x 32	3.6
UT380 Standard®	380	6.5–9	5	32 x 32	3.8
Neo-Safe® T380	380	6.5–9	5	31.9 x 31.8	3.7
Novaplus T 380® Cu	380	6.5–9	5	32 x 32	3.6
Novaplus T 380® Cu 'mini'	380	'Mini' size = 5	5	32 x 28.4	3.6
UT380 Short®	380	≥5	5	32 x 27	3.8
Multiload® Cu375	375	6–9	5	19.5 x 32.5	3.6
Multi-Safe® 375	375	6–9	5	19.5 x 34.8	3.6
Ancora® 375 Cu	375	≥6.5	5	20 x 35	3.8
Load® 375	375	≥7	5	19.5 x 32.5	3.6
Flexi-T® 300	300	6.6–9	5	28 x 32	3.5
Frameless					
GyneFix® 330 **GyneFix® 200**	330 200	Suitable for all uterine sizes	5	2.2 x 30	4.75
Silver IUD					
Novaplus T380® Ag	380	'Normal' size = 6.5–9 'Mini' size = 5	5	32 x 32	3.6

L, length; IUD, intrauterine device; W, width.
*See British National Formulary (BNF) (checked on 14/03/2023).

The intrauterine ball is not available in the UK at the time of guideline publication but further information is available here.[5]

Table 2 compares the product characteristics of LNG-IUD devices currently available in the UK.

Table 2: Types of levonorgestrel intrauterine device listed in the British National Formulary*

Parameter	Type of LNG-IUD				
	Benilexa®	Levosert®	Mirena®	Kyleena®	Jaydess®
Total LNG content (mg)	52	52	52	19.5	13.5
LNG release rate (mcg/24 h) **Initial** **At end of licensed use**	 20.1 6.5	 20.1 6.5	 20 7.0	 17.5 7.4	 14 5.0
Frame size (W x L, mm)	32 x 32	32 x 32	32 x 32	28 x 30	28 x 30
Inserter	One-handed inserter	Two-handed inserter	One-handed EvoInserter™	One-handed EvoInserter™	One-handed EvoInserter™
Insertion tube diameter (mm)	4.8	4.8	4.4	3.8	3.8
Silver ring for improved visibility on USS?	No	No	No	Yes	Yes
Colour of threads	Blue	Blue	Brown	Blue	Brown
Recommended duration of use for contraception (years)	8	8	8	5	3
Licensed duration of use for contraception (years)	8	8	8	5	3
Recommended duration of use for endometrial protection as part of HRT (years)‡	5	5	5	Not recommended	Not recommended
Licensed for endometrial protection?	No	No	Yes	No	No
Licensed for HMB?	Yes	Yes	Yes	No	No
Minimum uterine cavity length (cm)	5.5	5.5	Not indicated in SPC	Not indicated in SPC	Not indicated in SPC

HMB, heavy menstrual bleeding; HRT, hormone replacement therapy; L, length; LNG, levonorgestrel; LNG-IUD, levonorgestrel intrauterine device; SPC, Summary of Product Characteristics; USS, ultrasound scan; W, width.

*See British National Formulary (BNF) (checked on 14/03/2023).

‡The FSRH supports use of any 52 mg LNG-IUD for 5 years for endometrial protection as part of HRT.

5.4 Duration of use

The Cu-IUDs currently available in the UK are licensed for either 5 or 10 years of use. The FSRH supports extended use of the Cu-IUD when inserted at age 40 years or over. A Cu-IUD containing ≥300 mm^2 copper inserted at or after age 40 years can be used for contraception until menopause. Menopause can be diagnosed 1 year after the final menstrual period if this occurs when the individual is age 50 years or older.[6]

At the time of writing, Levosert, Benilexa and Mirena are licensed for contraception for 8 years, Kyleena 19.5 mg LNG-IUD for 5 years, and Jaydess 13.5 mg LNG-IUD for 3 years.

In line with established FSRH guidance, the GDG recommends that any 52 mg LNG-IUD inserted at age ≥45 years can be used for contraception until age 55 years.[6] There are no available data to support extension of use of 19.5 mg or 13.5 mg LNG-IUDs, even if inserted at an older age.

The evidence: contraceptive effectiveness of IUC during extended use

Evidence level 2+

Evidence regarding Cu-IUD use beyond the licensed duration is very limited given the ubiquity of these devices. However, a well-conducted systematic review[7] identified 'good to fair' evidence from two studies with a combined total of 473 subjects using the TCu380A beyond its licensed 10 years (total 670.5 person-years). The authors reported that the effectiveness of the TCu380A in years 10–12 was comparable to that in year 1 (overall pregnancy rate for years 11 and 12 was 0.0 per 100 person-years (95% confidence interval (CI) 0.0–0.8)). However, nulliparous individuals were excluded from the studies identified and there are minimal data regarding extended use of the TCu380A in younger individuals (one of the studies only included participants aged over 35 years).

The FSRH Clinical Effectiveness Unit (CEU) already supported individuals aged over 45 years at the time of insertion to use Mirena for contraception until age 55 years.[6] Very limited evidence is available for use of LNG-IUDs beyond the 8 years of licensed use. The ACCESS IUS study, which included 1714 women at baseline using Liletta (known as Benilexa in the UK), reported that no pregnancies occurred among 83 women who completed year nine or among 77 women who completed year 10 of the study[399]. **The FSRH do not recommend using the 52mg LNG-IUD beyond 8 years.**

5.5 Non-contraceptive use

5.5.1 Endometrial protection

Mirena is also licensed for use for endometrial protection as part of HRT. It is licensed for this indication for 4 years, but the FSRH supports its use for 5 years, in line with previous FSRH guidance.[6] Although Mirena is the only LNG-IUD licensed for endometrial protection, the GDG supports the use of any 52 mg LNG-IUD for up to 5 years as endometrial protection as part of HRT. This recommendation is supported by the Royal College of Obstetricians and Gynaecologists and the British Menopause Society (personal communications, August 2022). The 52 mg LNG-IUD can be used in the management of other gynaecological conditions, including polycystic ovary syndrome and treatment of endometrial hyperplasia.[15]

5.5.2 Heavy menstrual bleeding

The 52 mg LNG-IUD is effective for the management of heavy menstrual bleeding (HMB).[16–21] Studies use varied ways of assessing,[22] defining and reporting HMB, making it difficult to collate evidence from different studies, but the majority of the reduction in menstrual blood loss appears to be achieved in the first 3 months.[16,17,19] One well-conducted randomised controlled trial (RCT) (LNG-IUD n = 132 individuals with HMB) reported reductions in bleeding from baseline of up to 90%.[16] A prospective cohort study (n = 150) found similarly positive results with HMB no longer reported in 92.1% of subjects at 6 months.[17]

Limited evidence suggests that the 52 mg LNG-IUD achieves significant reduction in menstrual blood loss in individuals with fibroids. There have been very few studies regarding effectiveness of the 52 mg LNG-IUD for management of HMB in individuals with other underlying causes of HMB (e.g. bleeding disorder or anticoagulant use); however, clinical experience and the limited available evidence suggests the LNG-IUD may be beneficial in these groups.[23,24]

Evidence level 2+

No studies were found that reported on the use of 19.5 mg and 13.5 mg LNG-IUD for management of HMB.

Compared with other medical management options for HMB (norethisterone acetate, medroxy-progesterone acetate, oral contraceptive pill, mefenamic acid, tranexamic acid), the 52 mg LNG-IUD is significantly more likely to be effective, with fewer study subjects withdrawing from treatment with the LNG-IUD than with other medical management options.[18] The National Institute for Health and Care Excellence (NICE) recommends 52 mg LNG-IUD for management of HMB if there is no identified underlying pathology, or in the presence of fibroids if they are <3 cm and not causing distortion of the uterine cavity, or if there is suspected or diagnosed adenomyosis.[25]

Evidence level 2-

Evidence comparing effectiveness of the LNG-IUD to endometrial ablation/resection for management of HMB is not consistent, but it is likely that bleeding, satisfaction and quality of life outcomes are similar.

Use of the 52 mg LNG-IUD for management of HMB may be more cost effective than either endometrial ablation/resection or hysterectomy.[18]

The evidence: LNG-IUD versus other medical therapies

A 2020 Cochrane systematic review[18] concluded that the 52 mg LNG-IUD may improve HMB and quality of life relative to other medical therapies. LNG-IUD users and those receiving other medical therapies (norethisterone acetate, medroxyprogesterone acetate, oral contraceptive pill, mefenamic acid, tranexamic acid) experienced similar numbers of serious adverse events (relative risk (RR) 0.91, 95% CI 0.63–1.30; 1 study, 571 individuals; moderate-certainty). However, individuals using the LNG-IUD were less likely to experience treatment failure (RR 0.34, 95% CI 0.26–0.44; 6 studies, 535 individuals; moderate-certainty) and to withdraw from treatment (RR 0.49, 95% CI 0.39–0.60; 1 study, 571 individuals, moderate-certainty).

Evidence level 1-

The evidence: LNG-IUD versus endometrial ablation/resection

The performance of the LNG-IUD relative to endometrial ablation/resection is uncertain but likely similar across bleeding, satisfaction and quality of life outcomes.[18,26] Adverse events appear to be more common in LNG-IUD users, although this does not appear to lead to greater discontinuation.[18] A 2020 Cochrane review found treatment failure (RR 1.78, 95% CI 1.09–2.90; 5 studies, 320 individuals; low-certainty) and need for hysterectomy at 1 year (RR 2.56, 95% CI 1.48–4.42; 3 studies, 400 individuals; low-certainty) might be more common with the LNG-IUD than with endometrial ablation/resection.[18] However, the evidence was mixed, and another review found no difference in treatment failure (12.5% vs 20.9%, p = 0.15) or hysterectomy risk (RR 1.13, 95% CI 0.60–2.11, p = 0.71; 12 studies, 726 individuals)[26]. This latter review did, however, report a greater risk of hysterectomy for subjects aged 42 years or under with HMB managed by endometrial ablation/resection than those managed by LNG-IUD (RR 5.26, 95% CI 1.21–22.91, p = 0.03; 3 studies, 189 individuals).

Evidence level 1-

The LNG-IUD may have lower overall costs than either hysterectomy or endometrial ablation/resection.[18]

The evidence: LNG-IUD device type

To date only 52 mg devices have been studied for management of HMB.[18] One single-blind RCT (n = 280) found no difference in reduction in menstrual blood loss over 12 months between Mirena and Levosert.[19]

Evidence level 1-

The evidence: LNG-IUD and HMB associated with fibroids

A 2020 Cochrane review found only two small RCTs relating to LNG-IUD use in HMB caused by fibroids and concluded there was a lack of evidence to assess the performance of the LNG-IUD relative to combined oral contraception (COC) or norethisterone acetate in the reduction of HMB.[27]

Evidence level 1-

A 2014 systematic review of LNG-IUD use by individuals with fibroids identified six observational studies and found "menstrual blood loss was reduced by 50.0%–91.0% at 6 months (4 studies) and by 69.0%– 97.40% at 12 months (5 studies)".[28] One of the studies found the reductions in menstrual blood loss were similar between LNG-IUD users with fibroid-related HMB and idiopathic HMB (n = 104).[29] However, two of the six observational studies included individuals without HMB and overall the quality of the evidence was low.

Evidence level 2+

5.5.3 Dysmenorrhoea

Dysmenorrhoea can be primary (no underlying pathology) or secondary (due to e.g. fibroids, endometriosis, infection). The most common cause of secondary dysmenorrhoea is endometriosis, which affects 2%–10% of the general female population but up to 50% of individuals with subfertility.[30] Dysmenorrhoea can have a significant effect on an individual's quality of life. The 52 mg LNG-IUD has been shown to reduce pain associated with primary dysmenorrhoea or secondary dysmenorrhoea due to endometriosis or adenomyosis.[30] The 52 mg LNG-IUD is a recommended treatment option for pain associated with endometriosis in individuals who are not trying to conceive.[30] There are no published studies to inform whether lower dose LNG-IUDs have any effect on dysmenorrhoea.

Evidence level 2+

5.6 Mode of action

Both pre- and post-fertilisation effects contribute to the contraceptive action of IUC.[31,32] 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 are the main mode of action for both Cu-IUDs and LNG-IUDs.[31]

Evidence level 2-

A Cu-IUD is effective immediately following insertion. The main mode of action of a Cu-IUD is inhibition of fertilisation through the effect of copper on the ovum and sperm, but copper in the cervical mucus also inhibits the passage of sperm into the upper reproductive tract.[33–35] The Cu-IUD also causes an inflammatory response within the endometrium, which could impair implantation.

An LNG-IUD is effective for contraception 7 days after insertion. Progestogenic effects on cervical mucus prevent the passage of sperm into the upper reproductive tract,[36–38] whilst the effect on the endometrium may inhibit implantation.[32,39] In some individuals the LNG-IUD will also inhibit ovulation. A foreign body effect may also contribute,[40] as has been observed with other intrauterine methods.[35,41]

Within 1 month of insertion, high intrauterine concentrations of LNG induce endometrial atrophy,[40–44] and additional alterations within the endometrium (changes in the intercellular junctions between the endometrial epithelial and stromal cells)[39] and an increase in endometrial phagocytic cells[39,43,45] may also contribute to the contraceptive effect.

Progestogenic effects of the LNG-IUD on cervical mucus have been demonstrated[36–38] but it is not fully understood how quickly such changes are established. In a small descriptive study,[46] cervical mucus remained penetrable by sperm for up to 5 days after mid-cycle insertion of a 52 mg LNG-IUD.

The LNG-IUD has little effect on the hypothalamic-pituitary-ovarian axis,[47] serum estradiol concentrations are not reduced[47] and the majority (>75%) of individuals continue to ovulate.[48–50] The incidence of anovulation is lower with the 13.5 mg LNG-IUD than with the 52 mg LNG-IUD, with data from a small clinical trial reporting that in years 1, 2 and 3, respectively, 97.1% (34/35), 96.2% (25/26) and 100% (26/26) of 13.5 mg LNG-IUD users ovulated; 88.5% (23/26), 95% (19/20) and 100% (16/16) of 19 mg LNG-IUD users ovulated; and 76.5% (13/17), 85% (11/13) and 98% (52/53) of 52 mg LNG-IUD users ovulated.[48]

Evidence level 1-

Evidence level 1-

The effects on the endometrium and cervical mucus are similar for 13.5 mg, 19.5 mg and 52 mg LNG-IUDs.[48]

6 How effective is IUC?

Key information

C **The contraceptive failure rate for a Cu-IUD in the first year of use has been estimated at 0.8% (typical use) and 0.6% (perfect use).**

C **The contraceptive failure rate for a 52 mg LNG-IUD in the first year of use has been estimated at 0.2% for both typical and perfect use. Studies suggest that contraceptive failure during licensed use is around 0.3% for the 19.5 mg and 13.5 mg LNG IUD devices.**

6.1 Cu-IUD

Contraceptive effectiveness of Cu-IUDs is high, and effectiveness is not affected by enzyme-inducing drugs or weight/BMI. However, higher BMI is associated with an increased risk of IUC expulsion[401]. The overall failure rates in the first year of use have been estimated at 0.8% (typical use) and 0.6% (perfect use),[51] though failure rates may differ between devices.

Studies of framed Cu-IUDs with copper surface area >300 mm^2 report typical cumulative pregnancy rates of 0.1%–1.1% at the end of the first year of use.[8,52–54] Cumulative pregnancy rates for these devices remain low in later years of use.[8,53] First-year cumulative pregnancy rates may be slightly higher for devices with copper surface areas <300 mm^2 – a Cochrane review suggests 0.5% to 2.2%[53] – however, at time of publication there were no Cu-IUDs available in the UK with copper surface areas <300 mm^2.

Evidence level 1-

A Cochrane review and meta-analysis suggests a (non-significant) trend towards higher pregnancy rates with the unframed GyneFix® than with the T-Cu380A at 1 and 3 years.[55]

In contrast to findings described earlier, an article[56] re-evaluating the 1-year data from the European Active Surveillance Study for Intrauterine Devices (EURAS-IUD) cohort study[52] identified no significant differences between different types of Cu-IUD for pregnancy rates at 1 year among users aged under 30 years.

Evidence level 2-

The evidence

With regard to comparative effectiveness of framed devices that have different copper surface areas, a Cochrane systematic review of RCTs[53] found cumulative pregnancy rates at the end of the first year of use varying between 0.1% and 1.0% for devices with a copper surface area >300 mm^2 compared with 0.5% to 2.2% for devices with a lower copper surface area. Pregnancy rates were found to be lowest for the T-shaped devices TCu380A and TCu380S, which have a copper surface area of 380 mm^2 with copper bracelets on the arms in addition to the coiled copper wire on the stem. As the authors of the review note, these devices also have the longest duration of licensed use, thus reducing frequency of replacement and the associated risks. For the TCu380A, the Cochrane review reported a cumulative pregnancy rate of 2.2% at 12 years. This study drew on 35 RCTs making 18 comparisons of 10 different IUDs in approximately 48 000 individuals, making it the most robustly evidenced comparison of different Cu-IUDs identified.

Evidence level 1+

Evidence level 1+

A subsequent large RCT comparing effectiveness and safety of the TCu380A Cu-IUD and a 52 mg LNG-IUD reported a cumulative pregnancy rate at 7 years for the Cu-IUD of 2.45 per 100 users.[8]

Evidence level 1+

Comparing contraceptive effectiveness of the frameless Cu-IUD (GyneFix) with framed devices, a meta- analysis carried out as part of a 2005 Cochrane systematic review[55] (4

RCTs; n = 5939; 23 180 years of use) suggested a tendency towards higher pregnancy rates with the frameless device than the TCu380A at 1 and 3 years, but the difference was not statistically significant (RR of pregnancy for frameless vs T-framed 1.79, 95% CI 0.81–3.95 at 1 year and 1.34, 95% CI 0.85–2.10 at 3 years). The large World Health Organization (WHO) trial included reported cumulative data at 2–6 years (i.e. distant from insertion), indicating a 1.2% pregnancy rate with the frameless device and 2.3% with TCu380A (RR 0.53, 95% CI 0.32–0.91).

A 2021 secondary reanalysis of the EURAS data focused on subjects aged under 30 years at the time of Cu-IUD insertion (n = 5796).[56] This article classified 41 different Cu-IUDs by their copper content, design and size, and compared pregnancy rates across these different elements at 12 months. The study found no statistical difference in pregnancy rates by copper content, width, flexibility of the arms or IUD shape (T with arm bands/T without arm bands/frameless/horseshoe). They did, however, find differences in bleeding, pain, expulsion and continuation rates between devices with different copper loads and with different frame design, size and flexibility. Whilst this was an international study, almost half of the data came from the UK, meaning key relevant devices were included. However, as an observational study there may be confounding relating to the types of Cu-IUD that were recommended to and selected by individuals and the availability of data did vary significantly between devices; for instance, only 92 frameless device users were included compared with over 4000 T-shaped device users.

Evidence level 2-

Few studies compare a copper/silver IUD to a currently available copper-only device (some studies compare to LNG-IUD or to Multiload devices). An Indian study,[57] which randomised 600 subjects to receive either a TCu380Ag IUD or a TCu380 IUD, reported significantly higher continuation rates at 1 year for the silver-containing device (84% vs 76%) with fewer adverse events resulting in discontinuation in the silver/copper group. The pregnancy rate was slightly higher in the copper/silver group, but the difference was not significant. There are no robust data that directly compare contraceptive effectiveness of silver/copper and copper IUDs but reported pregnancy rates for silver/copper devices are consistent with those of other copper devices.

Evidence level 1-

6.2 LNG-IUD

There is a substantial body of evidence indicating high contraceptive effectiveness of LNG-IUD devices, with the overall typical and perfect use failure rate estimated at 0.2%.[51] Comparative studies generally indicate that the 52 mg LNG-IUD is even more effective than Cu-IUDs,[8,52] though in some studies the observed differences in effectiveness are not statistically significant.[58]

Pearl Indices (number of pregnancies per 100 users) for the different devices are generally reported as:

- 0.1–0.2 for devices with larger LNG reservoirs like the 52 mg LNG-IUD over 5–7 years[8,59–61], with PI of 0.0 to 0.4 reported in years 7 and 8 of use[13,400].
- 0.3 for 19.5 mg over 3–5 years[62,63]
- 0.3 for 13.5 mg over 3 years.[62,64]

It is considered that the contraceptive effectiveness of LNG-IUD devices with their local action on endometrium and cervical mucus is not affected by use of enzyme-inducing drugs. Contraceptive effectiveness of LNG-IUD devices is unaffected by weight/BMI.[65] However, a large cohort study has shown that there is an increased risk of LNG-IUD expulsion in individuals with a BMI over 25. This risk increases further as BMI increases.[401]

The evidence: contraceptive effectiveness of LNG-IUDs within licensed duration of use

Early data came from two large RCTs commenced in the 1980s. The first randomised parous individuals aged 18–38 years to either the LNG-IUD 20 (n = 1125) or the TCu380Ag IUD (n = 1121).[59] After 7 years of follow-up, they reported a PI of 0.18 ± 0.07 for the LNG-IUD 20 (3371 woman-years) and 0.27 ± 0.08 for the TCu380Ag IUD. These results were echoed by a second large RCT where healthy individuals aged 18–38 years with at least one previous pregnancy were randomised to either a Nova T® (n = 937) or the LNG-IUD 20 (n = 1821).[60] Again, the LNG-IUD 20 was highly effective with a PI of 0.09 after 5 years of use (5615 woman-years). The cumulative gross 5-year pregnancy rate for the LNG-IUD 20 was 0.5/100 individuals, significantly better than the Nova T (5.9/100 individuals).

Evidence level 1+

It should be noted that at 46 mg[59,60] and 60 mg[59] the LNG reservoirs in these studies were different from those in use in the UK today. However, both were reported to have the same 20 mcg/day initial release rate as current 52 mg devices.[66,67] Moreover, an RCT from the 1990s conducted predominantly in China did evaluate a modern 52 mg LNG-IUD, randomising 3386 parous individuals aged 16–39 years to either Mirena or a TCU380A.[8] By the end of the seventh year, they found Mirena had a cumulative pregnancy rate similar to those described earlier (0.53/100 users). A recent single-arm trial of another 52 mg device (Levosert) included 1568 users in the US aged 16–35 years and reported a 5-year PI of 0.20 (95% CI 0.09–0.37) in line with the other large-reservoir IUDs.[61]

Evidence for up to 8 years of use comes from two large trials (the Mirena Extension Trial[13] and ACCESS IUS[400]) and several smaller studies[8–12] A systematic review from 2020[7] found four good-to-poor-quality studies of the 52 mg LNG-IUD, with a total of 2098 users starting extended use. The pooled Pearl Index (PI; pregnancies per 100 woman-years) was 0.02 (95% CI 0.00–0.45) in year 6, 0.03 (95% CI 0.00–0.71) in year 7 and 0.02 (95% CI 0.00–0.29) in years 6 and 7 combined. The Mirena Extension Trial was a more recent, single-arm, phase III trial that assessed contraceptive effectiveness in years 6–8 of Mirena use and found low failure rates – PIs per 100 woman-years were 0.34 (95% CI 0.01–1.88) in year 6, 0.40 (95% CI 0.01–2.25) in year 7 and 0.00 (95% CI 0.00–1.90) in year 8, however numbers were small with only 223 individuals completing 8 years of use.[13] Beyond the initial six years of the ACCESS IUS trial, there was one pregnancy in year seven (PI 0.25, 95% CI 0.01 – 1.37) and no pregnancies in year eight (PI 0.00, 95% CI 0.00 – 1.31)[400]. The overall cumulative pregnancy rate over eight years was found to be 1.09% (95% CI 0.56 – 2.13) [400] when using the European Medicines Agency (EMA) criteria of conceptions within IUS use or within two days of discontinuation.

Evidence level 1+

Smaller non-randomised trials also support the 52 mg LNG-IUD's high contraceptive effectiveness,[68,69] as does real-world evidence from observational studies.[70–74] Two large retrospective cohort studies of US electronic healthcare records, each examining over 90 000 women and adolescents, compared Mirena with other LARCs in the first year of use and

Evidence level 2-

found pregnancy rates for Mirena of 1.1%–2.0%.[75,76] Whilst the LNG-IUD had a lower risk of uncomplicated pregnancy than the Cu-IUD (hazard ratio (HR) 0.80, 95% CI 0.74–0.86),[75] the etonogestrel (ENG) implant had either the same (or in the case of 15–19-year-olds better) effectiveness than the LNG-IUD.[76] The 2015 EURAS[52] was a multinational prospective cohort study that followed users aged 18–50 years for 12 months (52 mg LNG-IUD n = 41 001, Cu-IUD n = 17 323). It too found high effectiveness with a PI for the LNG-IUD of 0.06 (95% CI 0.04–0.09) and a crude pregnancy risk ratio for LNG-IUD versus Cu-IUD of 0.11 (95% CI 0.07–0.17).

Evidence level 2-

Whilst they have large sample sizes, the aforementioned 12-month studies do not reflect LNG-IUD discontinuation throughout the licensed duration. A prospective cohort study from the US[77] examined 52 mg LNG-IUD effectiveness over 3 years in terms of the method 'as-used' but also based on 'intent to use' (i.e. LNG-IUD was the method chosen at enrolment but not necessarily retained for 3 years). The 'as-used' analysis reported a PI of 0.2 for the LNG-IUD (8534 person-years). The 'intent-to-use' data, whilst still showing very high effectiveness, had a PI of 1.9 (5472 person-years). Adjusted hazard ratios (aHRs) for the 'intent-to-use' versus the 'as-used' analysis also reflected the reality that people switched and discontinued the LNG-IUD. For instance, relative to the LNG-IUD all methods except the implant had a higher risk of pregnancy according to the 'as-used' analysis: aHRs: Cu-IUD 3.1 (95% CI 1.5–6.2), injectable 4.5 (2.5–8.2), oral 28.0 (17.3–45.4), patch 22.8 (12.7–41.0) and ring 31.3 (19.1–51.3). However, these advantages diminished as people re-evaluated their initial choice of the LNG-IUD. The 'intent-to-use' aHRs for pregnancy risk demonstrate no benefit in terms of pregnancy risk of the LNG-IUD over the Cu-IUD or implant and reduced pregnancy aHRs for the LNG-IUD compared with the injectable (aHR 2.4, 95% CI 1.8–3.3), oral contraceptives (aHR 3.6, 95% CI 2.7–4.7), patch (aHR 4.1, 95% CI 2.7–6.2) and ring (aHR 3.3, 95% CI 2.4–4.5).

As well as the 52 mg LNG-IUDs, devices with LNG reservoirs of 19.5 mg (Kyleena) and 13.5 mg (Jaydess) are available in the UK. A multicentre RCT randomised 2885 individuals aged 18–35 years to either a 13.5 mg or 19.5 mg LNG-IUD.[62] The 13.5 mg device had a cumulative 3-year PI of 0.33 (95% CI 0.16–0.60) (3059 woman-years), whilst the 19.5 mg device had a PI of 0.31 (95% CI 0.15–0.57) (3211 woman-years). Effectiveness was unaffected by age, parity or BMI.[78] A smaller, single-blind, multicentre RCT randomised individuals aged 21–40 years to either Mirena (n = 254), a 19.5 mg LNG-IUD (n = 245) or a 13.5 mg LNG-IUD (n = 239). It found PIs of 0 (95% CI 0–0.59) for Mirena, 0.82 (95% CI 0.27–1.92) for the 19.5 mg device and 0.17 (95% CI 0.00–0.93) for the 13.5 mg device.[79] A primary outcome of both trials was to determine the PI, although neither trial was designed to compare effectiveness between devices.

Evidence level 1+

A 2-year extension study of the 19.5 mg LNG-IUD reported a cumulative 5-year PI of 0.29 (95% CI 0.16– 0.50) (4435 woman-years relevant exposure).[63] Other smaller trials of the 13.5 mg LNG-IUD have also been conducted, including in adolescents,[80] and all indicate high contraceptive effectiveness over 12–36 months of use.[64,81,82]

Literature reviews of LNG-IUD effectiveness tend to be older[58,83] or focus on subpopulations such as nulliparous[84] or young people.[85,86] However, all agree that the available evidence indicates the LNG-IUD

devices available in the UK are safe and highly effective contraceptives within their licensed durations.

The evidence: contraceptive effectiveness of LNG-IUDs versus Cu-IUDs

A 2004 Cochrane systematic review[58] found insufficient evidence to demonstrate a significant difference in pregnancy rates between large-reservoir LNG-IUD users and those with IUDs containing >250 mm^2 copper. Drawing on a single large RCT[87] (n = 2246), the review found no significant difference in pregnancy rates at 1 or 5 years' use (LNG-IUD 20 vs CuT380Ag, RR 1.01 (95% CI 0.71–5.82) and RR 0.66 (95% CI 0.25–1.75), respectively).

This contrasts, however, with the findings of a subsequent international multicentre RCT by Rowe *et al* (n = 3386) which found the cumulative 7-year pregnancy rate of the 52 mg LNG-IUD to be significantly lower than the TCu380A (0.53 per 100 vs 2.54 per 100 users).[8]

Evidence level 1+

Supporting the trial data from Rowe *et al,*[8] real-world evidence from the prospective cohort EURAS-IUD study also reported slightly higher contraceptive effectiveness for the LNG-IUD than the Cu-IUD.[52] The study followed 61 448 users over 12 months and reported an overall PI of 0.06 (95% CI 0.04– 0.09) in the LNG-IUD cohort and 0.52 (95% CI 0.42–0.64) in the Cu-IUD users. As an observational study the results of EURAS-IUD are susceptible to confounding, and there was a markedly different age distribution between the cohorts in the study (LNG-IUD users were significantly older). However, even when stratified for age, the LNG-IUD remained superior at all ages, except for subjects aged between 40 and 50 years. When adjusted for age, BMI and parity the aHR was 0.16 (95% CI 0.10–0.25) for LNG-IUD versus Cu-IUD.

Two large retrospective cohort studies based on insurance claims data in the US also suggest the Cu-IUD is highly effective, but potentially less so than the LNG-IUD. A Californian study[88] based on Medicaid claims data from over 80 000 individuals compared pregnancy rates 12 months after either tubal ligation, insertion of a Cu-IUD or insertion of an LNG-IUD. After adjusting for measures including age, race and baseline health, the LNG-IUD was associated with a lower rate of pregnancy than tubal ligation (adjusted incident rate ratio (aIRR) 0.72, 95% CI 0.64–0.82) whilst pregnancy rates were similar with the Cu-IUD and tubal ligation (aIRR 0.92, 95% CI 0.82–1.05). The second retrospective cohort study included over 90 000 individuals who had either an LNG-IUD or a Cu-IUD inserted.[75] Risk of method failure was lower with the LNG-IUD than the Cu-IUD (risk of normal intrauterine pregnancy (an International Classification of Diseases Ninth Revision (ICD-9) definition): LNG-IUD vs Cu-IUD 0.80, 95% CI 0.74–0.86). This study also stratified pregnancy risk by age; normal intrauterine pregnancy rates over 12 months with the Cu-IUD ranged from 3.6% for 15–19-year-olds to 1.3% for 25–44-year-olds.[75] Whilst this study methodology offers a large sample size and both studies attempted to adjust for confounders, there are inherent limitations to a retrospective cohort study based on claims data. For instance, pregnancies, expulsions and device removals will have been missed if no associated claims were filed with the relevant insurer.

Evidence level 2-

7 Assessing suitability

Few medical conditions contraindicate insertion or use of IUC. UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2] provides evidence-based recommendations on the use of contraceptive methods in the presence of different medical and social factors, and health professionals should ensure they are familiar with or refer to the most up-to-date version of this publication when assessing an individual's eligibility to use intrauterine methods (refer to UKMEC (2016)[2]). Each of the personal characteristics or medical conditions considered by the UKMEC is assigned to one of four categories as defined in **Table 3**. UKMEC categories apply only to contraceptive use and are not necessarily applicable when use is solely for medical indications such as HMB.

Table 3: Definition of categories for the UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2]

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

In addition to UKMEC recommendations, further guidance is given in this section for selected populations.

7.1 Suitability of IUC in specific populations

7.1.1 Young people, individuals who have never been pregnant and individuals who have never been sexually active

Key information

D **IUC can be used by young people, individuals who have never been pregnant and individuals who have never been sexually active.**

Young age and nulliparity are not contraindications to IUC use (**Table 4**).[2,89,90] Although historically some clinicians have been less confident in recommending IUC for adolescents and those who have never been pregnant,[91,92] evidence and experience suggest that IUC is safe, effective and acceptable for individuals in these populations.[56,80,93–96] From the very limited available evidence, IUC insertion could be more technically challenging in individuals who have never been sexually active, but appears to be well tolerated.[97]

Table 4: UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2] categories for the use of intrauterine contraception for age and parity

Condition	UKMEC category for Cu-IUD	UKMEC category for LNG-IUD
Age (years)	Menarche to <20 = 2 ≥20 = 1	Menarche to <20 = 2 ≥20 = 1
Parity		
a) Nulliparous	1	1
b) Parous	1	1

Cu-IUD, copper intrauterine device; LNG-IUD, levonorgestrel intrauterine device; UKMEC, UK Medical Eligibility Criteria for Contraceptive Use.
See **Table 3** for definition of UKMEC categories.

The evidence

A 2021 systematic review presented the published literature on the safety and effectiveness of IUC in adolescents and nulligravidas.[93] It concluded that IUC is safe for adolescents and nulligravidas, with no increased rate of adverse effects or pregnancy when compared with young adults and parous individuals. The review found an increased risk of expulsion among adolescents, but not nulligravidas, and increased rates of difficult or painful IUC insertions in adolescents and nulligravidas compared with adult and parous individuals.

Evidence level 1+

A 2017 systematic review of the literature pertaining to continuation of LARC in <25-year-olds concluded that adolescents and young people (whether parous or nulliparous) have high continuation rates with LARC methods.[94] This pooled analysis of 4131 IUC users reported a continuation rate of 74.0% (95% CI 61.0–87.0) at 12 months post-insertion. Looking specifically at younger individuals using a 13.5 mg LNG-IUD, a multicentre trial of 304 12–17-year-olds reported an 83.2% continuation rate at 12 months.[80]

A 2021 secondary reanalysis[56] of the EURAS data focused on individuals aged 18–30 years at the time of Cu-IUD insertion (n = 5796). The majority of users were aged 20–29 years: 323 (5.6%) individuals aged 18–19 years, 2008 (34.6%) aged 20–24 years and 3465 (59.8%) aged 25–29 years. The authors concluded that in individuals under 30 years, unwanted effects (a composite measure including multiple outcomes such as pregnancy, worse bleeding, pain, having to visit an HCP and expulsion) were lowest for IUDs with <300 mm^2 of copper, of horseshoe design and width 18–<24 mm. Meanwhile, users of IUDs that had 380 mm^2 of copper, 'gold standard' IUDs and frameless IUDs were more likely to report unwanted effects. Further research is required to support future recommendations regarding choice of Cu-IUD type for different user groups.

Evidence level 2-

A 2022 systematic review by Akintomide *et al* was the first to explore continuation rates of different IUC types in young, nulliparous individuals.[95] Whilst they identified 19 good quality, relevant studies, the review found only three involving nulliparous individuals aged <30 years using an IUC currently available in the UK. The remainder of the studies were of IUC types currently available in the UK used by nulliparous users of all ages (n = 5) or IUC types comparable to those available in the UK used by nulliparous users of all ages (n = 11). The review findings suggested that the highest continuation rates in this particular population were in users of Cu-IUDs with smaller frame size. However, due to a paucity of

Evidence level 1-

Evidence level 1-

studies with young, nulliparous IUC users and significant heterogeneity of the studies, further studies are required to better estimate continuation rates for different IUC types in young, nulliparous IUC users.

Similarly, a 2022 interim analysis of a 3-year, phase III single (participant) blind, randomised multicentre trial in the US randomised nulliparous subjects aged 17–40 years to either an NT380-Mini (n = 744) or a TCu380A (n = 183) Cu-IUD and compared first-year continuation rates and reasons for early removal[96]. They found that the smaller device (NT380-Mini) had higher 12-month continuation rates (78.7%, 95% CI 72.9−84.5 vs 70.2%, 95% CI 59.7−80.7, p = 0.014) and lower rates of removal for bleeding and/or pain (8.1% vs 16.2%, p = 0.003). Whilst this suggests that bleeding, pain and continuation rates may vary between devices, it is not possible to conclude that the differences were attributed only to the size of the devices (as there were other differences between the devices) or that these findings were specific to nulliparous individuals.

There is very limited published literature relating to IUC insertion in individuals who have never been sexually active. A 2018 retrospective chart review[97] of 10–20-year-olds attending a US health facility for IUC insertion identified 82 IUC users who had never been sexually active (defined as never having had consensual vaginal intercourse) that had a Mirena inserted. Just over half of insertions were undertaken in an office setting (52.4%), where the only analgesia options were paracetamol or ibuprofen. The remaining insertions were undertaken either as an outpatient with sedation (lorazepam, 23.2%) or under general anaesthetic (24.4%). When compared with sexually active individuals in the same study, never sexually active adolescents were less likely to have IUD insertion performed in the office setting (52.4% vs 94.5%, p<0.001). However, they were also younger at insertion (15.6 vs 16.7 years, p<0.001), more likely to have at least one medical problem (75.6% vs 54.7%, p = 0.046), and to have special needs (23.2% vs 4.7%, p<0.001) when compared with the sexually active group, all of which may be confounding factors. Almost all IUC insertions were successful within two attempts (98.7%), with 90% being successful on the first attempt. Across all clinical settings, there was no significant difference (never sexually active vs sexually active) in the success of IUC insertion on the first attempt (90.2% vs 96.1%, p = 0.086). However, looking only at the office insertions, never sexually active adolescents were more likely to have an unsuccessful IUD insertion (16.3% vs 4.3%, p = 0.015). In almost all cases, the procedure was reported as being well tolerated, although tolerability was lower in the never sexually active group compared with the sexually active group (81.7% vs 93.8%, p = 0.006 in all settings; 81.4% vs 93.4%, p = 0.034 in office settings). Follow-up, complications and continuation rates were not included in this study.

Evidence level 2-

7.1.2 Transgender and gender-diverse individuals assigned female at birth (TGD-AFB)

The medical indications and contraindications for IUC are the same for transgender and gender-diverse individuals assigned female at birth (TGD-AFB) and cis-gender women. The Cu-IUD may appeal to TGD-AFB individuals who wish to avoid hormones, whilst the LNG-IUD may be advantageous for individuals who desire menstrual suppression.

As pelvic cramping and bleeding can exacerbate gender dysphoria, clinicians should ensure adequate pre-procedure counselling is offered, to improve tolerability and inform individuals of expected side effects and their duration.[98,99] In addition, clinicians should be aware that TGD individuals experience varying

levels of dysphoria with their anatomy, and genital examination during IUC procedures may cause additional physical or emotional discomfort.

Some TGD-AFB individuals will use testosterone therapy. As testosterone can be associated with teratogenicity and is contraindicated in pregnancy,[100] effective contraception is recommended for TGD-AFB individuals who are using testosterone therapy and engaging in sex where there is a risk of pregnancy. Testosterone treatment does not provide effective contraception, even if the individual is amenorrhoeic.[101] Testosterone can cause vaginal atrophy and dryness, which may add to the physical discomfort of examination. Pre-procedure treatment with local vaginal estrogen for 2 weeks prior to IUC insertion can be considered to ease physical discomfort.[101]

Further information can be found in the FSRH CEU Statement Contraceptive Choices and Sexual Health for Transgender and Non-binary People.[102]

7.1.3 After pregnancy

Key information

B	**Immediate postpartum IUC (within 48 hours of childbirth) is safe, effective, convenient and associated with high continuation rates.**
✓	**When inserted within 48 hours of childbirth, the insertion technique is different to that of standard IUC insertion and clinicians need to be appropriately trained in this technique.**
B	**Interval IUC insertion (from 48 hours after childbirth) is associated with an increased risk of uterine perforation, particularly if the user is breastfeeding. Despite this, the risk of uterine perforation from 28 days after childbirth remains small.**
C	**Expulsion rates are higher when IUC is inserted within 48 hours after childbirth compared with interval insertion. Expulsion rates are higher when IUC is inserted after vaginal birth compared with caesarean section.**
B	**IUC insertion after abortion is convenient and acceptable and has been associated with high continuation rates and reduced likelihood of another abortion within the next 2 years.**
D	**After medical abortion, or medical or expectant management of miscarriage, IUC can be inserted any time after expulsion of the pregnancy, providing there is no clinical suspicion of sepsis and no new risk of pregnancy.**
A	**IUC can be inserted immediately after surgical abortion or surgical management of miscarriage or ectopic pregnancy, providing there is no clinical suspicion of sepsis.**

Clinical recommendations

B	**If >48 hours have passed since childbirth, insertion should be delayed until 28 days after childbirth (interval insertion). The risks of insertion from 48 hours until 28 days after childbirth generally outweigh the benefits (UKMEC3).**

More detailed information is available in FSRH Guideline Contraception after Pregnancy.[103]

Table 5 shows the UKMEC[2] categories for the use of intrauterine contraception for postpartum and post-abortion.

Table 5: UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2] categories for the use of intrauterine contraception for postpartum and post-abortion

Condition	UKMEC category for Cu-IUD	UKMEC category for LNG-IUD
Postpartum (in breastfeeding or non-breastfeeding individuals, including post-caesarean section)		
a) 0 to <48 hours	1	1
b) 48 hours to <4 weeks	3	3
c) ≥4 weeks	1	1
d) Postpartum sepsis	4	4
Post-abortion		
a) First trimester	1	1
b) Second trimester	2	2
c) Post-abortion sepsis	4	4

Cu-IUD, copper intrauterine device; LNG-IUD, levonorgestrel intrauterine device; UKMEC, UK Medical Eligibility Criteria for Contraceptive Use.
See **Table 3** for definition of UKMEC categories.

7.1.3.1 After childbirth

Postpartum status and breastfeeding are associated with an increased risk of uterine perforation,[104] but the risk remains small. It is established practice and long-standing UKMEC[2] guidance that unless IUC is inserted within 48 hours after childbirth, insertion should usually be delayed until 28 days after childbirth (interval insertion). This reflects concern about increased risk of perforation.

Immediate postpartum IUC insertion (within 48 hours of childbirth) has been shown to be safe, convenient, cost effective and associated with high continuation rates. There is no evidence of increased risk of uterine perforation if IUC is inserted within 48 hours of childbirth, compared with delayed insertion (>28 days after childbirth).[103,105–108] Infection rates for postpartum insertion (vaginal birth and caesarean section) have been shown to be low, similar to that of non-postpartum insertion.[103,109–112]

IUC insertion can take place as soon as the placenta is delivered at caesarean section or up to 48 hours after vaginal birth.[105] Contraindications to IUC insertion at this time include prolonged rupture of membranes, unresolved postpartum haemorrhage and sepsis.[103] When inserted within 48 hours of childbirth, the insertion technique is different to that of standard IUC insertion and clinicians need to be appropriately trained in this technique. See resources in the FSRH Member's Training hub. Due to an increased risk of expulsion or long or non-visible threads with PPIUC, routine IUC check-ups are recommended 4–6 weeks post-insertion when IUC has been inserted within 48 hours of a vaginal or caesarean birth. An example PPIUC pathway can be found in **Appendix 2**.

There is very limited published evidence to inform outcomes after insertion of Cu-IUDs between 48 hours and 4 weeks after childbirth. A decision as to whether it is appropriate to insert a Cu-IUD for EC between 3 and 4 weeks after childbirth should be made on a case-by-case basis, based on clinical judgement (UKMEC3). The decision should take into account likely pregnancy risk, any specific risk associated with pregnancy for that individual, potential risk of perforation and whether delaying the insertion until 4 weeks

after childbirth would be suitable for that individual (**Table 5**).[2]

The evidence

A large, prospective, non-interventional cohort study[113] of almost 9000 individuals who had IUC inserted within 12 months of childbirth indicated that the risk of perforation is increased after childbirth whether an individual is breastfeeding or not, but the risk was highest in those who were breastfeeding and <36 weeks' postpartum. Individuals who were <36 weeks' postpartum and were breastfeeding at the time of insertion had a relative risk of 6.8 (95% CI 4.5–9.9) per 1000 insertions compared with 5.1 (95% CI: 0.6–18.4) for individuals who were breastfeeding and gave birth >36 weeks prior to insertion. For individuals <36 weeks' postpartum and not breastfeeding, the RR was 3.0 (95% CI 1.5–5.4), and for individuals not breastfeeding and >36 weeks' postpartum the RR was 1.2 (95% CI 0.8–1.7).

Similar results have been seen in other studies. Another large, prospective cohort study[114] of 22 795 IUC users identified 30 cases of perforation. Of these, 87% (26/30) of perforations occurred in individuals who had IUC inserted within 18 weeks of childbirth and 66% (20/30) were in individuals who were breastfeeding at the time of insertion. A cohort study[115] of 8343 Cu-IUD users also found an increased risk of perforation in postpartum individuals, with IUD insertion 0–3 months postpartum and 3–6 months postpartum increasing the risk of perforation (RR 11.7 at 0–3 months, 95% CI 2.8–49.2; RR 13.2 at 3–6 months, 95% CI 2.8–62). There is no evidence to inform how long after cessation of breastfeeding the risk of perforation returns to that of a non-breastfeeding individual.

Evidence level 2+

A Cochrane review and meta-analysis reported that cumulative expulsion rates 6 months post-insertion have been shown to be higher with immediate postpartum insertion, compared with interval insertion (17% vs 3%; odds ratio (OR) 4.89; 95% CI 1.47–16.32).[105] Expulsion rates have been found to be higher when IUC is inserted after vaginal birth compared with caesarean section (adjusted relative risk (aRR) 4.57; 95% CI 3.49–5.99)[116] and may be higher with LNG-IUD devices compared with Cu-IUD devices[117], though the evidence relating to device types is limited.

Despite an increased rate of expulsion, immediate postpartum IUC insertion is associated with high continuation rates, with many individuals opting for reinsertion if expulsion occurs. The aforementioned Cochrane review found IUC method continuation at 6 months was higher in those who had immediate postpartum insertion compared with interval insertion (81% vs 67%; OR 2.04, 95% CI 1.01–4.09).[105]

Evidence level 1-

7.1.3.2 After abortion

Insertion of IUC at the time of abortion is convenient and highly acceptable to individuals.[103] It has been associated with high continuation rates and a reduced likelihood of another abortion within the next 2 years.[103]

IUC should not be inserted in the presence of post-abortion sepsis (UKMEC4) (**Table 5**).[2,103]

If an individual has a medical abortion, IUC can be inserted at any time after expulsion of the pregnancy, providing there is no new risk of pregnancy.[103] If the abortion occurs within a healthcare setting, expulsion of the pregnancy can be confirmed by an HCP who examines the products passed. Established FSRH

guidance[103] is that for individuals in whom successful expulsion has not been confirmed (e.g. those who pass the pregnancy at home), exclusion of an ongoing pregnancy is necessary prior to IUC insertion. Methods of excluding an ongoing pregnancy prior to the resumption of menses include either a negative low-sensitivity urinary pregnancy test at least 2 weeks after misoprostol administration or ultrasound examination at any time after the medical abortion.[103] Since the development of the Contraception After Pregnancy guideline, uptake and availability of early medical abortion (EMA) has increased. New evidence from studies of EMA will be reviewed by the relevant expert panel when the Contraception After Pregnancy guideline is updated and any changes to this recommendation will be updated in this guideline. In the meantime, although FSRH guidance continues to be that ongoing pregnancy needs to be excluded by pregnancy test, ultrasound scan, examination of pregnancy tissue passed by an HCP or resumption of menses, local protocols that reflect the most up-to-date evidence may vary, and clinicians may follow alternative, evidence-based local pathways and protocols.

If an individual has a surgical abortion, IUC can be inserted immediately after surgical evacuation of the uterus. Expulsion rates may be higher when IUC is inserted after late first-trimester or second-trimester surgical abortions, when compared with insertion after early first-trimester surgical abortion.[103]

Additional contraceptive precautions are not required if IUC is inserted immediately or within 5 days of an abortion.

7.1.3.3 After ectopic pregnancy or miscarriage

Individuals who do not wish to conceive after an ectopic pregnancy or miscarriage should have their chosen method of contraception initiated immediately after expulsion or resolution of the pregnancy. Where this is not possible, a bridging method should be provided.

IUC can be safely used by individuals after uncomplicated surgical, medical or completed expectant management of miscarriage or ectopic pregnancy. IUC should not be inserted in the presence of sepsis after miscarriage or ectopic pregnancy[2,103] or where there is any possibility of an ongoing pregnancy.

IUC can be inserted immediately following surgical evacuation of the uterus or surgical management of ectopic pregnancy.[103]

With medical or expectant management of miscarriage, IUC can be inserted any time after expulsion of the pregnancy.[103] For individuals for whom successful expulsion has not been confirmed (e.g. who pass the pregnancy at home), exclusion of ongoing pregnancy is necessary before insertion of IUC.[103] Methods of excluding an ongoing pregnancy prior to the resumption of menses include a negative low-sensitivity urinary pregnancy test at least 2 weeks after misoprostol administration or ultrasound examination[103].

7.1.3.4 After gestational trophoblastic disease

Current guidelines based on UK expert opinion recommend that IUC should not be inserted after gestational trophoblastic disease (GTD) until human chorionic gonadotropin (hCG) levels are normal because of a theoretical increased risk of uterine perforation and dissemination of the tumour by the insertion of the IUC (**Table 6**).[2] There are no reported data on the risk of uterine perforation with IUC insertion at the time of uterine evacuation in individuals with GTD.

Table 6: UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2] categories for the use of intrauterine contraception for gestational trophoblastic disease

Condition	UKMEC category for Cu-IUD	UKMEC category for LNG-ID
Gestational trophoblastic disease		
a) Undetectable hCG levels	1	1
b) Decreasing hCG levels	3	3
c) Persistently elevated hCG levels or malignant disease	4	4

Cu-IUD, copper intrauterine device; hCG, human chorionic gonadotropin; LNG-IUD, levonorgestrel intrauterine device; UKMEC, UK Medical Eligibility Criteria for Contraceptive Use.
See Table 3 for definition of UKMEC categories.

Ovulation after GTD can resume very quickly, and therefore if IUC insertion is unsuitable an alternative method of contraception can be used as a bridging method. Although IUC should not normally be inserted until hCG levels have normalised, use of Cu-IUD for EC may be considered in a specialist setting for individuals with decreasing hCG levels (UKMEC3).[2]

7.1.4 Perimenopause

Clinical recommendations

✓ **Additional investigations may be indicated prior to or at the same time as IUC insertion in individuals with abnormal uterine bleeding, or if an individual has risk factors for gynaecological disease.**

✓ **The FSRH supports the use of any 52 mg LNG-IUD for endometrial protection as part of HRT for 5 years.**

Further information can be found in the FSRH Guideline Contraception for Women Aged Over 40 Years.[6]

Perimenopause is a transition phase preceding menopause. During this phase, which can last a number of years, ovulation is intermittent as individuals move from normal ovulatory menstrual cycles to the cessation of ovulation and menstruation. As a result, problematic bleeding such as irregular cycles, HMB and dysmenorrhoea can be more common.

The LNG-IUD may be of particular benefit at this time, as bleeding will usually reduce with LNG-IUD use (see Section 9.1: Bleeding patterns). An additional non-contraceptive benefit of the 52 mg LNG-IUD in this population is that it can also be used for endometrial protection as part of HRT. Although Mirena is currently the only LNG-IUD that is licensed for this indication, the FSRH supports the use of any 52 mg LNG-IUD for endometrial protection as part of HRT for up to 5 years. This recommendation is supported by the Royal College of Obstetricians and Gynaecologists and the British Menopause Society (personal communications, August 2022).

In contrast, the Cu-IUD may be associated with heavier, more painful or prolonged bleeding and so may not be appropriate for individuals with HMB, or perimenopausal individuals who experience problematic

menstrual bleeding patterns.

Consideration of examination and endometrial assessment/investigation should be considered prior to IUC insertion for perimenopausal individuals who have heavy and/or erratic bleeding or a recent change in bleeding pattern. This should take into account any risk factors for gynaecological disease. Requirement for investigation should follow local guidelines.[6]

7.1.4.1 Extended use

The Cu-IUDs currently available in the UK are licensed for either 5 or 10 years of use. The FSRH supports extended use of the Cu-IUD when inserted at age 40 years or over. Any Cu-IUD containing ≥300 mm^2 copper inserted at or after age 40 years can be used for contraception until menopause.[6]

Although licensed for 8 years for contraception, the FSRH supports extended use of a 52 mg LNG-IUD by individuals aged ≥45 years at the time of insertion. When a 52 mg LNG-IUD is inserted at or after age 45 years, it can be used for contraception for as long as contraception is required, even if the individual is not amenorrhoeic. In line with established FSRH guidance,[6] contraception can be stopped at age 55 years as the risk of spontaneous pregnancy is extremely low. Although it is not routine practice to measure follicle-stimulating hormone (FSH) levels, if an individual is aged over 50 years with an LNG-IUD in situ and wishes to stop using contraception before age 55 years, an FSH level can be taken. If this is >30 IU/L, the individual can stop contraception after one further year. If removing an LNG-IUD because contraception is no longer required, it is important to ensure that the individual is not also using it for endometrial protection as part of HRT. (Note that a 52 mg LNG-IUD can be used for up to 5 years for endometrial protection as part of HRT.)

There is insufficient evidence at present to recommend using a 19.5 mg LNG-IUD or 13.5 mg LNG-IUD beyond their licensed durations.

7.1.5 After breast cancer

There are no contraindications to use of a Cu-IUD for an individual with current or previous breast cancer (UKMEC1) (**Table 7**).[2]

At the time of publication of this guideline, current breast cancer is a UKMEC4 condition for use of an LNG-IUD (UKMEC4: a condition which represents an unacceptable health risk if the method is used) and past history of breast cancer is a UKMEC3 condition for use of an LNG-IUD (UKMEC3: a condition where 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.[2] The available, limited evidence relating to use of the LNG-IUD by individuals who have experienced breast cancer is currently being reviewed by an expert group and recommendations will be published in the FSRH CEU Clinical Guidance 'Contraception After Breast Cancer'.[118]

Table 7: UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2] categories for the use of intrauterine contraception after breast cancer

Condition	UKMEC category for Cu-IUD	UKMEC category for LNG-IUD
Breast cancer		
a) Current breast cancer	1	4
b) Past breast cancer	1	3

Cu-IUD, copper intrauterine device; LNG-IUD, levonorgestrel intrauterine device; UKMEC, UK Medical Eligibility Criteria for Contraceptive Use.
See **Table 3** for definition of UKMEC categories.

7.1.6 Individuals with a raised BMI

IUC is a safe, feasible and highly effective contraceptive option for individuals who are overweight or obese. More detailed information can be found in the FSRH Clinical Guideline Overweight, Obesity and Contraception.[65]

Raised BMI is UKMEC1 for Cu-IUD insertion.[2] Although no studies have specifically evaluated the safety of the Cu-IUD in individuals with raised BMI, there are no theoretical reasons why the Cu-IUD would pose health risks to these individuals.

On its own, a BMI ≥30 kg/m^2 does not restrict the use of the LNG-IUD (UKMEC1). If an individual with a BMI ≥30 kg/m^2 also has other risk factors for cardiovascular disease (CVD) (e.g. smoking, diabetes and hypertension), use of the LNG-IUD is UKMEC2 (benefits generally outweigh risks).[2] Studies have not directly assessed whether individuals with raised BMI who use LNG-IUD are at increased risk of venous thromboembolism (VTE) or other adverse cardiovascular outcomes compared with individuals with a raised BMI who do not use LNG-IUD. However, one small (n = 106) RCT found no clinically relevant changes in subclinical markers of cardiovascular risk (waist circumference, blood pressure, blood glucose, insulin, lipid profile and endothelial function markers) in individuals with obesity at 12 months after LNG-IUD placement compared with users of non-hormonal contraceptive methods.[119]

The mechanisms of action of IUC are based on local effects and do not rely on systemic drug levels; therefore, an individual's weight would not be expected to affect contraceptive effectiveness of the Cu-IUD or LNG-IUD. However, a large cohort study has shown that there is an increased risk of IUC expulsion in individuals with a BMI over 25. This risk increases further as BMI increases.[401] In this study, 228,834 individuals (<50 years old) with IUD insertion and no delivery in the previous 52 weeks were identified. Both partial and complete expulsions were considered. The adjusted hazard ratio for expulsion was 1.20 (95% CI 1.13-1.29) in the overweight category, 1.55 (95% CI 1.45 – 1.66) for obesity and 2.02 (95%CI 1.86-2.20) for morbid obesity[401].

In practice, IUC insertion could be more challenging in individuals with raised BMI in terms of assessment of uterine position and gaining access to the uterus[120]; however, insertion difficulties should not be presumed in individuals with raised BMI. Some practicalities may need to be considered in order to maximise the chances of insertion success (e.g. having a range of speculum sizes and an examination couch with an appropriate weight limit). In addition, availability of a large blood pressure cuff for measuring blood pressure is essential.

7.1.7 Individuals with uterine cavity distortion

Uterine malformation

Key information

D	**For individuals with known distortion of the uterine cavity, risks associated with IUC insertion generally outweigh the benefits (UKMEC3).**

Clinical recommendations

✓	**The decision to insert an IUC in an individual with uterine cavity distortion should be made on an individualised basis, considering the degree of distortion, uterine cavity size, the accuracy of imaging available, the indication for use and other suitable alternatives, the type of device being inserted and the potential consequence of complications for that particular individual.**
✓	**IUC insertion for an individual with uterine cavity distortion due to fibroids or uterine malformation should be undertaken in a specialist setting with access to concurrent ultrasound or hysteroscopy.**
✓	**The uncertainty around the safety and contraceptive effectiveness of IUC in individuals with uterine cavity distortion should be explained to the individual, with advice on how and when to seek review.**
✓	**The decision to insert IUC at an interval following endometrial ablation should be made on an individualised basis, considering the indication for IUC insertion, the need for a reliable concurrent endometrial biopsy, and the ultrasound appearance of the endometrium.**
✓	**If IUC insertion is considered for an individual who has previously undergone endometrial ablation, the procedure should be undertaken in a specialist setting, with ultrasound or hysteroscopic assessment of the cavity to determine suitability.**

Congenital uterine anomalies are present in 3%–4% of individuals with a female reproductive tract.[122] Overall, uterine anomalies do not appear to have a significant impact on fertility[123] but are associated with pregnancy complications, with higher uterine anomaly rates seen in individuals with recurrent early pregnancy loss (5%–10%) or individuals who have experienced preterm delivery and/or late first- or second-trimester pregnancy loss (up to 25%).[6]

During embryonic development, the uterus is formed from the Mullerian ducts. After two separate halves of the uterus develop, they fuse together and the resultant septum between the two halves is resorbed. The majority of uterine malformations are caused by abnormal Mullerian duct development or fusion, or incomplete septal resorption.[123] In practice, this means that the uterine cavity may be distorted in a variety of ways, including:

- Unicornuate uterus – only one side of the Müllerian duct forms, resulting in a banana-shaped uterus.
- Bicornuate uterus – the uterus is heart-shaped, rather than pear-shaped, with a deep indent protruding down from the fundus.
- Septate uterus – a vertical septum either fully or partially separates the uterine cavity into two cavities.
- Arcuate uterus – a small (<1 cm) indentation protrudes downwards into the cavity from the fundus.
- Uterus didelphys – both Müllerian ducts have formed but do not fuse, resulting in two separate uterine cavities.

UKMEC 2016 recommends that for an individual with known distortion of the uterine cavity the risk associated with the use of any IUC method for contraception generally outweighs the benefit (UKMEC3) (**Table 8**).[2] This reflects concern that a distorted uterine cavity could be associated with increased risk of perforation, expulsion or malposition. However, the available evidence is extremely limited and therefore the safety and effectiveness of IUC for both contraceptive and non-contraceptive indications in individuals with uterine anomalies is unknown. If examination findings suggest there could be uterine malformation or cavity distortion, clinicians should consider delaying IUC insertion and arranging an ultrasound scan (USS) to assess the uterus.

In the absence of evidence, the GDG recommends that the decision to insert an IUC (or two IUCs) in an individual with uterine malformation should be made on a case-by-case basis. Clinicians should consider the degree of distortion, uterine cavity size, the accuracy of imaging available and certainty of the findings (e.g. two-dimensional ultrasound scan (2D USS)/three-dimensional (3D) USS/hysteroscopy), the indication for use, the type of device being inserted and the potential consequence of complications (such as expulsion, perforation or failure) for that particular individual. The uncertainty around the safety and effectiveness of IUC in this situation should be explained to the individual, with advice on how and when to seek review.

The GDG recommends that when an individual with known uterine malformation has an IUC inserted this should be done in a specialist setting with concurrent ultrasound and/or hysteroscopy.

Table 8: UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2] categories for the use of intrauterine contraception for individuals with anatomical abnormalities of the uterine cavity

Condition	UKMEC category for Cu-IUD	UKMEC category for LNG-IUD
Anatomical abnormalities		
a) Distorted uterine cavity	3	3
b) Other abnormalities	2	2

Cu-IUD, copper intrauterine device; LNG-IUD, levonorgestrel intrauterine device; UKMEC, UK Medical Eligibility Criteria for Contraceptive Use.
See **Table 3** for definition of UKMEC categories.

The evidence

Evidence level 3

The available evidence is limited to 20 case reports and case series[123,124] of IUC in individuals with uterine anomalies published between 1967 and 2016, and one retrospective, case–control study of 236 individuals with malpositioned IUC, of whom four had a uterine anomaly.[125] The case reports suggest that effectiveness of IUC may be reduced in individuals with more than one uterine cavity. Eleven case reports describe IUC failure, with a concurrent pregnancy and IUC in situ.[123] Six of these are cases of bicornuate uteri, with the IUC in one horn and the pregnancy in the other; and one describes a uterus didelphys with the IUC in one uterus and the pregnancy in the other.

Fifteen cases describing IUC expulsion in the presence of uterine anomaly (arcuate, bicornuate, septate or uterus didelphys) are reported,[123] with abnormal bleeding (9 cases), perforation (4 cases), pain (3 cases) and no complications (4 cases) also described in the case reports.[123,124] There is insufficient evidence to determine whether there is an increased risk of complications in individuals with uterine anomalies.

Three case reports describe the insertion of two concurrent IUC devices into uteri with known anomalies (two cases of uterus didelphys with one IUC in each uterus; one bicornuate uterus with one IUC in each horn).[126,127] Although the authors report no complications in these three cases, the individuals were only followed up for less than 1 year.

Evidence level 3

A 2018 retrospective case–control study from the US compared 236 individuals with malpositioned IUC with individuals with correctly placed IUC.[125] Subjects with malpositioned IUC had a statistically significant greater incidence of uterine anomalies than those with correctly positioned IUC (31.9% vs 23.5%, p = 0.02), suggesting that the presence of a uterine anomaly increases the risk of a malpositioned IUC.

Evidence level 2-

7.1.7.1 Fibroids

Fibroids (leiomyomas) are common, benign smooth muscle tumours that arise from myometrium.[128] They are sex hormone-sensitive, and the incidence and size of fibroids decreases after menopause. Fibroids may be single or multiple and are classified into three types, according to their position on the uterus. Intramural fibroids are the most common type.[129] They develop within the myometrium and may distort the uterine cavity. Submucosal fibroids grow into the uterine cavity causing distortion and subserosal fibroids develop on the outer uterine wall and do not usually cause cavity distortion.

Whilst the majority of individuals with fibroids are asymptomatic, some individuals will experience symptoms, the most common being HMB. Other symptoms include dysmenorrhoea, dyspareunia or other pressure-related symptoms such as urinary frequency, abdominal or back pain or constipation. NICE recommends an LNG-IUD as first-line treatment for individuals with HMB and fibroids <3 cm in size.[130] In contrast, as the Cu-IUD can be associated with heavier, prolonged or more painful menstruation, alternative methods of contraception may be more appropriate. With an increased incidence of HMB, a potentially larger cavity size and potential changes to uterine pressure due to the presence of fibroids, there is a theoretical concern that the presence of fibroids could increase the expulsion rates of IUC.

The UKMEC 2016 recommends that for an individual with fibroids and no known cavity distortion there is no restriction to IUC use (UKMEC1). For individuals with fibroids and known distortion of the uterine cavity, UKMEC indicates that the risk associated with the use of any IUC method generally outweighs the benefit (UKMEC3) (**Table 9**).[2]

Table 9: UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2] categories for the use of intrauterine contraception for individuals with uterine fibroids

Condition	UKMEC category for Cu-IUD	UKMEC category for LNG-IUD
Uterine fibroids		
a) Without distortion of the uterine cavity	1	1
b) With distortion of the uterine cavity	3	3

Cu-IUD, copper intrauterine device; LNG-IUD, levonorgestrel intrauterine device; UKMEC, UK Medical Eligibility Criteria for Contraceptive Use.
See **Table 3** for definition of UKMEC categories.

The GDG recommends that in the absence of evidence, the decision to insert an IUC in an individual with fibroids that are distorting or enlarging the uterine cavity should be made on a case-by-case basis, and

that the uncertainty around the safety and effectiveness of IUC in this situation should be explained to the individual, with advice on how and when to seek review. Clinicians should consider the degree of distortion, uterine cavity size, the accuracy of imaging available and certainty of the findings (e.g. 2D USS/3D USS/hysteroscopy), the indication for use, the type of device being inserted and the potential consequence of complications (such as expulsion or failure) for that particular individual. The GDG recommends that when an individual with fibroids and known uterine cavity distortion has an IUC inserted, this should be done in a specialist setting with concurrent ultrasound and/or hysteroscopy.

The evidence

A 2014 systematic review[28] to determine the effectiveness and safety of LNG-IUD as a treatment for symptomatic fibroids identified six studies that examined the rates of IUC expulsion. Expulsion rates ranged from 6.3% to 12%, with one RCT[131] concluding that the device expulsion rate in individuals with fibroids >3 cm (2/13, 15.4%) was higher than those with fibroids ≤3 cm (1/16, 6.3%). The fibroid position was not shown to be statistically significant; however, the mean fibroid size was, with individuals experiencing device expulsion having a mean fibroid size of 4.3 ± 2.8 cm compared with 2.8 ± 1.2 cm in individuals who did not experience device expulsion (p = 0.04). One study[132] reported that 12% (4/32) of cases experienced device expulsion during the first 3 months, and two studies[131,133] reported 10.3% (3/29) and 6.3% (6/96) of cases expelled the device during the 1-year study period. All studies were conducted in individuals using IUC for HMB and therefore the results may not be relevant to individuals without HMB who are using IUC only for contraception. No studies examined the safety or effectiveness of Cu-IUD use by individuals with fibroids and the studies excluded individuals with cavity distortion.

Evidence level 1-

7.1.8 After endometrial ablation

Endometrial ablation is a therapeutic procedure for HMB that destroys endometrial tissue. It is not contraceptive, and pregnancy occurring after endometrial ablation could be associated with higher risk of complications. Ongoing contraception is required even if the individual becomes amenorrhoeic.

There is no published evidence relating to IUC insertion after an interval following endometrial ablation. As the cavity could be partially or completely obliterated by adhesions, insertion could theoretically be technically difficult or impossible and there could be a higher risk of perforation.

The GDG sought expert opinion and was given the following advice:

- **IUC insertion concurrently with an endometrial ablation procedure**

IUC insertion concurrently with an ablation procedure is possible, but anecdotally there may be an increased risk of complications (e.g. infection) that could result in further interventions and lower satisfaction rates for the individual.

- **Insertion of an IUC after an interval following an ablation**

Insertion of an IUC after an interval following an ablation procedure requires an individualised approach, dependent upon the indication for IUC insertion, the need for a reliable concurrent endometrial biopsy, and the ultrasound appearance of the endometrium. Although ease of insertion cannot be accurately predicted by ultrasound, a homogeneous, triple-stripe endometrium with a normal-shaped cavity and an absence of any areas of haematometra would be favourable findings, suggesting a patent cavity at the time of ultrasound. The GDG suggests that IUC insertion in this circumstance should be undertaken by a specialist and only if an USS undertaken immediately prior to any insertion attempt is considered favourable by the

specialist. It would not be recommended that an IUC was inserted at an interval post-ultrasound. Hysteroscopy may be required to assess the endometrial cavity, with insertion of IUC concurrently or at a subsequent procedure.

- **Removal of an IUC that was inserted at the time of endometrial ablation**

It is not possible to reliably predict how difficult the removal procedure could be, and clinicians should consider each case individually, discussing the potential risks and benefits with the IUC user. An attempt to remove the IUC in an outpatient clinic would be reasonable; however, resorting to hysteroscopy may be required for a complex removal.

The evidence

A systematic review[134] of the literature relating to pregnancy outcomes after ablation identified 274 pregnancies, occurring in individuals aged 26–50 years, conceived a median of 1.5 years after ablation (range: 3 weeks prior to 13 years after). In almost all cases, the individual was not using contraception. Of the reported pregnancies, most ended in abortion, miscarriage or were ectopic; among those that continued there was an apparent high rate of pregnancy complications (including preterm birth, caesarean section, caesarean hysterectomy, morbidly adherent placenta, preterm premature rupture of membranes, intrauterine growth restriction, intrauterine fetal death, uterine rupture, and neonatal death). This may, however, represent reporting bias since the bulk of the published evidence comes from case reports.[134]

Evidence level 1-

Given that endometrial ablation is not contraceptive and pregnancy after ablation may be associated with increased risk of pregnancy complications, contraception is recommended. A 2021 systematic review[135] identified six studies that included a total of 427 individuals who had an LNG-IUD inserted at the time of endometrial ablation. The studies were limited by their small sample size and methodologies but inserting an LNG-IUD immediately after endometrial ablation/resection appears to be associated with lower hysterectomy and re-intervention rates compared with ablation/resection alone and no intra- or post-operative complications were observed. No studies were identified in which IUC was inserted at an interval post-ablation.

Four studies in the systematic review[135] described IUD removal following insertion at the time of endometrial ablation. A total of 13 removals were described (6 at menopause and 7 due to adverse effects). One removal was reported as being difficult due to adhesions, but removal was successful without hysteroscopic intervention.

7.1.9 After large loop excision of the transformation zone (LLETZ) procedure

Clinical recommendations

✓ **If an IUC is removed during LLETZ and not immediately reinserted, alternative contraception should be provided and EC considered.**

Due to a paucity of evidence and guidance on best practice in this situation, management of an IUD if the user requires large loop excision of the transformation zone (LLETZ) is varied. Whilst some colposcopists will retain the IUC during the procedure (either sparing or cutting the threads), some will remove the IUC and reinsert immediately and others will reinsert the IUC as an interval procedure.

The GDG suggests that where IUC is removed but not immediately reinserted, bridging contraception should be supplied. Local pathways should be in place to ensure access to services for reinsertion of the IUC once the cervix has healed. There will be variation in practice, and protocols should be followed/developed with the local colposcopy team.

As there is not robust evidence to inform outcomes following immediate reinsertion of IUC following LLETZ procedure, expert opinion was sought by the GDG. Expert advice was that if immediate reinsertion at the time of LLETZ was not appropriate by the clinician carrying out the LLETZ, clinicians should ensure that the cervix has healed before reinsertion, which might be expected to take 4–6 weeks. Resolution of bleeding and discharge post-LLETZ would suggest the cervix had healed, but healing would be confirmed by speculum examination of the cervix prior to IUC insertion.

7.1.10 Individuals at risk of infection

Key information

D	**Current pelvic inflammatory disease, postpartum or post-abortion sepsis, known gonorrhoea infection, symptomatic chlamydia infection, and purulent cervicitis are all contraindications to IUC insertion (UKMEC4).**

Clinical recommendations

✓	**If IUC insertion has to be delayed due to infection, bridging contraception should be offered.**
✓	**A sexual history should be taken prior to IUC insertion and screening offered to individuals at risk of sexually transmitted infections. Screening can be performed at the time of insertion.**

7.1.10.1 Chlamydia trachomatis, Neisseria gonorrhoeae and Mycoplasma genitalium

UKMEC currently gives the following guidance. Current pelvic inflammatory disease (PID), postpartum or post-abortion sepsis, known gonorrhoea infection, symptomatic chlamydiainfection, and purulent cervicitis are all contraindications to IUC insertion (UKMEC4). The risks associated with IUC insertion in the presence of known asymptomatic chlamydia infection are generally considered to outweigh benefits (UKMEC3). If an individual is considered to be at increased risk for sexually transmitted infections (STIs) but has none of the aforementioned specific conditions, benefits of IUC insertion are generally considered to outweigh risks (UKMEC2) (**Table 10**).[2]

Table 10: UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2] categories for the use of intrauterine contraception for individuals at risk of infection

Condition	UKMEC category for Cu-IUD		UKMEC category for LNG-IUD	
Pelvic inflammatory disease (PID)				
a) Past PID (assuming no current risk factor for STIs)	1		1	
b) Current PID	**I**	**C**	**I**	**C**
	4	2	4	2
Sexually transmitted infections (STIs)				
Chlamydia infection (current)				
a) Symptomatic	**I**	**C**	**I**	**C**
	4	2	4	2
b) Asymptomatic	**I**	**C**	**I**	**C**
	3	2	3	2
Purulent cervicitis or gonorrhoea (current)	**I**	**C**	**I**	**C**
	4	2	4	2
Other current STIs (excluding HIV and hepatitis)	2		2	
Vaginitis (including *Trichomonas vaginalis* and bacterial vaginosis) (current)	2		2	

Initiation: Starting a method by an individual with a specific medical condition.
Continuation: Continuing with the method already being used by an individual who develops a new medical condition.
Cu-IUD, copper intrauterine device; LNG-IUD, levonorgestrel intrauterine device; PID, pelvic inflammatory disease; STI, sexually transmitted infection; UKMEC, UK Medical Eligibility Criteria for Contraceptive Use.
See **Table 3** for definition of UKMEC categories.

Note that testing for and management of *Mycoplasma genitalium* (MG) has become widespread since the development of UKMEC 2016. Guidance relevant to IUC and MG will be considered by the GDG for the next update of UKMEC. MG may be a commensal but can be associated with PID. In the absence of robust evidence to guide practice and until a formal recommendation is made by UKMEC update, it is suggested that IUC insertion should, where possible, be delayed until known MG has been adequately treated and any associated symptoms have resolved.

Routine STI screening of asymptomatic individuals requesting IUC is not necessary; however, a sexual history should be taken prior to IUC insertion and screening offered, particularly if factors associated with increased risk of STI are identified[136] – see BASHH Guidance on sexual history taking[137] and STI testing.[138] Providing the individual is asymptomatic, screening can be performed at the time of IUC insertion[136]; the IUC can be inserted without awaiting results and without prophylactic antibiotic treatment so long as the user can be contacted and treated promptly, if indicated, when the results are known.

Following a positive chlamydia or gonorrhoea result, an intrauterine method can be inserted if the individual has completed antibiotic treatment (and, if applicable, completed any additional recommended follow-up or imaging, for example, in the case of complicated pelvic infection such as a tubo-ovarian abscess) and is asymptomatic. If an individual with asymptomatic chlamydia requires IUC as EC, the IUC could be

inserted on the same day as treatment is commenced.

Individuals who have symptoms of possible bacterial STI and/or PID should ideally delay IUC insertion until test results are available, until PID or confirmed STI have been treated, and until symptoms have resolved.[2] A bridging contraceptive method should be offered if required.

With specific regard to emergency IUD insertion that cannot be delayed:

- An individual with known asymptomatic chlamydia infection who requires an emergency IUD could consider insertion on the same day that chlamydia treatment is commenced. (UKMEC indicates that asymptomatic untreated gonorrhoea infection would contraindicate IUC insertion[2]).
- Where results of CT (chlamydia) and GC (gonorrhoea) tests are not yet available, antibiotic prophylaxis for CT and/or GC could be considered for an individual who requires emergency IUD insertion and has no symptoms relevant to CT or GC infection but has a current or recent partner who is known to have CT or GC infection.
- Where results of CT and GC tests are not yet available, antibiotic prophylaxis for chlamydia and/or gonorrhoea could be considered on a case-by-case basis for individuals who require emergency IUD insertion but have symptoms for which CT or GC infection cannot be excluded as a cause.

See FSRH CEU Statement on Antibiotic Cover for Urgent Insertion of Intrauterine Contraception in Women at High Risk of STI.[139]

Any treatment for confirmed or suspected chlamydia, gonorrhoea or PID should be in line with British Association for Sexual Health and HIV (BASHH) guidance.[140]

7.1.10.2 Other infections (and bacterial vaginosis)

There is no indication to screen for other lower genital tract organisms in asymptomatic individuals considering IUC.

If bacterial vaginosis, *Trichomonas vaginalis* or candida infection is diagnosed or suspected, these should be treated but the IUC can be inserted without delay. See **Table 10** for UKMEC recommendations.[2]

Group B streptococcus (GBS) is a commensal organism that may be incidentally detected if individuals have a high vaginal swab taken for another indication. If detected, GBS does not usually require treatment except in pregnant or symptomatic individuals and neonates. There is no need to delay IUC insertion or treat asymptomatic individuals who have been identified as having GBS.

Group A streptococcus (GAS) is a rare but serious infection that can cause life-threatening septicaemia, invasive GAS (e.g. necrotising fasciitis) and streptococcal toxic shock syndrome. Therefore, if GAS is incidentally detected it is important that it is treated urgently. IUC insertion should be delayed until treatment is complete.

7.1.11 Individuals who are immunosuppressed or taking immunosuppressants

Key information

D **The contraceptive effectiveness of Cu-IUD does not appear to be reduced in individuals who are immunosuppressed/on immunosuppressants.**

Clinical recommendations

✓ **Where an immunosuppressed individual is having an IUC procedure, the use of prophylactic antibiotics should be discussed with the individual's lead clinician in order to assess the suitability for that individual.**

As pregnancy may pose an increased health risk to an immunosuppressed individual, and immunosuppressive medication may be teratogenic, the use of effective contraception to plan and time pregnancies may be of particular importance in this population.[141,142]

There is a theoretical concern that immunosuppression/immunosuppressant medication could reduce the inflammatory response within the endometrium and therefore reduce the contraceptive effectiveness of the Cu-IUD. The published evidence is very limited but does not appear to support this theory.

Insertion of IUC is associated with a small risk of pelvic infection. There is very little published evidence to inform what the risk of infection would be in individuals who are immunosuppressed at the time of IUC insertion, and no studies assessing the benefit of antibiotic prophylaxis in this population were identified in the literature search. The GDG sought expert clinical opinion and were advised that in situations where an immunosuppressed individual is having an IUC procedure, the use of prophylactic antibiotics should be discussed with the individual's lead clinician in order to assess the suitability for that individual. This will be an individualised decision dependent on the degree of immunosuppression, the underlying health conditions, and any concurrent antibiotic prophylaxis already in use.

The evidence: contraceptive effectiveness

Given the immune-mediated aspects of a Cu-IUD's method of action, concern has been raised that Cu-IUDs could be less effective in immunosuppressed individuals.[143,144] Data to assess this theory are scarce, with a lack of prospective studies powered to accurately assess contraceptive efficacy. Moreover, for many causes of immunosuppression, such as splenectomy or idiopathic neutropenia, no published evidence regarding IUD efficacy could be identified. The data identified related predominantly to people living with HIV or post-organ transplant.

A commonly cited source is a 1981 case report in which two renal transplant patients conceived despite Cu-IUD placement.[145] However, subsequent RCTs enrolling hundreds of individuals with HIV do not support reduced Cu-IUD effectiveness.[146–148] In a 2015 Ugandan trial, participants living with HIV were randomised to either an LNG-IUD or a Cu-IUD. At 12 months, contraceptive failure rates were low, with three pregnancies in the Cu-IUD arm (0.9%, n = 3/338, including one post-IUD removal) and two in the LNG-IUD arm (0.6%, n = 2/334).[146] The findings could be affected by use of condoms; the majority of the participants used condoms at baseline, but the consistency of condom use post-IUC insertion was not described.

Evidence level 3

Evidence regarding immunosuppressive drugs and Cu-IUD use was scant but offered similar results. A French case–control study (216 cases, 657 controls) assessing risk factors for IUD failure (predominantly Cu-IUDs) found neither steroids (HR 1.97, 95% CI 0.79–4.89) nor nonsteroidal anti- inflammatory drugs (NSAIDs) (HR 0.92, 95% CI 0.51–1.66) reduced IUD effectiveness.[149] A trial published in *NEJM* involved 54 individuals with systemic lupus erythematosus (SLE) being randomised to the Cu-IUD, of whom 42.6% were taking immunosuppressive drugs (no more detail) and 64.8% were on prednisolone. Across 12 months of follow-up, only one pregnancy occurred, which was not statistically different from the groups randomised to COC or the progestogen-only pill (POP). However, as with most articles, the small sample size left the study underpowered to assess such comparisons.[141]

Evidence level 2-

Two very brief narrative reviews from 2018 and 2019 concluded there was no evidence of reduced Cu-IUD effectiveness in post-transplant patients.[143,144] However, given the paucity of direct data, this conclusion drew heavily on extrapolations from the HIV literature. They did describe one large retrospective Chinese study, which reported no pregnancies in the 178 individuals who had an IUD inserted post-renal transplant. However, as one review highlighted, the study failed to state the device type. The review authors suggested that in China 30% of IUDs might be expected to be Cu-IUDs and 63% stainless steel. Both reviews proposed that maintenance of Cu-IUD effectiveness despite immunosuppression likely stems from the Cu-IUDs' immune-mediation actions being macrophage- based, whereas HIV and many immunosuppressant drug regimens alter T-cell activity.

Although evidence is limited, the progestogenic effects of the LNG-IUD are not exerted through the immune system and therefore concerns over reduced effectiveness in immunosuppressed populations are limited.[143] Currently, small case series in post-transplant patients (n range 6–23, 0 unplanned pregnancies in any)[150–152] and larger RCTs in people living with HIV suggest LNG-IUD effectiveness remains very high in these populations.[146,148]

Evidence level 1-

The evidence: infection risk

As with the efficacy data, little evidence was identified to inform IUC-associated infection risk in immunosuppressed individuals, and of the evidence identified most focused on HIV. Whilst an increased risk of pelvic infection might be anticipated among immunosuppressed IUC users, the available evidence does not support this concern.[143,144,148,150,153,154] A well-conducted 2016 systematic review concluded that individuals living with HIV seemed to be at low risk of pelvic infection with IUC use, albeit based on limited data (8 fair- to poor-quality studies, n range 6–703).[154] All but one of the included studies considered initiation of a new IUC. A Ugandan RCT comprising 703 individuals living with HIV initiating IUC found that 0.6% of Cu-IUD users and 0.9% of LNG-IUD users developed PID over 12 months,[146] similar to PID rates observed in studies of individuals not living with HIV (see Section 14.4.1: Pelvic inflammatory disease). In addition, an included prospective cohort study (n = 150 HIV-positive individuals) had its results stratified by CD4 count and found no difference between severely, moderately or mildly immunocompromised individuals (no definitions provided).

Evidence level 1+

As regards other immunosuppressed populations, a short 2019 narrative review on transplant patients found there had been no reported cases of PID in the three case series

Evidence level 3

they identified.[143] In addition, whilst the *NEJM* SLE study[141] stated that severe infections were more common in the Cu-IUD arm (n= 5/54, including 2 meningitis, vs POP n = 2/54, COC n = 2/54), this did not reach statistical significance. A single case-report described a patient who elected to keep their LNG-IUD in situ during chemotherapy and haematopoietic stem cell transplant. They did not develop PID despite being severely neutropenic.[155]

No data weighing the benefits of prophylactic antibiotic coverage in this population were found.

7.1.12 Adrenal insufficiency

Key information

C **Individuals with adrenal insufficiency are advised to increase their steroid dose at times when an adrenal crisis may be provoked.**

Clinical recommendations

✓ **Individuals at risk of an adrenal crisis should ideally have their IUC procedure scheduled for early morning.**

✓ **Individuals at risk of an adrenal crisis will usually need to increase their steroid dose prior to, and for 24 hours after, IUC insertion.**

Steroid hormones, such as glucocorticoids (cortisol) and mineralocorticoids (aldosterone), are involved in metabolic processes, water and electrolyte balance, and blood pressure regulation, and have a critical role in the body's response to stress. They are produced in the cortex of the adrenal glands and their production is regulated by the hypothalamic-pituitary-adrenal axis and the renin-angiotensin system. Therefore, adrenal insufficiency can occur as a result of a disorder affecting the adrenal cortex (e.g. Addison's disease, congenital adrenal hyperplasia), the anterior pituitary gland (e.g. pituitary tumour or subarachnoid haemorrhage) or the hypothalamus (e.g. hypothalamic-pituitary-adrenal axis suppression).[156] Suppression of the hypothalamic-pituitary-adrenal axis is also seen in patients using exogenous steroids, particularly oral or injectable glucocorticoids.[156]

Acute adrenal insufficiency ('adrenal crisis') is associated with life-threatening consequences, including severe dehydration, hypotension, hypovolaemic shock, altered consciousness, seizures, stroke or cardiac arrest[156] and can occur when an individual has insufficient steroid hormones to produce an adequate response to stress. Individuals with adrenal insufficiency, and therefore at risk of an adrenal crisis, are advised to increase their steroid dose at times when an adrenal crisis may be provoked (e.g. when unwell or undergoing surgery or dental procedures).

There are no published studies to inform a recommendation specific to IUC procedures in this group of individuals, but expert opinion is that the risk associated with an IUC procedure is significant enough that additional steroid cover is required. Ideally, insertion of the IUD should be scheduled for early morning. As the group of individuals affected is diverse, individual guidance on adjustment to steroid therapy should be sought from their overseeing physician. However, as a general principle:

- Individuals with known adrenal insufficiency should be advised to take a double dose of glucocorticoids (usually hydrocortisone or prednisolone) 1 hour prior to the procedure and thereafter to take a double dose of glucocorticoids for the next 24 hours.
- Mineralocorticoid therapy (fludrocortisone) does not need to be adjusted.
- Individuals on long-term glucocorticoids for other health conditions may also need an increased dose prior to the procedure and for 24 hours afterwards, especially those on an oral prednisolone dose of <10 mg/day (or equivalent) or high-dose inhaled therapy (beclomethasone equivalent of >800 mcg/day), but this should be discussed with their overseeing physician.

7.1.13 Ehlers–Danlos syndrome (EDS)

Key information

D	**Some types of Ehlers–Danlos syndrome (EDS) are associated with an increased risk of uterine rupture in pregnancy and/or joint hyperlaxity, both of which may be relevant to IUC procedures.**

Clinical recommendations

✓	**Suitability of IUC and the most appropriate setting for IUC insertion should be discussed with the individual's EDS specialist.**
✓	**Clinicians should be guided by the individual with EDS as to their most appropriate/ comfortable positioning during IUC insertion.**

Ehlers–Danlos syndrome (EDS) comprises a heterogeneous group of hereditary connective tissue diseases characterised by joint hyperlaxity, cutaneous hyperelasticity and tissue fragility. It affects approximately 1 in 5000 people[157] and the disorders are classified into 13 types, each caused by a different genetic mutation and therefore with different clinical manifestations.[158] Some types of EDS are associated with uterine rupture in pregnancy; however, there is no published evidence to inform whether this would translate into any increased risks during IUC insertion. Some types of EDS are associated with joint hyperlaxity, which can vary in severity and may be relevant when positioning someone for an IUC procedure.

Whilst there may be a link between hormonal changes and EDS symptom severity, no evidence was identified to suggest that an LNG-IUD would have any impact on EDS symptoms.

As there is no identified published evidence to inform the safety of use of an IUC in an individual with EDS, and because individuals experience EDS differently and to different degrees of severity, the GDG would recommend discussing contraceptive options and appropriate setting for IUC insertion with the individual's own EDS specialist.

The evidence

No published studies relating directly to the safety of IUC in individuals with EDS were identified. Whilst there is discussion in online forums suggesting that EDS symptoms may be worsened by progestogens, there were no studies identified that evidenced this scenario.

There is limited evidence that EDS symptoms may be related to endogenous and exogenous	Evidence

hormones. A 2016 French study,[159] which surveyed 386 women with hypermobile EDS, found that 17% of respondents noted the onset of EDS symptoms at puberty and 52% noted a worsening of EDS symptoms at puberty, whilst 22% noted an improvement in symptoms after menopause. POPs had been used by 67 (17%) respondents. EDS symptoms improvement was reported by 25.4 % of those using the POP (p = 0.03, OR 0.46, 95% CI 0.23–0.94).	level 2-

7.1.14 Individuals with cardiac disease

Key information

C	**Antibiotic prophylaxis is not routinely recommended when an individual at increased risk of developing infective endocarditis has an IUC procedure.**
D	**There is a small risk of vasovagal reaction during IUC procedures.**
✓	**The majority of IUC insertions in individuals with postural orthostatic tachycardia syndrome (PoTS) should be straightforward and low risk, providing precautions (adequate hydration, salt intake and postural awareness) are in place.**

Clinical recommendations

✓	**Contraception choice for individuals with cardiac disease will often require a multidisciplinary approach and discussion with the individual's cardiologist is recommended.**
✓	**For individuals with pre-existing arrhythmia, Eisenmenger physiology, single ventricle (or Fontan) circulation, long QT syndrome or impaired ventricular function a vasovagal reaction could pose a serious risk of a significant cardiac event and therefore IUC procedures should be undertaken in a hospital setting.**
✓	**If an individual with PoTS has a history of postural syncope, advice should be sought from their cardiologist as it may be recommended that insertion should be undertaken in a hospital setting.**
✓	**IUC insertion for an individual who is anticoagulated should be undertaken by an experienced clinician, with consideration given to the timing of the procedure, as well as ensuring availability of haemostatic agents/equipment.**

See FSRH Clinical Guideline Contraceptive Choices for Women with Cardiac Disease.[160]

Table 11 shows UKMEC[2] categories for the use of intrauterine contraception for individuals with cardiac disease.

Table 11: UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[2] categories for the use of intrauterine contraception for individuals with cardiac disease

Condition	UKMEC category for Cu-IUD		UKMEC category for LNG-IUD	
Current and history of ischaemic heart disease	1		**I**	**C**
			2	3
Stroke (history of cerebrovascular accident, including TIA)	1		**I**	**C**
			2	3
Cardiac arrhythmias				
a) Atrial fibrillation	1		2	
b) Known long QT syndrome	**I**	**C**	**I**	**C**
	3	1	3	1

Initiation: Starting a method by an individual with a specific medical condition.
Continuation: Continuing with the method already being used by an individual who develops a new medical condition.
Cu-IUD, copper intrauterine device; LNG-IUD, levonorgestrel intrauterine device; TIA, transient ischaemic attack; UKMEC, UK Medical Eligibility Criteria for Contraceptive Use.
See Table 3 for definition of UKMEC categories.

Careful consideration should be given to contraceptive counselling for individuals with cardiac disease, to support them to time and plan their pregnancies. Some cardiac conditions are associated with high maternal morbidity and mortality, and pregnancy may exacerbate symptoms of cardiac disease. In addition, some commonly used cardiac medications (such as warfarin, angiotensin-converting enzyme (ACE) inhibitors and aldosterone antagonists) are teratogenic; pregnancy planning allows review of medications to optimise the maternal and fetal outcomes. IUC has the benefit of being highly effective at preventing pregnancy and not interacting with other medications. HMB may exacerbate cardiac symptoms and the LNG-IUD may have additional non-contraceptive benefit for people with HMB by reducing blood loss.

Contraception choice for individuals with cardiac disease will often require a multidisciplinary approach and discussion with the individual's cardiologist is recommended.

7.1.14.1 Infective endocarditis

Invasive contraceptive procedures could theoretically increase the risk of infective endocarditis; however, routine use of antibiotic prophylaxis does not appear to affect endocarditis rates. In line with guidance from NICE, the European Society of Cardiology and the American Heart Association, antibiotic prophylaxis is not routinely recommended when an individual at increased risk of developing infective endocarditis has an IUC procedure.[161–163] Known genital infection would normally be treated prior to IUC insertion; however, in the context of a known or suspected genital infection that cannot be treated prior to IUC insertion, the suitability of an IUC should be discussed with the individual's cardiologist, who might recommend antibiotic prophylaxis for that particular individual.

7.1.14.2 Vasovagal reaction

There is a small (approximately 2%) risk of vasovagal reaction during IUC procedures.[164] Instrumentation or manipulation of the cervix can stimulate the vagus nerve, resulting in hypotension and bradycardia (or less commonly tachycardia or other arrhythmia), which can lead to cerebral hypoperfusion and a transient loss of consciousness. In healthy individuals vasovagal reactions usually resolve with simple resuscitation measures. However, individuals with cardiac disease may be more prone to the effects of bradycardia/hypotension or may not respond as quickly to simple measures. For individuals with pre-existing arrhythmia, Eisenmenger physiology, single ventricle (or Fontan) circulation, long QT syndrome or impaired ventricular function, a vasovagal reaction could pose a serious risk of a significant cardiac event. For these individuals, IUC procedures should be undertaken in a hospital setting.

There is inadequate published literature to determine the risk of adverse health events associated with IUC insertion in individuals with no known underlying cardiac condition who have asymptomatic bradycardia unrelated to medication. Expert opinion is that there is no requirement for IUC procedures to be undertaken in a hospital setting for these otherwise healthy individuals.

7.1.14.3 Postural orthostatic tachycardia syndrome (PoTS)

Postural (orthostatic) tachycardia syndrome (PoTS) is a disorder that is associated with an excessively increased heart rate, without significant hypotension, when moving to a standing position. It may result from a variety of underlying pathological processes and has been associated with a number of comorbidities including autoimmune disorders and EDS.[165,166] The presence of comorbidities may also affect contraceptive choice.

Symptoms of PoTS vary in severity between individuals but include palpitations, dizziness, syncope, breathlessness, shaking and sweating. These symptoms may be triggered by pain and/or anxiety, both of which can be experienced with IUC procedures. There is no published evidence specific to IUC use by individuals with PoTS. The GDG sought expert advice and were advised that in the majority of cases IUC insertion should be straightforward and low risk, providing precautions (adequate hydration, salt intake and postural awareness) are in place. It would be advisable to seek advice from the individual's cardiologist if the individual has a history of postural syncope, in which case it might be recommended that insertion should be undertaken in a hospital setting.

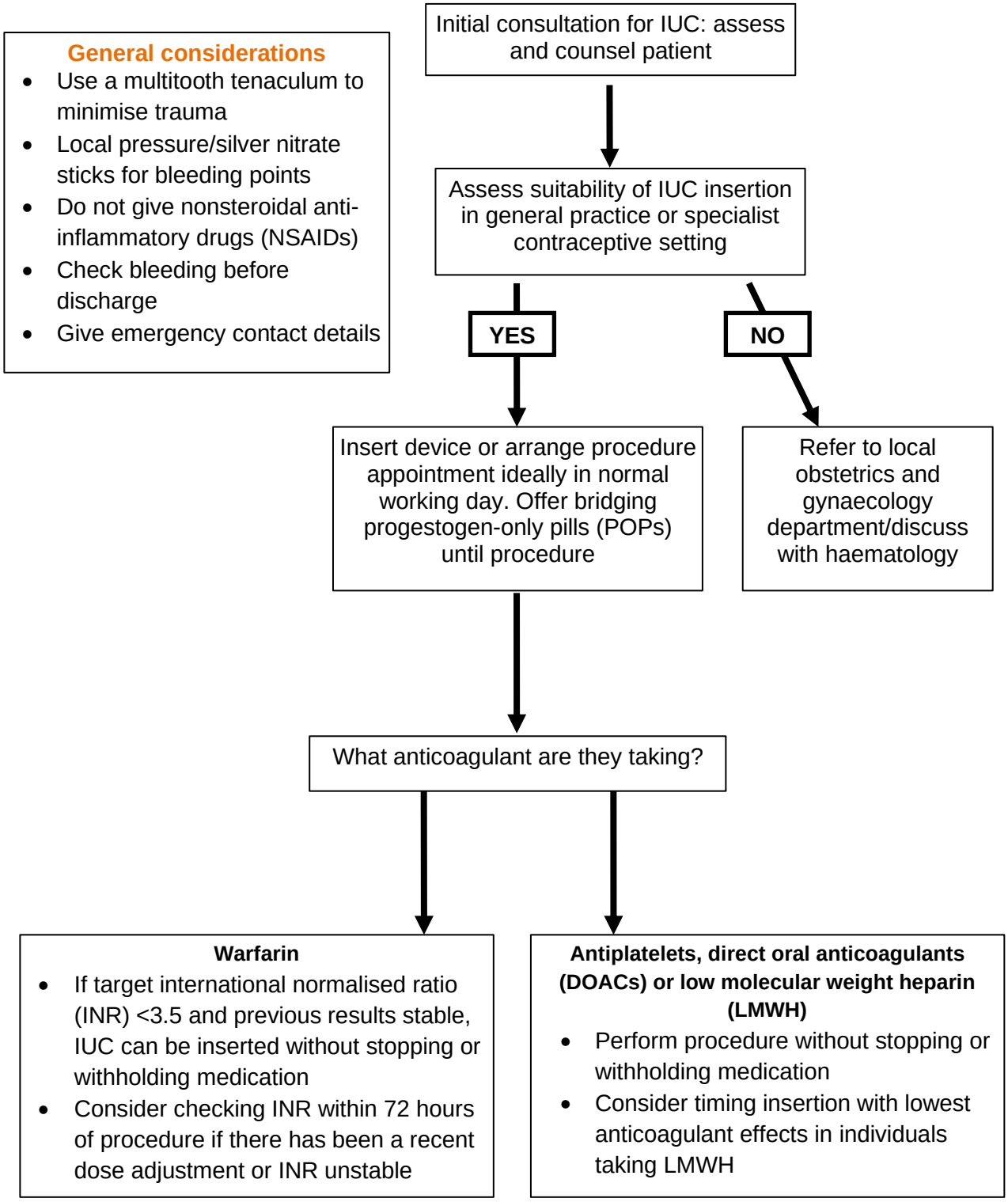
7.1.14.4 Individuals on anticoagulants

See FSRH CEU Statement Management of women taking anticoagulants or antiplatelet medications who request intrauterine contraception or subdermal implants.[167]

Individuals on anticoagulants can experience HMB for which an LNG-IUD may be of benefit.

Individuals who are anticoagulated can, in general, have their IUC procedure within a community setting (e.g. general practice or a community sexual health clinic). The procedure should be performed by clinicians who hold the relevant FSRH Letters of Competence and ideally are experienced IUC providers. Additional consideration should be given to the timing of the procedure, as well as ensuring availability of haemostatic agents/equipment, in line with the algorithm in **Figure 1**.

Figure 1: Algorithm for insertion of intrauterine contraception (IUC) in individuals taking anticoagulants or antiplatelet medication, adapted from the FSRH CEU Anticoagulant Statement[167]



7.1.14.5 Individuals using other cardiac medications

Beta blockers

Based on expert advice, individuals who use beta blockers would not normally be required to withhold this medication prior to IUC insertion. The indications for use for this group of medications are variable, and for some people withholding beta blockers could be detrimental. If there is any uncertainty about whether the medication should be withheld for an IUC insertion, advice should be sought from the individual's general practitioner (GP) or cardiologist.

Medications that prolong the QT interval

Based on expert advice, healthy individuals who are using medications that prolong the QT interval but have no history of unexplained syncope, or family history of long QT syndrome, can have their IUC inserted in a community setting without the need for any pre-assessment investigations (e.g. electrocardiogram (ECG), urea and electrolytes (U&Es)).

7.1.15 Individuals with inherited bleeding disorders

Clinical recommendations

✓ **When an individual with an inherited bleeding disorder requests IUC insertion, clinicians should take advice from the individual's haematologist as to the appropriateness of the method, where the procedure should be undertaken and whether any additional precautions are required.**

Inherited bleeding disorders are a diverse group of conditions that have mild, moderate and severe phenotypes, with wide variation in severity. Due to the heterogeneity of the conditions and the interpersonal variation in bleeding risk, the suitability of an IUC should be considered on a case-by-case basis. Clinicians should take advice from the individual's haematologist as to what the risk of bleeding is for that individual, whether IUC insertion is appropriate, where the procedure should be undertaken, if factor assays need checking prior to the procedure, and/or if haemostatic cover would be required before, during or after the procedure. Precautions should be taken to minimise the risk of bleeding during the procedure as per the 'General considerations' box in **Figure 1**.

Individuals with inherited bleeding disorders may experience HMB. From the limited studies of 52 mg LNG-IUD use by individuals with inherited bleeding disorders and HMB, the LNG-IUD appears to be effective in reducing blood loss and the UK Haemophilia Centres Doctors' Organisation Guideline recommends this as first-line treatment of HMB in individuals with inherited bleeding disorders.[23]

7.1.16 Allergy and sensitivity

Clinical recommendations

D **Use of IUC is contraindicated if there is a known or suspected allergy or hypersensitivity to any of the components of the device.**

Use of IUC is not recommended if there is a known or suspected allergy or hypersensitivity to any of the components of the device (e.g. copper, silver and LNG).

The evidence

Copper

In Cu-IUDs, ≥99% of the metallic component is copper; however, other metals such as nickel, gold and silver may be present in very small quantities.[168] The incidence of true copper allergy is very low[168,169]; however, there have been published case reports of dermatitis,[170–175] endometritis[176] and urticaria-angioedema syndrome[176] in individuals with a Cu-IUD in situ. Of the very few cases reported in the literature, some individuals went on to have allergy testing but not all of them had a positive patch test when tested against copper and/or nickel. Only three case studies reported the outcome once the copper IUD was removed, but in these three cases the symptoms resolved on removal of the device.

Evidence level 3

Silver

Individuals may report a suspected silver allergy following a reaction to jewellery. Most silver jewellery is made from sterling silver (92.5% pure silver alloyed with copper or other metals) or is silver-plated (a different base metal plated with silver) as pure silver (99.9% silver) is very soft. Therefore, without specific allergen testing it may not be possible to differentiate a silver allergy from that of another alloy.[177]

Kyleena and Jaydess contain a 99.95% silver ring on the vertical stem.[178,179] A systematic review of the literature did not identify any reports of silver allergy in individuals who use Kyleena or Jaydess (or Skyla in the US). The BNF currently lists one silver-containing Cu-IUD (TCu380 Ag) but no studies of its use by individuals with silver allergy were identified. Individuals with silver allergy may wish to use IUC that does not contain silver.

Evidence level 3

Levonorgestrel

The Drug Analysis Prints (DAPs)[180] list all suspected reactions to drugs reported to the Medicines and Healthcare products Regulatory Agency (MHRA) through the Yellow Card scheme. Between 1968 and 2022, DAPs recorded 46 allergic responses (which included hypersensitivity, anaphylactic and anaphylactoid responses), 81 cases of angioedoema or urticaria, and 21 cases of rash reported in individuals who used a single active constituent LNG product — which ***may*** include an LNG-IUD. The listing of a reaction in a DAP, however, does not necessarily mean that the drug ***caused*** the effect. Additionally, any adverse effect of an LNG-IUD could be related to the LNG or any other constituent in the device.

One case study of acute urticaria[181] and two case studies of dermatitis following Mirena insertion were identified in the literature. A 27-year-old developed acute whole-body urticaria, left lower quadrant pain and dizziness 2 hours after Mirena insertion. The Mirena was removed immediately, and the individual's urticaria resolved and did not recur. A 36-year-old was diagnosed with facial seborrhoeic dermatitis 6 months following insertion after presenting with a severe rash.[182] The other subject was 42 years old and diagnosed with "autoimmune progesterone dermatitis" after developing an "itchy eruption" on her thighs, chest and arms the day following insertion.[183] Both individuals with dermatitis were treated with topical steroids and the latter also with oral antihistamines. Treatment did not resolve the dermatitis in either subject and they each had their Mirena removed for this reason. In both cases, the dermatitis completely resolved following removal. The authors of one of the aforementioned case studies contacted the manufacturer of Mirena, who confirmed three additional cases of seborrhoeic dermatitis had been reported (as of 2006).

Evidence level 3

7.1.17 Wilson's disease and copper toxicity

Clinical recommendations

✓ **Cu-IUD use is not recommended for individuals with Wilson's disease.**

Wilson's disease is a rare genetic disorder of copper metabolism, resulting in accumulation of copper in the individual's organs and tissues.[184] There are no published studies that consider the effect of Cu-IUD use on copper accumulation or health outcomes in individuals with Wilson's disease. It is established practice that use of the Cu-IUD is avoided in those with Wilson's disease because of any potential risk that it could contribute further to the excessive accumulation of copper in the body. The BNF and the information leaflets that accompany Cu-IUDs indicate that use of the Cu-IUD is contraindicated in Wilson's disease.

There is limited published evidence concerning whether Cu-IUD use is associated with an increase in serum copper in healthy individuals, and the published evidence is conflicting.[185] However, any elevation seen is not to a level that would be expected to be associated with systemic symptoms and there is no evidence that a Cu-IUD is associated with copper toxicity in healthy individuals.[185]

The evidence

Evidence level 2-

The reference range for serum copper in women is currently quoted by specialist UK laboratories as 11–25 µmol/L[186] (which equates to about 0.7–1.6 mg/L), but serum copper levels have been demonstrated to vary significantly at different stages of the natural menstrual cycle[187] and increase markedly during pregnancy.[188] Severe copper toxicity with hepatorenal compromise is documented in cases of copper poisoning at levels above about 5 mg/L.[189] Gastrointestinal symptoms have been reported at whole blood copper levels of around 3 mg/L. (Whole blood copper appears to be similar to serum copper unless there is acute copper poisoning.[190]) Although there is information on the internet suggesting Cu-IUDs have been linked to copper toxicity, resulting in a wide variety of symptoms such as anxiety, depression, pain, headache and fatigue, there is no evidence of symptoms associated with the lower circulating copper levels observed in Cu-IUD users.

Most studies considering serum copper levels in users of the Cu-IUD have demonstrated no difference compared with non-users.[34,191–193] Imani *et al* found a slight but statistically significant increase after 3 months of use: 101 users of TCu380A had mean serum copper levels of 1.7 mg/L 3 months after insertion compared with 1.6 mg/L prior to insertion.[194] A 2005 Mexican study found a mean serum copper level of 2.16 mg/L in 86 T380A users compared with a mean of 1.07 mg/L in 8 non-IUD users.[195] The study did not report any related symptoms. No significant difference was seen relating to duration of use of the Cu-IUD. Symptoms related to serum copper concentrations at the level seen in these two studies are not described in the literature.

Symptoms experienced during Cu-IUD use may not relate to the Cu-IUD. Symptoms such as anxiety, depression, pain, headache and fatigue are common in the general population that is not using the Cu-IUD and contributing factors are many and varied. Adverse effects are commonly reported during use of all medications and interventions; they are also frequently reported by individuals receiving placebo treatment.[196]

8 Health risks associated with IUC use

8.1 Breast cancer

Key information

D **The available evidence suggests a possible association between current or recent use of hormonal contraception (including LNG-IUDs) and a small increase in risk of breast cancer; absolute risk remains very small.**

The available evidence suggests that there could be an association between current or recent hormonal contraception use (including LNG-IUDs) and breast cancer; however, any potential increased risk appears to be small.

The evidence

Evidence level2+

The number of incident breast cancers amongst women of reproductive age is very small, which makes effect of hormonal contraception on risk difficult to study. Some studies have found no effect of LNG-IUD use on breast cancer risk while others have reported a small increased risk. The available evidence derives from observational studies, and is thus inherently limited to evidencing associations rather than demonstrating causal relationships between LNG-IUD use and breast cancer. When interpreting the evidence, there are the following important considerations.

The observational, database-based nature of the studies that we *do* have means that findings could be affected by confounding factors that are not recorded or not considered. For example, a group of individuals that choose to use hormonal contraception may make other choices (eg lifestyle choices) that are different to those made by people that choose not to use hormonal contraception. There may be prescribing bias based on individuals' other risks. Individuals currently or recently using a given contraceptive method could have been using a different method prior to that and this is not always accounted for. The studies that have been combined in the different meta-analyses on this subject have taken a varied and sometimes limited approach to addressing confounding factors.

The meta-analyses brought together populations of different ages using the LNG-IUD for different reasons including contraception, HMB and other medical reasons. The studies also used different comparator populations, with some comparing LNG-IUD users with never-users of hormonal contraception and others making Cu-IUD users their only reference point. In addition, the follow up period in the studies limited their findings to reflecting relatively short-term associations.

Taken together, these factors make it difficult to ascertain the true nature of the relationship between LNG-IUD use and breast cancer risk.

Four recent systematic reviews[197,198,395,396] identified the same eight observational studies which assessed whether 52 mg LNG-IUD use was linked to an increased risk of breast cancer in healthy users. [199–206] Of the eight studies, half suggested there was increased risk[199–202] whilst half did not.[203–206] Heting *et al*[395] included one additional prospective cohort

study. The studies vary in the populations considered and the ability to adjust for potential confounding factors. Some studies included use of the LNG-IUD for non-contraceptive indications, including endometrial protection as part of HRT; use of other exogenous hormones was not always taken into consideration.

Evidence level2+

Three of the systematic reviews[197,198,395] have associated meta-analyses, but due to diverging views on statistical validity, different articles were included in the analyses and different results were produced. Conz *et al*[197] included seven studies (3 case–controls and 4 cohort studies of good–fair quality) and reported a small increase in breast cancer risk with LNG-IUD use (all women: OR 1.16, 95% CI 1.06–1.28; <50 years: OR 1.12, 95% CI 1.02–1.22; ≥50 years: OR 1.52 (95% CI 1.34–1.72). Silva *et al*[198] included four studies and found no significant increased risk: two cohort studies (RR 0.93, 95% CI 0.840–1.03, n = 144 996) and two case–control studies (OR 1.07, 95% CI 0.91–1.26, 5556 cases, 35 987 controls, moderate-quality evidence). Heting *et al*[395] undertook meta-analysis of data from 3 case-control and 3 cohort studies. They reported a non-significant increased breast cancer risk from meta-analysis of the cohort studies (OR 1.38 (95% CI 0.98-1.94; p=0.06) and a non-significant decreased risk from the case-control studies (OR 0.80 (95% CI 0.57-1.11, p=0.18). Zurcher et al concluded from their systematic review that the evidence suggested a small increased risk of breast cancer associated with LNG-IUD use, this being most evident amongst postmenopausal women and with longer durations of use. They highlight the heterogeneity of the studies in terms of the age group considered and the indication for LNG-IUD use.

Two large observational studies subsequent to those included in the reviews have reported a small but statistically significant increased risk of breast cancer with LNG-IUD use. The first was a Swedish retrospective cohort study by Hultstrand *et al*[393] that included data from over 1.5million women aged 15-34 years from 2005-2017. Compared with women who did not use hormonal contraception during the study period, current LNG-IUD users had a small increased risk of breast cancer (862,041 person-years of LNG-IUD use, n = 543 breast cancer events, adjusted RR 1.21 95% CI 1.01-1.33 p<0.01). Whilst they adjusted for some potential confounders, data on several key confounding factors were incomplete or absent (e.g. smoking, BMI, family history). The authors noted that selective prescribing may have factored into their results, as they found that overall breast cancer risk was not elevated with current combined hormonal contraceptive use, which ran counter to prior literature.

The second was a case-control study[394] using UK database data for the period 2007-2018 which compared current or recent use of hormonal contraception by individuals aged <50 years with incident breast cancer with use by matched controls. 509 people with incident breast cancer were currently using or had recently used an LNG-IUD. The study reported a small increased relative risk of breast cancer amongst current or recent LNG-IUD users (they could previously have used other hormonal contraceptives) compared with people who had not used hormonal contraception during the study period (adjusted OR 1.32, 95% CI 1.17-1.49). Adjustment was made for time since last birth, number of recorded births, BMI, and alcohol intake. This effect on risk was similar in size to that with the other progestogen-only methods investigated.

Meta-analysis by the Fitzpatrick *et al*[394] combined data from their study with data from 4 other observational studies (including the Hultstrand paper described earlier[393]) suggested

Evidence

a small but statistically significant increased breast cancer risk for current or recent premenopausal users of the LNG-IUD, compared with non-users of hormonal contraception (RR 1.21, 95% CI 1.14-1.28). This was similar to risk associated with use of other hormonal contraceptives. As the number of cases of breast cancer is very small amongst people aged under 50, the absolute risk of breast cancer remained very low amongst users of hormonal contraception, including the LNG-IUD. level2+

8.2 Ovarian cysts

Key information

D **Although incidence of ovarian cysts may be elevated during LNG-IUD use, this does not appear to be clinically significant.**

D **Presence of (or history of) ovarian cysts or polycystic ovary syndrome is not a contraindication to IUC use.**

Although rates of ovarian cyst appear elevated during LNG-IUD use, the clinical significance of this finding is unclear.[61,82,207–209] Whilst ovarian cysts can cause pelvic pain, dyspareunia and, very rarely, serious adverse events (e.g. cyst rupture), this is not typical.[64,67,178,208–210] The vast majority of ovarian cysts in LNG-IUD users are asymptomatic and transient, with typically 80%–90% resolving spontaneously within 3 months.[208,209] This is reflected in very low LNG-IUD discontinuation rates due to ovarian cysts, typically about 0.5% across the lifetime of the various LNG-IUDs.[8,61,64,69,209]

UKMEC 2016 states that benign ovarian tumours, including cysts, do not restrict use of the LNG-IUD.[2]

The evidence

Ovarian cysts are typically noted as adverse events in clinical trials if they are abnormal, non-functional and/or >3 cm in diameter (although this varies).[82,178,210] In LNG-IUD studies, ovarian cysts have been reported prior to LNG-IUD insertion or in control groups without hormonal contraception in 0.7%–5.2% of subjects.[207–209,211,212] Reported ovarian cyst rates are higher after LNG-IUD insertion[208,209] but prevalence estimates for the effect size vary widely. This is likely due to differences in how cysts are defined and identified in different studies. For instance, some trials routinely scanned all participants every 3–6 months,[208,209] whilst others restricted scans to symptomatic subjects.[61] The evidence suggests that risk of ovarian cyst during LNG-IUD use increases with increasing size of LNG reservoir. Evidence level 1-

In a high-quality comparative RCT (n = 2885), 7.7% of individuals with the 13.5 mg LNG-IUD and 13.8% of individuals with the 19.5 mg LNG-IUD had an ovarian cyst identified during the 3-year study (p<0.001).[62] Likewise, in a 3-year RCT (n = 738), ovarian cysts were the only drug-related adverse event that occurred significantly more frequently in any treatment group (52 mg: 22.0%; 19.5 mg: 8.6%; 13.5 mg: 5.9%; p<0.0001).[79]

Other studies have also reported higher rates of ovarian cysts with LNG-IUD use compared with hysterectomy (RR 5.9),[207] ENG implant (2.6% vs 0.8% over 12 months' use)[82] or COC (4.7% vs 1.3%[212], RR 5.5, 95% CI 1.2–25.3).[213]

13.5 mg LNG-IUD and ovarian cyst

In a secondary analysis of a large, well-conducted 3-year RCT that randomised subjects to either the 13.5 mg or 19.5 mg LNG-IUD, Nahum *et al* reported that 1.9%–2.4% of users of the 13.5 mg LNG-IUD had an ovarian cyst at each of the 3–6 monthly scans.[208] Over the course of 12 months' total use, 2.6%–8% of 13.5 mg LNG-IUD users were reported to have ovarian cysts.[80,82,208] Longer trials have found 3-year cumulative ovarian cyst rates of 5.9%–7.7%.[62,64,79]

Evidence level 1-

19.5 mg LNG-IUD and ovarian cyst

In their secondary analysis from the 19.5 mg arm of the LNG-IUD RCT, Nahum *et al* found the percentage of participants with ovarian cysts remained low over 5 years at 1.9%–4.8% per visit. Cumulatively across the first year, this equated to 15% of participants.[209] Two RCTs reported on 3 years of cumulative use, finding that 8.6%–13.8% of users had an ovarian cyst[62,79]; this climbed to 23.3% over 5 years of use.[63] In the latter RCT the investigators also noted that that the rate would be 15.7% if only those cysts judged by researchers to be study drug-related were included.

Evidence level 1-

52 mg LNG-IUD and ovarian cyst

At each study visit over 12 months, 3.2%–21.5% of individuals using the 52 mg LNG-IUD were found to have ovarian cysts in two RCTs.[207,211] This wide range continues in cumulative ovarian cyst rates, from 2.2% over 5 years in one RCT (n = 678)[69] to 22% over 3 years in another (n = 738).[79] A large, high-quality trial of Levosert (n = 1751) only scanned users when clinically indicated (e.g. abdominal pain, non-visible threads). This study found 4.5% of users had ovarian cysts over 5 years of device use.[61]

Evidence level1-

8.3 Bone mineral density

Key information

D **The limited evidence available suggests that IUC use has no significant effect on serum estradiol levels or bone mineral density.**

The limited available evidence suggests that there is no significant effect on serum estradiol levels or bone mineral density (BMD) in LNG-IUD users. As the Cu-IUD has no effect on the hypothalamic-pituitary-ovarian axis, no effect on BMD would be expected.

The evidence

The literature review identified a single case report suggesting a link between LNG-IUD and osteoporosis.[214] A young woman, with risk factors for osteoporosis (low BMI and a smoker), was diagnosed with osteoporosis in the femoral neck and radius at the age of 25 years after 6 years of LNG-IUD use. Serum estradiol levels ranged from 8 to 59 pg/ml (normal range (NR) pre-menopausal 30–400 pg/ml; NR post-menopausal 0–30 pg/ml) during LNG-IUD use but returned to normal (193 pg/ml) 17 days after removal and remained within the typical range of a normal ovulatory menstrual cycle in the subsequent months and years.

Evidence level 3

However, this case is in contrast to five small studies that showed no significant reduction in BMD or in estradiol levels. A pharmacokinetic study of LNG-IUD[48] monitored estradiol levels

Evidence level 2-

in 53 individuals with either 52 mg, 19.5 mg or 13.5 mg LNG-IUD on 12 occasions per year over 3 years. Mean estradiol levels showed high variability and remained within the typical range of a normal menstrual cycle, with no observed trend for levels to increase or decrease over time and no significant difference between the groups.

Normal estradiol levels were also seen on a single measurement at 7 years post-Mirena insertion in a study measuring BMD in 53 Mirena users.[215] This study of individuals aged 25–51 years observed that those using 52 mg LNG-IUD for 7 years had a mean BMD in the ulna midshaft and distal radius similar to Cu-IUD users in the control group. Thirty-seven of these individuals were followed up for a further 3 years[216] and the BMD remained similar to that of IUD users and unchanged between the seventh and the tenth years of use of the LNG-IUD.

Evidence level 2-

Similarly, a study of 103 13.5 mg LNG-IUD users and 102 19.5 mg LNG-IUD users[62] aged 18–35 years observed no change from baseline BMD at the lumbar spine or total hip over the 3-year period. A small study of 36 older individuals (aged 40–45 years at time of insertion) found no changes when comparing baseline BMD of the femur or lumbar spine with measurements 2 years after insertion of 52 mg LNG-IUD.[217]

9 Side effects associated with IUC use

9.1 Bleeding patterns

Key information

C	**Cu-IUD use is associated with an increase in menstrual blood loss and intermenstrual bleeding compared with natural menstrual cycles in individuals without Cu-IUD.**
D	**Increased menstrual bleeding associated with Cu-IUD use will often decrease over time.**
C	**Altered bleeding patterns are common after LNG-IUD insertion.**
C	**With the LNG-IUD there is a trend towards decreased bleeding over time.**

Clinical recommendations

✓	**Individuals should be informed about the expected changes in bleeding pattern with an IUC.**

9.1.1 Cu-IUD

The Cu-IUD has been associated with an increase in menstrual blood loss and intermenstrual bleeding, secondary to increased release of prostaglandin and other vasoactive agents within the endometrium as part of an inflammatory response.[218–220] Bleeding may be heavier, longer or more painful than prior to Cu-IUD insertion and users may experience intermenstrual bleeding.

Increased menstrual bleeding will often decrease over time[221–223]; however, intermenstrual bleeding is less likely to do so.[221] Studies do not suggest clinically significant decreases in haemoglobin and increased

incidence of anaemia among Cu-IUD users in general.[224,225]

As with other LARC methods, increased bleeding is often cited as the most common reason for discontinuation of a Cu-IUD.[223,226] However, continuation rates for Cu-IUDs are high, suggesting that in spite of this the method is often highly acceptable.[223]

Bleeding patterns may differ between different Cu-IUDs; however, there is insufficient evidence to recommend one Cu-IUD device over another or predict bleeding for any specific device.

The evidence

Hubacher *et al*'s 2009 prospective study of 1947 new Cu-IUD users examined the menstrual side effects of Cu-IUD use at 12 months and found that menstrual bleeding and pain decreased over time, but intermenstrual spotting and intermenstrual pain remained unchanged.[221]

Evidence level 2-

A smaller 2018 prospective, longitudinal, observational cohort study[222] evaluated the impact of bleeding and cramping on method satisfaction during the first 6 months of Cu-IUD use in 77 individuals. Bleeding significantly decreased (23%; p<0.05) over the 6-month course of the study.

A 2016 prospective cohort study of Cu-IUD users by Bateson *et al*[223] followed up 207 individuals at 6 weeks, 6 months, 1 year, 2 years and 3 years post-insertion. Prior to insertion, most individuals had menses that were regular (80.6%; n = 170) and not heavy (92.3%; n = 192). After 12 months, 167 individuals still had an IUD in situ and data were available from 105 of them. Of these individuals, 64 (60.9%) were happy with the frequency of their bleeding. Thirty-seven (35%) reported prolonged bleeding of more than 7 days and 45 (43%) reported increased dysmenorrhoea since the IUD was inserted. Forty-five (43%) individuals reported heavy bleeding in the previous month (43%), of whom only five (11%) discontinued due to ongoing heavy bleeding issues in the subsequent 12 months. Of the 207 individuals recruited for whom data were available at the end of the 3-year study period, HMB was the most common reason for early discontinuation in individuals still requiring contraception (28/59, 47.5%), in line with similar findings from a large prospective cohort study that found that bleeding disturbance was the reason for discontinuation in 41% of individuals who discontinued the Cu-IUD.[226] Bateson *et al* concluded that their findings, along with those of Hubacher *et al*, support the possibility that if individuals are provided with information about expected improvements in bleeding patterns they may tolerate short-term inconvenience for longer-term gain.

A 2022 interim analysis of a 3-year, phase III single (participant) blind, randomised multicentre trial in the US randomised nulliparous subjects aged 17–40 years to either a NT380-Mini (n = 744) or a TCu380A (n = 183) Cu-IUD and compared first-year continuation rates and reasons for early removal.[96] They found that the NT380-Mini had higher 12-month continuation rates (78.7%, 95% CI 72.9−84.5% vs 70.2%, 95% CI 59.7−80.7, p = 0.014) and lower rates of removal for bleeding and/or pain (8.1% vs 16.2%, p = 0.003). Whilst this suggests that bleeding, pain and continuation rates may vary between devices, it is not possible to conclude that the differences were attributed only to the size of the devices, as there were other differences (shape and design) between the devices.

Evidence level 1-

Evidence level 1-

Similarly, a small 2019 chart review[227] of 130 Cu-IUD users (63 who had a standard-sized TT380 Slimline inserted and 67 who had a Mini TT380 Slimline inserted) found that in those who had their IUD removed within the first year of use, pain and bleeding were more commonly reported in those who had a standard IUD removed versus those who had the mini-IUD removed (80%, n = 14 vs 30%, n = 3; p = 0.056). Removal within first year of use was also more common in the standard-sized group (20%, n = 32) compared with the mini-sized group (10%, n = 15).

Evidence level 2-

A 2021 secondary reanalysis of the EURAS data focused on subjects aged under 30 years at the time of Cu-IUD insertion (n = 5796).[56] This article classified 41 different Cu-IUDs by their copper content, design and size. They found differences in bleeding, pain, expulsion and continuation rates between devices with different copper loads and with different frame design, size and flexibility and concluded that higher Cu-IUD continuation and fewer unwanted effects were observed with Cu-IUDs of the lowest copper content (<300 mm^2 copper), horseshoe frame design, widths 18–30 mm and flexible Cu-IUD arms, whilst discontinuation and unwanted effects were greater with Cu-IUDs that were frameless or framed with ≥30 mm width, 380 mm^2 of copper and copper bands on their rigid transverse Cu-IUD arms. Whilst this was an international study, almost half the data came from the UK, meaning key relevant devices were included. However, the availability of data did vary significantly between devices, for instance only 92 frameless device users were included compared with over 4000 T-shaped device users. In addition, as an observational study there could be confounding relating to the types of Cu-IUD that were recommended to and selected by individuals. However, the results highlight that factors such as smaller uterine size could influence the tolerability and continuation of different Cu-IUDs for younger users.

Two systematic reviews concluded that there was no clinically significant decrease in haemoglobin in Cu-IUD users. Tepper *et al*[225] concluded that healthy Cu-IUD users did not show clinically significant changes in haemoglobin levels when followed for up to 5 years of use. Lowe et al[224] concluded that decreases in haemoglobin mean values in copper IUD users were not sufficient to induce anaemia in previously non-anaemic users.

Evidence level 1-

9.1.2 LNG-IUD

Altered bleeding patterns are common after insertion of the LNG-IUD[8,60–64,79,84,178,210,228–232] with much still to be understood about the aetiology of these changes.[233] Studies vary in their approach to assessing and reporting menstrual bleeding patterns, making overall conclusions challenging to draw. The WHO Belsey definitions of bleeding patterns with contraceptive use are shown in **Table 12**.[234] For all LNG-IUD types, however, prolonged, frequent and irregular bleeding and number of bleeding/spotting days reduce over the first year of use and rates of amenorrhoea and infrequent bleeding increase (**Tables 13** and **Table 14**).

Table 12: World Health Organization (WHO) Belsey definitions of bleeding patterns with contraceptive use[234]

Bleeding pattern	Definition
Amenorrhea	No bleeding or spotting during a 90-day reference period
Infrequent bleeding	One or two bleeding/spotting episodes during a 90-day reference period
Frequent bleeding	More than five bleeding/spotting episodes during a 90-day reference period
Irregular bleeding	Three to five bleeding/spotting episodes and fewer than three bleeding/ spotting-free intervals of 14 days or more during a 90-day reference period
Prolonged bleeding	Bleeding/spotting episode lasting more than 14 days during a 90-day reference period

Table 13: Clinically important bleeding patterns over the first year of levonorgestrel intrauterine device use*

Type of LNG-IUD	Pattern (WHO Belsey criteria[234])	First 90 days (%)	Second 90 days (%)	Last 90 days of first year (%)
52 mg[231]	Prolonged	51	10	5
	Frequent	26	10	5
	Irregular	38	14	6
19.5 mg[178]	Prolonged	57	14	6
	Frequent	25	10	4
	Irregular	43	25	17
13.5 mg[64,82,210]	Prolonged	39–55	14–19	5–8
	Frequent	20–31	5–13	3–10
	Irregular	39–49	25–32	18–25

LNG-IUD, levonorgestrel intrauterine device; WHO, World Health Organization.

*Note that figures for the different devices are from different studies and are not directly comparable.

Table 14: Amenorrhoea rates by levonorgestrel intrauterine device type over the first year*

Type of LNG-IUD	Pattern (WHO Belsey criteria[234])	First 90 days (%)	Second 90 days (%)	Last 90 days of first year (%)
52 mg[229,231]	Amenorrhoea	0.2	8	20
	Infrequent	13.5	25.1	30.6
19.5 mg[178]	Amenorrhoea	<1	5	12
	Infrequent	10	20	26
13.5 mg[64,82,210]	Amenorrhoea	<1	3–4	6–9
	Infrequent	8	19–20	19–20

LNG-IUD, levonorgestrel intrauterine device; WHO, World Health Organization.

*Note that figures for the different devices are from different studies and are not directly comparable.

Beyond the first year, the incidences of prolonged, frequent and irregular bleeding reduce, whilst amenorrhoea becomes more prevalent. By the end of licensed duration of use, studies report amenorrhoea in 11%–12% of 13.5 mg users,[64,210] 23% of 19.5 mg users[178] and

Evidence level 2-

33.6%[13] to 39%[400] of 52 mg users.

Data are limited, but clinical experience indicates that consecutive LNG-IUD use appears to induce a small, temporary increase in bleeding/spotting in the first 90 days after the replacement device is inserted. Thereafter bleeding/spotting return to a very low and constant level,[9,235] with higher rates of amenorrhoea than in first-time users at 4-6 weeks post-insertion.[236]

Whilst infrequent bleeding or amenorrhoea may be considered a benefit by some users, there are individual and cultural differences in views on bleeding patterns.[8] Amenorrhoea in particular may be viewed positively by many[82,235] but not all users.[8] Ensuring that potential LNG-IUD users are informed about possible bleeding pattern changes, including amenorrhoea, enables informed decision-making and improves satisfaction rates.[237]

The evidence: bleeding patterns with LNG-IUD devices

A systematic review examining the 52 mg LNG-IUD reported a reduction in the number of bleeding and/or spotting days across the first year from 35.6 days (95% CI 32.2–39.1) during the first 90-day period to 19.1 days (95% CI 16.6–21.5) in the second 90 days and 11.7 days (95% CI 9.7–13.7) by the end of the first year.[228] Evidence level 1-

Common initial bleeding patterns after LNG-IUD insertion include prolonged, frequent or irregular bleeding (as defined by the WHO Belsey criteria).[234] All these patterns are less frequently reported after the first 3 months post-insertion (**Table 13**).

Only one RCT was identified that directly compared the 13.5 mg, 19.5 mg and 52 mg LNG-IUD devices (n = 742). This well-conducted study of bleeding patterns over 3 years found that the initial number of bleeding/spotting days were similar and decreased at a similar rate across all three devices. The biggest reduction was from the first 90 days to the second 90 days, when mean bleeding and/or spotting days halved from about 40 days to about 23 days.[79]

A clinical trial found that 79.4% of 52 mg LNG-IUD users (n = 509) reported much lighter bleeding after a year of use whilst 16.7% reported no change; 69.4% felt the change in their bleeding pattern was beneficial.[232]

Beyond the first year, prolonged, frequent and irregular bleeding further reduce, whilst amenorrhoea becomes more prevalent.[64,178,210,231] A comparative RCT found that by the end of year 3, 12.7% of 13.5 mg users, 18.9% of 19.5 mg users and 23.6% of 52 mg LNG-IUD users reported amenorrhoea (p = 0.012 for 13.5 mg vs 52 mg; p = 0.30 for 19.5 mg vs 52 mg).[79]

By the end of their standard licensed durations of use (3 years, 5 years and 8 years, respectively), 11%– 12% of 13.5 mg users,[64,210] 23% of 19.5 mg users[178] and 33.6%[13] to 39%[400] of 52 mg users reported amenorrhoea. Evidence that amenorrhoea rates could continue to rise with extended use of the same device up to 15 years[12] is likely to reflect the Evidence level 1-

fact that individuals keeping the devices beyond 6 years were aged over 45 years. Other shorter studies have found little change in amenorrhoea rates from 5 to 6 years.[9,230]

9.1.2.1 Discontinuation due to bleeding pattern

Whilst bleeding is one of the more common reasons cited for LNG-IUD discontinuation,[71,238] in studies rates of discontinuation due to bleeding are low across the 13.5 mg, 19.5 mg and 52 mg devices at 5% or less over 3–5 years.[61–63,231] Data from a large clinical trial of Levosert suggests that most (77%) bleeding-related discontinuations occur in year 1 or 2,[61] and are predominantly due to flow that is heavy, irregular, prolonged or more frequent.[231] Discontinuation due to bleeding seems less likely with the LNG-IUD than with other LARC methods including the ENG implant[76,82,238] and Cu-IUD.[75,238]

Evidence level 1-

It is noted that other large studies reporting discontinuation rates due to bleeding collected data up to 40 years ago[59,60]; it is considered likely that these data would not necessarily represent continuation by current users and therefore more recent data are cited here.

9.1.2.2 Predictors of bleeding patterns with LNG-IUD devices

There are no identified robust predictors of bleeding pattern with the LNG-IUD. There is no apparent significant association with age, parity or obesity. Larger uterine cavity size could be associated with more spotting in the first 12 months of use.

There is little evidence to inform whether initial bleeding pattern depends on timing of LNG-IUD insertion. Evidence from a single study suggests that insertion of the 13.5 mg LNG-IUD on days 1–7 of a natural cycle could be associated with fewer bleeding days in the first 30 days after insertion (but not thereafter), and that there could be fewer bleeding days in the first 90 days if the individual had switched from another hormonal contraceptive.

Findings relating to the effect of LNG-IUD malposition on bleeding pattern are inconsistent, but limited evidence and clinical experience indicate that non-fundal LNG-IUD position could be associated with more frequent/prolonged and heavier bleeding than if the device is correctly positioned at the fundus.

The evidence: predictors of bleeding pattern with the LNG-IUD

Age does not appear to significantly impact bleeding pattern in the first year of use.[75,76] Likewise, neither parity nor obesity seem to have a consistent impact on bleeding patterns.[231] Based on limited evidence, increasing uterine cavity size may be associated with more spotting in months 1–3 and 1–12 post-insertion, whilst smoking could have an association with amenorrhoea.[239]

Evidence level 2-

A prospective cohort study of early (days 1–7) versus late (day 8+) 13.5 mg LNG-IUD insertion found insertion timing had no impact on the 90-day bleeding pattern (n = 132),[240] a finding supported by a small RCT for a 52 mg device.[241] However, the cohort study did find early insertion of the 13.5 mg LNG-IUD was associated with fewer bleeding days in the first 30 days (5 ± 3 days vs 7 ± 4 days, $p<0.01$). In addition, individuals who switched from another hormonal method to the LNG-IUD experienced fewer days of bleeding in both the 30-day and 90-day reference periods.[240]

Evidence level 2-

There is a lack of conclusive evidence of the impact of LNG-IUD position on bleeding patterns. One prospective cohort study (n = 413) found malposition at 6 weeks' post-insertion had no impact on bleeding at 4–6 weeks.[236] However, another, smaller prospective cohort study (n = 92) found non-fundal placement may be associated with more frequent/prolonged bleeding at 3 months (83.8% vs 51.2%, p = 0.002) and 6 months (58.3% vs 33.3%, p = 0.037) and greater menstrual blood loss at 6 months. Notably, both groups in this study perceived a reduction in bleeding with no statistically significant difference between them.[242]

9.1.2.3 Management of problematic bleeding

A 2020 systematic review of management strategies for LNG-IUD-induced bleeding irregularity identified six RCTS and two prospective cohort studies (total n = 677).[243] Study subjects were treated with a variety of medications including tamoxifen, mifepristone, ulipristal acetate, naproxen, estradiol, mefenamic acid, tranexamic acid and the progesterone receptor modulator CDB 2914. The review authors highlight positive results from a small RCT that found prophylactic use of naproxen (500 mg twice daily taken for the first 5 days in every 4-week period in the 12 weeks after insertion) reduced bleeding over that time compared with placebo (aRR for bleeding 0.90; 95% CI 0.84–0.97)[244]. However, this was a single RCT with 42 individuals in the naproxen arm so firm conclusions cannot be drawn.

Evidence level 1-

Overall, the studies were generally small and of low quality, with no conclusive evidence to support any intervention for either prophylaxis or treatment of bleeding irregularities post-insertion.

9.2 Hormonal side effects

Key information

D **Acne, breast tenderness, headache and mood changes are reported by some individuals using LNG-IUD. However, evidence is too limited to confirm or exclude a causative effect. When present these symptoms appear to be more prevalent in the first few months after insertion but decrease with time.**

Whilst the contraceptive mechanism of the LNG-IUD is primarily through local effects on the uterus,[66,67,178,179] hormonal symptoms could arise from LNG entering the systemic circulation.[245] Several hormonal symptoms are listed as common potential adverse effects by manufacturers of the 13.5 mg, 19.5 mg and 52 mg LNG-IUDs.[66,67,178,179] The side effect profiles for the different IUDs have been reported as being similar, and undesirable effects appear to be more prevalent in the first few months after insertion but decrease with time.[67]

Typical rates in LNG-IUD users in clinical studies include acne 8%–15% over 1–7 years,[61–63,80–82] headache 1%–14% over 1–7 years,[61–63,80–82] mood changes 5.8%–11.4% over 3–7 years[61,62,79] and breast tenderness/pain/discomfort 1.8%–20.3% over 3–7 years.[61,62,79] However, the high prevalence of such symptoms in the general population[246] combined with notable limitations in the evidence base, leave significant uncertainty as to whether any of these relationships are causal.[247–249]

Irrespective of causality, concerns about hormonal side effects can cause distress and contribute to LNG-IUD discontinuation. The rate of discontinuation for all the hormonal symptoms combined has been found to be low (2.8%–5.7% of all LNG-IUD users over 5–7 years).[8,61,250] Of all the hormonal side effects, acne is the most frequently cited reason for discontinuation, leading 1.4%–2.7% of all LNG-IUD users to discontinue device use early.[60,61,63]

Some evidence suggests that rather than a single hormonal symptom of high severity, it is often a constellation of side effects, both potentially progestogen-related and not, that leads to LNG-IUD discontinuation.[69,251] Therefore, understanding not just individual hormonal side effects, but the broader patient experience of the device, is essential.

The evidence

Of all the hormonal symptoms, acne was found to have the largest dedicated literature, with some evidence of new acne and worsening of existing acne with LNG-IUD use. A large, retrospective cohort study found the absolute risk difference for incident acne between the LNG-IUD and other contraceptive methods was less than 1%.[252] Two recent but limited-quality narrative reviews concurred that the existing data do suggest that the LNG-IUD increases the risk of acne, and that there is biological plausibility to support this finding.[247,249] However, they also emphasised evidentiary weaknesses, for instance a lack of validated tools to assess acne, and a failure to account for the impact of COC discontinuation prior to LNG-IUD initiation. As with other hormonal symptoms, active enquiry likely leads to much higher reporting rates. This likely explains why acne rates in the phase II trial of the 13.5 mg and 19.5 mg devices[79] were double those of the subsequent phase III trial[62] and other trials[63] (3-year acne incidence for phase II trial 13.5 mg: 25.9%, 19.5 mg: 22.4% vs phase III trial 13.5 mg: 10.1%, 19.5 mg: 9.9%).

Evidence level 1-

Several terms relating to mood are included in the literature such as mood changes, mood swings, emotional lability and altered mood, as well as depression.[61,63,250] A good-quality 2018 systematic review examined whether a link exists between progesterone-only contraception and depression.[248] The authors concluded that a definitive answer could not be reached given the weak quality of the evidence, but that most studies to date do not support a link between the LNG-IUD and depression. Challenges identified in the evidence included a lack of prospective studies, a lack of validated tools to assess depression, and evidence relating to subpopulations who might have reasons apart from the LNG-IUD to have low mood.

Patients may preferentially select the 13.5 mg and 19.5 mg devices due to their lower hormonal doses[251]. However, whilst having a larger reservoir device is typically associated with higher plasma LNG concentrations,[66,67,178,179] the available evidence does not indicate resulting higher rates of hormonal side effects.[62,79,253]

Three large RCTs comparing 20 mcg/day LNG-IUDs with a Cu-IUD found higher rates of discontinuation due to hormonal side effects with the LNG-IUD.[8,60,250] However, none of the trials were double-blind and two were open-label. Given that hormonal side effects would only be expected with a hormonal device, the lack of blinding leaves a significant risk of differential crediting of such symptoms to the LNG-IUD by both patients and clinicians. This

Evidence level 1-

could lead to differential discontinuation of the LNG-IUD compared with the Cu-IUD if such symptoms arose, even if this were coincidental.

9.3 Libido

Whilst individual experiences vary, the evidence suggests that for most users an IUC has either no impact or a positive impact on sexual experiences.[16,253–260] It is recognised that there are many factors that affect libido, and if an individual reports concern about their libido then other contributing factors should be explored. If an individual considers that an IUC is adversely affecting their libido they may wish to consider trying a different contraceptive method.

The evidence

Many of the studies are cross-sectional surveys[254,257,258] with only three RCTs identified, all focused on individuals with HMB.[16,255,256] This inherently limits any ability to ascribe any observed change to the IUC itself.

Of the studies that reported a generally positive effect, the scale of impact varied from small to significant. A large, prospective cohort study found that validated sexual functioning scores largely remained unchanged over 3 months despite participants reporting significant impacts on their sexual experiences (Cu-IUD, n = 311, 30.6% improved sex life a lot, 27.6% improved sex life a little; LNG-IUD, n = 669, 25% improved sex life a lot, 27.1% improved sex life a little).[260]

Evidence level 2-

A minority of IUC users report a negative impact on their sex lives.[67,179,260] There is some low-quality evidence that this could contribute to IUC removal rates, with individuals who perceived that their method negatively affected their sexual experience having higher removal rates than those who reported no changes or positive changes (aHR 8.04, 95% CI 1.53–42.24).[261]

A qualitative study of 50 subjects (both IUC users and never-users) examined reasons why IUC might impact on sexual experiences.[262] This study found that security in the IUC's contraceptive effectiveness and its lack of interruption of sex were viewed positively, but that bleeding/cramping were potential problems. The latter point is supported by a large, prospective cohort study which found bleeding reduction was significantly associated with more positive sexual perceptions of a contraceptive method (OR 1.43, 95% CI 1.18–1.74, p<0.001), whilst increased vaginal bleeding had significantly lower odds of being associated with positive sexual perceptions (OR 0.77, 95% CI 0.63–0.94, p = 0.01).[260]

One of the first concerns voiced by participants in the qualitative study was that IUD threads would detract from their male partner's experience.[262] However, a 2015 retrospective cohort study (n = 873) found that users reported that their male partners had not noticed or were not bothered by the threads in 93.4% of LNG-IUD and 97.7% of Cu-IUD users. There was a statistically significant difference with GyneFix for which 18.2% of users said their male partners had noticed and were bothered by the IUD threads, with doctors subsequently shortening and/or tucking the threads into the cervix in most cases.[263]

Evidence level 2-

No data comparing the effect on libido of the different types of LNG-IUD were identified.

Studies directly comparing the Cu-IUD and the LNG-IUD reported no significant difference in the devices' impact on sexual experience.[257,264,265] A large, cross-sectional survey of participants in the Contraceptive CHOICE Project (n = 1938) found that at 6 months, users of the Cu-IUD were less likely to report a lack of interest in sex compared with users of the vaginal ring (aOR 2.53, 95% CI 1.37–4.69), depot medroxyprogesterone acetate (DMPA) (aOR 2.61, 95% CI 1.47–4.61) or implant (aOR 1.60, 95% CI 1.03–2.49).[257] Likewise, a prospective cohort study (n = 2157) found that compared with oral contraceptive users, Cu-IUD users had significantly increased odds of ascribing positive sexual impacts to their method after 3 months (OR 1.88, 95% CI 1.45–2.44, p<0.001).[260]

In subjects with HMB, an RCT (n = 270) found that after 2 years the LNG-IUD had no impact on sexual functioning, and was no better or worse in this regard than endometrial ablation.[16] Similarly, an RCT comparing the LNG-IUD with usual medical treatments for HMB (n = 571) found no between-method differences in sexual activity scores at 5 years.[255] A third RCT (n = 236) found hysterectomy offered better sexual satisfaction outcomes than the LNG-IUD at 6 months, 12 months and 5 years, but the authors cautioned that the differences were small and potentially not clinically relevant. Notably, all these studies were affected by significant levels of crossover and discontinuation, which may affect the utility of the results.[256]

Evidence level 1-

9.4 Weight

In the general population there are no significant differences in weight gain when LNG-IUDs are compared with Cu-IUDs and no evidence to support a causal association between IUC use and weight gain.[266] There is no specific evidence relating to weight gain with IUC use by individuals with raised BMI.

10 IUC insertion

10.1 Discussion

IUC discussion and assessment is essential to ensure the method and procedure will be safe for the individual and that they have sufficient information to make an informed choice about their contraception options and be able to give informed consent. The discussion may be done at the time of the procedure, or at a prior appointment, depending on local service pathways and the urgency of the IUC insertion. The mode of discussion and assessment varies and may be undertaken face-to-face, via telephone or virtual appointment, or by self-assessment and signposting to patient resources. There is insufficient evidence to recommend one consultation model over another and clinicians should follow local pathways.

10.2 When can IUC be inserted?

IUC can be inserted at any time during the menstrual cycle providing that pregnancy can be reasonably excluded (see **Box 1**). Recommendations for starting or switching to IUC can be found in **Table 15** and **Table 16**.

The Cu-IUD can be used for EC if inserted within 5 days of the first episode of UPSI that cycle, or within 5 days of the earliest expected date of ovulation. Further information regarding the use of the Cu-IUD as EC can be found in FSRH Clinical Guideline Emergency Contraception.[4]

Box 1: Critieria for reasonably excluding pregnancy

Healthcare practitioners can be ***reasonably certain*** that an individual is ***not currently pregnant*** if any one or more of the following criteria are met ***and*** there are no symptoms or signs of pregnancy:

- They have not had intercourse since the start of their last normal (natural) menstrual period, since childbirth, abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- They have been correctly and consistently using a reliable method of contraception. (For the purposes of being reasonably certain that an individual is not currently pregnant, barrier methods of contraception can be considered reliable providing that they have been used consistently and correctly for every episode of intercourse.)
- They are within the first 5 days of the onset of a normal (natural) menstrual period. They are less than 21 days postpartum (non-breastfeeding individuals).*
- They are fully breastfeeding, amenorrhoeic ***and*** less than 6 months' postpartum.*
- They are within the first 5 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- They have not had intercourse for >21 days ***and*** have a negative high-sensitivity urine pregnancy test (able to detect human chorionic gonadotrophin (hCG) levels around 20 mIU/ml).

*See UKMEC 2016[2] and FSRH Guideline Contraception after Pregnancy[103] for recommendations regarding use of combined hormonal contraception after childbirth.

Table 15: Starting intrauterine contraception (no recent hormonal contraception)

Current situation	Method inserted	Timing of insertion	Additional contraceptive precaution required?
No recent hormonal contraception and no recent pregnancy	Cu-IUD	Any time in a natural menstrual cycle if reasonably certain the individual is not pregnant* or at risk of pregnancy (unless qualifies for use as EC)	No
	LNG-IUD	Any time in a natural menstrual cycle if reasonably certain the individual is not pregnant* or at risk of pregnancy	Yes, for 7 days (unless inserted in the first 5† days of the menstrual cycle)
Cu-IUD within licensed duration of use	Cu-IUD	Any time	Ideally abstain/use condoms for 7 days prior to change in case new device can not be inserted unless criteria for EC insertion are met
	LNG-IUD	Any time if no UPSI within the last 7 days (otherwise defer until no UPSI for 7 days)	Yes, for 7 days (unless inserted in the first 5† days of the menstrual cycle)
Cu-IUD past licensed duration of use	Cu-IUD	Any time in a natural menstrual cycle if reasonably certain the individual is not pregnant* or at risk of pregnancy (unless qualifies for use as EC)	No
	LNG-IUD	Any time in a natural menstrual cycle if reasonably certain the individual is not pregnant* or at risk of pregnancy	Yes, for 7 days (unless inserted in the first 5† days of the menstrual cycle)
Postpartum (vaginal birth or caesarean section, breastfeeding or non-breastfeeding)	Cu-IUD	Within 48 hours after childbirth or from 4 weeks after childbirth if it is reasonably certain the individual is not pregnant* or at risk of pregnancy (unless criteria for use as EC apply)	No
	LNG-IUD	Within 48 hours after childbirth	No
		From 4 weeks after childbirth if it is reasonably certain that the individual is not pregnant* or at risk of pregnancy	Yes, for 7 days (unless inserted in the first 5† days of the menstrual cycle or criteria for LAM are met)

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Table 15: Starting intrauterine contraception (no recent hormonal contraception) (continued)

Current situation	Method inserted	Timing of insertion	Additional contraceptive precaution required?
Following abortion or miscarriage	Cu-IUD	Post-surgical abortion or surgical management of miscarriage: ideally IUC should be inserted at the time of the procedure Post-medical abortion or miscarriage: IUC can be inserted any time after expulsion of pregnancy	No
	LNG-IUD	Post-surgical abortion or surgical management of miscarriage: ideally IUC should be inserted at the time of the procedure Post-medical abortion or miscarriage: IUC can be inserted any time after expulsion of pregnancy	If an LNG-IUD is inserted after Day 5† post-abortion or miscarriage, 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 natural menstrual cycle or within 5 days after the earliest estimated day of ovulation	No additional precautions required
		If there has been UPSI in this natural menstrual cycle that occurred >5 days ago ***AND*** it is >5 days after the earliest estimated date of ovulation (or date of ovulation cannot be estimated), a Cu-IUD cannot be inserted until pregnancy can be excluded by a high-sensitivity pregnancy test taken ≥21 days after last UPSI	Condoms or bridging contraception until Cu-IUD can be inserted
	LNG-IUD	Should not be inserted following administration of oral EC until pregnancy can be excluded by a high-sensitivity pregnancy test taken ≥21 days after last UPSI	Condoms or bridging contraception until LNG-IUD can be inserted

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

*See Box 1 for how to exclude pregnancy.

†Summary of Product Characteristics suggests this applies also to days 6 and 7 of a natural cycle.

Table 16: Switching to intrauterine contraception from a hormonal contraceptive method

Switching from	Switching to	Timing of intrauterine contraception (IUC) insertion	Additional contraceptive precaution required?
CHC	Cu-IUD	At any time if CHC has been used correctly (or criteria for use as EC are met)	No
	LNG-IUD	Weeks 2 or 3 of CHC use (or subsequent weeks of continuous CHC use) or Day 1 of the HFI	No, providing CHC used correctly
		After day 1 of the HFI or in week 1 of CHC use	If no UPSI since the start of the HFI – use condoms for 7 days or restart/continue CHC until used correctly for 7 days after HFI **OR** If UPSI since the start of the HFI – restart/continue CHC use for 7 days
POP – traditional	Cu-IUD	At any time if POP has been used correctly (or criteria for use as EC are met)	No
	LNG-IUD	At any time if POP has been used correctly	Continue POP for 7 days or use condoms for 7 days
POP – desogestrel	Cu-IUD	At any time if POP has been used correctly (or criteria for use as EC are met)	No
	LNG-IUD	At any time if POP has been used correctly	No
POP – drospirenone	Cu-IUD	At any time if POP has been used correctly (or criteria for use as EC are met)	No
	LNG-IUD	During HFI (placebo pills, days 25–28) assuming prior correct use of active pills or Days 1–7 of active pills (taken correctly) after HFI	If no UPSI since start of the HFI – use condoms for 7 days **OR** If UPSI since the start of the HFI – restart/continue DRSP POP until 7 consecutive active pills taken
		Days 8–24 of active pills (taken correctly)	No

(Table continues on next page)

Table 16: Switching to intrauterine contraception from a hormonal contraceptive method (continued)

Switching from	Switching to	Timing of IUC insertion	Additional contraceptive precaution required?
ENG implant within 3 years after insertion	Cu-IUD LNG-IUD	Any time	No
ENG implant in situ for 3-4 years	Cu-IUD	Any time if PT negative	No Repeat PT 21 days after last UPSI
	LNG-IUD	Any time if PT negative	Yes (7 days) Repeat PT 21 days after last UPSI
ENG implant in situ for >4 years and ***no*** UPSI in the last 21 days	Cu-IUD	Any time if PT negative	No
	LNG-IUD	Any time if PT negative	Yes (7 days)
ENG implant in situ for >4 years and UPSI in the last 21 days	Cu-IUD	If PT negative AND all UPSI that has taken place in the last 21 days was within the last 5 days, Cu-IUD can be inserted as EC	No
		Cu-IUD cannot be inserted if any UPSI occurred between 5 and 21 days ago	Consider PT and EC. Bridge with alternative contraception until pregnancy can be excluded by a high-sensitivity PT taken ≥21 days after last UPSI
	LNG-IUD	LNG-IUD cannot be inserted until pregnancy can be excluded*	Consider PT and EC. Bridge with alternative contraception until pregnancy can be excluded by a high sensitivity PT taken ≥21 days after last UPSI

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Table 16: Switching to intrauterine contraception from a hormonal contraceptive method (continued)

Switching from	Switching to	Timing of IUC insertion	Additional contraceptive precaution required?
Progestogen-only injectable (DMPA) ≤14 weeks post-injection	Cu-IUD	Any time	No
	LNG-IUD	Any time	No
Progestogen-only injectable (DMPA) >14 weeks post-injection and no UPSI since 14 weeks	Cu-IUD	Any time	No
	LNG-IUD	Any time	Yes (7 days)
Progestogen-only injectable (DMPA) >14 weeks post-injection **AND** UPSI since 14 weeks post-injection, all of which took place ≥21 days ago	Cu-IUD	Any time if PT negative	No
	LNG-IUD	Any time if PT negative	Yes (7 days)
Progestogen-only injectable (DMPA) >14 weeks post-injection **AND** UPSI since 14 weeks post-injection, some of which took place within the last 21 days	Cu-IUD	If PT negative **AND** all UPSI that has taken place in the last 21 days was within the last 5 days, Cu-IUD can be inserted as EC	No
		Cu-IUD cannot be inserted if any UPSI occurred between 5 and 21 days ago	Consider PT and EC. Bridge with alternative contraception until pregnancy can be excluded by a high-sensitivity PT taken ≥21 days after last UPSI
	LNG-IUD	LNG-IUD cannot be inserted until pregnancy can be excluded	Consider PT and EC. Bridge with alternative contraception until pregnancy can be excluded by a high-sensitivity PT taken ≥21 days after last UPSI

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Table 16: Switching to intrauterine contraception from a hormonal contraceptive method (continued)

Switching from	Switching to	Timing of IUC insertion	Additional contraceptive precaution required?
52 mg LNG-IUD in situ for <8 years† **OR** 19.5 mg LNG-IUD in situ for <5 years **OR** 13.5 mg LNG-IUD in situ for <3 years	Cu-IUD	Any time	No Ideally abstain/use condoms for 7 days prior to change in case new device can not be inserted
	Any LNG-IUD		
52 mg LNG-IUD in situ for >8 years† **AND *no*** UPSI within the last 21 days **OR** 19.5 mg LNG-IUD in situ for >5 years **AND *no*** UPSI within the last 21 days **OR** 13.5 mg LNG-IUD in situ for >3 years **AND *no*** UPSI within the last 21 days	Cu-IUD	Any time if PT negative on day of replacement	No
	Any LNG-IUD	Any time if PT negative on day of replacement	Yes (7 days)

(Table continues on next page)

Table 16: Switching to intrauterine contraception from a hormonal contraceptive method (continued)

Switching from	Switching to	Timing of IUC insertion	Additional contraceptive precaution required?
52 mg LNG-IUD in situ for >8 years† AND UPSI within the last 21 days **OR** 19.5 mg LNG-IUD in situ for >5 years AND UPSI within the last 21 days **OR** 13.5 mg LNG-IUD in situ for >3 years AND UPSI within the last 21 days	Cu-IUD	If PT negative **AND** all UPSI that has taken place in the last 21 days was within the last 5 days, Cu-IUD can be inserted as EC	No
	Any LNG-IUD	LNG-IUD cannot be inserted until pregnancy can be excluded	Consider PT and EC. Bridge with alternative contraception until pregnancy can be excluded by a high-sensitivity PT taken ≥21 days after last UPSI

CHC, combined hormonal contraception; Cu-IUD, copper intrauterine device; DMPA, depot medroxyprogesterone acetate; DRSP, drospirenone; EC, emergency contraception; ENG, etonogestrel; HFI, hormone-free interval; IUC, intrauterine contraception; LNG-IUD, levonorgestrel intrauterine device; POP, progestogen-only pill; PT, pregnancy test; UPSI, unprotected sexual intercourse.
*See Box 1 for how to exclude pregnancy.
†Recommendations for the 52 mg LNG-IUD insertion relate to devices inserted before age 45 years. If replacing a 52 mg LNG-IUD that has been in situ for >8 years but was inserted after age 45 years, follow guidance for replacing a 52 mg LNG-IUD that has been in situ for <8 years.

10.3 Insertion checklist

Clinical recommendations

✓	**Prior to insertion of their chosen IUC, individuals should be advised about contraceptive effectiveness, duration of use, potential bleeding patterns and side effects, any non-contraceptive benefits, the procedure (including associated risks), analgesia options, checking threads and when to seek review. The clinician should answer any questions the user has about the method.**
✓	**The clinician should confirm the type of device with the individual and assistant prior to IUC insertion.**
✓	**The expiry date on the IUC ± anaesthetic/analgesia should be checked prior to use.**

Recommendations for pre-insertion information and preparation are outlined in **Box 2**.

Box 2: Intrauterine contraception pre-insertion checklist

The clinician inserting the intrauterine contraception (IUC) should ensure that (as a minimum) the following criteria are met prior to insertion:

- ☐ Individual assessed as medically eligible
- ☐ Checked there are no indications for IUC to be inserted in an alternative setting/service
- ☐ Checked there are no allergies to IUC content or local anaesthetic
- ☐ Checked it is a suitable time to insert and any requirement for additional contraception/follow-up pregnancy testing
- ☐ Considered and offered sexually transmitted infection (STI) testing and/or cervical screening as appropriate
- ☐ Individual advised about:
- ☐ Different IUC types available
- ☐ Contraceptive effectiveness and time to effect (including need for additional contraception and/or follow-up pregnancy test)
- ☐ Duration of use (for contraception and other indications)
- ☐ Potential bleeding patterns
- ☐ Other potential side effects and risks
- ☐ Insertion procedure and associated risks including: pain, infection, expulsion, perforation, failure, ectopic pregnancy, non-visible threads
- ☐ Analgesia options and option to stop at any time during the procedure
- ☐ Signs/symptoms that require review
- ☐ How and when to check threads
- ☐ Removal procedure
- ☐ Individual given opportunity to ask questions and to reflect on new information and return for procedure or alternative at another time if they wish
- ☐ Type of IUC device confirmed with patient and assistant
- ☐ Expiry date on IUC and analgesia checked
- ☐ Suitably trained assistant present
- ☐ Appropriate equipment available (e.g. resuscitation equipment, appropriate examination couch/lighting, range of speculum sizes, analgesia options)

10.4 How can safe insertion of IUC be facilitated?

Clinical recommendations

✓ **Clinicians offering IUC insertion should hold the appropriate FSRH Letter of Competence in Intrauterine Techniques or have achieved equivalent recognised competencies and show evidence of recertification/reaccreditation.**

✓ **The insertion procedure for immediate postpartum intrauterine contraception (PPIUC) is different to that for standard IUC insertion and should only be performed by those who have been trained in this technique.**

✓ **An appropriately trained assistant should be present during all uterine instrumentation procedures.**

10.4.1 Training

Clinicians offering IUC should hold an in-date/appropriately recertified FSRH Letter of Competence in Intrauterine Techniques (LoC IUT) or have achieved equivalent recognised competencies and show evidence of recertification/reaccreditation.

At the time of writing, the FSRH recommends that to ensure they are able to maintain competence, clinicians should be able to show evidence of at least two continuing professional development (CPD) credits relevant to intrauterine techniques, completion of the e-SRH Intrauterine Contraception Module 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 individuals undertaken during a 12-month period within 24 months of recertification.

The FSRH website contains information about training requirements and recertification.

Immediate postpartum intrauterine contraception (PPIUC) insertion training is not part of the FSRH LoC IUT. The insertion procedure for immediate PPIUC is different to that of standard IUC insertion and should only be performed by those who have been trained in this technique. Theoretical training information for PPIUC can be found in the FSRH Member's Training hub and clinicians should follow/develop local pathways for practical training.

10.4.2 Informed consent

Informed consent for undertaking an IUC procedure should be obtained in line with local policy. FSRH Service Standard on Obtaining Valid Consent in SRH Services[267] provides further information.

10.4.3 Assistants

An appropriately trained assistant should be present during all cervical instrumentation procedures. They may be required to provide additional instruments or equipment, monitor the condition of the individual, call for additional assistance or perform basic life support.

10.4.4 Chaperones

A chaperone should be offered for all intimate examinations. The chaperone's role is to support the patient. The chaperone should usually be an HCP[268] and therefore the assistant will usually also fill the role of a

chaperone.

10.4.5 Check device has not expired

Prior to inserting an IUC, the device should be checked to ensure it has not expired.

If a device is inadvertently inserted after the expiry date stated on the packaging, the individual should be informed of the error and offered the option of retaining the device or having it removed and replaced. The error should be managed according to local clinical governance policies.

The expiry date relates to the microbiological sterility of the device. Risk of infection from loss of microbiological sterility could well be lower than the risk of infection if the device is replaced again when the error is identified. The GDG suggests that a device inserted after its expiry date does not necessarily need to be removed unless this is requested by the user. Clinical judgement is required if the device is long (>6 months) past its expiry date.

If the device has only recently expired (within the last 6 months) the GDG suggests that it is very unlikely to affect contraceptive effectiveness and that there is no need to amend the duration of use. For example, if a 5-year IUC is inserted 5 months after the expiry date, the user should still be advised to return for replacement in 5 years, not in 4 years and 7 months.

10.5 Practical aspects of IUC insertion

Clinical recommendations

✓	**A bimanual pelvic examination should be performed prior to inserting IUC.**
✓	**To reduce the risk of perforation and facilitate fundal placement of the device, tissue forceps should usually be used to stabilise the cervix and straighten the uterine cavity during IUC insertion, and a uterine sound should be used to assess the cavity length prior to insertion.**

10.5.1 Examination

A bimanual pelvic examination should be performed on all individuals prior to inserting IUC to allow the clinician to assess the position, size, shape and mobility of the uterus. The examination should be undertaken by the clinician inserting the device, immediately prior to the procedure.

Pelvic ultrasound pre-, intra- or post-procedure is not routinely required. However, for complex IUC procedures, ultrasound examination prior to or during the insertion procedure may be useful.

10.5.2 Measurement of pulse rate and blood pressure

Practice in the UK varies; however, the GDG considers that routine measurement of pulse rate and/or blood pressure before, during and/or after IUC procedures is not required. However, these measurements can be considered on a case-by-case basis, guided by the clinical picture.

10.5.3 Cervical cleansing

Cleansing the vulva, vagina or cervix prior to IUC insertion is not required. Cervical cleansing prior to IUC insertion has not been shown to reduce subsequent pelvic infection and none of the standard cleansing agents are effective bactericidally against chlamydia or gonorrhoea. Clinicians may choose to remove any mucus or debris from the cervix prior to insertion.

10.5.4 Sterile gloves

Gloves should be worn on both hands for pelvic examination. There is no requirement to use sterile gloves when inserting IUC if a 'no touch' technique is used to ensure that anything that is to be inserted into the uterine cavity remains sterile.

10.5.5 Use of forceps/tenaculum and assessment of the uterine cavity

In line with manufacturer instructions, the GDG recommends that to reduce the risk of perforation and facilitate fundal placement of the device, tissue forceps are used to stabilise the cervix and straighten the uterine cavity during IUC insertion, and a uterine sound should be used to assess the cavity prior to insertion. 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.

10.6 Pain associated with IUC insertion

Key information

D	**Experiences vary for individuals having IUC inserted, and clinicians may underestimate the pain and anxiety users experience.**
D	**Discomfort and pain may be experienced with any of the stages of IUC insertion: speculum insertion, tenaculum placement, uterine sounding and device placement.**
C	**Paracervical block, intracervical local anaesthetic injection, 10% lidocaine spray or cream containing 2.5% lidocaine plus 2.5% prilocaine appear to be beneficial in reducing insertion-related pain.**

Clinical recommendations

✓	**Individuals should be advised that most IUC insertions are associated with mild-to-moderate pain or discomfort, but that pain can range from none to severe.**
✓	**Clinicians should support and encourage users to tell them if they are experiencing pain or discomfort and reassure them that the procedure can be paused or stopped at any time.**
✓	**An assistant should be present to support the individual during the IUC procedure and monitor the patient for any signs of pain or distress.**
✓	**Analgesia options should be discussed and offered to all individuals having IUC inserted.**
✓	**Referral processes should be in place for circumstances where an individual requests an analgesia option that the clinician is unable to provide.**

Experiences vary for individuals having IUC inserted, and clinicians may underestimate the pain and anxiety users experience.[269,270] Discomfort and pain may be experienced with any of the stages of IUC insertion: speculum insertion, tenaculum placement and, in particular, uterine sounding and device placement itself.[271,272]

Whilst pain experienced during IUC insertion can range from none to severe, studies suggest that even without analgesia the majority of individuals report that any pain during IUC insertion is mild or moderate, rather than severe.[269,273,274] Within 5 minutes after insertion, reported mean pain scores are low.[272,275] In studies reporting both pain scores and a description of the experience, moderate pain scores correlate with descriptions of discomfort rather than pain.[272,275]

Evidence level 2-

Although it is not possible to accurately predict the level of pain or discomfort that any individual might experience during an IUC procedure, studies suggest that never having been pregnant, only having had caesarean section deliveries, or having a history of dysmenorrhoea are associated with higher mean pain scores.[239,269,276–280] Greater anxiety, greater anticipated pain and negative perceptions of IUC prior to the procedure appear to correlate with higher experienced pain scores,[276,277,281] and previous experience of painful gynaecological/obstetric procedures may contribute to higher anticipated pain scores.[281]

Technically difficult insertions may also be associated with higher reported pain scores[273,274] but studies report that at least 95% of insertions are successful[61,64,78–80,282] and typically 80%–90% of insertions are rated by the provider as being 'easy'.[64,78–80,251,270,282,283] No specific device, insertion equipment or inserter type is clearly associated with less pain at insertion.

Evidence level 2-

Whilst there is a lack of evidence around non-pharmacological interventions to minimise anxiety and pain during IUC insertion, clinical experience suggests that there is a significant benefit in having a calm environment with an assistant providing support and distraction to the patient (often referred to as 'vocal anaesthetic' or 'vocal local').

The published literature does not suggest there is a clear 'best' analgesic option for IUC procedures or that any one option should be offered routinely. Paracervical block, intracervical local anaesthetic injection, 10% lidocaine spray (applied to the surface of the cervix and external os 3 minutes prior to the procedure) or EMLA (2.5% lidocaine plus 2.5% prilocaine cream applied to the tenaculum site and into the cervical canal 7 minutes prior to the procedure) could all reduce insertion-related pain. However, there may be pain associated with a para- or intracervical injection, which could potentially be more significant than the insertion procedure itself; and having to wait for topical anaesthetic (lidocaine spray and EMLA) to work could increase levels of anxiety.

The GDG recommends that:

- Individuals requesting IUC insertion should be advised that most IUC insertions are associated with mild-to-moderate pain or discomfort, but pain can range from none to severe.
- Clinicians should support and encourage users to tell them if they are experiencing pain or discomfort and reassure them that the procedure can be paused or stopped at any time.

- An assistant is present to support the individual during the IUC procedure and monitor the patient for any signs of pain or distress.
- Analgesia/anaesthetic options should be discussed and offered to the individual. Anaesthetic can be offered by providers of IUC in all clinical settings. Referral processes should be in place so that if an individual requests an analgesia/anaesthetic option that is not available, there is a clear onward referral pathway to an alternative provider.

The evidence: non-pharmacological interventions

A range of non-pharmacological interventions for analgesia[274,284–291] have been studied, but most studies have high risk of bias and report no clinically significant effect.

One systematic review[284] identified studies on inhaled lavender versus placebo, timing of insertion related to menstrual cycle, slow versus fast vulsellum application, the use of a dental needle and syringe to apply paracervical block analgesia, and the use of a jet injector versus needle and syringe to apply paracervical block analgesia. None had clinically significant results for pain.

Three RCTs identified in another review[274] found no difference in mean pain scores between atraumatic vulsellum and a single-tooth tenaculum,[292] between tenaculum and Littlewood forceps[293] or a full or empty bladder.[294] Two RCTs not included in the review found no benefit from cold compress application[286] or coughing on tenaculum placement versus slow placement.[290]

Four studies were identified that supported non-pharmacological interventions to reduce pain or anxiety, but all had significant methodological limitations. One small RCT (n = 88) compared two insertion approaches. In the uterine sound-sparing approach (USSA group), instead of using a uterine sound to measure the uterus, individuals underwent transvaginal ultrasonography, and the uterine length was measured prior to IUC insertion. For the second group, a uterine sound was used to measure the uterine length prior to IUC insertion, and both the sounding and the insertion were completed under transabdominal scan guidance (TAS group). This study found reduced pain on insertion with a uterine sound-sparing approach (TAS 4.3 ± 1.23 vs USSA 2.55 ± 0.87, p = 0.001). However, the sound-sparing approach was also associated with lower ease of insertion (TAS 6.75 ± 1.10 vs USSA 5.70 ± 0.79, p = 0.0001) and only the TAS group had to have a full bladder.[288]

Evidence level 1+

A small survey in a UK clinic found individuals reported that watching TV during IUC insertion offered a distraction (92%, n = 35) and helped calm them and reduced their anxiety (68%, n = 16). However, the sample size was small and the respondents self-selecting.[287]

Another small RCT (n = 54) found verbal analgesia (so-called ‘vocal local’) was as effective as 50 mg tramadol in nulliparous subjects (mean pain: tramadol 4.5 ± 1.6, verbal analgesia 4.8 ± 2.4, p = 0.610). However, the limited data on the benefits of tramadol makes this result difficult to interpret.[285]

Evidence level 1-

Finally, an RCT (n = 107) found fewer individuals experienced severe pain when use of a tenaculum was replaced with patients performing the Valsalva manoeuvre on insertion. Severe pain was noted in 58.2% in the tenaculum group (unexpectedly high compared with other studies), whereas 57.7% of the subjects in the Valsalva manoeuvre group reported no pain and none experienced severe pain (p = 0.01). There was no difference in insertion success, but of the 238 individuals considered for the study, the cervix could not be passed in 124 and only 107 were randomised. This rate is high, as is the rate of severe pain in the tenaculum group, raising questions of generalizability.[291]

Whilst there is a lack of robust evidence to support any single non-pharmacological intervention, few studies have investigated anxiety,[284] and some non-pharmacological interventions could improve the experience of IUC insertion for users.

The evidence: pharmacological interventions

To date, no specific pharmacological intervention has been conclusively demonstrated to reduce IUC insertion pain.[284,295,296] A significant challenge is the heterogeneity in the evidence base. Studies vary as to IUC type and insertion technique as well as the nature and administration of the therapeutic agent. In addition, whilst the same tools for evaluating pain (10 cm or 100 mm visual analogue scale (VAS)) are used across the majority of studies, the point in the procedure that is studied and the timing of data capture vary[274]. Moreover, studies use different cut-offs to define clinically significant difference in pain, from 1.5 cm to 2 cm on a 10 cm VAS.[284,297] It remains unclear what VAS difference represents a meaningful difference to individuals. For instance, Akers *et al* found a 1% lidocaine paracervical block was associated with a much lower VAS score (30.0 ± 52 vs 71.5 ± 23.5, p<0.001), but no difference in user satisfaction (91.5% vs. 91.7%, p = 0.30) or willingness to recommend the procedure to a friend (91.5% vs 85.4%, p = 0.45).[298]

Evidence level 2+

Local anaesthetic

Multiple lidocaine formulations have found support in systematic reviews, but the picture is conflicted and the evidence limited.[284,295,299–301] Some meta-analyses have chosen to pool all lidocaine-based interventions, with one finding a positive effect on pain[300] whilst another reported no benefit.[301]

Whilst clinical experience suggests that other anaesthetic preparations (such as mepivicaine) are used in practice, studies assessing their effectiveness for IUC procedures are lacking.

Use of topical 2% lidocaine gel, either administered into the cervical canal and at the tenaculum site or self-administered, is largely unsupported by two systematic reviews.[274,295] However, three studies, each of a different novel lidocaine gel, have reported favourable results.[274,302] These formulations are not currently used in the UK and further research is needed on these preparations.

Some evidence of benefit from 2.5% lidocaine plus 2.5% prilocaine cream applied to the cervical surface and into the cervical canal has been reported.[274,299] In a network meta-analysis of 16 RCTs, this was the only intervention that reduced pain on tenaculum placement versus placebo (mean difference (MD) −2.38, 95% CI −4.07 to −0.68). This

Evidence level 1+

combination also reduced pain during IUD insertion compared with ibuprofen (MD −2.78, 95% CI −5.42 to −0.13), placebo (MD −2.76, 95% CI −4.61 to −0.91) and misoprostol (MD −3.34, 95% CI −5.48 to −1.21).[299]

Some evidence of benefit has also been identified for 10 ml of either 1% or 2% paracervical lidocaine block.[274,299,301] A 2014 meta-analysis reported significantly decreased pain among individuals injected with 10 ml 1% paracervical lidocaine (tenaculum placement: MD: −20.54, 95% CI −39.92 to −1.15; IUD insertion: MD: −28.99, 95% CI −53.14 to −4.84, 2 studies, n = 114).[301] Paracervical block was also supported by a network meta-analysis, but only with regard to pain on insertion and compared with misoprostol (MD −1.72, 95% CI −3.39 to −0.04).[299]

A 2020 Brazilian RCT (n = 302) found a 3.6 ml intracervical injection of 2% lidocaine reduced the proportion of individuals experiencing severe pain (tenaculum placement: intracervical block 2% vs sham 30.2% vs no intervention 15.2%, p<0.0001; IUD insertion: intracervical block 26.5% vs sham 59.4% vs no intervention 50.5%, p<0.0001).[303] This contrasts with a previous RCT which found no evidence of benefit with 1% lidocaine intracervical block over placebo.[274]

Evidence level 1+

Lidocaine spray has been reported to offer clinically significant reductions in pain in three RCTs and one non-RCT.[272,274] The three RCTs used four puffs of 10% lidocaine spray (net 40 mg) applied to the surface of the cervix and external os and left for 3 minutes. The fourth study did not report the lidocaine dose. However, whilst promising, most of the subjects in these studies were parous, with 50% of the population of one study having given birth 6–8 weeks previously.[272] In addition, consideration must be given to infection control when using reusable spray bottles. One RCT reported a much higher rate of vaginal irritation in the lidocaine spray group than in the placebo group (lidocaine: 34 (54.8%) vs placebo: 1 (1.6%), p<0.001).[272] Excess spray may be wiped away after application to try to reduce risk of vaginal irritation.

Cervical priming

Most current systematic reviews and meta-analyses report no reduction in pain with various preparations of the prostaglandin analogue misoprostol.[295,301,304] Some meta-analyses note an increase in pain post-insertion,[301] cramping and other side effects with misoprostol.[295,304] A 2021 systematic review and meta-analysis (5 RCTs, n = 862) examined use of 3 mg vaginal dinoprostone (prostaglandin E2) administered 2–12 hours pre-procedure by either a nurse or the patient.[297] They found dinoprostone was associated with a small reduction in pain scores at tenaculum placement (standardised mean difference (SMD) −0.79, 95% CI −1.43 to −0.16, p = 0.01), uterine sounding (SMD −0.88, 95% CI −1.54 to −0.22, p = 0.009) and IUD insertion (SMD −1.18, 95% CI −1.74 to −0.61, p<0.001). However, dinoprostone was associated with fever (RR 3.73, 95% CI 1.47–9.44, p = 0.006). The SMDs observed were smaller than is typically thought to be clinically significant, although dinoprostone was associated with increased patient satisfaction (SMD 1.41, 95% CI 0.62–2.20, p<0.001).

Evidence level 1+

The generalisability of these results to UK practice may be affected by the fact that all five studies were conducted in Egypt.

Oral analgesics and others

A 2019 systematic review[274] identified five RCTs examining the effectiveness of oral analgesia prior to IUC placement. One found a 15 mm reduction in mean pain score on visual analogue scale with 20 mg of the oral NSAID ketorolac taken 40–60 minutes pre-procedure. However, four RCTs found no impact on insertion pain from pre-insertion naproxen, nitrous oxide or ibuprofen. Naproxen 550 mg was associated with a reduction in VAS pain score at 5 and 15 minutes after placement in one study, but these differences (9 mm and 11.2 mm, respectively) would not typically be regarded as clinically significant.

Evidence level 1+

A 2015 Cochrane systematic review[295] similarly reported a lack of effectiveness from prophylactic ibuprofen on insertion pain. The review identified a study that supported the use of 550 mg naproxen or 50 mg tramadol 1 hour pre-procedure, but the study was very small (n = 34 in each of the naproxen and tramadol arms) and only included multiparous subjects.

Evidence level 1+

A 2006 Cochrane review did favour NSAIDs to manage post-insertion pain. However, the four included trials were from the late 1970s to the late 1980s, small (n = 35 or fewer), covered three different NSAIDs (naproxen, suprofen and diclofenac) and examined pain in the months post-insertion.[305] Samy *et al*'s 2019 network meta-analysis which included data on lidocaine, lidocaine plus prilocaine, ketorolac, nitroprusside, naproxen and misoprostol found no medication was effective in reducing pain 5–20 minutes post-insertion.[299]

Two studies of nitrous oxide were identified[306,307] with the only RCT finding no evidence of reduced pain scores.[306] This double-blind RCT[306] included 80 nulliparous individuals aged 13–45 years (mean age 25.6 years), randomised to either inhaled oxygen or a 50/50 nitrous oxide/oxygen mix for 2 minutes prior to IUC insertion. They found no evidence of increased adverse effects, but also no reduction in pain scores with nitrous oxide (mean maximum pain score at insertion: nitrous oxide 54.3 ± 24.8 mm, oxygen = 55.3 ± 20.9 mm, p = 0.86). However, individuals in the nitrous oxide group were also more likely to report being satisfied/very satisfied with their pain management (68% vs 43%, p = 0.04). Whilst the study was double blinded, 95% of individuals in the oxygen group correctly identified their allocation compared with 53% in the nitrous oxide group.

The other article described a prospective observational study which included 74 nulliparous adolescents (aged 12–20 years, mean 16 years).[307] Forty-five participants selected immediate IUC insertion and 28 opted for delayed insertion at a hospital-based sedation unit to receive nitrous oxide prior to and during insertion. The nitrous oxide started at a 50/50 nitrous oxide/oxygen mix but could be titrated up to a 70/30 nitrous oxide/oxygen mix. The nitrous oxide group were more likely to recommend an IUD to a friend and had lower pain scores 2 minutes post-insertion (change in pre- versus post-IUD insertion pain assessment: nitrous oxide = 18.91 mm, standard care = 48.23 mm, p<0.01). Whilst this study adjusted for BMI percentile, age and dysmenorrhoea history, its observational nature limits causal inference. In addition, with regards to generalisability, all participants received intracervical block and NSAIDs, were nulliparous adolescents and had a medical indication for IUC insertion (the nature of which was not reported).

Evidence level 2-

Single trials of other agents pre-insertion, including glyceryl trinitrate (GTN) cream,[308] celecoxib[309] and

hyoscine butylbromide,[309] reported favourable findings but further research would be required to establish effectiveness.

No studies assessing paracetamol as an analgesic during IUC insertion were identified.[274,284,295,299]

The evidence: device type

There is some evidence of variation in pain and ease of insertion according to device type. One recent prospective cohort study (n = 1149) found that subjects undergoing LNG-IUD placement were more likely to report high pain scores than those undergoing Cu-IUD insertion (RR 1.31, 95% CI 1.05–1.63).[277] A single-blinded RCT (n = 738) found that 72.3% of individuals receiving a 13.5 mg or 19.5 mg LNG-IUD reported either no or mild pain during placement versus 57.9% in the Mirena group. It is worth noting that despite the differences, over 90% of individuals receiving Mirena still described their pain as moderate or less. Investigators were more likely to rate placement as 'easy' in the 13.5 mg/19.5 mg group (94%) compared with the Mirena group (86.2%) (p<0.001). The authors attributed this to the different diameters of the inserters (3.8 mm vs 4.75 mm).[79] A 2019 review[274] found evidence that the modified placement device (Evoinserter®) for the 13.5 mg LNG-IUD may have contributed to ease of placement and manageable pain. However, analgesia options were left to the investigator, rendering the quality of the evidence weak.

A 2007 Cochrane review[53] found no difference in problems at insertion or insertion pain between different copper devices, despite five different frame types being studied. However, the trials included only multiparous individuals and were conducted 30–40 years ago, since which time devices, inserters and insertion techniques have evolved.

Evidence level 1-

The evidence base on insertion pain for novel IUC devices, such as the intrauterine ball, is currently very weak[310,311] due to a lack of robust data. The existing data regarding pain and ease of GyneFix insertion are broadly in line with other Cu-IUDs.[312] However, applying these data to current practice requires caution due to the limited quality of the evidence and significant variations in the insertion devices used in different studies.[55]

Evidence level 2-

The evidence: interventions to improve ease of insertion

A 2016 systematic review of interventions to ease IUD insertion concluded that most studies found no significant difference with the use of interventions (15 studies, covering misoprostol, lidocaine and nitric oxide).[313] The majority of the studies (n = 10) examined misoprostol and found that it did not improve provider-rated ease of insertion (7/9 RCTs), reduce the need for adjunctive insertion measures (7/7 RCTs) or improve insertion success (8/8 RCTs). The authors did highlight one trial in 100 subjects with a recent failed insertion attempt which reported a higher success rate on the second attempt with 400 mcg vaginal misoprostol than with placebo (prevalence ratio of failure with placebo vs misoprostol = 2.90, 95% CI 1.13–7.42).

The finding of no benefit from misoprostol was echoed by a second review[314] but is contrary to a network meta-analysis[299] which found that 400 mg oral misoprostol improved ease of insertion versus placebo (MD −2.00, 95% CI −2.17 to −1.83).

Evidence level 1+

A 2021 meta-analysis of five RCTs did support the use of dinoprostone to ease insertion (SMD −1.17, 95% CI −1.62 to −0.73, p<0.001). However, all the studies were conducted in Egypt and as with most of the literature there was intervention heterogeneity.[297]

10.7 Post-procedure analgesia

NSAIDs such as ibuprofen can reduce pain after IUC insertion[305] and can be offered to individuals who experience pain after insertion of an intrauterine method. Evidence suggests, however, that treatment is unlikely to improve discontinuation rates in individuals who cite pain as a reason for removal.[305,314]

Evidence level 1-

11 Emergency management for problems at IUC insertion

Clinical recommendations

✓ **All staff involved with IUC insertion should undergo training and regular updates in resuscitation.**

An invasive procedure such as IUC insertion can trigger a vasovagal response. It is recommended that all staff involved with IUC insertion should undergo training and regular updates in resuscitation. In addition to national guidelines from other relevant professional bodies and locally agreed policies and procedures, clinicians should be familiar with the guidance in FSRH Service Standards for Resuscitation in Sexual and Reproductive Healthcare[3]:

- All patients should have a documented medical risk assessment before treatment or practical procedures.
- Evidence of training and regular updates in resuscitation is essential for all staff dealing with emergencies arising during the provision of sexual and reproductive health (SRH) services.
- Drugs required for resuscitation must be available, accessible, clearly labelled, adequately maintained and their location known to all staff.
- Recommended drugs required for resuscitation are:
  - Adrenaline 1 mg (= 10 ml 1:10 000) as a prefilled syringe
  - Atropine 500 or 600 mcg IV/IM (two doses) for the treatment of symptomatic bradycardia
  - Oxygen.
- Essential resuscitation equipment should be available, accessible, maintained and its location known to all staff.
- Locally agreed risk management policies for the treatment of emergencies should be in place and take into account national recommendations.

Further guidance for the management of individuals with cardiac conditions is available in the FSRH Clinical Guideline Contraceptive Choices for Women with Cardiac Disease.[160]

12 Documentation

Clinicians inserting or removing IUC should document the procedure and consultation in line with local policy and protocol and notify (where applicable and with consent) other relevant healthcare providers (e.g. primary care) of the type of device, date of insertion and recommended duration of use. Recommendations for record-keeping are available within FSRH Service Standards for Record Keeping.[315]

13 Aftercare advice and follow-up

Clinical recommendations

✓	**After IUC insertion, individuals should be given information on the device inserted, including the name of the device, its mode of action, duration of use and time to become effective.**
✓	**Where IUC has been inserted outside of product licence or as EC, information about how and when to perform a pregnancy test should be given.**
✓	**With the exception of PPIUC, routine post-insertion check-ups with a clinician are not required.**
✓	**When IUC has been inserted within 48 hours of a vaginal or caesarean birth (PPIUC), an IUC check-up with a clinician 4–6 weeks after insertion is recommended.**
✓	**IUC users should be advised to feel for their threads within the first 4–6 weeks after insertion and then at regular intervals (e.g. monthly or after menses).**

13.1 Device information

After IUC insertion, individuals should be given information on the device inserted, including the name of the device, its mode of action, duration of use and time to effect. The manufacturer's booklet/card will usually be given to the patient.

13.2 Follow-up

Where IUC has been inserted outside of product licence or as EC, information about how and when to perform a pregnancy test should be given.

With the exception of PPIUC, routine post-insertion check-ups are not required. However, individuals who have had an IUC inserted should be advised they can seek review at any time if they have concerns, cannot locate their threads, or wish to change their method of contraception. They should be given information on who to contact and how.

Due to the increased risk of expulsion or long or non-visible threads with PPIUC, routine IUC check-ups are recommended when IUC has been inserted within 48 hours of a vaginal or caesarean birth. These check-ups are undertaken 4–6 weeks post-insertion and IUC users should be advised where this will take place, in line with local PPIUC pathways. An example PPIUC pathway can be found in **Appendix 2**. Advice on management of PPIUC thread problems can be found in **Appendix 3**.

13.3 Checking threads

Clinicians should explain how to feel for IUC threads and that users should seek review if threads are not palpable, thread length becomes shorter or longer, or the stem of the device is felt. Clinicians should explain that any of these changes could mean the IUC is incorrectly sited and therefore effectiveness cannot be guaranteed. The individual should be advised to abstain or use an alternative method of contraception until the IUC position is confirmed, and if there has been any recent, condomless sex they should seek advice from an HCP as EC may be required.

IUC users should be advised to feel for their threads within the first 4–6 weeks after insertion and then at regular intervals (e.g. monthly or after menses) and if they have any concerns suggestive of IUC displacement (e.g. change in bleeding pattern, new-onset pelvic pain).

13.4 When to seek review

In addition to seeking review if there are concerns when they check their threads, individuals should be advised to seek urgent review if they have:

- Symptoms of pelvic infection (e.g. change in vaginal discharge, pelvic pain and intermenstrual/ postcoital bleeding)
- Concerns regarding their bleeding pattern
- A positive pregnancy test.

13.5 Advice about use of menstrual cups, discs and tampons

Some IUC users will use menstrual cups, discs and tampons to contain menstrual loss.

Menstrual cups and discs are single or multi-use, available in different sizes and brands, and usually made from silicone, rubber or plastic. The menstrual cup sits low in the vagina and forms a seal with the vaginal walls. It is removed by pinching to break the seal and then pulling downwards, out of the vagina. The menstrual disc sits between the pubic bone and posterior fornix and does not require suction to stay in place. It is removed by using a finger to dislodge the disc and pulling downwards, out of the vagina.

Evidence suggests that there could be increased risk of expulsion associated with menstrual cup use. With many different brands available, users should be advised to follow the manufacturer's instructions, including any special considerations for IUC users. With any of these methods, care should be taken not to dislodge the IUC by accidently pulling the IUC threads when removing the menstrual device and, where applicable, users should be advised to ensure they release any suction from the menstrual device prior to removal.

Some clinicians advise avoiding tampons and menstrual cups for up to several weeks after IUC insertion, citing increased risk of expulsion or infection. There are not robust studies to inform effect of use of tampons on risk of expulsion. As stated earlier, risk of IUC expulsion could be increased by use of menstrual cups. It is not, however, clear that there is greater risk in the weeks immediately after IUC insertion than at any other time. There is no clear evidence of increased risk of infection associated with use of tampons, menstrual cups/discs or intercourse in the days or weeks after IUC insertion.

The evidence

A 2012 study of 930 IUC users included 96 individuals using menstrual cups, 690 using tampons and 402 using pads. There were no significant differences in expulsion rates at 6 weeks' post-IUC insertion among the different groups. This study is limited by a very short follow-up period and high loss to follow- up (23%).[316] Infection rate was not studied.

Evidence level 2-

Two further studies were published in 2019. One case series[317] reports seven instances of IUC expulsion (full or partial) during use of a menstrual cup. One of these cases documented an individual with two expulsions during concurrent IUC and menstrual cup use (one full

Evidence level 3

expulsion at 6 months post- insertion and a second full expulsion at 1 week post-insertion). The series included six LNG-IUD and one Cu-IUD user and the time the IUC had been in situ for ranged from 1 week to 13 months.

Evidence level 3

A conference abstract published in 2020 reports on a contraceptive efficacy trial that randomised users to two different Cu-IUDs.[318] The study included 266 menstrual cup users and observed significantly higher rates of IUD expulsion in menstrual cup users compared with non-menstrual cup users. In the first year of the study, the expulsion rate among menstrual cup users was 14.3% compared with 4.7% in non-users (p<0.001). At the end of year 2, the expulsion rates were 23.2% and 6.5% for menstrual cup users and non-users, respectively (p<0.001). However, this abstract contains very minimal information about the study design and results, and it is not possible to say whether there were any other confounding factors.

An internet-based survey[319] included 902 self-selected respondents, of which 71% reported current or previous IUC use and 19.7% reported menstrual cup use. IUC users were significantly more likely than non-users to use a menstrual cup or tampons. Among all IUC users, 56 individuals reported experiencing at least one expulsion (8.8%) and a positive association was found between IUC expulsion and concurrent menstrual cup use (OR 2.75, 95% CI 1.40–5.42, p = 0.002). However, among concurrent IUC and menstrual cup users who experienced an expulsion, only one reported it occurring whilst using the menstrual cup, with others reporting the expulsion at other times. There was no association with concurrent tampon or pad use.

Evidence level 2-

No study has considered possible differential risk of IUC expulsion between brands of menstrual cups and there is no published evidence to inform risk of IUC expulsion or infection associated with use of menstrual discs by IUC users.

13.6 Advice for individuals requiring magnetic resonance imaging

Mirena, Levosert and Benilexa contain no metallic, magnetic or conductive material and are safe at any magnetic field strength.

Individuals requiring magnetic resonance imaging (MRI) with a device containing a metallic component should inform their MRI department so that local guidelines can be followed. The limited published evidence suggests that it is safe for an individual with a copper IUD or a Kyleena or Jaydess to undergo MRI at a strength of 1.5 Tesla (T) or 3 T and therefore removal of the device would not normally be necessary unless the area of interest is very close to the position of the device (this could result in some imaging artefacts).

IUC inserted outside of the UK may contain different metals and might not be MRI safe. Advice should be sought from the local radiology department. Devices containing stainless steel (e.g. the Chinese ring) are not MRI safe and should be removed prior to MRI.[320]

The evidence

The limited published literature considers whether MRI scanning might result in movement

Evidence level 2-

or rotation of the device, heating of the device (resulting in endometrial damage) or artefacts affecting the scan image. The available studies have looked at MRI strengths of 1.5 T and 3 T and have shown no adverse effects with copper or gold[321,322]. IUDs made from alternative metals (e.g. stainless steel) are not currently used in the UK but may be inserted in other countries. Devices containing stainless steel are not MRI safe and should be removed prior to MRI.[320]

In 2020, following a literature review and Delphi process, the *Journal of Magnetic Resonance Imaging* published an expert consensus[320] on the safety of MRI and IUDs. They agree that "with respect to modern intrauterine devices, MRI can be performed safely at 3 T, with the exception of the Chinese ring, which is MR unsafe".

Kyleena and Jaydess have a silver ring on their stem. They were not included in the expert consensus; however, the Electronic Medicines Compendium states[179]: "Non-clinical testing has demonstrated that a patient can be scanned safely after placement of Jaydess under the following conditions: Static magnetic field of 3-Tesla or less, maximum spatial gradient magnetic field of 720-Gauss/cm or less. Under these conditions, with 15-min of scanning, the maximum temperature rise produced at the site of Jaydess was 1.8°C. A small amount of imaging artifact may occur if the area of interest is in the exact same area or relatively close to the position of Jaydess." As Kyleena has the same size silver ring and T-body, the Electronic Medicines Compendium states that Kyleena is safe under those same conditions.[178,179]

14 Managing problems associated with IUC

14.1 Unscheduled bleeding

Clinical recommendations

D	**Tranexamic acid or NSAIDs can be offered for management of HMB during use of IUC.**
✓	**A 3-month trial of COC can be offered to medically eligible individuals with problematic bleeding during use of IUC.**

The expected bleeding patterns for Cu-IUD and LNG-IUD can be found in **Section 9.1**: Bleeding patterns. As bleeding patterns will often change with IUC, provision of information about expected bleeding patterns is important.

Although unscheduled bleeding may be caused by the IUC itself, other causes (e.g. pregnancy, infection, pathology) should be considered and investigated in line with FSRH Clinical Guideline Problematic Bleeding with Hormonal Contraception.[323] Risk factors for endometrial cancer include older age, raised BMI, early menarche, late menopause, nulliparity, use of HRT, use of tamoxifen, history of polycystic ovary syndrome, diabetes and a family history of endometrial cancer.

In the absence of evidence to inform specific recommendations for management of HMB during Cu-IUD use, standard treatment for these conditions can be advised. NICE guidance recommends tranexamic acid or NSAIDs as suitable treatments for HMB, or medically eligible individuals could have their Cu-IUD removed and an LNG-IUD inserted (or other suitable contraception initiated).[25]

There is limited evidence for the management of bleeding irregularity during use of IUC. Overall, the studies are generally small and of low quality, with no conclusive evidence to support any intervention for

either prophylaxis or treatment of bleeding irregularities post-IUC insertion. In the absence of evidence, the GDG suggests that a 3-month trial of COC can be offered to medically eligible individuals with problematic bleeding with IUC, in line with FSRH guidance FSRH Clinical Guideline Problematic Bleeding with Hormonal Contraception.[323] However, it should be noted that bleeding patterns may return to the pre-intervention bleeding pattern after COC has been stopped.

The evidence

A 2020 systematic review of management strategies for LNG-IUD-induced bleeding irregularities identified six RCTS and two prospective cohort studies (total n = 677).[243] The findings did not support the use of tamoxifen, mifepristone, ulipristal acetate, naproxen, estradiol, mefenamic acid, tranexamic acid and the progesterone receptor modulator CDB 2914 to manage bleeding or spotting during LNG-IUD use. The review authors highlight positive results from a small RCT that found prophylactic use of 500 mg naproxen for 12 weeks reduced bleeding over that time compared with placebo (aRR for bleeding 0.90; 95% CI 0.84–0.97).[244] However, this was a single RCT with 42 individuals in the naproxen arm so firm conclusions cannot be drawn.

A 2022 Cochrane systematic review[324] of studies of interventions to prevent or treat HMB associated with IUC use identified 11 treatment trials (7 Cu-IUD, 1 LNG-IUD and 3 unknown IUD type) and 10 prevention trials (6 for Cu-IUD, 4 for LNG-IUD). The users were treated with medications that included a variety of NSAIDs, vitamin B1, ulipristal acetate and flavonoids. The authors concluded that available evidence was of low or very low certainty and that it was not possible to draw conclusions regarding a specific drug or regimen for the treatment or prevention of HMB or pain associated with IUC use.[324]

Evidence level 1-

14.2 New-onset pelvic pain

Clinical recommendations

✓ **New-onset pelvic pain in an IUC user should be assessed, and pregnancy should be excluded.**

There are a number of possible causes for new-onset pelvic pain in an IUC user, many of which are not related to the IUC. A clinical history and physical examination will identify the differential diagnoses and guide the investigation and management.

The clinical history should include:

- The nature, onset and duration of the pain
- Any associated symptoms, for example, change in vaginal discharge or bleeding pattern, urinary/bowel symptoms, nausea/vomiting, pyrexia, dizziness/syncope, pain elsewhere (back, shoulder tip)
- IUC history – time in situ, previous problems or checks, when threads were last felt or seen, changes in thread length, any suspicion that stem can be felt/seen
- Sexual history – to assess risk of pregnancy, infection or trauma
- Gynaecological history
- Past medical history.

The history will determine the examination and investigations required; however, an abdominal and pelvic

examination (speculum ± bimanual examination) and a pregnancy test would usually be required. Due to the potential serious consequences of an ectopic pregnancy, pregnancy should be excluded in all IUC users with new-onset pelvic pain. Other investigations/examinations that may be indicated would be urinalysis, STI screening, measurement of temperature/blood pressure/heart rate, pelvic ultrasound, rectal examination, blood tests. **Table 17** lists some of the possible causes of new-onset pelvic pain.

Where alternative causes have been excluded and the individual wishes IUC removal and replacement, the GDG suggests that clinicians could consider offering replacement with an alternative device (e.g. switching to a device with a smaller or different-shaped frame). There is, however, insufficient evidence to suggest one particular device over another.

Table 17: Possible causes of new-onset pelvic pain

Gynaecological causes	Other causes
IUC malposition/partial expulsion/expulsion	Appendicitis (± sepsis)
IUC perforation	Diverticulitis (± sepsis)
Pregnancy (ectopic, miscarriage, labour)	Irritable bowel syndrome/constipation
Pelvic inflammatory disease (± abscess/sepsis)	GI infection (± sepsis)
Ovarian cyst accident	GI obstruction/perforation/necrosis
	Urinary tract infection/pyelonephritis (± sepsis)
	Hernia

GI, gastrointestinal; IUC, intrauterine contraception.

14.3 Pregnancy

Key information

C	**The risk of any pregnancy, including ectopic pregnancy, during use of IUC and after insertion of a Cu-IUD for EC is very low.**
C	**If a pregnancy occurs with IUC in situ, the likelihood of it being ectopic is greater than if a pregnancy was to occur without IUC in situ.**
D	**A previous ectopic pregnancy is not a contraindication to use of intrauterine methods of contraception.**

Clinical recommendations

✓	**If an individual with an IUC in situ has a positive pregnancy test, local early pregnancy assessment pathways should be followed to determine the location of the pregnancy.**
D	**When an intrauterine pregnancy is less than 12 weeks' gestation, the IUC should usually be removed, if the threads are visible, as this could improve later pregnancy outcomes.**

The risk of any pregnancy, including ectopic pregnancy, during use of IUC and after insertion of a Cu-IUD for EC is very low. Risk of ectopic pregnancy during use of IUC is lower than using no contraception.[325] However, among pregnancies that occur with IUC in situ, the proportion that is ectopic is greater than

among pregnancies occurring without IUC in situ.[326] Very limited evidence suggests that the risk of ectopic pregnancy could be smaller with 52 mg LNG-IUDs than with lower dose LNG-IUDs, although the risk is low for users of all LNG-IUDs. Evidence is conflicting as to whether the proportion of pregnancies that are ectopic differs between LNG-IUD and Cu-IUD.

A previous ectopic pregnancy is not a contraindication to use of IUC (UKMEC1).[2]

If an individual with an IUC in situ has a positive pregnancy test, local early pregnancy assessment pathways should be followed to determine the location of the pregnancy.

Clinicians should explain to individuals who have an intrauterine pregnancy with an IUC in situ that the risk of adverse pregnancy outcomes (including miscarriage, preterm delivery and septic abortion) is greater than that for pregnancies without an IUC in situ. Removal of the device may improve pregnancy outcomes. Regardless of whether the individual decides to continue with the pregnancy, individuals whose intrauterine pregnancy is less than 12 weeks' gestation should be advised that the IUC should usually be removed, as long as the threads are visible or can be easily removed from the endocervical canal. There is insufficient evidence to guide the management of individuals who are continuing the pregnancy, have IUC in situ, and the pregnancy is either greater than 12 weeks' gestation or the threads are not visible. The decision to remove or retain the device should be considered on an individual basis with specialist advice from the individual's obstetric team.

When an IUC is in situ in pregnancy, the individual's obstetric/maternity team should be made aware of the presence of the device.

The evidence: ectopic pregnancies

The UK incidence of ectopic pregnancy is estimated at 1.1% of all pregnancies.[327]

An early, prospective UK study reported that among 90 pregnancies in individuals using IUDs, 8.9% were ectopic.[328] In a cross-sectional study[70] of LNG-IUD users (17 360 users, totalling 58 600 woman-years) there were 64 pregnancies reported with a 52 mg LNG-IUD in situ. The risk of pregnancy was therefore low (6-year cumulative pregnancy rate of 0.5 per 100 users); however, roughly half of the 64 pregnancies (53%) were ectopic.

The EURAS-IUD study,[52] a large observational study with 61 448 women enrolled from six European countries between 2006 and 2012, reported an ectopic pregnancy rate for the 52 mg LNG-IUD 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). In this study, 52 mg LNG-IUD users appeared to experience fewer ectopic pregnancies than Cu-IUD users. Of the pregnancies that did occur, however, a higher proportion were ectopic in LNG-IUD users than in Cu-IUD users (5/13 (38.6%) pregnancies observed in LNG-IUD users were ectopic compared with 10/56 (17.9%) in Cu-IUD users).

Evidence level 2-

A subanalysis of the Contraceptive Choice Project (a large prospective cohort study of individuals initiating a new method of contraception) identified 13 ectopic pregnancies in 23 546 woman-years of follow-up (across all methods of contraception).[325] The rate of ectopic

Evidence level 2-

pregnancy in this study for LNG-IUD users was 0.05 per 1000 woman-years. This was higher than the rate for the Cu-IUD (0.045 per 100 woman-years) and the oral contraceptive pill (0.039 per 1000 woman-years) and lower than no method/condoms (0.157 per 1000 woman-years).

The 5-year phase III study of Kyleena[63] reported a Pearl Index (PI) for ectopic pregnancy (the number of ectopic pregnancies that occur in 100 users during 1 year of method use) of 0.18 for Kyleena over 5 years. The 3-year phase III study[62] of Jaydess reported a PI for ectopic pregnancy of 0.1 per 100 woman-years. A recent Swedish retrospective cohort study[329] calculated the PI for ectopic pregnancy in LNG-IUD users and concluded that in those who became pregnant with an LNG-IUD in situ, the lower the dose of LNG, the higher the risk of ectopic pregnancy. The estimated PI for ectopic pregnancy was 0.136 (95% CI 0.106–0.176) for the 13.5 mg LNG-IUD, 0.037 (95% CI 0.021–0.067) for the 19.5 mg LNG-IUD and 0.009 (95% CI 0.006–0.014) for the 52 mg LNG-IUD. In comparison to the 52 mg LNG-IUD, the RR for ectopic pregnancy was higher during the first year for LNG 13.5 mg (RR 20.59, 95% CI 12.04–35.21) and for both 13.5 mg (RR 14.49, 95% CI 9.01–23.3) and 19.5 mg (RR 4.44, 95% CI 1.64–12.00) during the total study period. There are a number of limiting factors in this study design. Data on ectopic pregnancy risk in users of different dose LNG-IUDs are limited and further research is required to compare the rates between devices.

Evidence level 1-

Using EMA criteria (conception dates within two days after device removal), the only pregnancy reported during years six to eight of the ACCESS IUS study was ectopic (PI 0.25 (0.01 to 1.37)[400]. This occurred during year seven, out of 465 participants included in the trial at that time. Two pregnancies occurred during years six to eight of the Mirena Extension Trial. One of these (at 6.5 years, out of 346 participants) was ectopic (PI 0.14, 95% CI, 0.00 to 0.77)[13].

Evidence level 1+

The evidence: intrauterine pregnancies

A systematic review of nine observational studies[326] – eight of which studied Cu-IUD users and one which studied LNG-IUD users – concluded that compared with individuals who conceive without IUC in situ, those who conceive with IUC in situ are at greater risk of adverse pregnancy outcomes including miscarriage, preterm delivery and chorioamnionitis. The review found that compared with individuals who had their device removed in early pregnancy, those whose IUC remained in situ during pregnancy were at higher risk for miscarriage, preterm delivery and septic abortion. It also observed that pregnant individuals who had their IUC removed in pregnancy remained at higher risk for preterm delivery compared with individuals who did not conceive with IUC in situ. The data were insufficient to draw conclusions on whether conceiving with IUC in situ resulted in an increased risk of fetal anomalies. The data were insufficient to guide whether IUC should be removed at later gestations or when threads were not visible.

Evidence level 1-

Considering fetal exposure to the LNG-IUD, the Summaries of Product Characteristics (SPCs) state the theoretical possibility that adverse effects (particularly virilisation) could occur as a result of local exposure to LNG. There are very limited clinical data regarding the outcomes of pregnancies conceived with an LNG-IUD in situ due to the device's high contraceptive effectiveness. One case report and review of the

evidence[330] on the risk of adverse effects of fetal exposure to LNG-IUD reported a low frequency of congenital abnormalities. This study is limited, however, by the very small numbers: in the 35 pregnancies studied there were two cases of congenital abnormalities (6%).

14.4 Infection

Key information

C	**The risk of pelvic infection appears to increase in the first 3 weeks after IUC insertion, but overall the risk is very low (<1%).**
D	**The evidence pertaining to effect of IUC use on risk of vulvovaginal candidiasis (VVC) and/or bacterial vaginosis is limited and conflicting.**
D	**Pelvic actinomycosis is a very rare, chronic bacterial pelvic infection that is associated with long-term IUC use.**

Clinical recommendations

D	**Individuals with PID and IUC in situ should be given antibiotic treatment, managed in accordance with BASHH guidance and reviewed after 48–72 hours.**
D	**Individuals with mild-to-moderate PID and IUC in situ, whose clinical condition is improving over the first 48–72 hours, can retain their IUC.**
D	**Individuals whose clinical condition does not improve after 48–72 hours of antibiotics should usually have their IUC removed, but this decision should be considered alongside any potential risk of pregnancy if there has been unprotected vaginal sex within the preceding 7 days. EC and follow-up pregnancy testing should be considered if indicated.**
D	**IUC users with symptomatic, recurrent VVC or bacterial vaginosis not controlled by standard treatment may wish to switch to an alternative method of contraception.**
D	**Asymptomatic individuals with positive actinomyces-like organisms on cervical cytology are more likely to be colonised than infected, and there is no need to remove the IUC or to commence antibiotic treatment.**
D	**If actinomycosis is suspected, further investigation and management should be discussed on an individual basis with local radiology, microbiology and/or gynaecology teams.**

14.4.1 Pelvic inflammatory disease

Pelvic inflammatory disease (PID) occurs as a result of upper genital tract infection, often due to ascending infection from the vagina or endocervix. A variety of microbes are associated with PID; however, *Chlamydia trachomatis* is the most common causative organism, and is believed to be present in up to 35% of cases of PID.[331] Information about PID can be found in BASHH Guideline: Pelvic Inflammatory Disease.[331]

Instrumentation of the uterus for gynaecological procedures, including IUC insertion, can facilitate upward ascent of infection and therefore purulent cervicitis, gonorrhoea and symptomatic chlamydia infection are

considered contraindications to IUC insertion (UKMEC4) (**Table 10**)[2]. A sexual history should be taken prior to IUC insertion and screening offered to any individual at risk of an STI. For asymptomatic individuals, testing can be undertaken at the time of IUC insertion. See **Section 7.1.10**: Individuals at risk of infection.

The risk of PID appears to increase in the first 3 weeks after IUC insertion[332] but overall the risk is very low (<1% of IUC users). There is no evidence to suggest that cervical cleansing prior to IUC insertion reduces subsequent pelvic infection, and none of the standard cleansing agents are effective bactericidally against chlamydia or gonorrhoea.

IUC users with a clinical presentation suggestive of PID should be given antibiotic treatment, managed in accordance with BASHH guidance,[331] and reviewed after 48–72 hours. For individuals with mild- to- moderate PID, whose clinical condition is improving over the first 48–72 hours, the IUC can remain in situ. For individuals whose clinical condition does not improve after 48–72 hours of antibiotics, removal of IUC is normally recommended but should be considered alongside any potential risk of pregnancy if there has been unprotected vaginal sex within the preceding 7 days. An alternative method of contraception should be offered for ongoing contraception, and the need for EC and follow-up pregnancy testing considered.

Insertion of IUC when an individual has PID is a UKMEC4.[2] Therefore, for individuals with PID that have their IUC removed but wish another IUC inserted, it is recommended that IUC insertion is delayed until antibiotic treatment has been completed and all signs and symptoms have resolved.

The evidence

Evidence looking at associations between IUC and PID is limited by a significant risk of confounding and bias. The published evidence is often an indirect finding or secondary outcome, and not the main focus of the study.

A large retrospective cohort study[136] of 57 728 insertions found an overall risk of PID within the first 90 days after IUC insertion of 0.54% (95% CI 0.0048–0.006). The study included individuals who were and were not screened for gonorrhoea and chlamydia in advance of insertion and found that not screening and any screening had equivalent PID risk, and same-day screening and pre-screening had equivalent PID risk.

A systematic review[333] of six prospective studies reported an increased risk of PID in individuals who had chlamydia or gonorrhoea at the time of IUC insertion. The incidence of PID across the studies was 0%–5% for those with chlamydia or gonorrhoea at the time of insertion and 0%–2% for those without chlamydia or gonorrhoea at IUC insertion. None of the studies compared the risk of PID when an IUC was inserted with the risk of PID in the general population, and it is therefore not clear what impact the IUC insertion had on the risk of PID in those who had chlamydia or gonorrhoea.

Evidence level 2+

A review of 12 randomised and one non-randomised trial[334] (22 908 insertions and more than 51 399 woman-years of follow-up) reported an overall low rate of PID in IUC users at 1.58 per 1000 woman- years. The review found a statistically significant six-fold increased risk of PID diagnosis within 21 days of IUC insertion compared with >21 days post-insertion (<21

Evidence level 1-

days post-insertion, 9.66 cases per 1000; >21 days post-insertion 1.38 cases per 1000). After 21 days the risk was low and remained low unless there was exposure to STIs.

No significant differences in discontinuation rates due to PID were observed between different Cu-IUDs or when the 52 mg LNG-IUD has been compared with Cu-IUDs in randomised trials.[335,336] A systematic review primarily looking at appropriate follow-up after initiation of contraception found no difference in PID rates when comparing LNG-IUD, Cu-IUD, COCs or DMPA.[335]

Evidence level 1-

A systematic review of studies[332] comparing the clinical outcomes for individuals who had PID and retained their IUC versus those who had it removed concluded that individuals who retained their IUC had a similar or better outcome than those who had their IUC removed. They identified three studies that showed no difference in outcome, two of which observed that those who had their IUC removed had longer hospitalisations, and one study that showed clinical improvement in those who had their IUC removed when compared with those who retained it. The evidence to guide whether an IUC should be removed or left in situ when an individual is diagnosed with PID is limited, but the aforementioned recommendations align with established BASHH guidance.

14.4.2 Candida

Candida yeasts are part of the normal vaginal flora; however, overgrowth can lead to candidiasis, a candida fungal infection most commonly caused by *Candida albicans*[337]. Approximately three-quarters of women will have at least one episode of vulvovaginal candidiasis (VVC) in their lifetime, with 40%–45% having two or more episodes[337]. Recurrent VVC, where individuals experience at least four episodes of VVC in a 12-month period, affects approximately 6% of women.[337]

There are many risk factors associated with acute and recurrent VVC, of which IUC use could be one – the evidence is conflicting. There is some evidence to demonstrate that yeasts adhere to IUC and produce a biofilm that could facilitate recurrent VVC by protecting yeasts from antifungal agents.[338,339] Therefore, IUC users with symptomatic, recurrent, confirmed VVC not controlled by standard management may wish to switch empirically to an alternative method of contraception. See BASHH candida guideline for VVC risk factors and management.[337]

The evidence

Candidiasis is common in the general population and is associated with a number of genetic and behavioural risk factors.[338,339] The evidence pertaining to IUC use being a risk factor for VVC is limited and conflicting. Some studies have found that VVC incidence is higher among IUC users than non-users[340–343] and that IUC use is more common in individuals with VVC than individuals without VVC,[344–346] whilst others[347,348] found no association between VVC and IUC use.

Evidence level 2-

14.4.3 Bacterial vaginosis

Bacterial vaginosis (BV) can be asymptomatic (in approximately 50% of cases) or may present with an altered discharge that is typically thin and white with a fish-like odour.[349] It is the most common cause of vaginal discharge in individuals of reproductive age, but reported prevalence varies widely in studies, suggesting it could affect between 5% and 50% of individuals.[349]

Given this wide variation in the general population, it is difficult to assess the effect that IUC use has on prevalence of BV. The evidence is limited and conflicting. It suggests that there could be an increase in prevalence of BV in Cu-IUD users. Evidence relating to LNG-IUD users is too limited to inform any association. Treatment guidelines and risk factors for BV can be found in BASHH guidance.[349] IUC users with confirmed, recurrent, symptomatic BV that is not controlled by standard management may wish to switch empirically to an alternative method of contraception.

The evidence

Evidence level 2+

A 2018 systematic review[350] found nine studies examining the prevalence, incidence and/or persistence of bacterial vaginosis in IUC users. Most of these studies did not differentiate between Cu-IUD and LNG-IUD users; however, in those that did, no difference in occurrence or persistence of BV between the two types of IUC was observed. Eight of the nine studies found no significant correlation between BV and IUC use. One study from Zimbabwe reported a correlation between BV prevalence and Cu-IUD use. This small, prospective study of individuals seeking contraception included 48 individuals who had vaginal swabs taken at baseline and then at 30, 90 and 180 days after Cu-IUD insertion. They observed that BV prevalence significantly increased in individuals initiating Cu-IUD use from 27% at baseline, to 35% at 30 days, 40% at 90 days and 49% at 180 days. The authors postulated that Cu-IUD use could increase colonisation by BV-associated microbiota.

In a 2021 prospective, longitudinal cohort study,[351] 2585 individuals of reproductive age had vaginal swabs taken at baseline (initiation of contraception) and then every 6 months (or more frequently if symptomatic) for up to 33 months. This group included 323 Cu-IUD users and no LNG-IUD users. In Cu-IUD users in this study, there was a 28% greater risk of BV (RR 1.28, 95% CI 1.12–1.46) than in users of no contraception or another non-hormonal contraception. BV risk was 1.52-fold (95% CI 1.16–2.00) higher in the first 6 months of Cu-IUD use when compared with the 6 months prior to insertion and risk remained elevated over 18 months of use ($p<0.05$). Of the individuals who underwent Cu-IUD removal during the study, BV frequency was similar to pre-initiation rates within 1 year.

14.4.4 Actinomycosis and presence of actinomyces-like organisms

Actinomyces spp are commensal, Gram-positive, anaerobic bacteria that are found in the genital tract. If the mucosa is breached, actinomyces can become pathogenic, resulting in actinomycosis. Pelvic actinomycosis is a very rare, chronic bacterial pelvic infection that is associated with long-term IUC use.[352] Symptoms include pelvic pain, vaginal discharge, intermenstrual bleeding and, occasionally, fever.[353] Treatment is with long-term, high-dose antibiotic therapy.[353]

Previously, actinomyces-like organisms (ALO) were frequently reported on cervical smears in IUC users. However, where liquid-based cytology (LBC) and/or primary human papillomavirus (HPV) testing is used for cervical screening, incidental findings of ALO are rare, as LBC has lower rates of ALO detection than a conventional cervical smear[354]. Cervical cytology has poor specificity and sensitivity for actinomyces and a low positive predictive value for actinomycosis.[352] Asymptomatic individuals with positive ALO on cervical screening are more likely to be colonised than infected, and there is no need to remove the IUC or to commence antibiotic treatment.[355]

If ALO are identified and the individual presents with symptoms of pelvic infection, other more common causes (including STIs) should be excluded. If actinomycosis is suspected, further investigation and

management should be discussed on an individual basis with local radiology, microbiology and/or gynaecology teams. Where an IUC has been removed from a symptomatic individual, the device should be sent for culture testing, requirement for antibiotic treatment considered, and appropriate follow-up arranged[355] in line with local radiology, microbiology and/or gynaecology protocols.

14.5 Malpositioned IUC

Key information

D	**Correct IUC position at the fundus may be necessary for maximum contraceptive effectiveness and incorrect placement may be associated with increased risk of contraceptive failure.**
D	**The published evidence is too limited to predict failure rates of malpositioned IUC.**
D	**There is insufficient evidence to definitively guide whether a malpositioned IUC should be left in situ or removed and replaced, and clinicians should consider each case on an individual basis.**

Clinical recommendations

✓	**The GDG suggests that as a general guide any of the following findings would usually be an indication to suggest that the IUC is removed and replaced: IUC >2 cm from the fundus; IUC within the cervical canal (fully or partially); or IUC user experiencing symptoms that may be related to malpositioned IUC (e.g. pain or bleeding).**
D	**Clinicians should consider the need for EC and follow-up pregnancy testing when an IUC is found to be malpositioned.**

The expected position of a T-shaped IUC device would be that both horizontal arms are fully extended at the uterine fundus, parallel to the axis of the uterine cornua, with the vertical stem pointing directly downwards and centrally into the uterine cavity and not encroaching on the cervical canal. Correct IUC position at the fundus may be necessary for maximum effectiveness and incorrect placement could be associated with increased risk of failure. The published evidence is too limited to predict failure rates of malpositioned IUC.

Studies suggest that the incidence of IUC malposition is between 7% and 19%.[125,356] Malpositioned IUC may be identified on clinical examination, imaging (ultrasound, X-ray, computed tomography (CT) or MRI), at hysteroscopy or laparoscopy, or may be undetected. In the case of suspected malposition, 3D ultrasound (if available) may be helpful in improving diagnostic accuracy.

A malpositioned IUC may be:

- Malrotated – the IUC may be inverted (upside down), transverse or partially rotated on either the horizontal or vertical axis.
- Displaced: downward (non-fundal –within the uterine cavity but sitting lower than expected), lateral (not central in the cavity, arms may not be deployed/only partially deployed/embedded/in the fallopian tube), cervical (stem partially or fully within the cervix).
- Embedded – arm and/or stem partially or fully within the myometrium.

- Incorrectly deployed – one or both arms not fully extended.

A lack of homogeneity in the classification of malposition within studies makes it difficult to amalgamate results and describe the incidence of different types of malposition.

The available evidence regarding risk factors for malpositioned IUC is conflicting and contradictory. It is not possible to conclude whether individuals with a malpositioned IUC are more likely to experience pain or bleeding, or whether personal factors are associated with an increased incidence of IUC malposition.

The published literature suggests that IUC can move both upwards and downwards over time and that movement may be related to cyclical changes. There is insufficient evidence to predict whether an IUC will move and, if so, to what extent. In the studies of IUC movement, upward movement was more common than downward movement. However, we know downward movement is common, given that IUC expulsion rate is 1 in 20.[53,60,64,357,358]

14.5.1 Management of malpositioned IUC

There is insufficient evidence to definitively guide whether a malpositioned IUC should be left in situ or removed and replaced. Clinicians should consider management on a case-by-case basis, with their decision guided by:

- IUC position and degree of malposition
- Recent sexual history (to determine need for pregnancy testing ± EC and to assess suitability of new IUC insertion)
- Presence of associated symptoms (e.g. pain or bleeding)
- Accuracy of imaging available and certainty of the findings (e.g. 2D USS/3D USS/hysteroscopy)
- Indication for use of the IUD
- Type of device in situ
- Potential consequence of complications associated with leaving the device in situ (such as expulsion or failure) and consequences of removal/replacement (procedure-related complications, risk of pregnancy if unable to refit or if user switches to less effective method of contraception).

The IUC user should be made aware that IUC may need to be correctly positioned at the fundus for maximum effectiveness, and incorrect placement could be associated with increased risk of failure. However, the published evidence is too limited to predict failure rates of low-lying IUC, which could still be more effective than some alternative methods of contraception.

The GDG suggests that as a general guide any of the following findings would usually be an indication to suggest that the IUC is removed and/or replaced:

- IUC >2 cm from the fundus (measuring from the top (fundus) of the endometrial cavity to the proximal end of the device)
- IUC within the cervical canal (fully or partially)
- IUC user experiencing symptoms that may be related to the malpositioned IUC (e.g. pain or bleeding).

The timing of removal/replacement will depend on the presence or absence of symptoms and the recent sexual history/pregnancy risk.

Where the individual has a malpositioned IUC, is asymptomatic or experiencing only mild symptoms, and wishes removal without replacement, the GDG recommends that removal is deferred until at least 7 days after last UPSI, as the malpositioned IUC may still be providing contraception.

Where the individual has a malpositioned IUC, is asymptomatic or experiencing only mild symptoms, and wishes removal and replacement, the GDG recommends deferring the removal and replacement until pregnancy can be excluded (onset of a normal menstrual period for Cu-IUD users or 3 weeks after last UPSI with a negative pregnancy test for all IUC users) unless the individual meets criteria for Cu-IUD insertion as EC. Bridging contraception should be offered.

If there has been UPSI within the last 7 days and removal cannot be delayed (e.g. associated pain, patient request), EC should be considered, a new method of contraception should be offered, and a follow-up pregnancy test 3 weeks after last UPSI should be recommended.

The GDG does not recommend attempting to reposition a malpositioned IUC.

Serial ultrasound examination to assess IUC position is not recommended. The GDG does not recommend reviewing a malpositioned IUC at a later date to see if it has spontaneously moved, nor routine follow-up ultrasound after IUC insertion (even when there is a history of IUC malposition).

The GDG suggests that where ultrasound has suggested the IUC may be embedded, removal is only required if the user is symptomatic or requesting IUC removal. Clinical experience suggests that when IUC is noted to be embedded on USS, removal is often still straightforward and the GDG suggests that removal by gentle traction can be attempted in primary care/community settings, with low threshold for referral to a specialist service if the removal is not possible or is intolerable.

The evidence: incidence

Studies have suggested that the incidence of malpositioned IUC is between 7% and 19%.[125,356] However, this is difficult to determine as regular post-insertion and follow-up ultrasound is not routine practice and therefore if ultrasonography is undertaken due to symptoms (e.g. pain, unexpected bleeding, non-visible threads) the rates of malpositioned IUC on scan may be overrepresented in the population being investigated.

In a 2022 retrospective case–control study,[359] individuals who had an IUC inserted were routinely seen for a follow-up 3D ultrasound within 8 weeks of their IUC insertion, with the aim of determining the rate and type of IUC malposition. Of the 736 individuals who attended for follow-up, 127 (16.6%) were malpositioned and 67 (8.8%) required removal. Embedment was the most common type of malposition (53.5%) followed by misalignment (47.2%, which included malrotated IUC and incorrectly deployed IUC), downward displacement (low in the uterine cavity, 39.4%), cervical (14.2%) and perforated or extrauterine (4.1%).

Evidence level 2-

The evidence: risk factors

Moshesh *et al*[360] undertook ultrasonography at baseline prior to commencement of a separate cohort study. From this baseline assessment, they identified 168 individuals (10% of their study population) who had IUC in situ, of which 28 (17%) were low-lying. Twenty-five (89%) of these were partially within the cervix. In their study there were two statistically significant factors associated with a low-lying IUC: individuals whose highest level of education was high school had an adjusted odds ratio (aOR) of having a low-lying IUD of 3.1 (95% CI 1.14–8.55), and increasing BMI was associated with increasing odds of having a

Evidence level 2-

low-lying IUD (p = 0.002). This study was small, had a narrow age range (23–34 years) and the clinical significance of the findings is unclear.

A large cohort study demonstrated an increased risk of expulsion with increasing BMI. 228,834 individuals (<50 years old) with IUD insertion and no delivery in the previous 52 weeks were identified. Both partial and complete expulsions were considered. The adjusted hazard ratio for expulsion was 1.20 (95% CI 1.13-1.29) in the overweight category, 1.55 (95% CI 1.45 – 1.66) for obesity and 2.02 (95%CI 1.86-2.20) for morbid obesity[401].

The study by Connolly *et al*[359] identified that risk factors independently associated with malpositioned IUC were the presence of symptoms at the time of follow-up (36.2% vs 18.6%, aOR 2.58, 95% CI 1.67–3.98), Cu-IUD versus LNG-IUD (63.0% vs 46.1%, aOR 1.99, 95% CI 1.31–3.031), prior full or partial uterine rupture (6.3% vs 2.0%, aOR 2.78, 95% CI 1.06–7.30) and morbid obesity (8.7% vs 3.8%, aOR 2.462, 95% CI 1.10–5.50). Parity, type of delivery, breastfeeding, uterine anatomy (congenital uterine anomaly, fibroids, history of previous cervical procedure, uterine size and position) and difficult placement were not found to be significant risk factors for malpositioning. Two additional, smaller studies[125,361] have also shown an association between bleeding/pain and IUC malposition, whilst two other studies have not.[362,363]

Gerkowicz *et al*'s study[125] also reported that vaginal bleeding and pelvic pain were more common in patients with malpositioned IUDs compared with controls (30% vs 19%, p = 0.005 and 43% vs 30%, p = 0.002). This study identified different risk factors to Connolly *et al*.[359] Patients with malpositioned IUC were more likely than the control group to have been found to have non-visible threads (16% vs 10%, p = 0.03). The incidence of retroflexed uteri (7.6% vs 1.8%, p = 0.001) and all uterine anomalies (including septate and bicornuate uteri and fibroids, 31.9% vs 23.5%, p = 0.02) was higher in the group with malpositioned IUC. A higher total number of fibroids was noted in the malpositioned group (3.7 vs. 1.8, p = 0.01) and there was an increased incidence of submucosal fibroids in individuals with malpositioned IUC (p = 0.01). Statistical analysis showed that anterior midline position (OR 0.33, 95% CI 0.20–0.57) and absence of uterine anomalies (OR 0.59, 95% CI 0.38–0.93) were factors associated with a lower risk of IUD malposition, whereas vaginal bleeding (OR 2.25, 95% CI 1.38–3.67), pain (OR 2.85, 95% CI 1.84–4.44) or non-visible IUC threads at time of presentation (OR 3.58, 95% CI 1.88–6.82) were associated with an increased risk of malposition.

Benacerraf *et al*[361] conducted a retrospective case note review of 28 patients who had attended for ultrasound and been found to have a malpositioned IUC (identified on 2D ultrasound and confirmed on 3D ultrasound). Pain (39%) and bleeding (34%) were the most common indications for ultrasonography requests in those with a malpositioned IUC, with the proportion of patients whose principal indication for sonography was bleeding and/or pain found to be significantly greater in those with a malpositioned IUC compared with a correctly sited IUC (p = 0.0001).

In contrast, a case–control study by Faúndes *et al*[362] compared 236 individuals with IUC in situ who had bleeding and/or pain with 245 individuals with an IUC in situ and no bleeding or pain. They found no correlation between the presence of pain/bleeding and the position

Evidence level 2-

of the IUD, concluding that a malpositioned IUC was not more likely to cause pain or bleeding. A randomised trial[363] of an LNG-IUD that was placed intracervically in 151 individuals and at the uterine fundus in 147 individuals found no difference in the continuation rates or removal rates for bleeding between the two groups.

The evidence: effectiveness

Studies examining the IUC position in individuals who have become pregnant with IUC in situ have shown that IUC is more likely to be low-lying than fundally placed.[356] Although theoretically this could be due to downward displacement of the IUC by the gestation sac, low-lying IUC has been seen in very early pregnancy (4 weeks' gestation)[364] which may make this theory less likely. As IUC has been shown to move during the menstrual cycle[365,366] it could be that it can move during pregnancy. A retrospective case–control study[149] of 216 pregnant individuals with IUC and 657 non-pregnant individuals with IUC found that previous IUC expulsion was a risk factor for contraceptive failure (OR 3.31, 95% CI 1.4–7.8).This might support the theory that downward displacement of IUC could be a cause of failure.

Evidence level 2-

In theory, the effectiveness of the LNG-IUD could be less affected by its position in the uterine cavity because of the local release of progestogen. However, one study[211] suggested that intracervical placement of a specially designed intracervical LNG-IUD was associated with less uniform endometrial suppression and more days of bleeding and spotting than fundal placement of a standard LNG-IUD. Another study[363] (n = 298) comparing the small intracervical LNG-IUD with an intrauterine LNG-IUD showed that there was no difference in the number of pregnancies in the two groups. However, this study was small, it was not clear whether it was powered to demonstrate equivalence, and the effect of the intracervical LNG-IUD would not necessarily equate to a standard LNG-IUD sited within the cervix.

The evidence: IUC movement

In a prospective cohort study by Faúndes *at el*[367], 214 individuals with IUC in situ had ultrasonography on days 1, 30 and 90 following insertion. At insertion, 17 (8%) IUDs were low-lying, but 15 (88%) of these migrated upwards over the next 90 days. In contrast, at 90 days post-insertion 21 (10%) IUDs were malpositioned, of which only six had been malpositioned at insertion. Therefore, 7.6% (15/197) of IUDs that were correctly placed at insertion became malpositioned over the 90-day period, and 88% (15/17) of IUDs that were malpositioned at insertion were correctly positioned after 90 days. The authors concluded that IUDs can move upwards and downwards over time.

Evidence level 2-

In a separate study, Faúndes *at el*[366] analysed ultrasonography measurements of 481 individuals with IUC in situ. They measured and compared the distance from the upper end of the vertical stem of an IUC to the external uterine fundus, the thickness of the myometrium in the uterine fundus, and of the endometrium. They demonstrated a correlation between endometrial thickness and IUC–myometrium distance, concluding that the IUC can move vertically within the uterine cavity in relation to cyclical changes in endometrial thickness.

A small study by Morales-Roselló[365] followed up 32 individuals found to have a low-lying IUC. They had a repeat ultrasound scan at 2–3 months' post-insertion and for 97% of cases the IUC had moved upwards, whilst in 3% of cases it had moved downwards. The mean distance

Evidence level 2-

moved was 6.2 mm (range 14–17mm). It is not clear from the article how many IUC were correctly sited on the repeat scan.

De Kroon *et al*[368] conducted a prospective comparative study, performing ultrasonography at baseline (immediately after inserting IUC in 195 individuals) and 6 weeks later (181 individuals who attended follow-up). Seven IUCs were incorrectly sited and left in situ at baseline examination. Of these, five had migrated to a correct position by the 6-week follow-up.

The evidence: management

In a case series,[369] Ber and Seidman describe 18 cases where a low-lying IUC was repositioned, rather than removed and replaced. The individuals in the series had an asymptomatic low-lying IUD (within the cervix but not seen on speculum examination) noted during routine ultrasound. Alligator forceps were used to attempt to reposition the IUC at the fundus. In 17/18 (94.4%) cases this was successful. In 3/17 (17.6%) of these successful procedures the IUC was found to be malpositioned on repeat scan within 2 months. No complications were noted and no post-procedural infection occurred. A USS 6 months' post-procedure confirmed that all the remaining 14 IUCs were correctly positioned.

Evidence level 3

A malpositioned device may be identified on ultrasound or hysteroscopy. 3D ultrasound has been shown to be more sensitive in identifying malpositioned IUC than 2D ultrasound[370]. In a prospective study by Chen *et al,*[370] 130 individuals with suspected malposition due to either a failed attempt at removal or ultrasonography results suggesting malposition underwent 2D and 3D sonography prior to IUC removal at hysteroscopy, laparoscopy or laparotomy. The ultrasound findings were correlated with the findings at the time of removal. Among the 130 individuals with suspected malposition, 128 (98.5%) were diagnosed with confirmed malposition at hysteroscopy, laparoscopy or laparotomy. In 64.8% (83/128) of cases, 2D ultrasound had correctly identified the malposition; in 83.6% (107/128) of cases, 3D ultrasound had correctly identified the malposition and the diagnostic accuracy of 3D ultrasonography was therefore found to be significantly better than that of 2D ultrasonography ($p = 0.001$).[370]The increased sensitivity of 3D ultrasonography compared with 2D ultrasonography in detecting malpositioned IUC has also been reported in other studies.[356,359,361] Chen *et al*[370] concluded that the use of 2D ultrasonography should be recommended for routine follow-up of individuals with IUC; however, 3D ultrasonography should be used when malposition is suspected.

Evidence level 2-

14.6 Expulsion

Key information

C	**The overall risk of IUC expulsion is approximately 1 in 20 and expulsion appears to be most common in the first year of use, particularly within 3 months after insertion.**
C	**Expulsion rates are higher when inserted immediately postpartum compared with interval postpartum insertion or insertion in individuals who have not had a recent pregnancy.**
D	**Expulsion rates may be higher in adolescents, those who have IUC inserted after late first-trimester or second-trimester surgical abortions, individuals with fibroids and HMB,**

individuals with uterine cavity distortion, individuals concurrently using a menstrual cup with IUC, those who have had a previous expulsion, and individuals with a BMI over 25.

Clinical recommendations

✓ **If there have been ≥2 IUC expulsions, a pelvic ultrasound to assess the uterine cavity may be helpful prior to insertion of a further IUC.**

✓ **Post-insertion USS is not predictive of the likelihood of further expulsion but can provide immediate confirmation of correct positioning.**

The overall risk of IUC expulsion is approximately 1 in 20[53,60,64,357,358] and expulsion appears to be most common in the first year of use, particularly within 3 months of insertion.[66,67,178,179,357,358] Expulsion rates are higher when inserted immediately postpartum compared with interval postpartum insertion. They may be higher in adolescents, those who have IUC inserted after late first-trimester or second-trimester surgical abortions, individuals with fibroids and HMB, individuals concurrently using a menstrual cup with IUC, those who have had a previous expulsion, and individuals with a BMI over 25. When IUC is inserted for gynaecological indications, the risk of expulsion may be higher when IUC is inserted on days 1–8 of the menstrual cycle than later in the cycle.

Expulsion should not be assumed due to the absence of threads. Where expulsion is suspected but the expelled device has not been visualised by the user or clinician, a USS should be performed. If the IUC is not present on ultrasound, further imaging (a pelvic and abdominal X-ray or pelvic and abdominal CT depending on local protocols) should be undertaken to exclude uterine perforation before concluding that the device has been expelled. Alternative contraception should be offered during the investigative process.

If the individual wishes to have another IUC this can be inserted once expulsion is confirmed. Users should be advised that the risk of expulsion appears to be higher in those who have had a previous expulsion. There is no evidence to suggest that switching to a different IUD may reduce the risk of a further expulsion.

The published literature does not inform the best course of management for individuals with previous IUC expulsion who wish another IUC insertion. The GDG suggests that if there have been ≥2 IUC expulsions, a pelvic ultrasound to assess the uterine cavity may be helpful prior to insertion of a further IUC. Post-insertion USS is not predictive of the likelihood of further expulsion but can provide immediate confirmation of correct positioning. When IUC is being inserted for gynaecological reasons, clinicians may wish to consider inserting the IUC after day 8 of the menstrual cycle. Alternatively, or in addition, clinicians could offer individuals treatment to suppress menses (e.g. tranexamic acid, oral progestogen or continuation of their usual treatment for menstrual management/contraception) for one to three cycles post-insertion.

The evidence

The evidence regarding overall expulsion rates per type of IUC is limited and mixed. A Cochrane review found little difference in expulsion rates between devices studied, although there was a small significant excess of expulsions with Multiload Cu375 compared with TCu380A in the fourth and subsequent years. In years 1 and 4, the TCu380S was found to be associated with more expulsions than the TCu380A.[53] The frameless device, GyneFix, has been shown in trials to have problems with early expulsion.[371] Although limited evidence

Evidence level 1-

suggests an expulsion rate for GyneFix inserted using the updated inserter that is comparable to other Cu-IUDs,[55,312] the Cochrane review authors concluded that "there is insufficient data to show that problems of early expulsions have been overcome with the modified introducer used in GyneFix".

In a small, retrospective cohort study[372] of individuals who had a 52 mg LNG-IUD inserted for non- contraceptive indications (bleeding problems, dysmenorrhoea, endometrial hyperplasia), 39 patients (22%) experienced expulsion. When subjects were grouped into those who had their IUC inserted on days 1–8 of their cycle and those who had IUC inserted later in the cycle, expulsion was more likely if the IUD placement occurred during days 1–8 of the cycle (aOR 3.57, 95% CI 1.13–11.31). This study also found that a larger uterine cavity length (≥8.5 cm) was associated with an increased risk of expulsion when compared with a cavity length <8.5 cm (61.5% and 38.5%, p = 0.011). However, studies examining cavity length and risk of expulsion have been small and results have been inconsistent, so with the limited available evidence it is not possible to draw a conclusion on the risk of expulsion in relation to cavity size.[357,373]

Evidence level 2-

Evidence regarding expulsion rates after childbirth, abortion, in adolescents, those with fibroids,individuals using menstrual cups, and individuals with a high BMI can be found in the corresponding sections.

14.7 Perforation

Key information

C	**The rate of uterine perforation associated with IUC use is very low, with an overall risk of perforation in the general population of 1–2 in 1000.**
C	**Postpartum interval IUC insertion (from 48 hours after childbirth) is associated with an increased risk of uterine perforation, particularly if the user is breastfeeding.**
D	**Uterine perforation may be identified at the time of insertion or at a later date.**
D	**Lower abdominal pain, non-visible threads or changes in bleeding may indicate uterine perforation.**

Clinical recommendations

✓	**If perforation is suspected, an ultrasound scan ± plain abdominal and pelvic X-ray should be arranged as soon as possible in order to locate the device. EC and pregnancy testing should be considered, and ongoing contraception provided.**
✓	**Following confirmed or suspected uterine perforation, the GDG suggests waiting at least 6 weeks before inserting a subsequent IUC. Referral to a specialist service, where ultrasound is available, is suggested for the subsequent insertion.**

The rate of uterine perforation associated with IUC use is very low, with an overall risk of perforation in the general population of approximately 1–2 per 1000.[113–115,374] A greater risk of perforation has been observed in individuals who were breastfeeding and postpartum at the time of insertion.[113–115]

For those individuals 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 the individual's level of discomfort monitored until stable. Broad-spectrum antibiotics should be considered to reduce the risk of peritonitis.[375] The individual should be offered alternative contraception and advised to seek review if they develop significant pain or any signs or symptoms of infection.

Although some uterine perforations are identified at the time of insertion, there can be a delay before perforation is identified. Lower abdominal pain, non-visible threads or changes in bleeding could indicate uterine perforation. However, there may be other causes for these signs and symptoms (e.g. pregnancy) and other causes should also be explored (see sections on new pelvic pain, bleeding, thread problems). The presence of threads in the vagina does not exclude the possibility of perforation as the IUC could have breached the myometrium/other surrounding tissue or perforated the cervix.

If there is concern that a perforation has occurred, an USS ± plain abdominal and pelvic X-ray should be arranged as soon as possible in order to locate the device. In the interim, EC should be considered, and individuals should be offered alternative contraception. Uterine perforation can also involve damage to the abdominal or pelvic viscera, bladder or bowel, and therefore if perforation is confirmed, urgent liaison with gynaecology should be instigated for consideration of an urgent laparoscopy in line with local protocols. Evidence suggests, however, that morbidity associated with detection and removal of an intra- abdominal IUC appears to be low.

In the absence of evidence, the GDG suggests waiting at least 6 weeks after a known or suspected uterine perforation before inserting a subsequent IUD. Referral to a specialist service, where ultrasound is available, is suggested for the subsequent insertion.

The evidence

A large, prospective, non-interventional cohort study by Barnett *et al*[113] followed up 39 009 new users of LNG-IUD and Cu-IUD for 60 months and observed an overall perforation rate of 2.1 per 1000 insertions (95% CI 1.6–2.8) for LNG-IUD users (58 perforations/27 630 insertions) and 1.6 per 1000 insertions (95% CI 0.9–2.5) for Cu-IUD users (17 perforations/11 379 insertions). Similar results have been seen in other studies.[114,115,374]

Evidence level 2-

In the Barnett *et al* study,[113] a small number of perforations were diagnosed during or immediately after insertion (2% of LNG-IUD and 17% of Cu-IUD). The majority (69%) of perforations were diagnosed within 12 months of insertion, and the remaining perforations were diagnosed between 1 and 5 years post-insertion. For those who had a perforation diagnosed within the first 12 months of IUC use, the majority had pain and/or bleeding, with only 29% of LNG-IUD and 17% of Cu-IUD perforations being asymptomatic. Perforations diagnosed later (between 1 and 5 years post-insertion) were more likely to be asymptomatic (58% of LNG-IUD users and 75% of Cu-IUD users). No perforations in this study caused significant morbidity, such as bowel or bladder injury, septicaemia or peritonitis.

Evidence level 2-

Both breastfeeding and postpartum status are risk factors for uterine perforation at IUC insertion (see **Section 7.1.3.1**: After childbirth) and clinician experience may also be a risk factor, with some studies suggesting that risk of perforation could be higher if the clinician has less experience of the procedure.[104,374]

14.8 Thread problems

Key information

D	**IUC threads may not be visible in the vagina as a result of IUC expulsion, perforation or pregnancy, or the device being correctly sited but with threads within the cervical canal or uterus.**
D	**The prevalence of non-visible threads may be as high as 18% (standard IUC insertion), 30% (IUC insertion within 48 hours of vaginal birth) and 50% (IUC insertion at the time of caesarean section).**

Clinical recommendations

✓	**If no threads are visible on speculum examination, pregnancy should be excluded, EC considered, alternative contraception provided, and a USS (± abdominal and pelvic X-ray) undertaken to locate the device.**
✓	**If the IUC is confirmed to be correctly sited within the uterine cavity, the user can be reassured and the device left in situ.**
✓	**The uterus should only be instrumented by a clinician with appropriate training to do so, and it is not advisable to instrument the uterine cavity without first confirming the intrauterine location of the device and excluding pregnancy.**
D	**As threads may descend into the vagina after PPIUC insertion, they may need to be trimmed at a subsequent IUC check.**

14.8.1 Non-visible threads

IUC threads may not be visible in the vagina as a result of IUC expulsion, perforation or pregnancy. However, often the IUC is correctly sited and the IUC threads are within the cervical canal or uterus. Reasons for non-visible threads when an IUC is correctly sited include the threads being cut very short (at time of insertion or at a later date, e.g. during a LLETZ procedure) and/or retraction of the threads, which could be caused by non-fundal placement at insertion[376] and subsequent upward movement; a change in cavity size (e.g. post-pregnancy, fibroids) or instrumentation of the uterus following IUC insertion.

The exact prevalence of non-visible threads with an IUC in situ is unknown, with studies reporting rates in the general population ranging from 1.4%[377] to 18%[378] and rates of up to 30% and 50% when an IUD is inserted within 48 hours of vaginal birth or at the time of caesarean section, respectively.[379–381] This reflects the differences in insertion technique and anatomical changes occurring during the postpartum period. In some cases, the threads may descend into the vagina over time as the uterus returns to its non-pregnant state.

Evidence level 2-

If no threads are visible on speculum examination, pregnancy should be excluded, EC considered, alternative contraception provided, and an ultrasound scan undertaken to locate the device (Figure 2). If perforation is suspected (e.g. pain, recent insertion) an urgent ultrasound referral is recommended.

If the IUD is confirmed to be correctly sited within the uterine cavity, the user can be reassured, and the device left in situ. Clinicians should not attempt to retrieve the threads unless removal is required. As the

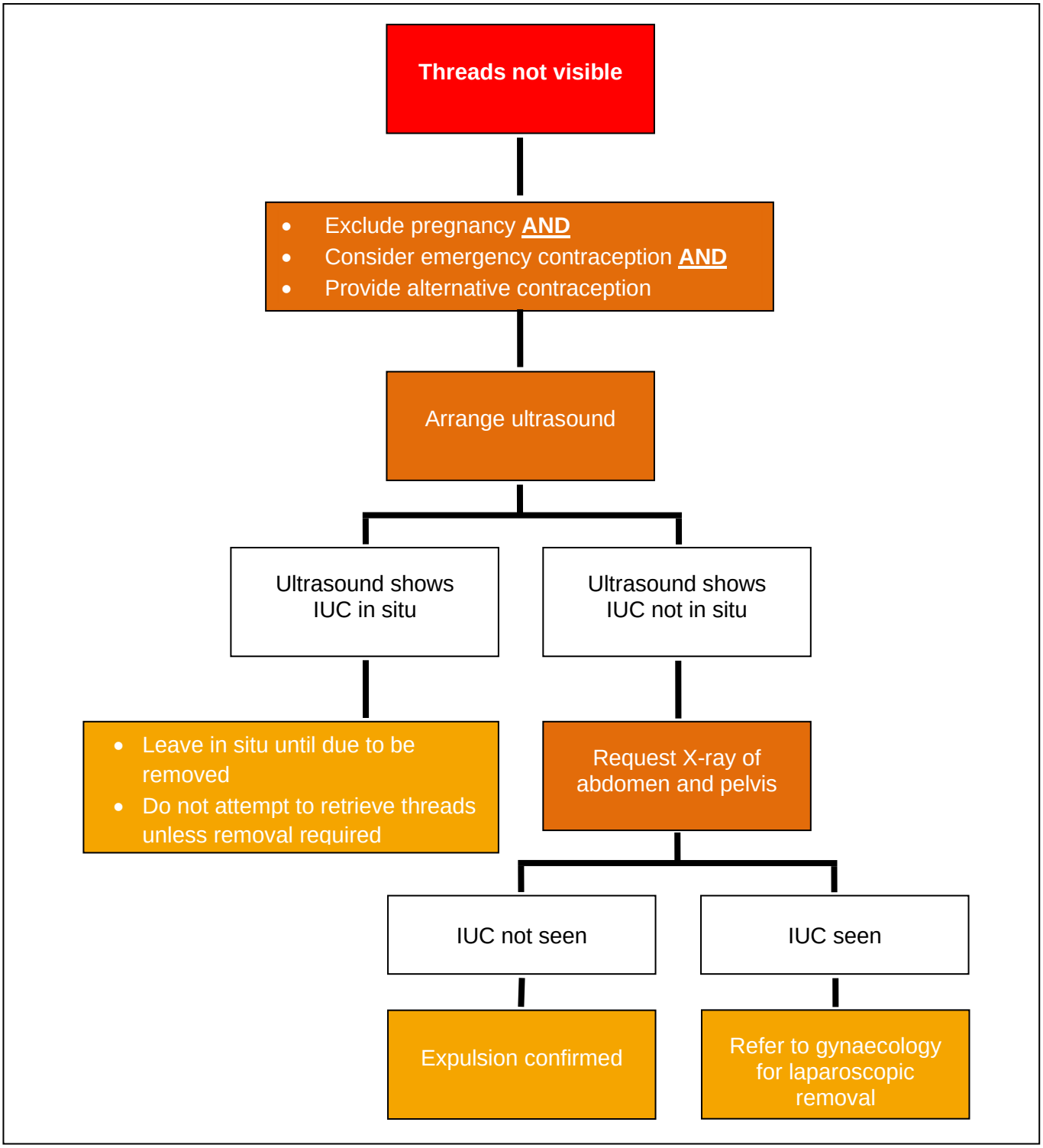
user will be unable to palpate the threads, they should be advised how and when to seek review (e.g. change in bleeding pattern, pain, suspected expulsion).

If the device is not seen within the cavity, further imaging should be undertaken in line with local radiology protocols. This will usually be a plain X-ray of the abdomen and pelvis or a CT of the abdomen and pelvis. If the device is not seen on X-ray/CT this suggests the IUC has been expelled. If the device is seen on X-ray or is seen outside of the uterine cavity on CT this suggests perforation and referral to gynaecology is required.

If the device is seen within the uterine cavity and is to be removed, it may sometimes be possible to retrieve the threads by inserting sterile forceps into the cervical canal. If this is not successful, Birketts/urology forceps, thread retrievers (such as Retrievette® or Emmett), crocodile forceps or flexible IUC graspers can be used to grasp the threads/IUC from the uterine cavity to facilitate removal. The uterus should only be instrumented by a clinician with appropriate training to do so, and it is usually not advisable to instrument the uterus without first confirming the intrauterine location of the device and excluding pregnancy.

If the IUD cannot be removed easily, individuals should be referred for specialist review. Ultrasound guidance may be helpful and hysteroscopic removal is occasionally required. Although it is recommended that an IUC is removed when it is no longer required, there may be some circumstances where it is left in situ if, after careful discussion with the user, it is felt that the risks of surgical removal outweigh the risks of infection from the retained IUC.

Figure 2: Management of individuals when intrauterine contraceptive (IUC) threads are not visible on speculum examination.



14.8.2 Thread problems after immediate PPIUC insertion

This section details some of the common clinical presentations encountered during PPIUC follow-up along with general advice regarding management. However, as specific guidance related to PPIUC aftercare can vary greatly between regions, clinicians are encouraged to familiarise themselves with local pathways.

14.8.3 PPIUC: long threads

Threads are generally left longer during PPIUC insertion to allow for involution of the enlarged postpartum uterus over subsequent weeks. As this occurs, the threads may descend into the vagina, and in some cases outside of the vaginal entrance. Users should be encouraged to seek advice if threads descend prior to the scheduled follow-up visit.

Management

- Arrange clinical review as soon as practical.
- Advise user not to pull on threads and to avoid sex until threads can be trimmed/IUC position confirmed.
- If they feel comfortable doing so, users can be advised to carefully trim externally visible threads to the level of the vaginal introitus whilst awaiting review, as this may prevent the IUD being inadvertently pulled down or removed.
- At review, the clinician should perform a speculum examination and trim the threads to the standard length (2–3 cm beyond external cervical os).
- A cotton-tipped swab can be used to help gently guide the ends of the threads into view within the speculum and allow for easier trimming.
- The ends of threads can be stabilised during trimming by gently applying sponge-holding forceps if available. This may help to reduce the chance of the IUC being inadvertently pulled out during the mobilisation and trimming of threads.
- In some cases, threads may be different lengths or only a single thread may be visible – one or both threads should be trimmed to standard length which may involve trimming a slightly different length from each one.

14.8.4 PPIUC: device visible at cervix (partial expulsion)

The risk of expulsion is higher for IUC insertion in the immediate postpartum setting. It is also higher for PPIUC insertion after vaginal birth compared with caesarean birth. A device expulsion may be 'complete' (where IUC has completely expelled into/out of the vagina and is no longer within the uterus or cervix) or 'partial' (where the IUC is within the cervical canal and partially seen within the vagina, usually identified during clinical or ultrasound assessment). The user may have preceding symptoms such as pain (particularly during intercourse) but these are not always present. IUC threads may not always be visible on speculum examination in this situation.

Management

A clear view of the cervix is required to exclude a partial expulsion – digital palpation of the cervix to feel for a protruding IUC tip can also be helpful if there is uncertainty following speculum examination.

- If the stem of the device is visible at the external cervical opening the IUC should be removed unless the user is asymptomatic and there has been a recent pregnancy risk.
- If there is any difficulty removing the device it should be left in situ and urgent referral made to a specialist service.
- Consideration should be given to the need for EC if UPSI has recently taken place.
- Plan for future contraception should be made with the user – if a further intrauterine method is requested and there is no risk of pregnancy this can be inserted from 4 weeks' postpartum (**Table 15**)
- If further IUC insertion needs to be delayed (or user requires onward referral) a bridging method of contraception should be offered.

15 IUC removal

15.1 Facilitating safe removal

There is no formal FSRH training for IUC removal and clinicians should follow their own local pathway for developing and maintaining competence. The following FSRH resources are available to support clinicians removing IUC:

- IUC removal consultation video IUC removal procedure video
- IUC removal 'Top tips' (requires FSRH log-in)
- E-lfh eSRH Module 15, Section 10 "Removal of IUC".

The GDG suggests that clinicians removing IUC should be:

- Able to discuss ongoing contraception needs and provide this or signpost to another provider. Able to provide preconception counselling or signpost to another provider.
- Able to recognise pregnancy risk and the need for EC.
- Competent at speculum examination, able to recognise an abnormal cervix and know how to refer for further examination.
- Aware of how to manage non-routine findings (e.g. non-visible threads). Up to date with basic life support training.

Clinicians should be aware that some individuals choose to remove their IUC themselves or with assistance from a partner and that this may be in the context of lack of access to removal options. It is therefore important to ensure timely access to IUC removal at an individual's request.

IUC users should be advised that IUC self-removal is not recommended in the UK, and that removal should be undertaken by a clinician. This ensures removal is correctly timed to avoid unintended pregnancy, minimises risk of complications such as failed/incomplete removal, trauma, pain and infection, and allows the device to be checked, ensuring it has been removed intact.

15.2 Timing of removal/replacement

Clinical recommendations

D	**Individuals who do not wish to become pregnant should be advised to avoid UPSI for 7 days prior to IUC removal.**
✓	**Individuals should be advised to avoid UPSI for 7 days prior to IUC removal and replacement in case it is not possible to insert the new device.**

Recommendations regarding the timing of intrauterine contraception removal and replacement can be found in **Table 18**.

Table 18: Recommendations for timing of intrauterine contraception removal/replacement

Situation	Advice
Removal for a planned pregnancy	• Offer preconception advice • IUC can be removed at any time • User should be advised that pregnancy is possible as soon as IUC is removed
Removal – not for planned pregnancy and not switching to an alternative	• Abstain/use condoms in the 7 days prior to removal • If there has been UPSI in the 7 days prior to removal, ideally defer IUC removal until no UPSI for 7 days • Where this is not possible, consider EC **AND** • Recommend a PT 21 days after the last episode of UPSI

• Removal – menopause	• Contraception is no longer required when an individual:
	  • Is aged 55 years or over **OR**
	  • Is a Cu-IUD user, aged >50 years and their LMP was >12 months ago OR
	  • Is an LNG-IUD user, aged >50 years, and an FSH ≥12 months ago was ≥30 IU/L
	• IUC should normally be removed when it is no longer required and not left in situ indefinitely
	• Although no longer required for contraception, an individual may continue to use a 52 mg LNG-IUD for endometrial protection as part of HRT. This should be replaced every 5 years

Removal and replacement	• See Section 10.2: When can IUC be inserted?
Removal – switching to an alternative method of contraception	• See FSRH Guidance Switching or Starting Methods of Contraception[382]

Cu-IUD, copper intrauterine device; EC, emergency contraception; FSH, follicle-stimulating hormone; HRT, hormone replacement therapy; IUC, intrauterine contraception; LMP, last menstrual period; LNG-IUD, levonorgestrel intrauterine device; PT, pregnancy test; UPSI, unprotected sexual intercourse.

15.3 Unexpected findings at IUC removal

Clinical recommendations

✓ **On removal the IUC should be checked to ensure it is intact and is the expected device.**

On removal of an IUC the device should be checked to ensure it is intact and not missing any components, and also that it is the expected device and therefore the correct information about duration of use/follow-up/ongoing contraception has been given.

15.3.1 Broken/incomplete device

An LNG-IUD that appears elongated and armless may be due to the hormone sheath moving over the arms (and holding the arms in an upright position) at the time of removal. Anecdotally, this appears to be more common if the cervical canal is tight. There have also been occasional case reports of the sheath being pulled completely off the device. This may be prevented by dilating the cervical canal prior to removal if there is significant resistance when attempting IUC removal.

If the hormone sheath is absent on removal of the LNG-IUD and retained within the uterus it may be spontaneously expelled, and a change of bleeding pattern from amenorrhoea to resumption of menses may indicate expulsion. However, hysteroscopy could be required to conclusively exclude presence of the sheath within the uterine cavity.

Due to a lack of published literature in this area it is not possible to determine what the risk of infection would be from a retained hormone sheath/copper fragment. It is also unclear what effect, if any, this would have on future pregnancy and future pregnancy outcomes. Where there is the possibility that a small piece of copper or hormone sheath remains in the uterus after device removal, clinicians should discuss with the individual the uncertainties surrounding potential complications, the possibility that the sheath/fragment may be spontaneously passed, and the potential risks associated with hysteroscopic or surgical removal. Expectant management after careful counselling may be appropriate. Immediate replacement of the device could be considered.

Where a larger component (e.g. the arm of a device) is absent, further assessment by ultrasonography/ hysteroscopy is required. Imaging by X-ray/CT (as per local protocol/radiology advice) may be required if perforation is suspected.

If the brand of IUC involved is known, the loss of the copper band/hormone sheath or the broken device should be reported to the MHRA who monitor adverse events with medical devices as well as medicines.

The evidence

No studies have been identified that consider the risk of complications arising if a small part of an IUC remains within the uterus. The effect on fertility of retention of a copper band or hormone sheath from a device that has reached expiry is unknown. There are very limited clinical data regarding the outcomes of pregnancies conceived with an LNG-IUD in situ due to their high contraceptive effectiveness (see **Section 14.3**: Pregnancy) and no studies examining the risk associated with an expired LNG sheath.

Case studies report loss of copper wire from the stem of the Cu-IUD[383] and IUC removed with an arm missing,[384–386] some after removal requiring moderate traction. The passage of the missing piece with subsequent menses has been reported[384,386–388] and hysteroscopic and surgical removal of IUC fragments has been described.[384,386,387] A case of a fragment left in situ without complication has been reported.[384] Not all fragments subsequently passed or retrieved have been visible on scan.[388] A case report describes two patients who had Cu-IUDs removed from the uterine cavity with missing copper. In one case, X-ray identified two small extrauterine foreign bodies in the peritoneal cavity; in the other, X-ray was normal, but CT identified a small foreign body in the uterine serosa. The authors highlight the potential risk of resulting adhesions.[389] Some authors have expressed concern regarding risk of pelvic infection or uterine perforation if a piece of IUC is retained.

Evidence level 3

15.3.2 Removal of an unusual device

Individuals who have had IUC inserted abroad may present requesting removal of a device that the clinician is not familiar with. Prior to removal the clinician should ensure they have sufficient information about the device to prepare for the removal (e.g. obtaining an electronic version of the manufacturer's information booklet) and ensure they have all the necessary equipment required for removal.

Clinicians without the knowledge, equipment or experience to remove the device should discuss this with their local sexual and reproductive healthcare (SRH) specialist and arrange referral for removal. In some cases, removal may require ultrasonography, hysteroscopy or specialist equipment.

In some instances the device type will not be known prior to removal. If a clinician removes an IUC that they are not familiar with it is recommended that they attempt to find out what the device is. This information will help inform clinical decision-making about ongoing contraception (e.g. by knowing whether the device is within licence) and to ensure the entire device has been removed.

15.3.3 Difficult removals

Clinical recommendations

✓ **When there is difficulty in removing an IUC a referral should be made to an experienced provider.**

For information about removal when IUC threads are non-visible see **Section 14.8.1**: Non-visible threads.

Most IUC removals are straightforward. Difficult IUC removals may be due to a number of factors including anatomical variations, IUC malposition (including perforation), clinician experience and/or the level of pain or discomfort experienced. The GDG recommends that when there is difficulty in removing an IUC a referral should be made to an experienced provider.

16 Cost-effectiveness of IUC

LARC methods (including IUC) have been shown to be cost effective in the UK NHS healthcare setting.[390] Costs associated with IUC include not only that of the device itself, but also those costs associated with insertion, removal and management of IUC-associated problems. These are weighed against costs associated with unplanned pregnancy and provision of other contraceptive methods. Non-contraceptive benefits may also be taken into account. Cost effectiveness is dependent on duration of continued use.

Recommendations for future research

- Incidence of and risk factors associated with non-visible threads
- Management of IUC in individuals requiring LLETZ procedure
- Management of PID when an individual has an IUD in situ
- Safety of IUD insertion when an individual has *Mycoplasma genitalium*
- Safety of IUD insertion when an individual has *Trichomonas vaginalis*
- Safety and effectiveness of using an LNG-IUD as EC
- Safety and effectiveness of quickstarting an LNG-IUD following oral EC
- Effectiveness of conscious sedation for IUC insertion
- Effectiveness of lower-dose LNG-IUDs used as endometrial protection as part of HRT
- Effectiveness of extended use of:
    - 52 mg LNG-IUD when being used as endometrial protection as part of HRT
    - 13.5 mg LNG-IUD beyond 3 years
    - 19.5 mg LNG-IUD beyond 5 years
    - Cu-IUDs beyond their licensed duration.

Considerations for implementation of this guideline

The FSRH CEU produces a range of resources (summaries, webinars, lectures) to facilitate dissemination of guideline content and raise awareness of any changes to recommended practice. Changes in FSRH guidance are highlighted in FSRH emails to its membership and via social media platforms and are incorporated into FSRH training and educational materials. The FSRH CEU supports and facilitates national audit relevant to the key auditable standards for each FSRH guideline.

Specific considerations for implementation of the IUC guideline

Duration of use

The recommendation that any 52 mg LNG-IUD can be used for contraception for 8 years is new. This will necessitate changes to patient information leaflets and local protocols, as well as updating FSRH educational materials and resources. Services may wish to consider how this information is disseminated to individuals with a 52 mg LNG-IUD in situ who may now be able to use their device for longer than they were originally advised. There is a risk that individuals will attend an unnecessary appointment for an LNG-IUD change based on the information they were given at the time of insertion, when in fact they are not required to have their LNG-IUD replaced until a later date. Services providing IUC may already have implemented a system for this during the COVID pandemic, when durations of use for LARC were temporarily extended. These systems (which included, for example, information on service websites, recorded information on telephone appointment lines, clinical triage of IUC change requests, or text message notifications) may be able to be replicated or adjusted.

Anaesthetic and analgesia options during IUC insertion

The guideline recommends that options for pain relief during IUC insertions are discussed with potential IUC users. There may be training required for some IUC providers in how to administer local anaesthetic and training materials are available (see FSRH Member's Training hub). Local referral pathways will need to be developed for circumstances where an individual's chosen method of pain relief is not available.

Postpartum intrauterine contraception

Although not routinely available in all UK maternity services, immediate postpartum intrauterine contraception (PPIUC) insertion has been shown to be safe, effective, convenient and cost effective. The PPIUC insertion technique is different to that of standard IUC insertion and training in this specific technique is required. Training resources are available (see FSRH Member's Training hub) and implementation of PPIUC services has been shown to be feasible and acceptable.[381,391]

The guideline recommends a routine thread check with a clinician 4–6 weeks after PPIUC insertion. A survey of UK SRH clinicians found that most respondents were happy to promote PPIUC and provide thread checks, but identified that potential challenges include staff time, clinical skills in managing complications, and availability of ultrasound for individuals with non-visible threads.[392] Guidance for clinicians providing PPIUC aftercare can be found in Appendix 3. Local pathways will need to be developed, with agreement as to who performs PPIUC checks. This may include multiple services (primary care, maternity, gynaecology, SRH and radiology services) and will need to be developed in line with local commissioning agreements, where applicable. An example follow-up pathway has been included in the guideline as a template for services to adapt and develop (see Appendix 2).

Useful links

Intrauterine contraception leaflets for patients from the Family Planning Association (FPA) are available online here:

- Cu-IUD IUD (intrauterine device) - your guide (sexwise.org.uk)
- LNG-IUD IUS (intrauterine system) - your guide (sexwise.org.uk).

References

Online references accessed on 14/03/2023

1 United Nations, Department of Economic and Social Affairs, Population Division (2019). Contraceptive Use by Methods 2019: Data Booklet (ST/ESA/SER.A/435).

2 Faculty of Sexual & Reproductive Healthcare. UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) 2016 (April 2016, amended September 2019). 2016. https://www.fsrh.org/ukmec/

3 Faculty of Sexual & Reproductive Healthcare. FSRH Service Standards for Resuscitation in Sexual and Reproductive Health Services (December 2022). 2022. https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-resuscitation/

4 Faculty of Sexual & Reproductive Healthcare. FSRH Clinical Guideline: Emergency Contraception (March 2017, amended December 2020). 2017. https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/

5 Faculty of Sexual & Reproductive Healthcare. FSRH New Product Review: Intrauterine Ball (IUB™) SCu300B MIDI (February 2019). 2019. https://www.fsrh.org/standards-and-guidance/documents/new-product-review-intrauterine-ball-iub-scu300b-midi-february/

6 Faculty of Sexual & Reproductive Healthcare. FSRH Clinical Guideline: Contraception for Women Aged Over 40 Years (August 2017, amended September 2019). 2017. https://www.fsrh.org/standards-and-guidance/documents/fsrh-guidance-contraception-for-women-aged-over-40-years-2017/

7 Ti AJ, Roe AH, Whitehouse KC, *et al.* Effectiveness and safety of extending intrauterine device duration: a systematic review. *Am J Obstet Gynecol* 2020;**223**:24-35.e3.

8 Rowe P, Farley T, Peregoudov A, *et al.* Safety and efficacy in parous women of a 52-mg levonorgestrel-medicated intrauterine device: a 7-year randomized comparative study with the TCu380A. *Contraception* 2016;**93**:498–506.

9 Rönnerdag M, Odlind V. Health effects of long-term use of the intrauterine levonorgestrel-releasing system. A follow-up study over 12 years of continuous use. *Acta Obstet Gynecol Scand* 1999;**78**:716–21.

10 McNicholas C, Swor E, Wan L, *et al.* Prolonged use of the etonogestrel implant and levonorgestrel intrauterine device: 2 years beyond Food and Drug Administration-approved duration. *Am J Obstet Gynecol* 2017;**216**:586.e1-586.e6.

11 Hidalgo CA MM, Hidalgo-Regina, C, Bahamondes, V, Monteiro, I, Petta, Bahamondes L. Serum levonorgestrel levels and endometrial thickness during extended use of the levonorgestrel-releasing intrauteirne system. *Contraception* 2009;**80**:84–9.

12 Bahamondes L, Fernandes A, Bahamondes MV, *et al.* Pregnancy outcomes associated with extended use of the 52-mg 20 µg/day levonorgestrel-releasing intrauterine system beyond 60 months: a chart review of 776 women in Brazil. *Contraception* 2018;**97**:205–9.

13 Jensen JT, Lukkari-Lax E, Schulze A, *et al.* Contraceptive efficacy and safety of the 52-mg levonorgestrel intrauterine system for up to 8 years: findings from the Mirena Extension Trial. *Am J Obstet Gynecol* 2022;S0002937822007293.

14 Wu JP, Pickle S. Extended use of the intrauterine device: a literature review and recommendations for clinical practice. *Contraception* 2014;**89**:495–503.

15 Royal College of Obstetricians and Gynaecologists (RCOG), British Society for Gynaecological Endoscopy. Green-top Guideline No. 67: Management of Endometrial Hyperplasia. 2016. https://www.rcog.org.uk/globalassets/documents/guidelines/green-top-guidelines/gtg_67_endometrial_hyperplasia.pdf

16 Beelen P, van den Brink MJ, Herman MC, *et al.* Levonorgestrel-releasing intrauterine system versus endometrial ablation for heavy menstrual bleeding. *Am J Obstet Gynecol* 2021;**224**:187.e1-187.e10.

17 Chen BA, Eisenberg DL, Schreiber CA, *et al.* Bleeding changes after levonorgestrel 52-mg intrauterine system insertion for contraception in women with self-reported heavy menstrual bleeding. *Am J Obstet Gynecol* 2020;**222**:S888.e1-S888.e6.

18 Bofill Rodriguez M, Lethaby A, Jordan V. Progestogen-releasing intrauterine systems for heavy menstrual bleeding. *Cochrane Database Syst Rev* 2020;**6**:CD002126.

19 Mawet M, Nollevaux F, Nizet D, *et al.* Impact of a new levonorgestrel intrauterine system, Levosert(®), on heavy menstrual bleeding: results of a one-year randomised controlled trial. *Eur J Contracept Reprod Health Care* 2014;**19**:169–79.

20 Health Quality Ontario. Levonorgestrel-releasing intrauterine system (52 mg) for idiopathic heavy menstrual bleeding: a health technology assessment. *Ont Health Technol Assess Ser* 2016;**16**:1–119.

21 Yoo HJ, Lee MA, Ko YB, *et al.* The efficacy of the levonorgestrel-releasing intrauterine system in perimenopausal women with menorrhagia or dysmenorrhea. *Arch Gynecol Obstet* 2012;**285**:161–6.

22 Magnay JL, O'Brien S, Gerlinger C, *et al.* Pictorial methods to assess heavy menstrual bleeding in research and clinical practice: a systematic literature review. *BMC Womens Health* 2020;**20**:24.

23 Curry N, Bowles L, Clark TJ, *et al.* Gynaecological management of women with inherited bleeding disorders. *Haemophilia* 2022;**28:**917–37.

24 Kadir RA, Chi C. Levonorgestrel intrauterine system: bleeding disorders and anticoagulant therapy. *Contraception* 2007;**75**:S123–9.

25 National Institute for Health and Care Excellence (NICE). NICE Clinical Guideline: Heavy Menstrual Bleeding: assessment and management [NG88]. Published 14 March 2018. Last updated 24 May 2021. 2021. https://www.nice.org.uk/guidance/ng88

26 Bergeron C, Laberge PY, Boutin A, *et al.* Endometrial ablation or resection versus levonorgestrel intra-uterine system for the treatment of women with heavy menstrual bleeding and a normal uterine cavity: a systematic review with meta-analysis. *Hum Reprod Update* 2020;**26**:302–11.

27 Sangkomkamhang US, Lumbiganon P, Pattanittum P. Progestogens or progestogen-releasing intrauterine systems for uterine fibroids (other than preoperative medical therapy). *Cochrane Database Syst Rev* 2020;**11**:CD008994.

28 Jiang W, Shen Q, Chen M, *et al.* Levonorgestrel-releasing intrauterine system use in premenopausal women with symptomatic uterine leiomyoma: a systematic review. *Steroids* 2014;**86**:69–78.

29 Kriplani A, Awasthi D, Kulshrestha V, *et al.* Efficacy of the levonorgestrel-releasing intrauterine system in uterine leiomyoma. *Int J Gynaecol Obstet* 2012;**116**:35–8.

30 Becker CM, Bokor A, Heikinheimo O, *et al.* ESHRE guideline: endometriosis. *Hum Reprod Open* 2022;**2022**:hoac009.

31 Ortiz ME, Croxatto HB. Copper-T intrauterine device and levonorgestrel intrauterine system: biological bases of their mechanism of action. *Contraception* 2007;**75**:S16–30.

32 Stanford JB, Mikolajczyk RT. Mechanisms of action of intrauterine devices: update and estimation of postfertilization effects. *Am J Obstet Gynecol* 2002;**187**:1699–708.

33 Jonsson B, Landgren BM, Eneroth P. Effects of various IUDs on the composition of cervical mucus. *Contraception* 1991;**43**:447–58.

34 Hagenfeldt K. Intrauterine Contraception with the copper-T-device: effect on trace elements in the endometrium, cervical mucus and plasma. *Contraception* 1972;**6**:37–54.

35 Ortiz ME, Croxatto MB. The mode of action of IUDs. *Contraception* 1987;**36**:37–53.

36 Barbosa I, Bakos O, Olsson S, *et al.* Ovarian function during use of a levonorgestrel-releasing IUD. *Contraception* 1990;**42**:51–66.

37 Barbosa I, Olsson SE, Odlind V, *et al.* Ovarian function after seven years' use of a levonorgestrel IUD. *Adv Contracept* 1995;**11**:85–95.

38 Lewis RA, Taylor D, Natavio MF, *et al.* Effects of the levonorgestrel-releasing intrauterine system on cervical mucus quality and sperm penetrability. *Contraception* 2010;**82**:491–6.

39 Pakarinen PI, Lähteenmäki P, Lehtonen E, *et al.* The ultrastructure of human endometrium is altered by administration of intrauterine levonorgestrel. *Hum Reprod* 1998;**13**:1846–53.
40 Silverberg SG, Haukkamaa M, Arko H. Endometrial morphology during longterm use of the levonorgestrel-releasing intrauterine devices. *Int J Gynaecol Pathol* 1986;**5**:235–41.
41 Jones RJ, Critchley HOD. Morphological and functional changes in human endometrium following intrauterine levonorgestrel delivery. *Hum Reprod* 2000;**15**:162–72.
42 Nilsson CG, Haukkamaa M, Vierola H, *et al.* Tissue concentrations of levonorgestrel in women using a levonorgestrel-releasing IUD. *Clin Endocrinol* 1982;**17**:529–36.
43 Critchley HOD, Wang H, Jones RL, *et al.* Morphological and functional features of endometrial decidualization following long-term intrauterine levonorgestrel delivery. *Hum Reprod* 1998;**13**:1218–24.
44 Pekonen F, Nyman T, Lahteenmaki P. Intrauterine progestin induces continuous insulin like growth factor-binding protein production in humans. *J Clin Endocrinol Metab* 1992;**75**:660–4.
45 Yin M, Zhu P, Luo H, *et al.* The presence of mast cells in the human endometrium pre- and post-insertion of intrauterine devices. *Contraception* 1993;**48**:245–54.
46 Natavio MF, Taylor D, Lewis RA, *et al.* Temporal changes in cervical mucus after insertion of the levonorgestrel-releasing intrauterine system. *Contraception* 2013;**87**:426–31.
47 Kurunäki H, Toivonen J, Lähteenmäki PLA, *et al.* Pituitary and ovarian function and clinical performance during the use of a levonorgestrel-releasing intracervical contraceptive device. *Contraception* 1984;**29**:31–43.
48 Apter D, Gemzell-Danielsson K, Hauck B, *et al.* Pharmacokinetics of two low-dose levonorgestrel-releasing intrauterine systems and effects on ovulation rate and cervical function: pooled analyses of phase II and III studies. *Fertil Steril* 2014;**101**:1656–62.
49 Nilsson CG, Lähteenmäki PLA, Luukkainen T. Ovarian function in amenorrheic and menstruating users of a levonorgestrel-releasing intrauterine device. *Fertil Steril* 1984;**41**:52–5.
50 Ratsula K, Toivonen J, Lähteenmäki P, *et al.* Plasma levonorgestrel levels and ovarian function during the use of a levonorgestrel-releasing intracervical conrtaceptive device. *Contraception* 1989;**39**:195–204.
51 Trussell J. Contraceptive efficacy. In: Hatcher R, Trussell J, Nelson A, *et al.*, eds. *Contraceptive Technology*. New York: Ardent Media, 2011.
52 Heinemann K, Reed S, Moehner S, *et al.* Comparative contraceptive effectiveness of levonorgestrel-releasing and copper intrauterine devices: the European Active Surveillance Study for Intrauterine Devices. *Contraception* 2015;**91**:280–3.
53 Kulier R, O'Brien PA, Helmerhorst FM, *et al.* Copper containing, framed intra-uterine devices for contraception. *Cochrane Database Syst Rev* 2007;**4**:CD005347.
54 Wen J, Li Y, Li Y-P, *et al.* Comparative safety and effectiveness of TCu380A versus MLCu375: a systematic review of randomized trials. *J Evid Based Med* 2009;**2**:226–41.
55 O'Brien PA, Marfleet C. Frameless versus classical intrauterine device for contraception. *Cochrane Database Syst Rev* 2005;**1**:CD003282.
56 Akintomide H, Brima N, Mansour DJ, *et al.* Copper IUD continuation, unwanted effects and cost consequences at 1 year in users aged under 30 - a secondary analysis of the EURAS-IUD study. *Eur J Contracept Reprod Health Care* 2021;**26**:175–83.
57 Kriplani A, Sehgal R, Konar H, *et al.* A 1-year comparison of TCu380Ag versus TCu380A intrauterine contraceptive devices in India. *Int J Gynaecol Obstet* 2019;**145**:268–77.
58 French R, Sorhaindo AM, Van-Vliet-Huib AAM, *et al.* Progestogen-releasing intrauterine systems versus other forms of reversible contraceptives for contraception. *Cochrane Database Syst Rev* 2004;**3**:CD001776.
59 Sivin I, Stern J, Coutinho E, *et al.* Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20 mcg/day (LNg 20) and the copper T380 Ag IUDS. *Contraception* 1991;**44**:473–80.
60 Andersson K, Odlind V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomized comparative trial. *Contraception* 1994;**49**:56–72.
61 Teal SB, Turok DK, Chen BA, *et al.* Five-year contraceptive efficacy and safety of a levonorgestrel 52-mg intrauterine system. *Obstet Gynecol* 2019;**133**:63–70.

62 Nelson A, Apter D, Hauck B, *et al.* Two low-dose levonorgestrel intrauterine contraceptive systems: a randomized controlled trial. *Obstet Gynecol* 2013;**122**:1205–13.

63 Gemzell-Danielsson K, Apter D, Dermout S, *et al.* Evaluation of a new, low-dose levonorgestrel intrauterine contraceptive system over 5 years of use. *Eur J Obstet Gynecol Reprod Biol* 2017;**210**:22–8.

64 Fan G, Kang S, Ren M, *et al.* A single-arm phase III study exploring the efficacy and safety of LNG-IUS 8, a low-dose levonorgestrel intrauterine contraceptive system (total content 13.5 mg), in an Asia-Pacific population. *Contraception* 2017;**95**:371–7.

65 Faculty of Sexual & Reproductive Healthcare. FSRH Clinical Guideline: Overweight, Obesity and Contraception (April 2019). 2019. https://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guideline-overweight-obesity-and-contraception/

66 electronic medicines compendium (emc). Gedeon Richter (UK) Ltd. Summary of Product Characteristics: Levosert 20 micrograms/24 hours IDS. Last updated on emc 01 Aug 2024. https://www.medicines.org.uk/emc/medicine/30120

67 electronic medicines compendium (emc). Bayer plc. Summary of Product Characteristics: Mirena. Last updated on emc 21 Aug 2024. https://www.medicines.org.uk/emc/medicine/1829

68 Hidalgo M, Bahamondes L, Perrotti M, *et al.* Bleeding patterns and clinical performance of the levonorgestrel-releasing intrauterine system (Mirena) up to two years. *Contraception* 2002;**65**:129–32.

69 Cox M, Tripp J, Blacksell S. Clinical performance of the levonorgestrel intrauterine system in routine use by the UK Family Planning and Reproductive Health Research Network: 5-year report. *J Fam Plann Reprod Health Care* 2002;**28**:73–7.

70 Backman T, Rauramo I, Huhtala S, *et al.* Pregnancy during the use of levonorgestrel intrauterine system. *Am J Obstet Gynecol* 2004;**190**:50–4.

71 Aoun J, Dines VA, Stovall DW, *et al.* Effects of age, parity, and device type on complications and discontinuation of intrauterine devices. *Obstet Gynecol* 2014;**123**:585–92.

72 Phillips SJ, Hofler LG, Modest AM, *et al.* Continuation of copper and levonorgestrel intrauterine devices: a retrospective cohort study. *Am J Obstet Gynecol* 2017;**217**:57.e1-57.e6.

73 Weisberg E, Bateson D, McGeechan K, *et al.* A three-year comparative study of continuation rates, bleeding patterns and satisfaction in Australian women using a subdermal contraceptive implant or progestogen releasing-intrauterine system. *Eur J Contracept Reprod Health Care* 2014;**19**:5–14.

74 Dubuisson JB, Mugnier E. Acceptability of the levonorgestrel-releasing intrauterine system after discontinuation of previous contraception: results of a French clinical study in women aged 35 to 45 years. *Contraception* 2002;**66**:121–8.

75 Berenson AB, Tan A, Hirth JM, *et al.* Complications and continuation of intrauterine device use among commercially insured teenagers. *Obstet Gynecol* 2013;**121**:951–8.

76 Berenson AB, Tan A, Hirth JM. Complications and continuation rates associated with 2 types of long-acting contraception. *Am J Obstet Gynecol* 2015;**212**:761.e1-8.

77 Reeves MF, Zhao Q, Secura GM, *et al.* Risk of unintended pregnancy based on intended compared to actual contraceptive use. *Am J Obstet Gynecol* 2016;**215**:71.e1-6.

78 Gemzell-Danielsson K, Apter D, Hauck B, *et al.* The effect of age, parity and body mass index on the efficacy, safety, placement and user satisfaction associated with two low-dose levonorgestrel intrauterine contraceptive systems: subgroup analyses of data from a phase III trial. *PloS One* 2015;**10**:e0135309.

79 Gemzell-Danielsson K, Schellschmidt I, Apter D. A randomized, phase II study describing the efficacy, bleeding profile, and safety of two low-dose levonorgestrel-releasing intrauterine contraceptive systems and Mirena. *Fertil Steril* 2012;**97**:616-622.e1-3.

80 Gemzell-Danielsson K, Buhling KJ, Dermout SM, *et al.* A Phase III, single-arm study of LNG-IUS 8, a low-dose levonorgestrel intrauterine contraceptive system (total content 13.5mg) in postmenarcheal adolescents. *Contraception* 2016;**93**:507–12.

81 Borgatta L, Buhling KJ, Rybowski S, *et al.* A multicentre, open-label, randomised phase III study comparing a new levonorgestrel intrauterine contraceptive system (LNG-IUS 8) with combined oral contraception in young women of reproductive age. *Eur J Contracept Reprod Health Care* 2016;**21**:372–9.

82 Apter D, Briggs P, Tuppurainen M, *et al.* A 12-month multicenter, randomized study comparing the levonorgestrel intrauterine system with the etonogestrel subdermal implant. *Fertil Steril* 2016;**106**:151-157.e5.
83 Mansour D, Inki P, Gemzell-Danielsson K. Efficacy of contraceptive methods: a review of the literature. *Eur J Contracept Reprod Health Care* 2010;**15**:4–16.
84 Zgliczynska M, Kocaj K, Szymusik I, *et al.* Levonorgestrel-releasing intrauterine system as a contraceptive method in nulliparous women: a systematic review. *J Clin Med* 2020;**9**:E2101.
85 Jatlaoui TC, Riley HEM, Curtis KM. The safety of intrauterine devices among young women: a systematic review. *Contraception* 2017;**95**:17–39.
86 Krashin J, Tang JH, Mody S, *et al.* Hormonal and intrauterine methods for contraception for women aged 25 years and younger. *Cochrane Database Syst Rev* 2015;**8**:CD009805.
87 Sivin I, Stern J. Health during prolonged use of levonorgestrel 20 mg/d and the copper TCu 380Ag intrauterine contraceptive devices: a multicenter study. *Fertil Steril* 1994;**61**:70–7.
88 Schwarz EB, Lewis CA, Dove MS, *et al.* Comparative effectiveness and safety of intrauterine contraception and tubal ligation. *J Gen Intern Med* 2022;**37**:4168–75.
89 Faculty of Sexual & Reproductive Healthcare. FSRH Clinical Guideline: Contraceptive Choices for Young People (March 2010, amended May 2019). 2010. https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-young-people-mar-2010/
90 National Institute for Health and Care Excellence (NICE). NICE Clinical Guideline: Contraceptive Services for Under 25s [PH51] Published 26 March 2014. https://www.nice.org.uk/guidance/ph51
91 Pritt NM, Norris AH, Berlan ED. Barriers and facilitators to adolescents' use of long-acting reversible contraceptives. *J Pediatr Adolesc Gynecol* 2017;**30**:18–22.
92 Bayer LL, Jensen JT, Li H, *et al.* Adolescent experience with intrauterine device insertion and use: a retrospective cohort study. *Contraception* 2012;**86**:443–51.
93 Bahamondes MV, Bahamondes L. Intrauterine device use is safe among nulligravidas and adolescent girls. *Acta Obstet Gynecol Scand* 2021;**100**:641–8.
94 Diedrich JT, Klein DA, Peipert JF. Long-acting reversible contraception in adolescents: a systematic review and meta-analysis. *Am J Obstet Gynecol* 2017;**216**:364.e1-364.e12.
95 Akintomide H, James A, Moffat M, *et al.* Systematic review of copper intrauterine contraception continuation in young nulliparous women based on intrauterine device type. *BMJ Open* 2022;**12**:e060606.
96 Hubacher D, Schreiber CA, Turok DK, *et al.* Continuation rates of two different-sized copper intrauterine devices among nulliparous women: interim 12-month results of a single-blind, randomised, multicentre trial. *eClinicalMedicine* 2022;**51**:101554.
97 Kebodeaux CA, Schwartz BI. Experience with intrauterine device insertion in never sexually active adolescents: a retrospective cohort study. *Am J Obstet Gynecol* 2018;**219**:600.e1-600.e7.
98 Abern L, Krempasky C, Diego D, *et al.* The intrauterine device experience among transgender and gender-diverse individuals assigned female at birth. *J Midwifery Womens Health* 2021;**66**:772–7.
99 Bentsianov S, Gordon L, Goldman A, *et al.* Use of copper intrauterine device in transgender male adolescents. *Contraception* 2018;**98**:74–5.
100 Joint Formulary Committee. Bristish National Formulary (online). Testosterone. London: BMJ Group and Pharmaceutical Press. https://bnf.nice.org.uk/drugs/testosterone/
101 Bonnington A, Dianat S, Kerns J, *et al.* Society of Family Planning clinical recommendations: contraceptive counseling for transgender and gender diverse people who were female sex assigned at birth. *Contraception* 2020;**102**:70–82.
102 Faculty of Sexual & Reproductive Healthcare. FSRH CEU Statement: Contraceptive Choices and Sexual Health for Transgender and Non-Binary People (October 2017). 2017. https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-contraceptive-choices-and-sexual-health-for/
103 Faculty of Sexual & Reproductive Healthcare. FSRH Clinical Guideline: Contraception After Pregnancy (January 2017). http://www.fsrh.org/documents/contraception-after-pregnancy-guideline-january-2017/
104 Heinemann K, Reed S, Moehner S, *et al.* Risk of uterine perforation with levonorgestrel-releasing and copper intrauterine devices in the European Active Surveillance Study on Intrauterine Devices.

Contraception 2015;**91**:274–9.
105 Lopez LM, Bernholc A, Hubacher D, *et al.* Immediate postpartum insertion of intrauterine device for contraception. *Cochrane Database Syst Rev* 2015;**6**:CD003036.
106 Sonalkar S, Kapp N. Intrauterine device insertion in the postpartum period: a systematic review. *Eur J Contracept Reprod Health Care* 2015;**20**:4–18.
107 Blumenthal PD, Lerma K, Bhamrah R, *et al.* Comparative safety and efficacy of a dedicated postpartum IUD inserter versus forceps for immediate postpartum IUD insertion: a randomized trial. *Contraception* 2018;**98**:215–9.
108 Makins A, Taghinejadi N, Sethi M, *et al.* FIGO postpartum intrauterine device initiative: complication rates across six countries. *Int J Gynaecol Obstet* 2018;**143 Suppl 1**:20–7.
109 Chen BA, Reeves MF, Hayes JL, *et al.* Postplacental or delayed insertion of the levonorgestrel intrauterine device after vaginal delivery: a randomized controlled trial. *Obstet Gynecol* 2010;**116**:1079–87.
110 Dahlke JD, Terpstra ER, Ramseyer AM, *et al.* Postpartum insertion of levonorgestrel--intrauterine system at three time periods: a prospective randomized pilot study. *Contraception* 2011;**84**:244–8.
111 Sucak A, Ozcan S, Çelen Ş, *et al.* Immediate postplacental insertion of a copper intrauterine device: a pilot study to evaluate expulsion rate by mode of delivery. *BMC Pregnancy Childbirth* 2015;**15**:202.
112 Turok DK, Leeman L, Sanders JN, *et al.* Immediate postpartum levonorgestrel intrauterine device insertion and breast-feeding outcomes: a noninferiority randomized controlled trial. *Am J Obstet Gynecol* 2017;**217**:665.e1-665.e8.
113 Barnett C, Moehner S, Do Minh T, *et al.* Perforation risk and intra-uterine devices: results of the EURAS-IUD 5-year extension study. *Eur J Contracept Reprod Health Care* 2017;**22**:424–8.
114 O'Brien PA, Pillai S. Uterine perforation by intrauterine devices: a 16-year review. *J Fam Plann Reprod Health Care* 2017;**43**:289–95.
115 Caliskan E, Oztürk N, Dilbaz B, *et al.* Analysis of risk factors associated with uterine perforation by intrauterine devices. *Eur J Contracept Reprod Health Care* 2003;**155**:150.
116 Averbach SH, Ermias Y, Jeng G, *et al.* Expulsion of intrauterine devices after postpartum placement by timing of placement, delivery type, and intrauterine device type: a systematic review and meta-analysis. *Am J Obstet Gynecol* 2020;**223**:177–88.
117 Jatlaoui TC, Whiteman MK, Jeng G, *et al.* Intrauterine device expulsion after postpartum placement: a systematic review and meta-analysis. *Obstet Gynecol* 2018;**132**:895–905.
118 Faculty of Sexual & Reproductive Healthcare. FSRH Clinical Guidance: Contraception after Breast Cancer. In preparation. https://www.fsrh.org/documents/fsrh-clinical-guideline-contraception-after-breast-cancer/
119 Zueff LFN, Melo AS de, Vieira CS, *et al.* Cardiovascular risk markers among obese women using the levonorgestrel-releasing intrauterine system: a randomised controlled trial. *Obes Res Clin Pract* 2017;**11**:687–93.
120 Grimes DA, Shields WC. Family planning for obese women: challenges and opportunities. *Contraception* 2005;**72**:1–4.
121 Saito-Tom LY, Soon RA, Harris SC, *et al.* Levonorgestrel intrauterine device use in overweight and obese women. *Hawaii J Med Public Health* 2015;**74**:369–74.
122 Rackow BW, Arici A. Reproductive performance of women with müllerian anomalies. *Curr Opin Obstet Gynecol* 2007;**19**:229–37.
123 Tepper NK, Zapata LB, Jamieson DJ, *et al.* Use of intrauterine devices in women with uterine anatomic abnormalities. *Int J Gynaecol Obstet* 2010;**109**:52–4.
124 Eskew AM, Crane EK. Levonorgestrel intrauterine device placement in a premenopausal breast cancer patient with a bicornuate uterus. *J Minim Invasive Gynecol* 2016;**23**:133–5.
125 Gerkowicz SA, Fiorentino DG, Kovacs AP, *et al.* Uterine structural abnormality and intrauterine device malposition: analysis of ultrasonographic and demographic variables of 517 patients. *Am J Obstet Gynecol* 2019;**220**:183.e1-183.e8.
126 Espey E, Ogburn T, Hall R, *et al.* Use of intrauterine device in the setting of uterus didelphys. *Obstet Gynecol* 2006;**108**:774–6.
127 Chaabouni M, Kamoun A, Chaabouni Z. [Intrauterine contraception in a "double uterus".] *Tunis*

Med 1969;**47**:367–72.
128 Florence AM, Fatehi M. Leiomyoma. In: *StatPearls*. Treasure Island, FL: StatPearls Publishing, 2022. http://www.ncbi.nlm.nih.gov/books/NBK538273/
129 NHS.uk. Health A to Z: Fibroids. Page last reviewed 17 September 2018. https://www.nhs.uk/conditions/fibroids/
130 National Institute for Health and Care Excellence (NICE). NICE Clinical Knowledge Summaries. Health Topics A to Z: Menorrhagia. Last revised December 2018. 2018.https://cks.nice.org.uk/topics/menorrhagia/
131 Sayed GH, Zakherah MS, El-Nashar SA, *et al.* A randomized clinical trial of a levonorgestrel-releasing intrauterine system and a low-dose combined oral contraceptive for fibroid-related menorrhagia. *Int J Gynaecol Obstet* 2011;**112**:126–30.
132 Mercorio F, Simone D, R. DSS, *et al.* The effect of a levonorgestrel-releasing intrauterine device in the treatment of myoma-related menorrhagia. *Contraception* 2003;**67**:277–80.
133 Socolov D, Blidaru I, Tamba B, *et al.* Levonorgestrel releasing-intrauterine system for the treatment of menorrhagia and/or frequent irregular uterine bleeding associated with uterine leiomyoma. *Eur J Contracept Reprod Health Care* 2011;**16**:480–7.
134 Kohn JR, Shamshirsaz AA, Popek E, *et al.* Pregnancy after endometrial ablation: a systematic review. *BJOG* 2018;**125**:43–53.
135 Oderkerk TJ, van de Kar MMA, van der Zanden CHM, *et al.* The combined use of endometrial ablation or resection and levonorgestrel-releasing intrauterine system in women with heavy menstrual bleeding: a systematic review. *Acta Obstet Gynecol Scand* 2021;**100**:1779–87.
136 Sufrin CB, Postlethwaite D, Armstrong MA, *et al.* Neisseria gonorrhea and Chlamydia trachomatis screening at intrauterine device insertion and pelvic inflammatory disease. *Obstet Gynecol* 2012;**120**:1314–21.
137 Brook G, Church H, Evans C, *et al.* 2019 UK National Guideline for consultations requiring sexual history taking: Clinical Effectiveness Group British Association for Sexual Health and HIV. *Int J STD AIDS* 2020;**31**:920–38.
138 BASHH Clinical Effectiveness Group. 2015 BASHH CEG Guidance on Tests for Sexually Transmitted Infections. 2015. https://www.bashhguidelines.org/media/1084/sti-testing-tables-2015-dec-update-4.pdf
139 Faculty of Sexual & Reproductive Healthcare. FSRH CEU Statement: Antibiotic cover for urgent insertion of intrauterine contraception in women at high risk of STI (May 2019). 2019. https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-on-antibiotic-cover-for-urgent-insertion-of/
140 British Association for Sexual Health and HIV. BASHH Guidelines. https://www.bashhguidelines.org/current-guidelines/all-guidelines/
141 Sánchez-Guerrero J, Uribe AG, Jiménez-Santana L, *et al.* A trial of contraceptive methods in women with systemic lupus erythematosus. *N Engl J Med* 2005;**353**:2539–49.
142 Ponticelli C, Moroni G. Fetal toxicity of immunosuppressive drugs in pregnancy. *J Clin Med* 2018;**7**:E552.
143 Gordon C, Harken T. Controversies in family planning: intrauterine device placement in solid organ transplant patients. *Contraception* 2019;**100**:250–2.
144 Sarkar M, Bramham K, Moritz MJ, *et al.* Reproductive health in women following abdominal organ transplant. *Am J Transplant* 2018;**18**:1068–76.
145 Zerner J, Doil KL, Drewry J, *et al.* Intrauterine contraceptive device failures in renal transplant patients. *J Reprod Med* 1981;**26**:99–102.
146 Kakaire O, Byamugisha JK, Tumwesigye NM, *et al.* Intrauterine contraception among women living with human immunodeficiency virus: a randomized controlled trial. *Obstet Gynecol* 2015;**126**:928–34.
147 Stringer EM, Kaseba C, Levy J, *et al.* A randomized trial of the intrauterine contraceptive device vs hormonal contraception in women who are infected with the human immunodeficiency virus. *Am J Obstet Gynecol* 2007;**197**:144–8.
148 Todd CS, Jones HE, Langwenya N, *et al.* Safety and continued use of the levonorgestrel intrauterine system as compared with the copper intrauterine device among women living with HIV

in South Africa: a randomized controlled trial. *PLoS Med* 2020;**17**:e1003110.
149 Thonneau P, Almont T, de La Rochebrochard E, *et al.* Risk factors for IUD failure: results of a large multicentre case-control study. *Hum Reprod* 2006;**21**:2612–6.
150 Ramhendar T, Byrne P. Use of the levonorgestrel-releasing intrauterine system in renal transplant recipients: a retrospective case review. *Contraception* 2012;**86**:288–9.
151 Juliato CRT, Stahlschmidt P, Fernandes A, *et al.* A case series on the use of levonorgestrel 52 mg intrauterine system after organ transplant. *Contraception* 2018;**98**:252–4.
152 Huguelet PS, Sheehan C, Spitzer RF, *et al.* Use of the levonorgestrel 52-mg intrauterine system in adolescent and young adult solid organ transplant recipients: a case series. *Contraception* 2017;**95**:378–81.
153 Browne H, Manipalviratn S, Armstrong A. Using an intrauterine device in immunocompromised women. *Obstet Gynecol* 2008;**112**:667–9.
154 Tepper NK, Curtis KM, Nanda K, *et al.* Safety of intrauterine devices among women with HIV: a systematic review. *Contraception* 2016;**94**:713–24.
155 Brady PC, Soiffer RJ, Ginsburg ES. Continuation of a levonorgestrel intrauterine device during hematopoietic stem cell transplant: a case report. *Anticancer Res* 2017;**37**:1985–7.
156 Joint Formulary Committee. Bristish National Formulary (online). Adrenal Insufficiency. London: BMJ Group and Pharmaceutical Press. https://bnf.nice.org.uk/treatment-summaries/adrenal-insufficiency/
157 Beighton P, De Paepe A, Steinmann B, *et al.* Ehlers-Danlos syndromes: revised nosology, Villefranche, 1997. Ehlers-Danlos National Foundation (USA) and Ehlers-Danlos Support Group (UK). *Am J Med Genet* 1998;**77**:31–7.
158 Ehlers-Danlos Support UK. Types of EDS. 2017. https://www.ehlers-danlos.org/what-is-eds/information-on-eds/types-of-eds/
159 Hugon-Rodin J, Lebègue G, Becourt S, *et al.* Gynecologic symptoms and the influence on reproductive life in 386 women with hypermobility type Ehlers-Danlos syndrome: a cohort study. *Orphanet J Rare Dis* 2016;**11**:124.
160 Faculty of Sexual & Reproductive Healthcare. FSRH Clinical Guideline: Contraceptive Choices for Women with Cardiac Disease (June 2014). 2014. https://www.fsrh.org/standards-and-guidance/documents/ceu-guidance-contraceptive-choices-for-women-with-cardiac/
161 National Institute for Health and Care Excellence (NICE). NICE Clinical Guideline: Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures. [CG64] Published 17 March 2008. Last updated 08 July 2016. 2008. https://www.nice.org.uk/guidance/cg64
162 Habib G, Hoen B, Tornos P, *et al.* Guidelines on the prevention, diagnosis, and treatment of infective endocarditis (new version 2009): the Task Force on the Prevention, Diagnosis, and Treatment of Infective Endocarditis of the European Society of Cardiology (ESC). Endorsed by the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) and by the International Society of Chemotherapy (ISC) for Infection and Cancer. *Eur Heart J* 2009;**30**:2369–413.
163 Wilson WR, Gewitz M, Lockhart PB, *et al.* Prevention of viridans group streptococcal infective endocarditis: a scientific statement from the American Heart Association. *Circulation* 2021;**143:**e963-e978.
164 Farmer M, Webb A. Intrauterine device insertion-related complications: can they be predicted? *J Fam Plann Reprod Health Care* 2003;**29**:227–31.
165 NHS.uk. Health A to Z: Postural tachycardia syndrome (PoTS). Page last reviewed 19 August 2019. https://www.nhs.uk/conditions/postural-tachycardia-syndrome/
166 National Institutes of Health. NIH Genetic and Rare Diseases Information Centre. Postural orthostatic tachycardia syndrome. Last updated 8 November 2021. https://rarediseases.info.nih.gov/diseases/9597/postural-orthostatic-tachycardiasyndrome
167 Faculty of Sexual & Reproductive Healthcare. FSRH CEU Statement: Management of women taking anticoagulants or antiplatelet medications who request intrauterine contraception or subdermal implants (March 2017). 2017. https://www.fsrh.org/documents/fsrh-guidance-fsrh-guidance-management-of-women-taking/

168 Vukelić-Nikolić M, Popović J, Đorđević L, *et al.* Hypersensitivity potential of gynecological devices. *Acta Medica Median* 2019;**58**:122–7.
169 Hausen BM, Hohlbaum W. [Do copper intrauterine devices cause contact allergy?] *Dtsch Med Wochenschr 1946* 1986;**111**:1016–21.
170 Gara S, Litaiem N, Bacha T, *et al.* Systemic allergic dermatitis caused by a copper-containing intra-uterine device. *Contact Dermatitis* 2021;**84**:132–4.
171 Pujol RM, Randazzo L, Miralles J, *et al.* Perimenstrual dermatitis secondary to a copper-containing intrauterine contraceptive device. *Contact Dermatitis* 1998;**38**:288.
172 Rongioletti F, Rivara G, Rebora A. Contact dermatitis to a copper-containing intra-uterine device. *Contact Dermatitis* 1985;**13**:343.
173 Romaguera C, Grimalt F. Contact dermatitis from a copper-containing intrauterine contraceptive device. *Contact Dermatitis* 1981;**7**:163–4.
174 Frentz G, Teilum D. Cutaneous eruptions and intrauterine contraceptive copper device. *Acta Derm Venereol* 1980;**60**:69–71.
175 Barkoff JR. Urticaria secondary to a copper intrauterine device. *Int J Dermatol* 1976;**15**:594–5.
176 Purello D'Ambrosio F, Ricciardi L, Isola S, *et al.* Systemic contact dermatitis to copper-containing IUD. *Allergy* 1996;**51**:658–9.
177 DermNet NZ. Dr Amanda Oakley. Nickel allergy. 1997. https://dermnetnz.org/topics/nickel-allergy
178 electronic medicines compendium (emc). Bayer plc. Kyleena 19.5 mg intrauterine delivery system. Last updated on emc 31 Dec 2021. https://www.medicines.org.uk/emc/product/769
179 electronic medicines compendium (emc). Bayer plc. Summary of Product Characteristics: Jaydess 13.5 mg intrauterine delivery system. Last updated on emc 01 Jul 2022. 2016. https://www.medicines.org.uk/emc/medicine/28672
180 gov.uk. MHRA: Check drug analysis profiles (iDAPs). https://www.gov.uk/drug-analysis-prints
181 Chen X, Wu X, Zhu H. Acute urticaria as a side effect of the Mirena® (levonorgestrel-releasing intrauterine system): a case report. *BMC Res Notes* 2014;**7**:209.
182 Karri K, Mowbray D, Adams S, *et al.* Severe seborrhoeic dermatitis: side-effect of the Mirena intra-uterine system. *Eur J Contracept Reprod Health Care* 2006;**11**:53–4.
183 Pereira A, Coker A. Hypersensitivity to Mirena--a rare complication. *J Obstet Gynaecol J Inst Obstet Gynaecol* 2003;**23**:81.
184 Patil M, Sheth KA, Krishnamurthy AC, *et al.* A review and current perspective on Wilson disease. *J Clin Exp Hepatol* 2013;**3**:321–36.
185 Crandell L, Mohler N. A literature review of the effects of copper intrauterine devices on blood copper levels in humans. *Nurs Womens Health* 2021;**25**:71–81.
186 NHS National Services Scotland. Scottish Trace Element and Micronutrient Diagnostic and Research Laboratory. Trace elements: Copper (Cu). https://www.trace-elements.co.uk/copper.asp
187 Ayala M, Pizarro F, Méndez MA, *et al.* Copper and liver function indicators vary depending on the female hormonal cycle and serum hormone binding globulin (SHBG) concentration in healthy women. *Biol Trace Elem Res* 2008;**121**:9–15.
188 Vukelić J, Kapamadzija A, Petrović D, *et al.* Variations of serum copper values in pregnancy. *Srp Arh Celok Lek* 2012;**140**:42–6.
189 Babić Ž, Tariba B, Kovačić J, *et al.* Relevance of serum copper elevation induced by oral contraceptives: a meta-analysis. *Contraception* 2013;**87**:790–800.
190 Barceloux DG. Copper. *J Toxicol Clin Toxicol* 1999;**37**:217–30.
191 Arowojolu AO, Otolorin EO, Ladipo OA. Serum copper levels in users of Multiload intra-uterine contraceptive devices. *Afr J Med Med Sci* 1989;**18**:295–9.
192 Anteby SO, Bassat HA, Yarkoni S, *et al.* The effect of intrauterine devices containing zinc and copper on their levels in serum. *Fertil Steril* 1978;**29**:30–4.
193 Prema K, Lakshmi BA, Babu S. Serum copper in long-term users of copper intrauterine devices. *Fertil Steril* 1980;**34**:32–5.
194 Imani S, Moghaddam-Banaem L, Roudbar-Mohammadi S, *et al.* Changes in copper and zinc serum levels in women wearing a copper TCu-380A intrauterine device. *Eur J Contracept Reprod Health Care* 2014;**19**:45–50.
195 De la Cruz D, Cruz A, Arteaga M, *et al.* Blood copper levels in Mexican users of the T380A IUD.

Contraception 2005;**72**:122–5.
196 Rief W, Avorn J, Barsky AJ. Medication-attributed adverse effects in placebo groups: implications for assessment of adverse effects. *Arch Intern Med* 2006;**166**:155–60.
197 Conz L, Mota BS, Bahamondes L, *et al.* Levonorgestrel-releasing intrauterine system and breast cancer risk: a systematic review and meta-analysis. *Acta Obstet Gynecol Scand* 2020;**99**:970–82.
198 Silva FR, Grande AJ, Lacerda Macedo AC, *et al.* Meta-analysis of breast cancer risk in levonorgestrel-releasing intrauterine system users. *Clin Breast Cancer* 2021;**21**:497–508.
199 Soini T, Hurskainen R, Grénman S, *et al.* Levonorgestrel-releasing intrauterine system and the risk of breast cancer: a nationwide cohort study. *Acta Oncol Stockh Swed* 2016;**55**:188–92.
200 Mørch LS, Skovlund CW, Hannaford PC, *et al.* Contemporary hormonal contraception and the risk of breast cancer. *N Engl J Med* 2017;**377**:2228–39.
201 Lyytinen HK, Dyba T, Ylikorkala O, *et al.* A case-control study on hormone therapy as a risk factor for breast cancer in Finland: intrauterine system carries a risk as well. *Int J Cancer* 2010;**126**:483–9.
202 Heikkinen S, Koskenvuo M, Malila N, *et al.* Use of exogenous hormones and the risk of breast cancer: results from self-reported survey data with validity assessment. *Cancer Causes Control* 2016;**27**:249–58.
203 Jareid M, Thalabard J-C, Aarflot M, *et al.* Levonorgestrel-releasing intrauterine system use is associated with a decreased risk of ovarian and endometrial cancer, without increased risk of breast cancer. Results from the NOWAC Study. *Gynecol Oncol* 2018;**149**:127–32.
204 Siegelmann-Danieli N, Katzir I, Landes JV, *et al.* Does levonorgestrel-releasing intrauterine system increase breast cancer risk in peri-menopausal women? An HMO perspective. *Breast Cancer Res Treat* 2018;**167**:257–62.
205 Backman T, Rauramo I, Jaakkola K, *et al.* Use of the levonorgestrel-releasing intrauterine system and breast cancer. *Obstet Gynecol* 2005;**106**:813–7.
206 Dinger J, Bardenheuer K, Minh TD. Levonorgestrel-releasing and copper intrauterine devices and the risk of breast cancer. *Contraception* 2011;**83**:211–7.
207 Inki P, Hurskainen R, Palo P, *et al.* Comparison of ovarian cyst formation in women using the levonorgestrel-releasing intrauterine system vs. hysterectomy. *Ultrasound Obstet Gynecol* 2002;**20**:381–5.
208 Nahum GG, Kaunitz AM, Rosen K, *et al.* Ovarian cysts: presence and persistence with use of a 13.5mg levonorgestrel-releasing intrauterine system. *Contraception* 2015;**91**:412–7.
209 Nahum GG, Kaunitz AM, Lukkari-Lax E, *et al.* Evaluation of the presence and persistence of ovarian cysts in users of a new low-dose levonorgestrel-releasing intrauterine contraceptive system over 5 years. *J Reprod Med* 2017;**1**:383–90.
210 Bayer plc. Skyla 13.5mg intrauterine delivery system: summary of product characteristics. 2021. https://labelling.bayerhealthcare.com/html/products/pi/Skyla_PI.pdf
211 Pakarinen PI, Suvisaari J, Luukkainen T, *et al.* Intracervical and fundal administration of leveonorgestrel for contraception: endometrial thickness, patterns of bleeding, and persisting ovarian follicles. *Fertil Steril* 1997;**68**:59–64.
212 Jokubkiene L, Sladkevicius P, Valentin L. Prevalence of extrauterine pelvic lesions on transvaginal ultrasound in asymptomatic 20-39-year-old women. *Ultrasound Obstet Gynecol* 2014;**44**:228–37.
213 Borgfeldt C, Andolf E. Transvaginal sonographic ovarian findings in a random sample of women 25-40 years old. *Ultrasound Obstet Gynecol* 1999;**13**:345–50.
214 Greiner CU, Brune K, Haen E. Osteoporosis in a young woman after 6 years of levonorgestrel administration from intrauterine devices? *BMJ Case Rep* 2009;**2009**:bcr07.2008.0484.
215 Bahamondes L, Espejo-Arce X, Hidalgo MM, *et al.* A cross-sectional study of the forearm bone density of long-term users of levonorgestrel-releasing intrauterine system. *Hum Reprod* 2006;**21**:1316–9.
216 Bahamondes MV, Monteiro I, Castro S, *et al.* Prospective study of the forearm bone mineral density of long-term users of the levonorgestrel-releasing intrauterine system. *Hum Reprod* 2010;**25**:1158–64.
217 Yang KY, Kim YS, Ji YI, *et al.* Changes in bone mineral density of users of the levonorgestrel-releasing intrauterine system. *J Nippon Med Sch* 2012;**79**:190–4.

218 Ylikorkala O. Prostaglandin synthesis inhibitors in menorrhagia, intrauterine contraceptive device-induced side effects and endometriosis. *Pharmacol Toxicol* 1994;**75 Suppl 2**:86–8.
219 Reinprayoon D, Taneepanichskul S. Menstrual problems and side effects associated with long-term TCu 380A IUD use in perimenopausal women. *Contraception* 1998;**57**:417–9.
220 Andrade AT, Pizarro Orchard E. Quantitative studies on menstrual blood loss in IUD users. *Contraception* 1987;**36**:129–44.
221 Hubacher D, Chen P-L, Park S. Side effects from the copper IUD: do they decrease over time? *Contraception* 2009;**79**:356–62.
222 Sanders JN, Adkins DE, Kaur S, *et al.* Bleeding, cramping, and satisfaction among new copper IUD users: a prospective study. *PloS One* 2018;**13**:e0199724.
223 Bateson D, Harvey C, Trinh L, *et al.* User characteristics, experiences and continuation rates of copper intrauterine device use in a cohort of Australian women. *Aust N Z J Obstet Gynaecol* 2016;**56**:655–61.
224 Lowe RF, Prata N. Hemoglobin and serum ferritin levels in women using copper-releasing or levonorgestrel-releasing intrauterine devices: a systematic review. *Contraception* 2013;**87**:486–96.
225 Tepper NK, Steenland MW, Marchbanks PA, *et al.* Hemoglobin measurement prior to initiating copper intrauterine devices: a systematic review. *Contraception* 2013;**87**:639–44.
226 Saloranta TH, Gyllenberg FK, But A, *et al.* Free-of-charge long-acting reversible contraception: two-year discontinuation, its risk factors, and reasons. *Am J Obstet Gynecol* 2020;**223**:886.e1-886.e17.
227 Akintomide H, Barnes P, Brima N, *et al.* Higher discontinuation rate with a standard-sized compared to a small-sized 'gold standard' copper intrauterine device: a case-control review. *BMJ Sex Reprod Health* 2019;bmjsrh-2018-200296.
228 Maldonado LY, Sergison JE, Gao X, *et al.* Menstrual bleeding and spotting with the levonorgestrel intrauterine system (52 mg) during the first-year after insertion: a systematic review and meta-analysis. *Am J Obstet Gynecol* 2020;**222**:451-468.e9.
229 Sergison JE, Maldonado LY, Gao X, *et al.* Levonorgestrel intrauterine system associated amenorrhea: a systematic review and metaanalysis. *Am J Obstet Gynecol* 2019;**220**:440-448.e8.
230 Westhoff CL, Keder LM, Gangestad A, *et al.* Six-year contraceptive efficacy and continued safety of a levonorgestrel 52 mg intrauterine system. *Contraception* 2020;**101**:159–61.
231 Schreiber CA, Teal SB, Blumenthal PD, *et al.* Bleeding patterns for the Liletta® levonorgestrel 52 mg intrauterine system. *Eur J Contracept Reprod Health Care* 2018;**23**:116–20.
232 Jensen JT, Nelson AL, Costales AC. Subject and clinician experience with the levonorgestrel-releasing intrauterine system. *Contraception* 2008;**77**:22–9.
233 Guttinger A, Critchley HOD. Endometrial effects of intrauterine levonorgestrel. *Contraception* 2007;**75**:S93–98.
234 Belsey EM, Machin D, d'Arcangues C. The analysis of vaginal bleeding patterns induced by fertility regulating methods. World Health Organization Special Programme of Research, Development and Research Training in Human Reproduction. *Contraception* 1986;**34**:253–60.
235 Heikinheimo O, Inki P, Schmelter T, *et al.* Bleeding pattern and user satisfaction in second consecutive levonorgestrel-releasing intrauterine system users: results of a prospective 5-year study. *Hum Reprod* 2014;**29**:1182–8.
236 Van Schoubroeck D, Van den Bosch T, Ameye L, *et al.* Pain and bleeding pattern related to levonorgestrel intrauterine system (LNG-IUS) insertion. *Eur J Obstet Gynecol Reprod Biol* 2013;**171**:154–6.
237 Backman T, Huhtala S, Luoto R, *et al.* Advance information improves user satisfaction with the levonorgestrel intrauterine system. *Obstet Gynecol* 2002;**99**:608–13.
238 Diedrich JT, Zhao Q, Madden T, *et al.* Three-year continuation of reversible contraception. *Am J Obstet Gynecol* 2015;**213**:662.e1-8.
239 Kaislasuo J, Heikinheimo O, Lähteenmäki P, *et al.* Menstrual characteristics and ultrasonographic uterine cavity measurements predict bleeding and pain in nulligravid women using intrauterine contraception. *Hum Reprod* 2015;**30**:1580–8.
240 Shimoni N, Choudhury T, Goldman AR, *et al.* Bleeding and spotting with the levonorgestrel 13.5 mg intrauterine system: the impact of insertion timing. *Contraception* 2019;**99**:340–4.

241 van der Heijden P, Geomini P, Herman MC, *et al.* Timing of insertion of levonorgestrel-releasing intrauterine system: a randomised controlled trial. *BJOG* 2017;**124**:299–305.
242 Alves RDMS, Rabelo MM, Andrade VR, *et al.* The influence of the levonorgestrel-releasing intrauterine system position on bleeding patterns in reproductive age women. *Int J Gynaecol Obstet* 2019;**147**:326–31.
243 van der Heijden P a. HH, Tibosch RMG, Geomini PM a. J, *et al.* What is the best drug treatment for premenopausal women with bleeding irregularities using the levonorgestrel-releasing intrauterine system? A systematic review. *Eur J Contracept Reprod Health Care* 2020;**25**:484–91.
244 Madden T, Proehl S, Allsworth JE, *et al.* Naproxen or estradiol for bleeding and spotting with the levonorgestrel intrauterine system: a randomized controlled trial. *Am J Obstet Gynecol* 2012;**206**:129.e1-8.
245 Seeber B, Ziehr SC, Gschlieber A, *et al.* Quantative levonorgestrel plasma level measurements in patients with regular and prolonged use of the levonorgestrel-releasing intrauterine system. *Contraception* 2012;**86**:345–9.
246 Suhonen S, Haukkamaa M, Jakobsson T, *et al.* Clinical performance of a levonorgestrel-releasing intrauterine system and oral contraceptives in young nulliparous women: a comparative study. *Contraception* 2004;**69**:407–12.
247 Bosanac SS, Trivedi M, Clark AK, *et al.* Progestins and acne vulgaris: a review. *Dermatol Online J* 2018;**24**:13030/qt6wm945xf.
248 Worly BL, Gur TL, Schaffir J. The relationship between progestin hormonal contraception and depression: a systematic review. *Contraception* 2018;**97**:478–89.
249 Williams NM, Randolph M, Rajabi-Estarabadi A, *et al.* Hormonal contraceptives and dermatology. *Am J Clin Dermatol* 2021;**22**:69–80.
250 Sivin I, el Mahgoub S, McCarthy T, *et al.* Long-term contraception with the levonorgestrel 20 mcg/day (LNg 20) and the copper T 380Ag intrauterine devices: a five-year randomized study. *Contraception* 1990;**42**:361–78.
251 Beckert V, Aqua K, Bechtel C, *et al.* Insertion experience of women and health care professionals in the Kyleena® Satisfaction Study. *Eur J Contracept Reprod Health Care* 2020;**25**:182–9.
252 Barbieri JS, Mitra N, Margolis DJ, *et al.* Influence of contraception class on incidence and severity of acne vulgaris. *Obstet Gynecol* 2020;**135**:1306–12.
253 Bastianelli C, Farris M, Benagiano G. Use of the levonorgestrel-releasing intrauterine system, quality of life and sexuality. Experience in an Italian family planning center. *Exp Ital Fam Plan Cent Contracept* 2011;**84**:402–8.
254 Sanders JN, Smith NK, Higgins JA. The Intimate Link: A Systematic review of highly effective reversible contraception and women's sexual experience. *Clin Obstet Gynecol* 2014;**57**:777–89.
255 Kai J, Middleton L, Daniels J, *et al.* Usual medical treatments or levonorgestrel-IUS for women with heavy menstrual bleeding: long-term randomised pragmatic trial in primary care. *Br J Gen Pract* 2016;**66**:e861–70.
256 Halmesmaki K, Hurskainen R, Teperi J, *et al.* The effect of hysterectomy or levonorgestrel-releasing intrauterine system on sexual functioning among women with menorrhagia: a 5-year randomised controlled trial. *BJOG* 2007;**114**:563–8.
257 Boozalis A, Tutlam NT, Chrisman Robbins C, *et al.* Sexual desire and hormonal contraception. *Obstet Gynecol* 2016;**127**:563–72.
258 Witting K, Santtila P, Jern P, *et al.* Evaluation of the female sexual function index in a population based sample from Finland. *Arch Sex Behav* 2008;**37**:912–24.
259 Higgins JA, Sanders JN, Palta M, *et al.* Women's sexual function, satisfaction, and perceptions after starting long-acting reversible contraceptives. *Obstet Gynecol* 2016;**128**:1143–51.
260 Higgins JA, Kramer RD, Wright KQ, *et al.* Sexual functioning, satisfaction, and well-being among contraceptive users: a three-month assessment from the HER Salt Lake Contraceptive Initiative. *J Sex Res* 2022;**59**:435–44.
261 Sanders JN, Higgins JA, Adkins DE, *et al.* The Impact of sexual satisfaction, functioning, and perceived contraceptive effects on sex life on IUD and implant continuation at 1 year. *Womens Health Issues* 2018;**28**:401–7.
262 Higgins JA, Ryder K, Skarda G, *et al.* The Sexual acceptability of intrauterine contraception: a

qualitative study of young adult women: IUDs' sexual acceptability. *Perspect Sex Reprod Health* 2015;**47**:115–22.
263 Wiebe ER. A comparison of male partners' reactions to different intrauterine device strings. *Int J Gynecol Obstet* 2015;**128**:267–267.
264 Ferreira J, Carreiro A, Fernandes A, *et al.* Sexual function and quality of life in a cohort of Brazilian users of two kind of intrauterine contraceptives. *Rev Bras Ginecol Obstet* 2019;**41**:236–41.
265 Enzlin P, Weyers S, Janssens D, *et al.* Sexual functioning in women using levonorgestrel-releasing intrauterine systems as compared to copper intrauterine devices. *J Sex Med* 2012;**9**:1065–73.
266 Faculty of Sexual & Reproductive Healthcare. FSRH CEU Statement: Contraception and Weight Gain (August 2019). 2019. https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-contraception-and-weight-gain-august-2019/
267 Faculty of Sexual & Reproductive Healthcare. FSRH Service Standards on Obtaining Valid Consent in Sexual Health Services (September 2018). 2018. https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-on-obtaining-valid-consent-in-srh/
268 General Medical Council (GMC). Intimate examinations and chaperones. Published 25 March 2013. https://www.gmc-uk.org/-/media/documents/maintaining-boundaries-intimate-examinations-and-chaperones_pdf-58835231.pdf
269 Akintomide H, Brima N, Sewell RDE, *et al.* Patients' experiences and providers' observations on pain during intrauterine device insertion. *Eur J Contracept Reprod Health Care* 2015;**20**:319–26.
270 Kaislasuo J, Heikinheimo O, Lahteenmaki P, *et al.* Predicting painful or difficult intrauterine device insertion in nulligravid women. *Obstet Gynecol* 2014;**124**:345–53.
271 Castro TVB, Franceschini SA, Poli-Neto O, *et al.* Effect of intracervical anesthesia on pain associated with the insertion of the levonorgestrel-releasing intrauterine system in women without previous vaginal delivery: a RCT. *Hum Reprod* 2014;**29**:2439–45.
272 Panichyawat N, Mongkornthong T, Wongwananuruk T, *et al.* 10% lidocaine spray for pain control during intrauterine device insertion: a randomised, double-blind, placebo-controlled trial. *BMJ Sex Reprod Health* 2021;**47**:159–65.
273 Chaves IA, Baêta T, Dolabella GB, *et al.* Pain scores at the insertion of the 52 MG levonorgestrel-releasing intrauterine system among nulligravidas and parous women. *Eur J Contracept Reprod Health Care* 2021;**26**:399–403.
274 Gemzell-Danielsson K, Jensen JT, Monteiro I, *et al.* Interventions for the prevention of pain associated with the placement of intrauterine contraceptives: an updated review. *Acta Obstet Gynecol Scand* 2019;**98**:1500–13.
275 Mody SK, Farala JP, Jimenez B, *et al.* Paracervical block for intrauterine device placement among nulliparous women: a randomized controlled trial. *Obstet Gynecol* 2018;**132**:575–82.
276 Akdemir Y, Karadeniz M. The relationship between pain at IUD insertion and negative perceptions, anxiety and previous mode of delivery. *Eur J Contracept Reprod Health Care* 2019;**24**:240–5.
277 Dina B, Peipert LJ, Zhao Q, *et al.* Anticipated pain as a predictor of discomfort with intrauterine device placement. *Am J Obstet Gynecol* 2018;**218**:236.e1-236.e9.
278 Allen RH, Carey MS, Raker C, *et al.* A prospective cohort study of pain with intrauterine device insertion among women with and without vaginal deliveries. *J Obstet Gynaecol* 2014;**34**:263–7.
279 Schneyer R, Lerma K, Conti J, *et al.* Dysmenorrhoea as a risk factor for pain with intrauterine device insertion. *BMJ Sex Reprod Health* 2022;**48**:e31–7.
280 Ferreira LS, de Nadai MN, Poli-Neto OB, *et al.* Predictors of severe pain during insertion of the levonorgestrel 52 mg intrauterine system among nulligravid women. *Contraception* 2020;**102**:267–9.
281 Hunter TA, Sonalkar S, Schreiber CA, *et al.* Anticipated pain during intrauterine device insertion. *J Pediatr Adolesc Gynecol* 2020;**33**:27–32.
282 Bahamondes MV, Hidalgo MM, Bahamondes L, *et al.* Ease of insertion and clinical performance of the levonorgestrel-releasing intrauterine system in nulligravidas. *Contraception* 2011;**84**:e11–6.
283 Harrison-Woolrych M, Zhou L, Coulter D. Insertion of intrauterine devices: a comparison of experience with Mirena and Multiload Cu 375 during post-marketing monitoring in New Zealand. *N Z Med J* 2003;**116**:U538.
284 Nguyen L, Lamarche L, Lennox R, *et al.* Strategies to mitigate anxiety and pain in intrauterine

device insertion: a systematic review. *J Obstet Gynaecol Can* 2020;**42**:1138-1146.e2.
285 Daykan Y, Battino S, Arbib N, *et al.* Verbal analgesia is as good as oral tramadol prior to intrauterine device (IUD) insertion, among nulliparous women: a randomized controlled trial. *Eur J Obstet Gynecol Reprod Biol* 2021;**258**:443–6.
286 Hylton J, Milton S, Sima AP, *et al.* Cold compress for intrauterine device insertional pain: a randomized control trial. *Womens Health Rep* 2020;**1**:227–31.
287 Akintomide H, Doshi J, Power J, *et al.* Television: a way of distracting patients during sexual and reproductive healthcare procedures. *J Fam Plann Reprod Health Care* 2016;**42**:220–1.
288 Ali MK, Ramadan AK, Abu-Elhassan AM, *et al.* Ultrasound-guided versus uterine sound-sparing approach during copper intrauterine device insertion: a randomised clinical trial. *Eur J Contracept Reprod Health Care* 2022;**27**:3–8.
289 Maged AM, Nada AM, Abdelwahab H, *et al.* The value of ultrasound guidance during IUD insertion in women with RVF uterus: a randomized controlled trial. *J Gynecol Obstet Hum Reprod* 2021;**50**:101875.
290 Lambert T, Truong T, Gray B. Pain perception with cervical tenaculum placement during intrauterine device insertion: a randomised controlled trial. *BMJ Sex Reprod Health* 2020;**46**:126–31.
291 Cimsir MT, Yildiz MS. Could the Valsalva manoeuvre be an alternative to the tenaculum for intrauterine device insertion? *Eur J Contracept Reprod Health Care* 2021;**26**:503–6.
292 Doty N, MacIsaac L. Effect of an atraumatic vulsellum versus a single-tooth tenaculum on pain perception during intrauterine device insertion: a randomized controlled trial. *Contraception* 2015;**92**:567–71.
293 Speedie JMM, Mansour D, Landy R, *et al.* A randomised trial comparing pain and ease of use of two different stabilising forceps for insertion of intrauterine contraception. *J Fam Plann Reprod Health Care* 2016;**42**:241–6.
294 Cameron ST, Glasier A, Cooper A, *et al.* Does a full bladder assist insertion of intrauterine contraception?: A randomised trial. *J Fam Plann Reprod Health Care* 2013;**39**:207–10.
295 Lopez LM, Bernholc A, Zeng Y, *et al.* Interventions for pain with intrauterine device insertion. *Cochrane Database Syst Rev* 2015;7:CD007373.
296 Anthoulakis C, Lordanidou E, Vatopoulou A. Pain perception during levonorgestrel-releasing intrauterine device insertion in nulliparous women: a systematic review. *J Pediatr Adolesc Gynecol* 2018;**31**:549-556.e4.
297 Abu-Zaid A, Alshahrani MS, Albezrah NA, *et al.* Vaginal dinoprostone versus placebo for pain relief during intrauterine device insertion: a systematic review and meta-analysis of randomised controlled trials. *Eur J Contracept Reprod Health Care* 2021;**26**:357–66.
298 Akers AY, Harding J, Perriera LK, *et al.* Satisfaction with the intrauterine device insertion procedure among adolescent and young adult women. *Obstet Gynecol* 2018;**131**:1130–6.
299 Samy A, Abbas AM, Mahmoud M, *et al.* Evaluating different pain lowering medications during intrauterine device insertion: a systematic review and network meta-analysis. *Fertil Steril* 2019;**111**:553-561.e4.
300 Perez-Lopez FR, Martinez-Dominguez SJ, Perez-Roncero GR, *et al.* Uterine or paracervical lidocaine application for pain control during intrauterine contraceptive device insertion: a meta-analysis of randomised controlled trials. *Eur J Contracept Reprod Health Care* 2018;**23**:207–17.
301 Pergialiotis V, Vlachos DG, Protopappas A, *et al.* Analgesic options for placement of an intrauterine contraceptive: a meta-analysis. *Eur J Contracept Reprod Health Care* 2014;**19**:149–60.
302 Abbas AM, Abd Ellah NH, Hosny MA, *et al.* Self-administrated vaginal 2% lidocaine in-situ gel for pain relief during copper intrauterine device insertion in women with previous caesarean delivery only: a randomised, double-blind placebo-controlled trial. *Eur J Contracept Reprod Health Care* 2021;**26**:132–8.
303 De Nadai MN, Poli-Neto OB, Franceschini SA, *et al.* Intracervical block for levonorgestrel-releasing intrauterine system placement among nulligravid women: a randomized double-blind controlled trial. *Am J Obstet Gynecol* 2020;**222**:245.e1-245.e10.
304 Tassi A, Parisi N, Londero AP. Misoprostol administration prior to intrauterine contraceptive device insertion: a systematic review and meta-analysis of randomised controlled trials. *Eur J Contracept*

Reprod Health Care 2020;**25**:76–86.
305 Grimes D, Hubacher D, Lopez LM, *et al.* Non-steroidal anti-inflammatory drugs for heavy bleeding or pain associated with intrauterine-device use. *Cochrane Database Syst Rev* 2006;**4**:CD006034.
306 Singh RH, Thaxton L, Carr S, *et al.* A randomized controlled trial of nitrous oxide for intrauterine device insertion in nulliparous women. *Int J Gynaecol Obstet* 2016;**135**:145–8.
307 Fowler KG, Byraiah G, Burt C, *et al.* Nitrous oxide use for intrauterine system placement in adolescents. *J Pediatr Adolesc Gynecol* 2022;**35**:159–64.
308 Abbas AM, Ragab E, Abd Ellah NH, *et al.* Effect of topical glyceryl trinitrate cream on pain perception during intrauterine device insertion in multiparous women: a randomized double-blinded placebo-controlled study. *J Gynecol Obstet Hum Reprod* 2019;**48**:715–8.
309 Darweesh FF, Samy A, Abbas AM, *et al.* Efficacy of oral celecoxib and hyoscine butyl-bromide versus placebo during copper intrauterine device placement in women delivered only by elective cesarean section: a randomized controlled study. *Proc Obstet Gynecol* 2020;**9**:5.
310 Yaron M, Viviano M, Guillot C, *et al.* Real-world experience with the IUB Ballerine MIDI copper IUD: an observational study in the French-speaking region of Switzerland. *Eur J Contracept Reprod Health Care* 2019;**24**:288–93.
311 Baram I, Aharon A, Klein R, *et al.* Real-world experience with the IUB Ballerine MIDI copper IUD: an observational, single-centre study in Israel. *Eur J Contracept Reprod Health Care* 2020;**25**:49–53.
312 Martinez F, Gimenez E, Hernández G, *et al.* Experience with GyneFIX® insertions in Spain: favorable acceptance of the intrauterine contraceptive implant with some limitations. *Contraception* 2002;**66**:315–20.
313 Zapata LB, Jatlaoui TC, Marchbanks PA, *et al.* Medications to ease intrauterine device insertion: a systematic review. *Contraception* 2016;**94**:739–59.
314 Hubacher D, Reyes V, Lillo S, *et al.* Pain from copper intrauterine device insertion: randomized trial of prophylactic ibuprofen. *Am J Obstet Gynecol* 2006;**195**:1272–7.
315 Faculty of Sexual & Reproductive Healthcare. FSRH Service Standards for Record Keeping (July 2019). 2019. https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-record-keeping-july-2019/
316 Wiebe ER, Trouton KJ. Does using tampons or menstrual cups increase early IUD expulsion rates? *Contraception* 2012;**86**:119–21.
317 Seale R, Powers L, Guiahi M, *et al.* Unintentional IUD expulsion with concomitant menstrual cup use: a case series. *Contraception* 2019;**100**:85–7.
318 Long J, Schreiber C, Creinin MD, *et al.* Menstrual cup use and intrauterine device expulsion in a copper intrauterine device contraceptive efficacy trial. American College of Obstetricians and Gynecologists 2020. https://escholarship.org/uc/item/5kz1t720
319 Schnyer AN, Jensen JT, Edelman A, *et al.* Do menstrual cups increase risk of IUD expulsion? A survey of self-reported IUD and menstrual hygiene product use in the United States. *Eur J Contracept Reprod Health Care* 2019;**24**:368–72.
320 Jabehdar Maralani P, Schieda N, Hecht EM, *et al.* MRI safety and devices: an update and expert consensus. *J Magn Reson Imaging JMRI* 2020;**51**:657–74.
321 Bussmann S, Luechinger R, Froehlich JM, *et al.* Safety of intrauterine devices in MRI. *PloS One* 2018;**13**:e0204220.
322 Neumann W, Uhrig T, Malzacher M, *et al.* Risk assessment of copper-containing contraceptives: the impact for women with implanted intrauterine devices during clinical MRI and CT examinations. *Eur Radiol* 2019;**29**:2812–20.
323 Faculty of Sexual & Reproductive Healthcare. FSRH Clinical Guideline: Problematic Bleeding with Hormonal Contraception (July 2015). 2015. http://www.fsrh.org/standards-and-guidance/documents/ceuguidanceproblematicbleedinghormonalcontraception/
324 Christelle K, Norhayati MN, Jaafar SH. Interventions to prevent or treat heavy menstrual bleeding or pain associated with intrauterine-device use. *Cochrane Database Syst Rev* 2022;**8**:CD006034.
325 Williams S, Peipert J, Buckel C, *et al.* Contraception and the risk of ectopic pregnancy. *Contraception* 2014;**90**:326.
326 Brahmi D, Steenland MW, Renner R-M, *et al.* Pregnancy outcomes with an IUD in situ: a

systematic review. *Contraception* 2012;**85**:131–9.
327 Royal College of Obstetricians and Gynaecologists (RCOG). Diagnosis and Management of Ectopic Pregnancy (Green-top Guideline No. 21; joint with the Association of Early Pregnancy Units). 2016. https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg21/
328 Vessey M, Meisler L, Flavel R, *et al.* Outcome of pregnancy in women using different methods of contraception. *Br J Obstet Gynaecol* 1979;**86**:548–56.
329 Elgemark K, Graner S, McTaggart J, *et al.* The 13.5-mg, 19.5-mg, and 52-mg levonorgestrel-releasing intrauterine systems and risk of ectopic pregnancy. *Obstet Gynecol* 2022;**140**:227–33.
330 Hopkins MR, Agudelo-Suarez P, El-Nashar SA, *et al.* Term pregnancy with intraperitoneal levonorgestrel intrauterine system: a case report and review of the literature. *Contraception* 2009;**79**:323–7.
331 British Association for Sexual Health and HIV. United Kingdom National Guideline for the Management of Pelvic Inflammatory Disease (2019 Interim Update). https://www.bashhguidelines.org/current-guidelines/systemic-presentation-and-complications/pid-2019/
332 Tepper NK, Steenland MW, Gaffield ME, *et al.* Retention of intrauterine devices in women who acquire pelvic inflammatory disease: a systematic review. *Contraception* 2013;**87**:655–60.
333 Mohllajee AP, Curtis KM, Peterson HB. Does insertion and use of an intrauterine device increase the risk of pelvic inflammatory disease among women with sexually transmitted infection? A systematic review. *Contraception* 2006;**73**:145–53.
334 Farley TNM, Rosenberg M, Rowe PJ, *et al.* Intrauterine contraceptive devices and pelvic inflammatory disease: an international perspective. *Lancet* 1992;**339**:785–8.
335 Steenland MW, Zapata LB, Brahmi D, *et al.* Appropriate follow up to detect potential adverse events after initiation of select contraceptive methods: a systematic review. *Contraception* 2013;**87**:611–24.
336 Toivonen J, Luukkainen T, Allonen H. Protective effect of intrauterine release of levonorgestrel on pelvic infection: three years' comparative experience of levonorgestrel- and copper-releasing intrauterine devices. *Obstet Gynecol* 1991;**77**:261–4.
337 Saxon GDGC, Edwards A, Rautemaa-Richardson R, *et al.* British Association for Sexual Health and HIV national guideline for the management of vulvovaginal candidiasis (2019). *Int J STD AIDS* 2020;**31**:1124–44.
338 Farr A, Effendy I, Frey Tirri B, *et al.* Guideline: Vulvovaginal candidosis (AWMF 015/072, level S2k). *Mycoses* 2021;**64**:583–602.
339 Gonçalves B, Ferreira C, Alves CT, *et al.* Vulvovaginal candidiasis: epidemiology, microbiology and risk factors. *Crit Rev Microbiol* 2016;**42**:905–27.
340 Apalata T, Longo-Mbenza B, Sturm A, *et al.* Factors associated with symptomatic vulvovaginal candidiasis: a study among women attending a primary healthcare clinic in Kwazulu-Natal, South Africa. *Ann Med Health Sci Res* 2014;**4**:410.
341 Cetin M, Ocak S, Gungoren A, *et al.* Distribution of Candida species in women with vulvovaginal symptoms and their association with different ages and contraceptive methods. *Scand J Infect Dis* 2007;**39**:584–8.
342 Demirezen S, Dirlik OO, Beksaç MS. The association of Candida infection with intrauterine contraceptive device. *Cent Eur J Public Health* 2005;**13**:32–4.
343 Donders GGG, Bellen G, Ruban K, *et al.* Short- and long-term influence of the levonorgestrel-releasing intrauterine system (Mirena®) on vaginal microbiota and Candida. *J Med Microbiol* 2018;**67**:308–13.
344 Amouri I, Sellami H, Borji N, *et al.* Epidemiological survey of vulvovaginal candidosis in Sfax, Tunisia: vulvovaginal candidosis epidemiology. *Mycoses* 2011;**54**:e499–505.
345 Guzel AB, Ilkit M, Akar T, *et al.* Evaluation of risk factors in patients with vulvovaginal candidiasis and the value of chromID Candida agar versus CHROMagar Candida for recovery and presumptive identification of vaginal yeast species. *Med Mycol* 2011;**49**:16–25.
346 Spinillo A, Capuzzo E, Nicola S, *et al.* The impact of oral contraception on vulvovaginal candidiasis. *Contraception* 1995;**51**:293–7.
347 Agarwal K, Sharma U, Acharya V. Microbial and cytopathological study of intrauterine

contraceptive device users. *Indian J Med Sci* 2004;**58**:394–9.
348 Hodoglugil NN, Aslan D, Bertan M. Intrauterine device use and some issues related to sexually transmitted disease screening and occurrence. *Contraception* 2000;**61**:359–64.
349 British Association for Sexual Health and HIV. UK National Guideline on the Management of Bacterial Vaginosis. 2012. http://www.bashh.org/documents/4413.pdf
350 Deese J, Pradhan S, Goetz H, *et al.* Contraceptive use and the risk of sexually transmitted infection: systematic review and current perspectives. *Open Access J Contracept* 2018;**9**:91–112.
351 Peebles K, Kiweewa FM, Palanee-Phillips T, *et al.* Elevated risk of bacterial vaginosis among users of the copper intrauterine device: a prospective longitudinal cohort study. *Clin Infect Dis* 2021;**73**:513–20.
352 Merki-Feld GS, Lebeda E, Hogg B, *et al.* The incidence of actinomyces-like organisms in Papanicolaou-stained smears of copper- and levonorgestrel-releasing intrauterine devices. *Contraception* 2000;**61**:365–8.
353 García-García A, Ramírez-Durán N, Sandoval-Trujillo H, *et al.* Pelvic actinomycosis. *Can J Infect Dis Med Microbiol* 2017;**2017**:1–17.
354 Kaban I. Comparison of liquid-based cytology and conventional Pap smear concerning detectability of cervicovaginal infectious agents. *Haydarpasa Numune Med J* 2021;**61**:114–6.
355 Tidy J, Luesley D, Bowring J. NHS Cervical Screening Programme. Colposcopy and Programme Management. NHSCSP Publication number 20. 2016;1–108.
356 Golightly E, Gebbie AE. Low-lying or malpositioned intrauterine devices and systems. *J Fam Plann Reprod Health Care* 2014;**40**:108–12.
357 Bahamondes MV, Monteiro I, Canteiro R, *et al.* Length of the endometrial cavity and intrauterine contraceptive device expulsion. *Int J Gynaecol Obstet* 2011;**113**:50–3.
358 Eisenberg DL, Schreiber CA, Turok DK, *et al.* Three-year efficacy and safety of a new 52-mg levonorgestrel-releasing intrauterine system. *Contraception* 2015;**92**:10–6.
359 Connolly CT, Fox NS. Incidence and risk factors for a malpositioned intrauterine device detected on three-dimensional ultrasound within eight weeks of placement. *J Ultrasound Med* 2022;**41**:1525–36.
360 Moshesh M, Saldana T, Deans E, *et al.* Factors associated with low-lying intrauterine devices: a cross-sectional ultrasound study in a cohort of African-American women. *Contraception* 2018;**98**:25–9.
361 Benacerraf BR, Shipp TD, Bromley B. Three-dimensional ultrasound detection of abnormally located intrauterine contraceptive devices which are a source of pelvic pain and abnormal bleeding. *Ultrasound Obstet Gynecol* 2009;**34**:110–5.
362 Faúndes D, Bahamondes L, Faúndes A, *et al.* No relationship between the IUD position evaluated by ultrasound and complaints of bleeding and pain. *Contraception* 1997;**56**:43–7.
363 Pakarinen P, Luukkainen T. Five years' experience with a small intracervical / intrauterine levonorgestrel-releasing device. *Contraception* 2005;**72**:342–5.
364 Anteby E, Revel A, Ben-Chetrit A, *et al.* Intrauterine device failure: relation to its location within the uterine cavity. *Obstet Gynecol* 1993;**81**:112–4.
365 Morales-Roselló J. Spontaneous upward movement of lowly placed T-shaped IUDs. *Contraception* 2005;**72**:430–1.
366 Faúndes D, Bahamondes L, Faúndes A, *et al.* T-shaped IUD move vertically with endometrial growth and involution during the menstrual cycle. *Contraception* 1998;**57**:413–5.
367 Faúndes D, Perdigão A, Faúndes A, *et al.* T-shaped IUDs accommodate in their position during the first 3 months after insertion. *Contraception* 2000;**62**:165–8.
368 de Kroon CD, van Houwelingen JC, Trimbos JB, *et al.* The value of transvaginal ultrasound to monitor the position of an intrauterine device after insertion. A technology assessment study. *Hum Reprod* 2003;**18**:2323–7.
369 Ber A, Seidman DS. Management of the malpositioned levonorgestrel-releasing intrauterine system. *Contraception* 2012;**85**:369–73.
370 Chen X, Guo Q, Wang W, *et al.* Three-dimensional ultrasonography versus two-dimensional ultrasonography for the diagnosis of intrauterine device malposition. *Int J Gynaecol Obstet* 2015;**128**:157–9.

371 Meirik O, Rowe PJ, Peregoudov A, *et al.* The frameless copper IUD (GyneFix) and the TCu380A IUD: results of an 8-year multicenter randomized comparative trial. *Contraception* 2009;**80**:133–41.
372 Harris S, Kaneshiro B, Ahn HJ, *et al.* Timing of insertion affects expulsion in patients using the levonorgestrel 52 mg intrauterine system for noncontraceptive indications. *Contraception* 2021;**103**:185–9.
373 Çintesun FNİ, Çintesun E, Esenkaya Ü, *et al.* Uterine dimensions and intrauterine device malposition: can ultrasound predict displacement or expulsion before it happens? *Arch Gynecol Obstet* 2020;**302**:1181–7.
374 Rowlands S, Oloto E, Horwell DH. Intrauterine devices and risk of uterine perforation: current perspectives. *Open Access J Contracept* 2016;**7**:19–32.
375 Shakir F, Diab Y. The perforated uterus. *Obstet Gynaecol* 2013;**15**:256–61.
376 Stephens EA. Removal of intrauterine contraception with non-visible threads: a case series. *BMJ Sex Reprod Health* 2018;bmjsrh-2018-200125.
377 Adewale F, Ashimi A. Missing intrauterine contraceptive device string: diagnosis and management at federal medical center Bida, Northcentral, Nigeria. *Trop J Obstet Gynaecol* 2018;**35**:298.
378 Moro F, Knez J, Pateman K, *et al.* Ultrasound-guided retrieval of lost intrauterine devices using very fine grasping forceps: a case series. *J Fam Plann Reprod Health Care* 2015;**41**:205–9.
379 Dewan R, Dewan A, Singal S, *et al.* Non-visualisation of strings after postplacental insertion of copper-T 380A intrauterine device. *J Fam Plann Reprod Health Care* 2017;**43**:186–94.
380 Heller R, Johnstone A, Cameron ST. Routine provision of intrauterine contraception at elective cesarean section in a national public health service: a service evaluation. *Acta Obstet Gynecol Scand* 2017;**96**:1144–51.
381 Cooper M, McGeechan K, Glasier A, *et al.* Provision of immediate postpartum intrauterine contraception after vaginal birth within a public maternity setting: health services research evaluation. *Acta Obstet Gynecol Scand* 2020;**99**:598–607.
382 Faculty of Sexual & Reproductive Healthcare. FSRH Clinical Guidance: Switching or Starting Methods of Contraception (November 2017, amended March 2021). 2017. https://www.fsrh.org/standards-and-guidance/fsrh-guidelines-and-statements/switching-or-starting-methods-of-contraception/
383 Asch E, Levine D, Brook OR. Fractured intrauterine device copper sheath with an intact polyethylene core. *J Ultrasound Med* 2013;**32**:1877–8.
384 Wilson S, Tan G, Baylson M, *et al.* Controversies in family planning: how to manage a fractured IUD. *Contraception* 2013;**88**:599–603.
385 Sarver J, Cregan M, Cain D. Fractured copper intrauterine device (IUD) retained in the uterine wall leading to hysterectomy: a case report. *Case Rep Womens Health* 2021;**29**:e00287.
386 Sinha P, Pradhan A, Diab Y. Expulsion of part of a spontaneously broken IUCD. *J Obstet Gynaecol* 2004;**24**:837–8.
387 Fernandez C, Cabiya M, Levine E, *et al.* The “broken” IUD: its detection and clinical management. *Open J Clin Med Case Rep* 2015;**1**:1049.
388 Nadgir A, Beere D, Barker K. Intrauterine fragmentation of Gyne T380: an uncommon complication. *J Fam Plann Reprod Health Care* 2004;**30**:175–6.
389 Dubovis M, Rizk N. Retained copper fragments following removal of a copper intrauterine device: two case reports. *Case Rep Womens Health* 2020;**27**:e00208.
390 Mavranezouli I, LARC Guideline Development Group. The cost-effectiveness of long-acting reversible contraceptive methods in the UK: analysis based on a decision-analytic model developed for a National Institute for Health and Clinical Excellence (NICE) clinical practice guideline. *Hum Reprod* 2008;**23**:1338–45.
391 Cooper M, Cameron S. Successful implementation of immediate postpartum intrauterine contraception services in Edinburgh and framework for wider dissemination. *Int J Gynecol Obstet* 2018;**143**:56–61.
392 Cooper M, Boydell N, Heller R, *et al.* Community sexual health providers’ views on immediate postpartum provision of intrauterine contraception. *BMJ Sex Reprod Health* 2018;**44**:97–102.
393 Hultstrand J, Gemzell-Danielsson K, Kallner HK, Lindman H, Wikman P, Sundström-Poromaa I. Hormonal contraception and risk of breast cancer and breast cancer in situ among

Swedish women 15-34 years of age: A nationwide register-based study. Lancet Reg Health Eur. 2022;**21**:100470.
394 Fitzpatrick D, Pirie K, Reeves G, Green J, Beral V. Combined and progestagen-only hormonal contraceptives and breast cancer risk: A UK nested case-control study and meta-analysis. PLoS Med. 2023;**1**;20(3):e1004188
395 Heting M, Wenping L, Yanan W, Dongni Z, Xiaoqing W, Zhli Z. Levonorgestrel intrauterine system and breast cancer risk: An updated systematic review and meta-analysis of observational studies. Heliyon. 2023.
396 Zürcher A, Knabben L, Janka H, Stute P. Influence of the levonorgestrel-releasing intrauterine system on the risk of breast cancer: a systematic review. Archives of gynecology and obstetrics. 2023 Jun;307(6):1747-61.
397 Jensen JT, Reinecke I, Post TM, Lukkari-Lax E, Hofmann BM. Extended use of levonorgestrel-releasing intrauterine system (LNG-IUS) 52 mg: A population pharmacokinetic approach to estimate in vivo levonorgestrel release rates and systemic exposure including comparison with two other LNG-IUSs. Contraception. 2023 Apr;120:109954. doi:10.1016/j.contraception.2023.109954.398 emc. Gedeon Richter UK Ltd. Benilexa One Handed 20 micrograms/24 hours Intrauterine Delivery System. Last updated: 30 Sep 2024.Available at: www.medicines.org.uk/emc/product/13055/smpc.
399 Chen BA, Kimble T, Harris LH, Kerns JL, Olariu AI, Creinin MD. Levonorgestrel 52-mg Intrauterine Device Efficacy and Safety After More Than 8 Years of Use. Obstet Gynecol. 2023 May 1;141(5):1004-1006. doi: 10.1097/AOG.0000000000005147
400 Creinin MD, Schreiber CA, Turok DK, et al. Levonorgestrel 52 mg intrauterine system efficacy and safety through 8 years of use. Am J Obstet Gynecol 2022;227:871.e1-7.
401 Anthony MS, Zhou X, Schoendorf J, Reed SD, Getahun D, Armstrong MA, et al. Demographic, reproductive, and medical risk factors for intrauterine device expulsion. Obstet Gynecol. 2022 Dec 1;140(6):1017-1030. doi: 10.1097/AOG.0000000000005000.

Appendices

Appendix 1: FSRH Clinical Guideline development process

Who has developed the guideline?

This guideline is produced by the Clinical Effectiveness Unit (CEU) with support from the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (FSRH). The FSRH is a registered charitable organisation which funds the development of its own clinical guidelines. NHS Lothian is contracted to host the CEU in the Chalmers Centre and to provide the CEU's services using ring-fenced funding from the FSRH. No other external funding is received. Chalmers Centre supports the CEU in terms of accommodation, facilities, education, training and clinical advice for the members' enquiry service. As an organisation, NHS Lothian has no editorial influence over CEU guidelines, although staff members may be invited to join the CEU's multidisciplinary guideline development groups (GDGs), in an individual professional capacity.

Development of the guideline was led by the secretariat (CEU staff) and involved the intended users of the guidelines (contraception providers) and patient/service user representatives as part of a multidisciplinary group. The scope of the guideline was informed by a scoping survey conducted among members of the FSRH and among service users from two sexual and reproductive health services across the UK. The first draft of the guideline was produced based on the final scope of the guideline agreed by the GDG. The first draft of the guideline (version 0.1) was reviewed by the GDG and a revised draft guideline (version 0.2) was produced in response to comments received, after which it was sent to international and UK-based external independent reviewers suggested by the GDG at the face-to-face meeting. A further revision generated a version of the draft guideline (version 0.3) which was placed on the FSRH website for public consultation between 18 November 2022 and 16 December 2022. The revised draft guideline (version 0.4) was sent to the GDG for final comments and to reach consensus on the recommendations (details of this process are given later).

Listed are the contributors involved in the development of this clinical guideline.

Secretariat: Clinical Effectiveness Unit (CEU)

- **Dr Katie Boog** — Co-Director, Guideline Lead
- **Dr Cat Carver** — Researcher (Clinical)
- **Helen Carrington-Riebicke** — Support Officer
- **Dr Zhong Eric Chen** — Senior Researcher (Non-Clinical)
- **Dr Sarah Hardman** — Co-Director
- **Dr Chelsea Morroni** — Co-Director
- **Claire Nicol** — Deputy Director

We would like to thank Dr Ewan Barrack and Dr Kizanne James as contributors to the writing of the guideline sections on pelvic inflammatory disease and implementation of the guideline, respectively.

We would like to thank NHS Lothian PPIUC Research Team for sharing their training resources (via the FSRH Member's Training hub) and Appendices 2 and 3 of this guideline.

Multidisciplinary Guideline Development Group (GDG)

- **Dr Catherine Bateman** — Associate Specialist (Barnsley Integrated Sexual Health, Spectrum Community Health CIC); Clinical Standards Committee Representative
- **Professor Deborah Bateson** — Professor of Practice (The Daffodil Centre, Faculty of Medicine and Health, The University of Sydney, Australia)
- **Karen Clough** — Patient Representative
- **Dr Michelle Cooper** — Consultant in Gynaecology & Sexual Health (Chalmers Centre, NHS Lothian)
- **Dr Rachel D'Souza** — Consultant in Sexual & Reproductive Health (Margaret Pyke Centre, London)
- **Dr Ashley Jefferies** — Community Sexual and Reproductive Health Specialty Registrar (Blackpool Teaching Hospitals NHS Foundation Trust); CSRH Trainee Representative
- **Dr Vinod Kumar** — Consultant in Integrated Sexual Healthcare (Haymarket Health, Leicester)
- **Dr Mayank Serge Madhra** — Consultant Gynaecologist (NHS Lothian); Royal College of Obstetrics and Gynaecologists (RCOG) Representative
- **Dr Diana Mansour** — Consultant in Community Gynaecology and Reproductive Healthcare (New Croft Centre, Newcastle-upon-Tyne)
- **Jacqueline Mason** — Patient Representative
- **Dr Seán Perera** — General Practitioner & Specialty Doctor in GU/HIV Medicine (University Hospitals Sussex); Clinical Effectiveness Committee Representative
- **Dr Sian Pearson** — Specialty Registrar in Community Sexual and Reproductive Health (Rotherham Sexual Health Services, The Rotherham NHS Foundation Trust); CSRH Trainee Representative
- **Nicky Ross** — Clinical Practice Educator – Reproductive Health Care Nurse Specialist (Abbey View Clinic, Bury St Edmunds, Suffolk); General Training Committee Representative

Independent reviewers

- **Dr Hannat Akintomide** — Specialty Doctor in Sexual Health (New Croft Centre, Newcastle-upon-Tyne)
- **Dr Niklas Envall** — Midwife and Affiliated Researcher (Department of Clinical Sciences, Danderyds Sjukhus, Department of Women's and Children's Health, Karolinska Institutet)
- **Dr Nadi Gupta** — Consultant in Genitourinary Medicine and Clinical Lead (Rotherham Sexual Health Services, The Rotherham NHS Foundation Trust)

We would like to thank the contributions of the following topic experts who provided valuable feedback during the development of this guideline: Dr Juliet Anderson (Haematology), Dr Patrick Gibson (Cardiology) and Professor Mark Strachan (Diabetes and Endocrinology).

Declaration of interests

Dr Diana Mansour: In the last 5 years I have received funding to give lectures and attend advisory board meetings for Bayer and Gedeon Richter who manufacture intrauterine systems.

Professor Deborah Bateson: List of financial support from commercial organisations related to SRH received by Family Planning NSW (FPNSW) n the past 5 years:

1. In my role as Medical Director of FPNSW I have attended advisory committees for the following entities (any financial remuneration for these activities has been received by my organisation and not personally by myself):
    - Bayer Health Care
    - Organon (formerly Merck Sharp & Dohme (MSD))
    - Besins (sponsor of drospirenone 4 mg POP Slinda in Australia)
    - Mayne Pharma (sponsor of estetrol (E4) pill Nextellis in Australia).
2. In my role as Medical Director of FPNSW I have provided clinical educational sessions in relation to contraception which have been sponsored by the following entities (any financial remuneration for these activities has been received by my organisation and not personally by myself):
    - Bayer Health Care
    - Besins
    - Organon (formerly MSD)
    - Mayne Pharma.
3. FPNSW receives/has received sponsorship for its educational courses for doctors from the following commercial entities:
    - Bayer Health Care
    - Organon (formerly MSD)
    - Medical Industries (sponsor of Cu-IUDs, Caya diaphragm).
4. FPNSW has undertaken an investigator-initiated study (2018–2021) funded by FPNSW and MSD (now Organon): Training midwives in the insertion of the contraceptive implant to increase uptake in the immediate postpartum period: a feasibility pilot study
5. FPNSW has been a recruitment site (2012–2021) for the prospective, controlled cohort study on the safety of a monophasic oral contraceptive containing nomegestrol acetate (2.5 mg) and 17β-estradiol (1.5 mg) (PRO-E2 study); Berlin Center for Epidemiology and Health Research (ZEG) Germany.

Patient involvement

Service users from three SRH services (Blackpool Teaching Hospitals, Rotherham Sexual Health Services and Chalmers Sexual Health Centre Edinburgh) across the UK were involved in providing feedback on the scope of the guideline.

Two patient representatives were involved consistently throughout the guideline development process. They provided valuable feedback on multiple drafts of the guideline; their input informed and supported content and the development of recommendations.

Public consultation contributors

We would like to thank the contributors who provided valuable feedback during the public consultation. We would also like to thank the Royal College of General Practitioners (RCGP) and the Royal College of Nursing (RCN) for supporting the public consultation of this guideline.

Guideline development methodology

This FSRH guideline was developed in accordance with the standard methodology for developing FSRH clinical guidelines (outlined in the FSRH's *Framework for Clinical Guideline Development* which can be accessed here). The methodology used in the development of this guideline has been accredited by the National Institute for Health and Care Excellence (NICE).

Systematic review of evidence

A systematic review of the literature was conducted to identify evidence to answer the clinical questions formulated and agreed by the GDG. Searches were performed using relevant medical subject headings and free-text terms using the following databases: PubMed, Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews. English language restrictions were applied to the searches.

Search date: The databases were initially searched up to 05/08/2021. The evidence identified up to this point was used to develop the first draft of the guideline. The search was performed again on 14/03/2022 and 03/10/2022 for any new publications. Any evidence published after this date was not considered for inclusion.

Search strategy: The literature search was performed separately for the different subcategories covered in this clinical guideline.

Articles identified from the search were screened by title and abstract and full-text copies were obtained if the articles addressed the clinical questions relevant to the guideline. A full critical appraisal of each article was conducted. Studies that did not report relevant outcomes or were not relevant to the clinical questions were excluded.

Synthesis of evidence and making clinical recommendations

The recommendations are graded (A, B, C, D and Good Practice Point) according to the level of evidence upon which they are based. The highest level of evidence that may be available depends on the type of clinical question asked. The CEU adopts the comprehensive methodology developed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) (http://www.gradeworkinggroup.org/) to assess the strength of the evidence collated and for generating recommendations from evidence.

The evidence used in this guideline was graded using the scheme below and the recommendations formulated in a similar fashion with a standardised grading scheme.

Classification of evidence levels		Grades of recommendations	
1++	**High-quality systematic reviews or meta-analysis of randomised controlled trials (RCTs) or RCTs with a very low risk of bias.**	A	**At least one systematic review, meta-analysis or RCT rated as 1++, and directly applicable to the target population; *or* A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results.**
1+	**Well-conducted systematic reviews or meta-analysis of RCTs or RCTs with a low risk of bias.**		
1–	**Systematic reviews or meta-analysis of RCTs or RCTs with a high risk of bias.**	B	**A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results; *or* Extrapolated evidence from studies rated as 1++ or 1+.**
2++	**High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal.**		
2+	**Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal.**	C	**A body of evidence including studies rated as 2+ directly applicable to the target population and demonstrating overall consistency of results; *or* Extrapolated evidence from studies rated as 2++.**
2–	**Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal.**	D	**Evidence level 3 or 4; *or* Extrapolated evidence from studies rated as 2+.**
3	**Non-analytical studies (e.g. case report, case series).**	✓	**Good Practice Points based on the clinical experience of the guideline development group.***
4	**Expert opinions.**		

*On the occasion when the GDG finds there is an important practical point that they wish to emphasise but for which there is not, nor is there likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. It must be emphasised that these are NOT an alternative to evidence-based recommendations and should only be used where there is no alternative means of highlighting the issue.

Considerations when making recommendations

FSRH clinical guidelines are produced primarily to recommend safe and appropriate clinical practice in relation to the provision of different contraceptive methods. Therefore, when formulating the recommendations, the GDG takes into consideration the health benefits, side effects and other risks associated with implementing the recommendations, based on the available evidence and expert opinion. Further, the GDG takes into consideration the different financial and organisational barriers that clinicians and services may face in the implementation of recommendations to ensure that the recommendations are realistic and achievable.

Reaching consensus on the recommendations

When further revisions based on public consultation feedback have been made, members of the GDG were asked to complete a form to indicate whether they agree or disagree with the recommendations proposed. The consensus process is as follows:

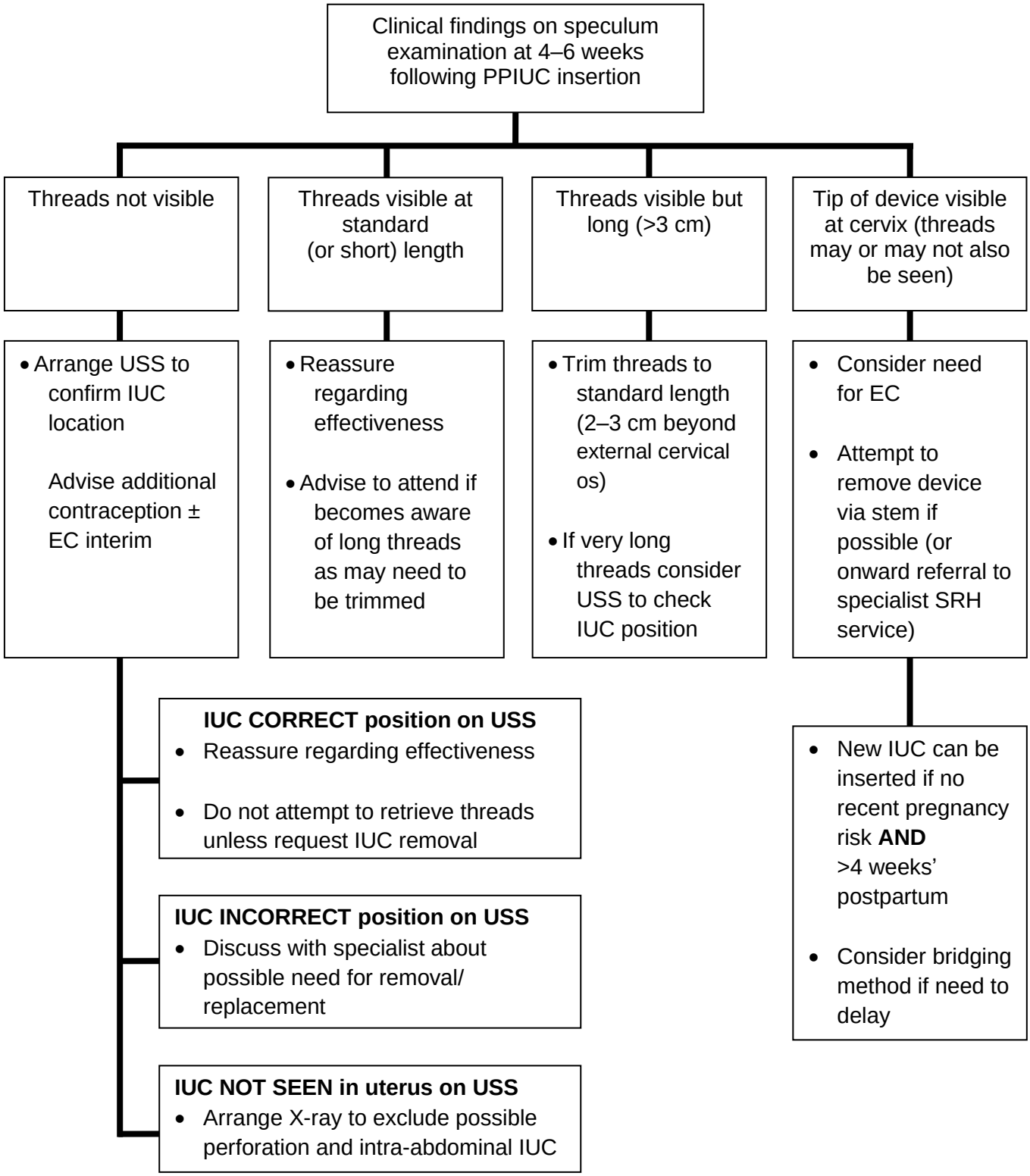
- Consensus will be reached when 80% of the GDG members agree with the recommendation.
- Recommendations where consensus is not reached will be redrafted in light of any feedback.
- The recommendation consensus form will be sent again for all recommendations. Consensus will be reached when 80% of the GDG members agree with the recommendation.
- If consensus is not reached on certain recommendations these will be redrafted once more.
- If after one more round of consultation consensus is still not reached, the recommendation will be taken to the CEC for final decision.
- Any group member who is not content with the decision can choose to have their disagreement noted within the guideline.

Updating this guideline

Clinical guidelines are routinely due for update 5 years after publication. The decision as to whether an update of a guideline is required will be based on the availability of new evidence published since its publication. Updates may also be triggered by the emergence of evidence expected to have an important impact on the recommendations. The final decision on whether to carry out a full or partial clinical guideline update is taken by the CEU in consultation with the CEC of the FSRH.

Appendix 2: Example pathway for postpartum intrauterine contraception (PPIUC) follow-up

The following PPIUC example pathway has been kindly shared by the Lothian PPIUC Research Team.



EC, emergency contraception; IUC, intrauterine contraception; PPIUC, postpartum intrauterine contraception; SRH, sexual and reproductive heathcare; USS, ultrasound scan.

Appendix 3: Aftercare following immediate postpartum intrauterine device (PPIUC) insertion – guidance for clinicians

The following aftercare guidance has kindly been shared by the Lothian PPIUC Research Team.

What is immediate postpartum intrauterine device (PPIUC) insertion?

This refers to the insertion of intrauterine contraception (IUC) (hormonal or non-hormonal) immediately after the placenta has delivered during childbirth, or within the first 48 hours. PPIUC insertion can take place following either a caesarean or vaginal birth following a clinical assessment of suitability. This procedure is usually performed by trained maternity professionals before the patient is discharged home from a hospital or birth unit.

What is the recommended follow-up after PPIUC insertion?

All individuals who receive PPIUC insertion should be provided with written and verbal information about what to expect afterwards and how they can seek help in the event of a problem. This should specifically include details of the type and duration of IUC inserted. Due to the unique nature of IUC insertion at this time, and the difference in risks of device expulsion and non-visible threads compared with non-postpartum IUC insertion, an initial routine follow-up review for a clinician thread check is recommended.

When should routine follow-up after PPIUC insertion take place?

A thread check would usually be expected to take place between 4 and 6 weeks' postpartum. This is when the uterus will have mostly returned to its non-pregnant size allowing for an accurate assessment of thread length and need for thread trimming. Scheduling a routine appointment after 4 weeks' postpartum may allow IUC to be replaced if requested in the event of device expulsion. However, some individuals may require an earlier review in the event of an unscheduled problem. For example, if the threads descend into the vagina earlier and require to be trimmed or if there are concerns about possible device expulsion.

Who should perform routine follow-up after PPIUC insertion?

The initial follow-up appointment in the weeks after PPIUC insertion will take place in a variety of settings including primary care, sexual health clinics and maternity hospitals depending on locally agreed pathways.

The clinician should be able to perform a speculum examination to visualise IUC threads and be comfortable trimming threads or removing a partially expelled device if required. If there is difficulty fully visualising the cervix, a bimanual examination may also be helpful to palpate threads and/or exclude the presence of partially expelled IUC at the external cervical os.

The clinician should also be able to either perform or refer for ultrasound scan in the event that the threads are not visible, or where further confirmation of IUC position is required. In some settings there may be access to immediate point-of-care ultrasound and reinsertion of further IUC, if expelled. It is not essential for the clinician performing the review to be trained in IUC insertion (in the event the PPIUC is found to have been expelled) but local pathways should be in place to facilitate expedited referral for IUC insertion in such circumstances if the patient wishes.

How should I manage IUC problems following immediate postpartum insertion?

This section details some of the common clinical presentations encountered during PPIUC follow-up along with general advice regarding management. However, as specific guidance related to PPIUC aftercare can vary greatly between regions, clinicians are encouraged to familiarise themselves with local pathways.

1) Non-visible threads

Threads may not be visible in up to 50% of individuals following intra-caesarean PPIUC insertion and up to 30% of individuals following postpartum vaginal insertion. This reflects the differences in insertion technique and anatomical changes occurring during the postpartum period. In some cases, the threads may descend into the vagina over time as the uterus returns to its non-pregnant state. Even in the absence of visible threads on speculum examination at follow-up, most devices will be correctly positioned in the uterus, but IUC expulsion needs to be excluded.

Management

- Enquire as to any symptoms which may be suggestive of IUC expulsion (e.g. pain). Perform or refer for ultrasound scan to confirm intrauterine location of IUC.
- Advise use of additional contraception/abstinence until IUC location is confirmed.
- Ultrasound findings
  - No IUC seen in uterus – refer for X-ray to exclude uterine perforation.
  - IUC seen in correct position in uterus – reassure; attempt at thread retrieval and regular self-checking of threads is not required.
  - IUC seen in incorrect position – discuss with local SRH/Gynaecology team for advice; a partially expelled device may require removal/replacement.
- If device removal is required in the context of non-visible threads, most of the time threads will be located higher up in the cervical canal and removal can be achieved easily using a thread retriever (by a clinician experienced in using this device).
- Specialist removal is sometimes required for IUC removal in the context of non-visible threads; local referral pathways to specialist services should be in place.

2) Long threads

Threads are generally left longer during PPIUC insertion to allow for involution of the enlarged postpartum uterus over subsequent weeks. As this occurs, the threads may descend into the vagina, and in some cases outside of the vaginal entrance. Patients are encouraged to seek advice if threads descend prior to the scheduled follow-up visit.

Management

- Arrange clinical review as soon as practical.
- Advise patient not to pull on threads and to avoid sex until threads can be trimmed/IUC position confirmed.
- If they feel comfortable doing so, patients can be advised to carefully trim externally visible threads (to level of the vaginal introitus) whilst awaiting review as this may prevent the IUC being inadvertently pulled down or removed.
- At review, the clinician should perform a speculum examination and trim the threads to standard length (2–3cm beyond external cervical os).
- A cotton-tipped swab can be used to help gently guide the ends of the threads into view within the speculum and allow for easier trimming.

- The ends of threads can be stabilised during trimming by gently applying sponge-holding forceps if available – this may help to reduce the chance of the IUC being inadvertently pulled out during the mobilisation and trimming of threads.
- In some cases, threads may be different lengths or only a single thread may be visible – one or both threads should be trimmed to standard length which may involve trimming off a slightly different length from each one.

3) Device visible at cervix (partial expulsion)

The risk of expulsion is higher for IUC insertion in the immediate postpartum setting. It is also higher for PPIUC insertion after vaginal birth compared with caesarean birth. A device expulsion may be 'complete' (where the patient visualises the expelled IUC) or 'partial' (i.e. usually only confirmed during clinical or ultrasound assessment). The patient may have preceding symptoms such as pain (particularly during intercourse) but these are not always present. IUC threads may not always be visible on speculum examination in this situation.

Management

- A clear view of the cervix is required to exclude a partial expulsion – digital palpation of the cervix to feel for a protruding IUC tip can also be helpful if there is uncertainty following speculum examination.
- If the stem of the device is visible at the external cervical opening the IUC should be removed.
- If there is any difficulty removing the device it should be left in situ and urgent referral made to SRH or Gynaecology.
- Consideration should be given to the need for emergency contraception (EC) if unprotected sexual intercourse (UPSI) has recently taken place – advice can be sought from the local SRH clinic.
- A plan for future contraception should be made with the patient – if a further intrauterine method is requested and there is no risk of pregnancy, this can be at any time after 4 weeks' postpartum (refer to UKMEC[2]).
- If further IUC insertion needs to be delayed (or patient requires onward referral) a bridging method of contraception should be offered.

Questions for continuing professional development

1. **Which of the following is NOT a recommendation in the FSRH CEU 2023 Intrauterine Contraception guideline?**
    a) Any 13.5 mg levonorgestrel intrauterine device (LNG-IUD) can be used for 3 years for contraception
    b) Any 19.5 mg LNG-IUD can be used for 6 years for contraception if the user is amenorrhoeic
    c) Any 52 mg LNG-IUD can be used as endometrial protection as part of hormone replacement therapy for up to 5 years
    d) Any 52 mg LNG-IUD can be used for 8 years for contraception if the user is <45 years old at the time of insertion
    e) Any 52 mg LNG-IUD inserted when the user is ≥45 years old can be used as contraception until age 55 years

2. **In which one of the following circumstances would it be recommended that an individual had their intrauterine contraception (IUC) insertion undertaken in a specialist setting?**
    a) When the individual has adrenal insufficiency
    b) When the individual has known cavity distortion
    c) When the individual has never been pregnant before
    d) When the individual is breastfeeding
    e) When the individual is immunocompromised

3. **Which of these scenarios is a UK Medical Eligibility Criteria for Contraceptive Use Category 4 (UKMEC4) (a condition which represents an unacceptable health risk if the method is used) for IUC insertion?**
    a) Current asymptomatic *Chlamydia trachomatis* infection
    b) Current bacterial vaginosis
    c) Current *Neiserria gonorrhoea* infection
    d) Past history of pelvic inflammatory disease
    e) Past history of post-abortion sepsis

4. **What follow-up is recommended when IUC has been inserted within 48 hours of vaginal or caesarean birth?**
    a) Ultrasound scan immediately after insertion
    b) Self-trim threads 4 weeks after insertion
    c) IUC check with a clinician 4–6 weeks after insertion
    d) Self-check threads within 6 weeks of insertion
    e) No follow-up required

5. **The rate of uterine perforation associated with routine IUC insertion is approximately:**
    a) 1–2 per 100
    b) 1–2 per 1000
    c) 1–2 per 10 000
    d) 1–2 per 100 000
    e) 1-2 per 1 000 000

6. **Which of these are NOT first-line management when an IUC user has non-visible threads:**
    a) Arrange an ultrasound scan
    b) Arrange an X-ray of the abdomen and pelvis
    c) Arrange ongoing contraception
    d) Consider emergency contraception
    e) Pregnancy test

7. **What advice should be given to individuals wishing copper intrauterine device (Cu-IUD) removal who do not want to be pregnant?**
    a) Avoid unprotected sexual intercourse (UPSI) for 24 hours prior to removal
    b) Avoid UPSI for 5 days prior to removal
    c) Avoid UPSI for 7 days prior to removal
    d) Avoid UPSI from last menstrual period (LMP) until removal
    e) No need to avoid UPSI prior to removal

8. **Which of the following is true with regards to LNG-IUDs and ovarian cysts?**
    a) Ovarian cysts associated with LNG-IUD use are almost always clinically significant
    b) The 52 mg LNG-IUD reduces the incidence of ovarian cysts
    c) The incidence of ovarian cysts may be elevated during LNG-IUD use
    d) LNG-IUDs are contraindicated in individuals with known ovarian cysts
    e) LNG-IUDs are not recommended in individuals with known polycystic ovary syndrome

9. **Considering bleeding patterns during LNG-IUD use, which of the following is true?**
    a) After 12 months of use, users of the 13.5 mg LNG-IUD are more likely to have amenorrhoea than users of the 19.5 mg LNG-IUD
    b) All 52 mg LNG-IUD users should be amenorrhoeic within 6 months of use
    c) Frequent or prolonged bleeding in the first 6 months of use are unlikely to improve over time
    d) The bleeding pattern in the first 3 months of use is predictive of the bleeding pattern over the first 3 years of use
    e) The number of bleeding/spotting days reduce over the first year of use and rates of amenorrhoea and infrequent bleeding increase

10. **Which of the following is recommended prior to *all* IUC insertions?**
    a) Bimanual pelvic examination
    b) Cervical cleansing
    c) Measurement of blood pressure and heart rate
    d) Pelvic ultrasound scan
    e) Sexually transmitted infection (STI) testing

Answers can be found onFSRH website here.

Auditable outcomes

Every FSRH clinical guideline includes a set of auditable standards. These reflect some of the recommendations made in the guideline that are key to making good prescribing decisions and achieving safe, effective contraception for the user. Some of the auditable standards may relate to key guidance that is new in the guideline; others are based on important aspects of already established guidance.

It is important for clinicians and services to collect information about whether they are practising according to recognised guidelines at a given point in time, use the information gathered to inform whether changes to their practice/protocols are indicated, and review at a later time point whether any changes implemented have led to improvement in adherence to guidelines. The auditable standards accompanying FSRH guidelines are a tool that can be used by clinicians and services when undertaking audit of their practice.

FSRH CEU offers additional materials and support for services to undertake National Benchmarking Audit (NBA). NBA facilitates review of current practice in a service as compared with guidance, comparison of the service's practice to that in other similar services, and evaluation of any changes made by the service designed to align practice with guidelines.

Suggested auditable standards

The following auditable standards are provided to accompany the FSRH 2023 Intrauterine Contraception guideline.

1. **100% of healthcare practitioners undertaking intrauterine contraception (IUC) insertion have been appropriately trained and have up-to-date FSRH certification or have maintained local accreditation through agreed local pathways.**

   FSRH recommends that all clinicians undertaking IUC insertions have been appropriately trained to do so and that they maintain their skills to ensure patient safety and delivery of best practice.

2. **Prior to insertion, 100% of IUC users have been given information about the expected changes in bleeding pattern with an IUC.**

   Changes in bleeding patterns are common with both copper intrauterine devices (Cu-IUDs) and levonorgestrel intrauterine devices (LNG-IUDs) and problematic bleeding is one of the more commonly cited reasons for requesting IUD removal. Giving information (which may include a verbal discussion, provision of written information or directing individuals to online information) allows the individual to consider the impact this may have on them and the acceptability of this prior to insertion. It is good practice to document that this information has been given.

3. **100% of individuals having IUC inserted should be made aware of the anaesthetic/analgesia options available.**

   Experiences vary for individuals having IUC inserted and there is no single 'best' option for pain relief during the procedure. Many individuals will not want or need pain relief during the procedure, but as pain can range from none to severe it is recommended that individuals are advised that that there are a range of possible pain relief options which may improve the insertion experience for some individuals. It is good practice to document that this has been discussed. Referral processes

should be in place for circumstances where an individual requests an analgesia/anaesthetic option that the clinician is unable to provide.

Services may also wish to consider collecting data on the number of individuals who require referral to an alternative provider because their preferred analgesia/anaesthetic option was not available and what type of anaesthetic/analgesia had been requested. This may be helpful in deciding whether changes in current service delivery would be beneficial, for example, training to be able to offer a commonly requested option or procurement of additional/different anaesthetic agents.

4. **Following insertion, 100% of individuals should be given information on the device inserted, including the name of the device, its duration of use and whether it can be relied upon immediately for contraception or if other precautions are required.**

   There are two broad types of IUD available in the UK – the Cu-IUD and the LNG-IUD – and there are multiple different devices within these two types. The duration of use of an IUD will depend on the device type, the indication for use and the age of the user. The Cu-IUDs are effective immediately after insertion. The LNG-IUDs are effective for contraception 7 days after insertion and the need for additional precautions (e.g. condoms or continuation of another method of contraception for 7 days after insertion) will depend on what (if any) contraception was used prior to insertion and/or where the individual is in their menstrual cycle.

   Services may also wish to collect data on whether this information is shared with other appropriate services, for example, informing the individual's general practitioner if the IUD is inserted at an SRH service.

5. **100% of individuals should be advised how and when to check their threads and when to seek review (e.g. threads are not palpable, thread length becomes shorter or longer, the stem of the device is felt or the user has concerns).**

   Clinicians should provide information on how to feel for IUC threads and that users should seek review if threads are not palpable, thread length becomes shorter or longer, or the stem of the device is felt, as any of these changes could mean the IUC is incorrectly sited and therefore effectiveness cannot be guaranteed. Documentation of this advice is considered good practice.

   Services may also wish to collect data on the management of non-visible threads. For 100% of IUC users noted to have non-visible threads on speculum examination, pregnancy should be excluded, emergency contraception considered, alternative contraception provided, and an ultrasound scan (± abdominal and pelvic X-ray) undertaken to locate the device. Depending on the patient record system used, identifying cases where a speculum confirmed non-visible threads may not be possible. However, it may be possible to audit the records of, for example, individuals who attended for pelvic ultrasound or who attended for a complex IUD removal appointment, and identify cases in this way.

Comments and feedback on published guideline

All comments on this published guideline can be sent directly to the Clinical Effectiveness Unit (CEU) of the Faculty of Sexual & Reproductive Healthcare (FSRH) via the FSRH website (www.fsrh.org). The CEU may not respond individually to all feedback. However, the CEU will review all comments and provide an anonymised summary of comments and responses, which are reviewed by the Clinical Effectiveness Committee and any necessary amendments made subsequently.

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